However, most food products and ingredients pass through at least one small business during commerce. In addition, more than 80 percent of the covered entities are considered very small businesses. If FDA were to exempt small businesses from these regulations, permit shorter record retention periods, or subject them to reduced records requirements, FDA's tracing investigations would be severely compromised. Given the foregoing, FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

(Comment 175) A few comments point out that the burden for maintaining records is proportionately similar for large transporter companies and small independent transporters. Therefore, according to the comments, the relative regulatory burden for small, independent transporters is no greater than for large companies. The comments contend that all carriers, regardless of the size of the company, should be required to comply with the same requirements on the same timetable.

(Response) As stated previously, the Bioterrorism Act specifically states that, in issuing these regulations, the Secretary shall take the size of a business into account. FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

IV. Analysis of Economic Impacts—Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866

classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

This final regulatory impact analysis reflects changes made in the regulation from the proposed rule to the final rule, as well as changes in estimates in response to comments. It also includes responses to comments on the preliminary regulatory impact analysis (PRIA) (see 68 FR 25188). Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA for a fuller explanation of the estimates over which there were no significant comments or changes. As noted in the previous section of this preamble, FDA received 212 submissions in response to the proposed rule, which raised over 200 issues. We continue with the discussion of the comments and FDA's responses to those comments using the same presentation as in section III of this document, focusing here on the comments FDA received on the PRIA. Accordingly, the word "Comment" again will appear in parenthesis before the description of the comment, and the word "Response" will appear in parenthesis before FDA's response.

A. Summary of the Costs and Benefits of the Final Rule

We revised the estimated costs of the final rule in response to comments on the proposed rule and to account for the changes between the proposed and final rules. The final rule will cover more than 1 million entities at a cost

of approximately $1.41 billion in present value with a 7-percent discount rate. With a discount rate of 3 percent, the estimated present value of the costs is approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the rule beginning in the second year for large and small firms, and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The total cost estimate can be computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 1 of this document. The recurring annual costs of the final rule (the sum of additional records maintenance and learning for new firms) are about $123 million. The annualized costs of this final rule are $108,000 using a 3-percent discount rate and $110,000 using a 7-percent discount rate.

TABLE 1.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,200
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.
[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during foodborne outbreaks by reducing the time required for preventive action. Furthermore, the final rule will eliminate the recurrence of outbreaks that may have been prevented had poor records quality not resulted in

prematurely terminating the initial traceback investigation. The number of illnesses prevented (excluded those associated with food security will be approximately 1,204. The food safety benefits reported in the table are the values of averted illnesses from increased food safety. Averted illnesses are valued by low, middle, and high cost of illness estimates for both $5 million and $6.5 million values of a statistical life. The estimated annual benefits from enhanced food safety range from $7 million to $25 million. These estimates should be interpreted as the minimum benefits from this final rule because they do not include the benefits from enhanced food security.

TABLE 2.—VALUE OF AVERTED ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

B. Description of Proposed Rule

The proposed rule required the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States and also by certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The proposed regulations would implement section 306 of the Bioterrorism Act. FDA expected that the requirements the agency proposed would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

C. General Comments

(Comment 176) FDA received a number of comments that asserted that the costs of the proposed rule were incorrectly estimated.

(Response) If the comment asserted costs or benefits were incorrectly estimated without specifying which costs or benefits, there was not sufficient information for FDA to respond. Comments that specified which costs or benefits the comments believed were incorrectly estimated are addressed in later sections of this analysis.

(Comment 177) There were several general comments that the costs that result from the rule are too high and would result in the failure of enterprises and small businesses.

(Response) In the PRIA, FDA estimated the impacts of the costs of compliance on small businesses using FDA's small business model using a cash flow metric (Ref. 1). In this analysis, we use the small business model to calculate the effects on small businesses using the difference between revenue and variable cost as the metric. A finding that firms incur costs greater than revenues as a result of this rule can be interpreted to mean that they may be driven out of business. We incorporated both the annualized value of one-time costs and the recurring costs for computing the effects of this final rule on small firms.

We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost

and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes in current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will incur negative cash flows (defined as revenues less than variable costs) as a result of this rule. The percentages of firms predicted to incur negative cash flows range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule.

D. The Tradeoff Between Costs and Risk Reduction

(Comment 178) Many comments argue that the benefits from the rule do not justify the costs to the food industry. Another comment states that it remains doubtful that the benefits from the regulation justify the costs, while another comment expressed the need for a proper model to compare the costs of the recordkeeping provisions with a measure of the risks averted from the provisions.

(Response) FDA agrees that the measure of the net benefits used to justify the regulation remains uncertain. A large portion of the uncertainty arises from FDA's inability to quantify the benefits from the regulation. In the PRIA, we used epidemiological evidence from four outbreaks to suggest qualitative results.

In the final rule, we develop a more comprehensive and detailed model to estimate the food safety benefits using information generated from FDA outbreak investigations (Ref. 2). We use this information to estimate the number of illnesses averted as improved recordkeeping practices lead to faster

traceback investigations and higher rates of successful traceback completions. These estimates understate the true expected benefits from the rule, because they are derived solely from food safety data and do not take into account the expected benefits of this rule to food security. The estimate of strictly food security benefits is based on classified data and is not used in this analysis. A qualitative description of the security benefits is provided below under section IV.E.1 of this document, entitled "Bioterrorism Considerations".

Although benefit-cost analysis is primarily a quantitative exercise, the existence of non-quantified benefits and costs, as well as uncertainty around the quantified measures, means that assessing whether costs justify benefits entails a qualitative element. Decision aids such as uncertainty analyses are used to help decision makers in these instances.

(Comment 179) There were several comments stating that the costs of compliance for specific sectors, including foreign facilities, food contact suppliers, and transportation facilities, did not justify the benefits of reducing the risks of contamination posed by those sectors.

(Response) In the final analysis that follows, we refine the analysis of the benefits of selected policy options including those expected from foreign firms, food contact substance suppliers, and transportation facilities.

(Comment 180) One comment states the need to measure benefits from the regulation against the existing traceback and recall capability of the industry. This comment questions whether the provisions in the recordkeeping rule would improve response times for removing product from the market, and potentially reduce the number of illnesses from a foodborne outbreak. The comment suggests that FDA should consider what the savings would be in anticipated response times and records recovery times, as well as how this

would translate into a reduction in illnesses and enhanced product recovery. Finally, the comment states that the burdensome exercise to produce records could actually slow and hinder the objectives of recalling a suspected product.

(Response) FDA agrees with the comment that a model is needed to determine the savings in investigation traceback times, and the numbers of illnesses that would be avoided from this regulation. FDA has developed a model of the benefits, which is described later in this section. However, FDA does not agree that the benefits should be compared to the current system for recalling products since few investigations result in recalls. Instead, FDA believes that benefits from this final rule will primarily be from faster investigations leading up to preventive actions, including recalls. A recall or other preventive action is made only after a product has been implicated. The benefits from the recordkeeping rule are to improve the accuracy and speed with which a product is implicated. If recalls or other preventive actions are made too quickly and cover too wide a range of products, there is the very real danger of a recurrence of the outbreak if the source is not investigated. For that reason, the benefits from the regulation include not only faster traceback investigation times, but also higher rates of completed traceback investigations, and the commensurate reduction in outbreak recurrences.

(Comment 181) One comment states that the analysis failed to meet Office of Management and Budget (OMB) guidelines for regulatory impact analysis by failing to do the following: (1) Adequately consider the need and consequences of the regulation and (2) show that the benefits outweigh the costs of the regulation. In addition, the comment states that the purpose of the regulation is to expand the agency's jurisdiction, rather than to maximize the net benefits to society, and that alternatives with the highest net benefits

(including the alternative not to regulate) were not chosen. Finally, the comment states that the analysis failed to consider the condition of the affected food industries, potential future regulatory actions, and the weak state of the national economy as required.

(Response) In the PRIA, we stated that the need for these regulations is to enable FDA to respond to, and help contain, food for which the agency has a reasonable belief that it is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. In the final rule we bolster the explanation of the need for the regulation by analyzing vulnerabilities due to shortfalls in current recordkeeping practices. These shortfalls are shown to inhibit current outbreak investigation efforts and, by extension, efforts to mitigate serious adverse health consequences or death to humans or animals. The perceived vulnerability of the U.S. food supply to an attack, as articulated by Congressional passage of the Bioterrorism Act, elevates the importance of addressing these shortfalls.

The analysis of the benefits of the final rule uses characteristics of conventional outbreaks and investigations to more clearly identify and quantify shortfalls in existing recordkeeping practices and how each is addressed by the recordkeeping regulation. We measure the effects in terms of the number of illnesses averted due to reductions in the duration of outbreak investigations and reductions in the number of investigations that are prematurely terminated because of poor records quality. When an investigation is prematurely terminated, there is both a loss of data that might prevent recurrences of the outbreak and a decrease in the effectiveness of any preventive action. The need for this regulation is underscored when the potentially large sizes of outbreaks from intentional attacks on the food supply are considered. Although the

probability of such an intentional attack is unknown, the size of the benefits from this regulation are larger, the larger the size of such an outbreak.

We estimate benefits using data from FDA outbreak investigations. We then compared estimated benefits for a number of regulatory options. In this way, the benefits of each regulatory option can be compared to its costs. While the costs and benefits of the policy alternative "not to regulate" are not considered in the final rule, they were analyzed in the proposed rule. We did not estimate the effects of potential future regulatory actions because we do not anticipate any such actions that would affect the estimated costs or benefits of this final rule.

In response to the comment that we have not shown that benefits exceed costs, the Executive Order requires that costs must be justified by benefits. We believe we have done so in this analysis. Finally, in the PRIA, FDA addressed the state of the national economy by examining the impact of the final rule on the most vulnerable firms in the industry, through simulations using our small business model (Ref 1.), and also in the Unfunded Mandates section by examining the impact of the rule on all consumers as well as producers in the food economy in general.

In this analysis we use the small business model to calculate the effects of the costs of this final rule on the survival of small businesses. We incorporated both the annualized one-time costs and the recurring costs for computing the effects on cash flows. We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms

in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will shut down as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

E. Estimating the Benefits

The benefits from the recordkeeping rule will be from illnesses averted due to faster traceback components of outbreak investigations, and an increased ability to complete investigations that previously would have been prematurely terminated due to poor records quality. Because of this new recordkeeping rule, a greater number of traceback investigations will be completed, and traceback investigations will take less time because of shorter records access times and better records quality.

The benefits estimated in this analysis are realized only in the event of a foodborne outbreak (intentional or unintentional) because the probability of a terrorist attack is unknown. However, the estimated costs are incurred at all times regardless of whether there is an outbreak investigation underway, as well as by all facilities, regardless of whether they are implicated in the outbreak.

1. Bioterrorism Considerations

Interviews with FDA traceback personnel indicate that traceback and source investigations involving fresh produce find that the contamination often occurs at the farm level (Ref. 2). The interviews suggest that bioterrorism scenarios envision possible intentional contaminations on the farm, in distribution, at processing, and at retail. Moreover, fresh products may be more likely targeted for intentional contamination when they are at intermediate levels of processing than when they are at the farm level.

The benefits from the recordkeeping rule are from enhanced food safety and enhanced food security. We can estimate the food safety benefits, but we cannot estimate the food security benefits, as the probability of the occurrence of a deliberate outbreak is unknown. The tangible benefits from the recordkeeping rule occur after an outbreak of food-related illness. With the records required by this rule, the agency can investigate outbreaks more quickly and will not be forced to terminate an investigation because of poor or nonexistent records. The speeding up of investigations generates benefits in some cases because the information from the records will enable the agency to take actions to reduce the size of the outbreak. Both the increased completion rate and faster investigations may reveal more sources of outbreaks and help to prevent recurrences.

The food security benefits of recordkeeping come from mitigating a terrorist attack on the food supply, and preventing unnecessary expense in the event of a hoax or a small terrorist event. While we are unable to estimate the benefits from such scenarios, we can point to investigative speed as a principal mechanism for mitigating their costs. The first benefit—mitigating the effects of an attack—is similar to the food safety benefit. Investigations will

be quicker because of better records. Investigation speed may be crucial in the early period after a terrorist attack to more quickly determine the likely scope and scale of the contamination. With quicker investigations, the government can act sooner to reduce the public health and other effects of a terrorist attack on the food supply. These benefits should be qualitatively the same as in the case of an accidental outbreak of food-related illness, but we expect them to be potentially larger for a terrorist attack on the food supply.

The second counterterrorism benefit from recordkeeping is also difficult to quantify but may be important: the ability to identify quickly a potential food security hoax. The hoax could be completely false, or it could be a small event masquerading as a large event. For example, a terrorist could contaminate a single container of some food and send out an Internet message stating that the entire national stock of that food was contaminated. If the goal is to spread terror rather than to cause mass illness, then a small attack or even an Internet announcement with no contaminated products could persuade consumers that the risk is real.

With a sufficiently plausible background story implicating a widely-consumed food, the hoax might lead to extensive protective efforts by businesses and consumers. Consumers might take costly preventive actions, such as throwing away food, stopping their consumption of the suspect food item, or visiting physicians or emergency rooms to determine if they have been exposed to some hazard. Producers and distributors might destroy inventories of the suspect food as a preventive measure. If there is widespread uncertainty about the extent of contamination, this protective behavior could easily generate high costs. If the terrorist attack on a food is a small-scale event masquerading as a national event, a full system of records will allow the

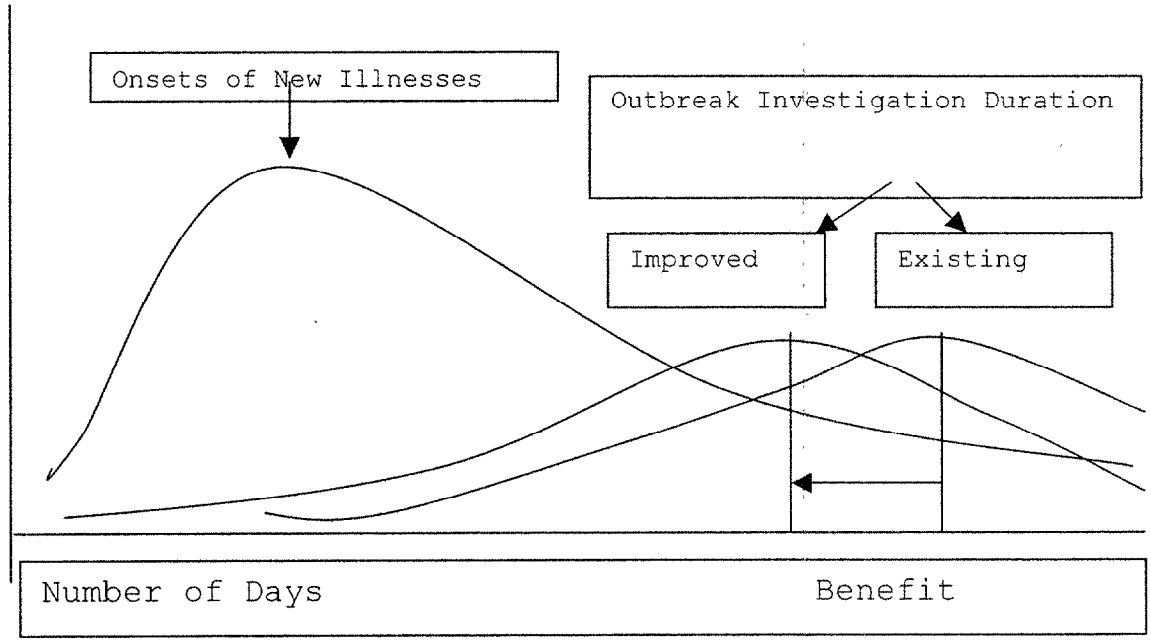
agency to trace the suspect foods through the food chain to determine the extent of contamination. The government could quickly narrow down the range of suspect foods and, if the risk is absent, reassure the public that the suspect foods are indeed free of contamination by terrorists. The ability to move quickly and authoritatively will possibly generate real benefits by preventing costly defensive actions by businesses and consumers.

2. Benefits: Model Framework

The primary food safety benefits from this rule are from the number of illnesses averted due to improved recordkeeping practices. Improved recordkeeping practices result in faster traceback investigations and higher traceback completion rates, which will reduce the expected number of illnesses from intentional and unintentional outbreaks.

The following diagram visually depicts the benefits from faster traceback times from the recordkeeping rule. The number of onsets of new illnesses and outbreak investigation duration curves overlap to estimate the number of days that an investigation is likely to reduce the duration of an outbreak. With faster traceback times, the distribution of the durations of outbreak investigations shifts to the left from "existing" to "improved," reducing even further the number of days of an outbreak. This diagram assumes the outbreak is still going on at the time the traceback investigation begins. The reduced number of days of an outbreak can then be translated into a reduced number of illnesses from an outbreak.

