

Evaluating the benefits by option using two mechanisms: (1) Complete records (which increase the probability of a thorough trace-back investigation), and (2) faster records access times (which may allow for more rapid identification of the source of an outbreak and limit its effects).

*Option 1, no action:* No impact.

*Option 2, comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products:* This option contains no exemptions, so it has the largest coverage of any of the options we consider and ranks high with regard to improving the ability to perform a thorough trace-back investigation. However, option 13 requires even greater additional record information collection, which would aid in trace-back investigations. So, based on mechanism 1, this option has the second highest benefits. With regard to the speed criterion—this option also has the quickest response time specified in any of the options. It is ranked second in overall benefits behind option 13.

*Option 3, same as option 2 except outer-packaging manufacturers and distributors are excluded:* The exclusion of outer food packagers from recordkeeping requirements reduces the coverage and the potential to perform a thorough trace-back investigation compared with option 2. It is also unclear what the relative risk of outer food packaging is compared with the risk of the food itself (including food contact substances), but FDA assumes that the potential harm through packaging adulteration, although serious, is lower than the potential harm through adulteration of food. This would tend to mitigate the consequences on potential trace-back capability from excluding these facilities. This option also scores relatively well if rated by the speed criterion since the records-access time is the same as in option 2. The exclusion of outer packaging manufacturers and distributors will not reduce benefits by much compared with option 2—especially because the risk of contamination through outer packaging is likely to be small.

*Option 4, same as option 3 except recordkeeping on outer-packaging is excluded:* The reduction in benefits from not requiring recordkeeping on outer food packaging is assumed to be negligible compared with option 3. Therefore, the benefits from this option are about the same as option 3 using both the complete records criterion and the speed criterion.

*Option 5, same as option 4 except records access requirement is relaxed to 24 hours:* This option does not differ much from option 4 by this ranking criterion, since it has the same domestic and foreign coverage and record scope requirements. However, this option scores relatively low by the speed criterion, since all other options would require a much faster response time for records access.

*Option 6, same as option 4 except intrastate facilities are excluded:* This option has lower benefits than many other options since it exempts the largest number of domestic facilities of any option. The relative ranking of options that offer exemptions will be affected by the total number of facilities exempted and the breadth of the supply chain these facilities cross. This intrastate exclusion would affect many different facility types throughout the supply chain, including approximately 91,383 domestic manufacturers, wholesalers, and warehouses. In addition, many facilities involved only in intrastate commerce handle food products that eventually will be introduced into interstate commerce farther along the supply chain. While intrastate facilities are likely to be small, if they are participants in the chain of custody of the food that causes a major outbreak, their exclusion could disrupt FDA's ability to identify the source of an outbreak and limit its effects. The overall ranking of this option is behind option 10.

*Option 7, same as option 4 except mixed-type facilities that engage in farming are excluded:* There are fewer exempted facilities in this option, owned by approximately 24,397 domestic firms, than in option 6. Furthermore, these exempt firms are mixed-type facilities that engage in farming and would be closer to the beginning of the chain of custody for food products. FDA considers this option to have lower benefits than option 5, since fewer facilities would be required to keep records that may be needed for a traceback investigation, but higher benefits than options 6 and 10–12, since fewer facilities would be exempt and especially since these facilities are closer to the beginning of the supply chain.

*Option 8, same as option 4 except there is a universal records-retention requirement of 1 year for perishables and all other products:* All other things being equal, the shorter the retention time for records, the more likely that those records would be missing when needed for a trace-back investigation. Most nonperishable products and perishable products that are processed

into finished food products may be in the supply chain for longer than a year, but it is very likely that the effects of a contamination of nonperishable goods would be seen within a year of being introduced in the market. FDA considers this option to have higher benefits than options 6 and 7, and higher benefits than the other exemptions offered in options 10–12. Option 8 is ranked lower than option 9 because of the nonzero probability that a nonperishable food is adulterated and that adulteration is not discovered until more than a year after the event.

*Option 9, same as option 4 except there is a universal records-retention requirement of 2 years for perishables and all other products:* Once again, all other things being equal, the longer the record retention the better, so this option probably has more benefits than option 2. While option 9 has the benefit of simplicity in that there is only one retention requirement for all records, in practical terms the danger from a perishable good will be known soon after that good is consumed. Consequently, keeping records longer than one year for perishable goods that are consumed in an unaltered state would most likely exceed the time period of many tracing investigations. Therefore, based on the ability to conduct a thorough investigation, FDA ranks the benefits of this option as roughly equal to option 4, especially since the longer records-retention requirement should not affect the speed of an investigation.

*Option 10, same as option 4 except that foreign coverage is the same as for the registration proposed rule:* The proposed option would generate more benefits than other options that exempt foreign facilities. Since the foreign coverage is progressively lower for options 10, 11, and 12, the benefits also decrease for those options accordingly. However, the benefit from improved recordkeeping practices by a given set of facilities also depends on the amount of food produced by those facilities. Because imported food accounts for a small percentage of total domestic food consumption, the average amount of domestically consumed food from foreign facilities is smaller than that from domestic facilities. Under this option, the reduction in the number of foreign facilities that are covered is proportionally greater than the reduction in the amount of food covered. As a result, the incremental reduction in potential costs caused by the exemption of foreign facilities should be larger than the incremental reduction in benefits. The exemption of foreign facilities under this option