

for lost value of products). We address all comments relevant to the economic analysis in detail as each issue appears in the analysis.

1. Need for Regulation

Section 307 of the Bioterrorism Act of 2002 requires prior notice of all food imported or offered for import into the United States. If FDA fails to issue a final regulation by December 12, 2003, section 307 of the Bioterrorism Act provides for a default minimum period of advance notice that is not fewer than 8 hours and not more than 5 days before an article of food is imported or offered for import into the United States. This regulation is needed to implement the statutory provisions.

2. Interim Final Rule Coverage

Unless excluded, this interim final rule applies to all FDA-regulated food for human and animal consumption that is imported or offered for import into the United States. This includes food that is imported for export, food transshipped through the United States to another country, and food for use in an FTZ. This interim final rule does not apply to food that is imported then exported from the port of arrival without leaving the port; meat, poultry, or egg products that are under the exclusive jurisdiction of USDA; food carried by or otherwise accompanying an individual when entering the United States for personal use. For the purpose of this rule, the definition of food does not include food contact substances (including food packaging), pesticide chemicals, or pesticide chemical residues.

As required by the Bioterrorism Act, the notification must provide the identity of the article, manufacturer, shipper, and grower (if known), the FDA Country of Production, the country from which the article is shipped, and the anticipated port of arrival. In addition, the notification must provide the identity of the person who submits and transmits the prior notice, the importer, the owner, the consignee, the carrier, the CBP entry identifier, anticipated time and date of arrival, anticipated shipment information, and, if the food has been refused admission and required to be held, the location where it is held.

For food shipments arriving in the United States through international mail, notification of the import must be sent before the article is mailed. Only the prior notice information that is relevant to that type of shipment must be submitted for articles of food arriving by international mail. Notification of mail entries will be received only

through the FDA PN System Interface. For food carried by or otherwise accompanying an individual when entering the United States that is not for personal use, such as food for sale that is brought into the United States in baggage, prior notice must be submitted through the FDA PN System Interface.

a. *Number of establishments affected.* Using 2001 fiscal year information from OASIS (industry codes 02 through 52, 54, and 70 through 72), FDA has estimated that there are 77,427 importers and consignees who receive imported food shipments. Commenters were concerned that this importer number represented only importers of edible food products, and not such items as food packaging. These commenters concluded that FDA's estimate was too low. OASIS does include all importers of food, for both humans and animals, and food-related items and therefore does not underestimate the number of food importers. Also, because food contact substances, including food packaging, are excluded from interim final rule coverage, our estimate of importers should sufficiently account for food importers that might not have been formally captured by the OASIS data.

Comments also indicated that they wanted an expansion of the persons allowed to submit prior notice. The proposed rule had restricted the submission of prior notice to U.S. importers or U.S. purchasers (or their brokers). For the interim final rule, FDA has authorized the submission of prior notice by any person.

Using information from the OASIS system, FDA has determined that there are approximately 100,000 foreign manufacturers/processors of an article of food. We assume here that foreign manufacturer/processor costs associated with this interim final rule will be spread across the supply chain; we therefore do not directly address the distribution of costs. We think it probable, however, that most of the ongoing costs of this interim final rule will be borne by consumers in the form of higher retail food prices.

i. *New and closing importer establishments.* In addition to the U.S. importers currently operating, in future years some new import businesses will open and some existing import businesses will close. According to the Small Business Administration, in 2001 about 10 percent of all businesses were new and 10 percent of all businesses closed. These new importers will have to become familiar with the FDA prior notice system, and some may need to obtain computer equipment and Internet

access to comply with prior notice requirements.

ii. *Baseline.* FDA considers the baseline for this analysis the state of the world before the Bioterrorism Act, and we assume this baseline has zero costs and benefits.

b. *Current state of the world.* The majority of the information that will be required by section 307 of the Bioterrorism Act now is supplied at the time of entry by a customs broker or self-filer, and usually is submitted electronically. Although importers already must notify CBP of entries, the Bioterrorism Act requires notification to FDA before the food shipment reaches the U.S. port of arrival. This requirement will change the current practice of notifying CBP and then subsequently FDA upon arrival (and as long as 15 days past arrival based on the time the consumption entry may be filed with CBP).

OASIS showed that approximately 2.9 million food entry lines were imported via sea and air transportation in fiscal year 2002. Information on food-importing practices indicates that importers bringing food products into the United States by vessel notify CBP and FDA before their arrival. Importers using vessels as their mode of transport for products can notify CBP well in advance of the actual shipping date, but CBP will not certify the entry until 5 days before the vessel is expected to dock at a U.S. port. FDA is notified of the shipment then, through CBP, as early as 5 days before the vessel's arrival at a U.S. port.

Importers bringing food products in by airplane can notify CBP of their intent to import food into the United States no more than 24 hours before the scheduled flight departure time, but cannot certify their cargo manifests with CBP until the airplane has taken off from the airport of the exporting country ("wheels-up"). FDA is notified after "wheels up", once the import entry has been filed and certified by CBP. CBP has informed FDA that they receive flight information for 87.6 percent of the flights at the time of "wheels up."

OASIS showed that around 2.3 million entry lines of food were imported into the United States via ground transportation in fiscal year 2002. The usual practice today for food brought in by truck or train (products coming directly from Canada or Mexico) is not to notify CBP until arrival. (Filers can certify their entry data up to 24 hours before arrival, but CBP does not give a "screening response" to the entry until actual arrival.) Even though these importers likely have the orders and invoices for these products in advance,