Figure 1: The Distributions of the Onsets of New Illnesses Over Time During an Outbreak, and the Duration of an Outbreak Investigation.



There are two ways that the recordkeeping rule speeds up traceback investigations: (1) Higher records quality means that traceback investigators spend less time trying to find and analyze information that might have been missing or incomplete had there been no rule and (2) the rule makes failure to provide records within the required time period a violation, thus increasing cooperation with investigators who need rapid access to records. Greater traceback speeds result in more recalls (if the product is still in the marketplace), administrative detentions (under section 303 of the Bioterrorism Act), import actions, closures, and other preventive actions that reduce the number of illnesses during an outbreak. The following is a description of the model used to measure the benefits from the recordkeeping rule.

i. *Given the speed of the initial recognition and epidemiological investigation of an outbreak, the benefits from the recordkeeping rule depend on the following factors*: (1) the average duration of a traceback investigation, (2) the average number of traceback investigations prematurely terminated for reasons of poor records quality, and (3) the distributions of outbreak durations and sizes.

ii. *The average duration of a traceback investigation depends on the number of point-of-service and distributor investigative visits per traceback investigation, and the average duration of an investigative visit.* The quantity of records that needs to be reviewed is an important determinant of the duration of a traceback investigation. However, we assume that the change in the quantity of records requested is much smaller than the change in the quality of the records requested as a result of this final rule. We therefore omit the quantity of records reviewed during a traceback investigation as a modeling consideration when measuring the impact of the final rule.

iii. *Because traceability information, such as lot codes, may be readily identified on the label of packaged products but is largely absent for fresh produce, the average number of investigative visits per outbreak may depend on the food category (e.g., fresh and packaged) of the contamination source.*

iv. *The average duration of an investigative visit depends on the following factors*: Average records access times, which depend in part on how records are stored and maintained; average travel times and overnight stays required to complete an investigative visit; and average records analysis times. The time required to analyze records depends on the quality of the records.

v. *The rate that traceback investigations are prematurely terminated due to poor records quality will decline as the average quality of records improves.* This improvement will reduce the number of outbreaks that result from recurring contaminations that may otherwise have been prevented.

vi. *The size, contaminating agent, and duration of an outbreak determines the number of illnesses averted from faster preventive action and higher success rates of traceback completion.* The value of the averted illnesses is the averted medical expenses, and the averted loss in welfare, including pain, suffering, and productivity that would otherwise result from the illness.

Thus, the model may be summarized as the following:

i. *Benefits are determined by*: (1) The sizes of outbreaks, and the nature of contaminating agents, which determine the baseline number and severity of illnesses potentially averted; (2) the reduced time needed to complete a traceback investigation, which reduces the number of illnesses by allowing faster preventive action; and (3) the increased rates of successful traceback completion, which reduce the number of illnesses that result from outbreak recurrences.

ii. Time to complete a traceback investigation is determined by the time needed to complete an investigative visit, and the number of investigative visits.

iii. *Time to complete an investigative visit is determined by the record access times, and the record analysis times.*

iv. *Record analysis times are determined by records quality (we ignore the quantity of records requested on the assumption that the changes in the quantity resulting from this final rule will be negligible compared with changes in the quality).*

v. *The rate of successfully completed traceback investigations is determined by the quality of the records.*

vi. *The value of the averted illnesses is computed by adding together the estimated value of averted healthy life days lost, and the averted medical expenses due to the illness.*

3. Data on Outbreak Sizes, Durations, and Contaminating Agents

Data used to estimate the numbers of illnesses, contaminating agents, and outbreak durations are taken from FDA information documenting investigations monitored by the agency from 2000-2003 (Ref. 2). The investigation information is drawn from multiple, non-standardized sources that irregularly document different aspects of investigations. The number of investigations reported in the table is not exhaustive; more investigations may be documented elsewhere. Moreover, it is possible that the information does not perfectly reflect the universe of FDA outbreak investigations because the methods for its collection and distribution are non-standardized. Nevertheless, we believe the information is sufficiently accurate, and that the list of

outbreaks is sufficiently exhaustive for purposes of estimating the benefits from the recordkeeping final rule.

The outbreak duration is calculated as the time between the first and last illness, and the sizes of the outbreaks are calculated as the numbers of known illnesses attributed to an outbreak. The charts that follow depict the sizes and durations of the outbreaks from 2000 to 2003 as estimated from FDA outbreak investigation data.

Chart 1:

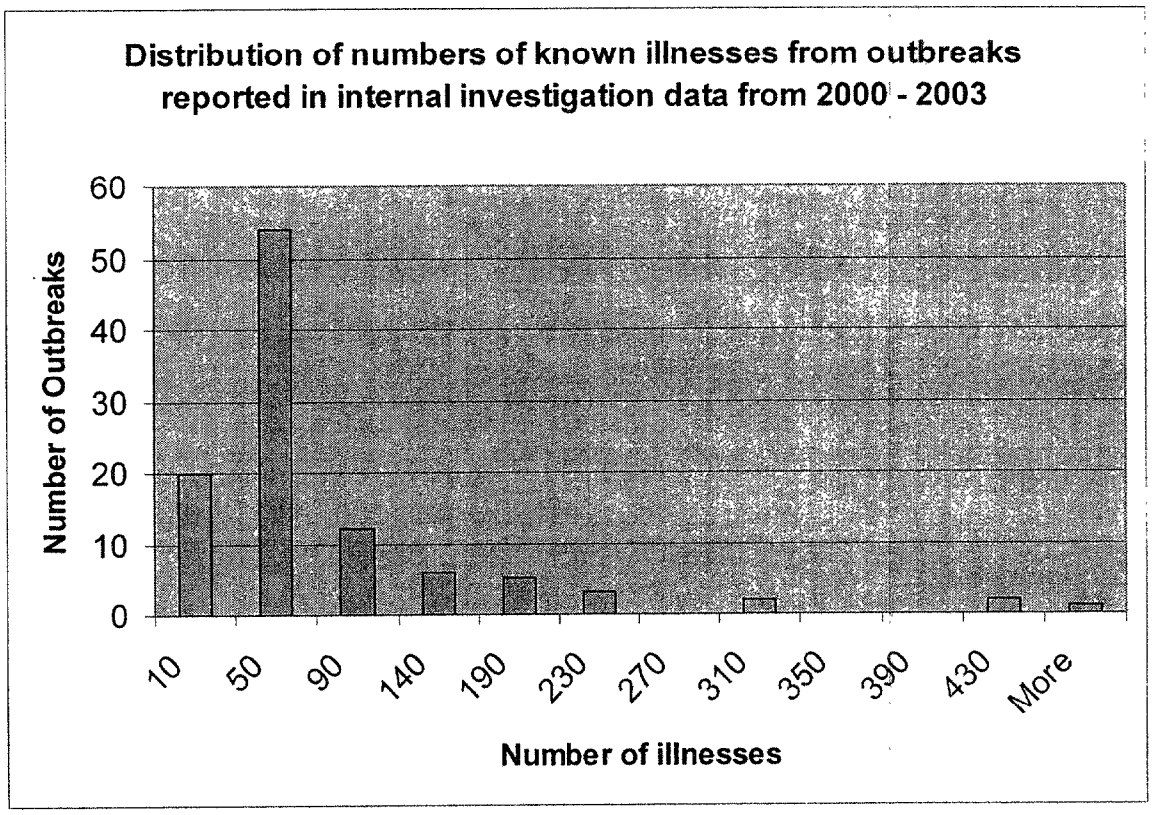
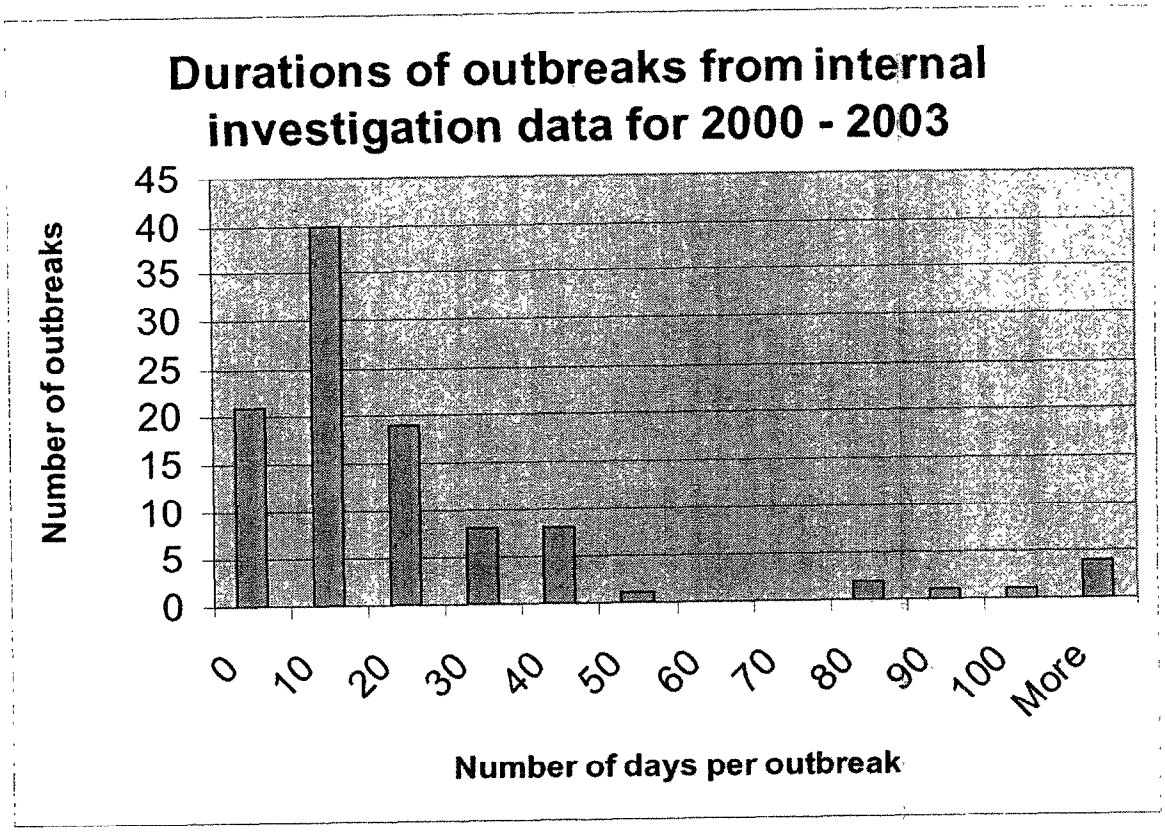
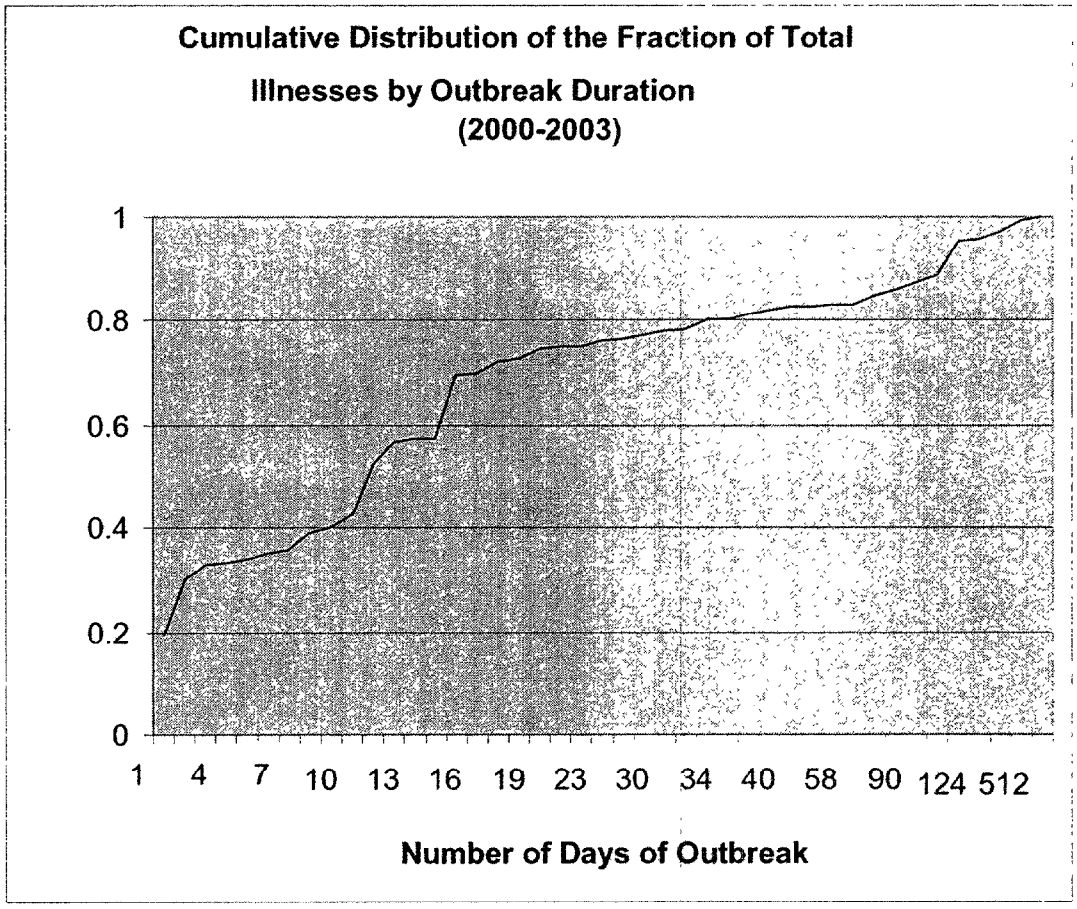

Distribution of numbers of known illnesses from outbreaks reported in internal investigation data from 2000 - 2003
Number of Outbreaks
60
50
40
30
20
10
0
10
50
90
140
190
230
270
310
350
390
430
More
Number of illnesses

Chart 2:


Durations of outbreaks from internal investigation data for 2000 - 2003
Number of outbreaks
45
40
35
30
25
20
15
10
5
0
0
10
20
30
40
50
60
70
80
90
100
More
Number of days per outbreak

The next diagram combines information from the two preceding diagrams and depicts the cumulative distribution by outbreak duration of the percent of all onsets of illnesses. The horizontal axis in the following diagram gives the number of days that outbreaks lasted, and the vertical axis gives the fraction of all illnesses that occurred during outbreaks of a given duration. The diagram shows that approximately 80 percent of illnesses were from outbreaks that lasted for 33 or fewer days, and 20 percent of all illnesses were from outbreaks that lasted more than 33 days.

Figure 2:


Cumulative Distribution of the Fraction of Total
Illnesses by Outbreak Duration
(2000-2003)
1
0.8
0.6
0.4
0.2
0
1
4
7
10
13
16
19
23
30
34
40
58
90
124
512
Number of Days of Outbreak

Estimates of the durations and magnitudes of outbreaks based on FDA outbreak investigation information may overestimate the true average outbreak magnitudes and durations. The outbreaks monitored by FDA may be the most difficult to investigate because they involve interstate commerce (so illnesses are geographically dispersed), and may sicken a greater number of people. Consequently, the duration and magnitudes of the outbreaks may be longer and more severe than the average duration and magnitude of all investigations, which includes investigations at the local level in addition to the national level. However, as indicated earlier, the estimates presented here are based on food safety considerations and may understate the benefits of this final rule when the possibility of bioterrorism (food security) is considered.

4. The Total Number of Illnesses

The following table 3 of this document reports agents, illnesses, and deaths taken from the FDA outbreak investigation information. The 129 outbreaks from approximately 21 agents resulted in reports of 8,325 illnesses, 444 hospitalizations, and 21 deaths. The data reported in the table are drawn from multiple, non-standardized, sources that irregularly document different aspects of investigations.

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Bacteria			
Campylobacter	1	20	0
E. coli 0157:H7	13	287	45
Listeria	2	51	10
Salmonella	59	4,411	253
Shigella	3	672	30
Vibrio P.	4	124	0
Chemical			
Ammonia	1	141	42
Methomyl	1	26	0
Sodium nitrite	1	5	0
Parasitic			
Cryptosporidium	1	19	0
Cyclospora	4	78	3

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003—Continued

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Toxin			
Ciguatera or Ciguatoxin	3	26	3
Histamine	3	26	7
Saxotoxin	1	17	0
Scromboid	2	14	4
Star Anise	1	20	0
Toxin	1	78	0
Viral			
Hepatitis A	4	945	18
Norovirus	18	1,246	11
Viral or Vitri	1	35	4
Unknown	5	84	14
Total	129	8,325	444

The number of illnesses reported in table 5 of this document represents only the known cases, cases that have been recorded elsewhere in the public health system. For each reported illness, there are many illnesses that are unreported, so the actual number of illnesses from outbreaks is much larger than the reported number. For example, CDC states that the ratio of total (unreported plus reported) illnesses to reported sporadic illnesses from *Salmonella* is 38 (Ref. 3).

