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May 14, 2004

Via E-mail (http://www.fda.gov/dockets/ecomments)
Food and Drug Administration
Dockets Management Branch (HFA – 305)
5630 Fishers Lane
Room 1061
Rockville, M.D. 20852

Re: 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 Numbers 2002N-0276 and 2002N–0278

Dear Sirs:

The following is submitted by the National Customs Brokers and Forwarders Association of America, Inc. ("NCBFAA") 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"), and the Registration of Food Facilities under the Bioterrorism Act, published in the Federal Register of October 10, 2003, (68 F.R. 58975 and 68 F.R. 58894, respectively, and collectively referred to as "IFRs").

The NCBFAA is a national organization with regular membership consisting of licensed customs brokers, international freight forwarders, non-vessel operating common carriers, and international air cargo agents. We have been actively involved with the evolution of the Prior Notice ("PN") IFR and the Registration of Facilities IFR, as both an enthusiastic participant in various outreach and public meetings in the industry to address issues raised by implementation

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of the IFRs, and in submitting comments to the Food and Drug Administration ("FDA") regarding several pressing issues.

At the outset, we must applaud FDA's tremendous efforts in redefining certain parameters of the IFRs from its infant stages set forth in the proposed rules. In response to many concerns raised regarding the negative and disruptive impact the proposed rules would have had on international trade and on the industry as a whole, the resultant IFRs instead crafted a more highly reasonable and workable scheme for protecting the integrity of the food supply chain yet with much less impact on trade and commerce than the industry had originally feared.

Although FDA has made tremendous strides with educational and outreach programs, as is often the case with the introduction of a highly complex group of regulations, there are still procedural and operational weaknesses that need to be addressed. Accordingly, we have highlighted certain issues that we believe should be taken into consideration in drafting the Final Rules on Prior Notice and Registration of Facilities.

Because the IFRs set forth in the two dockets are inter-related, the following comments relate to both dockets.

COMMENTS

1. Requiring Separate Prior Notices For Each FDA Line On An Entry Is Unduly Burdensome.

The IFR requires that a PN must be provided for each "article" of food. An article of food refers to a single food that is associated with the same complete FDA product code, the same quantity (i.e., amount and package size) and the same manufacturer/grower.[1] Therefore, as the rule currently stands, if a shipment has the same product code yet the goods are packaged in 3

different-sized containers, 3 different PNs must be filed.

The FDA noted in its Notice For Proposed Rulemaking that over 4.7 million entry lines of food were entered during the 2001 fiscal year. The IFR requirements now quadruple this already overwhelming amount of data in requiring PNs for each "article" as defined above.

This requirement has been nothing but unduly burdensome on importers/filers. Understandably, goods that come from a different manufacturer/grower should require separate PNs for purposes of the Bioterrorism Act, which is to strengthen the government's ability to track and or deter possible bioterrorist-related food imports to ensure the integrity of imported food. However, goods that arrive on the same bill of lading and that come from the same manufacturer should not require the filing of a PN for each line on the entry.

The integrity, or lack thereof, of the food product will *not* be compromised based on the product type, size and/or quantity. FDA's ability to contact the necessary parties or track down a contaminated shipment will also not be compromised if they do not have a separate PN for each different type of food product or amount of such product.

In addition, if a shipment of food is tainted, any additional food shipped from the manufacturer/grower at issue is, likewise, going to become suspect. It is a rare occurrence that government officials will find a shipment of corn from Manufacturer X to pose a health risk, yet not pursue all other food products shipped from that particular facility. Thus, the identity of the manufacturer/grower, as opposed to the type or size of food at issue, is the key information that will help officials track risk-related food products.

At the very least, in furtherance of FDA's intention to streamline the agency's procedures and systems with respect to the Bioterrorism Act, submission of PN should mirror the CBP entry,

[1] 68 F.R. 59003.

where the ABI system provides for the capability to submit information for multiple food items as lines in a single entry when the entry level information for multiple food items is consistent for any given number of articles in the same shipment. FDA should thus reformat the PN to allow for one PN submission for each entry of food information, where the only difference is the size or type of the imported food. This would eliminate repetitive data entry and/or the need for CBP or FDA to process the separate PNs.

Accordingly, the definition of "article of food" should be amended in the PN Final Rule to eliminate quantity and product code as distinguishing factors that require a separate PN. Further, differences in the food product "quantity" and product code should not require separate PNs; rather, submission of separate PNs should be based on the uniformity of entry level food data.

2. FDA Should Adopt Reduced Time Frames In The Prior Notice Final Rule That Mirror CBP's Time Frames For Advanced Electronic Reporting Of Manifest Information.

