

animals. The benefits of these proposed regulations would be realized by accomplishing this purpose.

*Reason for the regulations:* FDA is proposing several regulations that will work in harmony to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant—particularly if the plant is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of food-borne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The most important external effect of protection against deliberate contamination is information. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably 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 transaction 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 system works better the more establishments participate in it. 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 an integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to keep product and ingredient distribution records. However, as stated above, FDA is proposing several 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 deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

*Baseline:* FDA considers the baseline for this analysis the current state of the world, and we assume this baseline has zero costs and benefits. We also consider having no new recordkeeping

requirements as option 1 in our analysis. Section 414(b) of the act, as added by section 306(a) of the Bioterrorism Act, provides that the Secretary “may” by regulation establish recordkeeping requirements. Section 306(d) of the Bioterrorism Act, however, provides that the Secretary “shall” issue proposed and final regulations no later than 18 months from the date of enactment. FDA believes that Congress has directed the agency to exercise the authority in section 414(b) of the act, so the current state of the world as considered in option 1 is not legally viable. The agency recognizes, however, that the use of the term “may” in one section of the statute and “shall” in another section creates an ambiguity. We request comments on our interpretation that we are required by section 306(d) of the Bioterrorism Act to exercise the authority in section 414(b) of the act. However, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity costs of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Option 1 will serve as the baseline against which other options will be measured for assessing costs and benefits.

*Options:* The following section analyzes regulatory options that address the need for the recordkeeping regulation:

1. No recordkeeping requirements. Take no new regulatory action.
2. Require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import food destined for consumption or use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of the food, and its outer packaging. Also require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging destined for use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of that outer food packaging. The records requirements apply to both foreign and domestic persons. For domestic persons, this includes those who engage in the specified food-related activity whether or not those activities occur solely intrastate. Persons engaging in more than one type of activity, some of which is covered by this proposed