

Paper submissions are subject to longer lag times at several points. First, the facility may have to mail or phone in a request for a registration form.

Second, the facility may have to wait to receive the form. Third, the registration takes time to travel through the mail from the facility to FDA. Fourth, FDA

would require more time to process paper submissions, because the

information has to be entered manually into the ^{System} database. Fifth, FDA has to

a copy of the registration as entered, and the registration number mail out the registration confirmation, if the facility's information is complete

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and legible. ~~At this point the facility is considered registered, but the facility~~

~~would not have its registration number.~~ Sixth, the registration confirmation

has to travel through the mail to the facility. At this time, the facility would

know it is registered and have its registration number.

Because time will be important to foreign facilities bringing products into the United States, FDA assumes that they will choose to be registered by their U.S. agent, because the registration process will be much faster. Facilities that

do not have Internet access, that have representatives who can read and write in English, and learn about the registration requirements before exporting their product to the United States are most likely to register by a paper submission.

These facilities already would have invested the time to learn about the registration requirements and thus are likely to have a hard copy of the form.

If time were not a major consideration, a facility is likely to prefer to fill out the registration form on site. FDA plans to conduct extensive outreach efforts

to communicate the registration requirements to affected facilities both

domestically and abroad, both at the proposed rule stage and at the final rule

stage to minimize the number of facilities that find out about the requirements

at the port. FDA does not have the information to estimate how many foreign

facilities would not learn about the registration requirements until their goods

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are at the port. FDA instead estimates the number of foreign paper submissions to FDA as the percent of foreign facilities that do not have Internet access and whose managers are able to read and write in English. FDA requests comments on this assumption.

Under this option, U.S. agents would have a larger role than under other options. U.S. agents may charge a higher fee if they register for the facility. A higher U.S. agent fee is considered in the sensitivity analysis.

Port delays would be shorter under this option than under alternative options. Foreign facilities still would have delays associated with communication and finding a U.S. agent, but the process would be shortened by allowing the U.S. agent to register on behalf of the foreign facility. This would shorten the time that the product sits in storage and lower the loss of value of the product.

Tables ~~27, 28, and 29~~ ^{37, 38, 39, 40, and 41} of this document provide a summary of the data for cost estimates under option 7 for domestic facilities, foreign facilities, and FDA, respectively. The first year costs to foreign facilities would be reduced from \$319.6 million to \$311.8 million, annual costs would be reduced from \$228.4 million to \$227.6 million. Total costs for the first year would be reduced from ~~\$344.5 million~~ to \$336.2 million.

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TABLE 27. COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7

Facility count	
2000 CBP	103,125
1999 Nonemployer statistics	68,424
FACTS data	71,071
Mixed-type form <i>facilities that engage in farming</i>	30,497
Retail processors	10,110
Total domestic	202,046

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DIVIDE INTO TWO TABLES

TABLE 38. - SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7

Percent with Internet access US	71%
Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Research time w/Internet (hours)	1
Research time w/o Internet (hours)	2
Research cost w/Internet	\$3,601,000
Research cost w/o Internet	\$2,941,000
Form costs	\$6,670,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	\$3,322,000
Total domestic costs	\$13,212,000

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 TABLE 29. COSTS INCURRED BY
 FOREIGN FACILITIES UNDER OPTION 7

Foreign holders and packagers	100,027
Foreign facilities ^{covered} manufacturers/ processors	125,450
Stops exporting	16%
Total facilities	205,405

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TABLE 40. — SUMMARY
OF COSTS INCURRED BY
FOREIGN FACILITIES

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	\$1,000
Hourly wage rate	\$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	\$67,340,000
Agent fee (annual cost)	\$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	\$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	0
Additional time Internet (hours)	0
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	\$5,135,000
Total first year costs	\$311,762,000
Total annual costs	\$227,505,000

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TABLE 4. COSTS INCURRED BY FDA UNDER OPTION 7

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,500,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$115,012	\$119,612	\$124,306	\$129,372
Cost per paper submission	\$10	\$10.40	\$10.82	\$11.25	\$11.70
Number of domestic paper submissions	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	20,182	8,073	8,073	8,073	8,073
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
Total number of foreign registrations in database	182,805	182,805	182,805	182,805	182,805
Mailings to domestic facilities	\$1	\$1.04	\$1.08	\$1.12	\$1.17
Mailings to foreign facilities	\$1	\$1.04	\$1.08	\$1.12	\$1.17
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	\$15	\$15.60	\$16.22	\$16.87	\$17.55
Total costs	\$11,195,000	\$7,397,000	\$8,533,000	\$7,322,000	\$7,350,000
Discounted total costs	\$11,195,000	\$6,913,000	\$7,453,000	\$5,977,000	\$5,607,000

8. Option 8: Issue no new regulation and allow the Bioterrorism Act's default registration requirements to take effect

The Bioterrorism Act requires facilities to register with FDA by December 12, 2003, even if FDA has not issued final regulations by this date. Failure to do so for both foreign and domestic facilities is a prohibited act, and FDA must hold food from unregistered foreign facilities at the port of entry until they are registered. Thus, facilities have an incentive to register with FDA. Failure to issue a final regulation would result in an unworkable, chaotic system. The Bioterrorism Act also requires facilities that register in the absence of a final rule to re-register with FDA as specified in the final rule once it is issued.

It is not possible to predict the costs or benefits of this option because the statute is not specific enough to predict how it would be implemented. It seems likely that many facilities will attempt to register, given the penalties for failure to register. However, if FDA receives all paper, non-standardized

Table 41 p.90

FDA Costs	2003	2004	2005	2006	2007
Development/Modi	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/Stea	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper s	\$10	\$10	\$10	\$10	\$10
Number of domest	58,593	23,437	23,437	23,437	23,437
Number of foreign	22,677	9,071	9,071	9,071	9,071
Total number of	202,046	202,046	202,046	202,046	202,046
Total number of	205,405	205,405	205,405	205,405	205,405
Mailings to dome	\$1	\$1	\$1	\$1	\$1
Mailings to fore	\$1	\$1	\$1	\$1	\$1
Error rate for p	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,225,000	\$7,376,000	\$8,476,000	\$7,255,000	\$7,255,000
Discounted total	\$11,225,000	\$6,893,000	\$7,403,000	\$5,922,000	\$5,535,000

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registrations, it will be extremely difficult for FDA to process the registrations and to use the information provided. It would also be a slow process for FDA to issue registration numbers.

9. Summary of costs

Tables ~~30~~ and ~~31~~ present a summary of costs for options 2 through 7 for domestic facilities, foreign facilities, and FDA costs in future years ^{are} discounted at 7 percent.

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TABLE 30. TOTAL COST OF OPTIONS 2 THROUGH 4 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

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	Option 2	Option 3	Option 4
Domestic first year costs	\$13,557,000	\$7,038,000	\$11,237,000
Foreign first year costs	\$319,619,000	\$319,619,000	\$319,619,000
FDA first year costs	\$11,279,000	\$10,907,000	\$11,145,000
Total first year costs	\$344,455,000	\$337,564,000	\$341,981,000
Domestic second year costs	\$3,186,000	\$1,654,000	\$2,636,000
Foreign second year costs	\$213,430,000	\$213,430,000	\$213,430,000
FDA second year costs	\$7,416,000	\$7,272,000	\$7,820,000
Total second year costs	\$224,032,000	\$222,356,000	\$223,886,000
Domestic third year costs	\$2,978,000	\$1,546,000	\$2,464,000
Foreign third year costs	\$199,467,000	\$199,467,000	\$199,467,000
FDA third year costs	\$8,562,000	\$8,404,000	\$8,951,000
Total third year costs	\$211,007,000	\$209,417,000	\$210,882,000
Domestic fourth year costs	\$2,783,000	\$1,445,000	\$2,303,000
Foreign fourth year costs	\$186,418,000	\$186,418,000	\$186,418,000
FDA fourth year costs	\$7,354,000	\$7,187,000	\$7,734,000
Total fourth year costs	\$196,555,000	\$195,050,000	\$196,455,000

SEE REVISED TABLE 42a + 42b COMBINED (NEXT PAGE)

TABLE 31. TOTAL COST OF OPTIONS 5 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

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	Option 5	Option 6	Option 7
Domestic first year costs	\$12,256,000	\$13,212,000	\$13,212,000
Foreign first year costs	\$318,355,000	\$319,619,000	\$311,762,000
FDA first year costs	\$11,279,000	\$11,225,000	\$11,225,000
Total first year costs	\$341,890,000	\$344,056,000	\$336,199,000
Domestic second year costs	\$2,181,000	\$3,105,000	\$3,105,000
Foreign second year costs	\$212,831,000	\$213,430,000	\$212,696,000
FDA second year costs	\$7,758,000	\$7,411,000	\$7,411,000
Total second year costs	\$222,770,000	\$223,946,000	\$223,212,000
Domestic third year costs	\$2,039,000	\$2,902,000	\$2,902,000
Foreign third year costs	\$198,907,000	\$199,467,000	\$198,782,000
FDA third year costs	\$8,887,000	\$8,547,000	\$8,547,000
Total third year costs	\$209,835,000	\$210,916,000	\$210,231,000
Domestic fourth year costs	\$1,905,000	\$2,712,000	\$2,712,000
Foreign fourth year costs	\$185,895,000	\$186,418,000	\$185,777,000
FDA fourth year costs	\$7,668,000	\$7,336,000	\$7,336,000
Total fourth year costs	\$195,468,000	\$196,466,000	\$195,825,000

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a. Sensitivity to assumptions

A number of assumptions in the analysis significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under alternative assumptions. FDA uses option 7,

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	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Domestic first y	\$13,557,000	\$7,038,000	\$11,217,000	\$12,256,000	\$13,212,000	\$13,212,000
Foreign first ye	\$319,619,000	\$319,619,000	\$319,619,000	(\$318,335,000)	\$319,619,000	\$311,762,000
FDA first year c	\$11,279,000	\$10,907,000	\$11,145,000	\$11,279,000	\$11,225,000	\$11,225,000
Total first year	\$344,455,000	\$337,564,000	\$341,981,000	\$341,870,000	\$344,056,000	\$336,199,000
Domestic second	\$3,186,000	\$1,654,000	\$2,636,000	\$2,181,000	\$3,105,000	\$3,105,000
Foreign second y	\$213,430,000	\$213,430,000	\$213,430,000	\$212,831,000	\$213,430,000	\$212,696,000
FDA second year	\$7,385,000	\$7,243,000	\$7,342,000	\$7,294,000	\$7,376,000	\$7,376,000
Total second yea	\$224,001,000	\$222,327,000	\$223,408,000	\$222,306,000	\$223,911,000	\$223,177,000
Domestic third y	\$2,978,000	\$1,546,000	\$2,464,000	\$2,039,000	\$2,902,000	\$2,902,000
Foreign third ye	\$199,467,000	\$199,467,000	\$199,467,000	\$198,907,000	\$199,467,000	\$198,782,000
FDA third year c	\$8,498,000	\$8,343,000	\$8,442,000	\$8,394,000	\$8,476,000	\$8,476,000
Total third year	\$210,943,000	\$209,356,000	\$210,373,000	\$209,340,000	\$210,845,000	\$210,160,000
Domestic fourth	\$2,783,000	\$1,445,000	\$2,303,000	\$1,905,000	\$2,712,000	\$2,712,000
Foreign fourth y	\$186,418,000	\$186,418,000	\$186,418,000	\$185,895,000	\$186,418,000	\$185,777,000
FDA fourth year	\$7,276,000	\$7,122,000	\$7,221,000	\$7,173,000	\$7,255,000	\$7,255,000
Total fourth yea	\$196,477,000	\$194,985,000	\$195,942,000	\$194,973,000	\$196,385,000	\$195,744,000

the proposed option, to compare across assumptions. Table ^{43/} 32 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or hold food received from off the facility based on data from the Census of Agriculture and information from ~~County Extension Services~~ ^{ES} (Ref. 7). Because there are over ~~two~~ ² million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from \$13.2 to \$17.8 million.

