

Docket number 2002N-0278

**Comments by Agricore United to the Food and Drug Administration (FDA)
regarding the FDA's prior notice interim final rule (68 FR 58974)**

May 14, 2004

Agricore United is one of the largest grain exporters from Canada to the United States. We provide the following general comments regarding the FDA's prior notice interim final rule, together with comments on the specific questions posed by the FDA regarding C-TPAT/FAST and flexible alternatives.

General comments

?? Agricore United fully supports the move to integrate and harmonize the FDA prior notice time provisions with CPB notice provisions. Having identical data and notice provisions will streamline our administrative procedures and result in fewer errors and cross-border delays.

?? Agricore United is concerned about the level of staffing among those offices that have the responsibility to process prior notices. We have encountered situations where we have complied with the notice provisions and yet there has been a delay in processing at FDA offices. This has resulted in border delays, and in some instances, has led to additional charges being levied against us by the trucker. We believe improved staffing levels, and/or more streamlined processing procedures would minimize such delays.

C-TPAT/FAST Questions:

1. *Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?*

Yes. This can be accomplished through the integration of the CBP and FDA data systems. This will allow for one filing of the required information. The C-TPAT certification process delves into the critical aspects of a company's handling and documentation procedures, and requires a company to demonstrate it has good process controls in place throughout the supply chain.

2. *If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the CBP advance electronic rule, would a shorter timeframe be needed for members of FAST?*

Yes, a shorter timeframe consistent with the timeframe for FAST would be desirable.

3. *Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?*

No, the processes involved in becoming C-TPAT certified should not be modified to handle food and animal feed shipments regulated by the FDA. They should be the same for all C-TPAT certified members.

Flexible Alternative Questions:

1. *If timeframes are reduced in FDA's prior notice rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?*

Yes, such flexible alternatives would be welcome for FAST participants, and for meeting the regulatory requirements for food imported by other agencies. The prior notice timeframes and data requirements should be harmonized among all U.S. departments. This avoids confusion, reduces administrative costs and errors.

2. *In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?*

The FDA should consider C-TPAT certification as evidence that adequate safeguards are in place. Participation in flexible alternative arrangements, whether under C-TPAT, FAST or other programs should be voluntary.

3. *In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule have an updated registration on file with FDA that has been verified?*

We are not in a position to comment as we are not aware of the methods the FDA is currently using to verify registration information is updated.

4. *Are there conditions of participation that FDA should consider, e.g., inspection of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?*

C-TPAT certification should be considered a necessary and sufficient condition of expedited prior notice processing. C-TPAT covers all aspects of a company's supply chain.

5. *Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?*

Yes, absolutely. In our view, grain shipments represent a very low risk target for bioterrorism. All bulk grain shipments from Canada to the United States are for use in further processing or animal consumption. Thus, there is an extremely low bioterrorism risk to humans, when compared to risks on food products sold directly to consumers.

6. *If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?*

Yes, the FDA phase-in should be identical to the CBP phase-in.

7. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers to ensure the accuracy of the data being submitted?

Yes, this would be helpful, not only for Canadian exporters and their agents, but also for FDA staff, so that they can gain an appreciation for the business ramifications of the prior notice process.

Thank you for this opportunity to provide comment. We look forward to your continuing efforts to facilitate trade, while respecting the need to establish appropriate safeguards to protect against bioterrorism risks.

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