To estimate the number of unreported illnesses from outbreaks that FDA monitors, we assume the same pathogen-specific hospitalization rates as those used in the CDC estimates for the burden of foodborne illness (Ref. 3). For example, CDC assumes a 0.295 hospitalization rate for all illnesses caused by the pathogen *E. coli* 0157:H7. Moreover, CDC assumes that about one-half of hospitalizations related to foodborne illnesses are reported or diagnosed (Ref. 3). Consequently, we estimate that there were 90 hospitalizations due the *E. coli* pathogen from outbreaks monitored by FDA 2000 to 2003 (i.e., twice the number of hospitalizations from *E. coli* 0157:H7 reported in table 3 of this document). Based on the CDC hospitalization rate for *E. coli*, we estimate that the total number of illnesses (reported and unreported) from outbreaks caused

by *E. coli* contamination is approximately 305 (i.e., 90 divided by 0.295, the hospitalization rate for illnesses caused by *E. coli* 0157:H7).

In order to characterize uncertainty in the estimates, we assumed that the total number of unreported illnesses from outbreaks for almost all pathogens would be distributed as a negative binomial with the parameters defined by the case hospitalization rates, and twice the reported number of hospitalizations. The estimated total number of illness for each agent is extrapolated from the estimated number of hospitalizations, with two exceptions: Estimates obtained of the total number of illnesses from *Listeria monocytogenes* and *Vibrio parahaemolyticus* were less than the reported total from those pathogens, so we used the reported total instead of the estimated total.

Case hospitalization rates for chemical poisoning and for other toxins are not reported in the CDC report, and (because such cases are unusual and characterized by severe acute distress) we assumed that half of such cases would be hospitalized. Finally, we assumed that the total number of illnesses from unknown agents is the same fraction of the estimated total summed over all pathogens, as the reported total summed over all pathogens. The estimated ratio of the total number of illnesses to reported illnesses was computed by dividing the estimated total by the reported total summed of all pathogens.

The average estimate of the ratio of total illnesses to reported illnesses from all pathogens, as well as the high and low estimates representing the 95 percent and 5 percent levels are reported in the following table. We estimate a total of 71,928 reported and unreported illnesses from outbreaks monitored by FDA from 2000 to 2003. This total reflects 8,325 illnesses that were reported, and approximately 63,603 that were estimated to be unreported.

TABLE 4.—ESTIMATED RATIO OF THE TOTAL NUMBER OF ILLNESSES TO REPORTED NUMBER OF ILLNESSES

Mean	Low (greater than 5% of the range)	High (greater than 95% of the range)
8.64	7 89	9.51

5. The Costs of Each Illness

We estimate the direct medical costs as well as the indirect costs of illnesses from outbreaks monitored by FDA. The direct medical costs include the costs of any doctor visits and hospitalizations that are required. Indirect costs are from the loss in productivity and quality of life as a result of the symptoms and severity of the illness. We estimate the indirect and direct costs of each illness for mild, moderate, and severe cases.

Mild cases are assumed to remain untreated with no direct medical costs. We assume that persons with moderate cases visit a physician and that those with severe cases require hospitalization. The average costs of $64 for a physician visit was obtained from the online source, Medical Economics (Ref. 4), and hospitalization costs were obtained from the Health Cost and Utility Project's (HCUP) Nationwide Inpatient Sample (Ref. 5) by type of illness.

The numbers of days that symptoms persist for each illness and severity were estimated from the FDA-Center for Food Safety and Applied Nutrition (CFSAN) Bad Bug Book (Ref. 6), CDC's National Center for Infectious Diseases, Infectious Disease Information fact sheets (Ref. 7), and from a CFSAN report entitled "Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act" (Ref. 8). These estimates were assumed to be uniformly distributed with the means reported in table 5 of this document.

TABLE 5.—DURATION OF THE ILLNESS FOR MILD, MODERATE, AND SEVERE CASES

Mild	Moderate	Severe	
Bacteria			
Campylobacter	4	8	8
E. coli 0157	3	8	18
Listeria	4	30	37
Salmonella	4	12	16
Shigella	3	11	18

TABLE 5.—DURATION OF THE ILLNESS FOR MILD, MODERATE, AND SEVERE CASES—Continued

Mild	Moderate	Severe	
Vibrio P.	2	2	3
Chemical			
Ammonia	3	5	7
Methomyl	3	5	7
Sodium nitrite	3	5	7
Parasitic			
Cryptosporidium	17	22	60
Cyclospora	17	22	60
Toxin			
Ciguatera or Ciguatoxin	2	5	19
Histamine	2	5	19
Saxotoxin	2	5	19
Scromboid	2	5	19
Star Anise	2	5	19
Toxin	2	5	19
Viral			
Hepatitis A	22	22	28
Norovirus	2	2	6
Viral or Vitrio	2	2	6

The distributions over mild, moderate, and severe cases for most of the illnesses were estimated from the CDC (Ref. 3), and a CFSAN report entitled "Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness" (Ref. 9). The case distributions over mild, moderate, and severe cases were estimated for chemical and marine toxin poisoning from a study by Brevard et al. (Ref. 10), and a study reported by CDC (Ref. 11).

The indirect costs of an illness are the loss in welfare measured as a loss in life quality or, in the extreme case, death from the illness. This loss in quality of life also includes lost worker productivity while ill. Estimates of the indirect costs will vary depending on the symptoms of the illness and their severity. We use a quality of well-being scale for a typical gastrointestinal illness to adjust the well-being of a person with mild, moderate, or severe symptoms (Ref. 12). The well-being scale assumes a value of 1 for a person in good health, and is reduced according to the symptoms and impaired mobility, reduced physical activity, and reduced social activity that result from the illness.

We compute an index of lost quality adjusted life days (QALD) by subtracting the individual's health status when ill from one and then multiplying that fraction by the number of days the illness lasts. The result represents the number of health days lost from an illness; we estimate the loss for varying severities for each illness. The QALD losses for an average foodborne illness are reported in the following table 6 of this document.

TABLE 6.—LOST QALDS DUE TO AN AVERAGE CASE OF FOODBORNE ILLNESS

Severity of Illness	Symptom	Mobility	Physical	Social	Quality Adjustment	QALDs Lost
Mild	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Moderate	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Severe	-0.29	-0.090	-0.077	-0.061	0.48	0.52

To reflect uncertainty in the literature, FDA uses a range to estimate the values of the health days lost. We use a low estimate of $100,000 for the value of a life year. This is consistent with that proposed by Garber and Phelps, who suggest a value of approximately twice the annual income (Ref. 13). U.S. Census data reports that the median family income in 2001 was approximately $51,000 (Ref. 14).

Middle and high estimates of the value of a health day are derived from estimates reported in the literature of the value of a statistical life. A value of a statistical life of $6.5 million is consistent with the findings of a literature survey of the premium for risk observed in labor markets, reported by Aldy and Viscusi (Ref. 15). We derive middle and high estimates of the value of a health day by annualizing the value of a statistical life of $6.5 million over 35 years at discount rates of 3 percent and 7 percent. These computations yield middle and high estimates for the value of an additional year of life of about $300,000 and $500,000. We estimated the range in values of a health day by dividing each of the estimates of the value of an additional year of health by 365, which yields estimates of $274, $822, and $1,370.

To calculate the indirect costs of mild, moderate, and severe cases of the illnesses, we multiplied the low, middle, and high estimates of the value of a health day by the QALD estimated for each illness and severity. Consistent with OMB's guidance on the use of multiple values for a statistical life, we used values of $5.0 million and $6.5 million to compute the value of a death from an illness.

The estimated range of the average cost of an illness resulting from outbreaks monitored by FDA from 2000 to 2003 is reported in the following table. The averages reported in table 7 of this document are weighted by the total number of reported and unreported illnesses from each agent, as well as the assumed distributions of mild, moderate, and severe cases, including deaths, from those illnesses. As explained earlier, we valued statistical deaths at $5 million and $6.5 million, and the low, medium, and high estimates assume values of a healthy year of $100,000, $300,000, and $500,000.

TABLE 7.—AVERAGE COST OF AN ILLNESS ACROSS OUTBREAKS

	Low	Medium	High
VSL = $5 million	$6,136	$13,209	$20,282
VSL = $6.5 million	$6,810	$13,883	$20,955

6. The Stages of an Outbreak Investigation

There are four stages in an outbreak investigation. The first stage is the preliminary investigation of laboratory results and epidemiological evidence used to determine the parameters of the outbreak, including the following: number ill, food vehicle contaminated, microbial or other agent responsible, potential commercial sources of contamination, as well as the degree of confidence in the information on each of these parameters. The second stage of the outbreak investigation is the decision making part, when FDA determines what resources will be committed to proceed further in the

investigation. The third stage is the traceback investigation, which is conducted to do the following: (1) Identify the source and distribution of the implicated food and remove the contaminated food from the marketplace; (2) distinguish between two or more implicated food products; and (3) determine potential routes and sources of contamination in order to prevent future illnesses, or to treat persons sooner for the identified contaminants. The traceback investigation involves investigative visits by FDA inspectors to points of service, which are the facilities where consumers had purchased the contaminated food, and also distribution facilities.

A fourth stage is the source investigation of the specific practices at the farm, transportation, or other facility that may have led to the outbreak. For many outbreaks, the source investigation occurs well after any preventive action can be taken to limit the number of illnesses. This would be true for outbreaks from contaminated foods with short shelf lives that no longer are in circulation at the time of the source investigation, or from contaminations occurring at banquets, parties, or other one-time events where the source investigation cannot limit the size of the outbreak. For these outbreaks, the improved recordkeeping practices specified in the final rule would not improve FDA's current ability to limit the size of the outbreak, or prevent additional illnesses.

However, for certain products such as eggs, sprouts, and other fresh products, additional illnesses due to conditions at the source may continue if shipments from contaminated facilities continue. The same may also be true for perishable foods imported on a frequent basis from contaminated facilities. For these kinds of outbreaks, the ability to more rapidly implicate a

contaminated farm or manufacturing source will improve FDA's ability to limit the size of the outbreak, or prevent its recurrence.

7. The Duration of Traceback Investigations, and Numbers of Premature Terminations

FDA outbreak investigation personnel estimate that a full outbreak investigation lasts at least 3 to 5 weeks, with a most likely duration of 2 to 6 months, and a maximum duration of 10 months (Ref. 2). The numbers of outbreak investigations and investigative visits come from internal interviews with investigation personnel and from other data maintained by FDA (Ref. 2).

The annual numbers of outbreaks investigated, investigative visits, and investigations that are prematurely terminated for reasons of poor records quality are reported in table 8 of this document. A traceback is defined to be prematurely terminated for records quality reasons if investigators noted in summarizing information that data quality impeded the investigation which ended before investigators were able to determine the specific cause of the outbreak. We used the simple averages over the 4 years reported in the table to estimate the annual numbers of outbreaks investigated, the annual numbers of investigative visits per outbreak investigated, and the annual rates of investigations prematurely terminated for reasons of poor records quality. We characterized the uncertainty of these estimates as normal distributions with means and standard deviations taken from the data on annual numbers of outbreaks and investigative visits per outbreak. For the annual rate of prematurely terminated investigations, we characterized the uncertainty with a beta pert distribution using the average, low and high values reported in the table 8 of this document.

TABLE 8.—OUTBREAK INVESTIGATION DATA

Year	Number of Outbreaks Investigated	Number of Investigative Visits per outbreak	Rate of records quality related premature terminations
2000	9	12	0.11
2001	9	11	0.33
2002	18	7	0.06
2003	17	6	0.00

The recordkeeping requirements of this final rule will improve the quality of records established and maintained by persons that manufacture, process, pack, transport, distribute, receive, hold, or import food. For options that provide comprehensive coverage of all food facilities, we estimate that the number of investigations prematurely terminated because of poor records would fall to zero. For options that provide less than comprehensive coverage, the reduction in premature terminations is reduced in proportion to the coverage.

Because outbreaks whose investigations are prematurely terminated may recur, the benefits from reducing that number may be high (if many people continue to become ill as a result of the recurrence). Based on FDA outbreak investigation information, the average number of reported illnesses in outbreaks that occurred between the years 2000 and 2003 was approximately 65. However, many illnesses from outbreaks go unreported, so the average total number of illnesses from an outbreak is much larger than the reported number. Using the estimated average ratio of total illnesses to reported illnesses reported earlier, we estimate that by avoiding just one outbreak recurrence, approximately 559 persons would avoid becoming ill.

Traceback durations may be different for processed food sold in packages with labels with identifying barcodes than for fresh food items sold in packages with no labels. Eggs and fresh produce account for 90 percent of all outbreaks investigated by FDA, while labeled packaged foods account for only 10 percent

(Ref. 2). To determine the likely length of time it takes to investigate a packaged food product, we use a range that includes the low end, where investigators are able to obtain the exact package that contains the identifying barcodes, and the high end that assumes the package, with the identifying barcodes, is not available. In the latter case, any subsequent recalls would likely include more foods than the implicated lot.

The final rule relaxes the proposed requirement for lot codes to be established and maintained on all records. If FDA were to require all persons, including distributors, transporters, and retailers, to include lot numbers in the records they establish and maintain under this final rule, the traceback durations for many products would be reduced and would be comparable to those currently reported for tracebacks of packaged products that contain barcode information. If all retailers and distributors were required to establish and maintain lot codes for all processed products, then the duration of the traceback component of an outbreak investigation for many products could be reduced to 1 to 14 days. Examples of reported traceback times for fresh products and for packaged products that contain lot code information in bar code format are reported in table 9 of this document.

TABLE 9.—DURATION OF THE TRACEBACK COMPONENT OF AN OUTBREAK INVESTIGATION[1]

	Most Likely	Low	High
Eggs and fresh produce	6 to 8 weeks	2 to 5 weeks	12 weeks
Packaged products	3 days	1 day	14 days

[1] Estimates reported in Ref. 2 of this document.

8. The Duration of Investigative Visits

The main delays in traceback investigations are long travel times and overnight stays, slow and poor cooperation from recordkeepers, and inconsistent and incomplete records. Many recordkeepers may not be inclined to devote sufficient labor to providing records to inspectors during business

hours because that is a costly time of day to reallocate resources. Furthermore, sometimes companies follow time-consuming procedures before approving FDA's request for records access. The legally binding provision in this rule will expedite cooperation from recordkeepers and reduce access times. When we take into account the requirement in the rule that access be provided on weekends, we estimate a substantial amount of time saved due to the records access provision—especially when there are multiple point of service or distributor visits.

The inconsistency and incompleteness with which some records are maintained are also important causes for delay in an investigative visit. Records from approximately 50 percent of access requests require additional information from the recordkeeper. Examples of information that may be incomplete include supplier contact information, a description of a product received or shipped, or date of receipt or shipment. This information is used by analysts located at headquarters, along with inventory rotation and control information, to determine precisely what was shipped, by whom, and when it was received. Often, many similar products from different suppliers are received during the course of the day by any given receiver.

Frequently, records document transactions from regular suppliers or customers where the identity of the shipper and description of the product can be determined readily based on the regularity and composition of the shipments. Sometimes, an entity will receive an unusual shipment (especially during holiday seasons), or it may receive multiple shipments of similar products from different suppliers, making it difficult to precisely link an incoming product with an outgoing shipment. Other times, descriptions of products received differ from how they are referenced on the shipping

documents, making it difficult for the analyst to link the incoming product with an outgoing shipment.

Each category of incidents may result in confusion on the part of the analyst located at central headquarters and require an additional visit by the field inspector to the recordkeeper for further clarification. Because travel times account for a significant amount of time in a traceback investigation, and an estimated 20 percent of all point of service or distributor visits require an overnight stay, we estimated that the final rule would result in substantially reduced traceback durations.

Including travel time, 1 full day is usually required to obtain records after a request. A second full day is required when the records are not available on the first day. Furthermore, although records analysis times are typically only 7 to 10 hours, approximately 50 percent of all investigative visits require a return trip to clarify inconsistencies in the records, or to obtain additional information to compensate for incomplete records. In addition to slow compliance with records access requests, the unavailability of personnel and flight schedules may necessitate an overnight stay and an extra day of travel by an FDA investigator. Approximately 20 percent of all investigative visits require an overnight stay.