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Another significant source of uncertainty is the amount of time it would take facility employees to read and understand the requirements and for foreign facilities to find a U.S. agent. To test the time assumptions, FDA estimated the costs assuming all the time estimates for administrative activities were doubled. This increases the cost estimates for domestic facilities from \$13.2 to \$19.8 million and increases the cost estimates for foreign ~~entities~~ ^{facilities} from \$311.8 million to \$423.5 million.

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Hiring and retaining a U.S. agent is a significant cost for foreign facilities. FDA tested how this affects total cost estimates by doubling the percent of foreign manufacturers that have U.S. agents from 10 percent to 20 percent. This lowers the first year cost for foreign facilities from \$311.8 million to \$297.3 million.

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Also subject to a great deal of uncertainty is the number of foreign manufacturers/processors who can read and write in English. Research on the

topic shows widely ranging estimates of the number of English speakers in countries where English is not the primary language. Even in countries where English is a primary or secondary language, many inhabitants may not be fluent in English (Ref. 14). However, more than one individual may work in a facility in an appropriate position to fill out the registration form. This increases the probability that an individual with English skills sufficient to fill out the registration form may be available. FDA estimated that 16 percent of foreign facilities had employees that were fluent in English. To test our assumption about the percentage of foreign facilities with employees who are fluent in English, FDA looked at the alternate assumption that 32 percent of foreign facilities would have a worker with the capability to research and fill out the form in English. This change decreases the total cost to foreign facilities from \$311.8 to \$303.4 million.

FDA assumed that the number of foreign facilities that hold food products before exporting them to the United States is equal to the number of domestic brokers and consignees, because of the lack of data about foreign facilities holding and doing de minimis processing of food. To test this assumption, FDA looked at the costs if the number of foreign holders and de minimis processors is 160,000. Changing this assumption has a large effect on the foreign and total cost, increasing the foreign cost from \$311.8 to \$405.2 million and the total cost from \$336.2 to \$429.7 million.

FDA tested the effect of changing the annual U.S. agent fee. If the average U.S. agent fee is \$1,500, instead of \$1,000, the costs to foreign facilities will be increased from \$311.8 to \$409.2 million.

Finally, FDA tested the assumption that the foreign wage rate is the same as the domestic wage rate and re-estimated the costs for a foreign wage rate

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of \$15 per hour. The total cost to foreign facilities was reduced from \$311.8 million to \$265.0 million under this assumption.

See revised Table 43 next page

TABLE 43—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)

First Year Costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA Cost (dollars)	Total Cost (dollars)
Under current assumptions	13,212,000	311,762,000	11,225,000	336,199,000
100,000 facilities are mixed-type	17,756,000	311,762,000	11,484,000	341,002,000
Time costs are doubled	19,754,000	423,521,000	11,225,000	454,500,000
20 percent of foreign manufacturers have U.S. agents	13,212,000	297,357,000	11,225,000	321,694,000
32 percent of foreign facilities are fluent in English	13,212,000	303,395,000	11,474,000	328,081,000
160,000 foreign holders	13,212,000	405,168,000	11,304,000	429,684,000
U.S. agent fee \$1,500	13,212,000	409,195,000	11,225,000	433,632,000
Foreign wage rate \$15	13,212,000	265,004,000	11,225,000	289,441,000

* 30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers have U.S. agents, 16 percent of foreign facilities are fluent in English, 77,427 foreign final holders, and U.S. agent fee of \$1,000.

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b. Qualitative costs

For all of the options, except option one, there are a number of costs that FDA was unable to quantify. Loss of products from small exporters who would choose to stop exporting to the United States due to the increased cost of business may represent significant costs. Earlier in the analysis, we estimated that about 16% ^{percent} of foreign manufacturers export 10 or fewer line entries per year, and that these manufacturers would cease exporting to the United States. This could result in the elimination of some specialty products that market to very small niche markets in the United States, which would represent a loss to consumers who use these products.

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The cost of port delays for facilities that do not learn of the requirements before exporting is another cost FDA was unable to quantify. FDA is unable to estimate how many foreign facilities would not learn about the new requirements before exporting. For this analysis, we estimate the ^{expected} average cost of learning about registration as the number of hours a worker in a foreign facility needs to learn about the requirements. However, we expect that for some facilities, the cost of learning about the requirements would be much

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Table 43 p. 95

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First year costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA cost	Total Cost (dollars)
Under current assumptions*	\$13,212,000	\$311,762,000	\$11,225,000	\$336,199,000
Percentage change from baseline	(0%)	(0%)	(0%)	(0%)
100,000 mixed-type facilities that engage in farming	\$17,756,000	\$311,762,000	\$11,484,000	\$341,002,000
Percentage change from baseline	(34%)	(0%)	(2%)	(1%)
Time costs are doubled	\$19,754,000	\$423,521,000	\$11,225,000	\$454,500,000
Percentage change from baseline	(50%)	(36%)	(0%)	(35%)
20 percent of foreign manufacturers have US agent	\$13,212,000	\$297,257,000	\$11,225,000	\$321,694,000
Percentage change from baseline	(0%)	(-5%)	(0%)	(-4%)
32% of foreign facilities are fluent in English	\$13,212,000	\$303,395,000	\$11,474,000	\$328,081,000
Percentage change from baseline	(0%)	(-3%)	(2%)	(-2%)
160,000 foreign holders	\$13,212,000	\$405,168,000	\$11,304,000	\$429,684,000
Percentage change from baseline	(0%)	(30%)	(1%)	(28%)
US agent fee \$1500	\$13,212,000	\$409,195,000	\$11,225,000	\$433,632,000
Percentage change from baseline	(0%)	(31%)	(0%)	(29%)
Foreign wage rate \$15	\$13,212,000	\$265,004,000	\$11,225,000	\$289,441,000
Percentage change from baseline	(0%)	(-15%)	(0%)	(-14%)

*30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers/processors have United States agents, 16 percent of foreign facilities are fluent in English, 100,027 foreign holders and packagers, and United States agent fee of \$1000.

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higher than the ~~average~~ ^{expected cost}. Facilities that do not learn about the registration requirements before reaching the United States port would still have their shipment held at the port. The loss of value may be as low as the cost of storage, or as high as the value of the shipment, if perishable.

Under option 7, FDA expects this cost to be lower. If the U.S. agent registers the foreign facility, this will speed up the registration process and the product would be released into ~~United States~~ ^{United States} commerce faster.

FDA also was unable to quantify the costs incurred by FDA, trade associations, and others for outreach about the registration requirements. FDA will undertake outreach to notify domestic and foreign facilities about registration through public meetings, satellite downlink to five continents, and providing help desk support. FDA also anticipates that trade organizations and others, such as brokers, foreign governments, and ~~United States~~ ^{United States} businesses, will undertake to notify facilities of the registration requirements. FDA requests comments on the size and the basis for estimating these costs.

Benefits

These provisions would improve FDA's ability to respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. Based on historical evidence, a strike on the food supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement Title III of the Bioterrorism

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Act. Prior notice for imported shipments (section 307 of the Bioterrorism Act) would aid in the enforcement of registration and registration, in turn, would aid in the verification of prior notice submissions. Registration and recordkeeping also would work cooperatively. ✓

To understand possible costs of an intentional strike on the food supply, in table 33, FDA presents five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods. These outbreaks do not represent possible forms that a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is likely that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown. We instead examine four mechanisms through which each regulatory option may act and analyze how each of the options affects these mechanisms. e

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4 These regulations also improve FDA's ability to prevent and respond to accidental foodborne outbreaks. FDA lacks data on the number of ^{accidental} outbreaks that will be prevented or shortened from this proposed rule, as well as from registration working in conjunction with the other regulations being developed to implement Title III of the Bioterrorism Act. To understand possible costs of inadvertent foodborne illness and from an intentional strike on the food supply, FDA presents five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods in table 44. Registration will aid FDA in preventing and shortening foodborne outbreaks, but we do not know how frequently an outbreak would be ~~avoided~~ ^{occur} or the size and severity of the outbreak ~~in the absence of registration~~ ^{by}. These foodborne outbreaks also do not represent the form a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is likely that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown. Therefore, FDA is unable to quantify the benefits of registration arising from preventing or lessening the impact of a foodborne outbreak. Instead, we examine four mechanisms through which each regulatory option might act and analyze how each of the options affects these mechanisms.

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TABLE 33-44 SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
<i>Salmonella enteritidis</i>	Minnesota 1994	Ice cream	150 cases, 30 hospitalized	29,100 in MN, 224,00 nationwide	3,187,744,000 to 5,629,792,000
<i>Shigella sonnei</i>	Michigan 1988	Tofu salad	3,175 cases	Not available	45,183,000 to 79,797,000
Outbreaks resulting from deliberate contamination					
<i>Salmonella Typhimurium</i>	Dalles, Oregon 1984	Salad bars	751 cases, 45 hospitalized	Not available	10,687,000 to 18,874,883
<i>Shigella dysenteriae</i> type 2	Texas 1996	Muffins and doughnuts	12 cases, 4 hospitalized	All cases identified	83,000
Outbreaks resulting from imported foods					
<i>Cyclospora cayatanensis</i>	United States and Canada 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalized	Not available	3,941,000 to 3,941,000

a. *Salmonella enteritidis* in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with *Salmonella enteritidis*. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that carried non-pasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota.

