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, receive, or hold food contact substances other than the finished container that directly contacts the food, and who manufacture or process the finished container that directly contacts the food, as estimated by the number of applicable facilities, is small. Although relaxing requirements for these persons may expose a "soft target" for intentional contamination, the probability of foodborne illness from unintentionally contaminated food contact substance and finished container material is low. Furthermore, the likelihood of needing records from food contact substance and finished container facilities during traceback investigations is also low. When compared to the other issues considered for the final rule, relaxing the requirements for these persons ranks only seventh in the reductions in benefits relative to the baseline.

The reduction in benefits from relaxing the requirement to access records within 24 hours from 4- and 8-hour requirement would be substantial. We estimate that relaxing the records access requirement would increase the amount of time for any preventive action to be taken during a traceback investigation by about 5 days relative to the baseline, if all persons subject to an access request took the full 24 hours to respond. The loss of time relative to the baseline would limit the preventive benefits for 15 percent to 18 percent of outbreaks. Relaxing the record access requirement from 4 and 8 hours, to within 24 hours ranks second in reductions in benefits relative to the baseline.

The reduced benefits from extending the compliance period by 6 months for each person subject to the final rule are a twofold increase in the number of outbreak victims relative to the baseline in the first year only. Baseline benefits reduce the impact of 15 percent to 18 percent of outbreaks and eliminate the problem of prematurely terminated investigations because of poor records quality (i.e., about 10 percent of the total number of traceback investigations estimated from FDA outbreak investigation information). Extending the compliance dates by 6 months ranks sixth in the reductions in benefits relative to the baseline.

We estimate that allowing transporters to comply with this final rule by complying with existing requirements (e.g., records already required by FMCSA) will have a negligible impact on the benefits relative to that from the more comprehensive requirements of the proposal. Option 7 in table 16 of this document incorporates a 24-hour access provision, 6, 12, and 24 month retention requirements, extension of the compliance dates, and adjusted recordkeeping requirements for transporters based on existing requirements. In table 18 of this document, the costs and benefits of the final rule are compared with those from the adjusted comprehensive coverage of option 7 in table 16 of this document.

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
Baseline[1]: Proposed rule except requirement for all records to contain lot codes is relaxed.	$4.0 billion	$5.27 billion		

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS—Continued

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
(1) Baseline except existing interstate transporter requirements are sufficient.	$3.78 billion	$4.97 billion	No reduction[2]	1
(2) Baseline except retention of 6, 12, and 24 months per NIST standards	$4.0 billion	$5.27 billion	Negligible reduction	2
(3) Baseline except food contact entities are excluded.[3]	$3.92 billion	$5.16 billion	Exclude 37,000 facilities near the top of supply chain. Low risk of contamination and low risk of loss of the paper trail.	3
(4) Baseline except compliance dates are extended by 6 months.	$3.73 billion	$5.10 billion	An estimated one-time, two-fold increase in the number of victims compared with the baseline in the first year only.	4
(5) Baseline except foreign facilities are excluded.	$3.23 billion	$4.26 billion	Exclude 225,000 facilities near the beginning of the supply chain. Very high cost of enforcement and access.	5
(6) Baseline except relax records access from 4 and 8 hours, to 24 hours.	$3.74 billion	$4.95 billion	Adds a maximum of about 5 days to the time for preventive action during an outbreak.	6
(7) Adjusted comprehensive coverage	$2.59 billion	$3.57 billion	Incorporates all policy options and adjusted numbers of facilities	

[1] Note that option 1 is used as the baseline in the descriptions of all other options. The variation of the proposed rule with the relaxed lot code requirements is used as the baseline in this table because the high cost of requiring lot codes on all records ($16.58 billion) is overwhelming. While the reduction in benefits from relaxing the lot code requirements is also large, we thought that the inclusion of that option in this table would confuse the presentation and add little practical value to the policy analysis.

[2] Because this chart only reflects food safety, it does not include classified food security scenarios which envision intrastate shipments being targeted for tampering.

[3] This option overstates the cost reduction from provisions in the final rule that exclude food contact substance entities since it assumes that they will not have to incur learning, records redesign, and additional records maintenance costs. In the final rule these entities will incur learning costs since they will still be subject to access requirements for records that they keep during the course of normal business activity.

We constructed the policy options reported in the following tables to provide a range of net benefit and cost effectiveness measures for alternative coverage options. The records access, retention, and compliance date provisions, as well as the requirements for transporters for all options reported in the following tables, are the same as those reported for option 7 in the previous table. In addition, coverage for the option entitled "all entities" is the same as that for option 7 in the previous table. Persons handling the finished container that contacts food are excluded from all of the following coverage options for the policy reasons stated previously. However, while persons handling the finished container that contacts food other than those who place food directly in contact with the finished container, are not required to establish and maintain records in the final rule, they are required to provide access to FDA to existing records if the conditions for access are satisfied. This requirement is implicit in all of the options with different coverage reported in the following tables.

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
Option						
Adjusted Comprehensive	All	All	All	All	All	All

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS—Continued

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
A		All				
B	All					
C		All	All			
D		All	All	All		
E		All	All	All	All	
F		All	All	All	All	All
G (final rule)	Exclude very small	All	All	All	All	All
H	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small
I	Exclude very small	All	All	All	All	Only interstate

Note: Very small firms are defined as those with fewer than 10 full-time equivalent employees.

In the following table, costs, food safety benefits, and cost effectiveness measures are reported for each of the coverage options described in the above table, and the final rule. Costs are reported in terms of annualized costs and incremental costs using a 7-percent discount rate over a 20-year horizon. Benefits are reported in terms of the annual number of food safety illnesses averted (reported and unreported), and the incremental number of illnesses averted. The estimates of the numbers of averted illnesses should be interpreted as minimum values because they relate to only the food safety benefits; bioterrorism considerations are not incorporated into the estimates. Cost effectiveness measures are in terms of the incremental costs per averted illness, and the average cost per averted illness.

The incremental cost per averted illness is used to measure the relative cost effectiveness of an option when compared with successively more stringent requirements. It is computed by dividing the incremental costs from the option by the incremental benefits. Since option H averts a larger number of illnesses at lower cost then options A through F, option H dominates the other options and they can be eliminated from further consideration in an incremental cost effectiveness analysis. Thus, the cells for computing the incremental costs per averted illness for those options are left blank in table 18 of this document. Similarly, through the principle of weak (or extended) dominance, option I can be eliminated from the incremental cost effectiveness analysis. (For a full discussion of extended dominance in cost-effectiveness analysis, see Gold, M.L., J.E. Siegel, L.B. Russell, and M.C. Weinstein, "Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine, Oxford University Press," New York, p. 286, 1996). Consequently, only options H, the final rule, and the adjusted comprehensive coverage are used to measure the incremental cost effectiveness. We assume that bioterrorism considerations would not alter the relative order of the number of illnesses averted across all options.

The average costs per averted illness reported in table 18 of this document are calculated by dividing the annualized costs by the total number of illnesses averted for each option. The average costs per averted illness is the cost-effectiveness of each option relative to the baseline. For the final rule, the average cost-effectiveness expressed in costs per illness prevented is $110,000 discounted at 7 percent and $108,000 discounted at 3 percent.

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option A	$40,975,852		245			$167,248
Option C	$56,753,102		316			$179,598
Option D	$67,712,296		355			$190,739
Option E	$69,902,094		359			$194,713
Option B	$135,636,340		572			$237,126
Option F	$119,792,995		621			$192,903

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS—Continued

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option H	$30,610,378	$30,610,378	1,067	1,067	$28,688	$28,688
Option I	$106,138,020		1,072			$99,009
Final Rule	$132,750,092	$102,139,714	1,204	137	$745,545	$110,258
Adjusted Comprehensive	$244,134,086	$111,383,994	1,282	78	$1,428,000	$190,432

The distribution of the number of illnesses averted due to faster traceback investigations and more successfully completed traceback investigations for each policy option are also reported in the following tables. Of the 800 annual food safety illnesses averted due to improved recordkeeping practices, about 600 can be attributed to more successfully completed tracebacks, and about 200 from faster tracebacks. The sum of averted illnesses from faster tracebacks, plus that from more successfully completed tracebacks may differ from that reported in the table of totals because of rounding in the computations.

