

FRESH PRODUCE ASSOCIATION OF THE AMERICAS

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



(520) 287-2807
Fax (520) 287-2948/287-5430
info@fpaota.org
MAR 18 03 09:14

March 14, 2003

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

Chuck Ciruli
Chairman

William Sykes
Vice-Chairman

Directors

Robert Bennen, Sr.

Alicia Bon Martin

Juan Carlos Cardenas

Ana Astrid Celaya

Jaime Chamberlain

Francisco J. Clouthier

Jesse K. Driskill

Rosie Favela

Jorge A. Gámez

Brent Harrison

Martin Ley

Julio Lopez Podesta

George Mendez

Bert Monteverde, Jr.

Gilbert G. Munguia

Raul Paez

Gerardo Ritz

Miguel A. Suarez

Leonardo Tarriba

Chuck Thomas

Brian Vandervoet

Lee Frankel
President

Mike Masaoka Associates
Washington Representative

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

Docket Number: [0N-0278]

The Fresh Produce Association of the Americas (FPAA) strongly supports enhancing the security of the U.S. food supply as intended by the Bioterrorism Act of 2002. The FPAA represents U.S. importers and marketers of fresh produce grown in Mexico. For the calendar year 2002, total U.S. imports of fresh produce from Mexico were roughly 7 billion pounds valued at more than \$2.4 billion. The members of the FPAA are proud of the long and continuing contribution their products provide to the U.S. public and the health of all U.S. residents. As an underlying principle to all comments contained in this response, the FPAA believes the prior notice rule should be implemented in a manner that enhances the security and safety of the U.S. food supply, and that any aspect of the proposal that distracts valuable resources of the government and the industry from this goal should be modified and/or eliminated.

Therefore, the FPAA strongly opposes the proposed prior notice requirement of noon the day before product is to be physically entered into the United States. As well, the FPAA strongly opposes the creation of a duplicative data submission to unlinked databases held separately by the Food and Drug Administration and the Department of Homeland Security (DHS). The proposed prior notice rule as written will, in fact, significantly **increase** the risk of intentional contamination, significantly limit the supply of fresh fruits and vegetables for U.S. consumers, reduce the safety of the food supply, and potentially be in conflict with U.S. international trade obligations. The FPAA proposes that the prior notice rule should be that the FDA has the information required by the statute before the product can be

02N-0278

C52

released for physical entry into the United States beyond the designated Customs and Border Protection facilities, but not that the FDA should receive the information being proposed by noon the day before product arrives at the border.

Requiring prior notice by noon the day before physical entry will significantly impact and delay at least 80 percent of fresh fruit and vegetable imports from Mexico. Given that Mexico is the leading supplier of these products, there will be a significant impact on quality, availability, and safety of the fresh produce for U.S. consumers. The proposed prior notice period results in a *de facto* 18 to 32 hour prior notice window for food products using land transportation. It must be noted that most U.S. ports of entry on the U.S.-Mexico border do not open until 8 AM. Most fresh produce from Mexico is originating within a production and shipping zone that is much closer than 18 hours from the border. In addition, the most common harvesting and shipping practices for fresh produce is that product is harvested in the morning and then packed and/or cooled in packing or cooling facilities that same afternoon, with shipment to the border later that day or evening. Thus product that is ready for loading at 12:01PM that presently can be ready for inspection when FDA opens the following morning at the border will now be forced to wait another day and be subject to a 31 hour and 59 minute waiting period.

The FDA mistakenly claims that U.S. importers control all the orders for specified products and can therefore know the contents of any shipment before that shipment has even been harvested. This assumption is patently false for the majority of fresh produce from Mexico. Virtually all of fresh produce from Mexico is sent to a U.S. agent acting as a sales representative on behalf of the Mexican exporter. Direct sales to the United States are extremely limited for a variety of reasons. These include the lack of predictable crossing and delivery times to the United States resulting from delays caused by the lack of infrastructure by U.S. federal inspection agencies at the ports of entry, the difficulty of cross border enforcement of contracts, language barriers, and the increased ease and reliability of purchasing from concentrated distribution clusters that exist in places like Nogales and Rio Rico, Arizona rather than farms scattered throughout Mexico.

Thus, it is the Mexican exporter that controls what is being sent to the United States for consumption. In addition, the FDA has enforced sampling, testing, and trace back protocols that have transformed the industry practice regarding information currently being sent to the FDA. The information now transmitted is extremely detailed and absolutely unavailable until a trailer has been loaded. For example, fresh tomatoes commonly have four to six individual entry lines representing boxes containing different sizes of tomatoes on the same conveyance, even though all the products are fresh tomatoes and all are packed in the same size carton.

