

this proposed rule, when final, will be a major rule for the purpose of congressional review.

1. Need for Regulation

Section 307 of the Bioterrorism Act (Public Law 107-188), requires advance 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. The Reason for the Regulation

Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably be prohibitive for any single firm or third party organization.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: the need to know what imported foods are entering the United States, where they came from, and when they will arrive. FDA is proposing three regulations to address these needs so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With

the regulations in place, the agency would have the additional tools necessary to help deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

3. Proposed Rule Coverage

This proposed rule would apply to all FDA-regulated food for human and animal consumption imported or offered for import into the United States with the exception of food carried in a traveler's personal baggage for personal use. As required by the Bioterrorism Act, the notification must provide the identity of the article, the identity of importer, manufacturer, shipper, and grower (if known), the originating country, the country from which the article was shipped, and the anticipated port of entry. In addition, the notification must provide the identity of the person who submits the prior notice, the owner, the consignee, the carrier, the U.S. Customs entry number, anticipated time and date of arrival, and, if the food has already been refused admission and required to be held, the location where it is held.

A growing percentage of food consumed in the United States is imported; the value of food imports is now close to \$50 billion per year. (Ref. 2) In the aftermath of the terrorist attacks on the United States on September 11, 2001, Congress determined that the existing requirements for the importation of FDA-regulated food products were insufficient to protect the safety of the U.S. food supply.

Before September 11, 2001, FDA had approximately 150 personnel in the field processing imported food entries based on FDA's programs and assignments, all using guidance documents, such as Import Alerts, Compliance Policy guides, and other manuals. After September 11, 2001, FDA hired three hundred additional counterterrorism Consumer Safety Officers primarily for food imports. This step alone is insufficient to ensure the safety of food imported or offered for import into the United States.

When deciding which imported food shipments to physically inspect and sample, FDA inspectors consider, among other things, compliance programs, assignments, import alerts, and whether the product is a low-risk or high-risk food. New requirements imposed by Section 307 of the Bioterrorism Act will require importers to give notice to FDA of incoming articles of food before the shipment reaches a U.S. border, rather than when the shipment arrives at the U.S. border

or as part of the official U.S. Customs entry. Requiring prior notice of imported food shipments will allow FDA inspectors to have earlier information on foods that are coming into the United States, which will enable FDA to better deploy its inspection resources and to use this increased amount of information in cases where FDA action against the food is warranted, e.g., a credible threat to the food supply is suspected.

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive imported food shipments. Under the proposed rule, the U.S. importers or U.S. purchasers (or their agents) of the products will be responsible for submitting a timely and accurate prior notice to FDA. Using information from the OASIS system, FDA was also able to determine that there are approximately 100,000 foreign manufacturers (of a finished product). Foreign manufacturers are not responsible for submitting prior notice, and therefore, while not unaffected by prior notice, foreign manufacturer costs associated with this proposed rule will be assumed to be spread across the supply chain and therefore are not directly addressed in this analysis.

FDA requests information on the size of establishments likely to be affected by this rule, including the foreign manufacturers of food products and the importers and consignees receiving the imported food shipments.

New and closing importer establishments

In addition to the U.S. importers currently in existence, in future years some new import businesses will open and some existing import businesses will close. According to the Small Business Administration Office of Advocacy, in 2001 about 10 percent of all businesses were new and 10 percent of all businesses closed. These new importers would 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.

Baseline

FDA considers the baseline for this analysis the current state of the world, pre-statute, and we assume this baseline has zero costs and benefits.