The duration of each component of an investigative visit, both inclusive and exclusive of travel times, is reported in the following table. We assume a uniform distribution of between 1 and 3 days including travel times for obtaining requested records. We assume that the times for records analysis are uniformly distributed between 0.8 and 1.6 days, including travel times. The lower bound reflects the time for records analysis when documents are able to be quickly transferred to headquarters. The upper bound reflects 1 full day

of travel with 50 percent requiring an additional follow-up and 20 percent requiring an overnight stay.

TABLE 10.—DURATION OF THE COMPONENTS OF AN INVESTIGATIVE VISIT

		Including Travel Time and Overnight Stays
Obtaining requested records	4 to 48 hours	Uniformly distributed between 1 and 3 days
Records analysis	7 to 10 hours	Uniformly distributed between 0.8 to 1.6 days

We estimate the time for a traceback investigation by multiplying the duration of an average investigative visit by the number of investigative visits per traceback investigation. We estimate the duration of an investigative visit by adding the time to comply with a records access request to the time required to analyze those records. If obtaining requested records takes 1 to 3 days (i.e., 1 to 2 days to comply with the access request and 1 day of travel) and records analysis, inclusive of travel, takes between 0.8 and 1.6 days (i.e., 50 percent require return trips and 20 percent of trips require an overnight stay), the duration of an investigative visit is assumed to be uniformly distributed between 1.8 and 4.6 days (i.e., 1 to 3 days plus 0.8 to 1.6 days), with a simple average of 3.2 days.

From annual data we assume that the number of investigative visits per outbreak for the years 2000 to 2003 is normally distributed with a mean of approximately 9 visits and standard deviation of approximately 3 visits per traceback investigation. Using just the mean numbers of visits in a traceback investigation and visit durations, we estimate that the traceback component of an outbreak investigation takes approximately 29 days (the duration of an investigative visit multiplied by the number of investigative visits per outbreak).

9. Adjustments to Account for Records Requests Made on the Weekends

If there are 4 sets of weekends during the 29 day traceback time period in which records are inaccessible, then the estimated calendar duration (including weekends) of a current traceback investigation becomes much longer. To allow more accurate comparison of the time savings between current traceback times with those projected under alternative policy options requiring 4 and 8 hours, and up to 24 hours records access, we adjust the estimate of current traceback times to account for requests that would be made on weekends following issuance of this final rule. Most current records requests are made during the week, because establishments may not be open or key personnel may be absent on weekends. However, this final rule requires records access when requests are made on either weekdays or weekends. Consequently, we assume that there is a 1 in 7 chance of requesting records on a Saturday, and a 1 in 7 chance of requesting records on a Sunday if FDA were conducting a traceback investigation of a food for which it had a reasonable belief the food was adulterated and presented a serious threat of serious adverse health consequences or death to humans or animals.

A 24-hour records access requirement would improve current traceback times by allowing weekend records access requests. We assume that a records access request that would be made on a Saturday or Sunday following issuance of this final rule, would currently not be made until the following Monday. Taking this assumption into account, we estimate that the current time to satisfy a records request made on a Saturday to be 3 to 5 days (i.e., 2 days, plus 1 to 3 days), or an average of 4 days for 1/7 of all access requests (i.e., records requested on a Saturday), and 2 to 4 days (i.e., 1 day, plus 1 to 3 days),

or an average of 3 days for 1/7 of all access requests (i.e., records requested on a Sunday).

With the average of 1.2 days for records analysis times, the adjusted estimate of the total time for satisfying a records access request and records analysis is an average of 5.2 days (1.2 days, plus an average of 4 days) for requests made on a Saturday, and 4.2 days (1.2 days, plus an average of 3 days) for requests made on a Sunday. The adjusted estimate of current traceback times is computed as an expectation of traceback times taking into account the probabilities of records requests made on weekdays and weekends. Assuming nine investigative visits per traceback investigation, the adjusted estimate of the current traceback time is approximately 33 days (((3.3 days x 5/7) + (4.2 days x 1/7) + (5.2 days x 1/7)) x 9 visits). The adjusted estimate of the current traceback duration is reasonably consistent with the current traceback durations reported by traceback personnel of between 6 and 8 weeks for eggs and fresh produce, and 3 days for packaged products that contain lot code information on the labeling.

10. Estimate of the Time Required Before Preventive Action

We estimated the time required before taking preventive action using FDA outbreak investigation information. We estimated the time required for a preventive action as the time that elapsed between the onset of the first reported illness and the first action taken by FDA or a commercial or state entity. In 11 of 26 traceback investigations considered from 2000 to 2003, an average of 78 days had elapsed between the time of the onset of the first illness in the outbreak and any initial preventive measure.

The estimate of the time required for a preventive action may be overstated because for those investigations that had entries reporting an initial action, but

did not report a specific date of the action, we used the information entry date to approximate the date of the initial action. The information entry date is the date on which the initial action is recorded by FDA. Consequently, this procedure likely overestimates the time to preventive action because the information entry date is later than the date of the initial action it approximates, and in some cases may be significantly later than that date.

Moreover, many investigations do not involve any preventive action that would limit the magnitude of the outbreak, because either the investigation lasts longer than the shelf life of the implicated food product (so that there is no longer any implicated food in circulation), or the implicated source of the outbreak is determined to be an isolated event with no possible preventive action that would limit the size of the outbreak. Because information from such observations is not used in the analysis, the resulting estimate of the investigation duration is likely to be shorter than what would otherwise be obtained.

Based on the outbreak data used to create figure 2 of this document entitled "Cumulative Distribution of the Fraction of Total Reported Illnesses by Outbreak Duration," we estimate that between 15 and 18 percent of all illnesses were from outbreaks that lasted more than 78 days. This implies that, with an average of 2,081 reported illnesses per year, the faster tracebacks could potentially prevent up to a maximum of 312 to 374 (reported) illnesses per year. The average duration of outbreaks that last longer than 78 days is approximately 121 days, for an average net excess of 43 days (121 days minus 78 days). By dividing the maximum number of known illnesses per year, by the average duration of outbreaks that persist beyond 78 days, we estimate a

maximum daily average of 8 to 9 illnesses that occur each day after the 78 day threshold.

We characterize the uncertainty in the estimate of the time for preventive action as a Beta-Pert distribution with the most likely value of 78 and the minimum and maximum values (taken from the data) of 6 days and 150 days. The Beta-Pert distribution is a Beta distribution that has been re-scaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 times the most likely) + maximum) divided by 6. We use the Beta-Pert distribution since it is less sensitive to extreme values and generates more outcomes close to the mean than a Triangular distribution. We assume that the average duration of outbreaks that persist beyond the time for preventive action is distributed normally with a mean of 121 minus the time for preventive action, and a standard deviation (computed from the data) of 17. We assume a uniform distribution with a range between 0.15 and 0.18 in the estimate in the portion of annual illnesses that potentially could be averted by faster preventive action.

11. Estimating the Impact on Traceback Performance for Options With Different Coverage

Our framework for estimating the impact on baseline traceback speeds and completion rates for policy options with alternative levels of coverage uses the number of facilities in each sector to weight the sectoral contribution to baseline traceback performance. We adjusted the weights of the transportation, warehouse, and mixed-type facilities sectors to account for special considerations related to their contributions to traceback speeds and completion rates. For options that distinguish between very small and large

facility coverage, we also adjusted the contributions to traceback performance by facility size.

We estimated that options with the most comprehensive coverage will lead to the greatest decrease in times for preventive action, and eliminate the largest number of investigations that are prematurely terminated for reasons of poor records quality or nonexistent records. Options with more limited coverage will have a more limited impact on traceback speeds and completion rates. The factors used to scale baseline traceback speeds and rates of premature terminations are described by the following expression:

Total baseline performance = contribution by grocery outlets, given that contamination occurred further up the supply chain + contribution by wholesalers and importers, given that contamination occurred further up the supply chain + contribution by warehouses, given that contamination occurred further up the supply chain + contribution by manufacturers, given that contamination occurred further up the supply chain + contribution by transporters, given that contamination occurred further up the supply chain + contribution by mixed-type facilities.

The contribution to baseline traceback speeds by each sector is adjusted to reflect the probability that the food was contaminated further up the supply chain. Based on conversations with traceback personnel, we estimated that 10 percent of outbreaks requiring traceback records are from contamination at manufacturing facilities, and 90 percent are from contamination at the farm facilities (which may include mixed-type facilities subject to the recordkeeping requirements of this final rule).

a. *Adjustments to traceback performance for the grocery sector.* The baseline contribution from the retail sector to traceback performance is

composed of contributions from both the restaurant and grocery sectors. The contribution to traceback performance from grocery outlets represents only a fraction of the total contribution of the retail sector. We adjust the probability of requiring traceback records from grocery outlets downward to account for the possibility that initial traceback from retail could begin at a restaurant as well as at a grocery outlet. For the adjustment we use the estimated number of restaurant locations of approximately 900,000 reported in a recent survey conducted for the National Restaurant Association (Ref. 16).

b. *Adjustments to traceback performance for transportation and warehouse facilities.* We adjusted estimates of the contributions to traceback performance by warehouse and transportation facilities to reflect the "checks and balances" nature of traceback records from these facilities for many investigations. Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. This requirement allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. It is critical that FDA be able to locate and remove from commerce any adulterated food that presents a credible threat of serious adverse health consequences or death to humans or animals.

We assume that there is a uniform likelihood between zero and one that there are more than two transportation or warehouse facilities used in the provision of a transportation or storage service. For these cases there is no adjustment to the value of records from such facilities during a traceback investigation. When two or fewer facilities provide transportation and warehouse services (estimated to be approximately half of the total number of such services) we adjust downward the value of records to acknowledge

their role of verifying, rather than identifying, the buyer or seller of the food. For these cases we adjust the value of records to traceback performance by a factor of 0.5.

c. *Adjustments to traceback performance for large and very small facilities.* We adjusted the contributions by large and very small facilities to traceback performance to reflect the substantially different quantities of food each facility size is responsible for. While the number of very small facilities accounts for a large fraction of the total number of facilities, the quantity of food for which these facilities are responsible is relatively small. Consequently, estimates of the contributions to traceback performance should reflect the lower likelihoods of investigative visits at very small businesses.

For options that differentiate between coverage by facility size, we used estimates of the quantities of food passing through very small establishments and the quantities of food passing through all other sized establishments to scale each sector's contribution to traceback performance. In this way we were able to estimate the contribution by very small size establishments and other size establishments to traceback performance for each sector. We used U.S. Census data (Ref. 17) to estimate the percentage of the total number of food establishments that are very small, as well as their revenues, by sector and report them in the chart below. The fraction of the total number of facilities that are very small ranges from an estimated 73 percent of convenience outlets to 90 percent of transporters. In contrast, the percentage of total convenience store revenues from very small facilities is an estimated 18 percent, while very small transporters are responsible for an estimated 16 percent of total revenues from that sector.

TABLE 11.—THE PERCENTAGE OF VERY SMALL FOOD ESTABLISHMENTS THAT MAKE UP EACH SECTOR AND THE PERCENTAGE OF THE TOTAL SECTOR'S FOOD FOR WHICH THEY ARE RESPONSIBLE

Sector	% of Establishments That Are Very Small	% of Food Sector Revenue From Very Small Establishments
Manufacturers	77	15
Wholesalers	81	14
Transporters	90	16
Grocery outlets	88	18
Convenience outlets	73	18
Importers	82	14
Mixed-type facilities	82	15

Source: U.S. Census, 1997 Economic Census.

In addition to a lower probability of an investigative visit at very small compared with other size facilities, records quality or records access times might also be different for very small and other size facilities. However, conversations with FDA investigative personnel revealed that there are no differences in records quality or records access times across business sizes. Consequently, we estimate the duration of an investigative visit to be the same for very small and other size businesses.

12. Estimating the Benefits When Selected Sectors Are Excluded

In this section we describe the estimated reduction in benefits that would be incurred from excluding certain sectors. We will provide additional quantitative information on this later in the analysis. We selected specific sectors for analysis in this section based on comments received on the proposal. The reduction in benefits from excluding foreign persons, transport persons, and food contact substance persons (including the finished container that contacts the food) from establishing and maintaining records are estimated as affecting traceback performance and the number of outbreak victims. The final rule excludes food contact substance and foreign facilities from recordkeeping maintenance requirements. As stated earlier, these estimates all account for food safety benefits based on traceback investigations currently

performed and do not consider food security benefits, which are based on classified information.

a. *Excluding foreign facilities.* One policy option excludes approximately 225,000 foreign persons from all recordkeeping requirements. Although it is impossible to estimate the likelihood of intentional contamination at foreign facilities compared with domestic facilities, in this analysis we assume that there is no difference between the probabilities of foodborne outbreaks originating at foreign and domestic facilities. Consequently, the estimated reduction in benefits from excluding foreign persons is based solely on the number of facilities that are excluded, and the likely importance of their records for traceback performance. Because foreign facilities are close to the beginning of the supply chain for U.S. domestic consumption, the importance of their records during a traceback investigation is moderate while the costs to obtain those records during a traceback investigation are high.

b. *Excluding persons that manufacture, process, pack, hold, transport, distribute, receive, or import food contact substances.* Another policy option excludes food contact substance suppliers, estimated to be 37,000 manufacturers and distributors of the finished container that contacts the food, from the requirement to establish and maintain records. Because of the small number of manufacturers and distributors of the finished container that contacts the food compared with the total number of foreign suppliers, their exclusion from recordkeeping requirements would have a relatively small impact on traceback performance (if we ignore the possibility that excluding packaging suppliers increases their profile as potential targets for terrorist activities). Moreover, because manufacturers and distributors of the finished container that contacts the food occupy up-stream positions along the supply

chain relative to foreign entities, we estimate the reduction in benefits from excluding them to be less than that from excluding foreign entities. Finally, if the requirements of section 306(a) of the Bioterrorism Act were satisfied, FDA would have access to existing records at these facilities.

c. *Excluding transporters.* One policy option would exclude all transporters from the requirement to establish and maintain records. FDA determined, however, that the qualitative and quantitative impact on benefits in the classified and unclassified scenarios would greatly eliminate the effectiveness of the rule and FDA's ability to timely and efficiently respond to a threat of serious adverse health consequences or death to humans or animals. As a practical matter, because the final rule's requirements for interstate shipments can be satisfied by compliance with existing requirements for interstate shipments, the final rule only establishes new requirements for the following: (1) Intrastate transporters; and (2) intrastate shipments conveyed by interstate transporters. FDA estimates that there are approximately 115,000 intrastate carriers, and based on DOT data, almost one million commercial drivers report intrastate travel. In reviewing the truck tonnage by commodity, approximately 12 percent of the intrastate shipments are of FDA-regulated food products. The average distance these products are shipped is 231 miles, which means many shipments are intrastate, especially in the larger western states.

For some foods, distribution may be limited primarily to intrastate transportation, depending on the time of year and state. Many businesses have their own delivery trucks that are used intrastate, several use employee vehicles for deliveries, and many rent vehicles to deliver products. These vehicles are used to deliver all types of food products—refrigerated, cooked, as well as fresh food and produce, and grocery items. Some local firms pick

up their own merchandise from "warehouse" facilities to stock their own locations. Many of these "warehouses" (commonly referred to as "Bin warehouses") may receive product via interstate transporter and subsequently deliver to a variety of intrastate retail customers via many different intrastate means. Data on the volume of foods that move in intrastate commerce are maintained by individual state Department of Agriculture and by DOT. For example, from CA, LA, and TX alone, DOT reports over 12 percent of intrastate truck tonnage is from FDA-regulated products (ref. 18). Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003, there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

Most of the seafood consumed in Florida is transported only intrastate, but in Oklahoma most seafood is transported interstate. In 2002, there was an outbreak in New Jersey and Florida linked to fish. Intrastate records assisted us in pinpointing the portion of the Indian River, Florida that was causing the problem. Information on egg tracebacks from 1996–2003 indicates that 35 percent of the tracebacks that resulted in farm investigations were intrastate. This past summer, the State of Oregon was able to stop a sprout-associated outbreak from becoming a serious one by tracing back to a Washington sprouter that was just over the border from Oregon after some initial cases before the Salmonella serotype had been identified. The sprouts were recalled. If the sprouter had been located in Oregon so that the sprouts were not transported

interstate, it would have been problematic to a traceback investigation limited solely to interstate transporters.

The North Carolina green onion traceback investigation, which was part of the largest Hepatitis A outbreak that has ever occurred in the U.S., is another example of the importance of intrastate records. There, the amount of time spent on the traceback within that State was twice as long as the other three tracebacks done in other states because the distributor in North Carolina did not have records. Traceback from the Tennessee outbreak took over a month, the Georgia traceback took a month, and Pennsylvania traceback took a week. Because we had no intrastate records in the North Carolina outbreak, the traceback was determined to be inconclusive after two months, which meant that we would not have been able to identify the farms involved if it had not been for the other outbreaks.