However, ice cream produced during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 19).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of two to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small

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percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over ~~one~~¹ percent of cases develop short-term reactive arthritis and ~~two~~³ percent of cases develop chronic, reactive arthritis.

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FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table ~~3~~^{45 of this document} provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a ~~Quality Adjusted Life Year~~^{Quality Adjusted Life Year} (QALY), or the loss of a year of life is valued at \$100,000, based on economic studies of how consumers value risks to life (Ref. 20). Thus, an entire lost QALD would be valued at \$274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 21) and another based on a regression analysis approach (Ref. 22). This gives a range of costs for the average case of salmonellosis between \$14,231 and \$25,133.

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TABLE 45 THE COST OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown (percent)	Total QALDs Lost per Illness	Health Loss (dollars) per Case (Discounted)	Medical Costs (dollars) per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7	1.05	660	0	599
Moderate	8.1	3.68	2,310	283	209
Severe	1.2	9.99	6,266	9,250	188
Arthritis					
Regression approach					
Short-term	1.26	5.41	3,391	100	44
Long-term	2.40	2,613.12	452,554	7,322	11,048
Direct survey approach					
Short-term	1.26	10.81	6,778	100	87
Long-term	2.40	5,223.15	904,573	7,322	21,906
Death	0.04		5,000,000		2,143
Total expected loss per case					
Regression approach					14,231
Direct survey approach					25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between \$3,187,744,000 and \$5,629,792,000 from this accidental food disaster.

b. *Shigella sonnei* in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with *Shigella sonnei* and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 23). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of \$45,183,125 to \$79,797,275.

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c. *Salmonella typhimurium* in salad bars

During September and October of 1984, two outbreaks of *Salmonella typhimurium* occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying

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Salmonella typhimurium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout.

Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 24).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak.

We use the cost estimates for salmonellosis as ranging from \$14,231 to \$25,133.

This gives an estimated cost of known cases for the outbreak of \$10,687,481⁰⁰⁰ to \$18,874,993^{5,000} - AJ

Shigella dysenteriae type 2 among laboratory workers

H. Lewis

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 25).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of

gastroenteritis resulting from salmonellosis. This gives a cost of \$62,808 for illnesses associated with the event.

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 Table 46 summarizes the costs associated with this outbreak.

TABLE 46. SUMMARY OF COSTS FOR ~~CASES~~ ^{CASES} OF SHIGELLOSIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	0	0	0
Moderate	8	2,593	21,000 20,744
Severe	4	15,516	62,000 62,064
Grand total			83,000 82,808

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e. Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 26). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 27).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 27). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20

hospitalizations were reported from the cyclosporias outbreak (Ref. 26). No deaths were confirmed. ^{Table 47 summarizes the cost associated with this outbreak.}

TABLE 47—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,950 ⁰⁰⁰
Moderate	586	3,748	2,196,328 ⁰⁰⁰
Severe	19	15,516	294,784 ⁰⁰⁰
Grand total			\$3,941,000

f. Mechanisms

Requiring registration of manufacturers/processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways. One, by requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain. Two, if FDA is aware of a specific food threat, then it would be able to inform the facilities potentially affected by the threat. Three, FDA would be able to deploy more efficiently its domestic compliance and regulatory resources and better able to identify facilities affected by future regulations. Four, FDA inspectors, using prior notice and registration, can better identify shipments for inspection.

Registering with the FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. By creating this paper trail, persons who might intentionally contaminate the food supply and are considering starting a business in the food supply chain would be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply that refuse to register, if foreign, would risk having their product held at the port and, if foreign or domestic, would be subject to criminal sanctions.

With correct contact information and product categories, FDA can quickly contact domestic and foreign facilities that may be targeted by a specific food threat. This quick communication would allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination.

A complete list of facilities in the food supply chain would aid FDA in scheduling inspections and undertaking compliance activities. Domestically, a complete list of facilities with correct contact information would aid inspectors in contacting facilities, and with product information would aid in identifying facilities for inspections. Because of the turnover in the food industry and the ratio of inspectors to food facilities, FDA never has had a complete list of foreign or domestic facilities that provide food for consumption in the United States. Also, a complete list of facilities would aid FDA in understanding which facilities would be affected by a future regulation,^S which would result in targeting communication and outreach to these facilities.

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In conjunction with the prior notification requirements in 21 CFR Part 1, Subpart I, FDA can better identify imported food shipments for inspection at the port. The registration would identify the country of the manufacturer, which may not be the same as the country from which the product has been shipped. This information would assist FDA in identifying specific shipments to inspect, if we have information that a particular type of food or shipments from a particular country may be adulterated. Additionally, the database of registrants and products also would aid FDA in verifying that a product is correctly identified by where and by whom it was produced. For example, if the registration information identifies a facility as producing only dairy

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products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that shipment for verification based on the discrepancy.

~~Comparison of benefits under each option~~

Because we cannot quantify the benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we look at how effectively each of the mechanisms would operate under each of the options relative to no regulation (option one).

1. ~~One~~^R registration would deter persons who might intentionally contaminate the food supply from entering the food production chain.

Option 1: No impact.

Option 2: This option is the most comprehensive in the registration requirements and thus would have the largest impact on deterring persons who might intentionally contaminate the food supply.

Option 3: If FDA does not require intrastate facilities to register, then persons who might intentionally contaminate the food supply might be more likely to choose an intrastate facility for carrying out an attack on the food supply.

However, intrastate facilities are more likely to be small, and generally do not distribute product widely or in large quantities. These are all characteristics that would make intrastate facilities less attractive to a person who would intentionally contaminate the food supply. Therefore, FDA expects that excluding intrastate facilities would reduce the function of the first mechanism, but not to a great extent.

Option 4: Option four still would cover many of the same facilities as option 2. However, if mixed-type facilities are not required to register, then these types of facilities may be more vulnerable. However, many state and local

agencies have registration requirements for mixed-type facilities. Some of these facilities would be covered under these state or local agencies. Persons who might intentionally contaminate the food supply might be more likely to choose a mixed-type facility that is not required to register for carrying out an attack on the food supply.

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Option 5: This option provides the same coverage of facilities as option 2. It does not require the inclusion of food product categories on the registration form. FDA anticipates that excluding product categories, by reducing the amount of information required by the registrant, would reduce slightly this regulation's ability to deter persons who might intentionally contaminate the food supply.

Option 6: This option provides coverage of the food production chain similar to option two, and so will have a similar effect in deterring persons who might intentionally contaminate the food supply from entering the food production chain.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and so would be equally as effective in preventing persons who might intentionally contaminate the food supply from entering the food production chain.

2. ~~Two~~ *FDA would be better able to inform facilities if they are affected by a threat.*

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: Excluding intrastate facilities from registering would reduce FDA's ability to inform intrastate facilities of a specific threat. However, intrastate

facilities are less likely to be the focus of a threat because of their small size and small distribution range.

Option 4: FDA's ability to inform facilities would be better than without a registration system, but excluding mixed-type facilities from registering would reduce FDA's ability to inform mixed-type facilities of a specific threat.

Option 5: FDA's ability to inform facilities would be better than without a registration system, but not including product categories on the registration form would significantly limit FDA's ability to inform facilities of threats related to specific foods. For example, if FDA receives credible information that persons who might intentionally contaminate the food supply have threatened foreign or domestic cheeses, inclusion of product categories would allow FDA to communicate quickly with only those facilities impacted by this threat.

Option 6: This option provides coverage of food production chain similar to option two, and so would have a similar effect in ~~detering persons who might intentionally contaminate the food supply from entering the food production chain.~~ ^{aiding FDA in contacting} ~~facilities in response to a threat.~~ ~~intentionally contaminate the food supply from entering the food production chain.~~ -LE

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in contacting facilities in response to a threat.

3. ~~Three~~ *FDA would be more efficient in deploying its enforcement resources and better able to identify facilities affected by future regulations.* —

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest beneficial effect of the options.

Option 3: Because FDA exercises less regulatory authority over facilities that operate only in intrastate commerce, and thus seldom inspects these facilities, not requiring facilities that operate only in intrastate commerce to register will have a small effect on FDA's ability to deploy enforcement resources and identify facilities that are affected by future regulations.

Option 4: FDA shares enforcement responsibilities for a number of mixed-type facilities with other federal, state, and local agencies. Therefore, option 4 would aid FDA in its enforcement activities, though not as fully as option 2. However, FDA would be less able to identify mixed-type facilities that are affected by future regulations for outreach and other activities.

Option 5: Excluding product categories would limit FDA's ability to use the registration database to deploy its enforcement resources. Although FDA still would be aided by the registration requirements under option 5, our efforts would not be as efficient as under option 2. Information from registration makes enforcement more efficient; thus, the more information provided, the greater the increase in efficiency.

Option 6: This option provides similar coverage of the food production chain as option 2 and so will have a similar effect in ~~detering persons who might intentionally contaminate the food supply from entering the food production chain.~~ ^{aiding FDA in} ~~deploying enforcement resources and identifying facilities that~~ ^{are affected by future regulations.} LE

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in deploying resources as option 6.

4. ^R ~~Four~~ registration, in conjunction with prior notice, would give FDA information that will aid FDA in determining which shipments to inspect.

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: FDA's ability to target imported foods would be unaffected by excluding intrastate facilities. Option 3 would be as effective as option 2.

Option 4: FDA's ability to target imported foods would be lessened slightly by excluding mixed-type facilities.

Option 5: Not including food product categories would limit FDA's ability to target specific products and country product combinations at the ports.

Excluding food categories also would limit FDA's ability to evaluate as thoroughly as possible prior notifications of food imports we receive under 21 CFR part 1, Subpart I. For example, if a facility registers as manufacturing/processing only canned goods and we receive a prior notice purportedly from this facility for fresh seafood, FDA would have critical information indicating that the shipment may warrant examination.

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Option 6: this option provides similar coverage of the food production chain as option 2, and so would have a similar effect in ^{aiding FDA in determining} ~~detering persons who might~~ ^{which shipments to inspect.} ~~intentionally contaminate the food supply from entering the food production chain~~

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Option 7: Option 7 would be as effective as option 2 in aiding FDA in targeting import inspections.

V. B. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed 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 rule on small entities. FDA is unsure

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whether or not this proposed rule would have a significant economic impact on a substantial number of small entities, but has analyzed various regulatory options to examine the impact on small entities. The analysis ^{following} below, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

B. Economic effect on small entities

Of the 202,046 domestic entities covered by option 7, the proposed option, 99 percent are small according to the definitions of the Small Business Administration. Because such a large percentage of the domestic entities are small, all options considered in the Benefit-Cost Analysis in section IV.A ^{of this document} above are regulatory relief options. The expected burden for most small entities is low, between \$~~33~~⁵⁸ and \$~~58~~⁸³. However, over 200,000 entities are affected by this rule. If a small percentage of these entities incur costs significantly higher than the expected cost, then a substantial number of small entities may be significantly affected. FDA requests comment on the effect of this proposed rule on small entities.

