Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

June 2004

Implementation of the United States Food and Drug Administration Bioterrorism Rules for Prior Notice and Registration

Questions and Answers

1. Is the USFDA implementing additional requirements which will affect Canadian exporters?

Yes. The USFDA is requiring all foreign and domestic facilities, including Canadian facilities, which manufacture, process, pack, distribute, receive or hold food and animal feed for consumption in the U.S. to register with the FDA in order to export to the U.S. on or after December 12, 2003.
As well, FDA is requiring that information concerning all shipments of food and feed products for import into or via the U.S. be provided to them prior to the arrival of the shipment.

2. **What will happen if a shipment arrives at the border and this information has not been provided?**

We have been informed that it is not the intent of U.S. Customs or FDA to cause delays at the border during the initial period of implementation. Initial non-compliance will be dealt with through education and awareness. However, full enforcement including rejection of non-compliant shipments, will begin August 12, 2004.

3. **Are these rules applicable to all products?**

These regulations do not apply to products which are under the exclusive jurisdiction of the U.S. Department of Agriculture. These include processed meat, poultry and egg products.

4. **How can a facility register?**

It is strongly recommended that facilities register through the FDA website. FDA will also accept paper registrations, but they will be processed manually and facilities can expect delays in receiving their registration number.

1. **How is prior notice of the shipment provided**?

Prior notice can be sent by any person with knowledge of a food shipment and it must be received electronically by the FDA.
The easiest way to provide notice information for the FDA is to supply the information to the appropriate U.S. Customs Broker. The U.S. Customs broker will provide this information electronically to U.S. Customs, which in turn will communicate it to the

FDA. Prior notice can also be supplied electronically directly to the FDA using its new Prior Notice System Interface (PNSI).

2. **When can prior notice be provided?**

Prior notice can be provided no more than five days before arrival and, as specified by the mode of transportation, no fewer than: two hours by road; four hours by rail or air; and eight hours by water. In addition, for international mail shipments, including personal gifts and product samples, prior notice must be received and confirmed electronically by USFDA before the shipment is mailed.

3. **Where can I obtain more information concerning these rules?**

Agriculture and Agri-Food Canada has set up a website with excellent information and links to all the key U.S. websites.
AAFC website is at http://ats.agr.ca
As well, your U.S. Custom Broker is an excellent source of information.

4. **Will the FDA Bioterrorism Act Regulations have a major impact on Canadian exports to the U.S.? How specifically?**

Yes. These new requirements will affect the majority of exported commercial food and feed shipments as well as individuals shipping commercially-purchased food products as gifts to persons residing in the U.S.

5. **Are effected Canadians aware of these new FDA regulatory requirements?**

The Canadian Government and the U.S. Government are providing information through as many sources as possible to increase the awareness of these new rules to those people affected. For example, the Canadian Government has: developed a website to provide single-window access to key U.S. Government information sources; conducted many industry information sessions across the country; undertaken direct mailings to almost 2,000 Canadian food and feed firms; undertaken numerous media interviews; and produced printed materials that have been distributed via national and provincial stakeholder associations to their members.

10. The timeframes are different between U.S. Customs and the FDA. Which timeline must I follow?

For products covered by this rule, the FDA timelines must be followed.

11. **How do I know what to send in and when?**

Your U.S. Custom Broker will advise you of all of the information necessary to fulfill both the U.S. Custom's and FDA requirements and the time with which he will be required to have that information.

12. **How much will this cost Canadian business? Will these rules make them less competitive compared to their American counterparts? Is this just a non-tariff trade barrier in disguise?**

The USFDA has stated that the intent of the rules under the Bioterrorism Act was not to add unduly to the costs of firms exporting to the U.S. Rather, the rules were enacted to ensure that the FDA has greater knowledge of the facilities involved in supplying products for consumption by humans and animals in the U.S., and of the products they are supplying. There are certain costs associated with the implementation of the Rules, and we will be monitoring the situation.
Competitiveness is based on a number of factors, not just importing requirements. The Canadian Government will be monitoring the situation.

13. **What is Canada's position vis-à-vis the new FDA rules?**

Canada supports the rationale behind the new FDA rules, but will continue to monitor the situation.

14. **Will Canada make any formal representation to U.S. Administration on this issue?**

The issue has been given a high profile in the last year and numerous high level representations have been made by our Embassy and Ministers of Cabinet. We will continue to make representations as necessary should there be trade problems.

15. Does Canada have similar requirements for products entering Canada?

Yes. Canada has similar requirements for most imported products. For instance, products under FDA jurisdiction in the U.S., such as dairy, honey and processed products (including maple products), must be accompanied by an Import Declaration which is submitted when the shipment is presented at Customs as it actually enters the country or shortly after. As well, information concerning shipments of fish products must be provided to Canadian Food Inspection Agency by the importer within 48 hours after entry.

16. **Why has the Canadian government not adopted Bioterrorism regulations similar to those introduced by the U.S.?**

The Government of Canada appreciates that the USFDA's Bioterrorism Act regulations are a cause of concern for many Canadian exporters. Canada continues to review its import requirements to ensure that they are responsive to Canadian needs and maintain a safe and adequate food and feed supply.