April 3, 2003 file no - 65690a

Comments on rules proposed by the Food and Drug Administration (FDA) of the Department of Health and Human Services under the U.S. *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 notice of proposed rulemaking as presented by the Food and Drug Administration (FDA), Department of Health and Human Services in the *Federal Register* of February 3, 2003 and at the website http://www.fda.gov/OHRMS/DOCKETS/98fr/03-2444.htm. These technical comments are submitted on behalf of the Ministry.

This Province supports the objectives of the *Bioterrorism Act of 2002* and the objectives stated by the FDA in the proposed rule for "prior notice". 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 find ways to address the threat of bioterrorism in ways that do not permit such threats to succeed by disrupting our economies and trade patterns.

Our comments aim to reduce the economic costs to both sides of the border without sacrificing the FDA's ability to deter, prepare for and respond effectively to bioterrorism and other public health threats. We believe that our comments will lead to more efficient and lower cost border movements for both countries, in particular for the benefit of shippers, brokers, processors and final consumers in the United States (U.S.) Delays in border crossings would have significant impacts for the operations of a broad range of U.S. businesses. Adequate resources at the border, particularly more FDA staff, would mitigate some of the anticipated negative impacts of the proposed rulemaking.

We also believe that the FDA should move toward an integrated tracking and tracing system to respond more effectively to the full range of threats in the food

supply system, including reducing the impacts of the food-borne outbreaks, given as examples in this rulemaking proposal.

Minimum time for submission of prior notice

Based on our knowledge of the history, nature and magnitude of shipments across Canada-U.S. border, the proposed “one size fits all” minimum time for prior notice is not sufficiently flexible. Indeed, it actually may rob the FDA of any advantages it could realize from having a longer notice for slower modes of transport. It is important for the Canada-U.S. border that the minimum time allowed for notice strike the right balance between the FDA’s needs and the unique commercial environment of huge volumes shipped by truck and rail. We believe the minimum time afforded for prior notice requirements should reflect the relative risks involved. We suggest that shipments to the U.S. from Canada, for example for seafood and fruits and vegetables, are low risk or otherwise non-threatening and that therefore such shipments may have the benefit of reduced prior notice times. Some of our fruit and vegetable shipments originate on a daily basis from locations less than 30 minutes from the border.

Section 1.286 of the notice of proposed rulemaking will place British Columbia exporters at a distinct disadvantage by preventing delivery of same-day orders. We urge the FDA to amend this element of the rule to allow exporters to select alternative options, such as in the example alternative option below, which would better accommodate existing business practices, as well as providing accurate information in advance to the FDA.

Current proposal: Exporters whose business practices generally align, easily or with some restructuring, with the current proposal of noon the day before arrival (with the ability to submit limited amendments for product identity and quantity) would elect to comply with the FDA’s current proposal.

Alternative option: Exporters that generally service quick turnaround orders (e.g. same day orders, perishable products, “catch of the day”, “just-in-time” deliveries to meet U.S. buyer preferences) should be able to restructure commercial practices, if necessary, to ensure that all the required information is available and notified no later than four hours before arrival. This would facilitate fresh fruits and vegetables and fresh and perishable seafood shipments. Even here the ability to make amendments is necessary, as some horticulture shipments are only finalized at the time of loading.

This alternative option would better serve the daily just-in-time deliveries, yet also provide accurate and full information to FDA earlier than the two hours provided for amended notices in the FDA’s existing proposal. This would enable Canadian exporters to comply with the FDA’s need for accurate information enough in advance to interdict perceived risks, which appear to be consistent with the needs of border management. These practices would also support U.S. buyers'

just-in-time delivery preferences and their high quality requirements. In considering this approach, the FDA should consider that the vast majority of these types of transactions will be daily, repetitive shipments of low risk products from Canadian companies well known to the FDA. We believe that this would provide the needed commercial flexibility to our exporters and U.S. buyers and also ensure the highest level of compliance for the FDA.

Persons authorized to submit prior notice

When a British Columbia product is exported to the U.S., it is the exporter that knows, with the highest degree of accuracy, the precise information about the shipment that must be submitted to the FDA to meet its requirements. In transactions involving perishables or just-in-time deliveries or transactions involving companies located near to each other across the border, the current proposal will introduce errors. There are thirteen pieces of information required under the proposed regulations. Any errors in the notification can cause shipments to be held at the border. Such instances will be very serious and costly. The U.S. customer receives all the information third-hand and thus makes it more difficult to comply with the minimum time for advance notice. It is the Canadian exporter that will know the soonest and with the highest degree of accuracy precisely what is being shipped in an order. We therefore recommend that the proposed rule be amended to authorize the exporter to make prior notice submission instead of resident U.S. parties or their agents.

