



**Ministry of Agriculture
and Food**

**Ministère de
l'Agriculture
et de l'Alimentation**

Policy and Farm Finance Division

2005 04 JUL 13 15:28

2nd Floor
1 Stone Road West
Guelph, Ontario N1G 4Y2
Tel: (519) 826-3204
Fax: (519) 826-3492

2^e étage
1, rue Stone ouest
Guelph (Ontario) N1G 4Y2
Tél.: (519) 826-3204
Télééc.: (519) 826-3492

**Ministry of
Economic Development
and Trade**

**Ministère du
Développement économique
et du Commerce**

Hearst Block
900 Bay Street
Toronto ON
M7A 2E1

Édifice Hearst
900, rue Bay
Toronto ON
M7A 2E1

July 13, 2004

Docket No: 2002N-0278
FR Doc: 69 FR 19766
04-11247 (Extension of comment period)

Division of Dockets Management (HFA-305)
United States Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD. 20852

The Ontario Ministry of Economic Development and Trade (MEDT) and the Ontario Ministry of Agriculture and Food (OMAF) welcome the opportunity to provide additional comments on the Interim Final Rule on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as published on April 14, 2004 by the Food and Drug Administration (FDA), Department of Health and Human Services, Federal Register No. 2002N-0278.

We appreciate the FDA's decision to extend the comment period on Prior Notice. The additional 60 days has proven invaluable in our efforts to consult with the Ontario food and agricultural sector on the questions to which the FDA requested comment.

As we noted in our earlier comment submitted on May 14, 2004, the Government of Ontario recognizes the security objectives inherent in the Bioterrorism Act, and accordingly supports the concept of Prior Notice as a means for the FDA to prevent and

02N-0278

C362

respond to bioterrorist threats and potential food security vulnerabilities. We believe Prior Notice plays a significant role in enabling the FDA to assess which shipments are 'unknown' or 'high risk', and thus targeted for further inspection, and which are 'known' or 'low risk' and should be expedited.

We are encouraged by the FDA's request for thoughts on the possibility of using U.S. Customs and Border Protection's (CBP) existing commercial pre-clearance program – the Customs-Trade Partnership Against Terrorism (C-TPAT) – and the joint Canada-U.S. Free and Secure Trade (FAST) program as a means for meeting the objectives of the Prior Notice Rule.

We believe the FAST/C-TPAT program strengthens the FDA's ability to meet the objectives of the Prior Notice Rule. This is achieved in two ways. First, through the rigorous security screening participants must comply with to secure low-risk status. And second, by removing low-risk shipments from the queue, FAST/C-TPAT works to shrink the 'haystack' thereby 'freeing up' FDA officials to focus limited resources on higher risk shipments. Allowing food hauling carriers eligibility to C-TPAT and FAST is important to ensuring that all transporters operate on a level playing field.

FAST/C-TPAT

FAST and C-TPAT work hand in hand to secure and facilitate the movement of legitimate cross-border trade. C-TPAT is a voluntary program for business/importers. Members engage in extensive security and compliance screening in order to ensure their suppliers and carriers live up to established security standards.

FAST is a joint Canada-U.S. program offered to pre-approved importers, carriers and registered drivers. To use FAST into the U.S., both the importer and carrier must comply with the C-TPAT requirements.

FAST also requires drivers to undergo a risk assessment by the customs and immigration services of both countries. Those identified as low risk have their original identification and citizenship reviewed. Once approved, drivers are fingerprinted and digitally photographed. FAST participants therefore undergo extensive security screening to establish low-risk standing.

We believe that the security and verification processes mandated by FAST/C-TPAT meet the objectives of the FDA Prior Notice Rule to ensure the safe and secure import of food shipments. Indeed, the flexibility built into FAST/C-TPAT allows new products, such as food, feed and live animals, to apply to the program without requiring amendment.

Accordingly, we propose that the FDA adopt the FAST/C-TPAT template to allow for further flexibility to the FDA Prior Notice Rule. Moreover, in order to strengthen the incentive to enroll in the supply chain security program required by FAST/C-TPAT, we



suggest the FDA offer the same benefits currently extended by U.S. Customs and Border Protection (CBP). These include:

1. Fewer Data Elements for Each Shipment

FAST/C-TPAT participants presently submit three data elements to CBP in advance of shipments arriving at the border. We understand and acknowledge the FDA will likely need to add data elements in order to adequately assess the security of imports of food, feed and live animals. However, it is critical that the Prior Notice Rule require fewer data elements from those not enrolled as FAST/C-TPAT members. Otherwise, it will dilute a key advantage offered to FAST/C-TPAT participants, thereby weakening the incentive to join the program.

