

this option and each option hereafter are the costs of developing a stand-alone, web-based, electronic system to receive prior notice information and then to respond electronically with an acknowledgement of the transmission to the submitting party. The stand-alone prior notice system will be used until U.S. Customs new automated system, ACE, becomes operational. FDA will coordinate with U.S. Customs to develop ACE to accommodate the information required by prior notice. Once ACE is operational, it will simplify prior notice transmissions. For now, building a stand-alone IT system to handle prior notice submissions will require design, development, implementation, maintenance, modernization, and upgrades. These costs include the labor hours, hardware, and software costs needed to make the prior notice system operational. Table 4 shows that FDA estimates the costs to the agency for setting up the prior notice system to be about \$4.4 million. This total cost includes FDA personnel, contractor development of the hardware and software needed, industry outreach and training, and a computer firewall.

TABLE 4.—FDA PRIOR NOTICE SYSTEMS COSTS

Hardware	\$500,000
Analysis, Design, Implementation	\$3,000,000
Software licenses and Security	\$500,000
Network Interface	\$200,000
FTEs	2
Cost per FTE	\$110,588
Total FTE costs	\$221,176
Total Systems Cost	\$4,421,176

Current operating practices affected: A 4-hour minimum prior notice requirement would be less likely to change current food importing practices than would a longer minimum time requirement for prior notice submission. Some comments received indicated that it would be preferable if the minimum prior notice time were set at 4 hours or less. Comments requested the shorter minimum prior notice time because the source of some food products often is close to the U.S. border, and some products are perishable. However, it is the U.S. importer or U.S. purchaser or their U.S. agent who is responsible for submitting the prior notice, and the information required in prior notice should be sufficiently fixed after the

order is placed and will not depend on the location of the source of the food product.

How many business practices will be affected by prior notice requirements largely depends on how early the orders for the food products are placed compared to the time by which prior notice must be submitted. Most orders for products, even for those of a perishable nature, are often placed days or weeks if not months before the actual delivery date. Therefore, if the order for the product was sent a week, or even 1 day, before the delivery date, a minimum prior notice time of 4 hours should not cause any delay in the order. FDA requests comments on this assumption.

Also important in determining how business practices will be affected by the prior notice requirements is when the prior notice was submitted compared with when the shipment corresponding to that prior notice was loaded onto a vehicle. For example, if the prior notice was submitted as soon as the order was received, or even a few hours before loading the vehicle, there is a possibility that unforeseen factors, including composition of the actual shipment, may cause the prior notice information submitted to not match the actual shipment on the vehicle. However, if the prior notice is not submitted until the vehicle is actually loaded, the probability of submitting an incomplete prior notice is greatly reduced. Thus, when the order for the shipment is received, when the prior notice is submitted, and when the vehicle is loaded play large roles in how much the requirement for prior notice will affect operating practices for those importing some perishable products from Mexico and Canada. FDA requests specific information about how business practices for all operations could change as a result of the prior notice requirement.

If importers have orders for perishable products from Canada and Mexico filled more than 4 hours before scheduled arrival at a U.S. border point, then the only change in business practice that should occur is when they will submit their prior notice to FDA.

There will be those shipments by vehicle, however, for which the order was not received in advance of the shipping time, those shipments for which the quantity and composition of the product has changed since the time when the prior notice was submitted, and those shipments for which other changes to the information on the prior notice must be made. Importers, whose shipments fall into this "changed" category, must resubmit the prior notice

or risk that their products will be refused admission into the United States and held if the notice is deemed inadequate.

FDA does not have information on the number of ground shipments that, under this option, would need to submit or resubmit prior notice information due to a late order or a change in the information provided on the original notice. We know that changes will occur for some percentage of all prior notices; until better information is available, we will assume that 20 percent of the fresh produce and seafood being imported to the United States from Canada and Mexico would have a reason for which their original prior notice submission must be changed and resubmitted less than 4 hours before entry.

FDA chooses 20 percent as the percent of prior notices that need to be submitted based on information that most orders for products are placed well in advance of the actual shipping date, most orders are filled with the exact product and quantity the customer requests, and the 4 hour prior notice entry time is minimal when compared to when the order was actually received. Depending on the entry point, 40 to 100 percent of shipments are loaded onto vehicles less than 4 hours before entry. We chose one-half of the lower percent as the percent of prior notices that would need to be resubmitted under this option.

The following paragraphs and tables outline how FDA calculated a loss in product value to account for the time that fresh produce and seafood being brought by ground transportation into the United States might have to wait to cross the border due to prior notice resubmission. This wait at the border occurs if prior notice is resubmitted with revised information regarding the shipment when the shipment is closer to the border than the 4 hours required; the transporter of the shipment must wait for the minimum prior notice time to elapse before crossing the border or risk being refused entry.

Table 5 of this document shows the volume of fresh, perishable produce imported into the United States from Mexico for the calendar year 2001 (Ref. 4). Produce was included in the count if it was considered 'highly or very highly perishable' (Ref. 5) and if the produce was not regulated under section 8e of the Agricultural Marketing Agreement Act of 1937 (AMAA). Importers of products currently regulated by the Agricultural Marketing Agreement Act, e.g., tomatoes, avocados, oranges, are required to notify USDA at least 1 day prior to U.S. entry to make arrangements for inspection