



IACM

*International Association
of Color Manufacturers*

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April 3, 2003

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

ATTN: Docket No. 02N-0278 (Prior Notice)

On behalf of the International Association of Color Manufacturers (IACM), I am pleased to submit comments on the proposed regulation: "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," (The Bioterrorism Act) 68 Fed. Reg. 5428 (February 3, 2003). IACM is the international association of color additive manufacturers. IACM's members manufacture and market color additives that are incorporated into food, drugs and cosmetics in the United States.

The Proposed Regulation Is Unnecessarily Burdensome and Duplicative of Existing Requirements

The proposed regulation fails to take into consideration the operational practices of food importers and manufacturers. Requiring notice not more than five days before offering food for import and not less than noon the day before, is impractical and unnecessary to respond to an incident of intentional contamination of food imports.

In addition, the proposal fails to accommodate shipments arriving by different modes of transportation. For example, the proposed notice requirements would be the same whether a shipment arrives by sea or by airplane. Requiring notice no later than noon the day before a shipment is offered for import might be workable for importing by sea, however, an importer using air freight would find this to be a much more difficult requirement. We request that FDA revise the proposal to accommodate the different modes of transportation used for importing food.

Congressional conferees drafting The Bioterrorism Act instructed the Secretary of Health and Human Services to coordinate with the Secretary of the Treasury when developing these notice requirements. Given the proposed requirement to provide import notice to both FDA and the U.S. Customs Service, the coordination does not appear to be in place. Pending an integration of the requirements of these two important agencies, we request that FDA reconsider this proposal.

Multi Use Materials

We are concerned about the impact of this proposed regulation on materials that could be used to manufacture foods, but that could also be safe and legal to use in the manufacture of non-food products. The Bioterrorism Act amends the Federal Food, Drug & Cosmetic Act that 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" (21 U.S.C. § 321 (f)).

Under The Bioterrorism Act, the prior notice requirement applies to "food" rather than "food intended for consumption in the U.S." which appears under the registration provision.

We are concerned that this could result in compliance officials requiring prior notice on all products that *could be* used as food, even when the material is intended for use in a non-food product. It was clearly the intention of Congress that these provisions apply to food for consumption as such and therefore they should not apply to non-food products.

An example of a material that is routinely offered for import into the U.S. that may be used in both food or non-food products is titanium dioxide. This material and many others routinely imported into the U.S. can be used in both food and non-food products.

In order to clearly establish the responsibilities of importers regarding prior notice, the final regulation should include provisions relating to the declaration of intended use. Importers should be allowed to declare on the U.S. Customs request for entry that the materials are designated for non-food use and are therefore exempt from FDA prior notice requirements.

We appreciate the opportunity to comment on this proposed regulation. We are of course available to discuss any of these issues at your convenience.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn Roberts". The signature is fluid and cursive, with the first name "Glenn" being more prominent than the last name "Roberts".

Glenn Roberts
Executive Director