# FRESH PRODUCE ASSOCIATION OF THE AMERICAS

Post Office Box 848
Nogales, Arizona 85628-0848
www.fpaota.org

(520) 287-2707
Fax (520) 287-2948/287-5430
info@fpaota.org



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5630 Fishers Lane, rm. 1061
Rockville, MD 20852
(301) 443-6230

**Docket Number: [02N-0278]**

The Fresh Produce Association of the Americas (FPAA) commends the FDA on changes to the preliminary prior notice regulations. As mandated by the Bioterrorism Act of 2002, the FDA has been charged with securing the U.S. food supply. Members of the FPAA have a long history of supplying the U.S. with safe, quality produce and are proud of their efforts in working with the FDA in enhancing food safety and security. The industry relies on sensible, effective government regulations to ensure the continued advancement of the safety and security of the U.S. food supply. For this reason, the FPAA is submitting comments pertaining to the FDA's interim final rules for prior notice to communicate industry concerns and suggestions regarding the implementation of prior notice. The FPAA strongly supports the modification of any aspect of the new prior notice system that would eliminate distractions from valuable government and industry resources that strengthen safety and security.

**Time Frames and Coordination with Department of Homeland Security-** The FPAA believes that the FDA prior notice rules should be brought into concordance with the electronic prior notification rules of the Department of Homeland Security Customs and Border Protection (CBP). While the reduction of prior notice from 12:00 pm of the previous day to 2 hours before a shipment arrives for entry into the U.S. minimizes the food safety and food security threats identified in the FPAA's previous comments regarding the proposed rule, the FPAA supports further integration and cooperation with CBP regarding prior notice. Based on the prior electronic notification rules of Customs and Border Protection (CBP), the FPAA

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believes that the FDA prior notice rule remains excessive. The integration of systems, policies, and resources would result in 30 minutes to 1 hour prior notice for inbound truck cargo and "wheels up" for air cargo from certain parts of North and Central America.

The FPAA strongly supports the integration of prior notice requirements for both the FDA and the Department of Homeland Security (DHS), carried out by U.S. Customs and Border Protection (CBP). The differing timeframes for prior notice for FDA and CBP will create unnecessary redundancies in the importing and screening process, minimizing the coordination of government agencies' efforts. Sharing expertise and manpower is the most effective way to enhance food security.

In no circumstance should the prior notice period be increased for truck, air, and rail travel. Any increase in the prior notice requirement will in fact be counterproductive to the safety and security of imported fresh fruits and vegetables by forcing trucks to wait in unsecured areas waiting for the prior notice period to pass or by forcing the construction of larger storage facilities that represent a more attractive target for potential terrorist activities.

**Integration with OASIS**-The FDA, in implementing prior notice, has created a prior notice computer system separate from their Operations and Administrative System for Import Support (OASIS) database. To more effectively screen shipments entering the U.S., the FDA must work to integrate OASIS with the prior notice system. Not having complete integration of the two systems circumvents valuable FDA resources that could enhance the prior notice system and the FDA's ability to review and inspect shipments. The OASIS system contains a valuable history of risk factors and compliance history that would benefit the selectivity requirements in the new prior notice system. As well, new screening criteria in the prior notice system could modify and improve OASIS selectivity.

**Amendments Will Encourage Earlier Filings**-The prior notice system should be modified to allow for a small number of amendments to prior notices submissions. As filers wait for necessary information such as the Standard Alpha Carrier Code (SCAC) for transportation companies, they will wait to transmit prior notice until the last possible second. From an administrative point of view, the industry would be willing to submit a portion of the prior notices earlier if amendments were allowed and would assist the FDA in their OASIS reviews of food shipments. Allowing amendments to certain data fields such as port of entry, quantities, and SCAC will facilitate the steady flow of prior notice submissions, as filers will have the ability to add or change certain data fields as they receive the information. The FPAA understands that the current electronic systems may not be robust enough to allow for amendments now, but FDA should consider modifying the policy as the FDA's technology systems improve.

**Time of Arrival Should Remain Estimate**- Delays caused by enforcement sweeps, securing of federal customs facilities after encountering contraband, and the lack of infrastructure by the various federal agencies at the ports of entry mean that delays for trucks to enter federal inspection compounds vary from minutes to 12 hours. To avoid unnecessary canceling of submissions and resubmission (and/or amendments), the FDA

should retain the time of arrival field as a best estimate that does not require a new submission when conditions change the exact time of arrival.

**Clarification of Gray Market Imports-**To ensure that all companies follow the same guidelines, the FPAA asks that FDA give a written clarification regarding the correct registration number to use on prior notice submissions when a third-party exports product clearly packed by another company. Commonly called gray market exports, a third-party company buys product from the first processor-packer to export as a product from the third-party. Exported in the original carton or box, the third-party may place a small sticker on the box, but the identity of the original packer remains clearly evident. In the past, the FDA has looked to the original packer, not the third-party exporter, when there has been a problem with a product. Given that the prior notice requires the inclusion of the FDA registration number of the "processor," the FPAA supports requiring the registration number of the original processor-packer on prior notice submissions when a third-party is exporting the product to the U.S.

**Clarification Regarding Legal Authority of FDA Help Line-**The FPAA also asks that the FDA provides a clear statement as to the legal weight of information given to the industry by the FDA Prior Notice Help Line. The industry has encountered several instances where individuals have received conflicting advice from different Help Line representatives. Of particular importance, the FDA should outline what enforcement actions will be taken against a company that is noncompliant with prior notice requirements but has committed the error only by acting on incorrect advice from a Help Line representative. If future instances occur where a company faces large fines due to inaccurate FDA guidance, the industry needs to know what recourse is available.

**FDA Must Establish Debugging Period Prior to Significant Computer Changes-**As the industry struggles to implement the new prior notice changes, it is apparent that the FDA needs to allow time for a debugging period for future computer system changes. A debugging period would permit filers to work out problems with their computer system. It will also allow the government to identify their own problems and make the necessary programming changes. Without a trial period, new and untested computer systems could jeopardize the integrity of other systems such as CBP's Automated Commercial System (ACS) or FDA's OASIS system.

Due to the lack of a debugging period, prior notice warnings attributable to computer programming errors have been numerous. Filers submitting through the Automated Broker Interface (ABI) system attempting to comply with prior notice are receiving warnings or rejections because computer systems between CBP and FDA are not communicating properly. For example, the FDA prior notice system requires Affirmation or Compliance Qualifier Codes for specific data fields that are not being accepted by CBP's ACS. Therefore, when the data is submitted in those required fields, filers are receiving CBP rejections and the information is not being forwarded to FDA. When these required fields are left blank, shipments are Customs Cargo Release Certified; however, prior notice warnings are issued stating that submissions are

incomplete. Importers are penalized for trying to comply with prior notice and for submitting shipments in a way that the new computer system will allow.

**Grace Period for Errors Caused by Lack of FDA Planning-**Mnay mistakes made during the initial four months of implementation can be attributed to difficulties with both government and industry computer systems as everyone works to correct programming errors. Due to the potential consequences for failure to fully comply with prior notice and given that the industry did not have time to test computer systems, prior notice mistakes made during this initial time period should not be part of an importer's record.

**FDA Economic Analysis Contains Serious Flaws-**The FDA analysis regarding the losses due to the perishable nature of Mexican produce is seriously flawed on several counts. As mentioned before, many fresh products from Mexico are subject to USDA inspections outside of the federal compounds. The FDA in their cost analysis excluded all tomatoes, grapes, onions, and other products subject to the these inspections by stating that they must already notify the USDA one day in advance of any shipments. The FDA failed to recognize that the notification to USDA consists only of the intent to ship a certain product and to confirm a location for inspection; however, there is no detail regarding the many data fields requested by the FDA in the proposed rule. In addition, product that fails those inspections needs to be repacked or removed from the load and will cause a change in what will be crossing and what will be transmitted to Customs and the FDA. Thus, the exact contents of many trailers are not known until the completion of these USDA inspections near the border.

In addition, the FDA has underestimated both the wholesale and retail value. Because products subject to the USDA marketing orders should be added back to the calculation, the total value of fresh produce from Mexico was actually $2.45 billion in the calendar year 2002.[1] In addition, the FDA underestimates the wholesale-retail spread significantly. The most recent report for the entire fresh vegetable and fruit categories show that the import/farm-gate value relative to the retail price is actually 21 and 18 percent respectively of the retail value.[2] Using a basis of 20 percent for fresh produce from Mexico, the retail value is actually $12.25 billion per year.

The FPAA appreciates the efforts to date by the FDA to minimize the risks to the food supply. The FPAA believes that these aims can be achieved through a closer integration of systems with CBP while still reducing the prior notice period for most forms of transportation. Additionally, the FPAA believes that the FDA has made a mistake in not integrating the OASIS system more closely with the Prior Notice systems. FDA should also strive to create clearer definitions and requirements within the rule and with their

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[1] U.S. International Trade Commission Dataweb (http://dataweb.usitc.gov/). Data on this site have been compiled from tariff and trade data from the U.S. Department of Commerce, the U.S. Treasury, and the U.S. International Trade Commission. The value is the landed-duty paid value for HTS numbers 0701-0709 and 0803-0810. Therefore, it underestimates the wholesale value since it excludes value added marketing and transportation services that increase the value by approximately 15 percent.

[2] **Food Cost Review, 1950-97.** By Howard Elitzak, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture. Agricultural Economic Report No. 780, pp 31-32.

staff working the help line and communicating directly with industry and trade associations. Furthermore, the FDA should focus efforts on improving management and staffing to review information already being submitted to the FDA. The creation of a separate database with the requirements contained in the proposed rule will ultimately be costly to the industry, U.S. consumers and taxpayers, and most critically, the security of the U.S. food supply.

The FPAA stands committed to improving the safety and security of the U.S. food supply.

Respectfully yours,

Lee Frankel

Lee Frankel
President
Fresh Produce Association of the Americas