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FCPMC · FPACC

January 5, 2003

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

Dear Sir or Madam:

Re: FDA Interim Final Rules of the Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)

The Food and Consumer Products Manufacturers of Canada (FCPMC) is pleased to have the opportunity to provide comments on the Food and Drug Administration (FDA) interim final rules of the Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

FCPMC is the industry association representing 150 Canadian-operated member companies that manufacture and market food and consumer products sold through retail and foodservice outlets.

FCPMC is pleased that the FDA took into account our previous comments and incorporated most of them into the new interim final rules. FCPMC supports the FDA objective of the Bioterrorism Act to improve the ability to prevent, prepare for and respond to bioterrorism and other public health emergencies. It is important to have in place the appropriate mechanisms to ensure the security of the food supply is maintained. We believe that the interim final rules for prior notice and registration have taken into account the realities facing companies today.

REGISTRATION

- FCPMC recognizes that the Act requires that all non-U.S. food facilities identify a U.S. agent as a condition of import. We understand the need to have a contact for emergencies or other issues. However, FCPMC recommends that, for the purposes of registration, the U.S. agent identification be optional and be completed only by facilities electing to authorize a U.S. agent to complete the registration on behalf of the foreign facility. Further, the proposed registration form presupposes that a foreign facility may have only one U.S. agent, when in fact it may have several U.S. agents, depending on the nature and business practices of the foreign facility.

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- It is essential to protect the integrity and confidentiality of the registration number and information provided. Therefore, as FCPMC previously indicated in our April 2, 2003 comments to you, we recommend FDA investigate using an industry database, such as UCCnet or ECCnet. FDA can improve the process of registering electronically if multi-facility registrants were able to send a single transmission containing all the required data, in lieu of entering data interactively over the Internet.

PRIOR NOTICE

- FCPMC is concerned that companies may have to complete multiple prior notices per shipment. As the Canadian Food Exporters Association noted, if a company were shipping 30 different products, the rules as written would require the company to complete 30 prior notices instead of one with an itemized list. FCPMC encourages the FDA to develop one form that would allow prior notice for one shipment instead of a product-by-product basis. This would assist in streamlining the process and minimizing the paperwork required.
- FCPMC is pleased that the FDA has established prior notice timelines that reflect the mode of transportation and commercial transactions involved, and that these timelines are similar to those being implemented by the U.S. Customs and Border Protection (CBP). FCPMC recommends the timelines for imports by road and rail be amended to reflect those of CBP to reduce costly duplication and unnecessary disruption to trade.
- The rules currently indicate that a prior notice is deficient if a registration number is not provided. There are a variety of reasons food companies may import a food product where a food facility is not required to register with the FDA. For example, companies may submit prior notice for import of a food product, which does not require a food facility registration number, for the purpose of quality assurance or analysis. FCPMC encourages the FDA to amend the information required in prior notices, so that the absence of a food facility registration number does not render the notice inadequate.

FCPMC commends the FDA and the CBP for issuing the compliance policy guide, which provides a clear plan with regards to enforcement of the Bioterrorism Act. FCPMC is pleased that the policy guide indicates that during the next eight months, the FDA and CBP will primarily rely on communication and education initiatives for affected firms and individuals to ensure the Bioterrorism Act is implemented without causing unnecessary delays. FCPMC encourages the FDA to continue education and communication efforts to ensure companies are informed and understand these new rules.

If you have any questions about FCPMC's submission, please contact me at (416) 510-8024, ext. 2276.

Kindest regards,



Katharine Schmidt
Director, Public Policy