

CANADIAN ASSOCIATION OF IMPORTERS AND EXPORTERS INC.
ASSOCIATION CANADIENNE DES IMPORTATEURS ET EXPORTATEURS INC.

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Dockets Management Branch
Food and Drug Administration
Room 1061, 5630 Fishers Lane
Rockville, MD
20852

Subject: Docket Number 02N- 0278

This letter is respectfully submitted on behalf of the Canadian Association of Importers and Exporters Inc. (CAIE), a national, private, non-profit organization. The Association was founded in 1932 to promote Canada's international trade and to provide services for its membership. The Association has a membership base of over 640 corporations whose annual trade volumes are valued at over \$190 billion U.S.

The CAIE welcomes the opportunity to comment on the draft Prior Notice Regulations put forward in the Federal Register of February 3, 2003 concerning the implementation of the *Bioterrorism Act of 2002*. The CAIE supports the FDA initiative of securing the food supply chain and ensuring that goods destined for the United States from Canada and other countries are safe from all tampering or other malicious, criminal or terrorist actions. Smooth and efficient trade between Canada and the U.S. is critical to thousands of Canadian and U.S. companies. Hundreds of thousands of jobs depend upon the timely movement of goods across the Canada/U.S. border. Canadian companies and Canadians in general have the same food safety and security concerns as do U.S. companies and consumers in general. Canadian companies continue to make significant investments in securing their entire supply chains. Canadian exporters are more than willing to work with FDA to arrive at solutions that address safety and security needs but do not jeopardize the trade flows between our two countries.

Canada and the U.S. continue to have a unique and co-operative trading relationship and we feel that this fact should be taken into consideration in the establishment of any final pre-notification rules for Canadian exports to the United States. With the proximity of many Canadian exporters to the Canada/U.S. border we feel that consideration needs to be given to the large volumes of Canadian perishable food products and just-in-time deliveries being made on a daily basis. There needs to be flexibility in the

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pre-notification process rather than one standard that would be applicable to all U.S. imports. The FDA should consider programs such as C-TPAT which is a U.S. Customs initiative and Free and Secure Trade (FAST) which is a Canada/U.S. bilateral initiative for securing the supply chain and potentially adopt similar requirements in order to meet the objectives as outlined in the *Bioterrorism Act of 2002*.

The proposed rule which states that notice must be made by noon the calendar day before the day that the imported food product arrives at the border crossing of the port of entry will place Canadian exporters at a competitive disadvantage. This proposed rule would prevent Canadian exporters from being able to fill same day orders for their U.S. customers. This will in turn translate into delays in the shipping of perishable goods, the loss of customers, higher costs for the U.S. consumer and a reduction in the freshness and quality of low risk goods destined for the U.S. market. The CAIE would therefore strongly urge the FDA to work more closely with the Bureau of Customs and Border Protection and adopt some of the approaches soon to be implemented that address similar pre-notification requirements for goods destined for the U.S.

U.S. importers of record or their agents already supply much of the information that is requested to be included in the prior notice to U.S. Customs. Rather than having the FDA develop a system for capturing this data, procedures that are already in place between the FDA and U.S. Customs need to be further enhanced to be able to receive this data that for the most part is already being provided. Duplication needs to be avoided as that adds cost into the process both for industry and government.

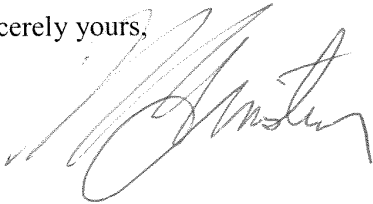
Another area of concern to Canadian importers is the proposal that goods transiting from Mexico and elsewhere, in bond, through the United States, will have been deemed "imported or offered for import". The proposal indicates that the same prior notice requirements be met for these goods. However, the proposed data elements in a number of cases are not applicable and the information being sought is Canadian commercial data and not U.S. commercial data. The requested data, in this case, needs to be reviewed by the FDA and further modified.

A critical concern for Canadian exporters contained in the proposed rule for prior notice revolves around the parties that would be authorized to provide the requested information to the FDA. The proposed rule indicates that the purchaser or importer resides or maintains a place of business in the United States or that their agent, acting on behalf of a U.S. purchaser or importer, resides or maintains a place of business in the United States. According to current commercial reality, in most cases it is the Canadian exporter that is the U.S. importer (non-resident importer) of record. According to the commercial transaction, it is the Canadian exporter who is the actual owner of the product until it is delivered to the U.S. customer. If only resident U.S. parties or their agents are permitted

to submit the prior notice to the FDA, another layer of reporting requirements will be introduced into the process, further reducing efficiencies, increasing costs and the chances for errors, along with providing a distinct competitive disadvantage for Canadian exporters. The *Bioterrorism Act* does not specify which parties must submit the notice. The CAIE would therefore urge the FDA to utilize currently established commercial and Customs processes for the gathering of the requested data.

We, along with a number of our members, would be pleased to meet with you to discuss this matter further. If you have any questions please do not hesitate to get in touch with me at (416) 595-5333 ext. 24 or via E-Mail at barmstrong@caie.ca.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'R.J. Armstrong', written over a light blue horizontal line.

R.J. (Bob) Armstrong
President
Canadian Association of Importers & Exporters Inc.