



July 8, 2003  
VIA ELECTRONIC AND U.S. MAIL

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

**RE: SEHSC Comments on the FDA's Notice of Proposed Rulemaking on the Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [FDA Docket No. 02N-0275]**

Dear Madam or Sir:

The Silicones Environmental, Health and Safety Council of North America (SEHSC) hereby respectfully submits these comments with regard to the Food and Drug Administration's (FDA) Notice of Proposed Rulemaking on the Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"), published in the *Federal Register* on May 9, 2003 (68 *Fed. Reg.* 25241).

SEHSC is a not-for-profit trade association whose mission is to promote the safe use and stewardship of silicones. The Council is comprised of North American silicone chemical producers and importers. SEHSC's members represent over 95 percent of silicone chemical manufacturing capacity in North America and include: Clariant LSM (Florida), Inc.; Crompton Corporation, OSi Specialties business; Degussa Corporation; Dow Corning Corporation; General Electric Silicones; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones, A Division of Wacker Chemical Corporation. SEHSC member companies provide silicone-based resins that are used to make, among other things, coatings, films, and adjuvants that are used in packaging and other food-contact materials, including packaging for food products, and as direct additives for food products.

SEHSC does not oppose the applicability of this proposal to food-contact materials. However, it is unclear whether FDA intends for just "finished" food packaging to be subject to the rule, or if the rule also will be applicable to the individual components that are used to make food packaging. Thus, we are requesting clarification on this point.

As SEHSC has discussed in comments to the Agency on the other proposed bioterrorism regulations, FDA has proposed to include suppliers of materials which do not contain food within the reach of the regulations by using 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." Food additives are included within this definition. Section 201(s) of the FFDCA defines a food additive to include "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food." This

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definition covers all the food additive substances listed in 21 CFR §§170-199, including those added directly to food and those used in food packaging and other articles that contact food.

Indeed, in the proposed regulations, the definition of "food" extends to the full breadth of the term's definition under the FFDCA, offering as an example, "substances that migrate into food from food packaging and other articles that contact food." 68 *Fed. Reg.* 25268. As written, this broad definition of "food" covers the many raw materials and formulated products used as components in the manufacture of food-contact articles such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins, polymer emulsions, colorants for polymers, rubber articles, release coatings, and the like.

On the other hand, the Agency appears to have expressed an intent to limit its administrative detention authority to finished packaging only that is in immediate contact with food by including the following language in the preamble to the proposed regulation:

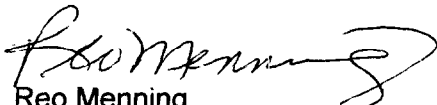
"substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

68 *Fed. Reg.* 25245. Quite clearly, the language in the regulation is not consistent with the proposed regulatory provision. We respectfully request that the proposed regulation be clarified accordingly.

Finally, as a matter of policy, SEHSC urges FDA to limit its use of this authority to actual instances involving real or suspected acts of terrorism. As currently phrased, the Act gives the Agency administrative detention authority whenever there is "credible evidence or information that [an] article [of food] presents a threat of serious adverse health consequences or death to humans or animals." Section 304(h)(1)(a) of the FFDCA. However, in providing this authority to FDA, congressional intent was only to "expand FDA's powers to prevent and respond effectively to **terrorist threats** against the food supply." (Emphasis added) Thus, the authority given to the Agency under the administrative detention provision should only be used to respond to threatened or actual acts of terrorism. This expanded authority should not be used to address concerns relating to the food supply in other regards, with which the Agency has authority to deal adequately under the existing provisions of FFDCA.

SEHSC appreciates the opportunity to provide comments on this proposed regulation. Please contact me at (703) 904-4322 if you need further clarification, or if SEHSC can be of assistance.

Sincerely,



Reo Menning  
Executive Director