C. Additional flexibility considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 305 of the Bioterrorism Act to allow small entities more time to register, since the Bioterrorism Act established a registration deadline that applies to all covered facilities. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the registration provision contains no such language. Thus, it appears that Congress intended for all

facilities to be subject to the deadline established in the Bioterrorism Act.

Nonetheless, the agency recognizes that the registration requirement may cause

an economic burden to some small businesses; therefore, we are seeking comment on whether it would be consistent with section 305 of the Bioterrorism Act for the agency to set staggered compliance dates that would give small businesses more time to comply.

However, the Bioterrorism Act does have considerable flexibility for small businesses built into the statute. First, retail facilities and farms are both exempt from registration. Many of these are small entities. Second, the economic impact on small entities is lessened by allowing entities to register either electronically or by mail. Small entities that do not have reasonable access to a computer or the Internet can submit their registration by mail.

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VI ^ • U • *Unfunded Mandates*

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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 would 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 \$112.3 million. because the total cost to the domestic private sector would be \$13 million, FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

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VII ^ • D • *SBREFA Major Rule*

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The Small Business Regulatory Enforcement Fairness Act of 1996 (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; 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 the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will be a major rule for the purpose of congressional review.

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~~VIII.~~
~~X~~ Paperwork Reduction Act of 1995

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This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given ^{in the following paragraphs} below with an estimate of the annual reporting 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.

FDA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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Title: Registration of food facilities

Description: The Bioterrorism Act contains a provision requiring the Secretary to ^{issue} promulgate a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. The Bioterrorism Act defines foreign facilities as those that manufacture/process, pack, or hold food for export to the United States without further processing or packaging outside the United States before export. Information FDA proposes to require on the form includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories ^{under} ~~21 CFR~~ 170.3; and a certification statement that includes the name, title/ ^{pursuant to} position, and phone number (e-mail address and fax number if available) of the registrant. Additionally, under the proposed rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under ~~21 CFR~~ 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is solely a warehouse/holding facility, and approximate dates of operation if the facility's business is seasonal. Under the proposed rule, facilities would also be required to submit timely updates when any information on their registration form changes, including cancellation of the registration on a separate form.

Description of Respondents: Domestic facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. This includes facilities engaged in both interstate and intrastate commerce and mixed-type facilities as described in option 6. Foreign facilities

are required to register if they are manufacture/process, pack, or hold food that is not further processed or packaged outside the United States.

The number of respondents is shown in Table 48.

~~TABLE 37~~
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RESPONDENTS

Foreign	182,806	265,405
Domestic	202,046	
Total	384,852	407,451

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Burden:

Hour Burden Estimate

FDA estimates that initially it would take an administrative worker with Internet access one hour to read and understand the registration requirements; this time is doubled to two hours of an administrative worker's time for those facilities without Internet access. Foreign facilities' workers would need one hour to read and understand the registration requirements, if they have access to the Internet and can read and write in English. An additional ~~five~~ ⁵ hours would be needed if they do not have Internet access, and an additional ~~five~~ ⁵ hours would be needed if they do not read or understand English. In subsequent years, facilities that enter the industry would have to register, facilities that close would have to notify FDA of their closure, and facilities that have changes in the registration information would have to provide updates to FDA. FDA estimates that annually 10 percent of covered facilities would close, 10 percent would open (Ref. 9) and 20 percent of registered facilities would have changes to their registration information.

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Next, FDA estimates that filling out a registration form would take a total of ~~one~~ ¹ hour: 45 minutes of an administrative worker's time and 15 minutes of a owner, operator, or agent-in-charge's time to certify the registration before submitting the form to FDA. Foreign facilities' workers would need ~~one~~ ¹ hour to fill out the form, if they have access to the Internet and can read and write

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in English. An additional ~~one~~^{one} (1) hour would be needed if they do not have Internet access and an additional ~~one~~^{one} (1) hour would be needed if they do not read or understand English. Table ~~28~~^{49 of this document} shows the burden by domestic and foreign facilities, availability of the Internet, and fluency in English. For foreign facilities, FDA only had data on the percentage of facilities with Internet access and percentage fluent in English, but no information on what percentages of facilities are both fluent in English and have Internet access. To calculate the total number of burden hours, FDA assigned the correct percentages of fluent facilities and facilities with Internet access to the total number of facilities, but for ease of computation excluded a category of facilities that are not fluent in English and have Internet access. FDA requests comments on the number of facilities not fluent in English and without Internet access.

TABLE 49 ~~58~~—ESTIMATED ANNUAL REPORTING BURDEN—FIRST YEAR¹

21 CFR Part	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1 241(a) ²	FDA 3537	143,457 ³	1	143,457 ³	2	286,914 ⁶
1 241(b) ³	FDA 3537	58,593	1	58,593	3	175,779
1 241(a) ⁴	FDA 3537	32,864	1	32,864	2	65,728
1.241(b) ⁵	FDA 3537	30,811	1	30,811	7	215,677
1 241(a) ⁶	FDA 3537	141,730	1	141,730	12	1,700,760
Total hours						2,444,848 ⁵⁰

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

² Domestic facilities with Internet access

³ Domestic facilities without Internet access

⁴ Foreign facilities with Internet access and fluent in English

⁵ Foreign facilities without Internet access and fluent in English

⁶ Foreign facilities without Internet access and not fluent in English

In the following years, new facilities will have to register with FDA. These new facilities will bear the same burden to register that facilities incurred in the first year. Based on estimates by SBA that 10 percent of all businesses are new (Ref. 8), FDA estimates that the number of new facilities each year will be equal to 10 percent of the total number of facilities. Also, facilities that go out of business will have to notify FDA to cancel their registration. FDA estimates that 10 percent of the total number of facilities will go out of business each year, also based on SBA statistics. Facilities exiting the business will have to send FDA a cancellation of their registration. FDA estimates that it will take these facilities approximately one hour to locate the correct form, enter their information, and send it to FDA. Finally, facilities that have a material change of information submitted in their registration will have to notify FDA of the new information. FDA estimates 20 percent of facilities will have a material change in the information submitted in their registration each year. It will take these facilities approximately one hour to locate the correct form, enter their information, and send it to FDA. Table 39 presents an estimate of the burden hours for new facilities, and updates and cancellations for existing facilities in future years.

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TABLE 33—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS¹

21 CFR Part	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New facilities						
1.241(a) ²	FDA 3537	14,345	1	14,345	2	28,690
1.241(b) ³	FDA 3537	5,859	1	5,859	3	17,577
1.241(a) ⁴	FDA 3537	3,286	1	3,286	2	6,572
1.241(b) ⁵	FDA 3537	3,081	1	3,081	7	21,567
1.241(a) ⁶	FDA 3537	14,173	1	14,173	12	170,076
Previously registered facilities						
1.244(a) ²	FDA 3537/3537a	43,036	1	43,036	1	43,036
1.244(b) ³	FDA 3537/3537a	17,578	1	17,578	1	17,578
1.244(a) ⁴	FDA 3537/3537a	9,859	1	9,859	1	9,859
1.244(b) ⁵	FDA 3537/3537a	9,243	1	9,243	1	9,243
1.244(a) ⁶	FDA 3537/3537a	42,519	1	42,519	1	42,519
Grand total						366,717

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¹ There are no capital costs or operating and maintenance costs associated with this collection of information.
² Domestic facilities with Internet access
³ Domestic facilities without Internet access
⁴ Foreign facilities with Internet access and fluent in English
⁵ Foreign facilities without Internet access and fluent in English
⁶ Foreign facilities without Internet access and not fluent in English

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

~~XII~~
~~VI~~ **References**
 The following references have been placed on display in theockets Management Branch (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 in this document but is not responsible for subsequent changes to the websites after this document publishes in the Federal Register.

1. United States Census Bureau, 2000 County Business Patterns, Available at <http://www.census.gov/epcd/cbp/view/cbpview.html>

2. United States Census Bureau, 1999 Nonemployer Statistics, Available at <http://www.census.gov/epcd/nonemployer/index.html>

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3. ~~United States~~ Food and Drug Administration } Field Accomplishments and Compliance Tracking System (FACTS) } Fiscal year 2002.

4. ~~United States~~ Food and Drug Administration } Operational and Administrative System for Import Support (OASIS) } Fiscal year 2002.

5. Impact Marketing Consultants } The Rauch Packaging Guide to the U.S. Packaging Industry, The Fourth Edition } 2002.

6. ~~United States~~ Department of Agriculture, National Agriculture Statistics Service } 1997 Census of Agriculture-~~United States~~ Data } Available at <http://www.nass.usda.gov/census/>

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8. ~~United States~~ Small Business Administration, Office of Advocacy } Small Business by the Numbers } May, 2002 } Available at <http://www.sba.gov/advo/stats/sbfaq.html>

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~~XI~~ VII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 C.F.R. 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.

~~XII~~ VIII. Federalism

FDA has analyzed this proposed 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

~~XIII~~ IX. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this ^{document} notice by ~~insert date~~

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~~60 days after date of publication in the Federal Register~~. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules ~~of a technical nature~~. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal ~~sanitary or phytosanitary~~ (SPS) measure of general application.

that are technical or sanitary or phytosanitary (SPS) measures.

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Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation ~~necessary to address~~ an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

or SPS measures of general application

or sanitary or phytosanitary protection

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 305 of the ~~Act~~ ^{Bioterrorism Act} requires FDA to propose and issue final regulations requiring the registration of food facilities within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 305 also provides that if

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FDA does not issue final regulations by this date, facilities still must register with FDA by December 12, 2003, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. In addition, section 801 of the ^{SBREFA} ~~Small Business Regulatory Enforcement Fairness Act~~ (5 U.S.C. 801), states that a major final rule may not take effect until 60 days after the agency has published the rule and submitted it to Congress for review.

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A major rule for this purpose is defined in 5 U.S.C. 804 as one that the Administrator of the Office of Information and Regulatory Affairs of the ~~Office of Management and Budget~~ (OMB) has determined has resulted in or is likely to result in: (A) An annual effect on the economy of \$100,000,000^{million} or more; or (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

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OMB has determined that this proposed rule, when finalized, will be a major rule. Accordingly, FDA must publish the final registration rule no later than October 12, 2003, for it to be effective by the statutory deadline of December 12, 2003. For these reasons, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after ^{the 60-day} ~~insert date 60 days~~ ^{comment period closes} ~~after date of publication in the Federal Register~~ and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's

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requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

Insert this here from pgs. 117-120
List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended ~~by adding subpart H to read~~ as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. ~~New~~ ^{part 1 to} subpart H is added to read as follows:

Subparts F–G [Reserved]
Subpart H—Registration of Food Facilities
General Provisions

Sec.

