DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Amendments to Registration of Food Facilities

Preliminary Regulatory Impact Analysis
FDA-2002-N-0323

April 2015

I. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. In accordance with Executive Order 12866, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if issued, will not be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a 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.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any 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 one year." The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for Regulation

This proposed rule proposes to amend FDA's regulation for registration of food facilities that requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. The proposed rule would codify the already effective, self-implementing requirements in section 102 of the FDA Food Safety Modernization Act ("FSMA"), which amends section 415 of the Federal Food, Drug & Cosmetic Act ("FD&C Act") regarding requirements for food facility registration. In addition, the proposed rule would implement other requirements of section 102 of FSMA, including mandatory electronic registration submissions

beginning in 2016 and amendments to the retail food establishment definition. Further, the proposed rule would implement other changes to improve the utility of the food facility registration database.

FDA finalized its existing food facility regulation, codified in 21 CFR part 1, subpart H, on October 3, 2005 (70 FR 57505). That final rule confirmed the interim final rule that FDA issued on October 10, 2003 (68 FR 58894). The interim final rule identified several important functions that food facility registration serves, including enabling FDA to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies and to determine the source and cause of an outbreak of foodborne illness. This proposed rule would further ensure that food facility registration fulfills those objectives. The proposed rule aims to achieve this by improving the accuracy of the information contained in the food facility registration database, requiring additional facility contact information, increasing the utility of the database, and implementing section 102 of FSMA. This proposed rule also aims to allow FDA to use its inspectional resources more efficiently.

The preliminary economic impact analysis that accompanied the 2003 notice of proposed rulemaking for the food facility registration proposed rule (68 FR 5378) explained that even though firms have powerful private incentives to avoid the deliberate contamination of food linked to their own products or facilities, those private incentives are not enough for firms to provide the optimal amount of information about the food production and distribution system as a whole. Market prices convey most of the information necessary for the ordinary production and distribution of food. However, in the event of an actual or suspected contamination in the food supply, more complete information is needed where it can be centrally used because a suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event. Although the nation's food processors and importers as a whole benefit from such a system, the private costs to create the system would be prohibitive for any single firm or third party organization.

The effectiveness of the registration system depends not only on the extent to which domestic and foreign food facilities register, but also on the extent to which the information provided in registration submissions is complete and accurate.

Since FDA implemented food facility registration in 2003, the agency has grappled with the problem of inaccurate and incomplete registration information. For example, in 2009, the Office of the Inspector General for the U.S. Department of Health and Human Services created a report (hereinafter referred to as the 2009 OIG Report) examining the extent to which selected domestic food facilities

actually registered with FDA and also whether the information provided by food facilities was complete and accurate. The report found that 7 of 130 (5%) surveyed facilities failed to register and 2 of 130 (2%) failed to cancel their registrations. The report also found that nearly half of selected registered facilities (62 of 130) either provided inaccurate information when they first registered or failed to provide accurate information after changes in the facility's information, as required (Ref.1) .

The proposed requirements would also facilitate creating and maintaining more accurate registrations than under the current authority. By improving the completeness and accuracy of the registration information, the agency will have more reliable information about food facilities and the food products handled at facilities. The more reliable information will better and more efficiently enable FDA to locate facilities during an outbreak of foodborne illness, as well as locate facilities for inspection.

This authority will further help the Agency aid in deterring and limiting the effects of foodborne outbreaks and thereby improve the safety of the food supply in the United States.

B. Summary of Costs and Benefits

Costs of meeting the proposed requirements of this rule will be incurred by both FDA and food facilities that are required to register.

Table 1 presents estimated costs associated with the provisions in this proposed rule. Estimated onetime costs to domestic and foreign facilities are about $22.3 million. Onetime costs in the first year include learning costs (i.e., the administrative costs incurred by domestic and foreign facilities in order to learn how to comply with any new regulation), first-time biennial registration renewal costs from the 2012 registration renewal cycle, and costs that stem from proposed requirements for certain data elements in the registration form. These costs are approximately $19.1 million. Estimated onetime costs to domestic and foreign facilities for the biennial renewal cycle in 2016, by which time we assume the proposed rule will go into effect, include onetime costs of obtaining a D-U-N-S® number, plus costs for entering additional data elements in the registration form. These costs are approximately $3.2 million.

Recurring biennial costs beginning in 2016 include costs from the requirement for both domestic and foreign food facilities to renew their registrations every two years and from requiring additional data elements in the registration form, as proposed in the proposed rule. These costs are approximately $18.7 million every two years. The $18.7 million in costs continue to accrue in each subsequent biennial

registration renewal cycle, and include costs associated with registration renewal activities and costs associated with other provisions of the proposed rule, such as certain verification procedures.

