

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

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 ¹	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 U.S. agents	13,212,000	297,257,000	11,225,000	\$321,694,000
Percentage change from baseline	0%	-5%	0%	-4%
32 percent 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%
U.S. agent fee \$1,500	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%

¹ 30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers/processors have U.S. agents, 16 percent of foreign facilities are fluent in English, 100,027 foreign holders and packagers, and U.S. agent fee of \$1,000.

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.

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 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 higher than the 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 U.S. 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 U.S. businesses, will undertake to notify facilities of the registration requirements. FDA requests comments on the size and the basis for estimating these costs.

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

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 occur or the size and severity of the outbreak in the absence of registration. 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 possible 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.

TABLE 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 18,875,000
<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

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 nonpasteurized 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 1 to 3 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 2 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 percentage of cases.

Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 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 (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.

TABLE 45.—THE COST OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown (percent)	Total QALDs Lost per Illness	Health Loss (dollars) per Case (Dis- counted)	Medical Costs (dol- lars) per Case (Dis- counted)	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					
<i>Regression approach</i>					
Short-term	1.26	5.41	3,391	100	44
Long-term	2.40	2,613.12	452,554	7,322	11,048
<i>Direct survey approach</i>					
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 \$45,183,000 to \$79,797,000.

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, OR. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying *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 \$10,687,000 to \$18,875,000.

d. *Shigella dysenteriae* type 2 among laboratory workers. 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 \$83,000 for

illnesses associated with the event. Table 46 summarizes the costs associated with this outbreak.

TABLE 46.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

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

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 cyclosporin outbreak (Ref. 26). No deaths were confirmed. Table 47 summarizes the costs associated with this outbreak.

TABLE 47.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIN

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,000
Moderate	586	3,748	2,196,000
Severe	19	15,516	295,000
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: (1) By requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain; (2) if FDA is aware of a specific food threat, then it would be able to inform the facilities potentially affected by the threat; (3) FDA would be able to deploy more efficiently its domestic compliance and regulatory resources and better able to identify facilities affected by future FDA actions (including possible regulations); and (4) FDA inspectors, using prior notice and registration, can better identify shipments for inspection.

Registering with 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, could 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 future FDA actions (including possible regulations), which would result in targeting communication and outreach to these facilities.

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

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.

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).

i. 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.

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.

ii. 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 2, and so would have a similar effect in aiding FDA in contacting facilities in response to a threat.

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.

iii. FDA would be more efficient in deploying its enforcement resources and better able to identify facilities affected by future FDA actions (including possible 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 aiding FDA in deploying enforcement resources and identifying facilities that are affected by future regulations.

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.

iv. 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.

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 which shipments to inspect.

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

V. 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 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 following analysis, 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 are regulatory relief options. The expected burden for most small entities is low, between \$58 and \$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.

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. Small Business Regulatory Enforcement Fairness Act Major Rule

The Small Business Regulatory Enforcement Fairness Act (SBREFA) 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.

VIII. Paperwork Reduction Act of 1995

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 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.

Title: Registration of food facilities

Description: The Bioterrorism Act contains a provision requiring the Secretary to issue 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 § 170.3; and a certification statement that includes the name, title/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 § 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 48.—
RESPONDENTS

Foreign	205,405
Domestic	202,046
Total	407,451

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 5 hours would be needed if they do not have Internet access, and an additional 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.

Next, FDA estimates that filling out a registration form would take a total of 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 1 hour to fill out the form, if they have access to the Internet and can read and write

in English. An additional 1 hour would be needed if they do not have Internet access and an additional 1 hour would be needed if they do not read or understand English. Table 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.—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	143,453	1	143,453	2	286,906
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(b) ⁶	FDA 3537	141,730	1	141,730	12	1,700,760
Total hours						2,444,850

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 1 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 1 hour to locate the correct form, enter their information, and send it to FDA. Table 50 presents an estimate of the burden hours for new facilities, and updates and cancellations for existing facilities in future years.

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS¹

21 CFR Part 1	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
<i>n</i> 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(b) 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(b) ⁶	FDA 3537/3537a	42,519	1	42,519	1	42,519
Grand total						366,717

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.

IX. Analysis of Environmental Impact

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

X. Federalism

FDA has analyzed this 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

Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application.

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

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 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 of the Bioterrorism Act also provides that if 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 SBREFA (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. 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 OMB has determined has

resulted in or is likely to result in: (a) An annual effect on the economy of \$100 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.

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 comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

XII. References

The following references have been placed on display in the Dockets 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 Web sites after this document publishes in the **Federal Register**.

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3. U.S. Food and Drug Administration, Field Accomplishments and Compliance Tracking System (FACTS), Fiscal year 2002.

4. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), Fiscal year 2002.