TABLE 19.—ALL AVERTED (REPORTED AND UNREPORTED) FOOD SAFETY ILLNESSES PER YEAR

	Mean	Low	High
Adjusted Comprehensive	1,282	0	6,400
Option A	245	0	1,079
Option B	572	0	2,660
Option C	316	0	1,452
Option D	355	0	1,612
Option E	359	0	1,750
Option F	621	0	2,846
Final Rule	1,204	0	6,061
Option H	1,067	0	5,372
Option I	1,072	0	5,504

TABLE 20.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM FASTER TRACEBACK INVESTIGATIONS

	Mean	Low	High
Adjusted Comprehensive	451	0	2,692
Option A	83	0	513
Option B	206	0	1,278
Option C	111	0	691
Option D	122	0	755
Option E	124	0	763
Option F	184	0	1,078
Final Rule	425	0	2,532
Option H	387	0	2,307
Option I	396	0	2,414

TABLE 21.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM MORE SUCCESSFULLY COMPLETED TRACEBACKS

	Mean	Low	High
Adjusted Comprehensive	826	0	3,024
Option A	161	0	605
Option B	364	0	1,296
Option C	203	0	778
Option D	232	0	864
Option E	234	0	864
Option F	434	0	1,728
Final Rule	775	0	2,592
Option H	676	0	2,592
Option I	673	0	2,592

The next table shows the food safety benefits as the number of averted illnesses valued by the low, middle, and high cost of illness estimates, and for the $5 million and $6.5 million estimates of the value of a statistical life. These are estimated annual food safety benefits and should be interpreted as minimum benefits from this final rule because food security benefits are not included.

TABLE 22.—VALUE OF AVERTED FOOD SAFETY 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.

V. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the final rule on small entities. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities.

We estimate that more than 75 percent of all businesses covered by this final rule are small or very small. The undiscounted per-facility costs for small and very small businesses are reported in the following table. Costs for learning and records redesign are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance 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.

TABLE 23.—ESTIMATED PER FACILITY RECORDKEEPING COSTS

21 CFR Section	Costs
1.337, 1.345, and 1.352 (learning)	$120.00
1.337, 1.345, and 1.352 (records redesign)	$411.00
1.337, 1.345, and 1.352 (additional records maintenance)	$219.00

Comments Summary

Comments cover topics such as reasons why staggering compliance dates will not achieve regulatory flexibility objectives, suggestions of regulatory alternatives that would achieve regulatory flexibility objectives, appeals to consider the cumulative costs of all four bioterrorism regulations together when considering the impact on small businesses, appeals for exclusion of certain categories of small businesses, as well as other general topics. The different categories of comments are summarized in the following paragraphs.

(Comment 214) One comment finds the definition of "small business" uncertain and asks whether it is based on either the number of employees at a

firm or the number of employees at a facility.

(Response) The U.S. Small Business Administration (SBA) establishes small business definitions (or size standards) by industry (Ref. 28). The most common SBA size standard applicable to manufacturers covered by this final rule is 500 employees. Other pertinent SBA size standards include 100 employees for wholesale distributors, $21.5 million in receipts for transporters, and $6 million or $23 million in receipts for retailers, depending on the type of store. After discussions with the SBA, we define a small business in the food industry as having more than 10 and fewer than 500 full-time equivalent employees, and we define very small firms as having 10 or fewer full-time equivalent employees.

Firm size, rather than facility size, is used in the cost estimates for regulatory flexibility purposes whenever the data permit. For purpose of the compliance dates, the firm size governs. For purpose of the retail exclusion, the number of employees at the facility applies.

(Comment 215) Several comments suggest that the recordkeeping requirements are so onerous that compliance periods should be extended to as many as 7 years.

(Response) In the PRIA, FDA assumed that the recordkeeping provisions required a limited amount of additional information over current business practices. Comments suggest that this may not be true for certain provisions. In the final rule, we have relaxed some of the more costly provisions, such as the requirement for records to contain lot code information for all persons subject to the final rule, and we have relaxed the records access requirement to 24 hours. We have also revised the requirements applicable to transporters so that they have multiple options for complying with the final rule. These modifications should reduce the costs of compliance for small businesses. In addition, we have extended the compliance dates of the final rule by 6 months to 12, 18, and 24 months for large, small, and very small businesses. The extension should further reduce the costs of compliance with the final rule because the costs of the required changes in records quality and records access fall as compliance time increases. Moreover, given the purpose of the Bioterrorism Act, FDA believes a 7-year compliance period is excessive.

(Comment 216) One comment states that large carriers account for only 0.28 percent of all carriers and that 0.28 percent of all carriers should not be unfairly burdened to comply with regulations 1 year before the rest. Another comment states that across-the-board compliance dates of 18 months better serves the purposes of the Bioterrorism Act, because it reflects the large volume of food that moves through big business.

(Response) The Regulatory Flexibility Act requires that special consideration be given to small businesses when such flexibility does not compromise the efficacy of the regulation. In the PRIA, FDA considered several other potential flexibility options and found that the policy of staggering the compliance dates and exempting very small retailers were the only ones that did not appreciably compromise the effectiveness of the regulation.

(Comment 217) Several comments state that large businesses would likely pass the costs of the regulation on to smaller firms. In addition, the proposed regulatory flexibility from staggered compliance dates would largely be ineffective, because large businesses will require their small suppliers to comply with the regulation to ensure their own compliance. Another comment suggests extending the compliance dates to 18 months for large businesses and 36 months to small businesses but acknowledged that staggering compliance dates would complicate business practices.

(Response) FDA acknowledges the difficulties in addressing regulatory flexibility considerations with staggered compliance dates. Nevertheless, FDA has decided that staggering the compliance dates is a viable mechanism to address regulatory flexibility considerations without compromising the effectiveness of the regulation as intended by Congress when it enacted section 306 of the Bioterrorism Act. However, to address the concerns expressed by these comments without compromising the effectiveness of the regulation, in the final rule compliance dates for all size businesses have been extended by 6 months to 12 months for large, 18 months for small, and 24 months for very small businesses. FDA further notes that small and very small businesses are not required by FDA to comply earlier than these timeframes even if they are doing business with larger businesses that have earlier compliance dates.

(Comment 218) At least one comment suggests that requiring the same compliance date for all firms and excluding small businesses from complying with the regulation compromises the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations. Such a compromise is contrary to the intent of the Regulatory Flexibility Act.

(Response) In the PRIA, FDA considered three regulatory flexibility options: (1) Exempting small business from all regulatory requirements, (2) offering small business exemptions from parts of the regulation, and (3) specifying longer effective compliance dates for small businesses. We found that specifying longer compliance dates for small businesses was one option that would not appreciably compromise the purpose of the regulation.

(Comment 219) Several comments state that the 4 and 8 hour provision for records access is more onerous for small businesses and suggest either flexibility in the extent of the records to be made available in that time period for small businesses, or extending the records access time requirements for small businesses. One comment suggests that the rule requires firms to keep more records than is necessary and that FDA should consider relaxing the level of detail in the small business records required to be made available in the 4 and 8-hour records access times. One comment states that the burden on a small firm from devoting a single employee, who generally performs multiple tasks, to accessing requested records is greater than that on a large firm devoting an employee who may generally perform only one task.

(Response) The proposed rule required large and small firms to provide access to records up to 4 hours after a request made during business hours, and up to 8 hours after a request made after business hours. FDA's current experience is that access to records generally takes 2 to 3 days and the requirements in the regulation will considerably increase the speed of traceback investigations. To acknowledge the concerns addressed by these comments, FDA has relaxed the records access requirement to as soon as possible, but within 24 hours. This longer requirement should provide regulatory relief to small businesses; however, FDA reiterates that it expects all businesses to provide access as soon as possible, given that an access request would only be made in a food-related emergency.

(Comment 220) Several comments request an exemption for some specific categories of small business, because they believe the estimated costs of compliance for small businesses are inadequate. Furthermore, one comment states that the regulatory flexibility provisions in the proposed rule did not satisfy SBREFA obligations.

(Response) FDA addresses SBREFA's regulatory flexibility issues by exempting very small retailers, and by staggering compliance dates so that small and very small businesses would have 18 and 24 months to comply with the regulation. Because food in commerce generally passes through at least one small business before reaching consumers, excluding small businesses in every sector from compliance with the regulation would risk severely compromising the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations.

(Comment 221) Some comments argue that FDA should address the relatively large burden on small businesses due to the cumulative cost of the four bioterrorism regulations when considered together. The comments state that the proposed registration rule estimated that approximately 16 percent of foreign businesses might cease to export to the United States as a result of that rule. The comments note that this figure was used in the sensitivity analysis in the proposed recordkeeping rule to estimate the costs of the rule with 16 percent fewer foreign facilities. However, the comments stated that FDA did not consider the costs of all the bioterrorism regulations combined on small (or other) businesses.

