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April 2, 2003

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

Re: **Docket No. 02N-0276**

To Whom It May Concern:

National Starch and Chemical Company (NSCC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed regulation entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002".

NSCC is a global manufacturer of food and food contact ingredients, including food and industrial starches, adhesives, and polymers.

We support the efforts put forth by Congress and the FDA in strengthening the safety and security of the U.S. food supply. However, there are two issues that we believe needs your further attention.

(1) FDA should exclude food contact substances from the scope of the regulation.

FDA is proposing in 21CFR 1.227(c)(4) to define "food" for the purposes of facility registration as it is defined in section 201(f) of the Federal Food Drug and Cosmetic Act. The proposed regulation includes a list of examples of products that FDA considers to be covered by the definition of "food", including "substances that migrate into food from food packaging and other articles that contact food". By using such a broad definition the FDA is bringing into the scope of this regulation a significant number of products and manufacturers, many of whom do not produce finished food packaging. Under the proposed regulation manufacturers of food packaging ingredients, such as monomers, resins, preservatives, production aids, adhesives, and components of coatings would be required to register their facilities, including warehouses where these materials are stored.

In addition, the scope of the regulation, which would clearly include food contact materials, and the information required for registration, which does not include food contact materials are inconsistent. The proposed regulation under 21CFR 1.232(e) indicates that product categories as identified in 21CFR 170.3 are required information in the registration. The food categories under 170.3(n) do not include food packaging or food packaging components.

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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. Requiring the registration of these manufacturers of food packaging ingredients would put a significant burden on a large number of companies, both foreign and domestic, many of which would likely be unaware of their facilities inclusion. There would also be an additional burden on U.S. companies in verifying that their foreign suppliers are aware of the requirements and register their facilities so that imported material shipments are not delayed.

(2) The status of pharmaceutical excipients should be clarified.

Pharmaceutical excipients are classified as "drugs" under Section 201(f) of the Federal Food, Drug and Cosmetic Act and therefore would not be covered by this regulation. However, many pharmaceutical excipients are also used as food ingredients, and the importer may not know the ultimate use of a particular shipment. It is unclear who is responsible for tracking the usage of specific excipient shipments.

In conclusion, we believe that registration of facilities producing food packaging materials would be exceedingly burdensome and 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". We respectfully request that FDA eliminate food contact substances from the materials covered by this proposed regulation. Finally, we request that the status of pharmaceutical excipients be clarified.

Sincerely,



Scott J. Grare
Regulatory Coordinator,
Product Assurance and Regulatory Affairs