



2094 Grand Island Boulevard • Grand Island, New York 14072 • (716) 773-9207 • FAX (716) 773-9445
IMPORT & EXPORT SPECIALISTS

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

Subject: Comment on Prior Notice of Imported Food (Docket Number 02N-0278)

Dear Sir/Madam:

We respectfully wish to submit comments on the Proposed Regulation of Prior Notice of Imported Food Shipments (Docket Number 02N-0278) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Our comments on the "Prior Notice of Imported Food" Regulation, concern the incompatibility of current systems to the proposed system. The incompatibility will arise from the impossibility of obtaining certain pieces of information prior to importation, the extreme extra burden in monetary cost, and the manpower for all parties involved in providing the required information for a specific shipment.

Under Border Cargo Selectivity (BCS), Pre-Arrival Processing System (PAPS) and other Immediate Delivery (ID) Release processes currently used to clear freight through U.S. Customs at the Northern Border, certain pieces of information would not be able to be submitted ahead of time. These pieces include the entry number, entry type, the arrival information and the U.S. Customs entry process information. The U.S. Customs entry process information, which includes the entry type and entry number, cannot be obtained prior to arrival because some information such as the entry summary information cannot be input and printed out until U.S. Customs and FDA (Food and Drug Administration) release the shipment. To try and obtain that information before the release of the shipment can result in a myriad of errors and inaccuracies, which would only complicate ID Release procedures, placing excessive burdens on U.S. Customs, the FDA and the whole import community.

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Border detentions would skyrocket because of these errors, resulting in extensive traffic congestion never before experienced along the Northern Border. Additional safety measures will be needed to be initiated to deal with the detention and subsequent congestion of commercial traffic at the Northern Border.

The border situation would deter further because the problems would take longer to solve with the limited FDA staff at the border. A 24 hour a day, seven days a week FDA staff will be necessary at the border.

The entry information that is required will not assist in ascertaining the risk and the possibility of contamination from a terrorist act. The information such as the entry number and entry type is U.S. Customs required generic information that is the same similar information as for thousands of different entries/shipments. The information lends no unique knowledge about the shipment to prevent an act of terrorism.

In your evaluation of the Prior Submission document listed in the Federal Register, the document is five pages long, the time to complete is one hour and the cost to a small business is \$770.00 a year. In order to get the full scope of the monetary cost and time, all businesses have to be reviewed. A mid-size or large business is going to have multiple shipments per day. Some businesses have a shipment on an average of every 20 to 30 minutes. Taking one hour per prior submission and considering every submission will not go smoothly, the amount of extra time involved will result in the hiring of more manpower, ending in an extra cost to the businesses of \$40,000 to \$80,000 a year.

This is a low monetary estimation as the purchaser or importer is responsible for completing the Prior Submission information. The importer or purchaser is not going to have this information, since the shipper arranges the transportation and the shipper often times is the Importer of Record and takes care of the U.S. Customs information at the border crossing.

Several remedies are available to curb the monetary and manpower costs. The FDA could change their definition of the word "importer" to match the definition used by U.S. Customs. U.S. Customs' definition of "importer" is the importer of record for a shipment. Importer of record can include a Canadian company. The Importer of Record/Canadian Company has more knowledge of the whole shipping process of their products.

U.S. Customs would have more information on the Importer of Record, especially if the company is a member of C-TPAT (Customs-Trade Pact Against Terrorism).

Then with the sharing of information between government agencies such as U.S. Customs and the FDA, duplication of information will be cut down and more necessary background information would be obtained on the Importer of Record/Canadian Company and their products. Generic information on each shipment will only yield a redundancy of non-pertinent information.

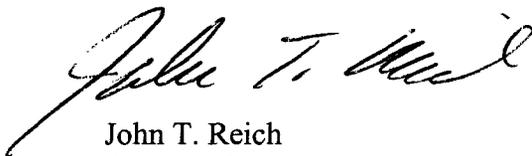
A request for more information at the time of registering will also eliminate the need for prior notice of continual repetitive information on a shipment by shipment basis.

Finally, the FDA has indicated the reasoning for the need of the Prior Notice of Imported Food Shipments in past publications and meetings. However, the use and benefit of receiving repetitive generic information from the Prior Notice has never been stated. If the FDA wanted the Bioterrorism Act passed for better security measures in the shipment of a product, this is more of a carrier issue. Nonetheless as long as an Importer of Record/Canadian Company is a member of C-TPAT their security measures are known. If a carrier is a member of C-TPAT or FAST, their security measures are known. Having this knowledge is more instrumental in fighting terrorism than a standard pro forma or commercial invoice with a product listing.

With the addition of the "Prior Notice of Imported Food" Regulation, all Northern Border Processes require addressing. With the changes, the processes have to be adapted to withstand the new difficulties arising from everyday import activity under ID Release.

Thank you for the time and consideration of our comments.

Respectfully,

A handwritten signature in cursive script, appearing to read "John T. Reich".

John T. Reich
Cataract CHB, Inc.
Telephone: 716-773-9207, ext. 13
jreich@cataractchbinc.com