(Response) The cumulative costs of multiple regulations are rarely considered in regulatory impact analyses. However, costs of the other three regulations were analyzed in their respective regulatory impact analyses. To estimate the cumulative costs of the regulation one could add together the costs determined for all four regulations.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule will include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this final rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates have been fulfilled in the Executive Order 12866 analysis in the PRIA. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future Costs

The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after promulgation of the final rule. These costs will be incurred by all domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food except very small retail facilities.

Recurring costs from collecting new information as well as the learning costs for new entrants will be incurred in each future year. An hourly burden of 30 minutes a week was estimated for the additional monitoring and recordkeeping that will be required from this final rule. This hourly burden estimate was modified for convenience stores to allow for structural differences assumed in their operations. Refer to the PRIA for a fuller illustration of the future costs of the final rule.

TABLE 24.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	$123,209,200	$121,980,000	$125,788,000

Particular Regions, Communities, or Industrial Sectors

The costs of the establishment and maintenance of records will be shared among all domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, except very small retail facilities that are exempted from the final rule. The higher costs incurred by domestic suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Because consumer demand for food is highly inelastic, almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports

This rule requires additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs will increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of United States exports could reduce the quantity of United States exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the final rule, the increases in the price of United States exports (and resulting decreases in quantity demanded) will be quite small.

VII. SBREFA

SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirement are shown below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Establishment and Maintenance of Records

Description: The Bioterrorism Act contains a provision authorizing the Secretary to establish requirements regarding the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food which are needed to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequence or death to humans or animals.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce. FDA received several comments about the hourly burden imposed by the rule on respondents.

(Comment 222) One comment states that the cumulative effect of the regulation is a staggering amount of required paperwork that needs to be organized and made available.

(Response) This comment is not directly responding to any specific request for comments but is a general comment. The duplication of records is unnecessary as long as existing records contain all of the required information. In this analysis we use the FDA small business model to calculate the effects on small businesses using the difference between revenues and variable costs as the metric. We incorporated both the one-time costs and the recurring costs to compute the effects on small businesses. The effects were computed for firms in the dietary supplements industry, candy manufacturing, and the ready-to-eat food manufacturing industry, including firms that manufacture 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 incur negative cash flows as a result of this rule. The percentages of firms predicted to incur negative cash flows are 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. 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.

(Comment 223) One comment states that the PRA was adopted to prevent the burden of collecting unnecessary information that has little practical utility or benefit. The comment further states that FDA needs to realign the benefits with the costs of the regulation.

(Response) This is a response to the request for comments on whether the information required in the proposal would have any practical utility. Compared with the description of the costs in the proposal, the benefits were not as well defined. In the final rule, the benefits of each provision are more clearly identified, which facilitates greater realignment of costs with the benefits of the regulation. As stated previously, however, the benefits are underestimated because they only consider food safety concerns and do not address food security concerns, which are based on classified information.

(Comment 224) One comment suggests that FDA should reduce the paperwork burden by integrating the paperwork requirements from this regulation with current U.S. CBP process so that only one form needs to be completed.

(Response) The final recordkeeping regulation excludes all foreign persons, except for foreign persons who transport food in the United States so that many foreign persons do not have to establish or maintain records. Moreover, neither the proposed nor final rules specify the form or format of required records. Accordingly, existing records used for U.S. CBP purposes may be used if they contain all of the information required by this final rule and are retained for the required time period.

Burden: FDA estimates that the paperwork burden of this final rule will be incurred by approximately 707,672 facilities owned by 581,943 firms. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food as well as foreign persons who transport food in the United States. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 of this final rule includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the registration interim final rule (68 FR 58894). The learning burden presented in table 25 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following issuance of the final rule.

The records redesign burden presented in table 25 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 25 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 26 of this document.

TABLE 25.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—FIRST AND SECOND YEARS[1]

21 CFR Section	No. of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352 (learning)	707,672	1	707,672	4.790		3,390,000
1.337, 1.345, and 1.352 (redesign)	150,358	1	150,358	29.084	$70,409,000	4,373,000
Total						7,763,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 26.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Record Keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (additional records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	70,767	1	70,767	4.790	339,000
Total					5,359,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

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3. Mead, P.S., L. Slutaker, V. Dietz, et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, Center for Disease Control and Prevention (CDC), vol. 5, no. 5, September-October 1999.
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15. Viscusi, W., Joseph E. Kip and Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World," February 2003, NBER Working Paper No. W9487, accessed at *http://ssrn.com/abstract=379270* on May 3, 2004.

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27. United States Census Bureau, 2002 NAICS Definitions accessed at *http://www.census.gov/epcd/naics02/def/ND488510.HTM* on September 15, 2003.

28. United States Small Business Administration, Small Business Size Regulations, 13 CFR 121.201, available at *http://www.sba.gov/size/indextableofsize.html*, accessed on February 27, 2004.

29. Memorandum on the Number of Restaurants Selling Retail Food, dated December 15, 2003.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. New subpart J (§§ 1.326 through 1.368) is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

Requirements for Transporters to Establish and Maintain Records

General Requirements

Compliance Dates

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, "processing" means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term "consumers" does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term "consumers" does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. 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 requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term "farm" includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

Requirements for Transporters to Establish and Maintain Records

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

(11) Trailer initials/number;

(12) Container initials/number;

(13) No. packages; and

(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

(1) Shipper's name and address;

(2) Consignee's name and address;

(3) Customs reference/status;

(4) Airport of departure and destination;

(5) First carrier; and

(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in § 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) Description of the records to be established and/or maintained;

(4) Provision for the records to be maintained in compliance with § 1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by § 1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under § 1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(c) to establish, maintain, or establish and maintain, records required under § 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2004, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (f) to read as follows:

§ 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: November 30, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Dated: December 2, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04-26929 Filed 12-6-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N-0277]

Final Regulation Implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—Establishment and Maintenance of Records for Foods; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; public meeting on final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic public meetings to discuss the final regulation implementing section 306 (Maintenance and Inspection of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which is publishing in this issue of **Federal Register**. The purpose of these public meetings is to provide information on the rule to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1584, FAX: 301-436-2605, e-mail: *marion.allen@fda.hhs.gov*, for general questions only about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002.

In this issue of the **Federal Register**, FDA is publishing the final rule implementing section 306 of the Bioterrorism Act and a draft guidance on records access under the Bioterrorism Act. During the public meetings, FDA will explain this rule and the draft guidance and answer questions of clarification.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

II. Final Rule and Draft Guidance

Section 306 of the Bioterrorism Act directs the Secretary of Health and Human Services (the Secretary) to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

In addition, the Bioterrorism Act provides records inspection authority to FDA such that if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and the records are necessary to assist FDA in making such a determination, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records.

III. Registration for the Public Meetings

Please submit your registration information (including name, title, firm name, address, telephone number, e-

[Federal Register: February 23, 2005 (Volume 70, Number 35)]
[Rules and Regulations]
[Page 8726-8727]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23fe05-7]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N-0277]

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final regulation that appeared in the Federal Register of December 9, 2004 (69 FR 71562). The document issued a final regulation that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records allow for the identification of the immediate previous sources and immediate subsequent recipients of food. The document was published with some errors. This document corrects those errors.

DATES: This rule is effective February 7, 2005.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1400.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-26929, appearing on page 71562 in the Federal Register of Thursday, December 9, 2004, the following corrections are made to the SUPPLEMENTARY INFORMATION:

1. On page 71562, in the first column, under DATES after ``Compliance Dates'' the phrase ``except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2005;'' is corrected to read ``except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2006;''.

2. On page 71564, in the second column, the sixth bullet, beginning in the 4\th\ line, the phrase ``except that the compliance date for small businesses employing fewer that 500, but more than 10 full-time equivalent employees is June 9, 2005,'' is corrected to read ``except that the compliance date for small businesses employing fewer than 500, but more than 10 full-time equivalent employees is June 9, 2006,''.

3. On page 71565, in the second column, the last bullet, second sentence, the sentence ``Small businesses have June 9, 2005, of this final rule to come into compliance with these regulations, and very small businesses have December 11, 2006, of this final rule to come into compliance with these regulations.'' is corrected to read ``Small businesses have until June 9, 2006, to come into compliance with these regulations, and very small businesses have until December 11, 2006, to come into compliance with these regulations.''

4. On page 71609, in the third column, in the 1\st\ complete paragraph, the sentences ``Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance within December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance within June 9, 2005, and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance within December 11, 2006.'' are corrected to read ``Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance by December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance by June 9, 2006, and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance by December 11, 2006.''