Dialogue by FDA with businesses affected by these proposals

We appreciate the level of consultation and communication that has been conducted by the FDA in soliciting and fully considering all comments and informing all the affected parties. We still find, each day, that there are businesses that have not yet fully heard of, or understood, the proposed rulemaking. In view of the many questions concerning the precise coverage of articles of food over which the FDA has jurisdiction and that would therefore require prior notice, we urge the FDA to disseminate more precise information with examples so that exporters can determine whether and how they will be affected.

With the creation of these new rules, extensive new information requirements and the creation of new electronic supporting systems, it will be even more important for the FDA to continue these valuable consultation efforts as implementation proceeds. It will be equally important for the FDA to ensure that administrative systems are fully maintained, with back-up systems, to avoid any need to revert to a paper system, when the system is operational.

Amending the prior notice – product quantity and late arrival times

Since amendments for product quantity or brand names have no bearing on the

decision to detain product imports based on bioterrorism related reasons, we recommend that amendments be allowed for product quantity and brand names. We do not see the usefulness to the FDA of providing an amendment notice of the initial notice for product quantity.

We recommend that the exporter that chooses to use a specific border crossing not be required to report lateness in the time of arrival. Such lateness may be due to factors beyond the shipper's control, such as weather or traffic. Border crossings should be staffed with FDA inspectors on a round the clock basis, instead of having FDA inspectors present at border crossings for short times based on notified shipment arrivals and related decisions on bioterrorism risks.

To address the potential for exceeding the four hour allotted window to arrive at and cross the border as a result of border line-ups, we support the concept of having an arrival registration mechanism. A vehicle arriving at the border area and entering a line-up would register its arrival time at the border area at a check-in point. If unusual delays in the line-up led to waits for processing longer than the four hours allotted, there would be proof that they had indeed arrived at the border in necessary time. While this would add another level of administration to the border proceedings, it would provide the carrier with the desired recognition that they had made every effort to comply with the required FDA processes.

Prior notice information

We urge the FDA to rethink the extensive requirements for information as set out in the proposed rule. In particular, multiple notices will be needed for essentially the same product from the same exporter 365 days a year. The FDA level of detail should be as compatible as possible with the entry line level of detail required to be submitted to the U.S. Customs Service. It is important for the FDA to clearly define the circumstances under which updates or amendments or resubmissions of notices must be made due to changes in the nature of the shipment after a notice is submitted.

We support the concept outlined by the Canadian Produce Marketing Association for a registry of licensed exporting firms to streamline the process of border crossings with a minimization of potential threats. A version of such a working system currently exists in the fresh fruit and vegetable sector. Such systems could reduce many of the proposed administrative requirements which will be burdensome to a non-problematic or non-threatening industry in both countries.

We have heard that packaging materials, such as plastic wraps, paper cartons, or paper containers that touch products also need to be registered. If this is the case, the FDA will need to indicate how the registration and notification process would work.

Country of Origin - Fish

We propose that the standard rules of origin used by U.S. Customs and under the World Trade Organization (WTO) trade rules be used to convey country of origin on the product being imported to the U.S.. FDA should amend the current provision to define the country of origin for fish products as the country in which the fish were last processed as opposed to the country under which the harvesting vessel is flagged.

Fish is a globally traded and sourced raw material which British Columbia processors may source from several countries to make a like product for export. Defining country of origin as proposed for fish will lead to inevitable and likely uncontrollable errors for prior notice purposes. From a risk perspective, the last point of processing before exportation to the U.S. would likely be the point of greatest risk and greatest interest to the FDA.

FDA and U.S. Customs: requirements and communications

It is important that the requirements of the FDA and U.S. Customs be as consistent as possible to avoid costly duplications and unnecessary disruptions at the Canada-U.S. border, for example in relation to the Customs Trade Partnership Against Terrorism (CT-PAT) and the Free and Secure Trade (FAST) bilateral arrangements. We are concerned about possible miscommunications or breakdowns between Customs and the FDA as their parallel systems are integrated. Even temporary shut downs of the electronic systems or the temporary use of paper systems will result in unmanageable congestion at the Canada-U.S. border.

Like others, we propose that the FDA create a field in their electronic prior notice form which the firm could complete if they have been approved as a CT-PAT shipper. This would be an item for the FDA to build into their system which will help identify shipments of low risk entering the U.S..

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 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 U.S. 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.