



# THE LOS ANGELES CUSTOMS BROKERS & FREIGHT FORWARDERS ASSOCIATION, INC.

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U.S. Food and Drug Administration  
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RE: Docket No. 2002N-278-Comments On Prior Notice Of Imported Foods Under The Public Health Security And Bioterrorism Preparedness And Response Act Of 2002 (BTA)

The Los Angeles Customs Brokers & Freight Forwarders Association Inc. (LACBFFA) is a trade association representing firms integrated into the various aspects of import and export logistics. Recognizing the need to protect our Nations food supply and the spirit of the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA), our membership have implemented many of the business procedures necessary to comply with the Food and Drug Administration (FDA) interim final rules for Registration and Prior Notice of Importer Foods. While applauding both FDA and Customs and Border Protection (CBP) efforts to craft workable regulations our membership have found some serious concerns that to date, have not been adequately addressed. Our membership is responsible for transmitting over 80% of the required information into FDA/CBP automated systems at the ports of Los Angeles/Long Beach and LAX. After working with the system for several months, and into the first phases of enforcement, we still have operational concerns that need to be addressed.

## **FDA To Continue Outreach Industry Training On Operational Prior Notice Procedures.**

After passage of the 2002 BTA legislation and during the Agencies initial introduction of its Interim Final Regulations (IFR), outreach seminars were held to inform the importing public. The FDA conveyed the requirements of the basic BTA law the agencies plans for its IFR's. Since the implementation of the IFR's on December 12, 2003 and its first two phases of enforcements FDA has not expanded its operational training. Our association feels this lack of training is a major shortcoming of the agencies efforts to implement a very complex security program while keeping the orderly flow of international trade. The lack of understanding by industry has created a vast amount of apprehension, misunderstanding, and paranoia. Our association feels additional specific training, directed towards each mode of transportation and port operation should be immediately started and completed before the final phase of enforcement.

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### **Data Validation System Required.**

By FDA's own statistics, after five months of implementation, half of all data transmissions are incomplete or inaccurate. A major reason for this poor compliance rate is the fact that the automated 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 to be in full compliance prior to the August enforcement deadline. Without this level of information industry cannot make the necessary adjustments in programming and databases before full implementation in August 2004. Some FDA staff has advised us that we will know on August 12 of any specific inadequacies in our transmissions -- once the cargo is rejected. This is unacceptable. Our industry is eager to assist in increasing compliance rates, but we need FDA's help to do so. 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.

### **Ability to Update And Correct MID Database**

The CBP Manufacturer Identification Database (MID) is over 18 years old and woefully out of date. Currently there is no mechanism by which to update the MID. Until the MID is updated, imported shipments may be subject to rejection or refusal for no legitimate reason. We urge FDA to work with CBP to allow the MID system to be updated, and to assure that cargo is not rejected due to a mismatch with the MID.

### **FDA Prior Notice System Interface Must Be Augmented Prior To Full Enforcement.**

FDA has established two separate systems for transmitting the required prior notice data to the agency for review. FDA originally estimated over 80% of the required data would be transmitted through the CBP Automated Broker Interface (ABI). The ABI system has been proven to be the most efficient means for meeting the prior notice time requirements. The trade community has devoted a large amount of resources in system programming and procedures with limited amount of FDA feedback on individual systems compliance status. The trades systems appear to be operating correctly but to date FDA and CBP have not confirmed this assumption. The WP-Independent Prior Notice system, while being a valuable tool, still leaves serious omissions and processing problems.

The second system available to transmit prior notice data is the FDA web base Prior Notice System Interface (PNSI). Individuals or transmitters who do not have the capability to transmit through ABI

can utilize this system in an interactive environment. This system was well designed for its intended use but does not lend itself for transmission of vast amounts of data. The time requirement for input through interactive systems is taking far too long in a real world environment. This system has been designated as the primary backup system should the ABI systems become unusable. During a recent failure of the ABI/OASIS system the PNSI was used for all PN transmission. It became impossible to log into the PNSI web portal. Transmitters were dropped from the portal during PN input and processing time became unacceptably long. Adding the requirement that all PN data be transmitted via the PNSI portal after the PN time limitations or refusal will increase the load on this limited system. 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.

#### **Review The Present Data Elements For Possible Elimination.**

The origin BTA mandated seven data elements be provided in order to determine possible risk to the American food supply. FDA expanded this mandate to a vast number of data elements that may also be furnished to Customs and Border Protection under their own security programs. There is some concern that all of these elements are necessary for intelligent risk analysis. To obtain some of this obscure information is very costly and burdensome to the importing trade. FDA should review all required data elements harmonizing data collect efforts with CBP and eliminate any unnecessary fields.

#### **Ability to correct simple clerical errors.**

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 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.

#### **Secured Storage Facilities and Procedures Needed**

With little more than three months before full implementation of the of the PN interim final enforcement FDA and CBP have not established adequate secured storage facilities and cargo movement procedures. Without these locations and procedures in place our port could very rapidly be adversely impacted.

#### **Inconsistency In Time Frame Requirements FDA And CBP**

A serious timing disparity exists between FDA Prior Notice and CBP Entry requirements. FDA permits data transmission five days before arrival but CBP restricts entry processing for air shipments to no more than wheels up. Land transportation requirements for PN and Entry are not equal causing excessive processing and shipment delays. We urge FDA and CBP to address these timing disparities.

#### **Exemptions For Normal Small Commercial Laboratory Shipments Which Will Not Enter Commerce Nor Reach The Public**

The Prior Notice Interim Final Rules offers exemption status for homemade foods and personal use food products accompanying individuals arriving in the United States. FDA deems these exempted products pose little risk to public health. Multinational firms send large number of repetitive test samples to maintain quality control. The prior notice requirement for small laboratory and test samples pose excessive burden and costs for products that would be of little security risk provided very specific security requirements are controlled. We recommend that such samples be exempt from PN requirements.

#### **Enforcement Deadline Should be Postponed**

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.

The LACBFFA and its membership are available and will to assist both FDA and CBP in meeting these stated operational challenges and any other anomalies as they arise. We support the Congressional goal to provide the American public the safest food supply possible while maintaining the

legitimate flow of international traffic. The LACBFFA recommends you also consider the comments being presented under separate cover by the National Customs Brokers And Forwarders of America and the Pacific Coast Council of Customs Brokers & Freight Forwarders Assns, Inc.

We thank you for your consideration of these comments. Our association and its membership pledge our comment to working towards resolving problems and making the final regulations a viable solution to the needs of both the BTA and the international community.

Respectfully submitted,

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