5. On page 71627, in the third column, beginning in the 12\th\ line from the bottom, the sentence ``For example, from CA, LA, and TX alone, DOT reports over 12 percent of intrastate truck tonnage is from FDA-regulated products (ref. 18).'' is corrected to read ``For example, for California in 1997, DOT reports 12.8 percent of revenue from specialized freight transportation is for intrastate traffic in agricultural products (ref. 18).''

6. On page 71651, in the first column, in Reference 18, the phrase ``U.S. Department of Transportation, available at http://www.transtats.bts.gov, accessed on April 6, 2004.'' is corrected to read ``1997 Economic Census, Transportation and Warehousing, Geographic Area Series, California 1997, issued January 2000, U.S. Department of Commerce.''

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

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Therefore, 21 CFR part 1 is corrected by making the following correcting amendments:

PART 1--GENERAL ENFORCEMENT REGULATIONS

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7. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

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8. In Sec. 1.363, revise paragraph (b) to read as follows:

Sec. 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

* * * * *

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under Sec. 1.352(e) to establish, maintain, or establish and maintain, records required under Sec. 1.352(a), (b), (c), or (d), or the refusal to permit access to or

[[Page 8727]]

verification or copying of any such required record, is a prohibited act under section 301 of the act.
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9. In Sec. 1.368, revise paragraph (a) to read as follows:

Sec. 1.368 What are the compliance dates for this subpart?

* * * * *

(a) The compliance date for the requirements in this subpart is June 9,2006, for small businesses employing fewer that 500, but more than 10 full-time equivalent employees.

* * * * *

Dated: February 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-3424 Filed 2-22-05; 8:45 am]

BILLING CODE 4160-01-S

Protecting the Food Supply

December 2004; Revised November 2005

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) directs the Secretary of Health and Human Services to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms, restaurants and certain others) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

Who must establish and maintain records? Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food in the U.S.; and persons who *place food directly in contact* with its finished container. For these regulations, the term *persons* includes individuals, partnerships, corporations, and associations.

How is food defined for purposes of this regulation? "Food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) which defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Who is excluded entirely or in part from these regulations?

Excluded Entirely
Farms
Foreign persons, except for foreign persons who transport food in the U.S.
Restaurants are excluded entirely. A combination restaurant/retail facility is excluded entirely *if* sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.
Persons performing covered activities with food *to the extent* that the food is within the exclusive jurisdiction of the U.S. Department of Agriculture
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption
Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging (the outer packaging of food that bears the label and does not contact the food), except for those persons who also engage in a covered activity with respect to food (see below)

Excluded From The Requirement To Establish And Maintain Records *But Not The Record Availability Requirements For Existing Records*
Fishing vessels not engaged in processing
Retail food establishments that employ 10 or fewer full-time equivalent employees
Nonprofit food establishments
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the record availability requirements with respect to its packaging (the outer packaging of food that bears the label and does not contact the food)
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food, except for those persons who place food directly in contact with its finished container

Additional Partial Exclusions
Persons who distribute food directly to consumers (the term *consumers* does not include businesses) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients
Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available

What records must be established and maintained by non-transporters of food? For non-transporters, i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation, the records have to:

1. Identify the immediate non-transporter previous *sources*, whether foreign or domestic, of all foods received, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety (e.g., Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce); date received; quantity and type of packaging (e.g., 12 oz. bottles); and identify the immediate transporter previous sources including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*
2. Identify the immediate non-transporter subsequent *recipients* of all foods released, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety; date released; quantity and type of packaging; and identify the immediate transporter subsequent recipients, including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.* The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

What records must be established and maintained by transporters of food?

The term *transporters* includes persons who have possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. The term *transporters* also includes foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody, or control of food for the sole purpose of transporting it. For transporters, records have to include names of the transporter's immediate previous source and transporter's immediate subsequent recipient, origin and destination points, date shipment received and date released, number of packages, description of freight, route of movement during the time the food was transported, and transfer point(s) through which the shipment moved.

Do transporters have alternative methods of meeting the requirements of the rule? Persons who have possession, custody, or control of food in the U.S. for the sole purpose of transporting the food, or foreign persons who transport

food in the United States, *regardless* of whether they have possession, custody, or control of the food for the sole purpose of transporting that food, have five alternative methods, depending on the mode of transportation, of meeting the requirements of the final rule.

Alternative Methods for Food Transporters
1. Establishing and maintaining the records described above
2. Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's Federal Motor Carrier Safety Administration contained in 49 CFR 373.101 and 373.103 as of December 9, 2004.
3. Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the Department of Transportation's Surface Transportation Board contained in 49 CFR 1035.1 and 1035.2 as of December 9, 2004.
4. Establishing and maintaining specified information that is in the records required of international air transporters by the Warsaw Convention
5. Entering into an agreement with a non-transporter immediate previous source or immediate subsequent recipient (if located in the United States) to establish, maintain, or establish and maintain the required records in options 1, 2, 3 or 4.

How must the records be maintained? FDA is specifying the information a covered entity must keep but not specifying the form in which the records must be maintained. The records may be kept in any format, paper or electronic, provided they contain all the required information.

Can existing records be used to satisfy the requirements of these regulations? The regulations do not require duplication of existing records, *if* these records contain all the required information.

How long must the records be retained? The rule requires records to be created when food is received, released or transported except to the extent the information is contained in existing records. The period for which the records must be retained depends on the perishability of the food:

Type of food	Record retention period for non-transporters	Record retention period for transporters or persons keeping records on their behalf
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days but within 6 months	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability occurring no sooner than 6 months	2 years	1 year
Animal food including pet food	1 year	1 year

Where must the records be retained? At the establishment where the activities covered in the records occurred (onsite) or at a reasonably accessible location.

What are the record availability requirements? When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information to which FDA has access must be available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food that are maintained by, or on behalf of, an entity subject to the recordkeeping regulation, and at any location.

What records are excluded from these regulations? Recipes, financial data, pricing data, personnel data, research data and sales data are excluded from these requirements. A recipe is defined as the formula, including ingredients, quantities and instructions necessary to manufacture a food product. Therefore, records relating only to the ingredients of a food product and not the other two components of a recipe are *not* excluded.

What procedures does FDA intend to follow before requesting access to records?

FDA has issued guidance for industry and FDA staff regarding records access which details the internal procedures the agency intends to follow (see Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

How does FDA intend to make a request to access or copy records under the Bioterrorism Act? Under the guidance, once FDA makes the necessary determination following the specified procedures, an investigator or other FDA personnel, upon presentation of credentials, will submit a written notice, FDA 482 - Notice of Inspection, to the owner, operator, or agent in charge, and inform that person of the records requested and FDA's legal authority to obtain these records. FDA may request additional records related to the implicated food article at a later time under the same authority.

How will FDA maintain the confidentiality of any protected information in records it obtains? Information obtained under the records access provisions of sections 414(a) and 704(a) may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR Parts 20 and 21 govern the agency's disclosure of information to the public. FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information.

What will happen if the required records are not established and maintained? The Bioterrorism Act makes failure to establish and maintain the required records or failure to make them available to FDA a prohibited act. The Federal government can bring a civil action in Federal court to enjoin persons who commit a prohibited act; the Federal government also can bring a criminal action in Federal court to prosecute persons who commit a prohibited act.

When is compliance with the recordkeeping regulation required? All businesses covered by this rule, must comply within 12 months from December 9, 2004, *except* small and very small businesses. Small businesses (11-499 full-time equivalent employees (FTEs)) must comply within 18 months from this date, and very small businesses (10 or fewer FTEs) have to comply within 24 months from this date. The term, *full-time equivalent employees* or *FTEs,* means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

For further information: For more details and information on the specific requirements of this final rule, please refer to the final rule. http://www.cfsan.fda.gov/~dms/firecord.html

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Part II

Department of Health and Human Services

Food and Drug Administration

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21 CFR Parts 1, 10, and 16

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 10, and 16

[Docket No. 2002N-0275]
RIN 0910-AC38

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals (``administrative detention''). The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which authorizes the use of administrative detention and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

DATES: This rule is effective July 6, 2004.

FOR FURTHER INFORMATION CONTACT: Kelli Giannattasio, Center for Food Safety and Applied Nutrition (HFS-007), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1432.