This year, there was an *E. coli* O157:H7 outbreak associated with bagged lettuce product in CA that was only in intrastate commerce. That traceback might have been lost had records not have been available. Exempting transporters could significantly impede FDA's ability to rapidly and effectively respond to a public health emergency involving a food transported within a state, particularly if the adulteration occurred during transport and the food was delivered to multiple sources within the State. In scenarios where time is of the essence to prevent serious injuries or death, having records available becomes even more critical. In addition, not only must FDA be able to rapidly obtain records, it is imperative that FDA be assured that those records contain certain essential information to allow FDA to prevent further harm in an efficient and effective manner.

Additional examples of circumstances involving food products that have significant intrastate manufacturing, processing or distribution are provided in the following paragraphs:

- An intrastate sandwich and snack food company that sells to retail outlets for consumption had an outbreak of *Listeriosis* or *Salmonellosis* that was traced back to the sandwiches. The product was completely distributed using the company trucks within the state. FDA was unable to determine which sandwiches caused the outbreak. The sandwiches were delivered to retail customers, and it was impossible to track which sandwiches went to which retailer. The transporter did not track which product was delivered to which location. In this case, the firm had to recall all of its products.

- Retail stores regularly purchase food, especially locally grown produce, from "truck farmers." These farm trucks travel from store to store within a state, sometimes selling an entire truckload to a store, other times a portion. There is no manifest or record other than a bill of sale—e.g., 200 cantaloupes from Farmer Brown. If the contamination occurred on the truck, FDA would not have a record from the truck of all other delivery sites.

- Several days into the investigation of a Hepatitis A outbreak from chicken salad in one city, FDA learned that the chicken was "cubed" at another facility in another city within the state, and transported to the "manufacturing facility." The source of the outbreak was the site where the chicken was "cubed" by an ill employee; however, there were no records to indicate when the cubed product was shipped or received by the salad manufacturing facility.

Having transporter documents would be critical if there was an intentional or unintentional contamination of the product while en route. Because of our

limited experience, we cannot anticipate how much additional time it would add to our investigation, should records not be available.

The probability that a traceback investigation will require records that document the movements and packaging of food items between transportation facilities is uncertain. At least one outbreak involving the contamination of dairy products while inside a truck that had previously carried non-pasteurized eggs is estimated to have infected about 224,000 persons (Ref. 19). This example illustrates only one potential way that food may be contaminated while in the possession of transporters, and suggests that these risks of contamination can be considerable.

13. Options With Different Access and Retention Requirements and With Different Compliance Dates

a. *24 hour and 4- and 8-hour records access requirements.* For options with comprehensive coverage (and using simple average numbers), when compared with current traceback times, we would save an estimated 10 days for the proposed option requiring 4 and 8 hour records access, and 5 days for the option requiring 24 hour records access. When travel times are included, the provisions of the recordkeeping rule will significantly reduce the records access as well as the records analysis times. When travel times are included, the 4 and 8 hour records access times in the proposed rule would reduce the range of records access times to 1 to 2 days. The final rule requires records access within 24 hours of a request, which would reduce records access times by a smaller amount than with the proposed 4 and 8 hour requirement. Because current records access times are between 1 and 3 days including travel times, we assume that relaxing the requirement to 24 hours would only speed up compliance for records requested on the weekends. The

proposed records access times of 4 and 8 hours would result in estimated records access times of between 1 and 2 days, and a records analysis time of 1 day (because the improved records quality would preclude the need for return investigative visits).

We assume that a 10-day reduction in the duration of the traceback component of an outbreak investigation would reduce the time required to take an initial preventive action by 10 days as well. A savings of 10 days would reduce the average amount of time required to take a preventive action to 68 days (based on the estimated current time of 78 days), and a savings of 5 days would reduce the time required to take a preventive action to 73 days. From data used to generate the cumulative distribution displayed earlier in this document in figure 2 entitled "Cumulative Distribution of the Fraction of Total Illnesses by Outbreak Duration (2000–2003)," we find that between 15 and 18 percent of all outbreak victims became ill from outbreaks that lasted more than 65 days. Consequently, the benefits from reducing traceback times by either 10 days for the 4-and 8-hour records access requirement, or 5 days for the 24-hour records access requirement can be considerable. We assume that with comprehensive coverage, the number of traceback investigations that are prematurely terminated because of poor records quality will fall to zero under either the 24-hour records access requirement, or under the proposed 4-and 8-hour records access requirement.

The reduced durations of traceback investigations computed in the previous paragraphs are based on the assumed comprehensive coverage of the proposed recordkeeping rule. Excluding certain persons from all or part of the requirements of the regulation results in a reduction in the benefits as measured by reduced times for traceback investigations. The extent of the

reduction in benefits from reduced traceback durations depends on the number of persons (and facilities for which the persons are responsible) that may be excluded from the regulation and the position along the supply chain of the excluded facilities. The position along the supply chain influences the probability of contamination, as well as the probability of losing the paper trail. We assess the relative benefits of excluding certain sectors as policy options later in this document.

Finally, if there is a deliberate attack on the food supply, with catastrophic consequences, then the duration of the preliminary and decision making parts of the outbreak investigation will likely be substantially compressed, and the importance of the traceback investigation in preventing additional illnesses from an outbreak will be elevated. If firms fully understand the seriousness of an outbreak, their reaction times may be compressed as well, which would tend to reduce the computed benefits from this rule. However, we expect FDA to be more likely than all firms to fully understand the seriousness of an outbreak.

As an example computing how compressed preliminary investigation and decision making times affect the benefits from faster tracebacks, we estimate the duration of the preliminary and decision making parts of the outbreak investigation to currently be approximately 55 days (i.e., the difference between 78 days for an initial preventive action and 33 days for the traceback investigation). If we assume a 50 percent reduction in the times for the preliminary and decision making components of an outbreak investigation, then a 10-day reduction in traceback times would result in preventive measures taken after approximately 56 days (28 days, rounding up, for the preliminary and decision making investigations plus 28 days for a traceback

investigation) compared with the current 78 day duration. For a 75 percent reduction in the duration of the initial parts of an outbreak investigation, a 10-day reduction in traceback times would result in preventive measures being taken after approximately 42 days (14 days for preliminary and decision making investigations plus 28 days for a traceback investigation) compared with the current 78 days.

b. *Records retention requirements of 6 months, 12 months, and 24 months based on three NIST definitions.* Many comments suggested that product shelf lives as defined by the NIST should determine which product records would be subject to retention requirements of 6 months, 12 months, and 24 months. We estimate a negligible reduction in costs (which we estimate to be zero) and benefits associated with reducing retention times in the final rule.

The provision specifying the shorter retention requirements of 6 months, 12 months, and 24 months may result in the destruction of records earlier than would be the case for the longer retention requirements. While we estimate the reduction in benefits from the reduced retention times to be negligible, we explain the logic behind the perverse incentive for the early destruction of records, and its potential impact on traceback performance. The benefits from the records access requirements cannot be realized without the records retention requirements. If records no longer exist, there is nothing for FDA to access.

Given the records access requirement, the records retention requirement in both the proposed and final rules may create a perverse incentive for entities to destroy records, even though we estimate that this incentive will lead to the actual destruction of very few records, and very small reductions in investigative speed. Private firms are quite reluctant to share their private

records with outsiders such as federal regulatory agencies. Facilities may choose to destroy records once legal retention requirements have been met rather than risk the possibility of sharing them with FDA. Consequently, there is a nonzero probability that facilities will destroy records subject to the retention requirements shortly after the legal retention requirement has been met, and that those records would not exist in the event of an FDA records access request.

The incentive to destroy records due to the access requirement will likely result in the destruction of a very small fraction of records because of the private utility from retaining records, and also the costs of destroying them. Because of the perverse nature of this incentive, it is informative to estimate its impact on the benefits from final rule—especially since the costs of the 1 and 2 years records retention provisions were estimated to be zero because the retention time periods are the same as or shorter than current business practices.

We used outbreak investigation data to estimate the reduction in benefits when retention requirements are redefined to be 6, 12, and 24 months based on NIST definitions of shelf lives. Investigations that remained open 6 months after initial exposure were considered possible candidates for continued investigative visits. From FDA investigation information, we estimated that about 20 percent of all FDA investigations from 2000 to 2003 remained open 6 months after initial exposure to the pathogen. However, it is likely that most of these investigations did not require access to a firm's records after 6 months.

We assume that a maximum of 20 percent of all traceback investigations are candidates for a records access request 6 months after initial exposure to the pathogen. We assume that half of the investigative visits in one of these

candidate investigations requires access to records after 6 months, and that 1/3 of these access requests are for records subject to the 6 month retention period (i.e., a 1/3 probability for 6 months, a 1/3 probability for 12 months and a 1/3 probability for 24 months). Consequently, 3.3 percent of records requests for records subject to the 6 month retention time are estimated to be made after 6 months (20 percent x 1/2 x 1/3).

We assume that the potential records destroyed (after retention requirements have been met) as a result of the access requirement would be from the set of establishments with the poorest food safety practices. To determine the percent of firms with the poorest food safety practices, we obtained information from FDA personnel indicating that inspections of approximately 3 to 4 percent of all FDA-regulated food and cosmetic facilities from 2001 to 2003 were classified as official action indicated (Ref. 20). Based on this information, we assume that the incentive for records destruction will result in approximately 3 to 4 percent of firms destroying their records after 24 months, with destruction taking place shortly after retention commitments have been met.

We assume that the private utility of records decreases over time, and that the rate at which records subject to 6 months retention are destroyed shortly after meeting the retention requirement is half that for records subject to 12 months retention, which is half that for records subject to 24 months retention. Consequently, an estimated 0.5 percent of records subject to the 6 month retention time are assumed to be destroyed shortly after the 6 months have been met (i.e., the solution for "X" when solving the algebraic problem, 3.5 percent = X + 2X + 4X, where 3.5 percent is the midpoint between 3 and 4 percent and the rate at which all records are destroyed, X is the rate that

records subject to the 6 month retention requirements are destroyed, 2X is the rate that records subject to 12 month retention requirements are destroyed, and 4X is the rate that records subject to the 24 month retention requirements are destroyed.). The destruction of records is estimated to affect about 0.02 percent of access requests (i.e., 0.5 percent records destruction rate x 3.3 percent of records requests made after 6 months). Finally, we assume that records destruction will slow down and terminate traceback investigations at the same rates at which the destruction takes place. Consequently, we estimate that both traceback speeds and rates of successful traceback completions will decline by 0.02 percent because of access requests when the requested records had been destroyed because of retention requirements.

c. *Extending the compliance dates.* Another policy option considers extending each of the proposed compliance dates by 6 months: Large, small, and very small firms would be required to be in compliance with the regulation 12, 18, and 24 months, respectively, after publication of the final rule instead of the proposed 6, 12, and 18 months after publication. The longer compliance dates reduce the time savings for a preventive action for 50 percent of the annual number of traceback investigations, and lead to a 50 percent increase in the annual number of outbreak investigations prematurely terminated for records quality reasons. Unlike the reduction in the benefits from the other policy options considered, these are one-time decreases in the benefits, because the option only extends the initial baseline compliance times by 6 months.

d. *Exemption of all very small entities.* FDA also considered whether it should exempt all entities with ten or fewer employees, not just those in the retail sector as is provided in the final rule; however, this would create a "Swiss Cheese" approach to trace back, as there would be a potential failure

of entities to keep records throughout the distribution chain. The number of very small entities account for a large fraction of the total number of food establishments.

Moreover, many of our failures in a typical trace back investigation (i.e., unclassified scenarios) have been at the wholesaler (distributor) level. As discussed above, we would have significant concerns if 90 percent of the transporters (as very small entities) would be excluded from the requirements to establish and maintain records, particularly if these are predominantly intrastate transporters that are not currently subject to DOT's requirements. (FDA notes that intrastate shipments carried by interstate transporters also are not subject to DOT's requirements.)

In light of the above, FDA does not believe we would have an effective recordkeeping system if we were to exempt all very small entities from the rule. Unlike the very small retailers who are at the end of the distribution chain only, a full exemption by size would create holes throughout the distribution chain and would not provide FDA adequate assurances that, in the event of a threat of serious adverse health consequences or death to humans or animals, FDA would be able to conduct an efficient and effective traceback investigation.

F. Costs

1. Estimates of the Number of Facilities Affected By the Final Rule

In the PRIA, FDA estimated the number of transporters and packers from data in the 2000 County Business Pattern statistics (Ref. 21) and the 1999 Nonemployer statistics (NES) (Ref. 22). We assumed that local and long distance specialized freight carriers devoted exclusively to transporting food were about 20 percent of the total of the specialized freight category. In the

PRIA, FDA requested comments on the assumption that 20 percent was appropriate for this estimate.

(Comment 182) Several comments suggest that the number of trucking entities covered by the rule was substantially underestimated. One comment suggests that while 20 percent of the specialized carriers transport food products at any specific time, most specialized carriers transport food at one time or another. Another comment suggests that FDA's estimate of the number of covered trucking entities was low; the comment cites information obtained from the U.S. DOT that indicated close to 600,000 operating authorities on file, which includes Mexican, Canadian, and domestic carriers. Moreover, the comment suggests that if half of the general carrier population (600,000 carriers) transports food on an occasional basis, then over 300,000 companies would be affected. These numbers suggest an estimate of covered trucking facilities much larger than FDA's estimate. To support the assertion of an underestimate, the comment suggests that FDA-regulated Mexican carriers alone likely account for 12,000 facilities. Another comment states that individual transporters, not only transportation firms, will hold food while it is in transit and that transportation vehicles do not appear to be exempt from the recordkeeping requirements.

(Response) FDA agrees with the concerns underlying many of these comments and revises its estimates of the number of transportation entities in a way that is consistent with the data and framework used in the PRIA. Although FDA does not dispute the comment that most specialized carriers transport food items at one time or another, the ease with which transporters enter and leave the food industry is considered in the PRIA. That analysis already accounts for the additional learning, records access, and planning costs

incurred by new entrants. In the PRIA, FDA estimated that there would be approximately a 10 percent rate of entry and exit of new and existing firms for all sectors. FDA calculated the startup costs for these new entrants and added them to the compliance costs incurred by existing facilities.

The County Business Pattern and NES used by FDA in the analysis include all potentially covered transporters (except foreign-based carriers that transport food in the United States), including individual carriers. However, in the PRIA, FDA neglected to include the number of establishments under North American Industry Classification System (NAICS) code 4841 for general freight trucking as well as for NAICS code 488510 for freight transportation arrangement. In the analysis of the final rule, we include entities that fall under both of these categories.

The combined data from the County Business Pattern and NES contain 384,358 establishments under code 4841 for general freight trucking. In addition, the County Business Pattern data contain 15,177 establishments for code number 488510 for freight transportation arrangement. To estimate the number of facilities under code 488510 in the NES data, we calculated the ratio of the number for code 488510 to the total number for code 488 in the County Business Pattern data, and then applied that ratio to the number of establishments under code 488 in the NES data. We assumed a uniform distribution of food and nonfood carriers under the general freight trucking category and estimated the number of establishments that transport food products under code 4841 to be half of the total for that category. We assumed the number of establishments under code 488510 that arrange freight transportation for food products to be 20 percent of the total for that category. We assumed that the same percentage applies to the total assumed for

specialized freight carriers dedicated to the food industry. As a result of these changes, the total number of domestic transportation and packing facilities is revised upward from 16,773 facilities used in the PRIA to 234,980. The numbers of establishments by code are reported in table 12 of this document.

TABLE 12.—NUMBER OF TRANSPORTATION ESTABLISHMENTS BY NAICS CODE

NAICS Code	Description	CBP 2000	NES 99
481112	Scheduled freight air transportation	584	2,413
481212	Nonscheduled chartered freight air transportation	217	
483111	Deep sea freight transportation	485	4,754
483113	Coastal and Great Lakes freight transportation	546	
483211	Inland water freight transportation	402	
4841	General freight trucking	27,937	164,242
48422	Specialized freight (exclusively used) trucking, local	6,499	4,946
48423	Specialized freight (exclusively used) trucking, long distance	2,580	8,189
488320	Marine cargo handling	607	2,415
488510	Freight transportation arrangement	3,035	3,814
488991	Packing and crating	1,315	

Foreign transportation carriers that cross the northern and southern U.S. borders are not counted in the County Business Pattern and NES data, because they are foreign based. All of these carriers are subject to DOT regulations, and the costs of compliance for these facilities are assumed to be zero because the final rule allows a transporter to meet its obligations by keeping the records currently required by DOT. However, foreign transportation carriers that cross the northern and southern U.S. borders are assumed to incur learning costs associated with this final rule.