Streamlining FDA's PN submission timeframes in accordance with those set forth in the Bureau of Customs and Border Protection's ("CBP") Advanced Electronic Reporting Rule[2], as proposed in the "Joint FDA-CBP Plan For Increasing Integration And Assessing The Coordination Of Prior Notice Timeframes" ("Joint Plan"), is essential in order for CBP and FDA to achieve their goal of creating a uniform, integrated system with respect to enforcement of the Bioterrorism Act. It is impossible to obtain a uniform system if certain procedural basics, such as submission deadlines, are not consistent.

Pursuant to FDA's publication "Compliance Summary Information: Prior Notice," dated

[2] 68 F.R. 68140.

April 2, 2004, 88% of all PNs are transmitted through CBP's Automated Broker Interface ("ABI") rather than through FDA's web-based Prior Notice System Interface ("PNSI"). The vast majority of ABI users are accustomed to transmitting through ABI on an entirely different set of timeframes than those currently in place under the PN IFR. The following chart illustrates the differences in timeframes per agency, depending on the mode of transport:

Mode of Transport	FDA	CBP
AIR	No later than 4 hours prior to arrival	No later than the departure time "wheels up" of the aircraft from any foreign port or place in North America north of the Equator, OR No later than 4 hours prior to arrival from all other areas
LAND BY RAIL	No later than 4 hours prior to arrival	No later than 2 hours prior to arrival at border
LAND BY ROAD	No later than 2 hours prior to arrival	No later than 1 hour prior to arrival at border, OR No later than 30 min to arrival for FAST/C-TPAT participants

The above-outlined differences in reporting times have led not only to confusion in the industry, but to documentation and systemic problems. For example, for air shipments, filers cannot obtain a release from CBP until the aircraft is "wheels up." Often, this means that brokers are forced to file twice for air shipments, on two different systems (ABI and PNSI or WP) to comply with FDA regulations. This current "dual filing" system has spawned confusion as well as clerical errors in the submission of CBP and FDA data from transmitters struggling to keep a matrix of rules and timeframes straight.

In recognition of this problem, FDA acknowledged in the preamble to the PN IFR that, by mid-March 2004, FDA would publish a plan, including implementation schedule, to achieve the goal of a uniform integrated system and to coordinate timeframes for PN information, while simultaneously fulfilling the Bioterrorism Act mandates for air and truck modes of transportation, with time frames promulgated by CBP under the Advanced Electronic Reporting Rule.[3]

FDA's adoption of uniform reporting deadlines is also in accord with section 801(m)(2)(A) of the Food Drug & Cosmetic Act, which requires FDA to choose timeframes that "shall be no less than the minimum amount of time necessary for the Secretary of Health and Human Services to receive, review, and appropriately respond to the PN notifications." Said section further provides for FDA to consider "other factors" such as effect on commerce when deciding the deadline for PN submission.

Clearly, industry confusion and resulting untimely PN submissions and its negative impact on commerce are factors to be considered. The slight reduction in submission time frames for air, land/rail and land/truck, as set forth in the Joint Plan, is in accord with both FDA's intentions to act in tandem with CBP and with the statutory guidelines imposed for such submissions.

Accordingly, as proposed in the Joint Plan, FDA should keep the vessel timeframes intact yet adopt CBP's guidelines to air, land/rail and land/truck PN submissions, including the 30 minute expedited submission procedures in place for FAST/C-TPAT participants, as set forth in the AERR. In addition, FDA should further adopt CBP's phase-in periods of advanced reporting,

[3] 68 F.R. 58995.

with respect to transportation mode or geographic location of ports.[4]

However, the proposed implementation plan is unnecessarily lengthy given the antecedent research and public comments analyzed in response to CBP's Notice of Proposed Rulemaking on Advanced Electronic Reporting.[5] If the goal is for FDA and CBP to cooperate in a sincerely joint effort, it is redundant for FDA to repeat a feasibility analysis of submission timeframes, when CBP has clearly addressed those issues and their system has been implemented with minimal interruption to the industry.

3. FDA's Prior Notice System Interface ("PNSI") Requires Significant Improvement.

On May 8, 2004, FDA announced a significant improvement in PNSI, called "copy web entry." This feature allows the user to copy and save web entries into a new folder, including associated PNs and draft PNs. Thus, when a filer has multiple PNs to submit, the filer can save the basic information using "copy web entry" allowing for the editing of one or more different data element (e.g., package size) when submitting additional PNs. While this is commendable, there remain other difficulties in using PNSI.