SUPPLEMENTARY INFORMATION:

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I. Background and Legal Authority

On May 9, 2003 (68 FR 25242), FDA issued a proposed rule providing procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The events of September 11, 2001, had highlighted the need to enhance the security of the United States' food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. Section 303 of the Bioterrorism Act amends section 304 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334) by adding paragraph (h) to provide that an officer or qualified employee of FDA may order the detention of any article of food that is

found during an inspection, examination, or investigation under the act if the officer of qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. This provision also requires the Secretary of Health and Human Services (the Secretary) to provide by regulation procedures for instituting seizure or injunction actions against perishable food subject to a detention order on an expedited basis. Section 303 of the Bioterrorism Act also amends the FD&C Act by adding a new prohibited act as paragraph (bb) to section 301 of the FD&C Act (21 U.S.C. 331).

The major components of section 303 of the Bioterrorism Act are as follows:

<bullet> Criteria used to trigger an administrative detention: Amends section 304 of the FD&C Act to authorize an officer or qualified employee of FDA to order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.

<bullet> Approval required: The Secretary, or an official designated by the Secretary, must approve the detention order. An ``official designated by the Secretary'' means the District Director of the district where the detained article of food is located, or an FDA official senior to such director.

<bullet> Period of detention: The detention period will be for a reasonable period, not to exceed 20 calendar days, unless a greater period, not to exceed 30 calendar days, is necessary to enable the Secretary to institute a seizure or injunction action.

<bullet> Required rulemaking: The Secretary must, by regulation, provide for procedures for instituting certain enforcement actions on an expedited basis with respect to perishable food subject to a detention order.

<bullet> Security of detained article of food: The detention order may require that the detained article of food be labeled or marked as detained. The order must require the removal of the detained article of food to a secure facility, as appropriate.

<bullet> Appeal procedure: Any person who would be entitled to claim the detained article of food if such article were seized may appeal the detention order to the Secretary. Within 5 calendar days after

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such appeal is filed, after providing opportunity for an informal hearing, the Secretary must confirm or terminate the detention order. The appeal process terminates if the Secretary institutes an action for seizure or injunction regarding the article of food involved. Confirmation of a detention order is considered a final agency action.

<bullet> Prohibited act: Amends section 301 of the FD&C Act making it a prohibited act to transfer a detained article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.

<bullet> Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this final regulation. The temporary hold provision authorizes FDA to ask the Secretary of the Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (Docket No. 2002N-0275). FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

Under the Homeland Security Act of 2002 (Public Law 107-296), the responsibilities and functions of the Secretary of the Treasury for all relevant Customs authorities have been transferred to the Secretary of Homeland Security, who has in turn delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP). Thus, wherever section 303 of the Bioterrorism Act refers to the Secretary of Treasury, we will refer to the Secretary of Homeland Security.

In addition to amending title 21 of the Code of Federal Regulations (21 CFR) by establishing a new subpart to part 1 (21 CFR part 1) consisting of subpart K entitled, ``Administrative Detention of Food for Human or Animal Consumption,'' this final rule also makes conforming amendments to part 16 (21 CFR part 16) entitled ``Regulatory Hearing Before the Food and Drug Administration'' and part 10 (21 CFR part 10) entitled ``Administrative Practices and Procedures.''

Although the statutory requirements in section 303 of the Bioterrorism Act are self-executing and are currently in effect, FDA is issuing this regulation to further refine aspects of the administrative detention requirements. Section 303 of the Bioterrorism Act requires FDA only to issue regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order; however, FDA also is describing in this regulation the procedures for how we will detain both perishable and nonperishable articles of food and the process for appealing a detention order. FDA established requirements for the process for appealing a detention order in this final rule to ensure that we meet section 303's timing requirements and to define certain terms used in the Bioterrorism Act (e.g., perishable food).

This final rule is not related to, and does not implement, section 801(a) of the FD&C Act (21 U.S.C. 381), even though it uses the term ``detention.'' This final rule implements section 303 of the Bioterrorism Act, which amends the seizure provision at section 304 of the FD&C Act by adding paragraph (h) to that section. This amendment grants FDA the authority to detain (i.e., prevent the further movement of) any article of food that is found during an inspection, examination, or investigation if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

Some of the comments that we received continue to reflect some confusion of our authority to detain food administratively under section 304(h) of the FD&C Act (as added by the Bioterrorism Act) with our authority to refuse admission of imported food under section 801(a) of that act, despite our explanation of this issue in the proposed rule. (See 68 FR 25242.) The following discussion provides additional explanation of FDA's authority under each of these provisions so as to make clear that our authority to detain food administratively under section 304(h) of the FD&C Act is separate and distinct from our authority to refuse admission of imported food under section 801(a) of the FD&C Act.

Section 801 of the FD&C Act sets out standards and procedures for FDA review of imports under its jurisdiction. Generally, when an FDA-regulated product is imported, customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. If FDA determines that refusal under section 801(a) FD&C Act appears appropriate, FDA, as set out in its regulations, gives written notice to the owner or consignee. (See Sec. 1.90(a).) In guidance dating back many years, FDA refers to this written notice as the notice of detention and hearing.

FDA's evaluation of imported foods under section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, packed, and held; contains no contaminants or illegal additives or residues; and is properly labeled. Section 801(a) of the FD&C Act provides that an article of food is subject to refusal of admission if it ``appears, from physical examination or otherwise'': (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act (21 U.S.C. 342 and 21 U.S.C. 343)) set out most of the FD&C Act's requirements for foods.

In section 304(h) of the FD&C Act, Congress gave FDA the authority to detain food administratively where we have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals so that we can bring such food under FDA control. Historically, FDA has had the authority to seize misbranded or adulterated food in domestic commerce; however, adulterated food could enter commerce and put consumers at risk during the time that it takes to file a seizure action. In some

instances, FDA has been able to partner with State authorities to have such food embargoed by the State where the food is located so that it is under their control while the seizure action is being prepared and filed, until the court issues the warrant, and until the U.S. marshal can seize the food. However, this process is not always possible.

We do not, at this time, foresee frequently using administrative detention under section 304(h) of the FD&C Act to control the movement of imported food subject to section 801 of the FD&C Act. When FDA determines it is appropriate to bring imported food under FDA control using the authority under section 304(h) of the FD&C Act, the standard for administrative detention will be the same as it is for other products, i.e., we must have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

This final rule implements the administrative detention requirements in section 303 of the Bioterrorism Act.

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This final rule, published today, as well as the interim final rules that FDA and CBP published on October 10, 2003, to implement section 307, prior notice of imported food shipments (68 FR 58974), and section 305, registration of food facilities (68 FR 58893), of the Bioterrorism Act, along with the final rule implementing section 306 of the Bioterrorism Act (maintenance and inspection of records for food), which will be published in the Federal Register in the near future, will help FDA act quickly when responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Administrative detention will provide FDA with an added measure to help ensure the safety of the nation's food supply. In establishing and implementing this final rule, FDA believes it has complied fully with the United States' international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA).

In addition to section 303 of the Bioterrorism Act, which amends the FD&C Act as described previously in this document, FDA is relying on section 701(a) of the FD&C Act (21 U.S.C. 371(a)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the FD&C Act.

II. Highlights of the Final Rule

The key features of this final rule are as follows:

<bullet> An officer or qualified employee of FDA may order the detention of food for up to 30 calendar days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.

<bullet> FDA's District Director in the district in which the article of food is located, or an FDA official senior to such director, must approve a detention order.

<bullet> FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. FDA's tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative.

<bullet> A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.

<bullet> FDA will state in the detention order the location and any applicable conditions under which the food is to be held.

<bullet> If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. An article of food moved to a secure facility remains under detention before, during, and after such movement.

<bullet> FDA may approve a request for modification of a detention order to permit movement of a detained article of food for purposes of destruction, movement to a secure facility, preservation of the detained article of food, or any other purpose that FDA believes is appropriate. In any of these circumstances, an article of food may be transferred but remains under detention before, during, and after the transfer.

<bullet> Any transfer of a detained article of food in violation of a detention order is a prohibited act.

<bullet> Any person who would be entitled to be a claimant for the article of food, if seized, may appeal a detention order and, as part of that appeals process, may request an informal hearing. If a hearing is granted, an FDA Regional Food and Drug Director (RFDD) or another official senior to an FDA District Director will serve as the presiding officer of the hearing.

<bullet> This rule includes appeal and hearing timeframes for both perishable and nonperishable detained articles of food.

<bullet> Perishable food:

<bullet> An appeal must be filed within 2 calendar days of receipt of the detention order.

<bullet> If a hearing is requested in the appeal and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal is filed.

<bullet> FDA's decision on appeal will be issued 5 calendar days after the appeal is filed.

<bullet> Nonperishable food:

<bullet> A notice of intent to file an appeal and to request a hearing must be filed within 4 calendar days of receipt of the detention order.

<bullet> An appeal must be filed within 10 calendar days of receipt of the detention order.