FDA estimates the number of Mexican carriers that are subject to DOT regulations from a study conducted for DOT by Economic Data Resources under the auspices of the International Association of Chiefs of Police (Ref. 23). Using 1999 U.S. Customs and Border Protection data on the use of annual decals and per-trip payments by commercial vehicles at Southwest border crossings, that study estimated the total number of vehicles that cross the

Southwest border to be approximately 76,177. Furthermore, using 1998 data on Mexican interstate commercial vehicle registrations, the DOT study estimated the number of commercial carriers of Mexican origin that use the Southwest border crossings to be approximately 63,000, or approximately 83 percent of the total. If one half of the total number of these trucks carry food items, then approximately 31,500 carriers of Mexican origin are subject to this final rule and would not be counted in the CBP or NES data.

In order to estimate the number of commercial carriers of Canadian origin that would be covered by this final rule, from the DOT study we obtain an estimate of approximately 79,643 carriers that purchase annual decals at the Northern border. We assume the same ratio of the total number of trucks that purchase annual decals for Southwest border crossings as that for northern border crossings (42 percent) and estimate the total number of trucks that cross the northern border to be approximately 191,167. Furthermore, we assume the percentage of these carriers that are of Canadian origin is the same as that used to estimate Southwest border crossings by Mexican carriers (83 percent). This assumption yields a total of 158,099 carriers of Canadian origin that are subject to DOT regulations. If one half of the total number of these trucks carry food items, then approximately 79,050 carriers of Canadian origin are subject to this final rule and would not be counted in the CBP or NES data. The number of transport facilities is revised upward by 110,550 (i.e., 79,050 plus 31,500) to account for the number of foreign based transporters that are subject to the final rule and not counted in the NES or CBP data.

(Comment 183) One comment states that direct selling businesses are clearly not accounted for because there are millions of such entities involved on either a full or part-time basis, while the combined estimate of domestic

retailers and wholesalers used in the analysis is only slightly more than 300,000. Furthermore, the comment states that the burden on these retailers would be higher than for other retailers.

(Response) FDA does not agree that there are millions of direct marketers of food in the United States. Nor does FDA agree that the burden on direct marketing retailers would be greater than for other retail establishments. However, FDA does agree that the data sources used in the PRIA may not account for many small direct marketers that may not have filed as a sole proprietorship business with the Internal Revenue Service (IRS). While these direct marketers may have been omitted in the PRIA, they are considered exempt in the final rule and are not included in the cost estimates in this analysis. Nevertheless, in order to respond to comments and to estimate the cost of policy options that include very small retailers, FDA does revise its estimate of the number of retail establishments to account for direct marketers that may not have been included in the PRIA.

FDA found estimates of 10 million (Ref. 24) and 12 million (Ref. 25) direct marketers in the United States, but these estimates included all the direct marketers of both nonfood and food products in the United States. FDA does not have a complete census of the number of marketers of food versus nonfood products. To approximate the percentage of direct marketers selling food, FDA divided the number of direct marketing companies selling food by the number selling all types of products, using data from the directory of companies on the Web site of a large direct selling trade organization (Ref. 25). Of the 141 companies in the directory, approximately 5 market food or beverages, or approximately 3.5 percent of the total.

The number of direct marketing establishments should be captured by the NES, which are generated chiefly from administrative records of the IRS. These data are primarily composed of sole proprietorship businesses filing IRS Form 1040, Schedule C (Ref. 22). Many of the nonemployer businesses are very small, and many are not the primary source of income for their owners. Furthermore, nonemployers account for 75 percent of all businesses.

There is the possibility that direct marketers are included in the estimate of the number of direct marketers cited earlier and excluded in the NES if they are casual market participants, and have temporarily left the industry, or if they do not file as a sole proprietorship business with the IRS. Casual market participants might be included in the estimate of the total number of direct market facilities even if they are not active members. This would tend to inflate the total number of direct marketers to include both active and inactive members. Because of the ease of entry and exit by these firms, casual direct marketers that have temporarily left the industry are assumed to be approximately half of the number of direct marketers of food, or 1.75 percent of all direct marketers. This assumption leaves an estimated 1.75 percent (175,000) of direct marketers that are not counted in the NES statistics because they did not file as a sole proprietorship business with the IRS. We use this estimate of the number of direct food marketers that did not file as a sole proprietorship business with the IRS to revise our estimate of the total number of retail facilities.

Direct marketers that did not file as a sole proprietorship business with the IRS are assumed to be part-time suppliers and to sell mostly at the retail level. Furthermore, because these are very small businesses that only sell food products on a part-time basis, the additional records maintenance costs for

these facilities will be considerably less than that for larger, full-time businesses. We estimate the additional records maintenance costs for these part-time facilities to be one half that for other retailers. The learning costs, records redesign costs, and records access planning costs for these facilities are assumed to be the same as for other facilities.

FDA does not agree that the burden of the rule would be higher for direct marketers than for other retailers. In the PRIA, FDA estimated that about 88 percent of retailers classified as very small firms have fewer than 10 employees. FDA believes it is reasonable to assume that compliance costs for direct marketers would be about the same as for other very small firms.

(Comment 184) One comment suggests that FDA underestimated the number of mixed-type facilities that engage in nut farming. The comment states that, in the almond industry, there are about 360 hullers and processors who are also growers, while FDA estimated that there were only 290 mixed-type facilities that engage in all categories of nut farming. Furthermore, because there are about 6,000 almond growers, the comment states that this implies that 6 percent of all almond growers would be classified as mixed-type facilities, compared to FDA's estimate of 2 percent of all nut farms.

(Response) FDA acknowledges considerable uncertainty in the estimates of the numbers of mixed-type facilities that engage in farming and is receptive to comments from industry that can improve them. There is likely to be more uncertainty in the estimates of the number of mixed-type facilities that engage in any individual category of nut farming than that for the estimate of the number of mixed-type facilities that engage in nut farming over all categories of nuts. FDA will use the estimate provided by the comment to revise its estimate of mixed-type facilities that engage in nut farming from 2 percent to

6 percent. The total number of mixed type facilities that engage in farming is revised upward to 31,077 from 30,497 used in the PRIA.

Table 13 of this document is a revised table of mixed-type facilities that engage in farming.

TABLE 13.—MIXED-TYPE FACILITIES ENGAGE IN FARMING

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Farms
Pig farms (feed mixing)	46,353	1.5%	695
Cattle (feed mixing)	785,672	1.0%	7,857
Poultry (feed mixing)	36,944	1.0%	369
Other animal production (feed mixing)	110,580	1.0%	1,106
Dairy	86,022	1.1%	903
Grain, rice, and beans	462,877	1.0%	4,629
Apples	10,872	1.5%	163
Oranges	9,321	1.5%	140
Peaches	14,459	1.5%	217
Cherries	8,423	1.5%	126
Pears	8,062	1.5%	121
Other fruit	29,413	1.5%	441
Nuts	14,500	6.0%	870
Berries	6,807	1.5%	102
Grapes	11,043	10.5%	1,160
Olives	1,363	3.5%	48
Vegetables and melons	31,030	0.5%	155
Organic vegetables	6,206	50.0%	3,103
Honey	7,688	50.0%	3,844
Syrup	4,850	100.0%	4,850
Herbs	1,776	10.0%	178
Total			31,077

(Comment 185) One comment states that FDA mistakenly omitted the number of food grade warehouses that are subject to the regulation included in NAICS code 49311. Consequently, FDA's estimate that a total of 76,952 wholesaler and public warehouse companies are affected by the regulation is too low, and these additional warehouses should be included in the cost calculation of the final rule.

(Response) FDA agrees that public warehouses included in NAICS code number 49311 were omitted from the count of total warehouse facilities. Table

14 of this document describes the primary activities performed by the warehouses included in this classification.

TABLE 14.—DESCRIPTION OF PRIMARY ACTIVITIES PERFORMED BY WAREHOUSES BY NAICS CODE

NAICS	SIC	Corresponding Index Entries
493110	4225	Bonded warehousing, general merchandise
493110	4225	General warehousing and storage
493110	AUX	Private warehousing and storage, general merchandise
493110	4225	Public warehousing and storage (except self storage), general merchandise
493110	4226	Warehousing (including foreign trade zones), general merchandise
493110	4225	Warehousing and storage, general merchandise

There are a total of 4,415 of such facilities listed in the County Business Pattern data. In the NES statistics, there are 4,700 reported for the aggregate NAICS code of 4931. To estimate the number of warehousing facilities that would be included in NAICS code 49311 in the NES statistics, we scaled the aggregate number in the NES statistics by the ratio of the numbers reported for code 49311 to the total of those reported under code 3931 in the County Business Pattern. When the imputed NES numbers for code 49311 are added to the reported County Business Pattern numbers for code 49311, the total number of facilities in the NAICS code is 7,328 facilities. We adjust the total number of warehouses by one half of the total number of facilities reported for code 49311 by assuming that half of the total number of facilities included in that code handle food items. The number of warehouse facilities is revised upward to 6,089 from the 2,425 in the PRIA. The facilities-to-firm adjustment factor used for the facilities listed in NAICS code 49311 is the average of that used for the other two warehouse codes in the analysis.

(Comment 186) One comment requests clarification as to whether all members of the International Bottled Water Association were included in the number of facilities covered by the regulation.

(Response) The NAICS code 3121 used in the PRIA includes all beverage manufacturers and specifically includes bottled water manufacturers. All other bottled water suppliers are included in the various NAICS codes used to count wholesalers and retailers, and other food suppliers.

Finally, the changes to the costs and benefits of the final rule due to the expanded coverage to include persons that export food for consumption outside of the United States are estimated to be small. We assume that the export of food and feed occurs at the manufacturing and wholesaling levels, with retailers unlikely to engage in export. The U.S. Census Bureau's 1997 Economic Census (Ref.17) indicates that approximately 4 percent of wholesale trade in all grocery and related products (NAICS code 4224) was from export sales. We assume that the same percent also applies to exports in the manufacturing sector and also to the numbers of facilities in those sectors. An estimate of 4 percent likely overstates the true incremental cost of covering exported food and feed since most, if not all of the establishments engaged in export are also likely to be engaged in domestic commerce and consequently would not incur additional learning and records redesign costs. Moreover, firms that export and also engage in domestic commerce are unlikely to incur additional maintenance costs because it is unlikely that they would follow two sets of recordkeeping practices. Consequently, only firms that are exclusively exporters will incur incremental recordkeeping costs as a result of expanded coverage. We assume that half of all wholesale and manufacturing establishments estimated to engage in export, or 2,736 facilities, are exclusively exporters and will incur recordkeeping costs as a result of expanded coverage to include export of food and feed.

The incremental benefits from expanding the coverage to include exported food and feed are from the possibility that some of these shipments may be diverted for domestic consumption, and their coverage may enhance traceback investigations should they be necessary. The food safety (but not food security) benefits from expanded coverage are likely to be negligible since the likelihood of diversion is small, and the likelihood that a diverted shipment is accidentally contaminated is also small. However, the food security benefits, while not quantifiable, include classified scenarios that could include diversion of food and feed. Further, FDA is concerned that exempting foods intended for export from the recordkeeping regulations could lead to such foods being targeted for tampering by terrorists and reintroduction into domestic commerce as they would prove more intractable to tracing investigations. Including the revisions described previously, we estimate that a total of 707,672 facilities will be covered by this final rule. This represents a reduction of 96,642 facilities compared with the number estimated in the analysis of the proposed rule.

2. High Cost of Tracking by Lot Code

(Comment 187) Many comments state that lot codes are not currently used in tracking products at the distributor and retailer levels, and that requiring lot codes to be recorded by these entities would represent a large change in business practice. One comment states that only 10 percent of food distributors currently use lot numbers to track their food products. One comment states that its facility tested the proposed requirement to establish records of lot numbers in its daily operations and concluded that there would be an 80 percent loss in productivity as a result of the requirement. Another comment states that labor costs for unloading a truck at a distributor would increase

by a factor of 15 under an exhaustive check of shipper and lot code information. The comment further states that a conservative estimate of the unloading costs would be a threefold increase in current costs if a less exhaustive spot check of the lot codes is required.

Other comments illustrate the dramatic change in current business practices that would result from requiring lot codes to be included in records. However, several comments indicate that although the technology to maintain lot codes in bar code format does not currently exist, the industry is moving in that direction and such a requirement might be feasible in 5 to 7 years.

(Response) In estimating the costs of the rule, FDA assumed that all required information provided for in the regulation represented only small deviations from current business practice. The comments received strongly suggest that the cost estimates for maintaining records on lot codes for distributors and retailers were substantially understated. The results reported by one comment of an experiment that tested the requirement in their daily operations indicated an 80 percent loss in productivity. Other estimates of the increase in labor costs that would result from this requirement ranged from three-fold to fifteen-fold. FDA revises the estimates of the costs to maintain records on lot codes by assuming an 80 percent loss in productivity for retailers and distributors from compliance with this provision. For other policy options included in this analysis as well as in the final rule, the requirement to establish and maintain records containing lot codes is relaxed to be consistent with current feasibility.

3. Records Retention Costs

(Comment 188) Several comments address the costs of records retention. Several comments suggest that records are often stored off site or at corporate

headquarters, with a nonzero cost for retrieval. Another comment recommends that we review our estimate of records retention costs of zero. The comment states that firms that handle products not covered by the juice HACCP regulation (part 120) may not have a records retention strategy and may have to implement a new strategy for records retention and recovery. Several comments express uncertainty with regard to the appropriate records retention time of either 1 year or 2 years for the products that they handle. These comments suggest definitions of "perishable" that would be more consistent with the terminology used in the trade, which is different from the definition in the proposed rule. Recommended records retention times ranged from a low of 6 months for perishable foods, up to 2 years for other foods.

(Response) In the PRIA, we used information from preliminary outreach to tentatively conclude that requirements for records retention of 1 year for perishable products, and 2 years for all other foods were consistent with current industry norms. The respondents to the outreach were not necessarily subject to the recordkeeping requirement of the juice HACCP rule, and we assume that the understanding of the term "perishables" by the respondents to that outreach was based on the conventional use of the term, rather than the definition of the term used in the PRIA.

In response to comments, the record retention requirements for nontransporters in the final rule now provide: (1) 6 months for food for which a significant risk or spoilage or significant loss of value occurs within 60 days under normal shipping and storage conditions for that food; (2) 1 year for food for which a significant risk of spoilage or significant loss of value occurs within 61 days to 6 months under normal shipping and storage conditions for that food; and (3) 2 years for food for which a significant risk of spoilage or

significant loss of value occurs greater than 6 months under normal shipping and storage conditions for that food.

(Comment 189) One comment suggests that the estimates of zero storage costs from records retention are too low. The comment estimates that offsite storage and recovery costs range between $2.50 and $3.50 per cubic foot per year.

(Response) The costs for records storage and retrieval are not zero, but the additional storage costs likely to be incurred by covered entities as a result of this regulation are assumed to be zero. We assume that the private benefits from retaining records for the 1 and 2 years time frames required by this rule exceed the private costs of doing so. The range of comments to the proposal suggests that this assumption is reasonable. The private benefits of retaining records include enhancing a firm's ability to do the following: (1) file claims for shortages in quantities or qualities of products received, (2) respond to claims for shortages in quantities or qualities of products shipped, (3) sue suppliers for damages resulting from products received, and (4) respond to suits filed by downstream users for damages resulting from products shipped. FDA also believes that most firms retain these records for at least two years for income tax purposes. Therefore, FDA is not persuaded by the comment that most firms do not currently retain these records.

Evidence gathered from interviews with FDA traceback investigation personnel indicate that current records retention practices in the food industry have not been a major obstacle to successful traceback investigations. In addition, comments suggest that records retention requirements should be linked to the shelf life of the product (which is presumably the current practice), and suggest retention times of 6 months to 2 years, depending on

the shelf lives of the products. FDA interprets this evidence to indicate that even in the absence of records retention requirements, the private incentives to retain records would result in records retention times in excess of those required in the regulation.

(Comment 190) One comment draws comparisons of the proposed records retention burden on small and large trucking firms. The comment contains a calculation of the number of records that would be required to be retained by a typical owner and operator of a single truck. The comment states that a 2 year retention requirement would obligate an owner and operator of a single truck to have on hand approximately 598 sets of load documents at any given time. If the average set of documents contained 20 pages, then this person would be required to retain approximately 11,960 pages at any given time. The comment suggests that this amount of documentation could be easily kept inside the truck in a side box and later transferred to an office corner or file cabinet at the owner's convenience. By assuming the number of documents to be retained by a firm is commensurate with the number of trucks owned by the firm, the comment argues that the proposed retention requirement would require large firms to retain an unreasonable amount of paperwork requiring substantially more storage space.

