

Canadian Embassy



Ambassade du Canada

501 Pennsylvania Ave., N.W.
Washington, D.C. 20001

May 14, 2004

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

ATTN: Docket No. 2002N - 0276

Registration of Food Facilities

The Government of Canada welcomes the opportunity to review and provide comments on the above-referenced notice of the reopening of the comment period of the interim final rule making concerning the Registration of Food Facilities as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of April 14, 2004.

If you have any questions on the submission, please contact the undersigned at 202- 682-7787.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'R. Krystynak'.

Ronald Krystynak
Agriculture Counsellor

6029 04 MAY 14 21:43

2002N-0276

C236

3 Impact on Small Foreign Facilities

Canada agrees with the assumption of the FDA that the number of foreign facilities which will choose to stop exporting to the United States will depend on the cost of registration for the individual facility and the return on the shipment in the United States versus its return in other markets. According to our information, the FDA has identified fairly accurately the cost of finding and engaging a U.S. agent to individual facilities. However, the economic analysis does not consider the impact of these costs proportionate to the value of the exporter's shipments and the larger impact on Canadian/U.S. trade.

The impact of the cost of a U.S. agent for Canadian exporters of small value shipments to multiple importers in the United States is greater than the impact on those exporters of large value shipments to single importers. Exporters of small value shipments do not generally engage a U.S. Custom Broker. As well, the importing clients of these exporters are commonly various individuals and multiple small retail outlets which cannot be easily identified as a U.S. agent.

Due to our shared border, the number of Canadian facilities exporting small value shipments to the United States is much greater than that of other countries, such as those in Asia or Europe. Therefore, the impact of the cost of the U.S. agent requirement for individual Canadian facilities is much greater than for other countries.

Canada requests that the economic analysis identify the impact on the cost of registration for exporters of multiple shipments of small value separately from those exporters of shipments of large value and that the requirement for the U.S. agent for such exporters be reassessed.

4 Impact of Prior Notice Fees

The fees charged by U.S. agents for registration purposes are in many cases directly linked to the costs charged by the U.S. agent for prior notice. The cost of engaging a U.S. agent is lower in instances when the prior notice fees are higher. For example, a U.S. agent costing \$400 per year per facility charges \$12 per prior notice submission, whereas a U.S. agent costing \$750 per year per facility charges \$5 per prior notice submission.

Canada requests that the economic analysis of the impact of the cost of engaging a U.S. agent takes into consideration as well the cost to exporting facilities for compliance with the Prior Notice Rule.

**Comments of the Government of Canada on the Interim Final Rule concerning
Registration of Food Facilities Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002;
Reopening of the Comment Period**

Docket No: 02N-0276
FR Doc.: 04-8516

RE: Registration of Food Facilities

1 Introduction

The Government of Canada welcomes the opportunity to provide further comments during the reopening of the comment period of the *Interim Final Rule concerning Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* as published by the Food and Drug Administration (FDA) Department of Health and Human Services, in the *Federal Register of April 14, 2004* (Volume 69, Number 72).

As per the Federal Register notice, these comments are limited to the identified set of issues concerning the economic impact on the cost to Canadian facilities of hiring and retaining a United States' agent. Canada trusts that, as per the Federal Register notice, the FDA will also address our previous concerns which were submitted to the FDA on December 22, 2003, and, as such, have not been reiterated in this submission.

From our consultations with Canadian stakeholders, it is clear that the cost of engaging a U.S. agent is a disadvantage to Canadian exports of food and feed products to the United States.

2 Unnecessary Cost Burden

Under the interim final Registration rule, the majority of Canadian facilities have identified both an emergency contact and a U.S. agent. The cost of engaging a U.S. agent varies between \$400 and \$1200 per facility per year. FDA will only contact the U.S. agent if the emergency contact identified by the facility is unavailable. Having two contacts for the same purpose is an unnecessary cost burden for Canadian industry.

Canada requests that where an emergency contact has been identified by a facility, the FDA use that contact and exempt such facilities from the requirement to have a U.S. agent. With this approach, the FDA could reasonably require that such an emergency contact be able to communicate in the English language.