Annualized costs are calculated using a discount rate of 7 percent and 3 percent over 20 years. Total annualized costs to food facilities, which include annualized onetime costs and annualized recurring costs, are approximately $5.4 million and $6.2 million per year using a discount rate of 7 percent and 3 percent, respectively, over a period of 20 years. Annualized recurring costs to FDA are approximately $0.9 and $1.2 million, also using a discount rate of 7 percent and 3 percent, respectively.

Table 1.—Annualized Cost and Benefit Summary ($Millions)[1]

	Total One Time Costs	Total Annualized Costs 7%	Total Annualized Costs 3%	Benefits
Domestic Facilities	$ 9	$ 1	$ 1	Not Quantified
Foreign Facilities	$ 13	$ 4	$ 5	
Subtotal Facilities	**$ 22**	**$ 5**	**$ 6**	
Costs to FDA	$ -	$ 1	$ 1	
Total	**$ 22**	**$ 6**	**$ 7**	

This analysis estimates costs and benefits of the provisions in this proposed rule only, which are assumed to accrue in addition to the estimated annual costs already incurred due to the implementation of the provisions in the 2003 interim final rule. Those estimated costs were calculated in an economic impact analysis that accompanied the interim final rule (68 FR 58893 at 58932) (hereinafter referred to as the "2003 economic impact analysis"). For the final rule, the economic impact analysis was modified slightly with respect to the costs associated with the U.S. agent requirement at the final rule stage (70 FR 57505 at 57506). Persons interested in the costs and benefits estimated in 2003 should visit: http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm08163.htm. We also expect that at least some foreign food facilities could increase prices as a result of the costs they would have to incur as a result of the rule. Any such potential price increases that could occur as a result of compliance costs would likely be very small relative to the total costs to manufacture, process, pack and hold foods for sale in the United States. We expect that the benefits of the proposed rule would include aiding FDA's ability to deter and limit the effects of foodborne outbreaks and other food-related emergencies. Although we are unable to quantify these and other benefits, we discuss the expected benefits qualitatively. In addition, we monetize the impact associated with different foodborne outbreak scenarios in order to determine the amount of savings from illness reduction that would be required in order for the proposed rule to reduce costs that result from foodborne illness by approximately the same

amount that the compliance costs the proposed rule would impose on food facilities. We expect the proposed rule would have additional benefits that we are similarly unable to quantify, including providing for the more efficient use of FDA's inspectional resources.

C. Conventions

We use the following conventions throughout the analysis

1. Adjustment for Inflation

We estimate all costs using 2012 dollars. All estimated costs of this proposed rule (including the estimates in Table 1) are relative to the estimated costs in the 2003 economic impact analysis. We have therefore adjusted the 2003 cost estimates to 2012 dollars. We calculate the rate of inflation of 1.247 by dividing the 2012 consumer price index (CPI) of 229.6 by the 2003 CPI of 184. Thus $1.00 in 2003 is equivalent to $1.25 in 2012 (Ref. 2).

2. Costs covered in the 2003 Economic Impact Analysis

The costs of the requirements in this proposed rule are in addition to the costs of meeting the registration requirements enacted as a result of the 2003 interim final rule. We do not include as costs of this proposed rule the costs that were already addressed in the 2003 economic impact analysis. The costs that were already addressed in the 2003 economic impact analysis include, among other things, the costs of: 1) new facilities registering with FDA, 2) cancelling a registration, 3) categorizing products and entering them into appropriate food product categories; and 4) hiring and retaining U.S. Agents for foreign facilities. We do not believe that this proposed rule would affect those costs, and we only estimate the costs of requirements that are in addition to those that were implemented in 2003. The 2003 economic impact analysis also included cost estimates for the requirement to update a registration within 60 calendar days of an update. We estimate additional update-related costs because this proposed rule would change the update requirement from 60 to 30 calendar days.

3. Estimated time for certain activities

Many of the estimated costs of this rule are based on the time that food facilities would require to complete certain activities. When applicable, we use time estimates from the 2003 economic impact analysis in estimating the additional time needed to meet the requirements of this proposed rule. That is, for purposes of this economic analysis, some of the 2003 time estimates function as a point of reference for estimating additional costs that we expect will result from this proposed rule.

In the 2003 economic impact analysis, FDA estimated the costs to both domestic and foreign facilities of complying with the interim final rule based largely on the amount of time it would take facilities to: 1) become aware of the requirements; 2) learn what the requirements are; 3) have an administrative worker complete the form; and 4) have the owner, operator, or agent in charge of the facility confirm the submission is correct. FDA estimated that foreign facilities would incur additional costs associated with finding and then hiring a U.S. Agent. The 2003 economic impact analysis further estimated that domestic facilities with Internet access and fluent in English would need, on average, one hour to research the regulation and one hour to complete the form. For domestic facilities without Internet access, FDA estimated that the time required to research requirements would be 2 hours, but that the same amount of time would be required to complete the form (69 FR 58948). In addition, FDA estimated that a facility would require 15 minutes to categorize products and enter them into the appropriate food product categories, 30 minutes to find the remaining registration information and enter it onto the form, and 15 minutes for confirming all the registration information is correct. These estimates were based on a per facility, not a per firm, basis (See 68 FR 58939). For foreign food facilities, FDA estimated the amount of time required to research and comply with registration requirements with Internet access, without Internet access, if fluent in English, and if not fluent in English (68 FR 58949). The time estimates for completing certain tasks were greater for foreign facilities without Internet access than for foreign facilities with Internet access. In addition, time estimates for researching requirements were greater for foreign facilities without Internet access than for domestic facilities without Internet access (compare 68 FR 58949 and 68 FR 58948). Further, the time estimates for completing certain tasks were greater for foreign facilities not fluent in English than for foreign facilities fluent in English (68 FR 58949).

Thus, some of the time estimates in the 2003 economic impact analysis were premised on the following assumptions: (1) it would take food facilities more time to complete certain tasks if they did not have access to the Internet; (2) it would take foreign food facilities without Internet access more time to research requirements than it would take domestic food facilities without Internet access to complete that same task; and (3) it would take foreign facilities more time to complete certain tasks if they were not fluent in English.

For purposes of this economic impact analysis, we do not make these same assumptions. According to data from the World Bank, the number of Internet users worldwide increased by nearly 300 percent between 2004 and 2013 (Ref. 3). Not only has Internet use increased since 2003, but also

more than 98 percent of foreign and domestic food facility registrations we received in 2014 were submitted electronically, suggesting that nearly all foreign and domestic food facilities have access to the Internet. Because of these developments, we do not make the same assumptions regarding the effects of Internet access in this preliminary economic impact analysis. That is, we do not make different estimates for the time required to complete certain tasks based on whether or not a facility has access to the Internet. Because we don't make different time estimates based on access to the Internet, we also do not assume that foreign food facilities without Internet access require more time to research requirements than domestic food facilities without Internet access. Given that access to the Internet does not serve as the basis for time estimates, it would not make sense for this assumption to apply.

We also do not make the assumption that it would take foreign facilities more time to complete certain tasks if they are not fluent in English. Because the 2003 economic impact analysis accounted for the costs of new foreign facility registrations, this preliminary economic impact analysis does not account for such costs in estimating the costs of the proposed rule. Instead, this preliminary economic impact analysis only estimates the marginal costs that we expect the proposed rule would place on non-new foreign facility registrants. By virtue of having already participated in food facility registration, these registrants are necessarily familiar with the requirement to register and the food facility registration framework. We believe this familiarity makes it unnecessary to distinguish between foreign facilities that are fluent and not fluent in English in estimating the amount of time required to comply with requirements in the proposed rule.

Because of these assumptions, we use the estimate from the 2003 economic impact analysis for domestic facilities that facilities will require one hour to research the regulation. We apply this estimate to both domestic and foreign facilities. Further, where the 2003 economic impact analysis estimated that time would be required for researching, we instead treat that as time required for learning--- time which is accounted for in this preliminary economic impact analysis as learning costs.

Another convention we use in this preliminary economic impact analysis relates to the time required to enter the e-mail addresses that this proposed rule proposes to require for food facility registrations. For such e-mail address information, we estimate that each e-mail address requirement will require one minute of an administrative worker's time. We also estimate that for every hour or fraction of an hour spent filling out a registration form, three quarters of that time would be spent by an administrative worker and one quarter would be spent by an owner, operator, or agent in charge to

certify the information before submitting the registration form to FDA. These estimates are approximate, and some facilities may require more or less time.