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11. NUA, How Many Online? available at http://www.nua.com/surveys/how_many_online/index.html, accessed on 9/4/2002.

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16. Estrin, A., Memorandum to the file, 10/04/2002.

17. Jessup, A., Memorandum to the file, 11/21/2002.

18. Pope, Angela, Memorandum to the file, 10/7/2002.

19. Hennessy, T. W., C. W. Hedberg, L. Slutsker, et al., "A National Outbreak of *Salmonella enteritidis* Infections From Ice Cream," *The New England Journal of Medicine*, May 16, 1996, 1281–1286.

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22. Scharff, R. and A. Jessup, "Valuing Chronic Disease for Heterogeneous Populations: the Case of Arthritis," 2002, Mimeo.

23. Lee, L. A., S. M. Ostroff, H. B. McGee, et al., "An Outbreak of Shigellosis at an Outdoor Music Festival," *American Journal of Epidemiology*, 133:6:608–615.

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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 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. Subpart H is added to part 1 to read as follows (subparts F and G are reserved):

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.

(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. 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;

(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 section 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 the regulations in this subpart; and

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

(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.

(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 U.S. Internal Revenue Code.

(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.

(10) *Restaurant* means a facility that 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.

(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 [a Web site that will be provided in the final rule], 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 paragraph (a) of this section, 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].

(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.

(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, full address, phone number, fax number, and e-mail address of the facility;

(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.

Additional Provisions

§ 1.240 What other registration requirements apply?

In addition to these regulations, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other registration requirements that apply to the facility.

§ 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 801(l) of the act (21 U.S.C. 381(l)) as set out in this subpart, or otherwise violates any requirement under section 801(l) of the act, or any person who causes such an act, commits a prohibited act within the meaning of section 301(dd) of the act.

(c) Under section 302 of the act (21 U.S.C. 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. 333), the United States 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 debarment of any person who has been convicted of a felony relating to importation of food into the United States.

(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 directs its removal to a secure facility in accordance with paragraph (e) of this section.

(e) Under paragraph (d) of this section, if FDA 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 in the port of entry), FDA 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 storage of the article of food in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(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 § 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 801(l) 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 5 U.S.C. 552 (the Freedom of Information Act).

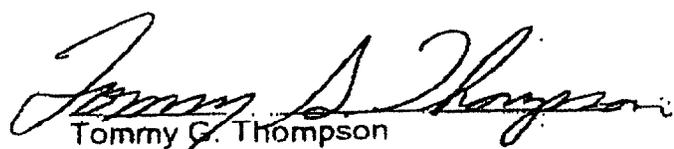
(b) Paragraph (a) does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

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~~135~~

KMS
1-29-03

JAN 24 2003

Dated: _____


Tommy G. Thompson
Secretary

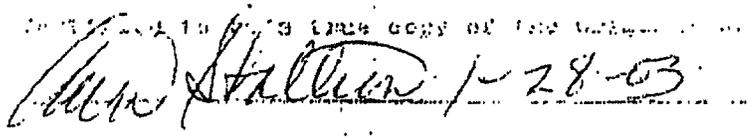
Note: The following appendix will not appear in the Code of Federal Regulations.

KMS
1-29-03

[INSERT GLOSSARY]

[FR Doc. 02-???? Filed ??-??-02; 8:45am]

BILLING CODE 4160-01-S

APPROVED TO BE A TRUE COPY OF THE ORIGINAL
 1-28-03

Dated: January 29, 2003



 Kenneth W. Dam,
 Acting Secretary of the Treasury.

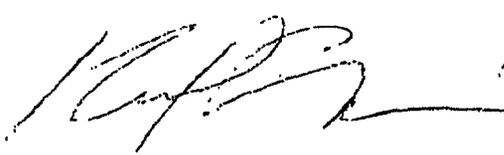
Note: The following appendix will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

Certified to be a true copy of the original

 1/29/03

Richard S. Carro
 Senior Advisor to the General Counsel
 (Regulatory Affairs)

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE)	
NAME OF PARENT COMPANY:	
STREET ADDRESS OF PARENT COMPANY:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS (if available):
Section 5 - FACILITY EMERGENCY CONTACT INFORMATION	
INDIVIDUAL'S NAME:	
TITLE:	OFFICE PHONE (If a foreign facility, include Area & Country Codes):
HOME PHONE (If a foreign facility, include Area & Country Codes):	CELL PHONE (if available; if a foreign facility, include Area & Country Codes):
E-MAIL ADDRESS (if available):	
Section 6 - TRADE NAMES (IF THIS FACILITY USES TRADE NAMES OTHER THAN THAT LISTED IN SECTION 2 ABOVE, LIST THEM BELOW (E.G., "ALSO DOING BUSINESS AS," "FACILITY ALSO KNOWN AS")):	
ALTERNATE TRADE NAME #1:	
ALTERNATE TRADE NAME #2:	
Section 7 - UNITED STATES AGENT (TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.)	
NAME OF UNITED STATES AGENT:	
TITLE:	
ADDRESS:	
CITY:	STATE:
ZIP CODE:	COUNTRY:
PHONE NUMBER (include Area Code):	
FAX NUMBER (if available; include Area Code):	
E-MAIL ADDRESS (if available):	

