Border Trade Alliance
Alianza del Comercio Fronterizo
Alliance du Commerce Transfrontalier

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Rockville, MD 20852

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Gentlemen:

The Border Trade Alliance (BTA) thanks the Food and Drug Administration (FDA) for the opportunity to comment on the interim final rules for Food Facility Registration and Prior Notice under the Bioterrorism Preparedness Act of 2002 (the "Act") published on October 10, 2003 [Federal Register: Volume 68, Number 197, Page 58893-59077].

As we stated during the previous public comment period this year, the BTA and our trade community constituency has monitored the implementation process of this legislation with great interest and we welcome the occasion to once again offer our insight gained from BTA's 17 years of cross-border trade experience. Founded in 1986, the BTA serves as a voice for the cross-border trade community and the communities of the shared U.S.-Canada and U.S.-Mexico borders. In this post-September 11th environment, BTA supports the federal government's efforts to secure our borders while fostering a legitimate trade and travel-friendly environment.

General Comments

We begin by taking this opportunity to applaud the efforts of Customs and Border Protection (CBP or Customs) and FDA since the publication in February 2003 of the preliminary rules regarding prior notice and registration to work together to achieve the common goal of securing the food supply chain. The revisions which took place between the rules published in February and those published in October are dramatic, make clear that the practical concerns of the trade have been considered and further confirm that FDA recognizes that the active and willing participation of the trade is needed, and is, in fact, mandatory, in order to achieve the legislation's stated goals.

FDA's recognition that the tasks involved in getting such a massive program up and running are overwhelming is also to be acknowledged, and so the agency is to be further applauded for its wisdom in deciding to stay full enforcement until both the trade and the agency's personnel are much more familiar with the ins and outs of prior notice and registration. There was also great wisdom in waiting until the supporting software was fully developed and tested prior to full enforcement.

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In the interim, the agency has wisely chosen to continue with its outreach to industry, coupled with education and training.

Finally, since full enforcement of the Act has been delayed until August 13, 2004 and since industry has only limited experience with the new Bioterrorism Act rules, it is suggested that FDA consider an additional comment period of 30 days beginning on October 1, 2004 to allow industry to provide input after a reasonable time period during which both sides will have had an opportunity to experience full enforcement.

Section 305, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

I. Industry Concerns

Our members have expressed several concerns about the registration process:

For those who import products or samples of products into the United States merely for research purposes, such as reverse engineering or clinical trials, but not for general consumption or commercial distribution, there is concern that those importers will not be able to present Prior Notice with the required registration number. For example, one company makes the product, but a competitor purchases that product for reverse engineering purposes. The maker is not likely willing to give its competitor the registration number for the foreign processor making the product. Therefore, it is unclear how the competitor could legitimately import the other company's product without that registration number in light of § 1.281(6) of the Act's regulations. That section allows the omission of a registration number only if the product is intended for future export, which clearly does not apply in such a circumstance.

It appears to us that a clarification of the definition of food which states explicitly that samples not entered for consumption in the U.S. food chain, would solve this dilemma as these imports do not pose a threat to the health or safety of any animal or human in the U.S.

A second area of concern regarding registration is inter-company gifts. This situation arises when one or more executives in a foreign office elect to send food to American executives as holiday gifts. Under a strict reading of the Act's regulations, such gifts do not qualify under the personal gift exemption currently articulated which apply to non-business settings, see § 1.281(6).

Such gifts have no commercial value and are sent as business gifts, so to force manufacturer's registration numbers on Prior Notices for articles sent as business gifts appears to be unnecessary. After all, the agency acknowledges the difficulty in obtaining registration numbers in the non-business setting. Why is that logic any different in the business gift setting? We think the solution in this context lies in allowing the same approach for business and non-business gifts, i.e. a listing of the manufacturer's name and address as it appears on the product's label.

An additional concern has arisen regarding the flexibility of carriers if goods are refused. The concerns in this area could arise either because of faulty registration data or because prior notice itself is inadequate. Carriers have neither title nor interest in the goods they transport. FDA has

directed that carriers give notification in the event of refusal. While it remains unclear why the burden is on the carrier as opposed to the transmitter or sender, we contend that carriers should have the option of unloading the problem shipment(s) and delivering the rest of their load without being held up any longer than necessary to unload.

There is a further concern in that carriers are required to notify FDA regarding delivery of these refused shipments within 24 hours of arrival and then to make delivery immediately, see § 1.283(2)(ii). Such a requirement imposes an unreasonable burden on carriers.

Carriers generally arrive with mixed loads, i.e., products belonging to multiple importers/consignees. Carriers are required to deliver those loads within set windows of time. To disrupt the delivery chain so the carrier can provide notice of refusal and then segregate and deliver one shipment to the exclusion of all others, is unrealistic. It would better serve FDA's purposes to allow carriers the option of leaving a problem shipment at their own warehouse for a short period of time, provided it is bonded by Customs, and then allowing the carrier to arrange delivery to an FDA-designated warehouse within a short window of time thereafter.

