

SEHSCSILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL of North America

April 4, 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 Proposed Regulation, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [Docket No. 02N-0278]

Dear Madam or Sir:

The Silicones Environmental, Health and Safety Council of North America (SEHSC) hereby respectfully submits these comments with regard to the Proposed Regulation on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the Federal Register on February 3, 2003 (68 *Fed. Reg.* 5428).

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; Degussa Corporation; Dow Corning Corporation; General Electric Silicones; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones. 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.

SEHSC asserts that the prior notice requirement with respect to materials defined as food contact materials or indirect food additives 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," which includes food additives. 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 used in food packaging and other articles that contact food.

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Such a broad definition in the proposed regulation with respect to food contact materials is contrary to the intent of Congress, which was intended to cover food products as commonly understood, and not materials used to package or otherwise contact food. This seems to be clearly borne out by the legislative history of the Act, as indicated by the Joint Explanatory Statement of the Committee of Conference and the remarks of the bill manager in the House of Representatives, Representative John Shimkus in the May 24, 2002 Congressional Record. A clarification needs to be made to the regulation to define food to refer to edible food and not food contact materials, indirect food additives, or substances that might migrate to food.

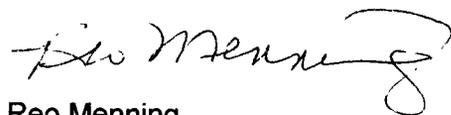
This broad definition of "food" will require prior notice for materials that may be used for the manufacture of food contact articles such as conveyor belts, oven gaskets, coatings on metal substrates, adhesives, antifoam agents used in food processing, components of polyolefin films, colorants used in polymers, rubber articles, release coatings, etc. This would impose a significant burden on the silicone industry companies that do not now file entry information with FDA because most of the materials which may be used in food contact materials are primarily used as industrial non-food contact materials. In most cases, it is impossible to know if a silicone material will be used to mold, for example, parts for an automobile gasket or for an oven gasket. Thus, the regulation as proposed could require notification of all silicone products imported into the U.S. based on the fact that they might be used in a food contact application.

Additionally, the burdens this regulation will impose on the industry are disproportionate to any minimal risk from and will provide no protection against terrorism. Food contact materials have not been connected to any occurrence of food borne illness from accidental or intentional contamination of edible food. Further, because food contact materials such as silicone elastomers, resins, various polymers, antifoams, and pulp and paper treatment chemicals to name a few, are in most cases imported as industrial chemical products, and used in food contact applications only once they are sold within the United States, it is inconceivable that such materials could purposefully be used as a vehicle to contaminate food.

In conclusion, the requirement on industry to provide prior notice of importation of "food" should not be extended to any food contact materials that 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 protection against terrorism.

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