

02N-0278_emc-000148.txt

From: Chris Mahony [Cmahony@cmaconline.ca]
Sent: Tuesday, December 23, 2003 4:44 PM
To: fdadockets@oc.fda.gov
Cc: dralston@ora.fda.gov
Subject: Docket No. 02N-0278

Please find attached CMAC's comments on the interim final rule for the Bioterrorism act 2002 Docket No. 02N-0278. We attempted to post electronically but the website was down. A hard copy of our submission has also been forwarded to you. Thank you and happy holidays.

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<<CMAC Bio Submission.doc>> <<CMAC Bio Submission.pdf>>



CONFECTIONERY MANUFACTURERS ASSOCIATION OF CANADA
L'ASSOCIATION CANADIENNE DES FABRICANTS DE CONFISERIES

23 December 2003

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

Re: Docket No. 02N-0278 Comments of the Confectionery Manufacturers Association of Canada on the Interim Final Rule concerning Prior Notice of Imported Food under the U.S. *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*.

CMAC welcomes the opportunity to submit comments pertaining to the Interim Final Rule for Prior Notice under the Bioterrorism Act of 2002. While the CMAC and its members support the objectives of the Act, we do have serious concerns with the application and practicality of some of the proposed regulations.

CMAC is one of Canada's oldest and most respected national trade associations. Our members comprise manufacturers, first importers and suppliers to an industry that includes all manner of sugar confectionery, chocolate and other cocoa-based products, chewing gum, cough drops and portable breath fresheners.

CMAC members are located across Canada, represent multinational, national, regional and local operations, and make an important contribution to Canada's economic prosperity.

In 2002, CMAC members manufactured confectionery product, destined for Canadian and international markets, most notably the U.S., valued in excess of \$2.3 billion at the factory gate.

Many CMAC members represent the Canadian presence of U.S. and multinational interests operating under rationalized North American manufacturing strategies. As well, a number of CMAC members provide inputs for further processing in the U.S. and/or finished product to U.S. customers.

In the same way that CMAC members supply product to sister operations and customers in the U.S., so too do CMAC members look to U.S. supply to complete their product offering to the Canadian marketplace.

Key to this strong interdependence between Canada and U.S. confectionery interests is the ability to move goods north and south with the utmost of efficiency and the minimum of delay, disruption and duplication of reporting requirements.

As noted CMAC supports the objectives of the Bioterrorism Act of 2002, however we do have specific concerns with the proposed interim rules as they relate to the following:

Docket #2002N-0278:

1. Multiple Prior Notice

The proposed interim final rule states that one prior notice must be given for each individual product with a separate FDA code. CMAC strongly believes that this proposed rule will detract from the FDA receiving the most accurate and timely information in prior notices and therefore will cause adverse and unnecessary financial consequences for Canadian confectionery exporters and their U.S. customers.

We respectfully submit that in order to preserve the integrity of the process, from an administrative standpoint one form per shipment with an itemized list would be more effective.

It is our hope that the FDA produces such a list that would be ample for a full shipment as opposed to implementing the rule in a product-by-product basis. Such a structure would assist the FDA and exporters and achieve a more effective and efficient partnership while reducing the risk of delays to shipments.

2. Amendment of Timelines

We are pleased that the FDA has established prior notification timelines that reflect the mode of transportation and the commercial transactions involved. The proposed interim final rule would require prior notice to be submitted to FDA no later than two hours (by road) prior to confectionery exports arriving at the U.S. border entry point.

A number of CMAC members ship product to the U.S. on a "just-in-time" (JIT) delivery and/or "same-day" basis. Moreover, the majority of these transactions are daily, repetitive shipments of low risk products from long-established Canadian confectionery companies well known to FDA and often between related operations.

The CMAC recommends that timelines for imports by road and rail be amended to reflect those of the U.S. Bureau of Customs and Border Protection (CPB) who regulate shorter prior notice timelines than the FDA. The convergence of these two systems would result in a reduction to prior notice timelines to one hour by road but more importantly will help to avoid costly duplication and unnecessary disruptions to trade.

CMAC is under the firm belief that this change will drastically reduce the administration inconvenience to 'JIT' shipping companies at little or no consequence to the objectives of the Bio-terrorism act.

3. Prior Notice for shipments sent by international mail not for re-sale

The proposed final interim rule for "Prior Notice of Imported Food" stipulates that articles imported via international mail are subject to prior notice, which must be submitted before the articles are sent to the U.S. (21 CFR 1.279(c)). This applies to companies who send individual shipments to residents in U.S. not for resale.

As the regulations stand many of these companies are exempt from registration due to their retail status. Given this portion of the policy it is our desire to realize the success of this most important new regulatory process. In this regard we are concerned that the magnitude of the not for re-sale cross boarder trade regulations will make it most difficult to monitor and unnecessarily encumber the choice of U.S. customers.

Given the sheer volume of not for re-sale trade between our countries this could potentially generate a system that is difficult to manage and control. This would, in turn, hinder the ability of small and medium Canadian confectionery exporters to work within confines of the present system.

We therefore believe that the FDA should consider providing exemptions for not re-sale exporters thereby promoting fair and equitable trade practices between our countries as well as an administrative module to ensure the success Bio-terrorism act 2002.

We greatly appreciate this opportunity to comment of the Interim Final Rules and fully support the objectives of the Bio terrorism act. CMAC looks forward to working closely with US Customs, FDA and others to ensure the implementation of the Bio-terrorism act of 2002.

Yours Sincerely,



John Rowsome
President