2. Shorter Timeframes for Prior Notice

We believe the ability of FAST/C-TPAT to ensure only low-risk participants are enrolled as members means that the FDA will require less time to assess the risk of such shipments and thus offer shorter Prior Notice timeframes to program participants.

This is a critical aspect of any flexible alternative to the Prior Notice Rule. The need to meet demanding just-in-time (JIT) delivery schedules is why so many auto companies were the first to apply, gain approval and participate in FAST/C-TPAT. The same commercial realities apply to the food industry. While delays in cross border commerce have serious repercussions for all sectors exporting to the U.S., the implications are particularly acute for those sectors handling perishable goods, where quality is intrinsically linked to product freshness. Shelf life for horticultural products is brief. Commercial competitiveness in agricultural trade is dependent upon timely, reliable delivery of goods.

Accordingly, it is critical that any flexible alternative, FAST/C-TPAT or otherwise, offer preferential treatment in the form of shorter timeframes to its participants. We ask that the FDA consider a 30-minute timeframe for submitting Prior Notice for food arriving by land, as an alternative to the two-hour timeframe currently required. Many Canadian facilities are strategically located close to the Canadian/U.S. border to facilitate just-in-time shipments into the U.S. market, and would benefit from the even shorter timeframe.

Shorter timeframes would also not only help ensure the integrity of JIT systems, but would also increase the security of trans-border shipments by strengthening the incentive to enroll in the supply chain security programs required by FAST/C-TPAT. Without such a benefit, carriers, in many cases, would be unable to deliver their shipments on time, thereby putting products at risk. As a result, companies would need to retool and redesign their manufacturing processes, which could significantly raise the cost of trans-border shipments, thus weakening the integrative nature of the Ontario and U.S. food industries.



3. Streamlined Release

Membership in FAST/C-TPAT should also result in faster processing at the border. This is an important aspect of FAST/C-TPAT because apart from the issue of capacity and efficiency of highways and roads leading up to border crossings, many contend that the main source of border delays is customs processing. Combining faster processing with infrastructure improvements and enhancements, an area in which the Government of Ontario has joined with the Government of Canada to invest approximately \$635, will go a long way toward reducing wait times. This in turn will increase the security of shipments by bolstering the appeal of the program.

4. Reduced Number of Examinations

Since FAST/C-TPAT members undergo intense validation of their security procedures to gain low risk status, the need for further verification at the border by FDA officials could be substantially reduced. For this to work efficiently, the FDA must be kept abreast of FAST/C-TPAT shipments that have been approved. Accordingly, we would encourage the FDA and CBP to establish a system that transmits FAST/C-TPAT shipments and approvals to the FDA. This should eliminate the need to transmit prior notices to both agencies and reduce the potential for confusion and delay.

It is important to note, however, that C-TPAT is presently not afforded to Canadian companies unless they are registered as the Importer of Record with U.S. CBP. Our proposals stated above are based on the assumption that the program will be amended to include Canadian manufacturers.

Data Submission

The administrative costs of complying with the Prior Notice Rule were a major issue raised by the agriculture and food industry. To address these concerns, we support the Government of Canada's proposal for a uniform, fully integrated prior notice data submission for non-FAST shipments and another for FAST shipments, alike. We also support Canada's recommendation to eliminate the need to re-enter information on Prior Notice data submissions that is common to all items (e.g. shipper, regulations number). These recommendations will serve to simplify and reduce the time needed to complete prior notice submissions without compromising security.

Finally, the FDA requirement for individual prior notices to be filed for each food item, including those instances where numerous food items make up a single shipment, also adds considerable administrative cost and increases the potential for error, which will lead to more shipments being sent to secondary inspection, thus resulting in longer wait times at border crossings.

We propose the FDA allow food items to be consolidated under one shipment when the same consignee is shipping the goods. Accordingly, it is essential that the FDA and



CBP border requirements, including timelines and documentation requirements, are coordinated between the two agencies. It is equally important that the administration of these rules at the border be well coordinated, sufficiently resourced, and implemented in a complementary manner to ensure smooth and efficient transactions at the border.

We hope you find our observations and comments helpful in your deliberations and development of a Final Rule. We respect and value the FDA's willingness to subject its proposals to regular public review and comment, and encourage you to give serious consideration to those submissions tendered by the many Ontario and Canadian stakeholders affected by this Rule.

Sincerely,



Jim Wheeler
Assistant Deputy Minister
Policy and Farm Finance Division,
Ontario Ministry of Agriculture and Food



Bob Séguin
Assistant Deputy Minister
Competitiveness and Business Development Division
Ontario Ministry of Economic Development and Trade