For example, filers are still experiencing technical difficulties in the processing and filing of PNs. While we recognize that PNSI was designed for the "casual user," it is often necessary for filers to use PNSI. Currently, it takes a customs broker approximately thirty minutes to input a PN using PNSI. This input would be expedited if FDA revised the information required on the PN. Problems associated with PNSI crashes, slow processing speed and limited system capacity, also need attention.

[4] For example, CBP has promulgated compliance dates of July 12, August 10 and September 9, 2004 for implementation of advanced reporting for land/rail shipments, depending on a port's geographic location. (69 F.R.

4. Food Product Categories Should Be Considered As Criteria For Expedited Processing Of Prior Notice.

Expedited procedures should be instituted for certain fresh and perishable foods. Foods including baked goods, produce and fresh fish or seafood are often packed and shipped as soon as possible to ensure freshness of the food. As such, the exact variety and quantity of such products are often not determined until well after the current PN deadlines. This scenario occurs most often for food that is grown and/or produced along the northern and southern borders, and then transported by land/truck, arriving at the border in less than 2 hours. By the nature of how those foods are handled in the industry, adherence to the current PN guidelines is almost impossible. In furtherance of creating a uniform system, NCBFAA recommends that the expedited processing should be held to CBP's 30-minute deadline in place for FAST/C-TPAT shipments.

5. The Filer Should Be Notified When An Entry Is Refused Due To Inadequate Prior Notice.

The IFR, as applied, only requires that the *carrier* be notified when goods are refused at the border due to inadequate prior notice.[6] Under this current reporting procedure, it is the responsibility of the carrier, rather than CBP or FDA, to notify interested parties of the refusal. In its rationale for this practice, FDA asserted that neither FDA nor CBP currently had sufficient capability at the border to communicate these refusals to other persons and still process arrivals and examinations in a reasonable amount of time.[7]

19207).
[5] 68 F.R. 43574.
[6] 68 F.R. 59017.
[7] Id.

We respectfully disagree with that assertion and strongly urge FDA to reconsider its point of contact when goods are refused at the border. At a minimum, the filer who transmitted the PN should be notified. In addition, all information needed to contact the filer is readily available on the ABI submission and/or PN for any given shipment. Further, the importer of record and/or consignee, if different from the filer, and if known, who have an economic interest in the goods, should also be notified. Essentially, the current reporting procedure places an unnecessary burden on carriers, by imposing a duty to report such refusal, but with no assurance that the appropriate parties will be contacted in a timely fashion.

If FDA is prepared to hold parties who import foods that may pose health risks to timeframes within which to respond to a "refusal," FDA should inform these parties that their goods were stopped. FDA has a duty to report to these people directly, rather than rely on a middleman who has zero interest in the goods, to act timely or accordingly. In effect, as there is a narrow window within which interested parties may refile an adequate PN before goods are moved to General Order, the duty to report the refusal should lie with FDA, so that the interested parties are timely informed of the refusal and are not prejudiced by any delay in the reporting.

6. It Is Unduly Burdensome And Duplicative For The "Submitter" To Complete All Contact Information Fields When The Submitter Is A Registered Facility.

Many registered facilities transmit/submit numerous PNs on a daily basis. As a registered facility, these filers have already provided FDA with complete contact information. Mandating such filers to re-enter all contact information is a time-consuming and duplicative process.

To facilitate efficiency and minimize duplicate reporting of information, the PN form should be revised. A facility's registration contains all necessary contact information for the

submitter, which can be easily accessed and cross-referenced by FDA. This will significantly reduce the amount of time necessary to complete the PN while still providing FDA will all required information

7. FDA Should Provide An Electronic Method Through WP For Curing A "Reject" Due To A Defective Prior Notice.

Currently, although a filer is allowed to initially transmit PN through either ABI or PNSI, and to cure a facially rejected PN through either system, the only method for a filer to resubmit a PN when goods are refused at the border is to transmit solely through PNSI.[8] FDA provided no rationale for excluding WP as a means to *ever* correct a PN.

As stated earlier, the vast majority of filers transmit using ABI. Most ABI software has the capability of automatically filling in particular data fields, pre-fill certain PN data and/or save PN drafts or submissions. Requiring ABI filers to retype all PN information into PNSI, when they most likely have a saved version of the original submission and/or relevant PN information in their system, is time-consuming and unduly burdensome. In addition, there is no reasonable explanation to support not allowing the resubmission of a refused PN through WP or that doing so would not enable FDA officials to process and review the resubmitted PN. In any event, irrespective of how the corrected PN is transmitted, FDA should adopt guidelines that will assure that the revision is promptly acted upon.

Accordingly, the Final Rule should be revised to allow post-refusal PN submissions to be transmitted via either PNSI or WP.