<bullet> If a hearing is requested in the notice of intent and the appeal and FDA grants the request, the hearing will be held within 2 calendar days after the appeal is filed.

<bullet> FDA's decision on appeal will be issued 5 calendar days after the appeal is filed.

<bullet> The expedited procedures for initiating certain enforcement actions with respect to perishable foods require FDA to submit a seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

<bullet> Confirmation of a detention order by FDA's presiding officer is considered final agency action.

In response to comments that were received, FDA has made two changes to the proposed rule. First, the required information in the detention order did not include the name of the authorized FDA representative who approved the detention order. This is required information in this final rule (Sec. 1.393(b)(14)). Second, the proposed rule stated that, if a hearing is requested in the appeal, and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal has been filed for perishable food, and within 3 calendar days after the date the appeal has been filed for nonperishable food (Sec. 1.402(d)). This section III.I.2 of this final rule is revised to state that the hearing will be held within 2 calendar days after the date the appeal is filed for both perishable and nonperishable foods. In addition, FDA has also made clarifying revisions to the procedures that apply to an informal hearing on an administrative detention. Revised. Sec. Sec. 1.403(h) and 1.405(a) provide that the presiding officer must issue a written report of the hearing, including a proposed decision with a statement of reasons. The hearing participant may review this report and suggest changes within 4 hours of the issuance of the report. The presiding officer will then issue the final agency decision. In addition, FDA has added Sec. 1.403(i) and (k) to clarify the components of the administrative record and the record of the administrative proceeding. We have also included clarifying comments in the preamble to this final rule.

We have made two other changes to the proposed rule in order to avoid confusion with CBP terminology and requirements. First, the proposed rule used the term ``limited conditional release'' to refer to the process whereby FDA grants a request to modify a detention order to permit movement of a detained article of food. The term ``limited conditional release'' has a different meaning as used by CBP. In order to avoid confusion, we have therefore changed applicable sections of the codified in this final rule to eliminate the use of this term, and instead use the term ``request for modification of a detention order.''

Second, Sec. 1.381(a) in the proposed rule prohibited delivery of a detained article of food ``to another entity under the execution of a bond.'' This section could have been misinterpreted to prohibit delivery of an article to a

storage facility just because it is under a customs bond (as opposed to a penal bond), thereby potentially slowing the flow of trade. In the final rule, Sec. 1.381(a) has been revised to make clear that the existence of an appropriate customs bond required by Customs law and regulation does not prohibit movement of a detained article at FDA's direction.

As noted in the proposed rule, FDA intends to define ``serious adverse health consequences'' in a separate rulemaking.

III. Comments on the Final Regulation

FDA received approximately 100 submissions in response to the proposed rule, and each of them raised one or more comments. To make it easier to identify comments and FDA's responses to the comments, the word ``Comment'' will appear in parentheses before the description of the comment, and the word ``Response'' will appear in parentheses before FDA's response. FDA also has numbered the sets of comments to make it easier to identify a particular issue. The number assigned to each set of comments is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted to FDA's docket.

A. General Comments

(Comment 1) Many comments state that administrative detention should be limited to use only when there is intentional adulteration (bioterrorism) against the food supply. One comment indicates that administrative detentions should be imposed only when there are no other means to prevent the product from moving in commerce, e.g., when a responsible company will not recall or hold the product. Some comments argue specifically that we should continue to request Class I recalls in situations involving unintentional adulteration. One comment argues that we should not use administrative detention to deal with imported food containing undeclared allergens.

(Response) The Bioterrorism Act gives FDA the authority and flexibility to detain administratively articles of food for which FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act does not limit FDA's administrative detention authority to only those situations involving intentional adulteration. Unintentional adulteration can pose the same threats of serious adverse health consequences or death. Therefore, the agency has not changed the final rule as requested by comment 1 in section III A. of this document.

In response to the comment that FDA should only employ an administrative detention when voluntary cooperation is not available, FDA believes that a detention may not be necessary if a firm takes prompt and complete voluntary action, e.g., in a Class I recall situation. However, FDA may nonetheless choose to detain administratively an article of food that has been recalled. Circumstances under which FDA may choose to do so include, but are not limited to, when there is concern that the food may reenter commerce. Thus, FDA will not limit its authority to detain an article of food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 2) FDA sought comments on whether its conclusion that it has authority to detain food in intrastate commerce administratively is correct, and if so, whether the agency should use that authority. A few comments agree with FDA's conclusion that it has authority to impose an administrative detention on articles of food that are only in intrastate commerce. One comment is concerned about the broader jurisdictional implications of FDA not meeting the interstate commerce criterion. Another comment argues that FDA's conclusion that it has authority to detain food administratively that does not enter interstate commerce is inconsistent with limitations imposed by the commerce clause of the U.S. Constitution. In response to FDA's assertion that Congress, in the Bioterrorism Act, gave the agency authority to detain food administratively in intrastate commerce, this comment states that the commerce clause generally restricts Congress' power to regulate purely intrastate commerce, and that Congress cannot delegate power to FDA that it does not possess. The comment argues that FDA should have assumed that Congress did not intend to violate the Constitution, and that FDA should amend the administrative detention provisions accordingly.

Another comment argues that the agency's use of administrative detention authority on articles of food that are engaged only in intrastate commerce challenges long established federal and state jurisdictional boundaries. This comment further states that, under these new regulations, FDA is moving into areas delegated to state control under the enabling statute and the 10th Amendment to the U.S. Constitution, and that by proposing this regulatory scheme, the agency can avoid and circumvent the very safeguards established to provide against rampant unauthorized expansion of federal authority.

(Response) In the preamble to the proposed rule, FDA tentatively concluded that all food would be subject to administrative detention under section 303 of the Bioterrorism Act if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals, whether or not the food enters interstate commerce. FDA is mindful that our interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (See Solid Waste Agency of Northern Cook County v. U.S., 531 U.S. 159 (2001).) The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the commerce clause of the Constitution (Art. I, section 8). Based on these considerations, FDA does not change its conclusion that it has the authority to detain food administratively that does not enter interstate commerce.

Section 304(h) of the FD&C Act, as added by section 303 of the Bioterrorism Act, provides that:

> An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

This language does not include a limitation similar to that in section 304(g) of the FD&C Act providing for administrative detentions of devices during inspections conducted under section 704 of that act (21 U.S.C. 374), a provision that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(bb) of the FD&C Act, unlike some other prohibited acts in section 301, does not include an interstate commerce component. Accordingly, FDA concludes that the Bioterrorism Act does not limit administrative detention only to those foods that enter interstate commerce.

Congress's constitutional power to legislate under the commerce clause is very broad. However, such power is not without limits, see, e.g, United States v. Lopez, 514 U.S. 549, 567 (1995); U.S. v.

Morrison, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of Wickard v. Filburn, 317 U.S. 111 (1942), noting that, ``although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not `enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.' '' 514 U.S. at 556. This principle applies to the administrative detention provision of the Bioterrorism Act. Administrative detention prevents the movement of food where there is credible evidence or information that the food presents a threat of serious adverse health consequences or death. Even if that food is so-called ``intrastate'' food, the collective impact of that food on interstate commerce is such that FDA believes Congress acted within its power under the commerce clause when it enacted legislation subjecting that food to administrative

detention.

FDA's conclusion is also consistent with section 709 of the FD&C Act, which states that, in any action to enforce the FD&C Act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress' goal in enacting the Bioterrorism Act because the potential harm from bioterrorist attacks or other food emergencies can be great, whether or not the food moves from one state to another. The usefulness of the administrative detention authority also can be significant in food emergencies where interstate shipment has not occurred. As a practical matter, FDA believes that this decision should have little if any impact on whether a given food is subject to administrative detention because virtually all food manufactured, processed, packed, transported, distributed, received, held, or imported, moves, or is considered to move, in interstate commerce. Accordingly, FDA is retaining its conclusion that it has the authority to detain any food administratively when the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals, regardless of whether that food enters interstate commerce.

(Comment 3) A few comments state that FDA should make clear that the detention of cargo always should be managed so as to minimize delay or interference with the orderly movement of an oceangoing vessel or other conveyance. They note that this clarification will be consistent with the intent of the Bioterrorism Act and FDA's relationship with CBP. These comments state that the Bioterrorism Act grants FDA limited detention authority, which should not be interpreted as expanding the agency's authority to inspect and detain imported food on a vessel at a port of entry when this authority belongs, in the first instance, to CBP. These comments note FDA's acknowledgment in our proposal that it intends, primarily, to continue to regulate imported food in conjunction with CBP and under section 801(a) of the FD&C Act. They also note that the provision in section 303(c) of the Bioterrorism Act, which allows an officer of qualified employee of FDA to ``* * * request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate'' further confirms that the authority to detain cargo on board a vessel remains primarily with the CBP service and not FDA.