While the FDA proposed rule does allow for amendments under certain limited circumstances, the proposed rule creates new risk problems for the antiterrorism efforts of other agencies such as Customs & Border Protection (Customs) as well as creating an unfair burden for importers. FDA is proposing that the Customs entry identification number is included in the prior notice submission. However, the entry number is

commonly assigned when information regarding a shipment is sent to Customs.¹ Given that Customs does not permit electronic amendments on its system at this time, FDA would be forcing U.S. filers to provide inaccurate, incomplete, and false information to Customs that will require manual correction and reentry by Customs when the specific entry is ultimately made. In addition, U.S. filers would still then be forced to incur the expense of resubmitting the final and correct information to FDA. Furthermore, FDA will have significant differences in their prior notice database and their Operations and Administrative System for Import Support (OASIS) database, which will ultimately hurt FDA's ability to target and inspect merchandise that is most relevant for more intensive scrutiny, since so much staff time would be spent attempting to reconcile the databases.

Agreements between the U.S. and Mexican governments will require in the next months that the U.S. Customs entry identification number be presented to Mexican Customs before any shipment is allowed to proceed to the U.S. inspectional facility. This will mean that 100 percent of land crossings from Mexico will have electronically submitted information that is available to FDA through OASIS prior to all shipments physically arriving at the border. This also eliminates the historic practice when information regarding certain trucks was not submitted electronically in advance and used a paper entry at the time of physical entry. Customs requirements on ocean freight mean that the FDA also has all information electronically well in advance of physical arrival to the United States through OASIS. Thus, the existing OASIS system is meeting the statutory requirement for prior notice. If the FDA finds that there is a conveyance or country where it is not meeting the statutory requirements, the FPAA asserts that it will be less costly to the government and the industry to establish mechanisms for those exceptions, rather than jeopardize the safety and security of FDA regulated products.

As mentioned, the proposed rule would typically result in at least four submissions of prior notice information to Customs, the FDA, and the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS). The FPAA also asserts that the existing information currently sent to Customs, with much of it forwarded to FDA through the OASIS system, meets all statutory requirements listed in the Bioterrorism Act of 2002. Section 801(m) of the act specifically requests "the identity of each of the following: The article, the manufacturer and shipper of the article; if known within the specified period of time the notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article." Virtually all of the information in the proposed rule that exceeds what is specified in the statute is already being sent to Customs or is readily available from other existing information and can be matched to the registration databases being implemented by the FDA.

All other information not submitted to Customs is also readily available from other agencies working at the ports of entry. For instance, the U.S. Department of

¹ While it is theoretically possible to generate a Customs entry identification number without transmitting data to Customs, Customs would then be forced to subject all entries not submitted in advance to Customs to a formal inspection, which would significantly degrade Customs' ability to secure our borders.

Transportation has specific contact information for the carriers as requested in the proposed rule, even though this information is not required by the statute. If this information is truly important and relevant for the FDA and just cause can be shown to have this level of detail reproduced in an FDA database, the FPAA would support FDA's efforts to have the Facility Registration requirements amended to cover other parties such as carriers and customhouse brokers.

Of extreme concern to the FPAA is the significant increase in vulnerability of the nation's food supply to potential terrorism attacks that will result from the proposed rule. Most fresh produce commodities imported from Mexico, as well as Canada, are items that are relatively perishable, i.e., not stored for several months like apples. This means that the current infrastructure minimizes storage, with most crops sent for export immediately after they are packed and cooled. Given that, if importers wish to remain compliant with both Customs and the proposed FDA prior notification systems, the only practical solutions are to significantly increase storage and holding areas at packing sheds or to have trucks idling along the sides of the highways leading to the ports waiting for the prior notice period to expire. The construction of larger holding and storage areas at the packing house level would increase the value of those facilities as potential targets of intentional contamination, given that any particular facility would subsequently have a greater impact on more product and more consumers. Likewise, the prior notice rule would force more trucks to sit unsecured on highways leading to the borders waiting for the prior notice period to expire. Trucks in such a situation would increase the vulnerability of the product that they are carrying and facilitate potential terrorist strikes. Any increase in time when the product is not in motion towards the border significantly increases the statistical probability of an attack.²

