

Comments of the Canadian Produce Marketing Association on the Interim Final Rule concerning Registration of Food Facilities Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*; Reopening of the Comment Period

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

1 Introduction

The Canadian Produce Marketing Association is pleased to provide additional 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 (Bioterrorism Act)* 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).

Our comments are focused primarily on the identified set of issues concerning the economic impact on the cost to foreign facilities of hiring and retaining a United States' agent. We understand from consultations with our Canadian government that the FDA will be addressing other comments that were previously submitted by Canada.

From our consultations with our members, it is evident that the cost of engaging a U.S. agent is a disadvantage to Canadian exports of fresh fruits and vegetables to the United States.

2 Cost Burden

Under the interim final Registration rule, it is our understanding that the majority of our industry member's facilities have identified both an emergency contact and a U.S. agent. The cost of engaging a U.S. agent based upon our member's responses ranges between \$700 (U.S.) and \$1200 (U.S.) per facility per year. It is our understanding that the FDA will only contact the U.S. agent if the emergency contact identified by the stakeholder is unavailable. Having two contacts for the same purpose is a further unnecessary cost burden for Canadian industry.

It is also our understanding that a number of farms that grow and pack their own produce have also hired a U.S. Agent based upon the recommendations of border brokers. This has added a cost exceeding \$500 (U.S.) for a farm type "registration.

We definitely seek a very clear explanation as to whether farms which grow and pack their own produce are exempt from the facilities registration requirement. We would appreciate any changes which would lessen the charges being incurred by our industry due to both the facilities registration requirement and the prior notice requirement. We have been told by Canadian agriculture officials that such farms are exempt, but border brokers have been providing contrary advice.

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3 **Small Foreign Facilities**

We concur with the FDA assumption 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.

Our feedback from industry members has not identified any cases of firms ceasing export operations to the United States as a result of the cost of a U.S. Agent. However, it has introduced a level of extra direct and indirect cost.

4 **Impact of Prior Notice Fees**

We have been advised that 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.

This has been supported by our member survey, which indicates the direct cost of filing a prior notice ranging from \$10 (U.S.) to \$25 (U.S.) per Prior Notice. For one of our members, this has added an annual cost to their business of \$35,000 U.S.; which is extremely costly. For some potato shippers, this prior notice requirement adds a cost between \$15 (U.S.) and \$120 (U.S.) per load. For export loads with multiple commodities and consignees, the cost would be exponentially higher, and excessive.

We would sincerely hope and request that the USFDA completes an economic analysis of the impact of the cost of engaging a U.S. agent, and the impact of the cost of the prior notice requirements to exporting facilities for compliance with the Prior Notice Rule. We sincerely hope USFDA will give positive consideration to ways in which to reduce these costs; for example, a single prior notice per consignee, which could still capture the data fields required by USFDA.

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May 11, 2004