

SEHSC

SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL of North America

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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 Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [FDA Docket No. 02N-0277]

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 Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the *Federal Register* on May 9, 2003 (68 *Fed. Reg.* 25187).

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 materials, including packaging for food products, and as direct additives for food products.

SEHSC asserts that FDA has misinterpreted the statute with respect to the applicability of the recordkeeping requirement to food-contact materials, and, further, that inclusion of these materials in the requirement is contrary to congressional intent. 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 in 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 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.

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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 of food, "substances that migrate into food from food packaging and other articles that contact food." 68 *Fed. Reg.* 25238. Thus, the proposal would apply to all food-contact substances that meet the definition of "food additive," and, possibly, to literally all food-contact articles and materials.

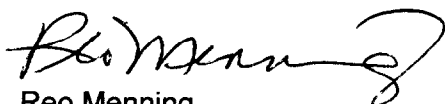
Although in the preamble to this proposal, the Agency attempts to distinguish between "outer packaging," which it is considering exempting from the regulations, and "food contact substances," which includes packaging materials that are directly in contact with food, and "which are included in the definition of food," 68 *Fed. Reg.* 25190, there is a much more pressing issue with respect to such materials to which the Agency needs to give further consideration. This has to do with the extension of regulations' coverage to basic polymeric materials, resins, additives, and adjuvants, which can have extremely limited food additive and food contact substance application compared to the host of non-food industrial applications that may be available. The manner in which the definition of "food" is currently set out in the proposed regulation would appear to encompass these basic raw materials. Therefore, we respectfully request the Agency to clarify whether such materials are intended to be covered by the regulations.

Exclusion of these materials from the scope of the proposal would clearly coincide with the intent of Congress, which was not to extend the Bioterrorism Act's requirements to any packaging or packaging materials not yet containing food. On the subject of recordkeeping, the Bioterrorism Act states that FDA may implement regulations to require recordkeeping by persons (excluding farms and restaurants) who "manufacture, process, pack, transport, distribute, receive, hold, or import **food**," to the extent such records are needed to allow FDA to identify the "immediate previous sources and the immediate subsequent recipients of **food, including its packaging**, in order to address credible threats of serious adverse health consequences or death to humans or animals" (emphasis added). This reference to packaging does not mandate recordkeeping by *packaging* suppliers or transporters. Rather, it requires that *food processors* have records identifying the suppliers of their packaging. Nothing else is required, and, SEHSC submits, nothing else is needed.

In conclusion, the recordkeeping requirement should not be extended to any food-contact materials, indirect food additives, or substances that might migrate to food and which do not already contain food or are in contact with edible food. FDA's proposed regulation is contrary to congressional intent and will not provide any significant assistance to FDA in deterring or responding to terrorism directed at the food supply.

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