



3155 5 2005 3 27

facsimile
TRANSMITTAL

to: Food and Drugs Administration; Docket Management
 fax #: 301 827-6870
 re: Docket No: 2003D-0554
 date: April 4, 2005
 pages: 2

Attached please find the Comments of the Government of Canada regarding the alternative proposed by the FDA under the Bioterrorism Act with respect to the prior notice of shipments transiting the United States to Canadian enclaves. These have also been submitted through the electronic dockets website: Comment number - 15407.

CC. Fred Gorrell, Canadian Embassy, Washington - 202 682-7795

From the desk of...

Sharon Flack
 Senior Bilateral Relations Officer
 International Affairs
 59 Camelot Drive
 Ottawa, Ontario K1A 0Y9

(613) 225-2342 ext. 3827
 Fax: (613) 228-6634

2003D-0554

C3



Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

59 Camelot Drive
Ottawa, Ontario
K1A 0Y9

April 4, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

ATTN: Docket No. 2003D-0554

RE: Prior Notice of Imported Food - Intransit - Enclaves

Please find attached comments from the Government of Canada on an alternative proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)* with respect to the prior notice of shipments transiting the United States to Canadian enclaves.

The Government of Canada continues to support the objectives of the Bioterrorism Act and its associated regulations, which are aimed at strengthening the ability of the Government of the United States to counter bioterrorism. However, it remains Canada's view that the Prior Notice rule must be implemented using effective risk management principles and grounded in "smart" application at the border, in order to achieve the objectives of the Bioterrorism Act in a manner that does not unnecessarily disrupt commerce. This view was reconfirmed by our leaders during their March 23, 2005 meeting in Waco, Texas in which they committed to establishing a "common approach to security to protect North America from external threats, prevent and respond to threats within North America, and further streamline the secure and efficient movement of legitimate, low-risk traffic across our shared borders."

Canada has previously indicated to the FDA in our comments submitted to the US Federal Register in December 2003 and May and July 2004, that the programs and approaches being developed under the Canada/US Smart Border Action Plan would be good models upon which to base their regulations and procedures. Canada therefore requests the FDA to use the risk management approach of the US Customs and Border Protection Agency (CBP) in these unique low-risk situations to meet the FDA prior notice requirements.

Sincerely,

Paul Haddow
Executive Director
International Affairs

Attachment

Canada

Comments of the Government of Canada on the Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002(Bioterrorism Act)

Docket No: 2003D-0554

RE: Revision to Compliance Policy Guide: Section 110.310

The Government of Canada welcomes the opportunity to provide comments on the revised Compliance Policy Guide, Section 110.310, entitled: "Prior Notice of Imported Food of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" as notified under Docket No. 2003D-0554 and published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the Federal Register of March 4, 2005 (Volume 70, Number 42).

The Government of Canada continues to support the objectives of the Bioterrorism Act and its associated regulations, which are aimed at strengthening the ability of the Government of the United States to counter bioterrorism. However, it remains Canada's view that the Prior Notice rule must be implemented using effective risk management principles and grounded in "smart" application at the border, in order to achieve the objectives of the Bioterrorism Act in a manner that does not unnecessarily disrupt commerce. This view underlies our objective of identifying alternatives to electronic prior notice for imported products which are of low-risk for intentional adulteration and which are otherwise in compliance with the Act.

The Government of Canada appreciates that the FDA has continued to recognize the unique low-risk situation of in-transit shipments destined for Canadian "enclaves" (e.g. Campobello Island). We also note that the current proposal decreases the time required to assess the information from that which was originally considered by the FDA for use in such circumstances.

In the past few months, the US Customs and Border Protection Agency (CBP) has implemented advance notification under the US Trade Act 2002 for all shipments transiting to Campobello Island. To comply with these requirements, shippers provide information concerning their imports to the US border officials, and the carrier vehicle may be secured, inspected and verified upon reentry into Canada. This risk management approach is working well and is sensitive to the low-risk nature of this situation.

Canada reiterates that this is a unique low-risk situation. The repetitive nature of the shipments, with a defined range of products, allows for the officer reviewing the shipment information to quickly attain a knowledge of the importers, shippers and products. With this knowledge, the time required to fully assess the risk of the products being transshipped is decreased.

Canada has previously indicated to the FDA that the programs and approaches being developed under the Canada/US Smart Border Action Plan would be good models on which to base their procedures. Canada therefore requests the FDA to use the CBP risk management approach (eg. assessment at border entry point; reduced timelines) in this low-risk situation to meet the FDA prior notice requirements.

Canada also requests that, prior to implementation of any alternative to deal with this unique low-risk situation, the FDA conduct outreach with the applicable industry to ensure that any additional procedures are well understood.