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Comments of the Government of Canada on rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the [U.S.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*.

Docket No. 02N-0278

Prior Notice of Imported Food

The Government of Canada welcomes the opportunity to provide comments on the above-referenced notice of proposed rulemaking as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of February 3, 2003.

The Canadian Government supports the objectives of the *Bioterrorism Act of 2002* and the objectives stated by the FDA in the proposed rule for "prior notice". During Congressional consideration of the *Bioterrorism Act*, the Canadian Government expressed its support to Congress and noted the importance of the prior notice provisions to both the United States and Canada, given the that the two countries enjoy the world's largest trading relationship across the Canada-United States border. Consequently, the Canadian Government urged Congress to provide the Secretary of Health and Human Services with the necessary regulatory authority to implement the prior notice provisions in a way which achieved the objectives of the provisions, while at the same time taking account of the unique circumstances of movements across the Canada-United States border and the highly integrated nature of the economies of the two countries. Congress opted to provide FDA with this flexibility rather than mandating more rigid statutory requirements as originally considered.

As FDA implements this provision, the Canadian Government has the same direct interest. We want the FDA to succeed in its stated objectives to counter bioterrorism while at the same time, as stated in Section III of the proposed rule, meeting United States international trade obligations, including the World Trade Organization agreements and the North American Free Trade Agreement, for example, by not making the rule "more trade restrictive than necessary to meet the objectives of the *Bioterrorism Act*". In order to be effective, the prior notice rule must take into account the unique commercial environment present at the Canada-United States border, which include large volumes of just-in-time deliveries and perishable food products.

General Comments

We would urge FDA to reconsider elements of its fundamental approach in the proposal. As stated, we fully support its purpose. However, these objectives must be achieved in a way which specifically takes into account the unique circumstances of the Canada-United States border. In this connection, we note that Section 302 of the *Act* includes a direction to the FDA to facilitate the importation of food in compliance with the requirements. The minimum time afforded prior notice requirements should also reflect the relative risks involved.

The *Act* also gives the FDA fairly wide latitude to establish prior notice requirements that fit the circumstances applicable to various situations.

“In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration.”

The FDA should make full use of the discretion consistent with the other objectives of the statute.

In particular, the proposed “one size fits all” minimum time for prior notice is not flexible enough for the Canada-United States border and actually may rob FDA of any advantages it could realize from having more advance notice for slower modes of transport.

The FDA should establish a minimum time for vessels that reflects this mode of transport. For example, the U.S. Customs Service has established a requirement for a notice 24 hours in advance of the lading of vessel. The FDA could benefit from a similar rule for vessels by having the same requirement but “capping” it to by a maximum time of five days to reflect the FDA’s statutory maximum. In addition, imports by vessels will generally represent imports in higher risk categories than imports from Canada.

For imports by truck, rail or aircraft, the FDA should establish times that reflect these modes and the commercial transactions involved. This approach is being promoted by the U.S. Customs Service. It is important for the Canada-United States border that the minimum time allowed for notice strikes the right balance between the FDA’s needs and the unique commercial environment of huge volumes shipped by truck and rail. It is also important that the requirements of the two agencies be as consistent as possible to avoid costly duplications and unnecessary disruptions at the Canada-United States border.

Also unique for Canada-United States transactions is the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) bilateral arrangements which are available for low risk imports. They flow from the Smart Border Plan directed by Department of Homeland Security Secretary-designate Ridge and Deputy Prime Minister Manley. The FDA should be building on these Customs initiatives which share the FDA's counter-bioterrorism objectives. Canadian exporters enrolled in these programs have invested heavily in preventative measures which clearly result in reduced bioterrorism risks from an FDA perspective. The proposal therefore needs to take this into account through reduced prior notice times or otherwise acknowledging the reduced risk.

In our review of the proposed rule, there are two main elements which should be amended. These are: (1) the limitations on who is to submit the prior notice; and (2) the minimum allowable time prescribed for submission of the notice.

When Must the Prior Notice Be Submitted to FDA?