1.225 Who must register under this subpart?

1.226 Who is exempt from this subpart?

1.227 What definitions apply to this subpart?

Procedures for Registration of Food Facilities

Sec.

1.230 When must you register?

1.231 How and where do you register?

1.232 What information is required in the registration?

1.233 What optional items are included in the registration form?

1.234 How and when do you update your registration information?

Additional Provisions

Sec.

1.240 What other registration requirements apply?

1.241 What happens if you fail to register?

1.242 What does assignment of a registration number mean?

1.243 Is food registration information available to the public?

General Provisions

§ 1.225 Who must register under this subpart?

(a) You must register under this ~~subpart~~ if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless you qualify for one of the exemptions in § 1.226. ✓ JE

(b) An owner, operator, or agent in charge of a domestic facility must register whether or not the food from the facility enters interstate commerce.

(c) An owner, operator, or agent in charge of a foreign facility must register the facility. A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the facility.

§ 1.226 Who is exempt from this subpart?

This subpart does not apply to the following facilities:

(a) Foreign facilities, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. ~~Such further manufacturing/processing (including packaging) does not include adding labeling or any similar activity of a de-~~ ✓

~~minimis nature.~~ This exemption does not apply to a facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature;
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(b) Farms;

(c) Retail facilities;

(d) Restaurants;

(e) Nonprofit food facilities in which food is prepared for, or served directly to, the consumer;

(f) 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. However, those fishing vessels otherwise engaged in processing fish, which for purposes of this ~~sub~~ subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding are subject to all of the regulations in this subpart; and

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(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture 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.*).

§ 1.227 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Facility* means any establishment, structure or structures under one management at one general physical location or, in the case of a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or

Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce.

more contiguous structures. A single building may house distinct facilities if they are under separate management.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(ii) *Foreign facility* means a facility ^{other than a domestic facility} ~~located outside the United States~~ that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes:

(i) facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(ii) 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.

(4) *Food* ~~as set out above~~ 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 components of food, animal feed, including pet food, food and feed ingredients and additives including substances that migrate ^{into} ~~to~~ food from food packaging 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.

(5) *Holding* means storage of food. Holding facilities include, but are not limited to, warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

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(7) *Nonprofit food facility* means a charitable entity that prepares, serves, or otherwise provides food to the public. The term includes, but is not limited to, food banks, soup kitchens, and nonprofit food delivery services. To qualify as a nonprofit food facility, the entity must be exempt from paying federal income tax under the ~~United States~~ Internal Revenue Code.

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(8) *Packing* means placing, putting, or repacking food into different containers without making any change to the form of the food.

(9) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the ~~port~~ where food first arrives in the United States. ~~This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.~~

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(10) *Restaurant* means a facility ~~or that part of a facility~~ that ~~solely~~ prepares and sells food directly to consumers for immediate consumption. Restaurants include, but are not limited to, cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. Facilities that provide food to interstate conveyances, rather than directly to consumers, are not restaurants.

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(11) *Retail facility* means a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and

convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility.

(12) *U.S. agent* means a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent. A U.S. agent cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present. The U.S. agent acts as a communications link between FDA and the facility. FDA will treat representations provided by the U.S. agent as those of the foreign facility, and consider information provided to the U.S. agent as the equivalent of providing the same information or documents to the foreign food facility.

(13) *You or registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Procedures for Registration of Food Facilities

§ 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, holds, or packs food for consumption in the United States must be registered no later than December 12, 2003. Facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities.

§ 1.231 How and where do you register?

(a) Electronic registration: To register electronically, you must register at the appropriate Web site will be www.fda.gov/ which is available for registration 24 hours a day, 7 days

a week. This Web site ^{will be} is available wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as a foreign facility's U.S. agent ~~or broker~~ if the facility makes such arrangements. FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. Once you complete your registration, FDA will provide you with an automatic electronic confirmation of registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number ^{unless notified otherwise}

(b) *Registration by mail:* (1) If you do not have ^{reasonable} access to the Internet through any of the methods provided under this paragraph (a), you must register by obtaining a copy of ^{the registration} ~~Form FDA~~ from (Office name or mail code), the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or by phone at ^[toll-free number that will be provided in the final rule] ~~1-888-SAFEFOOD~~

(2) When you receive the form in the mail, you must fill it out completely and legibly and mail it to the address in paragraph (b) of this section.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will send the form back to you for completion, provided that your mailing address is legible and valid.

(4) FDA will enter completed registration submissions into the system as soon as practicable, in the order received.

(5) FDA will then mail to the mailing address shown on the registration form a copy of the registration as entered, confirmation of registration, and your registration number.

(6) If any information you previously submitted is incorrect as entered into the system, you must update your registration as specified in § 1.234.

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(7) You will be considered registered once FDA enters your registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language.

§ 1.232 What information is required in the registration?

Each registrant must submit the following information through either of the methods described in § 1.231:

(a) The name ~~and full address~~ of the facility; phone number, fax number, and e-mail address

(b) The name and address of the parent company, if the facility is a subsidiary of the parent company;

(c) Emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available);

(d) All trade names the facility uses;

(e) Product categories as identified in § 170.3 of this chapter;

(f) For a foreign facility, the name, address, phone number, fax number (if available), and e-mail address (if available) of its U.S. agent; and

(g) A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

§ 1.233 What optional items are included in the registration form?

FDA encourages, but does not require, you to submit the following optional items in your registration. These data will enable FDA to

communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by, an outbreak of foodborne illness. This information includes:

- (a) Preferred mailing address, if different from that of the facility;
- (b) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);
- (c) Food categories not included under § 170.3 of this chapter, but which are helpful to FDA for responding to an incident (e.g., infant formula, dietary supplements, and food for animal consumption);
- (d) Type of storage, if the facility is solely a holding facility;
- (e) A food product category of "most/all food product categories", if the facility manufactures/processes, packs, or holds foods in most or all of the categories under § 170.3 of this chapter; and
- (f) Approximate dates of operation, if the facility's business is seasonal.

§ 1.234 How and when do you update your registration information?

(a) The owner, operator, or agent in charge must submit an update to the registration within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge of a facility. (b) A facility canceling its registration must do so on the cancellation of registration form. (c) The cancellation of a facility's registration must include the following information: (1) the facility's registration number; (2) whether the facility is domestic or foreign; (3) the facility name and address; (4) the name, address, and e-mail address (if available) of the individual submitting the cancellation; and (5) a statement in which the individual submitting the cancellation will certify that the information submitted is true and accurate and the submitter is authorized by the facility to cancel its registration.

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Additional Provisions

§ 1.240 What other registration requirements apply?

In addition to these regulations, you must comply with the registration regulations found in ~~21 C.F.R.~~ ^{of this chapter} part 108, related to emergency permit control, and any other registration requirements that apply to the facility.

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§ 1.241 What happens if you fail to register?

(a) Failure of a domestic or foreign facility to register in accordance with this regulation is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) Any person who imports or offers for import an article of food without complying with the requirements of ^{section 301(l) of the act} 21 U.S.C. 381(l) as set out in this subpart, or otherwise violates any requirement under ^{section 301(l) of the act} 21 U.S.C. 381(h), or any person who causes such an act, commits a prohibited act within the meaning of ^{section 301 of the act} 21 U.S.C. 381(e).

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(c) Under ^{section 302 of the act} 21 U.S.C. section 332, the United States can bring a civil action in federal court to enjoin persons who commit prohibited acts. Under ^{section 303 of the act} 21 U.S.C. section 333, the ^{United States} U.S. can bring a criminal action in federal court to prosecute persons who commit prohibited acts. Under ^{section 306 of the act} 21 U.S.C. 335a) FDA can seek

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debarment of any person who has been convicted of a felony relating to importation of food into the United States.

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(d) If an article of food is imported or offered for import and a foreign facility that manufactured/processed, packed, or held that food has not registered in accordance with this subpart, the food must be held at the port of entry unless FDA ^{in consultation with} or U.S. Customs Service directs its removal to a secure facility in accordance with paragraph (e) of this section.

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(e) Under paragraph (d) of this section, if FDA ^{in consultation with} or U.S. Customs Service determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations

FDA, in consultation with ¹³³ U.S. Customs Service

in the port of entry), ~~either agency~~ may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility approved by FDA.

(f) Under paragraph (d) of this section, the owner, purchaser, importer or consignee must arrange for ~~movement of the article of food, under appropriate secure facility custodial bond, within the port of entry or to the secure facility~~ and must promptly notify FDA of the location. ~~Transportation and storage expenses shall~~ ^{storage of the article of food in an FDA-designated secure facility} ~~be borne by the owner, purchaser, importer, or consignee.~~ ^{Any movement of the article to the facility must be accomplished under bond.}

(g)(1) Under paragraph (d) of this section, the article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility in accordance with ~~section~~ [§] 1.231, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the article of food no longer is subject to a hold under section 301(l) ~~(1)~~ of the act.

(2) Under paragraph (d) of this section, notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

(h) Under paragraph (d) of this section, a determination that an article of food is no longer subject to hold under section 801(l) ^{of the act} is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way denote FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) Registration forms submitted under this subpart, and any information contained in those forms that would disclose the identity or location of a specific registered person, is not subject to disclosure under ~~section 552 of title 5, United States Code~~ ^{5 U.S.C.} ~~section 552 of title~~ _h (the Freedom of Information Act).

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(b) Paragraph (a) does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

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Dated: _____

Note: The following appendix will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 02^P-~~R~~????? Filed ??-??-02³~~R~~: 8:45 am]

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BILLING CODE 4160-01-S

Revisions made by
FDA's Center for Food Safety and Applied
Nutrition, Economics Staff
In Consultation with OMB/OIRA, while the
Document was Under Review at OMB/OIRA

TABLE 5.—COUNT OF FACILITIES IN FACTS

Type of Facility	Number of Facilities
Manufacturers	34,437
Repackers/packer	6,204
Warehouses	34,760
Shippers	1,519
Caterers	664
Commissary	705
Subtotal	78,289
Collapsed to account for multiple firms.	71,871

TABLE 6.—NUMBER OF FACILITIES IN INTERSTATE AND INTRASTATE COMMERCE

2000 200 CBP	103,125
1999 Nonemployer statistics	88,424
Subtotal of facilities in inter and intrastate commerce.	171,549
FACTS (interstate commerce)	71,871
Facilities only in intrastate commerce	99,678

ii. *Mixed-type facilities.* Although farms and retail facilities are exempted from registration by the Bioterrorism Act, some mixed-type facilities perform activities of a farm or retail facility and activities of a facility that is required to register. Under this regulatory option, FDA would require mixed-type facilities that manufacture/process food that is not consumed at that facility to register. Examples of manufacturing/processing include canning, freezing, cooking, pasteurization, homogenization, irradiation, milling, grinding, chopping, slicing, cutting, coloring, waxing, shelling of nuts, peeling, labeling, and packaging. Farms that mix feed would be considered mixed-type facilities if they manufacture/process feed at the facility with ingredients obtained from another source, and the feed is then sold or transferred for final use off-farm.

