

probably would be prohibitive for any single firm or third party organization.

We estimate that an effective system of information would require several hundred thousand participants to gather information and provide it to a central system. The private transactions costs to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover the cost. Also, because the provision of information by some participants makes it available for all, there would be a tendency for establishments to try to be free riders in the information system. But the more information and participation in the system, the more effective it is.

Another way of looking at the problem of participation is in terms of marginal private benefits and marginal social benefits. By gathering and providing the information used in a food safety system, an individual establishment receives additional private benefits from enhancing the safety of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the more establishments participate in the system, the better it works. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

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 facilities manufacture/process, pack, or hold food for consumption in the United States, what types of food each facility handles, and how each facility can be contacted. However, as stated previously, 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 prevent and respond to threats to the nation's food supply as well as to other food safety problems.

D. Options

FDA analyzes the costs and benefits of eight regulatory options that address the goal of deterring or containing purposeful or accidental contamination of the U.S. food supply. Option 1 is the status quo and provides the baseline against which all the other options are measured. Option 2 has the most complete coverage of domestic and foreign facilities and required information in the registration. Options 3 through 5 are each less comprehensive than option 2. Options 6 and 7 use a different definition of mixed-type facilities and option 7 permits U.S. agents to register on behalf of the foreign facility they represent. Option 7 is the proposed option. Option 8 is a discussion of the costs and benefits of the Bioterrorism Act's registration provisions becoming requirements without FDA issuing a regulation (statutory default provision).

- Option 1 is to not impose any new regulatory or statutory requirements.

- Option 2 requires the registration of domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States, whether or not food from the facility enters interstate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform some activities of a farm or retail facility but that also manufacture/process food for consumption off that facility must register under this option. Foreign facilities are also required to have a U.S. agent to facilitate communication between the foreign facility and FDA.

- Option 3 has the same requirements and coverage as option 2, but excludes facilities that participate only in intrastate commerce. FDA tentatively concludes that this option is not legally viable, as the Bioterrorism Act does not seem to exempt facilities participating only in intrastate commerce.

- Option 4 has the same coverage and requirements as option 2, but excludes all mixed-type facilities, regardless of whether they also manufacture/process food for consumption off the facility or pack or hold food not grown or raised on that facility. As discussed in the following paragraphs, FDA does not believe this option is legally viable.

- Option 5 has the same requirements and coverage as option 2, but does not

require that facilities include information about the types of products they manufacture/process, pack, or hold on their registration.

- Option 6 has the same requirements and coverage as option 2, but mixed-type facilities are required to register if they pack or hold food not harvested on that facility or manufacture/process food not for consumption on that facility. However, facilities that manufacture/process food are exempted as retail facilities if they sell the food directly to consumers from that facility.

- Option 7, the proposed option, requires the same coverage of facilities as option 6. Under this option, the U.S. agent can register on behalf of the foreign facility.

- Option 8 is to allow the registration requirement of the Bioterrorism Act to be implemented without issuing a regulation. The Bioterrorism Act requires facilities to register by December 12, 2003, regardless of whether FDA issues a regulation. Due to uncertainty about how this option would be implemented, FDA does not attempt to estimate costs or benefits for this option.

1. Option One: Do Not Require Facilities to Register

Option one is to maintain the status quo, i.e., no statutory or regulatory registration requirement. This option will serve as the baseline against which other options will be measured for assessing costs and benefits. OMB's cost-benefit analysis guidelines recommend discussing 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.

The Bioterrorism Act requires that FDA implement through regulation registration for food facilities; therefore, this is not a legally viable option.

2. Option Two: Comprehensive Registration of Domestic and Foreign Manufacturers/Processors, Packers, and Holders of Food

Option two requires domestic facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA, including facilities engaged in interstate and intrastate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform activities of a farm or retail facility but