(Response) FDA notes that we computed the retention costs of the proposed rule on a per-facility basis and that we assumed that costs did not differ significantly from those of current business practices. The example documented in the comment illustrates the small amount of storage space that is required per facility. In the PRIA, FDA assumed that all firms keep most of the proposed records so that larger firms with a larger quantity of records may find it necessary to retain off-site records storage. In the final rule, FDA

has revised the recordkeeping retention and other requirements for transporters to be consistent with current requirements for interstate transportation. Consequently, the retention requirements from this final rule should impose no extra burden on these facilities.

(Comment 191) One comment from an association of wholesalers states that its members typically retain invoices and shipping records for approximately 6 months and will find it difficult to find the storage space to retain records under the proposed requirements. The comment states that a 2-year retention requirement would constitute a dramatic change in distributors' operations and lead to a substantial increase in data storage costs.

(Response) FDA does not agree that the retention requirements from this final rule will impose a large burden on food businesses. Only a small fraction of information is required to be added to existing records. Furthermore, based on preliminary research, a survey of dietary supplement manufacturers, and our interpretation of most of the comments to the proposed rule, the retention requirements in this final rule do not differ substantially from the industry norm. We believe that any change in practice from wholesalers that generates costs is mostly included in the estimated redesign and other set-up costs.

4. Records Access Costs

(Comment 192) One comment states that a 4 and 8 hour records access cost is an additional cost, because it requires retrieval on the weekends, which may require companies to renegotiate storage contracts to allow for weekend access.

(Response) FDA researched typical records storage contracts and found that at least one company's standard records retention contract explicitly provides that "unscheduled or emergency delivery of records" was to be

charged on a "per event" basis (Ref. 26). FDA assumes this to be the norm in the industry. For both the proposed and final rules, FDA does not estimate the probability of a records access request, and weekend access is assumed to be charged on a per-event basis, which is considered a cost of performing a records access request. Because the records access costs are estimated to be the private costs of planning for a records access request, rather than for performing a records access request, the estimates for planning for a records access request in the analysis of the final rule do not change.

(Comment 193) Many comments assert that the cost estimates for requiring 4 and 8 hour records access were too low or inappropriate. Comments support this assertion by citing factors ranging from the additional staffing requirements necessary to respond to a records request at such short notice, to the burden of a records access request being dependent on the number of records, and to the length of time covered by the records requested. Some comments state that a 48-hour records access requirement would be reasonable, and some comments state that 24 hours would be reasonable.

(Response) FDA acknowledges the difficulties faced by firms complying with the 4 and 8-hour records access requirements. This final rule requires providing access to records as soon as possible, but no later than 24 hours after an FDA request. The costs for 4 and 8 hours and 24 hours are analyzed as policy options later in this document. In the PRIA, we estimated the records access costs as the costs for planning for a records access request. FDA assumed that the 4-and 8-hour response time required would compel business practices to change as firms developed preemptive emergency plans, while a 24-hour response requirement would not compel firms to modify their current business practices. Interviews with FDA traceback personnel suggest that firms

are able to comply with a 24-hour records access request. Many comments support the notion that a 24-hour response time is not an unreasonable requirement given current business practices. Consequently, FDA maintains the assumption that a 24-hour records access requirement is reasonable under current business practices and that a 4 and 8 hour records access requirement would require additional planning for a records request.

Relaxing the records access requirement from 4 and 8 hours to 24 hours leads to an estimated cost savings relative to the PRIA. The access planning cost estimate assumed that 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) would be a one-time requirement for each firm. FDA estimated that new businesses would also have to incur records access costs. As a result of relaxing the records access request time to 24 hours, these costs will no longer be incurred.

5. Additional Records Maintenance and Redesign Costs

The cost estimates assume that the information a covered entity must keep is specified, but that the form or type of system in which those records are maintained is not specified; we expect that firms will collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements in the manner most economically feasible for them, including modifying shipping or purchase records, such as bills of lading, invoices, or purchase orders.

(Comment 194) Several comments question the format for presenting the additional required information and whether existing records could satisfy the requirements. These comments cite specific types of transactions to illustrate the difficulties in maintaining the required information on one form. In addition, several comments state that the required information is typically

available. One comment states that it is already standard business practice to maintain all required information on bills of lading in the trucking industry. Several comments state that FDA should maintain flexibility in the information required, as well as the type of forms maintained.

(Response) Neither the proposed nor final rule specifies the form or format in which records are to be established and maintained. There are no restrictions on the kinds of forms maintained. Commercial invoices, bills of lading, packing lists, and other forms commonly used when executing business transactions can all be used to record the information required by the regulation. We assume that most of the required information is already maintained on forms ordinarily used in conducting business. Persons subject to this final rule can choose to record the required information in one record or to use existing and newly created supplemental records to capture the required information.

(Comment 195) One comment requests clarification that "transportation record" includes the various documents that may be developed by a company and that it is not necessary to include all of this information in one shipping document. Furthermore, the comment asks us to clarify that existing records can be used to satisfy the requirements, even if they are not in the same location within the manufacturing facility (i.e., all required information is there, but not in the same location).

Others comment that the proposed regulation is not practical or reasonable, and fails to consider the business practices currently in place for food protection.

(Response) FDA believes that most of the information required by this regulation is currently collected as a matter of normal business practices and

that any changes to current business practices as a result of this final rule are small. The revised language in the final rule removing the requirement to record lot codes for distributor and retail facilities increases the agency's belief that changes to existing recordkeeping practices will be small.

(Comment 196) One comment states that the need for both manufacturers and third party warehouse or wholesalers to keep the records is redundant.

(Response) Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. It allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. In a traceback investigation, it is critical that FDA be able to locate and remove from commerce any adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 197) Several comments suggest that the information required by the proposed regulation is excessive and that it would require significant changes in business practices to collect and maintain the required information. One comment suggests that requiring records of names, addresses, and telephone numbers of each supplier for each transaction is excessive. A comment suggests that its firm has no way to capture all of the proposed data elements through current sources of transaction documentation.

(Response) FDA assumes, and comments agree, that most of the information required by this regulation is already collected and maintained through currently used transaction documents. The final rule requires lot codes or other identifiers only of persons who manufacture, process, or pack food, and only to the extent this information exists. The final rule also does not require that a responsible individual be identified for the immediate previous

source and immediate subsequent recipient for each transaction, as was required by the proposed rule. Accordingly, FDA does not modify its assumptions underlying the estimate of the costs of establishing and maintaining records.

6. Estimates of Additional Records Maintenance Costs Too Low

In the PRIA, FDA assumed that the burden of maintaining and collecting additional information would be shared among more than one facility.

(Comment 198) Comments state that FDA's estimates of recordkeeping burden obtained from the juice HACCP rule are inappropriate. The comments state that using the juice HACCP model substantially underestimates time requirements because most other types of firms would require more resources to achieve the proficiency required under the HACCP rule.

(Response) The juice HACCP cost estimates that we used to estimate costs in the PRIA were published before the juice HACCP rule took effect. The cost estimates for that rule were for firms that were not yet in compliance. FDA continues to believe that those cost estimates are an appropriate reference for this final rule, because they represent a precedent for cost estimates of activities similar to those required in this regulation.

(Comment 199) According to numerous discussions with those who are subject to HACCP regulations, the time and money estimates of the costs FDA provided in the seafood HACCP rule were about 1/10 the actual values. This represents a big underestimate of the true costs of the regulation.

(Response) The costs estimated in the PRIA use cost estimates of the juice HACCP rule as a reference, not those of the seafood HACCP regulation. FDA has also received information that costs for compliance with the seafood HACCP rule were underestimated. FDA developed the estimates for the juice

HACCP rule much later than those for the seafood HACCP rule. In addition, the burden for the additional records maintenance required in this final rule is considerably less than that required by the juice HACCP rule, particularly because FDA has relaxed the requirement for maintaining lot code information in the final rule and removed the requirement to record and maintain contact information for each transaction.

(Comment 200) Some comments state that FDA failed to account for the effect of higher transaction costs (as a result of the regulation) on reducing arbitrage opportunities. Food arbitrage is a line item in most food distributors' and retailers' financial statements. The comments assert that this final rule will result in fewer arbitrage opportunities, because the cost of a transaction will rise, which will cause a substantial reduction in profits, encourage layoffs, and raise consumer prices.

(Response) FDA agrees that the recordkeeping provisions in this regulation may increase the costs of transactions, thereby decreasing the total number of transactions. FDA believes, however, that transactions will be only slightly costlier and the effect on consumer prices and arbitrage opportunities will be small.

(Comment 201) One comment urges FDA to clarify and confirm that it would not consider records identifying producers of coffee cherry for traceback purposes as information that would be considered to be "information reasonably available." The comment states that it would be prohibitively costly to link the identities of individual coffee cherry growers to any processed food item, because the cherries from many growers are typically mixed upon delivery to a processing facility.

(Response) Both the proposed and final rules require incoming ingredients to be linked specifically to outgoing food products only if that information is reasonably available (as discussed previously). What is reasonably available is determined on a case-by-case basis and depends on the operating practices of a specific facility. FDA does not intend the rule to require covered entities to reconfigure their operations. If cherries from many growers are typically mixed (i.e., commingled), then full information linking ingredient source to final product may not be reasonably available. If, however, the cherries are in separate bins based on supplier or easily can be separated and identified, then full information linking source to final product may be reasonably available. In the PRIA, FDA acknowledged the prohibitive cost of a policy option requiring producers to be able to link specific ingredients to specific food products (option 13 in the proposal). That option was ultimately rejected, in part, because of the high cost of identifying the producers of traditionally commingled raw commodities. Instead, both the proposed and final rules required linkage only when the linkage is reasonably available.

7. Labor Cost Estimates

(Comment 202) Several comments suggest that the wage rate used by FDA in the PRIA of $25.10 is too low. One comment suggests that an hourly wage of $33 would be more appropriate for the analysis, because it would reflect the need for higher-level personnel involvement due to complexities in the proposed rule. Another comment suggests that the $25.10 wage is reasonable, but that the hour estimates are too low.

(Response) FDA disagrees with the suggestion to increase the wage rate used in the analysis because the implied annual wage and overhead cost of

more than $52,000 seems more than reasonable, as suggested in another comment.

(Comment 203) One comment argues that there is no evidence that the wage of $25.10 used in the analysis has been doubled to account for overhead in any of the calculations.

(Response) The hourly wage of an administrative worker reported by the Bureau of Labor Statistics of about $12.55 was doubled in the computations to account for overhead costs. FDA acknowledges that this was not clearly stated in the PRIA.

8. Learning Costs

(Comment 204) Some comments state that FDA's estimate of 3 hours for learning costs is low. The comments state that access to the Internet and lack of fluency in English are not the only costs. The comments maintain that learning cost estimates did not include the time for an FDA explanatory video and did not include adequate time for evaluating the information in the rule.

(Response) Although the comment states that 3 hours is too low an estimate, the comment did not indicate how the learning cost estimates as a whole, or any of the component cost estimates, can be improved. FDA explicitly incorporates the costs of searching, learning, and comprehending the rule in the PRIA. Learning cost estimates are composed of costs for searching for a copy of the requirements, and reading and understanding them. Because of the approximate nature of the calculation, FDA rounds up to the nearest half hour to 3 1/2 hours for the time required for reading and comprehending the requirements of this final rule for all English reading users. Although the cost of viewing the explanatory video was not explicitly included in the PRIA, such a viewing was assumed to reduce the burden from other searching and

learning activities. Consequently, in the analysis of the final rule, FDA maintains the learning costs estimates used in the PRIA.

9. Specific Sector Cost Estimates

a. *Transportation and warehouse sector.* (Comment 205) At least one comment states that trucking companies already maintain the required records to comply with another Federal regulation and therefore additional Federal requirements would be duplicative.

(Response) FDA has included several options in this final rule for transporters to comply with their obligations to establish and maintain records under this final rule. One option is for transporters to keep some of the records currently required by the FMCSA regulations as of the date of publication of this final rule. The FMCSA regulations already require interstate transporters to establish and maintain transportation records, and we assume that interstate transporters who already comply with the FMCSA recordkeeping requirements will choose to comply with this final rule by maintaining such records. However, the FMCSA regulations cover only interstate common carriers, while this regulation covers all persons who transport food, including intrastate carriers. Moreover, domestic air carriers, and interstate transporters of low-value packages may not be required to comply with FMCSA regulations. Consequently, as a result of this final rule, intrastate carriers, intrastate shipments by interstate carriers, domestic air cargo carriers, and transporters of low-value packages may incur recordkeeping costs, in addition to learning costs, as a result of this final rule.

To estimate the costs incurred by intrastate carriers, domestic air cargo carriers, and transporters of low value packages, we first estimate the number of facilities that engage in only intrastate food transportation. Then, we adjust

this number to account for domestic air cargo carriers of food shipments and carriers of low-value food packages. Additional records maintenance costs incurred by interstate carriers of intrastate shipments are estimated to be zero since it is unlikely that a transportation establishment would use two sets of recordkeeping practices.

To determine the number of intrastate carriers subject to this final rule but not subject to FMCSA requirements, we take a weighted average of the ratios of local to total general freight trucking in the CBP data under NAICS code 4841, and the local to total specialized freight trucking in the County Business Pattern data under NAICS code 4842. Weights are applied to reflect the importance of local specialized and local general freight in all local trucking to estimate the overall number of intrastate carriers. This computation estimates that 50 percent of all freight carrying trucks are intrastate carriers. Consequently, we assume that 50 percent of all transportation facilities are not already subject to recordkeeping requirements under FMCSA, and will incur the full records redesign and additional records maintenance costs of this regulation.

The total number of domestic air cargo carriers of food packages is estimated from NAICS code 481112 in the CBP and NES data which was used for estimating the total number of transporters in the PRIA. Since not all of the carriers reported under NAICS code 481112 transport food items, we used a factor of 50 percent to scale data from the CBP and the NES to estimate the number of air cargo carriers that have a significant portion of their business transporting food items. The resulting estimate of the number of air cargo carrier facilities that transport food items is approximately 1,825 or 0.078 percent of the total number of transporters. These facilities will incur records

redesign costs and additional records maintenance costs, in addition to learning costs as a result of this final rule.

The number of carriers of low-value food items is estimated using the number of couriers under NAICS code number 49211, which was not included in the PRIA. According to the U.S. Census Bureau, this NAICS includes establishments primarily engaged in providing air, surface, or combined courier delivery services. From the CBP and NES statistics there are approximately 141,931 establishments engaged in courier services. Since this includes courier services that use both air and surface transportation, we reduce this number by 50 percent, under the assumption that only establishments engaged in surface courier services are likely to carry food items, resulting in an estimate of 70,965 surface courier facilities.

Most surface courier services may carry food items as an incidental part of their business and will incur learning costs as a result of this rule. However, only a small fraction will carry food items as a significant part of their business and will incur additional records maintenance and records redesign costs. We estimate that 10 percent of surface couriers services will have more than an incidental portion of their business transporting food items and will incur records redesign and additional maintenance costs in addition to learning costs. This is consistent with the fraction of restaurants that report retail sales as a secondary activity of their establishment (Ref. 29). The resulting estimated number of surface transporters of low-value packages of food items that would incur additional records maintenance and records redesign costs is 7,097 facilities.

(Comment 206) Several comments suggest that transportation carriers have only a limited knowledge of the contents of the packages that they carry and

should not be held liable for much of the information. These comments suggest that transporters have detailed information on sources and recipients of the products that they carry but do not have the capacity to track other details of the contents of the packages, such as lot codes and other details. For example, one comment states that air carriers typically rely on the shippers for information, and shipments may not be identified as containing food. Others comment that because carriers lack knowledge of the contents of packages, the default records retention times for all shipments will be the longer required time of 2 years, even if the contents are perishable products. The comments state that this 2-year default retention time will only add to the records retention burden already faced by many trucking firms.

(Response) FDA acknowledges that, currently, the transporter may have limited knowledge of the contents of the packages that it carries and that an undue records retention burden would result if the default would be the longer retention period. FDA notes, however, that under this final rule transporters must know that they are transporting food and be able to record a description of that food. Nonetheless, FDA has relaxed the records retention requirement for transporters from the proposed rule to this final rule. Transporters, or nontransporters retaining records on behalf of a transporter, are required to retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released. FDA also has codified in this final rule an option for transporters to comply with recordkeeping

requirements of this final rule by keeping records already required by the existing bill of lading requirements applicable to interstate transporters.

