

### Current State of The World

The majority of the information that will be required by section 307 of the Bioterrorism Act now is currently supplied at the time of entry by a U.S. Customs broker or self-filer, and usually is submitted electronically. Although importers already must notify U.S. Customs of entries, the Bioterrorism Act requires notification to FDA prior to the food shipment reaching the U.S. border or point of crossing. This requirement will change the current practice of notifying U.S. Customs 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 U.S. Customs) at a U.S. port of entry.

FDA's OASIS reporting system shows that approximately 2.5 million food entry lines were imported via sea and air transportation in FY 2001. Information on food-importing practices indicates that U.S. Customs and FDA are notified of imported food products traveling to the United States by vessel before the products' arrival. Vessels can notify U.S. Customs months before the actual shipping date, but U.S. Customs will not certify the entry until 5 days before the ship is expected to dock at a U.S. port. FDA is notified of the shipment then, through U.S. Customs, as early as 5 days before the vessel's arrival at a U.S. port.

Importers bringing food products in by airplane can notify U.S. Customs 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 U.S. Customs until the plane has taken off from the airport of the exporting country ("wheels-up"). FDA is then notified through U.S. Customs of the plane's scheduled arrival. U.S. Customs has informed FDA that they receive flight information for 87.6 percent of the flights at time of "wheels up."

FDA's OASIS reporting system shows that around 2.2 million entry lines of food were imported into the United States via ground transportation in FY 2001. The usual practice today for food brought in by truck or train (mainly products coming directly from Canada or Mexico) is not to notify U.S. Customs and FDA until their actual arrival at a U.S. border or point of entry. (Filers can certify their entry data up to 24 hours before arrival at the border, but U.S. Customs does not give a "screening response" to the entry until actual arrival.) Even though these importers most likely have the invoices and orders for these products in advance, they do

not currently notify U.S. Customs and FDA until their arrival at the border.

### 4. Regulatory Options Considered

We analyzed five options for a prior notice regulation:

1. Current state of the world, pre-statute (baseline).

2. Prior notice time of 4 hours or less; electronic submission of information. This option would require the persons responsible for all food imported or offered for import into the United States to notify FDA of their intent to import articles of food through a United States based-importer or purchaser (or their U.S.-based agent). This option applies to all imported foods, except for food exclusively regulated by USDA and food imported with personal baggage for personal use, regardless of entry type or mode of transportation used for import. Submission of prior notice information (including addresses of all importers, owners, manufacturers, consignees, identity and quantity of food, originating country, country of shipping, date, expected time of arrival, expected port of entry, and grower if known) must be electronic.

3. Require all components of option 2, but lengthen the minimum prior notice time to 8 hours (statutory self-executing provision).

4. Require all components of option 2, but lengthen the prior notice time to noon of the calendar day prior to crossing the U.S. border.

5. Require all components of option 4, but allow some prior notice information to be revised prior to arrival at a U.S. port (proposed option).

*Option one: Current state of the world, pre-statute.*

Having no prior notice requirements is option 1 in our analysis. The statute requires that FDA issue prior notice regulations, so this is not a legally viable option. However, OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. This option will serve as the baseline against which other options will be measured for assessing costs and benefits.

*Option two: Minimum prior notice timeframe of 4 hours or less; electronic submission of information; any change in information requires resubmission.*

**Costs:** The party responsible for transmitting prior notice to FDA will incur administrative and notification

costs to comply with this proposed regulation. The responsible party likely will become aware of the prior notice requirement through normal business activities: reading the trade press, reading industry news, FDA outreach, trade outreach, or conversation with other business operators who also must comply with prior notice. Once the U.S. importer or U.S. purchaser of the food becomes aware of the regulation, he or she will need to learn the requirements of the regulation, which will require finding a copy of the prior notice requirements and reading and understanding them.

To become familiar with the requirements for this rule, FDA estimates that it initially will take responsible parties with Internet access about 1 hour to research the prior notice requirements, and responsible parties without readily available Internet access about 2 hours to research the requirements. Comments from both the Produce Marketing Association (PMA) and the National Food Processors Association (NFPA) indicate that about 96 percent of the industry has readily available Internet access.

FDA used wage rates from the Bureau of Labor Statistics National Compensation Survey (Ref. 3), doubled to include overhead costs, to estimate the cost of the time to research the prior notice requirement. For an administrative worker, the cost per hour is \$25.10; for a manager, \$56.74. FDA assumes that only the administrative worker's time will be used to research the prior notice requirements. As shown in table 1, total costs of this research activity for firms with Internet access are \$1,865,683; for firms without Internet access, the total research costs are \$155,469.

Given the 10 percent turnover in business reported by the Small Business Administration, FDA expects 10 percent of the total search costs to be incurred in each subsequent year after prior notice is in effect as new firms enter the industry. This cost and the present value of this cost, using a 7 percent discount rate, are also shown in table 1.

TABLE 1.—COST TO RESEARCH PRIOR NOTICE

Cost to Research Prior Notice	With Internet Access	No Internet Access
Number of Firms	74,330	3,097
Administrative wage rate per hour (including overhead)	\$25.10	\$25.10