



March 1, 2003

PO Box 785
603 North Fries Avenue
Wilmington, CA 90748
310/834-6458
310/834-5984 fax
www.williamsclarke.com

Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Bldg
725 17th St. NW, Rm. 10235
Washington, DC 20503

Attn: Mr. Stuart Shapiro, Desk Officer for FDA

SUBJECT: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Act of 2, Docket No. 02N-0278, RIN 0910-AC41, 21 CFR Part

Gentlemen,

We are a small Custom Brokerage firm located at the ports of Los Angeles/Long Beach and LAX. With a large client base in the seafood and produce industries I feel we have first hand actual operational knowledge with which to comment on the collection of information of the proposed FDA Prior Notice requirements. As we support the efforts for security, we also feel a workable solution to the mandated requirements of this act can be achieved but it must be done within a framework that does not adversely affect the consumer, our economy, or the United States position in the world marketplace.

In review of these proposals we feel the information assumptions and cost estimates are flawed. I would like your office to consider the following points.

1. Based on 2001 OASIS data FDA is estimating the average import entry to contain 2.6 FDA lines with an average time of 23 minutes to complete each line item.

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*Customs Brokers
Freight Forwarders
Established 1921
017 #0570F*

(2)

In the areas of produce and seafood FDA does not presently require (only on a voluntary bases) the reporting of each produce grower and seafood size or can code per line item. Only produce shipper information is now required. Grower information is being furnished under hard copy as requested by FDA. Comparison between 2001 and proposal line item:

Produce shipment containing 2 types of produce, from one shipper, with each type from five different growers:

Present line item requirement:

2 types with same shipper = 2 OASIS line items and one OASIS transmission

Under this proposal:

2 types from 5 different growers = 10 OASIS line items (three growers per notice transmission) with 4 prior notices transmissions.

The number of required line items for the same shipment increased five-fold indicating. This 2001 average produce shipment (FDA 2.6 lines per entry) would not take the estimated 1-hour to compile the data etc. but would take 3.8 hours (23 min. per line x 10 lines) under this proposal.

The same would be true for a seafood shipment, which now does not now require line items for size or can codes.

Bottom line is that the costs involved in complying with this proposal are inaccurate as they are based on a different 2001 requirement base. I would suggest a more accurate determination be made based on standard approved statistical sampling of current data and the increased estimated line items which will be required under this proposal.

(3)

2. The estimated labor cost for complying with this proposal is based on a normal 8 hour, five day work week, but the provision for notification of exact arrive date and arrival time with in a 4 hour window would require some type of 24/7/365 operation. The extra labor overtime have not been factored into the estimated compliance cost.
3. The duplication of data and costs required by this proposal can be vastly reduced by using data now being collected by other agencies and available within established security programs. U.S. Customs is now requiring full manifest information be furnished into the Automated Manifest System 24 hours prior to loading of vessel cargo. This program will be expanded to include air and land transportation in the near future. FDA was inaccurate in the assumption that this data could not be obtained by the present interagency channels. By opening up the manifest information for direct download into the FDA OASIS system and the filing of the present entry data, within the required prior notice time limits, much of the data duplication would be eliminated. The Department of Agriculture now uses the screening of manifest data in accomplishing their security issues. This would also reduce the cost for FDA review time as all data for both security and admissibility would b available at the same time.
4. This proposal requires the transmission of registration codes and again keying in full entity information as part of the prior notice requirement. The proposed web based system offers no validation of information for adequacy or accuracy until cargo has arrived. Only a verification of receipt is furnished. The importer or filer has no way to verify data entered under the registration requirements of this proposal is complete or accurate and thus could incur added costs in complying.
5. FDA is inaccurate in its assumption that vast amounts of data can efficiently be transmitted through the Internet using a basic computer and an ISP \$20.00/month service. U.S. Customs has many years of experience in the transmission of data required by this proposal. Even using ISDN high-speed technologies they are not always able to meet the data flow during peek times of the working day. The true cost of high-speed data transmission and its associated programming, equipment, and training must also be factored in.

(4)

We question the accuracy of FDA in projecting the true costs in complying with the provisions of this Prior Notice proposal. In dealing with many aspects of this proposal, on a daily basis, we estimate our cost as a professional filer and knowledgeable party will increase by at least 50% per entry in acting as an agent of the importer. The costs to an importer, without established knowledge and equipment, would be much higher if they attempted self compliance. These new proposals will change the way international food trade is conducted by the United States and deserve a coalition of all parties involved to analyze the best approach to meet the mandated requirements and ascertain their true cost to our economy.

Sincerely,

Williams Clarke Company, Inc.

A handwritten signature in cursive script that reads "Roger M. Clarke". The signature is written in black ink and is positioned above the printed name.

Roger M. Clarke, President