

April 3, 2003



Dockets Management Branch (HFA-305) 9945 '03 APR -4 19 '22
Attention Docket Numbers 02N-0276; 02N-0278
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Proposed Rules

To Whom It May Concern:

The National Paint and Coatings Association (NPCA) is submitting comments concerning the Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the "Proposed Rule").¹ NPCA appreciates the opportunity to comment on this important proposal and hopes its comments will assist the U.S. Food and Drug Administration (FDA) in developing appropriate regulations in keeping with the intent of the underlying legislation.

NPCA is a voluntary, nonprofit trade association representing some 400 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. As the preeminent organization representing the coatings industry in the United States, NPCA's primary role is to serve as ally and advocate on legislative, regulatory and judicial issues at the federal, state, and local levels. In addition, NPCA provides members with such services as research and technical information, statistical management information, legal guidance, and community service project support. NPCA member companies have a long history of consistent supply of high quality, safe, reliable and effective food contact coatings.

Registration of Food Facilities

The Proposed Rule's Definition of "Food" is Too Broad

NPCA commends Congress and FDA for taking actions to protect the US food supply from terrorist acts, and encourages FDA to continue working with the appropriate industries to take reasonable steps to protect the public. NPCA, however, is concerned that the Proposed Rule's registration requirements - "facilities engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States,"² and in particular FDA's classification of "food," may be so broadly construed as to apply to various industries not intended under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the "Bioterrorism Act"). This broad application will not only

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¹ 68 Fed. Reg. 5378 and 5428 (February 3, 2003).

² Proposed 21 CFR §1.225.



unduly burden industry, but will defeat the purpose of the legislation by limiting FDA's performance of its stated goals.

The Proposed Rule's definition of a food facility relies on the Federal Food, Drug, and Cosmetic Act's (FFDCA) definition, 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* (emphasis added).³ In addition, the Proposed Rule goes on to state that the definition of food includes "food and feed ingredients and additives, including *substances that migrate into food from food packaging and other articles that contact food* (emphasis added)."⁴ Further, FDA states, "[s]ubstances that migrate into food from food packaging include immediate food packaging or components of immediate food packaging that are intended for food use."⁵ Lastly, FDA has historically used FFDCA's definition of "food additive" in conjunction with its definition of "food," which includes substances intended for use in packing or packaging food. This definition encompasses a vast area of industries imposing the burdensome requirements on facilities not truly in the food business.

The Proposed Rule's Scope Was Not Intended Under The Bioterrorism Act.

FDA's terminology in this regard, potentially imposes the registration requirements of the Proposed Rule to NPCA members, as it would cover substances such as coatings, resins, lubricants, and adhesives, that are used in food packaging. NPCA is concerned, therefore, that the Proposed Rule would apply to coatings manufacturers and other food-contact article manufacturers, when this was not the intention of the Bioterrorism Act. The Bioterrorism Act's purpose with respect to food safety is to develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. This strategy "shall address threat assessments; technologies and procedures for *securing food processing and manufacturing facilities* and modes of transportation; response and notification procedures; and risk communications to the public (emphasis added)."⁶ In a conference report on the legislation, Representative John Shimkus, one of the sponsors of the Bioterrorism Act, stated that with respect to prior notification requirements under the Bioterrorism Act, that it "should not be construed to apply to food packaging materials or other food contact substances..."⁷ NPCA believes this statement would apply to the entire Proposed Rule, not just the prior notification requirements under Section 307. In fact, even the examples of food borne illnesses that FDA provides as justification for the rulemakings, are of contamination of actual food, not of food contact articles or packaging.⁸

To construe the legislative intent as applying to food contact articles such as food packaging and coatings would frustrate the purposes of the Bioterrorism Act. Not only would the registration of the vast amount of food contact industry facilities be unduly burdensome, it would divert FDA's

³ 21 USC §321(f).

⁴ See 68 Fed. Reg. 5382 (February 3, 2003).

⁵ Id.

⁶ See Public Law 107-188, Title 111, §301(a).

⁷ See 148 Cong. Rec. E916-01.

⁸ See Table 44 – Summary of Five Foodborne Outbreaks, 68 Fed. Reg. 5409.

attention and resources from its mission to respond to threats on this nation's food supply. NPCA members provide coatings and adhesives to the food industry for use in packaging, such as spray interior coatings, sheet coatings, side seam stripe coatings, and end seal compounds. These same products, however, may be supplied to non-food industry customers as well. Furthermore, under the Proposed Rule's current scope, facilities merely used to store food contact or food packaging materials (warehouses) would have to be registered. To require these facilities to register would be counterproductive to the FDA's goal to "act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply."⁹ Registration of coating manufacturers, whose products may or may not be used in the food industry, as well as other similarly situated industries, will merely increase the data in FDA's registry with immaterial facilities, diluting FDA's ability to use the registry to respond quickly to any threat or event.

The Proposed Rule is Unwarranted With Respect to Coatings Industry

In addition, NPCA believes that the processes and procedures employed by coatings manufacturing facilities, as well as the very formulations of the coatings themselves, warrants exemption from the registration requirements of the Proposed Rule. The coatings manufacturing industry has historically been progressive and proactive at putting forth industry programs that improve safety, health and environmental practices in the manufacturing setting and among commercial and consumer users of coatings products. Coatings Care®, the paint and coatings industry's health, safety and environmental management initiative, was launched in 1995 to help member companies improve their performance through adherence to four codes of management practice (Manufacturing Management, Product Stewardship, Transportation and Distribution, and Community Responsibility). In addition, many NPCA members are also American Chemistry Council Responsible Care® participants and certified under ISO 14000 and 14001 as well as 9000 and 9001 standards.

These quality control and quality assurance standards provide great assurance that our products are of the highest standards. These coatings are very specialized and are subject to quality checks from manufacture to application and post-application. Contaminated coatings would not likely pass the rigorous quality assurance measures of coating manufacturers or users. Thus, the prospect of contaminated coatings reaching a stage of direct food contact is extremely remote. Given our industry's highly specialized formulations as well as quality control processes, food packaging coatings should be specifically exempted from the registration requirements of the Proposed Rule.

Prior Notice of Imports

For the same reasons as articulated above, NPCA respectfully submits 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 also in direct contravention of Congressional intent and will unduly burden industry while providing no significant protection against terrorism. As previously stated, FDA has disregarded the express congressional intent that the prior notification requirements of the Bioterrorism Act not be applied to the "importation of food

⁹ See 68 Fed. Reg. 5378 (February 3, 2003).

packaging materials not yet containing food.”¹⁰ In addition, by nevertheless subjecting food packaging materials to the prior notification requirements of the Proposed Rule, FDA again imposes burdens on the industry that are disproportionate to any risk. Again, as the Proposed Rule apparently covers all components of immediate packaging that migrate to food, like registration, prior notification would apply to an enormous number of companies and shipments, thereby diverting attention and resources from activities directed toward more immediate food security risks.

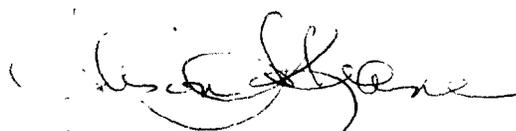
Conclusion

Once again, NPCA appreciates the intent of the Bioterrorism Act in protecting the nation’s food supply from terrorist attacks and responding quickly in the event an attack occurs. However, FDA must balance the regulatory burden on industry of recordkeeping and reporting requirements under the Proposed Rule with the need for tracking and monitoring all industries associated with the food industry. NPCA believes that the definition of “food” under the Proposed Rule does not appropriately strike this balance. Requiring coatings and food packaging manufacturing facilities to register and provide prior notification of imports under the Proposed Rule unnecessarily burdens our industry without commensurate benefit to the intention of the Bioterrorism Act – deterring and responding to terrorism of US food supply.

Therefore, NPCA respectfully submits that food packaging coatings be exempt from coverage in the final rule.

We hope that you will consider our comments on these matters and act accordingly. If you have any questions, or need additional information, please do not hesitate to contact us at 202.462.6272.

Sincerely,



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Lance “Skip” Edwards
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¹⁰ See 148 Cong. Rec. E916-01.