The proposed rule, in Section 1.286, requires the notice to be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing point. In addition, the prior notice, except for two specific product identity amendments, cannot be submitted until all of the extensive required information exists.

This proposal is premised both on the FDA's need to have adequate time to review prior notices and dispatch inspectors to interdict suspect shipments. As well, it appears to derive from FDA's sampling of actual Customs entries. The proposed rule does not address how representative was the sample of 64 entries, and upon which the proposal was initially developed. It does not state whether or to what extent entries for imports from Canada were included. If the FDA intends to use such a sample to underpin the minimum notice time, we strongly encourage FDA to draw a sample representative of the enormous volume of shipments by truck and train at the Canada-United States border that would more accurately reflect the nature of imports from Canada.

The Canadian Government recognizes that FDA has proposed the use of amendments to product identity and quantity for up to two hours before arrival as a means of taking into account perishable products and "just in time" deliveries. This in part appears to be based upon the economic analyses included in the proposed rule. For example, a four-hour advance notice appears to have been rejected, in part due to the significant occurrence and cost to companies of dealing with inadequate notices in circumstances where the full information does not exist until less than 4 hours before arrival. It would appear that the proposal for noon the day before plus the ability to make limited amendment until up to 2 hours before arrival was developed as a solution.

The proposal will place Canadian exporters at a distinct disadvantage by preventing delivery of same day orders. The Canadian Government therefore urges the FDA to amend this element of the rule to allow exporters to select one of two options, as

follows, that would accommodate their general business practices and provide accurate information in advance to FDA. If necessary, FDA could require that, once selected, the option would be locked in.

Option 1: 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 existing proposal.

Option 2: Exporters that generally service quick turnaround orders (e.g. same day orders, perishable products, "catch of the day", "just-in-time" deliveries) could elect to restructure commercial practices, if necessary, to ensure that all the required information is available and notified no later than four hours before arrival. Under this option, no amendments would be permitted. This approach would better serve these types of transactions and 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 FDA's need for accurate information enough in advance to interdict perceived risks.

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 FDA.

The above "two options" approach we think would be consistent with FDA's objectives and provide the needed commercial flexibility to Canadian exporters to ensure the highest level of compliance for FDA.

Who Can Submit the Notice ?

The proposed rule, under Section 1.285, would require the prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States, acting on behalf of the U.S. purchaser or importer. With respect to the unique commercial environment at the Canada-United States border, this proposal will detract from FDA receiving the most accurate and timely information in prior notices and will cause serious adverse and unnecessary commercial consequences for Canadian exporters and their U.S. customers.

Most imports from Canada at the land border are sold on the basis of the Canadian exporter taking responsibility for the entire U.S. Customs and FDA transaction at the border. The Canadian exporter is the actual owner of the food product until delivered to the U.S. customer. The invoice price to the U.S. customer will normally be inclusive of all U.S. customs or other U.S. border agency charges. The Canadian exporter normally hires and pays a U.S. Customs house broker to act as its agent at the border, including all liabilities for duties or fees, including, for example, any redelivery to FDA and

Customs (or liquidated damages) of any food shipments found to be non-compliant upon sampling and testing by FDA. It is the Canadian exporter, for legal purposes, that is the U.S. importer of record.

If only resident U.S. parties or their agents are permitted to submit the notice, the FDA will be creating obstacles to its objectives.

The resident U.S. customer will need to provide information third hand in the notice as obtained from the Canadian exporter. In transactions involving perishables or just in time deliveries or transactions involving companies located near to each other across the border, this will introduce errors and make 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.

In any case where the shipment may be the subject of an inadequate notice, it is the Canadian exporter that normally owns the products at the border that would be held or sent to a secure facility. However, under the proposal the FDA will be requiring the resident U.S. customer which does not have a financial interest in the product to bear responsibility for complying or disposal of the product. The inclination may be to simply abandon the shipment and cease to do business with the Canadian exporter.

