



**Comments on the Prior Notice of Imported Food Rule under the
*Public Health Security and Bioterrorism Preparedness and
Response Act of 2002 (Bioterrorism Act):
Reopening of the Comment Period***

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The Food Processors of Canada welcomes the opportunity to provide additional comments during the reopening of the comment period of 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)* as published by the Food and Drug Administration (FDA) Department of Health and Human Services, in the *Federal Register of April 14, 2004* (Volume 69, Number 72).

The FPC is an internationally respected business association serving food industry executives on matters concerning trade, commerce and manufacturing. The members of FPC own or manage Canadian food processing companies who add value to inputs sourced from around the world and service markets in 80 countries including the United States and therefore affected by the final rules implemented by the FDA.

We are pleased that the FDA is working with Customs and Border Protection (CBP) to synchronize advance notice timeframes for information concerning shipments arriving by different modes of transportation. Since CBP already has a program and computer system in place to handle this, the FDA should just have the CBP handle all prior notices for them with one time frame for all agencies.

C-TPAT/FAST

Canadian exporting food companies already have established food safety and security procedures under CFIA and HACCP requirements. Companies that have gone beyond this and are participating members of C-TPAT/FAST programs have proven yet another layer of security measures. We recommend the FDA recognize products imported under these programs as low risk and to afford them benefits such as reduced information requirements for each shipment; reduced time for advance notification of information; reduced clearance time at the border; and reduced number of verifications of information.

Timeframes

Since CBP already has timeframes of one hour or less for prior notice and, according to FDA figures, 88% of prior notices are done through the ACS system, it would seem logical to have the same timeframe for FDA. This would eliminate the need to do two prior notices. Certain fields could be added to the ACS system to satisfy the product information for FDA.

Modification of C-TPAT for FDA Products

The FDA should accept the C-TPAT designation as is. Since the food industry is regulated by the CFIA in Canada, with almost parallel rules to match the U.S., food safety in North America is unmatched around the world. As far as members' suppliers are concerned, they can only buy raw materials from suppliers that are certified by the CFIA.

FDA Training

The FDA should institute a training program for companies to ensure that proper prior notice is given. At this point every company is training their own employees as best they can without fully understanding all the requirements needed by FDA. If a standardized training program can be instituted by the agency, we would see a dramatic rise in the accuracy of the prior notices.

The following is a list of other concerns or clarifications expressed by our members:

1. Prior to December 2003 transports to the US could cross the border 24/7. Now all shipments have to cross during specified hours Monday – Friday only. This increases costs, makes scheduling more difficult, makes greater delays at the border, and delays delivery making customers unhappy. We recommend the border return to a 24/7 system.
2. An FDA registration number was assigned to each facility upon completion of the registration process. This was to be considered confidential and only to be given out sparingly. If a company is obtaining a competitor's sample from outside the U.S. how does one complete the Prior Notice if the facility registration number of the manufacturer is unknown?
3. When importing food into the U.S. a Prior Notice is filed with the FDA within the specific timeframe per mode of transportation. Once the transaction is entered into the system a computer generated confirmation number to proceed should take place. There have been several instances that the confirmation response has been delayed and the driver is at the border without this clearance number. How can the timeliness of this response be improved?
4. Some members have voluntarily become C-TPAT partners and have in return demonstrated their commitment to food security throughout their organizations. As a direct result of this they were given quicker release at customs border crossing points into the US. However, since December 12, 2003 this benefit has been eliminated even though they are still considered low risk importers. Can a similar policy be developed that could give C-TPAT partners preferred treatment at all border crossing points?
5. Exempt samples intended for R&D or for non-commercial use since they are not intended for public consumption and are highly unlikely to pose a security risk.
6. Extend the exemption for shipments that don't leave port of entry to include trans-shipments through the US since it's not intended for consumption within the US.
7. Exempt small dollar value mail-order sales to US customers [\$100 or less] since the prior notice system is difficult and costly to implement for this type of business, especially if the company is registered with the USFDA, under CFIA inspection, participates in C-TPAT and has no negative history.

8. Clarify the interpretation pertaining to gift baskets. It's unclear whether prior notice is based upon the description of the entire gift basket as an entity, which is currently the case for US Customs processing, or on the individual items within the basket.

Additional Concerns

Each of these concerns may be minor when considered individually but when combined, significantly impede the movement of safe goods into the US.

1. FDA Website - Help Desk: 1-800 Telephone number - US only – could this be extended to cover Canada?
2. E-mail problems designated to an Answer and Question format. Unable to obtain help if problem pertains to another issue.
3. Password change requested approximately every two months. Is this a glitch or a security procedure? Either way, could this process be revised so that password is permanent?
4. USFDA should create a multi-line prior notice page in their PNIS system.
5. Lack of consistent understanding and interpretation of rules. A member spoke to three different people at the FDA Help Desk office in Rockville, Maryland and received three different solutions to his problems. Unfortunately, the problem was still unresolved.