



THE **ADHESIVE AND SEALANT** COUNCIL, INC.

WHERE THE INDUSTRY MEETS

March 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane rm. 1061
Rockville, MD 20852

Re: Comments on Proposed Rules for Registration for Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-276]

To Whom It May Concern:

The Adhesive and Sealant Council, Inc. (ASC) is an international trade association representing 125 manufacturers of adhesives and sealants and suppliers of raw materials to the industry. The Council's member companies offer a wide range of adhesive and products utilized by consumer and commercial markets including adhesives utilized by the food packaging industry.

ASC on behalf of its members respectfully submits these comments with regard to the regulation proposed by the U.S. Food and Drug Administration (FDA) entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002," published in the Federal Register on February 3, 2003. (68 Fed. Reg. 5377) This notice requested public comment on the paper work burden with regard to the implementation of the provision of the registration of facilities that manufacture, process, pack or hold food for human or animal consumption in the United States.

The Council commends Congress and the FDA for taking actions to protect the nation's food supply from acts of terrorism and we assure the agency that our members are committed to working with the agency to take all reasonable steps to protect the public food supply. However, in reviewing this proposal we respectfully submit the FDA has mistakenly extended these registration requirements to facilities that manufacture food-packaging adhesives that may in some cases come in contact with food. Such an inclusion

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is a clear contravention of Congress' intent when they were drafting the original legislation.

As background, FDA appears to have brought suppliers of food-contact materials into parameters of the proposal by referring to the definition of 'food' found in Section 201(f) of the Federal Food, Drug, and Cosmetic Act (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" to provide a basis for the Agency to assert regulatory authority over any food-contact materials that are also food additives. The FFDCA's language defines in part, "food additive" to include any substance the intended use of which results or may be 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) In the proposed regulation the Agency lists examples of products it considers to be covered by the definition of "food", which includes substances that migrate into food from food packaging and other articles that contact food." It would seem clear from this present language that packaging materials such as adhesives would be included in the proposal.

FDA has attempted to clarify exactly which packaging materials would fall within this description. Their proposal states that substances that migrate into the food from food packaging include "immediate food packaging or components of immediate food packaging that are intended for food. Outer packaging is not considered a substance that migrates into food." The terms immediate food packaging or components of immediate food packaging," could conceivably cover a vast range of products, including plastic resins, glass, paper, metal, rubber and many other products used in food packaging.

ASC members contend the scope of the present language in the proposal with respect to food contact materials is contrary to the intent of Congress as evidenced by the language of the statute itself. With regard to who should be the registering parties, the Bioterrorism Act clearly states that facilities, that "manufacture, process, pack or hold **food for consumption** in the United States" will be required to register (emphasis added). It would be presumable that the term "food for consumption" be properly interpreted as referring to edible food, not food-contact articles.

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Further indication that Congress did not have food-contact articles as triggering facilities registration in mind under the Bioterrorism Act is the legislators' reference to food categories in 21 C.F.R §170.3. The Bioterrorism Act states that FDA may require each facility to submit the general food category, as identified under §170.3, of the food manufactured, processed, packed, or held at that facility. And while FDA has proposed to include the categories from 170.3 as a mandatory field on the registration form, that section does not include categories for food contact materials.

It should also be noted that by apparently drawing all food packaging materials into the proposal, FDA creates increased uncertainty of what materials are actually included in the regulation. Interpretation of the present language could justifiably extend to all components of the immediate packaging that have the opportunity to migrate into the food. Construal in that manner could extend this regulation to a vast number of companies, many of which would be likely unaware of their products' inclusion.

Theoretically the new regulation would not only apply to facilities manufacturing packaging materials but to warehouses where these products are stored.

ASC members also are concerned that requiring their facilities to register 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." Manufacturers of adhesives utilized in the food packaging also provide these same products to non-food industry customers. Often they are merely the raw material supplier to various like industries with little knowledge of the specific end-use of their products. Requiring these facilities to register simply because their products may be used in a food packaging operation would seem counterproductive to FDA's goal of responding quickly to an imminent terrorist threat or attack on the U.S. food supply. Registering adhesive manufacturers, as well as other similarly situated industries, will merely increase the data in FDA's registry with immaterial facilities, diluting the agency's ability to use the registry as a rapid response tool as it was intended.

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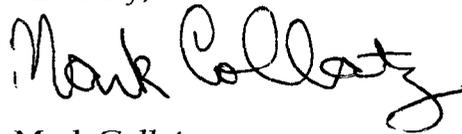
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In conclusion, it would appear that FDA has misconstrued Congressional intent with regard to registering facilities that manufacture and store food-contact materials. Additionally, such registrations may only further Burden FDA's investigatory efforts to deter and respond to terrorist attacks on the U.S. food supply.

Nevertheless, if FDA continues to propose the inclusion of some food-contact materials within the proposed regulation, the scope of the products covered must be clarified in the final regulation.

If you have any further questions, or need additional information, please do not hesitate to contact me at 301/986-9700 ext. 112.

Sincerely,

A handwritten signature in black ink that reads "Mark Collatz". The signature is written in a cursive, slightly slanted style.

Mark Collatz
Director of Government Relations