From an operational standpoint, FDA is requiring detailed and extensive information for the prior notice. The level of detail is consistent with the information normally submitted by U.S. Customs brokers acting as agents for importers of record. As noted above, it is the Canadian exporter that hires such a customs broker and provides this information to the broker acting as the exporter's legal agent. The proposed rule would result in this information continuing to be submitted by Canadian exporters and their U.S. customs brokers for Customs Service purposes yet, at the same time, requiring for the same transaction the submission of essentially the same data by a resident U.S. party (hiring the same or different broker) solely to comply with the FDA prior notice requirement. This will inevitably introduce complications, delays and inaccuracies for the FDA.

From a commercial standpoint, if resident U.S. customers have to hire a U.S. customs broker, incur additional expenses for submitting the notice and incur liabilities for holding products at the border, solely for purposes of the proposed rule, then a distinct competitive disadvantage will be newly introduced for Canadian exporters.

The FDA should therefore amend the rule to include food exporters in the requirements for who must submit the notice. We note that Congress did not specify which parties must submit the notice. To our knowledge, these circumstances are unique to the Canada-United States border and, if necessary, FDA should exercise the needed regulatory flexibility to provide specifically for these circumstances. The FDA will receive the most accurate information available and in the most timely way consistent with FDA's objectives.

Outreach

The Canadian Government appreciates the efforts of FDA officials to inform affected parties and to fully consider all comments. 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 FDA to continue these outreach efforts as implementation proceeds. It will be equally important for FDA to ensure that administrative systems are fully operational and maintained to avoid any need to revert to a paper system. Even temporary shut downs will result in unmanageable congestion at the Canada-United States border. In addition, in view of the many questions being received concerning the precise coverage of articles of food over which FDA has jurisdiction and that would therefore require prior notice, we urge FDA to disseminate more precise information with examples so that Canadian exporters can determine whether they will be affected.

Quantity Changes Before Arrival

The Canadian Government would also urge the FDA to amend Section 1.294, to allow for the update of product quantities prior to two hours of arrival time. As noted in the sensitivity analysis which was conducted, the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. It is our understanding that a greater volume of 20% of the notifications of perishable product shipments will need to be amended due to quantity changes and not identity changes. This will increase costs and errors caused through increased amendments. It is understood that amendments to the quantity of product arriving will impact sample sizes, however, it should not be a factor in decisions on whether to interdict a shipment for bioterrorism-related reasons based on the prior notice.

We also suggest that for quantity amendments a notice to update is not requested. Rather the notifier would be responsible for submitting an update a minimum of 2 hours prior to arrival if the information concerning quantity or arrival port or time is amended.

Information That Must be Submitted

For each prior notice, the FDA is proposing to require much more information than Congress intended and we urge FDA to rethink some of these. 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. For example, it not clear how requiring a notice for different sizes of containers for the same product will substantially aid the FDA in targetting shipments.

In addition, 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 if the shipment after a notice is submitted.

The FDA should also amend/clarify the provision defining country of origin for fish products. It defines the originating country for wild caught fish for purposes of originating in the United States as being harvested in the U.S., or by a U.S. flagged vessel or processed on a U.S. flagged vessel. Otherwise the originating country is the is country under which the harvesting vessel is flagged.

FDA should amend this provision to define the country of origin as the country in which the fish were last processed. Fish is a globally traded and sourced raw material which Canadian processors often 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 United States would likely be the point of greatest risk and greatest interest to the FDA.

Future Amendments

As noted above, the Canada-United States Smart Border Plan and programs like C-PAT is a unique bilateral initiative to combat terrorism and, at the same, expedite low risk shipments, allowing enforcement agencies to focus on higher risks. In December 2002, Department of Homeland Security Secretary-designate Ridge and Deputy Prime Minister Manley announced that Canada and the United States agreed to cooperate on biosecurity under the Smart Border Plan. 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 area of food safety and countering bioterrorism.

We strongly urge FDA to build into the final rule, the capability to amend administratively the prior notice provisions in respect of imports from any country for which the FDA has reached an arrangement that would serve as the basis for having different (e.g., more efficient or effective) prior notice requirements. Such a provision would be important for the FDA to adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements.