

they do not currently notify CBP until the arrival of the food or thereafter.

The constraints prior notice places on those wishing to import food into the United States depend on: When the order for the product is placed, the minimum prior notice submission time, and the manufacturing/processing or other location where the product to be imported is held before importing into the United States. A longer prior notice submission time would change more business practices for food operations nearer to the U.S. border than for those farther away from the United States. For example, an 8-hour prior notice minimum timeframe will not significantly affect most food shipments imported from China, because they are likely to come by sea or by air and the length of the journey by either mode of transportation is longer than 8 hours. If the food to be imported is instead located in Mexico or Canada, and the prior notice submission timeframe is 8 hours, there is a greater likelihood that the food is located less than 8 hours driving time from the U.S. border, and transporting some shipments to the U.S. buyer of the product within a specified time would be much more difficult. Whereas there is no expectation that a product ordered from China will arrive in the United States in 8 hours, in the case of some products from Mexico or Canada, normal business practices do include the expectation of a quick or rushed delivery to a U.S. destination; this expectation may not be met for some prescribed minimum prior notice submission timeframes.

Given the standard importing business practices described in the previous paragraphs, and given the restraints that prior notice places on food importers using land transportation (and in some cases air transportation), we classify options for this analysis by minimum prior notice time based on costs for those shipments of imported food that arrive in the United States by ground and, in longer minimum submission time options, by air transportation as well. Therefore, while we include food shipments imported by vessel in the learning, coordinating, and submitting costs of each option considered, we do not calculate a lost product value or waiting time for products arriving by vessel because they are not constrained by the minimum prior notice timeframes considered in any of the options. Highly perishable food products are generally not imported to the United States by sea.

3. Regulatory Options Considered

Comments on the estimates used in the analysis of the proposed rule

indicated that FDA should reexamine the following factors: (1) The time it takes to learn about the prior notice rule; (2) the time it takes to coordinate information for prior notice submission; (3) the number of entries expected yearly; (4) the lost value for perishable products; (5) the cost of carrier waiting time; and (6) the costs to current BRASS users. These comments have led FDA to assess additional options, and revise the estimated costs for other options.

We analyzed 12 options for a prior notice regulation. Each option covers all food subject to the interim final rule that is imported to the United States; the mode of transportation for the food is specifically addressed in options where minimum prior notice time constrains importation:

Option 1. Current state of the world, pre-Bioterrorism Act (baseline).

Option 2. Prior notice time of 1 hour (constrained by shipments arriving by land modes of transport); 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 an importer, customs broker, purchaser, or other agent. This option applies to all imported foods subject to the interim final rule. Submission of prior notice information must be electronic. Any change in prior notice information requires resubmission of corrected or new information.

Option 3. Require all components of option 2, but lengthen the minimum prior notice time to 2 hours (constrained by shipments arriving by land transportation modes).

Option 4. Require all components of option 2, but lengthen the minimum prior notice time to 4 hours (constrained by shipments arriving by air and land modes of transport); electronic submission of information.

Option 5. Require all components of option 2, including a 1-hour minimum prior notice time for vehicles, but lengthen the minimum prior notice time to 4 hours for articles of food arriving by train and by air, and 8 hours for articles of food arriving by vessel; electronic submission of information.

Option 6. Require all components of option 2, but lengthen the minimum prior notice time to 2 hours for articles of food arriving by vehicle, 4 hours for articles of food arriving by train and by air, and 8 hours for articles of food arriving by vessel; electronic submission of information (interim final rule).

Option 7. Require all components of option 4, but allow some prior notice

information to be revised 1 hour before arrival at a U.S. port.

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

Option 9. Require all components of option 7, but allow some prior notice information to be revised 1 hour before arrival at a U.S. port.

Option 10. Require all components of option 2, but lengthen the prior notice time to 12 noon of the calendar day before crossing the U.S. border.

Option 11. Require all components of option 9, but allow some prior notice information to be revised 1 hour before arrival at a U.S. port.

Option 12. Require all components of option 9, but allow some prior notice information to be revised 2 hours before arrival at a U.S. port (proposed rule).

a. *Option 1: Current state of the world, pre-Bioterrorism Act.* Having no prior notice requirements is option 1 in our analysis. The Bioterrorism Act requires that FDA issue prior notice regulations or default times take effect, so this option is not legally viable. The 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.

b. *Option 2: Minimum prior notice timeframe of 1 hour; electronic submission of information; any change in information requires resubmission—i. Costs—(1) Learning costs.* The party responsible for submitting prior notice to FDA will incur administrative and notification costs to comply with this 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 conversations with other business operators who also must comply with prior notice. Once the submitter of the information 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.

In response to comments received, FDA has re-estimated the costs of learning about the prior notice regulation. Comments said that the FDA underestimated the learning costs in the