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Food and Drug Administration
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ATTN: Docket No. 02N-0278

RIN 0910-AC41

Prior Notice of Imported Food

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 Prior Notice of Imported Food as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of October 10, 2003.

We urge FDA to reconsider elements of its proposal to ensure that provisions are risk based and take into consideration the unique circumstances of the Canada-United States border and the efforts our two countries are making through such initiatives as the Smart Border Declaration.

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

Yours sincerely,

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

Comments of the Government of Canada on the Interim Final Rule concerning Prior Notice of Imported Food under the *Public Health Security and Bioterrorism Preparedness and Response Act* of 2002 (*Bioterrorism Act*)

Docket No: 02N-0278
RIN 0910-AC41

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).

Canada continues to share and support the objectives of the Bioterrorism Act and these regulations as instruments by which the Government of the United States can more effectively counter bioterrorism. However, in implementing the regulations, we are concerned that the United States remains cognizant of their international trade obligations, including under the World Trade Organization and the North American Free Trade Agreement, and ensures that the regulations are not more trade restrictive than necessary to meet the objectives of the *Bioterrorism Act.*

Canada acknowledges and appreciates that, in drafting the interim final Rule, the FDA has taken into consideration many of Canada's comments on the proposed Rule which we had submitted in April 2003. We are convinced that these changes will improve the effective implementation of the Rule by taking appropriate account of the unique commercial environment at the Canada-United States border e.g., large volumes of just-in-time deliveries, in bond transhipments, and perishable food products. Canada also appreciates the considerable efforts made by the FDA to inform Canadian officials and stakeholders of the intended implementation of this regulation. Finally, Canada is very supportive of the decision by the FDA to extend the phase-in of the Rule to eight months.

Despite the improvements incorporated to date, it is clear from our extensive consultations with Canadian stakeholders that there remain some significant concerns regarding particular provisions, as well as how a number of provisions will be implemented in a clear and predictable manner. There are many areas where the current interpretation of the interim final Rule is causing confusion and imposing questionable costs on Canadian firms and individuals.

We must reiterate the commitment of our two countries to the Smart Border Declaration in which we agreed to collaborate to enhance the security of our shared border, while facilitating the legitimate flow of people and goods upon which our economies depend. In 2002, Prime Minister Chrétien and President Bush requested that collaboration be extended to include how both countries can best respond to threats to biosecurity. The risk management approach that underlies the security initiatives we have achieved under the Smart Border Plan is premised on

the understanding that the most sustainable security measures are those that focus on high-risk traffic while expediting low-risk movement.

The current interim final Rule does not appear to be grounded on this sound approach to effective risk management. Specifically, the Rule does not appear to differentiate sufficiently between high risk and low risk products/sources. For example, the full weight of the Prior Notice provisions are applied equally to large commercial and personal shipments. To the extent that personal shipments of bakery products do pose a risk, such risks could more effectively be addressed by other instruments and methods.

The following comments from the Government of Canada are aimed at clarifying the Rule by improving the predictability and consistency of its application. This will in turn help to avoid unnecessary disruption and disadvantage to Canadian exports of food and feed products to the United States.

2 Risk Based Approach

The Government of Canada noted in our previous comments that the following Section of the *Act* gives the FDA wide latitude to establish prior notice requirements that fit the circumstances applicable to various situations.

> *Section 307(2)(A): "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."*

We appreciate that the FDA has reconsidered the application of Section 307(2)(A) as it relates to the notification process. In particular, the FDA has amended the Rule to identify the minimum time for advance notice based on mode of transport and has removed the limitations on who can submit the prior notice. However, we previously recommended that the FDA should also build on, and take into consideration, successful United States-Canada risk-based initiatives which share the FDA's counter-bioterrorism objectives.

For example, the interim final Rule does not take into account the Smart Border Plan (SBP) agreed to and directed by Department of Homeland Security Secretary Ridge and former Deputy Prime Minister Manley. A key element of the SBP is the Free and Secure Trade (FAST) bilateral program. Under the United States Customs-Trade Partnership Against Terrorism (C-TPAT) and the Canadian Partners 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.

The Government of Canada again recommends that the FDA assess the use of a voluntary risk based program, such as FAST, to allow the FDA to focus its resources on sources of higher risk.

3 Future Amendments

As Canada noted in its previous comments, the ability to amend the Rule quickly is critical. The Prior Notice requirements, despite careful design, could have immediate, significant and unintended consequences for the FDA's operations, foreign and domestic carriers, Canadian exporters, United States' importers and consumers; indeed, for the smooth operation of the Canada-United States border in general. Lessons learned and better ways of achieving the objectives should be able to be quickly adopted under the Rule.

As noted above, the SBP is a unique bilateral instrument to combat terrorism and, at the same time, expedite low risk shipments, allowing enforcement agencies to focus on higher risks. Under the SBP, biosecurity cooperative activities in the area of food safety and countering bioterrorism will be agreed to under the broad based umbrella of regulatory cooperation. It is imperative that the Rule be able to be amended quickly in order to take into consideration these activities.

The Government of Canada strongly urges the FDA to build the capability into the Final Rule to administratively amend the prior notice provisions in respect of imports from any country with 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 allow the FDA to adjust procedures quickly and efficiently to reflect reductions in risks achieved through such arrangements. Equally, such a provision would allow the FDA to respond quickly to serious unanticipated issues that arise after implementation.