Based on comments made by the FDA regarding limitations to the existing Customs data system, the FPAA believes that it is completely unreasonable to assume that FDA can notify Customs electronically if a shipment complied with the proposed prior notification requirements. This means that every truck that approaches a land port of entry and presents their documentation will be forced to enter the secondary inspection areas if they are an FDA regulated product. This destroys Customs ability to limit unnecessary activity in inspection areas, limits the ability to target higher risk shipments, and overwhelms the physical infrastructure at most high traffic land ports-of-entry with Mexico and Canada. The only alternative would be to have local FDA authorities stamp entry documents for those conveyances the FDA does not wish to inspect and then pass that back to truck drivers. However, this would alert any terrorists if FDA would be reviewing the shipment and allow them to transfer intentionally contaminated goods to other shipments. The notification system as proposed clearly defeats the intent of Congress and the President to prevent and minimize terrorism attacks. In fact, as

² The FPAA does not wish to create a blueprint for terrorist attacks by detailing additional vulnerabilities created by the delays in the supply chain that would result from the proposed FDA rule. The FPAA suggests that FDA contact the Department of Defense and the Department of Energy, both of which have conducted extensive analysis and research in minimizing the vulnerability of shipping sensitive materials that may be the target of criminal or terrorist groups.

proposed, the prior notification rule weakens the present ability of the FDA to limit the effects of terrorism on the U.S. food supply.

In addition, the FPAA believes that the FDA analysis of the benefits to the U.S. economy resulting from the proposed rule is seriously flawed. Apart from the decrease in food security that will result from the proposed rule, the proposed rule will significantly increase the cost to the U.S. economy in terms of increased food borne illnesses, higher costs to the industry, and increased diet related illnesses.

While growers in all parts of the world that supply the U.S. market make significant efforts to minimize the likelihood of food borne contamination from common pathogens such as *Salmonella*, there still exists the possibility of unintentional contamination that results in food borne illnesses. By delaying shipments from the time of harvest to the time of importation, and ultimate consumption, the FDA will allow what were previously low levels of bacterial contamination to significantly multiply. This increase in bacterial loads of potential infectious organisms will then reach concentration levels high enough to provoke food borne illnesses. If we take a very low estimate that this exponential increase in the number of bacteria results in just a 10 percent increase in *Salmonella* illnesses from the 1,412,498 reported in for 2000, the cost to the economy using the FDA's range of \$14,231 and \$25,133 per case will result in annual cost of \$19 billion to \$34 billion from just one pathogen.³ Given that the Centers for Disease Control and Prevention estimates that there are between 6 million and 81 million cases annually attributed to food sources, the costs will be much higher, even if one were to argue a smaller increase in illnesses resulting from the delays imposed on the food supply as a direct result of the proposed rule.

The FDA is significantly undervaluing the cost that will be incurred by the industry and the loss of value for fresh produce. Principal areas of faulty assumptions include the number of transmissions, the percentage of product degraded, and the wholesale and retail values of fresh produce from Mexico. The FDA has asked that each lot be separately identified and be reported as a separate and individual prior notice. Given that the majority of the industry now uses pallet tags to individually track product, there will be approximately 18 submissions per trailer, much higher than the two to three estimated by the FDA. Even if the FDA decides against having each "lot" reported separately, the number of line items per trailer has significantly increased in just the last few years. That is because FDA regional and local offices have requested that detail be provided on each size of product shipped within each trailer load. For instance, a trailer carrying nothing but round field grown tomatoes all packed in the same size carton will have 4 to 6 line entries to distinguish the various size designations of the tomatoes (small, medium, large, etc.). This would double the FDA transmission estimate for the industry to \$120 million.

³ Number of illness relating to Salmonella taken from journal article *Food-Related Illness and Death in the United States* by Paul S. Mead, Laurence Slutsker, Vance Dietz, Linda F. McCaig, Joseph S. Bresee, Craig Shapiro, Patricia M. Griffin, and Robert V. Tauxe appearing in *Emerging Infectious Diseases*, Centers for Disease Control and Prevention, Atlanta, GA, Vol. 5, No. 5.

Furthermore, differences in the maximum weight regulations and their enforcement in Mexico and the United States for over-the-road trucks and trailers mean that the exact contents of a trailer are not known until product arrives at staging areas close to the border. Given waits of several hours waiting for processing by U.S. federal agencies at many land ports of entry, trucks often have to put on additional fuel to make sure that they can cross the border. After fueling, trucks may then exceed U.S. weight limits, requiring some pallets to be removed from the trailer. In addition, at the Mariposa Cargo Port in Nogales, Arizona, which is the largest single port of entry for all fresh produce in the United States, there is no room to conduct USDA Marketing Order Inspections. This means that all fresh round tomatoes, table grapes, certain citrus fruits, onions, and other commodities are offloaded at these staging areas in Nogales, Sonora for inspection in addition to being weighed. Thus, the final contents of the truck and the exact carrier that will cross the trailer is not known by noon the day before the product is crossed, resulting in significant delays to fresh produce. Even with a generous interpretation and expansion of the types of amendments allowed, the existing requirements from other agencies will require a majority of submissions to be amended, significantly increasing the submission costs to the industry.

In addition, delays caused by 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. Given that it is necessary to submit amendments every time a trailer is outside the range allowed by the proposed rule and that there is a two-hour limit for amendments, many trucks will be forced to sit idly on the side of the road waiting for their proper window when FDA will allow entry. If there has already been the amendment for changes to the carrier and box count, then the process will have to start over again resulting in additional two day delays for product to cross the border.

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 2002.⁴ 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.⁵ Using a basis of 20 percent for fresh produce from Mexico, the retail value is actually \$12.25 billion per year. Even under the most optimistic assumptions used by the FDA of only a 1.2 percent reduction in value, the industry will lose \$37 million in value. However, this submission has noted how the FDA assumptions regarding the amount of delay and the number of loads subjected to the delay are grossly underestimated. The FPAA estimates that the average increase in delays in the supply chain would be 24 hours across all products. Using the FDA's retail value loss formula, the actual value of fresh fruits and vegetables from Mexico alone raises the industry cost to \$1.75 billion per year. This more likely scenario will result in losses just from the decline in retail value well over the \$112 million threshold for consideration as a significant rule under the Unfunded Mandates Reform Act.

Furthermore, even if retail prices did not rise, the decline in appearance and quality of the fruit will definitely result in lower fresh produce consumption by U.S. consumers. Health and Human Services Secretary Thompson has identified diet related illnesses as a major problem for the United States in terms of losses due to illness as well as the impact on increased health insurance costs. In fact, the Secretary told the United Fresh Fruit and Vegetable Washington Public Policy Conference in September of 2002 that he has even ordered his office staff to lose weight and increase their consumption of fruits and vegetables. Given that declining produce consumption will likely result in increased incidences of obesity, cancer, and other health related diseases, the FDA should not be enacting policies that damage the health of U.S. consumers.

In addition, the FPAA believes that the FDA is not correct in its interpretation of the legislation that states, "Nothing in this section may be construed as a limitation on the port of entry for an article of food." The FPAA maintains that the intent of Congress was that FDA would not be allowed to limit the ports of entry that may import food. The proposed rule, in fact, creates a disparate impact against all ports that handle air or truck shipments. In addition, the Bioterrorism Act reinforces existing FDA authority for the FDA to hold any FDA regulated product at the port of entry while waiting for an FDA inspector to conduct any physical inspection.

The FPAA also believes that in establishing and implementing the proposed rule in its current form, the FDA will not comply with the international trade obligations of the United States under the applicable World Trade Organization agreements and the North American Free Trade Agreement. The proposed rule is clearly more trade restrictive than

⁴ 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.

⁵ **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.

necessary to meet the objectives of the Bioterrorism Act. In addition, the FDA has not demonstrated the need to have a significantly more restrictive protocol for imported foods relative to domestically produced foods.

In summary, the FPAA strongly opposes the proposed rule. In particular, the proposed rule creates an excessive burden on the trade and importers with respect to the prior notification by noon the previous day, to the number of data fields requested but not required by law, and to the creation of duplicative submissions to various agencies. The FPAA asserts that the existing information currently sent to Customs, with much of it forwarded to FDA through the OASIS system meets all statutory requirements listed in the Bioterrorism Act of 2002. Section 801(m) of the act specifically requests “the identity of each of the following: The article, the manufacturer and shipper of the article; if known within the specified period of time the notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article.” Clearly that is met through existing practices and protocol. Food security and food safety would be better served by working to enhance the existing OASIS system. Agreements between the U.S. and Mexican governments will require that the U.S. Customs entry identification number be presented to Mexican Customs before any shipment is allowed to proceed to the U.S. inspectional facility. This will mean that 100 percent of land crossings with Mexico will have electronically submitted information that is available to FDA through OASIS prior to all shipments physically arriving at the border. FDA efforts should focus 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,

A handwritten signature in cursive script, appearing to read "Lee Frankel".

Lee Frankel
President
Fresh Produce Association of the Americas