



July 7, 2003

Dockets Management Branch (HFA-305)
Attention Docket Numbers 02N-0277
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Proposed Rule

To Whom It May Concern:

The National Paint and Coatings Association (NPCA) is submitting comments concerning the Establishment and Maintenance of Records (hereinafter referred to as the "Proposed Rule"),¹ under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the "Act"). This Proposed Rule is one of four proposed regulations under the Act. NPCA previously filed comments on two of these proposals, namely the registration of food facilities and prior notice of imported foods in April 2003. NPCA appreciates the opportunity to once again comment on the proposed regulations under the Act and hopes our 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 reiterates the need for FDA to clarify the definition of food, such that food packaging and food contact coatings are not subject to these final rules.

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 packaging and food contact coatings. NPCA's interpretation of the Proposed Rule's requirements is that "packaging" does not extend to the supplier of the food contact package (i.e. to the supplier of that packaging coating). However, as with the prior two proposed regulations under the Act, FDA has not made this applicability clear and must do so in order to facilitate compliance and achievement of the Act's goals.

¹ 68 Fed. Reg. 25187 (May 9, 2003).

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

Once again, 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. However, the Proposed Rule's recordkeeping and reporting requirements apply to those "domestic persons that manufacture, process, pack transport, distribute, received, hold or import food intended for human or animal consumption . . .,"² and in particular FDA's classification of "food," may be so broadly construed as to apply to various industries not intended to be covered under the Act. FDA again relies on 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. Outer food packaging is not considered a substance that migrates into food"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 number of industries, imposing the burdensome requirements on facilities not truly in the food business.

Under the Proposed Rule's recordkeeping and reporting requirements, FDA requires that the manufacturer, processor, packer, transporter, distributor, receiver or holder of food, establish and maintain records to allow for the identification of the immediate previous sources and immediate subsequent recipients of food packaging as well.⁶ While FDA proposes in the preamble to the Proposed Rule to exempt "outer food packaging" from the requirements because of the minimal risk to human and animal health from contamination from this packaging, it does not actually do so in the proposed regulations. NPCA supports an exemption for packaging, however, FDA's narrow interpretation of the term packaging under the Act is "outer packaging of food that bears the label,"⁷ leaving the majority of manufacturers of food packaging and food contact coatings subject to regulations. NPCA does not believe this interpretation furthers the goals of the Act or is a necessary component of any effective traceback investigation. NPCA requests that the final regulation actually contain an exemption for packaging within the regulatory language itself, and that this exemption encompass food packaging and food contact coatings. Unless the regulation is specific with regard to its applicability, FDA can not attempt to meet the stated goals of the Bioterrorism Act.

² Proposed 21 CFR §1.326.

³ 21 USC §321(f).

⁴ See 68 Fed. Reg. 25193 (May 9, 2003).

⁵ See 68 Fed. Reg. 25194 (May 9, 2003).

⁶ See 68 Fed. Reg. 25190 (May 9, 2003).

⁷ See 68 Fed. Reg. 25190 (May 9, 2003).

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

FDA's terminology in this regard, potentially imposes the recordkeeping and reporting 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. As stated in our prior comments, 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).⁸" 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..."⁹ NPCA believes this statement would apply to all the proposed regulations under the Act, including the registration, prior notification, and the currently proposed recordkeeping requirements.

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, the subsequent establishment and maintenance of records detailing even the "immediate" previous source and subsequent recipient of every supplier and customer of those coatings would be imprudent. The sheer amount of paperwork that this system would generate alone would be astronomical and would certainly not facilitate the quick and effective traceback that FDA envisions. 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, these coatings are made from various raw materials supplied by numerous manufacturers at any given time. The Proposed Rule's scope with respect to chain of custody is currently unlimited and never ending given its broad definition of food. FDA must limit its reach with these proposed regulations to conform to the Act's stated goal of quickly responding to any threat or event relating to the nation's food supply. The currently proposed breadth of registered entities and recordkeeping requirements only serve to impede an effective registry and traceback system to respond to such.

The Proposed Rule is Unwarranted With Respect to the Coatings Industry

Again, as stated in previous comments, 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 recordkeeping requirements of the Proposed Rule. To reiterate, the coatings manufacturing industry has historically been progressive and proactive at

⁸ See Public Law 107-188, Title 111, §301(a).

⁹ See 148 Cong. Rec. E916-01.

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 recordkeeping requirements of the Proposed Rule. By attempting to expand the reach of the Act to the coatings industry with respect to food packaging and food contact coatings, FDA merely imposes great burdens on the industry disproportionate to any risk.

The Proposed Rule's Availability of Records Timeframe is Unreasonable for Coatings Industry

Given the remoteness of deliberate food contamination via the food packaging and food contact coatings, FDA's proposed 4-hour and 8-hour availability of records timeframe is unreasonable. FDA does not specify what time zone the 8 a.m. to 6 p.m. 4-hour or nights and weekends 8-hour standard applies to. Furthermore, FDA does not define "reasonable belief" with respect to the demand for such records. NPCA believes there may be an urgency for FDA to obtain these records with regard to contaminated food, however, if FDA persists in regulating the raw material suppliers to the industry as well, more appropriate availability standards should be proposed that are more commensurate the potential risk.

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 establish and maintain records with regard to previous sources and subsequent recipients of coatings, which may or may not end up used for some component of food packaging, unnecessarily burdens our industry without commensurate benefit to the intention of the Bioterrorism Act – deterring and responding to terrorism of the US food supply.

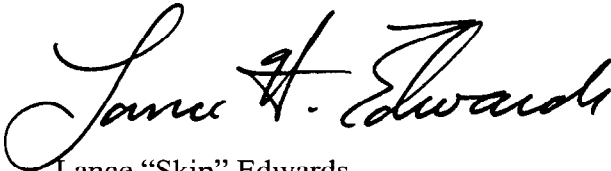
Therefore, NPCA respectfully submits that food packaging coatings be exempt from coverage in the final rule.

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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