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 8 - OPTIONAL: SEASONAL FACILITY DATES OF OPERATION

(GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS)

DATES OF OPERATION:

Section 9 - OPTIONAL: ESTABLISHMENT TYPES

(CHECK **ALL** TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING, PROCESSING, PACKING OR HOLDING OF FOOD)

Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)
NOTE: If the facility is a warehouse / holding facility only, go to Section 10 (solely warehouse / holding facility) and check all that apply.

<input type="checkbox"/> Acidified / Low Acid Food Processor	<input type="checkbox"/> Labeler / Relabeler
<input type="checkbox"/> Interstate Conveyance Caterer/Catering Point	<input type="checkbox"/> Manufacturer / Processor
<input type="checkbox"/> Molluscan Shellfish Establishment	<input type="checkbox"/> Repacker / Packer
<input type="checkbox"/> Commissary	<input type="checkbox"/> Salvage Operator (Reconditioner)
<input type="checkbox"/> Contract Sterilizer	<input type="checkbox"/> Animal food manufacturer / processor / holder

Section 10 - OPTIONAL: IF YOUR FACILITY IS SOLELY A WAREHOUSE / HOLDING FACILITY, COMPLETE THIS SECTION; ALL OTHER FACILITIES, COMPLETE SECTION 11 (human or animal product categories) INSTEAD OF THIS SECTION.

<input type="checkbox"/> Ambient Storage (including heated storage)	<input type="checkbox"/> Refrigerated Storage	<input type="checkbox"/> Frozen Storage
--	---	---

Section 11 - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION

To be completed by all human food facilities except those that are solely warehouses.

[Note: Categories are derived from the Product Code Builder (www.fda.gov/search/databases.html), with cross-references to the categories found under 21 CFR 170.3. Please see instructions for further examples.]

- | | |
|---|--|
| <input type="checkbox"/> 1. ALCOHOLIC BEVERAGES
[21 CFR 170.3 (n) (2)]

<input type="checkbox"/> 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)

<input type="checkbox"/> 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS
[21 CFR 170.3 (n) (1), (9)]

<input type="checkbox"/> 4. BEVERAGE BASES
[21 CFR 170.3 (n) (3), (16), (35)]

<input type="checkbox"/> 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM
[21 CFR 170.3 (n) (6), (9), (25), (38)] | <input type="checkbox"/> 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS
[21 CFR 170.3 (n) (4)]

<input type="checkbox"/> 7. CHEESE AND CHEESE PRODUCTS
[21 CFR 170.3 (n) (5)]

<input type="checkbox"/> 8. CHOCOLATE AND COCOA PRODUCTS
[21 CFR 170.3 (n) (3), (9), (38), (43)]

<input type="checkbox"/> 9. COFFEE AND TEA
[21 CFR 170.3 (n) (3), (7)]

<input type="checkbox"/> 10. COLOR ADDITIVES FOR FOODS
[21 CFR 170.3 (o) (4)]

<input type="checkbox"/> 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]

<input type="checkbox"/> 26. NUT AND EDIBLE SEED PRODUCTS
[21 CFR 170.3 (n) (26), (32)] |
|---|--|

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

- 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods)
[21 CFR 170.3 (n) (31)]

- 12. DIETARY SUPPLEMENTS
 - Proteins, Amino Acids, Fats and Lipid Substances
[21 CFR 170.3 (o) (20)]
 - Vitamins and Minerals [21 CFR 170.3 (o) (20)]
 - Animal By-Products and Extracts (Optional Selection)
 - Herbals and Botanicals (Optional Selection)

- 13. DRESSINGS AND CONDIMENTS
[21 CFR 170.3 (n) (8), (12)]

- 14. FISHERY/SEAFOOD PRODUCTS
[21 CFR 170.3 (n) (13), (15), (39), (40)]

- 15. SUBSTANCES THAT MIGRATE INTO FOOD FROM FOOD PACKAGING AND OTHER ARTICLES THAT CONTACT FOOD (Optional Selection)

- 16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING
[21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]

- 17. FOOD SWEETENERS (NUTRITIVE)
[21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]

- 18. FRUITS AND FRUIT PRODUCTS
[21 CFR 170.3 (n) (16), (27), (28), (35), (43)]

- 19. GELATIN, RENNIN, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]