To estimate the number of mixed-type facilities that grow crops or raise animals and would be subject to the proposed requirements, FDA used the 1997 USDA NASS Census of Agriculture (Ref. 6), and data obtained from various county level Cooperative Extension Service (CES) offices (Ref. 7). The Census of Agriculture provides the total number of farms producing specific commodities. To estimate the number of farms that are mixed-type facilities,

TABLE 15.—YEARLY COST ESTIMATE FOR FDA UNDER OPTION 2

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,580,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10.00	\$10.00	\$10.00	\$10.00
Number of domestic paper submissions	60,124	24,050	24,050	24,050	24,050
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Mailings to foreign facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	3,312	3,312	3,312	3,312
Cost per error	\$15	\$15.00	\$15.00	\$15.00	\$15.00
Total costs	\$11,279,000	\$7,398,000	\$8,498,000	\$7,276,000	\$7,276,000
Discounted total costs	\$11,279,000	\$6,914,000	\$7,422,000	\$5,939,000	\$5,551,000

3. Option three: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in interstate commerce, including mixed-type facilities.

Option three has the same requirements as option two, but does not require domestic facilities that participate only in intrastate commerce to register. FDA tentatively concludes that this option is not legally viable. The Bioterrorism Act does not seem to limit the scope of the statute to facilities that engage only in interstate commerce. Tables 16, 17, 18, 19, and 20 of this document provide a summary of the data for cost estimates under option 3 for domestic facilities, foreign facilities, and FDA, respectively.

Excluding intrastate facilities would lower the number of affected domestic facilities from 207,324 affected facilities under option two to 107,646. This would lower the first year cost for domestic facilities from \$13.6 to \$7.0 million dollars. The annual cost would be lowered from \$3.4 to \$1.8 million

TABLE 42.—TOTAL COST OF OPTIONS 2 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Domestic first year costs	\$13,557,000	\$7,938,000	\$11,217,000	\$12,256,000	\$13,212,000	\$13,212,000
Foreign first year costs	\$319,619,000	\$319,619,000	\$319,619,000	\$318,335,000	\$319,619,000	\$311,762,000
FDA first year costs	\$11,279,000	\$10,907,000	\$11,145,000	\$11,279,000	\$11,225,000	\$11,225,000
Total first year costs	\$344,455,000	\$337,564,000	\$341,981,000	\$341,870,000	\$344,056,000	\$336,199,000
Domestic second year costs	\$3,186,000	\$1,854,000	\$2,636,000	\$2,181,000	\$3,105,000	\$3,105,000
Foreign second year costs	\$213,430,000	\$213,430,000	\$213,430,000	\$212,831,000	\$213,430,000	\$212,696,000
FDA second year costs	\$6,914,000	\$6,769,000	\$6,800,000	\$6,817,000	\$6,845,000	\$6,875,000
Total second year costs	\$223,530,000	\$221,993,000	\$223,866,000	\$222,838,000	\$223,375,000	\$221,777,000
Domestic third year costs	\$2,978,000	\$1,546,000	\$2,464,000	\$2,039,000	\$2,902,000	\$2,902,000
Foreign third year costs	\$199,467,000	\$199,467,000	\$199,467,000	\$198,907,000	\$199,467,000	\$198,782,000
FDA third year costs	\$7,422,000	\$6,996,000	\$7,314,000	\$7,331,000	\$7,332,000	\$7,476,000
Total third year costs	\$209,867,000	\$208,969,000	\$209,245,000	\$209,240,000	\$209,701,000	\$209,160,000
Domestic fourth year costs	\$2,783,000	\$1,445,000	\$2,303,000	\$1,905,000	\$2,712,000	\$2,712,000
Foreign fourth year costs	\$186,418,000	\$186,418,000	\$186,418,000	\$185,895,000	\$186,418,000	\$185,777,000
FDA fourth year costs	\$5,939,000	\$5,814,000	\$5,894,000	\$5,855,000	\$5,924,000	\$5,922,000
Total fourth year costs	\$195,140,000	\$194,685,000	\$194,615,000	\$194,655,000	\$195,052,000	\$194,411,000

a. Sensitivity to assumptions. A number of assumptions in the analysis

significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under alternative assumptions. FDA uses option 7, the proposed option, to compare across assumptions. Table 43 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or hold food received from off the facility based on data from the Census of Agriculture and information from ES (Ref. 7). Because there are over 2 million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from \$13.2 to \$17.8 million.

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Editorial Revisions made by
FDA's Regulations Editorial Section

- 2. How and Where Do You Register? (Proposed § 1.231)
- 3. What Information is Required in the Registration? (Proposed § 1.232)
- 4. What Optional Items are Included in the Registration Form? (Proposed § 1.233)
- 5. How and When Do You Update Your Registration Information? (Proposed § 1.234)

D. Additional Provisions

- 1. What Other Registration Requirements Apply? (Proposed § 1.240)
- 2. What Happens if You Fail to Register? (Proposed § 1.241)
- 3. What Does Assignment of a Registration Number Mean? (Proposed § 1.242)
- 4. Is Food Registration Information Available to the Public? (Proposed § 1.243)

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(now p 39)*

IV. Analysis of Economic Impacts

- A. Benefit-Cost Analysis
- B. ~~Initial Regulatory Flexibility Analysis~~ *Need for the Regulation*
- C. ~~Unfunded Mandates Options~~ *Reason for the Regulation*
- D. ~~Small Business Regulatory Enforcement Act (SBREFA) Major Rule~~ *Initial Regulatory Flexibility Act*
- V. ~~Paperwork Reduction Act of 1995~~ *Unfunded Mandates*
- VI. ~~Analysis of Environmental Impact~~ *FAIRNESS*
- VII. ~~Federalism~~ *Small Business Regulatory Enforcement Act (SBRECA) Major Rule*
- VIII. ~~Comments~~ *Paperwork Reduction Act of 1995*
- IX. ~~References~~ *Analysis of Environmental Impact*
- X ~~Federalism~~ *XII - References*
- XI ~~Comments~~ *ll*
- I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the

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Act FDA has endeavored to make the registration process as simple as possible for both domestic and foreign facilities.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- Owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register the facility with FDA;
- Facilities covered under this rule must be registered by December 12, 2003;
- Domestic facilities must register with FDA, whether or not food from the facility enters interstate commerce;
- A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the foreign facility;
- Foreign facilities are exempt from registering if food from these facilities undergoes further processing or packaging by another facility outside the United States. The facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register.
- The following facilities are also exempt from registering: farms; retail — MS facilities; restaurants; nonprofit food facilities in which food is prepared for, or served directly to, the consumer; fishing vessels not engaged in processing, as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection

regulated by FDA and USDA include slaughter facilities that slaughter cattle and deer, and food processing facilities that process meat and nonmeat products, such as frozen T.V. dinners containing both meat, which is regulated by USDA, and fish, which is regulated by FDA.

As specified in the Bioterrorism Act, FDA also is proposing to exempt several other facilities from the registration requirement. These facilities, which are discussed in the definitions section, include farms (§ 1.226(b)); retail facilities (§ 1.226(c)); restaurants (§ 1.226(d)); and nonprofit food facilities in which food is prepared for, or served directly to, the consumer (§ 1.226(e)).

3. What Definitions Apply to This Subpart? (Proposed § 1.227)

As specified in proposed § 1.227, the following definitions are used throughout the proposed rule:

a. *The act.* The proposed rule (§ 1.227(a)) defines “the act” as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms in the proposed rule.

b. *Calendar day.* FDA is proposing in § 1.227(c)(1) to define “calendar day” as every day shown on the calendar. This term includes weekend days.

c. *Facility.* FDA is proposing in § 1.227(c)(2) to define a “facility” as “any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce.” In response to comments that FDA received during its early

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outreach efforts, FDA is clarifying in the proposed rule that a facility is not limited to one building, but can consist of several contiguous structures.

The definition of "facility" also specifies that a facility must be under one management. This means that, for purposes of the proposed rule, a single building may house distinct facilities if they are under separate management. If a facility is under joint management of two or more companies, the joint management arrangement is considered one management.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. In order to determine whether a mixed-type facility must register, FDA will consider whether the activity that would require registration is merely incidental to the activities of an exempt facility. If these activities are merely incidental, the facility need not register. For further clarification, see the discussion of the definitions of "farm," "retail facility," and "restaurant" ^{that follow} ~~below~~. ✓ 6b

¶ ⁱ 1. *Domestic facility.* FDA is proposing in § 1.227(c)(2)(A) to define "domestic facility" consistent with the definition of "State" in section 201(a)(1) of the act (21 U.S.C. 321(a)(1)). That is, FDA is proposing to define a domestic facility as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. — MS

¶ ⁱⁱ 2. *Foreign facility.* FDA is proposing in § 1.227(c)(2)(ii) to define a foreign facility as a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States. — MS

^{incident 5} ¶ ³ d. *Farm.* FDA is proposing in § 1.227(c)(3) to define "farm" in part as "a facility ⁱⁿ one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both." A farm may consist R as a - c on prev. pg.

entered into the system is incorrect, the registrant must mail an update to correct the information within 30 calendar days.

For electronic registrations, FDA is proposing in § 1.231 to consider the facility registered when FDA electronically transmits the facility's registration number. If a registration is done by mail, the facility is registered once the data are entered into the registration system and the system generates a registration number. This means that the facility information will be entered into the registration system before the facility receives its registration number, if registration is done by mail. FDA strongly encourages all facilities, both foreign and domestic, to register electronically, as that minimizes the delay in having FDA mail the registrant a form, the registrant returning the completed form to FDA, FDA entering the facility's data manually into the registration system, and FDA subsequently mailing the registration number and receipt of registration to the facility. To the extent possible, all covered facilities should make every effort to register electronically or send in their registration form as far in advance as possible of the date they are intending to import their products into the United States (but not sooner than the announced date) since the Bioterrorism Act requires FDA to hold imported products of any unregistered facility at the U.S. port of entry until the facility is registered with FDA.