II. High-Risk Shipments

We recognize that FDA lacks familiarity with Customs security programs, such as C-TPAT. At this juncture, it appears FDA views these programs as inadequate for the integrity and safety of the food supply chain. Nonetheless, companies have put in place systems to ensure and certify the security mechanisms and procedures of their carriers, brokers, manufacturers, exporters and warehouses. Those companies surely pose lower risks than companies that have little or no certified systems. To ignore this fact in favor of uniform review of all Prior Notices regardless of submitter, leads to more work than FDA really needs to undertake. FDA is encouraged to pursue risk management and to work with Customs to come up with recommended enhancements to the existing security programs and to share those findings with the trade. There is no question FDA will have more work than it is capable of handling with this new regime and if every shipment must be reviewed from every importer every time, FDA will not be able to focus its understandably limited resources on high risk shipments, which is where we all agree FDA's efforts should be directed.

The preamble to the Act's regulations itself speaks to the intention "to focus on conducting these inspections when our information suggests the potential for a significant risk to public health." Unless FDA is able to weed out the compliant shipments, how will it ever be able to focus on those shipments that pose the greatest risk to public health?

In order to address transmission of security program membership, we urge FDA to include a data element allowing transmitting parties to identify which company in its supply chain is a member of which Customs security program.

III. PN Confirmation Numbers

We are concerned that any trucker who is not PAPS-certified may be required to present the PN Confirmation Number upon arrival at the border, even if the PN was submitted via the ACS

system. We hope this will not be the case as such a position would be contrary to the interim regulations which indicate that the PN Confirmation Number will only be required to be presented in the event the PN was submitted via the FDA PN interface.

We recognize FDA's interest in associating data with actual shipments. However, truck drivers are generally unable to obtain the PN Confirmation number prior to arrival given the short distance between Canada and the United States and Mexico and the United States (where the FAST program is the model) coupled with the fact that the PN is generally not submitted until after the trucker has left with his load. Put another way, the PN is not submitted by the driver because submissions through ACS systems will only be possible by brokers and other certified personnel and, although arguably truck drivers may be able to transmit the PN through the FDA interface system themselves, companies are not interested in trusting truck drivers to provide services beyond trucking.

Requiring PAPS authorization as the only means of avoiding these delays is to mandate that all truck companies become C-TPAT certified and otherwise comply with the designation requirements. For a variety of reasons, this is not possible, sometimes simply due to cost. Moreover, the FDA has distanced itself from all Customs-related certification programs finding them to be inadequate to meet FDA's security guidelines. Accordingly, it is contrary to both FDA's position and the goals of the Act to advise truckers that unless they participate in the PAPS system, they are unlikely to be able to unload their cargo. We have similar concerns regarding the FAST-program at the Southern border.

IV. Registration Process

Here, too, there are a variety of concerns. Perhaps the biggest concern industry has in this context is the inability to obtain details from FDA about which facilities have registered and their proper registration numbers. Absent a means of verification, it is impossible for an importer to know whether the details provided by a supplier are accurate. FDA gains nothing if the importer is given phony registration information, plus the importer loses his ability to import the product. That importer is not authorized to register the facility and so by failing to provide a means to confirm registration, FDA encourages dishonest exporters to sell to importers with limited buying clout, and then collect payment but fail to provide the details necessary to obtain their goods upon arrival. We do not think FDA intended such an outcome. Therefore, we encourage the agency to allow a means for American importers to be able to query a database which would do nothing more than confirm whether the details provided are accurate.

Such a means could also lead to fewer duplicate registrations resulting from desperate importers trying any means to get their goods cleared. While unauthorized by the foreign facility, pressing commercial reality being what it is, there is no doubt importers will use all available means to get their goods released and a verification means eliminates the need for attempted registration actions.

The liability for not registering a facility required to be registered under the Act's regulations lies with the owner, operator, or agent in charge of that facility. Is this the owner of the building who leases out to perhaps hundreds of different tenants portions of that space, only a small percentage

of which are related to food storage? If that owner has no obligation to identify the specific tenants within its building in food-related businesses, then registration of that building merely by address will not serve the stated purpose of facility registration: "Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States" because the FDA will have no information with which to identify those tenants in that building who perform operations related to food products. Moreover, the "agent in charge" of a facility may not have the necessary authority to register a particular facility, as this is an undefined term in the regulations. While certainly the manager of a particular facility may have the knowledge about that facility necessary to adequately complete the registration submission, there may be particular facility owners who elect not to register certain facilities for a variety of legitimate reasons. Finally, while it certainly relieves the burden on a facility to enable authorization of a third party to register that facility, without a uniform method of evidencing such authority there is the possibility that multiple parties may believe they have the authority to register and may proceed accordingly.