4 Personal Shipments of Manufactured Food Products

The Government of Canada questions whether the cost and implications of applying this Rule to manufactured food products sent via international mail for non-commercial purposes has been adequately assessed against the perceived benefit. As well, we question the ability to manage this requirement uniformly and consistently.

The economic analysis provided by the FDA in the preamble to this Rule does not appear to take into consideration the cost of implementation by individuals sending manufactured food products to the United States for non-commercial use. This cost would include obtaining familiarity with, and understanding of the Rule, access to a computer terminal by the individual, and the establishment of tracking mechanisms by international mail operators.

We, therefore, request that the FDA exempt manufactured food products sent via international mail for non-commercial purposes from the Rule, especially if the application of this Rule to these products cannot be consistently and effectively managed.

5 Timelines

The Government of Canada is pleased that the FDA has established prior notification timelines that reflect the mode of transportation involved; that these timelines are similar to those being implemented by the Bureau of Customs and Border Protection, Department of Homeland Security (CBP) and that a linkage has been established with the CBP information systems to collect the information. However, we continue to recommend that timelines for imports by road and rail be amended to reflect those of CBP. This will help to avoid costly duplication and unnecessary disruptions to trade.

As well, it has come to our attention, that ocean freight shipments being exported to the United States via Canada are often en route from the offshore exporter for a period of time greater than 5 days. In these instances, the transit times are not under the control of the offshore exporter (i.e., submitter of prior notice). Similarly, the Canadian exporter does not have control of rail containers which are often delayed for more than five days prior to being sent to the United States.

We appreciate that prior notice for food imported via international mail is exempt from the maximum 5 day time frame for submission and recommend that shipments entering the United States via rail or water also be exempt from this requirement.

6 Cooperation with Other Departments or Agencies of the United States

The Government of Canada appreciates the actions taken by the FDA to establish an arrangement with the CBP for the delegation of authority to administer the prior notice requirements.

We note that products such as live animals, fresh fruit and vegetables and game that are under shared jurisdiction, must fulfill the FDA prior notice requirements as well as the United States Department of Agriculture (USDA) certification and permit requirements. This results in duplicate information being supplied to the FDA and USDA prior to import.

Canada recommends that the FDA delegate authority to the USDA, as it recently has to CBP, to enable USDA to administer the FDA prior notice requirements on shared jurisdiction products. The establishment of such a process would avoid costly duplication, unnecessary disruptions to trade and reduce inconsistencies relating to the application of this Rule.

7 Transhipments

Canada questions the need for providing additional prior notice to the FDA for transhipments through the United States. It is our understanding that the CBP will require advance manifest information for transhipments under the Final Rules of the *US Trade Act* of 2002. These CBP reporting rules are designed to capture the information necessary to conduct risk assessments for the purposes of ensuring health, safety and security.

Canada recommends that the FDA eliminate the requirement for prior notice of transhipments due to the fact that this information will be collected by CBP. This would avoid costly duplication, unnecessary disruptions to trade and reduce inconsistencies relating to the application of this Rule.

8 Application of the Rule

Canada notes that the application of the Rule must be able to accommodate all unforeseen situations of notification and product types in a simple manner.

For example, the Rule does not appear to address situations in which gift baskets, each containing multiple units of distinct food products, such as packages of chocolates, cookies and smoked salmon, are shipped to various clients. In such circumstances, it is not clear whether prior notification would be based on identification and description of the respective gift baskets as entities, which is currently the case for CBP processing, or on the individual products contained in the basket, ie., chocolate, cookies, herbal tea or smoked salmon. As well, the application of the Rule does not easily accommodate situations in which shipments containing multiple distinct food products are sent from a single facility in Canada to a single facility in the United States. As we currently interpret the Rule, if a shipment from facility A contains 40 distinct food products destined for facility B, information must be submitted for each food product separately.

The Government of Canada recommends that the electronic notification systems be modified to allow information to be listed by product and copied where the information is applicable to more than one distinct product. This process will simplify the entry of the information, while still providing for the prior notice by food product.

In April 2003, Canada recommended that the FDA provide the option of submitting prior notice on a monthly or quarterly basis for recurring shipments. A recurring shipment could be defined and limited by conditions. For example, daily shipments of the same product, such as live lobster, to the same customer would fall in this category. Canada continues to support incorporation of this approach.

9 Technical Requirements

The Government of Canada notes that access to the FDA Prior Notice System Interface (PNSI) is limited by the versions of web browsers available for use by the submitter of prior notice. In addition, all information pertaining to the entry must be entered within the 30 minute period. This requirement is difficult to meet in the case of shipments with a large number of distinct products, and is extremely onerous without high speed internet access.

We recommend that the PNSI system be simplified to allow for universal access from all web browsers, and that the data entry system be simplified to allow for complete entry within the 30 minute time limit, or that the "time out" period be eliminated.

We also note that certain information, such as company name and email address, required to obtain an account on PNSI is not applicable to individuals exporting food to the United States for non commercial purposes. As stated previously, the Government of Canada recommends that food sent for non- commercial purposes be exempt from the requirements for Prior Notice.

10 Conclusion

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.