(Response) As stated in the background section I. of this rule, because of the authorities available to FDA and CBP to control the movement of imported food under section 801(a) of the FD&C Act and various provisions of title 19 of the U.S. Code, FDA does not foresee frequently using administrative detention under section 303 of the Bioterrorism Act to control the movement of imported food subject to those authorities. However, it is within FDA's authority to detain food under section 303 of the Bioterrorism Act that has been offered for import into the United States upon credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals. Consequently, FDA may detain imported food cargo on a conveyance under section 303 of the Bioterrorism Act. If FDA detains imported articles of food on a conveyance, we will consult with CBP to minimize the disruption of the conveyance movement in trade.

(Comment 4) One comment indicates that most tank truckloads of food are sealed at all openings and that these seals will be broken by FDA inspectors who investigate a suspected problem load. They state that, in the bulk food trucking industry, ``a broken seal equals a rejected load.'' The comment requests that FDA develop a process whereby an FDA representative who breaks a seal to gain access to a load that is found not to present a problem would then reseal the load with an FDA seal and so indicate it on an official FDA document. While not required to, a receiver may be more inclined to accept the load.

(Response) FDA agrees in part with this comment, but is not sure what is meant by an official document upon resealing. Under current practice, which will be continued after the effective date of this rule, whenever FDA reseals a conveyance (e.g., a truckload of goods) after an FDA investigator has broken the seal to examine the goods, the FDA investigator reseals the conveyance with an official FDA metal seal. An FDA document does not accompany the metal seal because the FDA seal is the official indication that FDA has opened and resealed the conveyance. Our internal practice is to record the number of the seal in the investigator's official notes.

(Comment 5) A couple of comments suggest that FDA should avoid implementing a ``one size fits all'' rule for transportation providers to accommodate the operational differences within the transportation industry. These comments suggest that, instead, FDA should examine the operational capabilities and realities of the differing transport modes to formulate mode-specific rules, as is currently being done by CBP for the Trade Act of 2002 (Trade Act). These comments further suggest that the agency work closely with CBP to ensure that any rules for importation and exportation of food do not conflict with CBP requirements. The comments suggest that FDA work with CBP to take advantage of the cross-border supply chain security program already in place, to avoid burdensome duplication of effort.

(Response) FDA does not agree that it is necessary to adopt different administrative detention requirements for different modes of transport. The Trade Act deals with advance notice of items arriving in the United States, not with detention of potentially unsafe food to ensure it does not move into distribution pending the filing of a court action. Congress specifically directed CBP to consider different advance notice timeframes for items arriving on different modes of transport (e.g., truck, air, vessel, rail). This Congressional directive did not extend to actions taken by FDA to implement section 303 of the Bioterrorism Act. In the implementation of section 303, different transport modes are irrelevant because food subject to administrative detention will either be detained in place or detained by offloading it from the transport mode

and transferring it to another facility. This is true regardless of whether the mode of transport is truck, air, vessel, or rail. FDA will continue to work with CBP to coordinate actions at the border.

(Comment 6) One comment states that bulk transportation of food products in tank trailers and dry bulk trailers is significantly different from packaged or prepared food transportation. This comment urges FDA to recognize these differences either in the language of the regulation, or by a separate section strictly dealing with bulk transportation.

(Response) Section 1.393(b)(8) states that FDA must include in the detention order any applicable conditions of transportation of the detained article of food. FDA will take into consideration the mode of transportation being used for the detained product, and the form in which the article of food is being transported, e.g., packaged or dry bulk, when setting forth these conditions.

(Comment 7) With respect to detained shipments of imported food, one comment believes that FDA should work with CBP to immediately control these foods, and to program CBP's Automatic Commercial System (ACS) and Automated Broker Interface (ABI) to not issue a CBP release for any such shipment.

(Response) When imported food at the border is found to warrant administrative detention under section 304(h) of the FD&C Act, FDA will continue to work with CBP as the agency currently does with respect to section 801(a) of the FD&C Act. FDA will issue a detention order under Sec. Sec. 1.392 and 1.393, which will specify the terms of the detention. Under Sec. 1.393(b)(9), the order will include a statement that ``the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under Sec. 1.381.'' Accordingly, FDA does not believe it is necessary to communicate detentions through ACS or ABI.

(Comment 8) One comment is concerned about where imported food will be detained. The comment describes FDA's current procedures of only detaining imported food at the port where the consumption entry is filed with CBP, which may not be the port of arrival. Currently, imported food is detained at the port where the consumption entry is filed after FDA receives the declaration and the Operational and Administrative System Import Support declaration is made. The comment wants this procedure to continue unchanged.

(Response) In this comment, the person is describing FDA's current procedures for refusing admission under section 801(a) of the FD&C Act. In the event that imported food is detained administratively under

section 303 of the Bioterrorism Act, the product would be detained as soon as FDA had credible evidence or information that the food product posed a threat of serious adverse health consequences or death. This could presumably occur while the product was still at the port of entry where the goods arrived in the United States. Thus, it is conceivable that FDA could administratively detain a food product at the port of entry where arrival took place, the port of destination, or any location in between. This is consistent with the purpose of administrative detention, which is to hold in place, and protect against any movement that could lead to further distribution of, the food that poses the threat of serious adverse health consequences or death to humans or animals. Under Sec. 1.393(b)(7), the detention order will specify the address and location where the article of food is to be detained and the appropriate storage conditions.

(Comment 9) One comment suggests that their written comments can at best only highlight some of the issues and implications raised by FDA's proposal. The comment further states that the best way to address these subjects is through a working group that brings together members of the trading community with officials from FDA and CBP. If a meeting is not possible, the comment requests to schedule a meeting at FDA's earliest convenience to further discuss the matter.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international and domestic meetings to ensure that affected parties were aware of the Bioterrorism Act administrative detention requirements and understood the proposed requirements so that they could provide meaningful comments. On May 7, 2003, FDA held a public meeting (via satellite downlink) to discuss both the administrative detention and recordkeeping proposed rules. (See 68 FR 16998, April 8, 2003 or http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm.) The live broadcast was available to participants in North America, Central America, and South America, and the Caribbean. The meeting was later rebroadcast to Europe, Southern Africa, Asia, and the Pacific. FDA also has posted transcripts of the broadcast in English, French, and Spanish (the three official WTO languages) on the agency's Web site.

(Comment 10) One comment is concerned that pet products will be administratively detained due to unwarranted association with countries or geographic areas that may face animal health or food safety emergencies. Another comment questions whether FDA's administrative detention authority applies to transit shipments in the United States, i.e., goods in transit through the United States that are not declared for U.S. consumption. Another comment asks what relationship or obligation has been established between the Bioterrorism Act and hazard analysis and critical control points (HACCP) and good manufacturing practices (GMPs).

(Response) FDA can detain an article of food administratively only if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. That is the standard that must be met for administrative detention of all food, including pet food. FDA also has authority to detain administratively any food in the United States that meets the standard for administrative detention, including transit shipments of food. Finally, it is not clear what is meant by the terms ``relationship'' and ``obligation'' with respect to the Bioterrorism Act and HACCP and GMPs. FDA has authority to detain food administratively when that food meets the standard for administrative detention, regardless of how the food comes to meet that standard, e.g., by failure to follow GMPs, as the result of an act of bioterrorism, etc. FDA's decision to employ administrative detention or other applicable authorities under the FD&C Act will be made on a case-by-case basis depending on the facts of each particular case.

(Comment 11) One comment asks if FDA is suggesting that carriers, warehouses and others in the supply chain process must adhere to specific security standards, and if so, suggests that such standards be clearly identified.

(Response) This final rule does not establish general requirements or guidance relating to specific security standards or practices for carriers, warehouses and others in the supply chain. However, FDA recently published several guidance documents concerning preventative food safety measures that individual firms may wish to consider as they develop their own security measures. FDA's guidance documents can be found on the agency's Web site.

(See http://www.cfsan.fda.gov/~dms/fsterr.html.)

If FDA does issue a detention order, the order would

contain the address and location where the article of food is to be detained, and the appropriate storage conditions.

(Comment 12) One comment indicates that if an officer detains a product in temporary hold for 24 hours, then the total time invested in the appeal and hearing process will exceed the timeframe for perishable foods. This comment asks FDA to specify 7 days for the detention process from the formal detention until the final resolution or termination based on the definition for perishable food, which is that the quality of the product is adversely affected after 7 days of storage. The comment states that a product that has been under a temporary hold and detained for 7 days will exceed the useful time of a perishable food.

