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United States Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD. 20852

The Ontario Ministry of Economic Development and Trade (MEDT) and the Ontario Ministry of Agriculture and Food (OMAF) welcome the opportunity to provide comments on the *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: Reopening of Comment period*, as published on April 14 by the Food and Drug Administration (FDA), Department of Health and Human Services, Federal Register No 2002N-0276. These comments are provided in addition to any submissions tendered by the Government of Canada.

Ontario recognizes the security objectives inherent in the Bioterrorism Act, and accordingly supports the FDA's general approach to improve its ability to prevent and respond to bioterrorist threats and potential food security vulnerabilities. We also seek an implementation approach that takes into account the unique trading relationship between Ontario and the U.S.

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From our consultations with stakeholders, there is significant concern regarding the requirement that all foreign food facilities identify an agent who lives or maintains a place of business and a physical presence in the U.S. as a condition of import.

We understand the FDA's need to have a contact for emergency or other situations, and that this contact be readily accessible and speak English. However, this requirement has unduly affected many of Ontario's agri-food exporters with additional costs.

The majority of Ontario facilities complying with the registration requirements have identified both an emergency contact and a U.S. agent. Having two contacts for the same purpose is an unnecessary cost burden for Ontario exporters, a burden borne more significantly by our small and medium sized exporting operations.

The impact of these costs is greater for small to medium sized exporters transporting small shipments to a variety of small US retailers because they have not engaged a U.S. Customs Broker, as Customs and Border Protection (CBP) does not require advance information on low value shipments. Moreover, since most of their U.S. clients are individuals or small retail outlets, they are ill suited to act as a U.S. agent. These exporters therefore must find and engage a U.S. agent, the cost of which varies between \$400 and \$1,200 per facility per year.

In contrast, larger firms who already have a U.S. customs broker on retainer and/or are shipping to single or only several US destinations in accordance with long-standing relationships with U.S. clients, are better able to blend these costs with those attributable to retaining a U.S. customs broker.

These impacts are compounded for those operations working through third party warehousing facilities and affiliates, who are also required to comply with the pre-registration requirements and therefore must also engage a U.S. agent. These costs tend to accumulate throughout the production chain, and place Ontario firms at a competitive disadvantage with respect to U.S. suppliers.

Alternatively, we suggest that the FDA consider accepting the emergency contact or the Canadian broker identified in the registration submission as fully satisfying the registration requirements, and in turn exempting these firms from the additional burden of engaging a U.S. agent.

We hope you find our observations and comments helpful in your deliberations and development of a Final Rule. We respect and value the FDA's willingness to subject its

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proposals to regular public review and comment, and encourage you to give serious consideration to those submissions tendered by the many Ontario and Canadian stakeholders affected by this Rule.

Sincerely,



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Competitiveness and Business Development Division
Ontario Ministry of Economic Development and Trade



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Assistant Deputy Minister
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