

December 19, 2003

file no - 65690a

Comments on the interim final rule proposed by the Food and Drug Administration (FDA) of the United States Department of Health and Human Services under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*.

Submitted by the Ministry of Agriculture, Food and Fisheries of the Government of the Province of British Columbia, Canada

Re: Docket No. 02N-0278 - **Prior Notice of Imported Food**

The Ministry of Agriculture, Food and Fisheries of the Province of British Columbia in Canada welcomes the opportunity to provide comments on the above-referenced rulemaking as presented by the Food and Drug Administration (FDA), Department of Health and Human Services in the *Federal Register* of October 10, 2003 and at the website <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-25877.htm>. These technical comments are submitted on behalf of the Ministry.

As specified in our April, 2003 comments on the previous version of the rule, this Province supports the objectives of the *Bioterrorism Act of 2002*. We want the FDA to succeed in its stated objectives to counter bioterrorism. We believe it is advisable and necessary that the provisions of the Act be implemented in regulation in a way that achieves the objectives of the provisions. In this context, we recommend that the FDA take into account the unique circumstances of product movements across the Canada-United States border, and the highly integrated nature of the economies of the two countries. This includes large volumes of just-in-time deliveries and perishable food products, delivered by means of truck traffic. It is in the interest of the United States, Canada and British Columbia that we work to address the threat of bioterrorism in ways that do not permit such threats to succeed by disrupting our economies and trade patterns.

We appreciate that in drafting the interim final rule, the FDA has taken into consideration several of our April, 2003 comments on the proposed rule. We are particularly pleased that the minimum time to submit prior notice has been shortened.

We have heard from stakeholders in British Columbia that there is still confusion regarding the application of the rules and encourage you to continue with your efforts towards education and outreach. We appreciate the "Transitional Compliance Policy" that allows for a "phase-in" of the regulations.

Stakeholders have expressed concern over additional, sometimes prohibitive costs that must be incurred to ship included products over the border (e.g., increased brokerage fees associated with multiple prior notifications). Other concerns include difficulties and delays while working with the United States electronic systems established to handle prior notifications. Users are concerned with delays due to heavy traffic on your website

and when calling your “help desk” for assistance. Some stakeholders believe there is a disincentive towards product diversification when exporting to the United States because of the requirements which puts them at a competitive disadvantage compared to United States originating shipments. There is also frustration because of the lack of a *de minimus* exemption for small shipments, especially by small businesses.

Cooperation with Other United States Departments

Delays in border crossings would have significant impacts for the operations of a broad range of United States and Canadian businesses. Adequate resources at the border will mitigate some of the anticipated negative impacts of the proposed rulemaking.

We appreciate the action taken by FDA to strengthen the implementation of the Bioterrorism Act by collaborating with the Bureau of Customs and Border Protection (CBP), particularly when it comes to commissioning staff to conduct examinations and investigations in accordance with the rule and information sharing. We hope these arrangements allow for sufficient resources to be available in a timely manner to ensure delays are minimized.

The British Columbia Ministry of Agriculture, Food and Fisheries encourages the FDA to delegate authority to the United States Department of Agriculture (USDA), as it has with CBP, to enable the USDA to implement prior notice requirements on products where the USDA shares jurisdiction. This would avoid costly disruptions to trade.

Expedited low risk shipments

The interim final rule does not take into account the Canada-United States Smart Border Plan (SBP). A key element of the SBP is the Free and Secure Trade (FAST) bilateral arrangements. Under the United States Customs-Trade Partnership (C-TPAT) and the Canadian partnerships in Protection (PIP) programs, companies approved by both countries have invested in specific counter-terrorism and supply-chain integrity measures and are therefore accorded more expedited treatment at the Canada-United States border in recognition of the lower risk they present.

We propose that the FDA allow for the use of a voluntary risk-based program, such as FAST, to allow the FDA to focus its resources on higher risk shipments.

Ongoing flexibility to amend the final rule

We strongly urge the FDA to build into the final rule the capability to amend administratively the prior notice provisions quickly if needed. This would be particularly important for imports from any country with which the FDA has reached a bilateral arrangement. Such arrangements would serve as the basis for having different (e.g., more efficient, effective or risk based) prior notice requirements. Such a provision would be important so that the FDA could adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements. Regulatory agencies in Canada

and the United States already cooperate on a unique and unprecedented basis. Under the Smart Border Plan, this cooperation will be enhanced, including in the areas of food safety and countering bioterrorism.

Prior notice information

There are extensive requirements for information for each prior notice in the interim final rule. Multiple notices will be needed for essentially the same product from the same exporter 365 days a year. We recognize that the requirements can be quite onerous for small shipments and recommend that a *de minimus* threshold be established.