The Bioterrorism Act precludes FDA from requiring facilities to register electronically. Given FDA's preference for electronic registration and the ease of electronic registration for both registrants and FDA, FDA is requesting comments regarding what other means FDA should use to encourage electronic registration. FDA also is requesting comments from facilities that believe they

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The Bioterrorism Act does not provide specific procedures for the disposition of food under hold under section 801(l) of the act when no subsequent registration is submitted. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances. Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 calendar days after the food arrives in the United States (See 19 CFR 142.2). If entry is not made within this timeframe, the carrier or other authorized party is required to notify U.S. Customs ^{Service} and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR ~~part~~ ^{part} 127.

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Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be re-exported. FDA and U.S. Customs ^{Service} plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to failure to register.

Even though delivery is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under section 801(l) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food. FDA recognizes that food may be shipped in the same container or truck with nonfood items. Since articles that are not food are not subject to these regulations, when mixed or consolidated

as defined in 21 CFR 20.81. FDA is proposing to codify this provision in § 1.243.

IV. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

B. Need for the regulation

The purpose of this regulation is to ensure FDA has knowledge of all domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related public health emergency, such information will help FDA and other authorities determine the source and cause of such an event, and allow FDA to communicate with potentially affected facilities. The benefits of this regulation would be realized

by accomplishing this purpose, as well as other, related benefits. For example, FDA is developing a regulation, 21 CFR part 1, subpart I, to implement prior notice provisions in section 307 of the Bioterrorism Act. Information provided to FDA in a facility's registration would be helpful in FDA's assessment of whether a shipment may present a threat of serious adverse health consequences or death to humans or animals.

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C. Reason for the regulation

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

Although private incentives lead to private efforts to protect against deliberate contamination at the facility level, there are external effects associated with privately produced protection. Private incentives fail to provide the optimal amount of information about the food production and distribution system. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much

of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the more establishments participate in the system, the better it works. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to know what facilities manufacture/process, pack, or hold food for consumption in the United States, what types of food each facility handles and how each facility can be contacted. However, as stated previously, FDA is proposing three regulations to address these needs, so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help prevent and respond to threats to the nation's food supply as well as to other food safety problems.

D. Options

FDA analyzes the costs and benefits of eight regulatory options that address the goal of deterring or containing purposeful or accidental contamination of the U.S. food supply. Option 1 is the status quo and provides

of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866.

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

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

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Option two requires domestic facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA, including facilities engaged in interstate and intrastate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform activities of a farm or retail facility but that also manufacture/process food for consumption off that facility must register under this option. Registration may be electronic or by mail, although FDA strongly encourages all facilities to register electronically. The information required on the registration includes the facility's name, address, parent company name and address (if applicable), emergency contact information, trade names, general food product categories under § 170.3, and certification by the owner, operator, or agent in charge of the facility as to the accuracy of the information and the submitter's authority to register the facility.

Under the Bioterrorism Act, foreign establishments are required to register if they manufacture, process, pack, or hold food for consumption in the United States without the food undergoing further processing or packaging outside the United States. In addition to registering, the Bioterrorism Act requires foreign facilities to have a U.S. agent. The U.S. agent is a person residing in or maintaining a place of business in the United States, who the owner, operator,

or agent in charge of a foreign establishment designates as its agent. Only one U.S. agent per foreign establishment is permitted and the U.S. agent must reside or maintain a place of business in the United States. The U.S. agent is responsible for acting as a communications link between FDA and the facility.

a. Coverage ^{U.S.} Domestic establishments. Consistent with the Bioterrorism Act, this proposed regulation's legal requirements apply to facilities, as opposed to firms. A firm is composed of facilities under common ownership. As a result, changes in behavior may occur at the firm- or facility-level to comply with this proposed regulation. However, for ease of analysis, FDA will focus on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (CBP) (Ref. 1), 1999 Nonemployer Statistics (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS) (Ref. 3), and the Census of Agriculture (Ref. 4). The Census Bureau created the 2000 CBP by analyzing data from the Business Register, the Census Bureau's file of all known single and multi-facility companies. These data for single-location firms are obtained by the Census from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the Internal Revenue Service, Social Security Administration, and the Bureau of Labor Statistics.

Table 1 of this document provides a count of businesses in the relevant North American Industry Classification (NAICs) codes in the 2000 CBP. There are 103,125 affected facilities in the 2000 CBP under option two. Facilities not included in the CBP are counted in the Nonemployer Statistics, which is also from the Census Bureau (Ref. 2). Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about

manufacturing/processing, packing, or holding basic chemicals or other components incorporated into packaging for both food and nonfood use, and (2) manufacturers/processors, packers, and holders of both immediate and outer food packaging. Because this approach results in an overestimation of the number of facilities subject to this proposed rule, FDA requests comments on the number of these types of facilities that would be required to register.

Also covered under this proposed rule are slaughterhouses that process FDA regulated meats and renderers. FDA requests comments on the number of these facilities.

The Census data sets do not identify facilities engaged only in intrastate commerce (Refs. 1 and 2). To be considered a facility engaged only in intrastate commerce, a facility must obtain all its ingredients and sell all its products within a single State. FDA assumes that facilities that participate only in intrastate commerce will be very small and are unlikely to be warehouses or wholesalers. To determine which facilities are in interstate commerce, FDA compared the number of facilities in Census data sets with the number of facilities in the FACTS database. FACTS is a database of facilities regulated by FDA that includes data on operations accomplished by the field (e.g., inspections, investigations, sample collections, sample analyses, etc) (Ref. 3). FACTS and FDA's Operation and Administration System for Import Support (OASIS) identify firms as workload and nonworkload obligations for FDA. FACTS uses different product categories for facilities than the Census datasets, making a direct comparison of the number of firms within categories with the Census datasets difficult. Table 5 of this document presents a count of facilities in the FACTS database by FDA categories. The FACTS database has some facilities that appear in more than one category, so a single facility may appear

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b. *Costs*—i. *Market reaction*. It is expected that most firms will register correctly and on time. If most facilities do not register correctly and on time, then the costs will be higher than estimated. It is also likely that some manufacturers/processors will not register prior to attempting to introduce their products into U.S. interstate commerce, which would increase the amount of time their products are held at the port. In addition, some foreign facilities may determine that registration, in conjunction with prior notice, would make it no longer profitable to continue to manufacture/process and ship food to the United States. That is, if the expected profit from exports is projected to be less than the cost of a U.S. agent, the cost of registration, and the cost of prior notification, they would cease to export to the United States. The marginal costs and benefits that would result from these changes in manufacturer/processor behavior are estimated in the following paragraphs.

ii. *Wage rates*. FDA uses two hourly wage rates from the Bureau of Labor Statistics' National Compensation Survey (Ref. 9). These wage rates then are doubled to include overhead costs, such as office space, health insurance, and retirement benefits. For an administrative worker, the cost per hour is \$25.10, and for a manager, who would be the owner, operator, or agent in charge, \$56.74. FDA lacks wage data specific to food industry workers in each of the foreign countries that export to the United States and thus used the wage rate for an administrative worker in the United States for the foreign wage rate. We assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries. However, FDA tests this assumption in the

TABLE 15.—YEARLY COST ESTIMATE FOR FDA UNDER OPTION 2

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10.00	\$10.00	\$10.00	\$10.00
Number of domestic paper submissions	60,124	24,050	24,050	24,050	24,050
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Mailings to foreign facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	3,312	3,312	3,312	3,312
Cost per error	\$15	\$15.00	\$15.00	\$15.00	\$15.00
Total costs	\$11,279,000	\$7,398,000	\$8,498,000	\$7,276,000	\$7,276,000
Discounted total costs	\$11,279,000	\$6,914,000	\$7,422,000	\$5,939,000	\$5,551,000

3. Option three: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in interstate commerce, including mixed-type facilities

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Option three has the same requirements as option two, but does not require domestic facilities that participate only in intrastate commerce to register. FDA tentatively concludes that this option is not legally viable. The Bioterrorism Act does not seem to limit the scope of the statute to facilities that engage only in interstate commerce. Tables 16, 17, 18, 19, and 20 of this document provide a summary of the data for cost estimates under option 3 for domestic facilities, foreign facilities, and FDA, respectively.

Excluding intrastate facilities would lower the number of affected, domestic facilities from 207,324 affected facilities under option two to 107,646. This would lower the first year cost for domestic facilities from \$13.6 to \$7.0 million dollars. The annual cost would be lowered from \$3.4 to \$1.8 million

TABLE 20.—COSTS INCURRED BY FDA UNDER OPTION 3

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	31,217	12,487	12,487	12,487	12,487
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	107,646	107,646	107,646	107,646	107,646
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,389	2,156	2,156	2,156	2,156
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$10,907,000	\$7,243,000	\$8,343,000	\$7,122,000	\$7,122,000
Discounted total costs	\$10,907,000	\$6,769,000	\$7,287,000	\$5,814,000	\$5,433,000

4. Option four: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in interstate and intrastate commerce, not including mixed-type facilities

Option four has the same registration and U.S. agent requirements as option two, but does not require mixed-type facilities to register. Tables 21, 22, 23, 24, and 25 provide a summary of the data for cost estimates under option 4 for domestic facilities, foreign facilities, and FDA, respectively.

FDA does not believe this option is legally viable, since some mixed-type facilities engage in activities (such as manufacturing/processing for commercial distribution) that are clearly within the scope of the registration requirement as enacted by Congress. Nevertheless, we are including a discussion of this option for comparison purposes.

Excluding mixed-type facilities lowers the number of affected domestic facilities, from 207,324 affected facilities under option 2 to 171,549. This would lower the first year cost for domestic facilities from \$13.6 to \$11.2

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TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	49,749	19,900	19,900	19,900	19,900
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	171,549	171,549	171,549	171,549	171,549
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	7,243	2,897	2,897	2,897	2,897
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,145,000	\$7,342,000	\$8,442,000	\$7,221,000	\$7,221,000
Discounted total costs	\$11,145,000	\$6,862,000	\$7,374,000	\$5,894,000	\$5,509,000

5. Option five: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in interstate and intrastate commerce for consumption in the United States, including mixed-type facilities as defined in option 2, but not including product categories on the registration form. *EPD/bb*

Option five covers the same facilities as option two, but requires less information from the registrants. Registrants still would be required to submit the facility's name, address, emergency contact information, name and address of the parent company, trade names, U.S. agent information (if a foreign facility), and the name of the owner, operator, or agent in charge of the facility, but would not be required to submit the general food product categories under § 170.3. Tables 26, 27, 28, 29, and 30 of this document provide a summary of the data for cost estimates under option 5 for domestic facilities, foreign facilities, and FDA, respectively.

