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Washington, D.C. 20001

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

ATTN: Docket No. 02N-0276

RIN 0910-AC40

Registration of Food Facilities

The Government of Canada welcomes the opportunity to review and provide comments on the above-referenced notice 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 October 10, 2003.

If you have any questions on the submission, please contact John Masswohl at 202-456-7629.

Yours sincerely,

William R. Crosbie
Minister-Couonsellor
(Trade and Economic Policy)

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 (*Bioterrorism Act*)

Docket No: 02N-0276
RIN 0910-AC40

1 Introduction

The Government of Canada welcomes the opportunity to provide comments on the above-referenced notice of interim final rule-making as published by the Food and Drug Administration (FDA) Department of Health and Human Services, in the *Federal Register of October 10, 2003* (Volume 68, Number 197).

From our consultations with Canadian stakeholders, it is clear that confusion exists concerning the interpretation of the interim final Rule for Registration of Facilities. The comments which the Government of Canada offers are aimed at improving the Rule to avoid unnecessary disruption and disadvantage to Canadian exports of food and feed products to the United States, while meeting the objectives of the *Bioterrorism Act.*

2 Potential Inconsistent Interpretation

The Government of Canada is pleased that exemptions have remained in the final Rule dealing with farms, fishing vessels, transporters and other types of facilities. However, we are concerned that many of the exemptions are based on and defined according to location and the activity performed at the location. For example, a vessel which eviscerates and freezes fish is not required to be registered. However, a land-based facility which eviscerates and freezes fish is required to be registered.

We are concerned that this approach will result in inconsistent interpretation of the requirements, since border officials may not be in a position to validate where the activity took place and therefore, to know whether registration of the facility is required. This may potentially disrupt trade.

We request that the FDA implement a mechanism which will enable both border officials and Canadian exporters to clearly identify whether a facility is required to be registered.

3 Application to Holding Facilities

We are also concerned as to how the FDA plans to enforce the requirement for registration of foreign facilities which hold or store products exported to the United States. We note that information concerning the holding facility of the product is not required to be provided through the prior notice process.

The Government of Canada strongly urges that the requirement for foreign holding facilities to be registered be removed from the Rule. If this requirement cannot be realistically administered, it may result in an inconsistent application of the requirement.

4 Clarification of Exemptions

The Government of Canada appreciates the outreach and guidance documents provided on the interpretation and application of this Rule. However, we are concerned that certain activities, which are normally conducted on farms, have not been specifically identified as activities which may be performed on a farm facility exempt from registration. We are concerned that the inadvertent exclusion of these activities will cause misinterpretation and application of the farm exemption.

For example, we request that the Rule be amended to clarify that farms performing common routine activities in preparing and maintaining products for sale be exempted from the requirement of registration. These activities include, but are not limited to the following:

- Farms which raise, eviscerate and pack fish products;
- Farms which pack food products grown on other farms;
- Farms which dry products as part of the holding process;
- Farms which apply pesticides to products prior to and after harvesting to permit the holding of the product (i.e., sprout inhibitors on potatoes);
- Farms which supply fruit trees for landscaping; and
- Farms which pack herb plants in pots.

5 U.S. Agent Requirement

We recognize that the *Bioterrorism Act* requires that all foreign food facilities identify an agent, who is a resident of the United States, as a condition of import. We understand the need to have a contact for emergencies or other issues, and that this contact be available and speak English. However, we find the residency requirement for such agents to be unnecessary and excessively burdensome. We believe that the United States would find such a measure to be unacceptable if imposed on United States' exporters by other countries. We also note that the requirement of all foreign food facilities to identify such an agent as a condition of import will result in an additional cost to be borne by foreign facilities, which is not borne by domestic United States' facilities.

Therefore, the Government of Canada requests that the FDA review the requirement that agents for registered food facilities be residents of the United States, and if possible, that it be eliminated.

6 Concluding Remarks

We understand that many Canadian stakeholders are providing comments directly to the FDA and we would urge the FDA to give serious consideration to all of these comments. While the Government of Canada's comments take into account views from various Canadian stakeholders, they are not exhaustive in covering all these views.

We request that the FDA takes all comments into consideration and distributes an improved Final Rule as a basis for further consultation in the near future.