

1598 '03 APR -3 AIO :48

National Starch and Chemical Company

10 Funderne Avenue
P.O. Box 6500
Bridgewater, New Jersey 08807-0500
908-685-5000

Internet: <http://www.nationalstarch.com>

Writer's Direct Dial 908-685-2738

Fax Number 908-685-6955

April 2, 2003

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

Re: Docket No. 02N-0278

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 "Prior Notice of Imported Food 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 three issues that we believe need your further attention.

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

FDA is proposing in 21CFR 1.277(c)(3) to define "food" for the purposes of prior notice 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 submit prior notice of import.

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 prior notification 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 inclusion in these requirements. There would also be an additional burden on U.S. companies in verifying that

02N-0278



C 129

FDA
April 2, 2003

their foreign suppliers are aware of the requirements and register their facilities so that imported material shipments are not delayed.

(2) The definition of "port of entry" should be consistent with US Customs regulations.

FDA is defining "port of entry" in this proposed rule as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the food first arrives in the United States." Under this definition the "port of entry" could be different from the "port of entry" for U.S. Customs purposes. The FDA is also proposing to require the Prior Notice be submitted noon the day before the article of food arrives in the United States. In many cases the importer does not know the port of arrival in the U.S. until shipment arrives at the Customs' port of entry. This would increase the likelihood that Prior Notice would not be provided within the required timeframe, delaying shipments at the ports of arrival. Section 307 of the Bioterrorism Act requires only that notice be provided of the anticipated port of entry for the article. There was no further definition provided in the Act and it is conceivable that when Congress used the term "port of entry" it was referring to the commonly used and existing definition under the U.S. Customs regulations.

(3) 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 prior notice for food contact materials would be exceedingly burdensome and would have limited utility 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. In addition, we request that the U.S. Customs definition for "port of entry" be adopted for the purposes of this regulation. The Customs' port of entry information is readily available and would still allow FDA sufficient time to inspect imported food products prior to distribution to consumers in the United States. Finally, we request that the status of pharmaceutical excipients be clarified.

Sincerely,



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