Another comment states that FDA must take into account the 24-hour period of the temporary hold in the detention time of 30 days. Another comment states that they do not challenge the right of FDA to inspect food products at the border, but that, in their view, the 24 hour temporary hold is an unreasonable time to force a truck and driver to wait for FDA to conduct an inspection and issue a decision. This comment indicates that the proposed recordkeeping rule will require companies to turn over records to FDA within 4 hours during normal business hours, and 8 hours on evenings and weekends, and suggests that, if FDA is willing to impose such short timeframes on industry, then it should also be required to adhere to them in the conduct of its own operations.

Another comment suggests that the guidance on temporary holds should be made available as soon as possible because there is no explanation about why FDA must ask specifically the ``Secretary of Treasury'' to institute the temporary hold. This comment states that it is not clear if the alternative exists for the ``Secretary of Treasury'' to designate or to enable someone with proper skills to replace him when he is not available. A few comments state that the proposed provision for the temporary holding of imports for 24 hours is open to abuse. They indicate that not only is there no comparable provision for domestic products, but there is a real risk that the provision could amount to a ``holding bay'' for import inspections while FDA resources are used to deal with domestic alerts elsewhere.

(Response) As indicated in the background section I. of this rule, the temporary hold provisions authorized in section 303 of the Bioterrorism Act are outside the scope of this rulemaking. FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

FDA notes, however, that the period of detention for administrative detention under section 303 of the Bioterrorism Act does not begin until the detention order is issued.

(Comment 13) Several comments ask that the implementation date of these regulations be pushed back because the new authorities are extensive and the timeframe for implementation is unusually quick for such a sweeping change. Furthermore, the comments state that the proposed timeframes are not sufficient for producers in exporting countries to adapt their products to the requirements of the Bioterrorism Act, and will result in unnecessary costs and delays.

(Response) Even if FDA delayed implementation of the regulations, the authority for administrative detention is self-executing and currently in effect. In addition, FDA believes that it is in the public's interest to implement these regulations as soon as possible to facilitate the resolution of administrative detentions.

(Comment 14) One comment indicates that the new regulations are burdensome and overlap with current requirements under parts 7, 110, 123, and 1240 (21 CFR parts 7, 110, 123, and 1240). This comment states that if these provisions were properly implemented, they would be more than adequate to address concerns FDA may have with rapid location of affected product and ingredient traceability that are the major concerns with this new provision. Another comment states that FDA's Investigations Operations Manual (IOM), subchapter 750, describes the procedure that FDA must follow currently for detention activities and that the new regulations do not appear substantially different. Another

comment questions the need for this rulemaking because it appears that FDA considers the threshold for detention to be equivalent to the standard for initiating a Class I recall.

(Response) FDA disagrees with these comments. The regulations in parts 7, 110, 123, and 1240, and subchapter 750 of the IOM, do not address administrative detentions of food under section 303 of the Bioterrorism Act. Further, the regulations cited in the comment are not based on the substantive standard for administrative detention under section 303 of the Bioterrorism Act, which is that the detained article of food presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 15) Numerous comments ask that FDA provide compensation for losses incurred as a result of a detention. Some comments refer to detentions where the product is eventually released, but is no longer marketable. Other comments want compensation for detentions in which damages are incurred as a result of any detention, i.e., including detentions where the product is confirmed to present a threat of serious adverse health consequences or death to humans or animals. Another comment states that the regulation does not adequately address the legal and financial responsibility for the disposal of food as a result of the threat it presents. This comment suggests that an entity with a vested interest in the product, e.g., the owner, would bear the responsibility, and that failure on the part of the food product owner to pay storage, handling and related costs should be considered a violation of the FD&C Act. One comment argues that, rather than adding to industry's burden for food security, we should provide government funding to help industry institute measures to improve food security.

(Response) Neither the FD&C Act nor the Bioterrorism Act provides for damages or other costs associated with administrative detention. In addition, the failure to pay storage, handling, and related costs is not a violation of the FD&C Act. With respect to the comment that FDA should provide government funding to help industry institute measures to improve food security, that issue is beyond the scope of this rulemaking and would require statutory authorization and appropriations.

(Comment 16) A few comments suggest that the rule should require that FDA determine the party actually responsible for the threat against the food and define their responsibility. One comment indicates that FDA must consider that the party responsible for the threat could be a third party, i.e., a party not included in the importation or distribution of the product. Another comment asks who will be held responsible in the case where a product is packaged in bulk in one country and repackaged in another country for export to the United States. One comment asks how FDA will differentiate between an actual threat and a hoax and if it will matter. Another comment asks what penalty exists for the supplier of suspect shipments. Another comment requests that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information.

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(Response) The Bioterrorism Act allows FDA to detain articles of food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. It does not require FDA to determine who is responsible for the threat in order to detain the product. Whether the person responsible for that threat or the person responsible for supplying the suspect article of food may be held liable or subject to criminal prosecution under other statutory provisions is beyond the scope of this rulemaking.

The purpose of any FDA investigation is to determine and document facts concerning a particular issue so that the agency can make informed and sound decisions. FDA cannot rule out the possibility that a hoax could give rise to an administrative detention and, in evaluating the evidence or information to determine whether it is credible, FDA will be mindful of the fact that hoaxes do occur.

In response to the comment that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information, we will provide a statement of the reasons for a detention in the detention order, but we will not divulge classified information to those without the proper security clearance.

(Comment 17) Many comments state that industry is motivated to cooperate with FDA to protect consumers and maintain national security interests in the event of a real threat. They indicate that it is imperative that FDA and industry work together as a team to quickly address such occurrences. These comments state that FDA must devise a clear communications strategy and that the agency should test such plans to make sure that they will work seamlessly.

(Response) These comments are outside the scope of this rulemaking. We agree that it is imperative that FDA and industry work together to protect the U.S. food supply. The agency recognizes the cooperation and effort that the industry has already shown in the area of food safety and security. One such example of industry and FDA partnering to protect the U.S. food supply was in the development of a Food Security Guidance that food producers can use if they choose to improve the protection of their products against tampering or terrorist actions. (See http://www.cfsan.fda.gov/~dms/fsterr.html.) FDA also agrees that it is imperative to have clear communication strategies in place and to test such plans to ensure that they will be effective in the event of a bioterrorism or other food-related emergency. We have been developing plans in this area and continue to examine other possible ways to better manage food emergencies and consult with industry on this.

(Comment 18) One comment states that development of reasonable preventative measures and appropriate responses, including rational governmental activities that are effective within every facet of the food system, are critical to protecting public safety. This comment asserts that, to be effective, these measures must be driven by the public and the food industry, not by regulation.

(Response) This comment is outside of the scope of this rulemaking. As stated in FDA's response to the previous comments, the agency recognizes the outside cooperation and effort that have already been shown in the area of food safety and security. However, FDA also believes that it is important for the agency to implement the statutory provisions on food safety and to fulfill its statutory mandates concerning food safety. FDA will provide ongoing opportunities for consumers, industry, state and local governments, and other constituents to keep informed of, and involved in, the agency's activities related to the development of preventative measures and responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Before issuing the proposed rules concerning sections 303, 305, 306, and 307 of the Bioterrorism Act, the agency provided an opportunity for constituents to identify concerns and suggest ways to address them. It is imperative that FDA and its constituents work together to protect the U.S. food supply.

(Comment 19) Some comments assert that the regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade. One comment states that this negative impact will likely result in negative ramifications for U.S. food exports because the future may well find retaliatory trade restrictions placed upon U.S. exports as a direct result of the regulatory requirements generated from the Bioterrorism Act.

(Response) In drafting the final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act. FDA carefully considered comments received regarding the burden imposed by this rule, including its impact on international trade.

(Comment 20) Several comments ask that FDA provide clear guidance and training to industry personnel at all levels and agency field personnel about the procedures for implementing the regulation. A few comments suggest that an easy to follow guide for the appeal process would be desirable. A few comments request that FDA establish consultation services at U.S. embassies staffed with speakers of various different foreign languages, such as Japanese and Spanish, and that the Bioterrorism Act and all documents associated with the detention be accompanied by official translations to facilitate comprehension and proper use. The comments suggest that we disseminate the translated material on our Web site and by other means.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international and domestic meetings, to ensure that affected parties were aware of the Bioterrorism Act administrative detention requirements.

FDA plans similar future outreach efforts. More specifics regarding our outreach activities will be included on FDA's Web site at http://www.fda.gov.

FDA also plans training for its field personnel on the