
**NATIONAL CUSTOMS BROKERS AND
FORWARDERS ASSOCIATION OF AMERICA, INC.**

Office of General Counsel
One Astor Plaza
1515 Broadway - 43rd Floor
New York, N.Y. 10036

Phone: (212) 944-6611
Facsimile: (212) 944-9779
e-mail: hisaacs@tdllp.com

June 22, 2004

Via E-mail (fdadockets@oc.fda.gov)

Food and Drug Administration
Dockets Management Branch (HFA – 305)
5630 Fishers Lane
Room 1061
Rockville, M.D. 20852

**Re: Supplemental Comments on Prior Notice Of Imported Food Under
The Public Health Security And Bioterrorism Preparedness And
Response Act Of 2002—Reopening Of Comment Period
Docket Number 2002N-0278**

Dear Sirs:

The following is submitted by the National Customs Brokers and Forwarders Association of America, Inc. (“NCBFAA”), as supplemental comments to those previously filed by the NCBFAA on May 14, 2004 in connection with the Interim Final Rules on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”) published by the Food and Drug Administration (“FDA”) in the Federal Register of October 10, 2003, (68 F.R. 58975) (hereinafter referred to as the “IFR”).

**Requiring Submission Of Prior Notice Through The Prior Notice System Interface When
The Automated Broker Interface Is Not Operational Interdicts The Flow Of Commerce**

Under the interim regulations, a filer may submit Prior Notice (“PN”) through the Customs & Border Protection’s (“CBP”) Automated Broker Interface of the Automated Commercial System (“ABI/ACS”). Although an ABI filer receives a Prior Notice Confirmation (“PNC”), which confirms the PN submission, a hard copy of the PNC is not required to accompany the article of food when it arrives at the port of first arrival.

21 C.F.R. §1.280(b) requires brokers, self-filers and other ABI users to file PN through FDA’s Prior Notice System Interface (“PNSI”) when ABI is not working. Similar to an ABI filing, a PNSI filer will receive a PNC verifying submission of the PN. However, in comparison to an ABI filing, the carrier must present a copy of the PNC to CBP officers when clearing the

respective food shipments at the border.

If the PN is filed through PNSI, the PN is considered inadequate if the PNC does not accompany the shipment at the border. Accordingly, all articles of food that arrive in the United States (“U.S.”) without adequate PN are subject to refusal of admission and may be held at the port of arrival or other secure location until adequate PN is submitted.

In theory, the contingency system set forth in the Interim Final Rule is simple: when ABI is down, use PNSI. In practice, however, the system falls subject to timely submission and port congestion issues, the effect of which has been to interdict the flow of imported cargo at the border. This system is especially problematic on the northern and southern U.S. borders, where the most common modes of transportation used in the importation of food articles—trucks and rail—are subject to 2 hour and 4 hour submission timeframes, respectively.¹ Assuming that the transmitter files the PN at the time provided for, the enforcement of this rule will not only create additional problems on the part of CBP or FDA (*i.e.* the duplicate transmission and confirmation of the PN over ABI and PNSI), but will also result in the untimely transmission of the PN via PNS by the time the filer realizes that ABI is down.²

Further, entries are typically pre-filed on the northern and southern borders, and the releases are done electronically (via PAPS, etc.). Because the FDA PNSI system does not confirm the issuance of a PNC to CBP, currently, CBP officials have no way of determining whether a PNC was issued. Even assuming that this problem is corrected, CBP still cannot receive the PNC when the ABI system is down.³ Normally, in the latter instance, the practice of CBP officials has been to allow release of the entry and accept the documents after the fact. Because of this rule, food entries will not be subject to this conditional release. We suggest that under the revised and Final PN Rule, FDA should also allow conditional release of the shipment and process the PNC when ABI is restored.⁴ Otherwise, this requirement will interdict all electronic entries of food shipments, which will unnecessarily congest the ports. Even more problematic is the effect this requirement will have on perishable food articles, including shipments of fresh fish and produce.

¹ If the proposed “Joint FDA-CBP Plan For Increasing Integration And Assessing The Coordination Of Prior Notice Timeframes” (“Joint Plan”) is adopted, the submission timeframes for trucks and rail will be reduced to no later than 1 hour or 2 hours prior to arrival at the border, respectively.)

² In excess of 90 percent of PNs are submitted through ABI simultaneously with the certified entry; at the least, this will result in the filing of duplicate PNs and confirmations via PNSI and ABI. Further, by the time the filer makes alternative arrangements to file through PNSI, the problems inherent in PNSI will significantly reduce the filer’s ability to adequately complete the PN, print out the PNC, *and* forward the PNC to the carrier, so that a hard copy of the PNC can be submitted to border officials at the time of arrival, within the applicable time frame.

³ This problem is also present if ABI is operating but the OASIS system or the interface as between OASIS and ABI are down.

⁴ Although an ABI filer will receive a PNC, which verifies the submission of an adequate PN for purposes of review, there is no specific requirement in the BTA for the issuance of a PNC – all that is required is the filing of the PN and an appropriate “response” by FDA. If ABI is “down,” FDA will not receive the PN. In these rare cases, absent evidence that a shipment is suspect, FDA should allow CBP to conditionally release the shipment.

To alleviate these problems, FDA's contingency system should be amended. Rather than providing for PNSI as a contingency system with ABI is down, PN submissions should function according to all other submissions processed through ABI when CBP declares either a "national snow day" or "power outage."

In those instances, submission/entry rules are essentially suspended until the system is back on-line. Time frames are extended without subjecting the filer to any penalties for filings or payments that would have been due if ABI was functioning properly. Documents submitted to ABI are queued for processing but are not actually processed and replied to until the system is back on-line. So that shipments still pass smoothly through the border, CBP conditionally releases the goods. Only shipments that are clearly "suspicious" are not released, pending a risk assessment. When ABI is again functioning properly, the information is processed and any non-conforming or suspect food shipments may be subject to redelivery or other recall measures, if such action is necessary.

In order to avoid the above problems and the inherent inefficiencies of e-mailing or faxing the PNSI to FDA, amending the PN submission procedures to allow for this "conditional release" would avoid the timing and port congestion issues that the industry has experienced under the current rules.

CONCLUSION

We recommend that consideration be given to eliminating the PNSI requirement if ABI is not working and allowing the shipment to proceed, pending later issuance of a PNC via ABI.

We thank you for the opportunity to submit these supplemental comments and implore FDA to incorporate this recommendation into the final PN rule.

Sincerely,

Harvey A. Isaacs,
General Counsel

cc: NCBFAA Board of Directors
Cathy Saucedo, Department of Homeland Security
Customs & Border Protection

HAI:lh