TABLE 30.—COSTS INCURRED BY FDA UNDER OPTION 5

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	60,124	18,037	18,037	18,037	18,037
Number of foreign paper submissions	22,677	6,803	6,803	6,803	6,803
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	2,484	2,484	2,484	2,484
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,279,000	\$7,294,000	\$8,394,000	\$7,173,000	\$7,173,000
Discounted total costs	\$11,279,000	\$6,817,000	\$7,332,000	\$5,855,000	\$5,472,000

6. Option six: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in interstate and intrastate commerce, including mixed-type facilities. Mixed-type facilities that engage in farming are covered if they pack or hold food not grown or raised on that facility or manufacture/process food not for consumption on that facility. However, facilities of these types that manufacture/process food solely for direct sale to consumers from that same facility are exempt.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. Mixed-type facilities that are required to register differ under options 2 and 6. In option 2, mixed-type facilities that manufacture/process food for consumption offsite, where offsite includes both distribution directly to consumers and distribution to nonconsumers, must register. In option 6, facilities that manufacture/process food and distribute it directly to consumers would not be included in the registration requirement.

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TABLE 30.—COSTS INCURRED BY FDA UNDER OPTION 5

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	60,124	18,037	18,037	18,037	18,037
Number of foreign paper submissions	22,677	6,803	6,803	6,803	6,803
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	2,484	2,484	2,484	2,484
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,279,000	\$7,294,000	\$8,394,000	\$7,173,000	\$7,173,000
Discounted total costs	\$11,279,000	\$6,817,000	\$7,332,000	\$5,855,000	\$5,472,000

6. Option Six: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Including Mixed-Type Facilities.

Mixed-type facilities that engage in farming are covered if they pack or hold food not grown or raised on that facility or manufacture/process food not for consumption on that facility. However, facilities of these types that manufacture/process food solely for direct sale to consumers from that same facility are exempt.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. Mixed-type facilities that are required to register differ under options 2 and 6. In option 2, mixed-type facilities that manufacture/process food for consumption offsite, where offsite includes both distribution directly to consumers and distribution to nonconsumers, must register. In option 6, facilities that manufacture/process food and distribute it

TABLE 36.—COSTS INCURRED BY FDA UNDER OPTION 6

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,225,000	\$7,376,000	\$8,476,000	\$7,255,000	\$7,255,000
Discounted total costs	\$11,225,000	\$6,893,000	\$7,403,000	\$5,922,000	\$5,535,000

7. Option seven: Require registration of domestic and foreign facilities that manufacture/process, pack, or hold food that sell their products in intrastate and interstate commerce, including mixed-type facilities, as defined in option 6. Permits the U.S. agent to register on behalf of the foreign facility.

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Permitting the U.S. agent to register on behalf of the foreign facility would reduce the number of paper registrations significantly. Foreign facilities still would have to go through administrative steps to learn about the regulation and to find and hire a U.S. agent. However, foreign facilities now would have a third option for registering. In addition to electronic and paper registration by a representative at the facility, the foreign facility can authorize its U.S. agent to register the facility. FDA assumes that U.S. agents who register on behalf of foreign facilities will register electronically. Characteristics of foreign facilities, such as access to the Internet, fluency in English, and whether they are informed about the registration requirement before their product reaches

TABLE 41.—COSTS INCURRED BY FDA UNDER OPTION 7

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,225,000	\$7,376,000	\$8,476,000	\$7,255,000	\$7,255,000
Discounted total costs	\$11,225,000	\$6,893,000	\$7,403,000	\$5,922,000	\$5,535,000

8. Option ^{Eight} ~~B~~: Issue no new regulation and allow the Bioterrorism Act's default registration requirements to take effect *Consistent w/ 1-7 ✓
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The Bioterrorism Act requires facilities to register with FDA by December 12, 2003, even if FDA has not issued final regulations by this date. Failure to do so for both foreign and domestic facilities is a prohibited act, and FDA must hold food from unregistered foreign facilities at the port of entry until they are registered. Thus, facilities have an incentive to register with FDA. Failure to issue a final regulation would result in an unworkable, chaotic system. The Bioterrorism Act also requires facilities that register in the absence of a final rule to re-register with FDA as specified in the final rule once it is issued.

It is not possible to predict the costs or benefits of this option because the statute is not specific enough to predict how it would be implemented. It seems likely that many facilities will attempt to register, given the penalties for failure to register. However, if FDA receives all paper, non-standardized

registrations, it will be extremely difficult for FDA to process the registrations and to use the information provided. It would also be a slow process for FDA to issue registration numbers.

9. Summary of costs

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Table 42 of this document presents a summary of costs for options 2 through 7 for domestic facilities, foreign facilities, and FDA. Costs in future years are discounted at 7 percent.

TABLE 42.—TOTAL COST OF OPTIONS 2 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Domestic first year costs	\$13,557,000	\$7,038,000	\$11,217,000	\$12,256,000	\$13,212,000	\$13,212,000
Foreign first year costs	\$319,619,000	\$319,619,000	\$319,619,000	\$318,335,000	\$319,619,000	\$311,762,000
FDA first year costs	\$11,279,000	\$10,907,000	\$11,145,000	\$11,279,000	\$11,225,000	\$11,225,000
Total first year costs	\$344,455,000	\$337,564,000	\$341,981,000	\$341,870,000	\$344,056,000	\$336,199,000
Domestic second year costs	\$3,186,000	\$1,654,000	\$2,636,000	\$2,181,000	\$3,105,000	\$3,105,000
Foreign second year costs	\$213,430,000	\$213,430,000	\$213,430,000	\$212,831,000	\$213,430,000	\$212,696,000
FDA second year costs	\$7,385,000	\$7,243,000	\$7,342,000	\$7,294,000	\$7,376,000	\$7,376,000
Total second year costs	\$224,001,000	\$222,327,000	\$223,408,000	\$222,306,000	\$223,911,000	\$223,177,000
Domestic third year costs	\$2,978,000	\$1,546,000	\$2,464,000	\$2,039,000	\$2,902,000	\$2,902,000
Foreign third year costs	\$199,467,000	\$199,467,000	\$199,467,000	\$198,907,000	\$199,467,000	\$198,782,000
FDA third year costs	\$8,498,000	\$8,343,000	\$8,442,000	\$8,394,000	\$8,476,000	\$8,476,000
Total third year costs	\$210,943,000	\$209,356,000	\$210,373,000	\$209,340,000	\$210,845,000	\$210,160,000
Domestic fourth year costs	\$2,783,000	\$1,445,000	\$2,303,000	\$1,905,000	\$2,712,000	\$2,712,000
Foreign fourth year costs	\$186,418,000	\$186,418,000	\$186,418,000	\$185,895,000	\$186,418,000	\$185,777,000
FDA fourth year costs	\$7,276,000	\$7,122,000	\$7,221,000	\$7,173,000	\$7,255,000	\$7,255,000
Total fourth year costs	\$196,477,000	\$194,985,000	\$195,942,000	\$194,973,000	\$196,385,000	\$195,744,000

a. *Sensitivity to assumptions.* A number of assumptions in the analysis significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under alternative assumptions. FDA uses option 7, the proposed option, to compare across assumptions. Table 43 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or hold food received from off the facility based on data from the Census of Agriculture and information from CES (Ref. 7). Because there are over 2 million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from \$13.2 to \$17.8 million.

Nonetheless, the agency recognizes that the registration requirement may cause an economic burden to some small businesses; therefore, we are seeking comment on whether it would be consistent with section 305 of the Bioterrorism Act for the agency to set staggered compliance dates that would give small businesses more time to comply.

However, the Bioterrorism Act does have considerable flexibility for small businesses built into the statute. First, retail facilities and farms are both exempt from registration. Many of these are small entities. Second, the economic impact on small entities is lessened by allowing entities to register either electronically or by mail. Small entities that do not have reasonable access to a computer or the Internet can submit their registration by mail.

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 would 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 \$112.3 million. Because the total cost to the domestic private sector would be \$13 million, FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. (SBREFA) Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (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

Small Business Regulatory Enforcement Fairness Act KMS

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X. Federalism

FDA has analyzed this proposed 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XI. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or ~~Sanitary~~ or phytosanitary (SPS) measures. FDA believes that a 60-
day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative

not enter commerce. A facility may consist of one or more contiguous structures. A single building may house distinct facilities if they are under separate management.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(ii) 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.

(4) *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 components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging 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.

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on or after December 12, 2003, must be registered before they begin such activities.

3 1.231 How and where do you register?

(a) Electronic registration: To register electronically, you must register at the appropriate Web site, which will be available for registration 24 hours a day, 7 days a week. This Web site will be available wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as a foreign facility's U.S. agent if the facility makes such arrangements. FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. Once you complete your registration, FDA will provide you with an automatic electronic confirmation of registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise.

(b) Registration by mail: (1) If you do not have reasonable access to the Internet through any of the methods provided under ~~this~~ ^{of this section} paragraph (a), you must register by obtaining a copy of the registration from (Office name or mail code), the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or by phone at [toll-free number that will be provided in the final rule]. ✓b

(2) When you receive the form in the mail, you must fill it out completely and legibly and mail it to the address in paragraph (b) of this section.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will send the form back to you for completion, provided that your mailing address is legible and valid.

(4) FDA will enter completed registration submissions into the system as soon as practicable, in the order received.

Revision made in Response to a
Suggestion from OMB/OIRA

product categories. This information, including these categories, will assist FDA in conducting investigations and surveillance operations in response to a bioterrorist incident. If this information is outdated it will interfere with FDA's ability to quickly ascertain the nature and scope of the problem and to alert affected facilities and prevent further distribution of harmful food. Therefore, for efficient and effective implementation of the Bioterrorism Act, FDA is proposing to require registrants to update previously submitted information in both the mandatory and optional categories, if the registrant originally submitted information in both categories and that information changes. FDA requests comments on this proposed requirement and how it will affect the submission of optional information.

A facility canceling a registration must do so on a separate cancellation form electronically or by mail.

Additional Provisions

1. What Other Registration Requirements Apply? (Proposed § 1.240)

In proposed § 1.240, FDA has included a provision reminding registrants that they must comply with all other applicable registration requirements, including those found in part 108 (21 CFR part 108), related to emergency permit control. FDA wants to ensure that registrants subject to the registration regulation being proposed to implement the Bioterrorism Act are aware that this registration does not take the place of that required in part 108, or any other registration requirements.

seeks to minimize the burden of this rule on covered facilities and the
 FDA is aware that existing registrations required by FDA and other federal agencies ask for information that may be duplicative of some of the information

FDA is proposing be submitted under this rule. The Bioterrorism Act requires that certain facilities register with FDA. The Bioterrorism Act also specifies

submission
of duplicative
information,
FDA

OMB
1-23-03