[8] 21 C.F.R. §1.280.

8. FDA Should Allow Prior Notice Amendments Within The Applicable Time Frame For Submission, Without Having To Cancel And Resubmit An Entry, If The Amendment Does Not Effect The Integrity Of A Certified Entry.

Currently, PNSI and WP ("PN Systems") do not allow the filer to correct or amend the PN submission after it is filed. At a minimum, FDA should revisit the concepts outlined in proposed rules 21 C.F.R. 1.289 through 1.294, which allowed amendments to be made to product identity, quantity, and arrival information, without having to cancel the entry and resubmit the PN under a new entry. Such amendments were acceptable and would not taint the adequacy of a PN so long as they were made within the applicable 8, 4 or 2-hour timeframes per mode of transportation at issue. This concept allowed for a degree of flexibility in the PN Systems and acknowledged a well-known fact in the industry that often, FDA PN information may change, without affecting the data on the entry.[9]

The IFR, by eliminating the ability to amend a PN, specifically in situations where such amendment would not effect the integrity of a certified entry, created a situation where, should a minor clerical error occur while inputting several hundred lines of data into the computer, such as the reversal of 2 digits in a facility's registration number, the entire entry must be cancelled and resubmitted. One minor, careless, mis-stroke of a computer key has led to hundreds of cancellations and resubmissions, creating an unreasonable and time-consuming burden on the industry.

As one of the designated goals of the Bioterrorism Act is to achieve a system that can accurately and adequately track risk-related food articles, it does *no* good to either the FDA or the people of this country for the FDA to have inaccurate information with respect to where the goods even arrived in the country! In order for FDA to be able to track and deter suspect

shipments, all material shipment and food information must be accurate and updated within the the PN Systems, otherwise the system will never achieve its purpose. FDA should revamp the PN Systems to allow room for human error and change in shipment or food information, so long as such PN revisions are timely.

9. Prior Notice Confirmation Should Include The Entry Identifier Number For Which FDA Is Acknowledging Receipt.

Commentary to the PN IFR states that FDA believes that submission of the entry and line identifier is critical for matching the PN to the corresponding CBP entry.[10] The commentary further states that for in-bond entries and FTZ PNs submitted through PNSI, an entry identifier is critical for matching the PN to the corresponding CBP entry if a consumption entry is submitted, so that FDA and CBP can ensure that PN requirements were satisfied.[11]

Similarly, the filer's ability to match-up its own records to ensure that PN requirements were satisfied is equally as important. However, though the commentary specifically addresses the crucial importance of matching identifiers when a PN is submitted through PNSI, in-bonds and FTZ transmissions through other modules likewise must be matched up to their respective files to ensure proper PN compliance.

Currently, in-bond filers using WP are receiving PN confirmations that do not reflect an entry identifier (i.e., the in-bond number or FTZ number assigned by CBP) for which FDA is acknowledging receipt. Although WP filers are left with confirmation that a PN was received for review, it is extremely difficult, if not impossible, to trace the confirmation to its respective shipment. Thus in these circumstances, where there is no way of linking a PN confirmation to

[9] Until the customs entry is "certified" and "selectivity" performed, CBP allows changes in the entry information.
[10] 68 F.R. 59002.

particular shipments, filers are never certain whether PN requirements were satisfied.

Therefore, NCBFAA recommends that the WP software and/or PNSI system be redesigned in order for filers to receive the relevant entry identifier information with the PN confirmation.

10. The Factory Name For "Gray Market" Food Shipments Should Be Sufficient For the PN Where A Submitter Does Not Know The Factory's Registration Number.

When a buyer purchases food products from a middleman or other entity, rather than directly from the manufacturer, the facility's registration number is often unknown, cannot be obtained from the manufacturer, or does not exist. Under these circumstances, when the submitter can only provide the manufacturer's name, PN should nevertheless be considered adequate and complete.

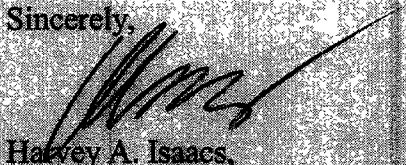
CONCLUSION

The NCBFAA is confident in FDA's ability to address the above-raised issues and we urge FDA to incorporate our recommendations into the final PN rule. We believe that the above comments will aid both FDA and CBP in achieving their goal of developing a truly joint and uniform system with respect to enforcement of the Bioterrorism Act and its subsequent regulations.

We appreciate the opportunity to submit these comments.

[11] 68 F.R. 59002-59003.

Sincerely,



Harvey A. Isaacs,
General Counsel

cc: NCBFAA Board of Directors