

f. *Mechanisms.* Requiring registration of manufacturers/processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways: (1) By requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain; (2) if FDA is aware of a specific food threat, then it would be able to inform the facilities potentially affected by the threat; (3) FDA would be able to deploy more efficiently its domestic compliance and regulatory resources and better able to identify facilities affected by future FDA actions (including possible regulations); and (4) FDA inspectors, using prior notice and registration, can better identify shipments for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. By creating this paper trail, persons who might intentionally contaminate the food supply and are considering starting a business in the food supply chain would be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply that refuse to register, if foreign, would risk having their product held at the port and, if foreign or domestic, would be subject to criminal sanctions.

With correct contact information and product categories, FDA can quickly contact domestic and foreign facilities that may be targeted by a specific food threat. This quick communication would allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination.

A complete list of facilities in the food supply chain would aid FDA in scheduling inspections and undertaking compliance activities. Domestically, a complete list of facilities with correct contact information would aid inspectors in contacting facilities, and with product information would aid in identifying facilities for inspections. Because of the turnover in the food industry and the ratio of inspectors to food facilities, FDA never has had a complete list of foreign or domestic facilities that provide food for consumption in the United States. Also, a complete list of facilities would aid FDA in understanding which facilities would be affected by future FDA actions (including possible regulations), which

would result in targeting communication and outreach to these facilities.

In conjunction with the prior notification requirements in 21 CFR part 1, subpart I, FDA can better identify imported food shipments for inspection at the port. The registration would identify the country of the manufacturer, which may not be the same as the country from which the product has been shipped. This information would assist FDA in identifying specific shipments to inspect, if we have information that a particular type of food or shipments from a particular country may be adulterated. Additionally, the database of registrants and products also would aid FDA in verifying that a product is correctly identified by where and by whom it was produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that shipment for verification based on the discrepancy.

Because we cannot quantify the benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we look at how effectively each of the mechanisms would operate under each of the options relative to no regulation (option one).

*i. Registration would deter persons who might intentionally contaminate the food supply from entering the food production chain.*

Option 1: No impact.

Option 2: This option is the most comprehensive in the registration requirements and thus would have the largest impact on deterring persons who might intentionally contaminate the food supply.

Option 3: If FDA does not require intrastate facilities to register, then persons who might intentionally contaminate the food supply might be more likely to choose an intrastate facility for carrying out an attack on the food supply. However, intrastate facilities are more likely to be small, and generally do not distribute product widely or in large quantities. These are all characteristics that would make intrastate facilities less attractive to a person who would intentionally contaminate the food supply. Therefore, FDA expects that excluding intrastate facilities would reduce the function of the first mechanism, but not to a great extent.

Option 4: Option four still would cover many of the same facilities as option 2.

However, if mixed-type facilities are not required to register, then these types of facilities may be more vulnerable.

However, many state and local agencies have registration requirements for mixed-type facilities. Some of these facilities would be covered under these State or local agencies. Persons who might intentionally contaminate the food supply might be more likely to choose a mixed-type facility that is not required to register for carrying out an attack on the food supply.

Option 5: This option provides the same coverage of facilities as option 2. It does not require the inclusion of food product categories on the registration form. FDA anticipates that excluding product categories, by reducing the amount of information required by the registrant, would reduce slightly this regulation's ability to deter persons who might intentionally contaminate the food supply.

Option 6: This option provides coverage of the food production chain similar to option two, and so will have a similar effect in deterring persons who might intentionally contaminate the food supply from entering the food production chain.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and so would be equally as effective in preventing persons who might intentionally contaminate the food supply from entering the food production chain.

*ii. FDA would be better able to inform facilities if they are affected by a threat.*

Option 1: No impact.

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

Option 3: Excluding intrastate facilities from registering would reduce FDA's ability to inform intrastate facilities of a specific threat. However, intrastate facilities are less likely to be the focus of a threat because of their small size and small distribution range.

Option 4: FDA's ability to inform facilities would be better than without a registration system, but excluding mixed-type facilities from registering would reduce FDA's ability to inform mixed-type facilities of a specific threat.

Option 5: FDA's ability to inform facilities would be better than without a registration system, but not including product categories on the registration form would significantly limit FDA's ability to inform facilities of threats related to specific foods. For example, if FDA receives credible information that persons who might intentionally contaminate the food supply have threatened foreign or domestic cheeses,