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From: Alex Lofthouse [alofthouse@chamber.ca]
Sent: Tuesday, December 23, 2003 6:29 PM
To: fdadockets@oc.fda.gov
Cc: Bob Keyes; Michael Murphy; Nancy Hughes Anthony
Subject: Docket No. 2002N-0278: Bioterrorism Act of 2002, Prior Notice of Imported Food

Dear sir or madam,

With regard to Docket No. 2002N-0278: Prior Notice of Imported Food, Public Health Security and Bioterrorism Preparedness and Response Act of 2002:

As the FDA's "e-comments" website does not currently permit the attaching of documents, I trust that you shall accept the attached document (in PDF format) as a comment on the above docket. This letter is being submitted on behalf of Robert J. Keyes, Senior Vice-President (International), Canadian Chamber of Commerce.

If you have any questions, please feel free to contact me at the co-ordinates below.

Sincerely,

Alexander Lofthouse
Senior Policy Analyst
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THE CANADIAN CHAMBER OF COMMERCE
LA CHAMBRE DE COMMERCE DU CANADA

Division of Dockets Management(HFA-305)
United States Food and Drug Administration
5630 Fishers Lane, r m.1 061
Rockville, Maryland
20852 USA

December 23, 2003

Subject: 21 CFR Part 1
[Docket No. 2002N-0278]

Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*

Dear Sir or Madam:

The Canadian Chamber of Commerce is Canada's largest and most representative business association. We represent businesses from every industry and region of our country, as well as local Chambers of Commerce and Boards of Trade in hundreds of communities throughout Canada, the largest trading partner of the United States.

On behalf of our members, we are pleased to have the opportunity to comment on the FDA's Interim Final Rules regarding Prior Notice of Imported Food, under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

The Canadian Chamber and its members believe that Canada and the United States share not only a common border and an integrated economy, but also common security interests. As such, we fully support measures that will improve the secure and efficient shipments of goods, and enable the detection and targeting of high-risk shipments. Indeed, North American industry has already been a constructive partner in this regard through active participation in initiatives such as CT-PAT and the Container Security Initiative.

In general, the Interim Final rules published on October 10, 2003 are a significant improvement upon the regulations which were initially published in February 2003. The timeframes for advance reporting are more realistic than were the previous timeframes. This is positive.

However, there are still two key issues which we would bring to your attention as the FDA makes its final rules.

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1. Co-ordination Across US Government Agencies

At present, it is still not clear how the *Bioterrorism Act* regulations will work with other border-security initiatives. It is critical that the FDA and other federal agencies—most notably the Customs and Border Protection Bureau (CBP) at the Department of Homeland Security—ensure that their respective advance data requirements are not inconsistent or duplicative.

The Canadian Chamber notes that CBP and the FDA have committed to working together to integrate and streamline their respective pre-arrival requirements and processes. It is a positive development that, under the Interim Final rules, prior notice for food shipments can now be submitted either through CBP's existing ABI/ACS system, or through the FDA's new Prior Notice (PN) System Interface.

However, the Canadian Chamber believes that the integration of the two systems should go much further. The FDA and CBP have stated that they are expecting to announce a plan relating to timeframes in March 2004, and the Canadian Chamber hopes for positive developments in this regard. At present, the timeframes for the two systems are still inconsistent in all four modes of transportation, and it is not entirely clear what the implications of these differences will be.

In addition, the FDA's proposed rules also cancel any potential benefit to the FAST program for food exporters and shippers, as no consideration is given to companies who have spent the time and money to sign up for the FAST program (unlike CBP's rules, which give FAST users an extra half-hour). It seems self-defeating for the United States and Canada to be promoting a program which grants benefits to known, low-risk traffic, only to have an entire multi-billion dollar industry excluded from those very benefits.

The Canadian Chamber urgently recommends that CBP and the FDA bring their respective requirements as close as possible to a "single-window" system for pre-arrival notification. Businesses exporting food products to the United States cannot realistically be part of a security solution if they do not have a clear, reasonable, and simple set of requirements that enable them to meet the needs of their customers.

2. Contingency Plans/Transition Periods

As with the CBP advance notice regulations, the changes under the *Bioterrorism Act* represent a "paradigm shift" in the cross-border operations of many companies. We appreciate that the FDA will be emphasizing "education" during the first eight months of enforcement (as outlined in the Compliance Policy Guide issued in December 2003).



However, the implementation plan must also include a contingency plan to ensure that border traffic can still be cleared and does not come to a standstill, as new systems are put in place and as problems are worked through. It is essential that CBP and the FDA have appropriate mechanisms and procedures in place (such as referral to secondary inspection, where appropriate) so that border congestion is not increased by the application of these new rules.

The Canadian Chamber of Commerce appreciates the opportunity to comment on these Interim Final rules. We look forward to working further with the FDA on this matter, and we would be pleased to provide any further information that is required.

Sincerely,

Robert J. Keyes
Senior Vice-President, International
Canadian Chamber of Commerce