- 20. ICE CREAM AND RELATED PRODUCTS
[21 CFR 170.3 (n) (20), (21)]

- 21. IMITATION MILK PRODUCTS
[21 CFR 170.3 (n) (10)]

- 22. MACARONI OR NOODLE PRODUCTS
[21 CFR 170.3 (n) (23)]

- 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED)
[21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]

- 24. MILK, BUTTER, OR DRIED MILK PRODUCTS
[21 CFR 170.3 (n) (12), (30), (31)]

- 28. SHELL EGG AND EGG PRODUCTS
[21 CFR 170.3 (n) (11), (14)]

- 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]

- 30. SPICES, FLAVORS, AND SALTS
[21 CFR 170.3 (n) (26)]

- 31. SOUPS
[21 CFR 170.3 (n) (39), (40)]

- 32. SOFT DRINKS AND WATERS
[21 CFR 170.3 (n) (3), (35)]

- 33. VEGETABLES AND VEGETABLE PRODUCTS
[21 CFR 170.3 (n) (19), (36)]

- 34. VEGETABLE OILS (INCLUDES OLIVE OIL)
[21 CFR 170.3 (n) (12)]

- 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS)
[21 CFR 170.3 (n) (33)]

- 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH
[21 CFR 170.3 (n) (1), (23)]

- 37. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 11a - OPTIONAL GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION

- | | |
|--|--|
| <input type="checkbox"/> 1. GRAIN PRODUCTS (E.G., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE AND WHEAT) | <input type="checkbox"/> 18. NON-PROTEIN NITROGEN PRODUCTS |
| <input type="checkbox"/> 2. OILSEED PRODUCTS (E.G., COTTONSEED, SOYBEANS, OTHER OIL SEEDS) | <input type="checkbox"/> 19. PEANUT PRODUCTS |
| <input type="checkbox"/> 3. ALFALFA AND LESPEDEZA PRODUCTS | <input type="checkbox"/> 20. RECYCLED ANIMAL WASTE PRODUCTS |
| <input type="checkbox"/> 4. AMINO ACIDS | <input type="checkbox"/> 21. SCREENINGS |
| <input type="checkbox"/> 5. ANIMAL-DERIVED PRODUCTS | <input type="checkbox"/> 22. VITAMINS |
| <input type="checkbox"/> 6. BREWER PRODUCTS | <input type="checkbox"/> 23. YEAST PRODUCTS |
| <input type="checkbox"/> 7. CHEMICAL PRESERVATIVES | <input type="checkbox"/> 24. MIXED FEED (POULTRY, LIVESTOCK, AND EQUINE) |
| <input type="checkbox"/> 8. CITRUS PRODUCTS | <input type="checkbox"/> 25. PET FOOD |
| <input type="checkbox"/> 9. DISTILLERY PRODUCTS | <input type="checkbox"/> 26. MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES |
| <input type="checkbox"/> 10. ENZYMES | |
| <input type="checkbox"/> 11. FATS AND OILS | |
| <input type="checkbox"/> 12. FERMENTATION PRODUCTS | |
| <input type="checkbox"/> 13. MARINE PRODUCTS | |
| <input type="checkbox"/> 14. MILK PRODUCTS | |
| <input type="checkbox"/> 15. MINERALS | |
| <input type="checkbox"/> 16. MISCELLANEOUS AND SPECIAL PURPOSE PRODUCTS | |
| <input type="checkbox"/> 17. MOLASSES | |

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 12 - CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to register on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

PRINT NAME OF PERSON SUBMITTING THE REGISTRATION FORM

PHONE NUMBER (If a foreign facility, include Area & Country Codes):

FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):

E-MAIL ADDRESS (if available):

FDA USE ONLY

DATE REGISTRATION FORM RECEIVED

DATE NOTIFICATION SENT TO FACILITY

Public reporting burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN (HFS-024)
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DHHS/FDA - CANCELLATION OF FOOD FACILITY REGISTRATION	
PROVIDE THE FACILITY REGISTRATION NUMBER:	
<input type="checkbox"/> DOMESTIC REGISTRATION	<input type="checkbox"/> FOREIGN REGISTRATION
FACILITY NAME / ADDRESS INFORMATION	
FACILITY NAME:	
FACILITY STREET ADDRESS:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	
CERTIFICATION STATEMENT	
<p><i>The owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to cancel the registration on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.</i></p>	
PRINT NAME OF PERSON SUBMITTING THE CANCELLATION FORM	
ADDRESS	E-MAIL ADDRESS (IF AVAILABLE)
FDA USE ONLY	
DATE CANCELLATION FORM RECEIVED	DATE CONFIRMATION SENT TO FACILITY

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 CFSAN (HFS-024)
 5100 Paint Branch Parkway
 College Park, MD 20740

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