(Comment 207) One comment expresses concern that differing knowledge of the contents of food packages between transporters and nontransporters would require standards of information exchange to be created to coordinate the contents of records maintained by the two types of entities. The comment suggests that without such standards, the coordination costs may be high, because certain records maintained by nontransporters would need to be exchanged with transporters for them to have the full knowledge of the contents and extent of the packaging. Failure to create these standards would result in elevated costs for transporters.

(Response) FDA acknowledges the limited knowledge that transporters currently may have about the contents of the packages that they carry. FDA has included less detailed information requirements in the final rule to respond to these comments; however, FDA believes the information it is requiring is necessary to allow the FDA to conduct a tracing investigation efficiently and effectively. In addition, FDA included an option whereby transporters can fulfill their recordkeeping requirements by keeping records already required for interstate transporters. Furthermore, the final rule provides an option allowing transporters to enter into a contractual arrangement with the non-transporter immediate previous source located in the United States or with the non-transporter immediate subsequent recipient located in the United States; any contractual arrangements would redistribute the burden of establishing and maintaining transportation records between transporters and non-transporters but would not change the total recordkeeping costs since the same number of records would be established and maintained under all

negotiated arrangements. FDA assumes that current business practices are the low-cost arrangement for the establishment and maintenance of records and does not revise its estimate of recordkeeping costs to account for higher coordination costs between transporters and nontransporters.

(Comment 208) Some comments state that FDA's estimated cost per facility in the public warehousing sector is likely to be incorrect because of the apparent assumption that costs incurred would be similar for both a public warehouse and a wholesaler. The comments argue that, because wholesalers own a product, they are more knowledgeable about its contents and packaging than are warehouse facilities. The comment notes that a warehouse is a third party provider of warehousing, storage, and other value added services; does not have direct knowledge of where a product originates; and may not have full knowledge of the contents and packaging of a product, or of the product's next destination. Another comment states that the information asked for in the proposal is reasonable, but that this information will be difficult, costly, or impossible to obtain for public warehouse facilities.

(Response) FDA acknowledges that warehouse facilities and wholesalers perform different functions. FDA has accounted for the differences in its cost estimates. The NAICS definition of the wholesale trade includes, "* * * selling merchandise, generally without transformation* * * to other business* * *." The definition also characterizes wholesalers as normally operating from a warehouse or office (Ref. 27). In contrast, the NAICS defines the warehousing and storage sector as providing facilities to store goods but not sell the goods that they store. In addition, warehouse facilities may also provide logistical services for the goods that they store (Ref. 27).

Although the warehouse and wholesaler functions are clearly different, FDA assumes that both kinds of facilities would have records giving an immediate previous source and an immediate subsequent recipient of the product. Because warehouse facilities do not take ownership of the products that they handle, they may not have specific information about the products and their packaging.

In the course of their day-to-day business dealings, warehouses may not be privy to a description of the type of food or details of its packaging sufficient to satisfy this regulation. To acquire this knowledge and maintain the required records, warehouses may incur costs in addition to those that would be incurred by the owners of the product. FDA assumes that as part of their normal business practices, warehouse facilities may be required to maintain a limited amount of information on the immediate previous source and immediate subsequent recipient of a comparable magnitude to that of the owners of the products. However, the detailed information on the product and its packaging required by the regulation may be more costly to obtain for warehouse personnel than for the owners of the product. For some products, warehouse facilities are assumed to have the same required knowledge of the required information on the stored product and its packaging as that of the owner of the product. For other products, the warehouse personnel's knowledge of the required information on the stored product and its packaging is less than that of the owner. We estimate that, for half of all food products stored, warehouse personnel have the same amount of the required knowledge of the food and its packaging as the owner of the product, and that the additional records maintenance costs would be comparable to those incurred by the product owners. For products for which warehouses currently lack the

required knowledge, we assume that the additional records maintenance costs for warehouse facilities would be approximately 50 percent higher than those for owners of the products. Much of the extra cost may involve contracting with product owners to provide the required information.

b. *Interstate conveyances and catering services sector.* (Comment 209) Several comments suggest that the costs to the interstate conveyance catering industry were greatly underestimated and that this sector should be excluded from the regulation. One comment states that for airline caterers, each flight typically includes hundreds of individual foods from scores of different sources and suppliers. The comment further states that this industry is further complicated by the large number of special meal requests by individual passengers on each flight.

(Response) In the PRIA, we assumed that persons subject to this final rule may be required to add a limited amount of new information to existing transactions records, such as bills of lading, commercial invoices, and other shipping documents. We did not model the costs of compliance for each sector in the food economy, and assumed that the private incentives to maintain most, if not all, of the required information were sufficient. Examples of private incentives to maintain the required records are provided in our response to comment 189. Moreover, we do not require that the information be in any particular form or format, which further reduces the potential costs of compliance.

c. *Pet foods sector.* (Comment 210) Some comments suggest that FDA eliminate requirements for pet food because the risk of exposure through that sector is small. Other comments acknowledge potential targets and impacts

from terrorist attacks through the pet food sector and encourage FDA to require all in the pet food sector to be subject to the final rule.

(Response) In the proposed rule, pet food not subject to the BSE rule was excluded from the requirement to establish and maintain records. In this final rule, all animal feed entities, including all pet food entities, are subject to all requirements of the rule, but have a records retention requirement of 1 year. There are approximately 19,600 facilities that were excluded in the proposed rule and that have been included in this final rule. In the PRIA, rather then estimate the cost savings from excluding these facilities from complying with the regulation, we noted that the costs were overestimated because pet food facilities were included in the estimates. In the final rule, pet food entities are subject to the regulation and are included in the cost estimates.

d. *Food contact substances and the packaging sector.* (Comment 211) FDA received many comments that FDA underestimated the number of facilities covered by the definition of substances and components of substances that contact food. One comment states that FDA does not include the "upstream" manufacturers that make ingredients and components that go into food packaging who would be required to comply with the recordkeeping provisions of this regulation. The comment further states that there is no logical conclusion to this chain. Some other comments assert that FDA did not account for warehouses that hold articles that can migrate to food from food packaging, or other articles that contact food.

Another comment states that FDA's count of the number of domestic facilities is overly inclusive if FDA's intention is to include only finished packaging and that the Operational and Administrative System for Import Support (OASIS) database used for the count of foreign facilities does not

include suppliers of food contact articles. Other comments indicate that FDA understated the number of facilities covered by the regulation by not identifying transporters of food contact materials, and that the 20 NAICS codes do not cover all food packaging manufacturers and distributors. Several comments state that all packaging firms handle both outer packaging and food contact substances, and for all practical purposes, will have to track all products they produce, because they may not know if a shipment is destined for food or nonfood use. One comment states that FDA's count of foreign facilities from OASIS did not include all imported food contact substances.

(Response) The final rule does not require persons who manufacture, process, pack, transport, distribute, import, receive, or hold packaging (the outer packaging of food that bears the label and does not contact the food) to establish or maintain records. However, these persons are subject to the records access requirements with respect to any existing records if they also engage in another regulated activity with respect to the food in, or to be placed in, such packaging. Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. Moreover, all other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the establishment and maintenance requirements with regard to the finished container, and are only subject to the records access provisions for existing records under §§ 1.361 and 1.363.

In the final rule, records access costs are estimated to be zero and we assume that the only costs incurred by persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that

directly contacts the food are learning costs. Because the economic burden on these facilities in the final rule has been substantially reduced from that estimated in the PRIA, we assume that the impact on costs of any possible underestimation of their numbers will be very small.

e. *Foreign facilities and related impacts.* (Comment 212) There were many comments that state that the expansion of requirements to foreign facilities would have a large impact on international trade by making imports more expensive. Some comments state that costs for compliance by developing countries were underestimated in the PRIA because their labor and technology are so different from those that prevail in developed countries.

(Response) In the final rule, all foreign persons are excluded from all requirements in this rule, except for foreign persons who transport food in the United States. Because all foreign persons who transport food in the United States are currently subject to FMCSA regulations as interstate transporters, and can meet the requirements of transporters in subpart J of this final rule by keeping records already required by FMCSA, the costs of compliance for these facilities, including the costs for the records access requirement, are assumed to be zero.

(Comment 213) One comment questions the implied assumption in the PRIA that foreign transporters share the cost burden with other foreign facilities when foreign transporters are not covered by the rule.

(Response) Foreign persons who transport food in the United States are covered by this final rule. The revised costs of compliance by these facilities to establish and maintain records are assumed to be zero because they will be in compliance with this final rule if they keep the records currently required by FMCSA for interstate transporters.

10. Compliance Dates

Several comments suggest changes in the compliance dates. In the design of the regulation, the compliance dates are used primarily to address regulatory flexibility considerations. Consequently, these comments are treated in the regulatory flexibility section of the final analysis.

G. Summary of the Costs and Benefits of the Final Rule and Policy Options Considered

The revisions to the cost estimates based on comments to the proposed rule and on changes in records requirements between the proposed and final rule result in estimated costs of approximately $1.41 billion expressed in present value terms, using a 7-percent discount rate. Using a discount rate of 3 percent, the estimated costs of the final rule expressed in present value terms are approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the final rule, beginning in the second year for large and small firms and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The details of the assumptions used to estimate the costs are provided in the PRIA. The estimated total cost is computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 15 of this document.

TABLE 15.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,000
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.
[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during a foodborne outbreak by reducing the time required for preventive action. Furthermore, the final rule will reduce the recurrence of outbreaks that may have been prevented had nonexistent or poor records quality not resulted in prematurely terminating the initial traceback investigation. In addition to relaxing elements of the requirement for records to contain lot code information, the reduction in benefits from the final rule compared to the proposal results from excluding foreign facilities except those that transport food in the United States, relaxing recordkeeping requirements for food contact substance facilities, relaxing recordkeeping requirements for very small retail facilities, adopting retention requirements based on the NIST food shelf life definitions, and relaxing the records access requirement from 4 and 8 hours to as soon as possible, not to exceed 24 hours.

The estimated costs and benefits of many policy options considered in this section summarize the details of the analyses based on the comments FDA received and are reported in the following tables. The costs for the options are reported in present value terms for both 7 percent-and 3-percent discount rates. We summed the discounted annual costs over a 20 year horizon to obtain the estimate of the total costs. A 20-year horizon for measuring the costs from the regulation is reasonable, given uncertainty in the regulatory environment and technological change. The reduction in benefits relative to the proposal

from each modification is based on the impact that each option would likely have on traceback times and the rates of traceback completions. Again, the benefits are based solely on food safety concerns (i.e., typical traceback scenarios with which FDA has been involved) and do not take into account food security concerns.

In table 16 of this document we compare the costs of the options considered to the baseline option of the proposed rule, with the caveat that the provision requiring all records to contain lot code information, which was included in the proposed rule, is no longer in the baseline. All other provisions included in the proposed rule are in the baseline for this analysis.

All options consider relaxing one provision, or excluding one sector from the recordkeeping requirements. In that way, a comparison of the cost of a policy option with the cost of the baseline yields the marginal cost savings from either relaxing a provision in the baseline, or reducing the coverage by one sector relative to the baseline. The columns containing the absolute amount and percentage cost savings show the savings relative to the baseline. In the final rule reported in table 18 of this document, the provisions requiring lot code information, 4- and 8-hour records access, and short compliance dates are all relaxed to yield cost savings relative to the baseline. Additional cost savings result from excluding the following: (1) Foreign persons, except for foreign persons who transport food in the United States; (2) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances except the finished container that directly contacts the food; and (3) persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished containers that directly contacts food except for those who place food directly in contact with its finished container.

The option to relax the requirements for all records to contain lot code information when feasible saves more costs relative to the baseline than any other option. The cost savings from relaxing the lot code information requirement is approximately $13 billion in present value terms with a 7 percent discount rate, and $18 billion with a 3 percent discount rate. Based on detailed information in the comments, requiring lot code information to be contained in all records by retailers and distributors would result in approximately an 80 percent loss in productivity for distributors and retailers.

Excluding many foreign persons and relaxing the 4- and 8-hour records access requirement also result in significant cost savings. By excluding all foreign persons except those who transport food in the United States, approximately 225,000 facilities would not have to establish and maintain records relative to the baseline. This exclusion results in a cost savings of approximately $770 million, or 19 percent, relative to the baseline in present value terms when a 7-percent discount rate is used, and a savings of $1 billion when a 3 percent discount rate is used. A 24-hour records access requirement results in a cost savings of approximately $260 million relative to the baseline with a 7-percent discount rate, and $318 million with a 3-percent discount rate.

Extending the compliance dates and broadening the scope of foods subject to the limited 1-year records retention period relative to the baseline are all provisions in the final rule. Cost savings from extending the compliance dates by 6 months relative to the baseline result from reductions in inventory losses and discounts in the costs realized when incurred 6 additional months into the future. These cost savings are approximately $271 million relative to the baseline with a 7-percent discount rate, and $163 million with a 3 percent

discount rate. Adopting retention requirements based on NIST definitions based on shelf life is not assumed to increase costs, but will reduce the benefits by a negligible amount.

Throughout the analysis, we have estimated costs based on the number of facilities, and assume that this number, whenever used, approximately reflects the number of persons covered by the regulation. The revised number of facilities covered by the final rule is estimated to be 707,672 (including persons who manufacture, process, pack, transport, distribute, receive, hold, or import food, and foreign based transporters that transport food in the United States). Learning costs are assumed to be incurred by all facilities and persons 2 years following enactment of this final rule and are computed by multiplying the number of facilities by the cost of learning per facility. Based on details outlined in the proposed rule, learning costs are computed using a $25.10 wage rate and 4.5 hours spent learning for Internet users (approximately 71 percent, and 5.5 hours spent learning for non-Internet users). The total learning costs are computed to be $85,082,000.

Records redesign costs are assumed to be incurred by approximately 101,153 large and small firms 2 years following issuance of this final rule and by 222,316 very small firms after 3 years following issuance of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food, and foreign based transporters that transport food in the United States are assumed not to incur records redesign costs. In this analysis, FDA assumed that all sizes of firms will bear the $1,365 per-firm records redesign cost estimate that was used in the proposal as the most likely records redesign cost for small and very small

firms. The redesign costs are $53,508,000 after the second year and $151,731,000 after the third year following issuance of this regulation.

FDA assumes the additional records maintenance costs to be incurred by 110,081 large and small facilities 2 years following issuance of this final rule and by 379,493 facilities after 3 years and for all subsequent years following issuance of the final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food and foreign based transporters that transport food in the United States are assumed to not incur additional records maintenance costs. FDA assumes the 34,634 convenience store facilities will spend 2.5 hours per year and that persons who directly market food are excluded from the rule. All other facilities (344,859) will spend 13 hours per year on additional records maintenance at an hourly cost of $25.10. The undiscounted total additional records maintenance costs 2 years following enactment of the rule are $70,745,000. After 3 years, and for each subsequent year, the undiscounted additional records maintenance costs are $114,701,000. The annual costs for records access planning and for records retention for all persons are assumed to be zero in the final rule.

The following table includes the estimated reduction in benefits relative to the proposal from policy options that would exclude select sectors from recordkeeping requirements, or that would relax certain provisions, which are considered in detail earlier in this analysis. The benefits from each policy option are ranked by size, so that policy options that would result in large reductions in benefits relative to the proposal are ranked highest, where a ranking of one represents the largest reduction in benefits relative to the proposal.

The reduction in benefits from relaxing the requirement for all persons to establish and maintain records containing lot numbers is very high. With lot codes contained on all records, the duration of a traceback investigation for many products would likely be between 1 and 14 days (estimated current times for many packaged products that contain all lot code information on the package). Relaxing the lot code requirement may increase the traceback times of these products to between 6 to 8 weeks (estimated current times for many fresh products not accompanied by lot code information). Relaxing the requirement for all records to contain lot code information leads to the largest reduction in benefits relative to the baseline.

The reduction in benefits from excluding all foreign persons except those who transport food in the United States is considerable because the large number of excluded entities increases the likelihood of hampering traceback investigations. Moreover, the risk of contamination (unintentional) is generally higher for many products earlier in the supply chain. In addition, enforcement costs for foreign persons would likely be prohibitively high—decreasing the likelihood of obtaining records required for a traceback even if these persons were covered. When compared to the eight other individual options considered for the final rule, the large number of excluded foreign persons ranks third highest of the reductions in benefits relative to the baseline considered. This reduction in benefits, however, is mitigated in one respect: The risk of not being able to complete traceback investigations due to this exclusion is considered low because most of these foreign entities occupy positions early in the supply chain.

The reduction in benefits from relaxing the recordkeeping requirements for persons who manufacture, process, pack, transport, distribute, import,