We think it would assist the agency if it clarified whether it was the multi-use building itself in which FDA was interested, or whether it is willing to focus its interest on the food-related uses of that building. Further, clarification as to the term "agent in charge" would also be helpful.

The regulations clearly indicate that FDA intends to validate foreign facility compliance with the registration requirements by cross-linking the information contained in the Prior Notice with facility registration information. However, in connection with domestic facilities, no such verification procedures appear to be in place. This invites discriminatory treatment between foreign and domestic food facilities, which we think the agency did not intend. We suggest the agency make that point clear.

While mobile facilities are required to register, by their very definition, these facilities are mobile and so have no address and may perhaps lack additional information required to be submitted in the present form of registration. We recommend FDA acknowledge the unique nature of mobile facilities in its regulations.

Section 307, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

I. Coordination Between Agencies

In our public comments filed on April 3, 2003, BTA took issue with FDA's proposal calling upon an importer to give prior notice of shipment on noon the day prior to that shipment's arrival at the border. We also stated, albeit reluctantly, "that advance notification of no more than one hour prior to arrival should be the norm in the land border context."

In FDA's interim final rules released on October 10, 2003, FDA states that prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and no fewer than two hours before arrival by land by road. BTA is pleased to see that this regulation is much more in tune with commercial reality at the U.S. land borders.

However, it must be noted that the U.S. Bureau of Customs and Border Protection has released its own rules regarding advance manifest notification so as to comply with the Trade Act of 2002. According to CBP, a truck carrier certified under the terms of Free and Secure Trade (FAST) must submit its manifest information no later than 30 minutes prior to arrival, while non-FAST carriers must submit their manifest information no later than one hour prior to arrival.

The apparent contradiction in these two timeframes underscores the critical need for FDA and CBP to closely coordinate their efforts. While we look favorably upon both agencies' recent public statements that this issue will be addressed as the Act is phased in over the next several months, we urge both FDA and CBP to closely coordinate their respective rules to eliminate contradiction and confusion regarding prior notice. Industry needs as much clarity as possible on this issue to promote a secure, predictable, transparent and efficient business environment.

II. Prior Notice Data Elements

One notable change between the February and October regulations is FDA's acknowledgment that a change in arrival date does not invalidate an existing Prior Notice. Our question is why is arrival data even needed any more? In light of the Memorandum of Understanding between FDA and CBP, it would seem arrival data is no longer an important factor to FDA, as CBP will provide the personnel to conduct the necessary inspections.

We understand there may well be certain types of shipments FDA may still want to inspect. However, it would appear a more efficient means of identifying these shipments would be to flag them in the system and have CBP report arrival. By so doing, this would free space in the computer system and still accomplish the intended goal of identifying high-risk shipments.

In the context of truck shipments, there is generally no bill of lading number. Some, but not all, carriers use a Pro Number, which is a unique identifier. Pro Numbers are not likely to be used by small carriers and owner/operators. As such, we encourage FDA to use the Entry Number in lieu of the bill of lading.

III. Dual Use Products

FDA wisely acknowledges that some products could have both food and non-food applications and allows the importer to disclaim food uses. Our concern arises because there is no clear methodology provided for such a disclaimer beyond an initial designation in FD-3. Our concern is that in the absence of a clear protocol, a question could arise, a shipment ends up held and then it is too late.

We recommend the agency outline the elements of a due diligence protocol which then becomes part of the disclaimer process, subject, of course, as are many other elements regarding the Act's regulations, to spot checks by either Customs or FDA.

IV. Non-Food Products Subject to FDA Jurisdiction

There appear to be some glitches in the software which has been released. For example, perfume is a non-food product which is subject to FDA's 801(a) jurisdiction but not prior notice. However, from the way in which Customs has issued a procedures memo, it appears that if one disclaims FDA in FD-3, it is disclaimed for all purposes. Similarly, if one acknowledges FDA jurisdiction in FD-3, then prior notice must be submitted whether or not the importation involves foodstuff.

Similarly, there is a problem with the in-bond system. If one assumes a shipment arrives in Los Angeles but is destined in-bond for New York, upon arrival, the shipment is subject to prior notice. However, in order to properly comply with Customs' requirements, the arrival date is entered based upon the expected arrival date in New York, not Los Angeles. As such, the data exchange between the CBP and FDA computers is then triggered by the New York arrival date rather than the L.A. arrival date. Put another way, one could timely transmit prior notice to Customs but have it held up due to computer programming so as to be untimely. What the brokers have done in the short term to fix this problem is input the Los Angeles arrival date in both places for prior notice purposes and then change it after prior notice has been concluded.

We recommend the two agencies continue working together to iron out these glitches.

CONCLUSION

Once again, the BTA appreciates the opportunity to work with FDA in keeping the U.S. food supply secure while expediting the flow of legitimate commerce. Our organization offers its years of collective knowledge of cross-border affairs as FDA addresses these important issues.

Sincerely,

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