

inclusion of product categories would allow FDA to communicate quickly with only those facilities impacted by this threat.

Option 6: This option provides coverage of food production chain similar to option 2, and so would have a similar effect in aiding FDA in contacting facilities in response to a threat.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in contacting facilities in response to a threat.

iii. FDA would be more efficient in deploying its enforcement resources and better able to identify facilities affected by future FDA actions (including possible regulations).

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest beneficial effect of the options.

Option 3: Because FDA exercises less regulatory authority over facilities that operate only in intrastate commerce, and thus seldom inspects these facilities, not requiring facilities that operate only in intrastate commerce to register will have a small effect on FDA's ability to deploy enforcement resources and identify facilities that are affected by future regulations.

Option 4: FDA shares enforcement responsibilities for a number of mixed-type facilities with other Federal, State, and local agencies. Therefore, option 4 would aid FDA in its enforcement activities, though not as fully as option 2. However, FDA would be less able to identify mixed-type facilities that are affected by future regulations for outreach and other activities.

Option 5: Excluding product categories would limit FDA's ability to use the registration database to deploy its enforcement resources. Although FDA still would be aided by the registration requirements under option 5, our efforts would not be as efficient as under option 2. Information from registration makes enforcement more efficient; thus, the more information provided, the greater the increase in efficiency.

Option 6: This option provides similar coverage of the food production chain as option 2 and so will have a similar effect in aiding FDA in deploying enforcement resources and identifying facilities that are affected by future regulations.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in deploying resources as option 6.

iv. Registration, in conjunction with prior notice, would give FDA information that will aid FDA in determining which shipments to inspect.

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: FDA's ability to target imported foods would be unaffected by excluding intrastate facilities. Option 3 would be as effective as option 2.

Option 4: FDA's ability to target imported foods would be lessened slightly by excluding mixed-type facilities.

Option 5: Not including food product categories would limit FDA's ability to target specific products and country product combinations at the ports. Excluding food categories also would limit FDA's ability to evaluate as thoroughly as possible prior notifications of food imports we receive under 21 CFR part 1, subpart I. For example, if a facility registers as manufacturing/processing only canned goods and we receive a prior notice purportedly from this facility for fresh seafood, FDA would have critical information indicating that the shipment may warrant examination.

Option 6: This option provides similar coverage of the food production chain as option 2, and so would have a similar effect in aiding FDA in determining which shipments to inspect.

Option 7: Option 7 would be as effective as option 2 in aiding FDA in targeting import inspections.

V. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA is unsure whether or not this proposed rule would have a significant economic impact on a substantial number of small entities, but has analyzed various regulatory options to examine the impact on small entities. The following analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

B. Economic Effect on Small Entities

Of the 202,046 domestic entities covered by option 7, the proposed option, 99 percent are small according to the definitions of the Small Business Administration. Because such a large percentage of the domestic entities are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options. The expected burden for most small entities is low, between \$58 and \$83. However, over 200,000 entities are affected by this rule. If a small percentage of these entities incur costs significantly higher than the expected cost, then a substantial number of small entities may be significantly affected. FDA requests comment on the effect of this proposed rule on small entities.

C. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 305 of the Bioterrorism Act to allow small entities more time to register, since the Bioterrorism Act established a registration deadline that applies to all covered facilities. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the registration provision contains no such language. Thus, it appears that Congress intended for all facilities to be subject to the deadline established in the Bioterrorism Act. Nonetheless, the agency recognizes that the registration requirement may cause an economic burden to some small businesses; therefore, we are seeking comment on whether it would be consistent with section 305 of the Bioterrorism Act for the agency to set staggered compliance dates that would give small businesses more time to comply.

However, the Bioterrorism Act does have considerable flexibility for small businesses built into the statute. First, retail facilities and farms are both exempt from registration. Many of these are small entities. Second, the economic impact on small entities is lessened by allowing entities to register either electronically or by mail. Small entities that do not have reasonable access to a computer or the Internet can submit their registration by mail.