

**WACKER**

**SHARRONN E. ETTER**  
DIRECTOR, REGULATORY  
AFFAIRS AND PRODUCT  
SAFETY  
DEPARTMENT

**Wacker Chemical Corporation**  
3301 Sutton Road  
Adrian, MI 49221-9397, USA  
Tel. 517-264-8367  
Fax 517-264-8293  
sharronn.etter@wacker.com

1587 '03 APR -3 A10 :37

VIA ELECTRONIC AND EXPRESS MAIL

**March 31, 2003**

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

***RE: Wacker Chemical Corporation and Wacker Specialties Comments on the FDA Proposed Regulation Titled Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [Docket No. 02N-0276]***

Dear Sir or Madam:

Wacker Chemical Corporation and Wacker Specialties of Adrian, Michigan hereby respectfully submit these comments with regard to the Proposed Regulation on Registration of Food Facilities 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. 5377).

Wacker Chemical Corporation and Wacker Specialties assert that the requirement to register manufacturing facilities and warehouses 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 FFDCFA 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". Section 201 of the FFDCFA 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. Furthermore FDA's definition of food even extends to substances that migrate into food from food packaging and other articles that contact food.

<sup>1</sup> Wacker Chemical Corporation is the United States based headquarters for Wacker Silicones and Wacker Ceramics business divisions of Wacker-Chemie, GmbH. Wacker Silicones manufactures silicone fluids, rubbers and resins; silanes; and fumed silica's. Wacker Ceramics manufactures advanced ceramics, boron compounds, functional coatings, and microporous insulation materials. Wacker Specialities imports redispersible powders, solid resins, polyvinyl butyrals, specialty chemicals, catalysts and manufactures biotechnology products.

02N-0276

C100

This broad definition of “food” requires that facilities that import materials that may be used for the manufacture of indirect 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 register their facilities with FDA. This would impose a significant burden on many companies including the Wacker Companies that do not now file entry information with FDA because most of the materials with indirect food contact are also primarily used as industrial non food contact materials. In most cases it is impossible to know if a Wacker material will be used to mold parts for an automobile gasket or for an oven gasket.

Such a broad definition in the proposed regulation with respect to food contact materials is contrary to the intent of Congress, which was to protect “food for consumption in the United States”. A clarification needs to be made to the regulation to define food consumption as referring to edible food and not food contact materials, indirect food additives or substances which might migrate to food.

Additionally including food contact materials, indirect food additives or substances, which might migrate to food in the regulation will impose burdens on the industry that are disproportionate to any minimal risk and will provide no protection against terrorism. The requirement would apply not just to facilities that manufacture food contact materials but also to the warehouses where they are stored. An inordinate amount of time will have to be spent simply identifying the facilities that have to be registered and in putting into place the procedures to meet this obligation including the proposed updates. It is our belief that this information will have limited usefulness in FDA’s abilities to prevent and respond effectively to terrorist threats against our food supply. Registration of facilities that manufacture or store food contact materials, indirect food additives or substances, which might migrate to food would not deter the intentional contamination of food or assist the FDA in determining the source and cause of contamination. Food contact materials, indirect food additives or substances, which might migrate to food have not been related to any occurrences of food borne illness from accidental or intentional contamination of edible food.

Indirect food contact materials such as elastomers, resins, various polymers, antifoams and pulp and paper treatment chemicals to name a few, are only used in indirect contact with food. These materials are in most cases manufactured or imported as industrial chemical products that may have an indirect food contact use once they are sold and used within the United States. They are not manufactured or imported with the sole purpose of being consumed as edible food in the United States nor are they in contact with food when sold and used.

**WACKER**

Page 3 of 3

In conclusion, the requirement on industry to register facilities that manufacture and store "food" should not be extended to any food contact materials, indirect food additives or substances which 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.

Wacker Chemical Corporation and Wacker Specialities appreciates the opportunity to provide comments on this proposed regulation.

Sincerely,



Sharronn E. Etter  
Director, Regulatory Affairs and Product Safety