

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

RE: Docket No. 2002N-278 - Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA) Reopening Comment Period

The following comments are submitted by the Agriculture Ocean Transportation Coalition (AgOTC), on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

The AgOTC represents thousands of U.S. agriculture exporters and importers who are impacted by the Prior Notice regulations. Our members are increasingly concerned that the system is not working adequately to ensure that legitimate cargo won't be stopped when full enforcement begins in August. We urge FDA to address the problems listed below, and to ensure that filers have a minimum of 90 days to adjust to the changes BEFORE full enforcement occurs:

1. **FDA Feedback on PN Errors Critical to Compliance.** After five months of implementation, we understand that half of all data transmissions are incomplete or inaccurate. A major reason for this poor compliance rate is the fact that the filing system does not have the capability to advise the filer of the specific data inadequacies of the submission. Thus, there is no mechanism to educate filers as to the changes that must be made in order to be in full compliance prior to the August enforcement deadline. FDA must either find a way to provide such feedback well in advance of August 12, or it must postpone full enforcement to assure that the trade has sufficient time to make programming changes necessary to assure compliance.
2. **Filers Need More Education and Outreach by FDA.** It is obvious, based on the low rate of compliance, that filers do not have a clear understanding of exactly what is required for Prior Notification. We have read the regulations, and we still have questions. Yet we have found it very difficult – and sometimes impossible – to get the answers we need from FDA. We believe further clarification is needed. FDA must find a way to reach out to the regulated public to provide the education needed to assure greater compliance. This could be accomplished through additional guidance documents, educational seminars, web-based training, etc.

FDA's own Compliance Policy Guide states that such outreach would be carried out throughout the eight months between implementation and full enforcement: We are unaware of any efforts in this regard, and urge FDA to undertake them before full enforcement occurs.

3. Filers Should Be Able to Correct Minor Errors. We understand that in ABI, once the CBP entry/entry summary has been certified, there is currently no mechanism by which to make corrections without canceling the entry and submitting a new entry. In the air and truck environment, where cargo is processed on weekends and at off-hour operations, CBP is unavailable to process these entry cancellations. In such circumstances legitimate cargo could be forced into refused status due to CBP's inability to act in a timely manner. We urge FDA and Customs to find a way to address this problem, either by allowing clerical revisions even after the entry has been certified, permitting entry deletions under certain circumstances, or assuring CBP availability on a 24/7 schedule.

4. Adequate Storage Facilities Needed. We are concerned that a) no procedure for handling refused merchandise has been published and b) there are insufficient storage facilities at many of our nation's ports. Without adequate storage facilities, our ports could be rapidly overwhelmed once full enforcement begins.

5. Cargo Already at Port of Arrival. The current ABI system cannot accept Prior Notice once cargo arrives in the U.S. Instead, filers must use the PNSI system. This should be resolved to allow filers to use the ABI system even after cargo has arrived in the U.S.

6. MID Disparities. The CBP Manufacturer Identification Database (MID) is over 18 years old and woefully out of date. Until the MID is updated, imported shipments should not be subject to rejection or refusal due to a mismatch in the MID system.

7. FDA Help Desk Needs Help. The FDA Prior Notice help desk has proven to be incapable of answering specific operational questions in a timely manner. This office must be staffed with people who can provide the assistance sought by the regulated community. Further, once questions are addressed, FDA must have an effective mechanism for disseminating this information to other filers. Such a system would eliminate the need for one importer to contact FDA on an issue that has already been resolved in response to another importer's request.

8. Exemptions Needed. The objective of the Bioterrorism Act was to protect the nation's food supply. We do not feel there is adequate threat to the nation's food supply posed by certain classes of goods entering the country, including:

- a. U.S. exports that have been returned to the U.S.
- b. Small commercial laboratory samples used for testing and evaluation purposes, not for sale or other distribution

We recommend that these items be exempt from PN requirements.

9. PNSI System Capability Must be Improved. The FDA's Prior Notice Internet System Interface (PNSI) was intended as an alternative to the primary CBP

automated entry interface. It also serves as a back-up system when Customs' system is inoperable. With its current limited capacity, the PNSI system has been proven inadequate to serve as back up for all Prior Notice entries. The PNSI system capacity must be dramatically increased before the August enforcement deadline in order to assure that legitimate trade is not impacted due to a failure of the system.

10. Filer Needs Immediate Notice of Rejections and Refusals. According to the Prior Notice Interim Final Rule, the carrier is the point of contact if an article of food is refused. Since the carrier has neither the incentive nor the ability to resolve the refusal, FDA should also notify the filer when rejections or refusals occur. This will assure that valuable time is not lost between notification of the carrier and notification of the filer, which could be much later. By contacting both the filer and the carrier, FDA can help to reduce delays and congestion associated with refused food.

11. Enforcement Must Be Delayed. We understand that FDA is working hard to get its own system glitches corrected prior to the August 12 enforcement deadline. Obviously such programming changes take time. Yet FDA must also understand that there are programming requirements on our end that must also be made. Thus, we need additional time – a minimum of 90-days -- after FDA has finalized its internal revisions to make the necessary adjustments on our end. Again, we urge FDA to consider postponing enforcement beyond August 12 to allow for such adjustments to be made.

Thank you for your consideration of the above comments. If you have questions or require additional information, please contact me at 202-783-3333.

Sincerely,

Peter Friedmann, Executive Director
Agriculture Ocean Transportation Coalition
1201 Pennsylvania Avenue, NW Suite 315
Washington, D.C. 20004
Tel: 202-783-3333
Fax: 202-783-4422