4. Wages

We use the same 2003 hourly rate for a manager of $28.37 and $12.55 for an administrative worker used in the 2003 economic impact analysis, and then adjust those rates into 2012 dollars. These two wage rates are from the Bureau of Labor Statistics' National Compensation Survey (Ref. 4). These wage rates were doubled in the 2003 economic impact analysis to include overhead costs, such as office space, health insurance, and retirement benefits. When doubled, the overhead-adjusted wage rate for an administrative worker per hour was $25.10 and the equivalent rate for a manager, who would be the owner, operator, or agent in charge, was $56.74. After adjusting for inflation to 2012 dollars, we estimate the manager wage in 2012 to be equivalent to $70.80/hour and the administrative worker wage to be equivalent to $31.32/hour. We lack wage data specific to foreign food industry workers from each of the foreign countries that export food to the United States and thus use the same wage rate for an administrative worker and manager in the United States for the foreign wage rate. We acknowledge that this could overestimate wages for some foreign facilities, especially those facilities located in developing countries. However, since many registration activities may be performed by U.S. agents on behalf of foreign facilities, it is appropriate to use U.S. wage rates when calculating costs for foreign facilities. For many activities that require three quarters (0.75) of an administrative worker's time and one quarter (0.25) of an owner, operator, or agent in charge's time, we use a weighted average wage rate of $41.19 ($70.80 x 0.25 + $31.32 x 0.75 = $41.19).

D. Affected Food Facilities

Food facilities affected by this proposed rule include 195,766 facilities that are currently registered or required to register. Table 2 presents the number of affected facilities as of February 2014.

Table 2.—Domestic and Foreign Registrations

	Total Registrations	Online Registrations	Percent Online	Paper Registrations	Percent Paper
Domestic	81,627	79,702	97.6%	1,925	2.36%
Foreign	114,139	113,943	99.8%	196	0.17%
Total	195,766	193,645	98.9%	2,121	1.08%

Other facilities potentially affected by this proposed rule include facilities that may be affected by the provision in the proposed rule that would amend FDA's food facility regulations in accordance

with section 102(c) of FSMA. Section 102(c) of FSMA directs FDA to amend the definition of retail food establishment in section 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include: (1) the sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture (CSA) program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by FDA.

The proposed amendment to the retail food establishment definition addresses off-farm sales by an establishment located on a farm. How these off-farm sales relate to an establishment's status as a retail food establishment is significant because if manufacturing/processing activities of a farm are part of a retail food establishment, they do not trigger the requirement to register. Otherwise, unless all food used in such activities is consumed on that farm or another farm under the same ownership, the manufacturing/processing operation is required to register (see 21 CFR 1.227(b)(3)(ii)). If all sales from an on-farm manufacturing/processing operation must be made on-farm for that operation to qualify as a retail food establishment, then an on-farm establishment that sells processed food at a direct sales platform such as a farmer's market could not qualify as a retail food establishment and would be required to register. To prevent this, proposed § 1.227(b)(11) clarifies that all sales by an on-farm establishment do not have to be on the farm by specifically addressing how off-farm sales directly to consumers are to be counted in determining whether the on-farm establishment is a retail food establishment. This amendment would therefore further clarify which facilities are exempt from the food facility registration requirements.

According to data from the United States Department of Agriculture (USDA) Economic Research Service (ERS), and table 3 below, there are about 71,000 farms that only use Direct to Consumer Marketing (DTC) channels such as farmers markets, road side stands and Community Supported Agriculture (CSAs). A subset of these establishments will probably meet FDA's amended definition of a retail food establishment and will be exempt from registration. There are also 13,348 and 22,624 farms that use intermediated marketing channels or both DTC and intermediated marketing channels, respectively. These farms sell to other retailers, such as restaurants and local grocery stores and would probably not meet FDA's definition of retail food establishment. These farms would

therefore not be exempt under current or proposed § 1.227(b)(11) from registration (unless the establishment's primary function is to sell food directly to consumers).

Table 3.—Marketing Channels Used by Local Food Sales Farms by Farm Size

Farm Revenue Class	Size Class	Farms	Direct to Consumer	Intermediated Marketing	Both
< $50,000	Small	86,726	62,529	9,800	14,397
$50,000 - $249,000	Medium	15,202	7,069	1,581	6,537
>$250,000	Large	5,301	1,643	1,967	1,691
Total		107,229	71,242	13,348	22,624

Source: USDA Economic Research Service (ERS) calculations based on 2008 Agricultural Resource Management Survey (ARMS), conducted by USDA, National Agricultural Statistics Service (NASS) and ERS. Viewed on January 10th, 2014. http://www.ers.usda.gov/publications/err-economic-research-report/err128.aspx

We do not know how many of these farms are currently required to register and would, under the proposed rule, no longer be required to do so. Although we do not have data that would allow us to quantify the expected net change in the number of facilities that would be affected by the proposed amendment to the retail food establishment definition, we expect that the proposed rule would reduce the number of facilities subject to food facility registration. We request comment on this issue.

E. Regulatory Options- Cost and Benefits

FDA evaluates three regulatory options in the analysis of this rule:

1. Option 1 - Take no action
2. Option 2 – The proposed option. Codify the already-effective, self-implementing FSMA provisions, and also promulgate the additional proposed provisions.
3. Option 3 – Codify only the already-effective, self-implementing FSMA provisions, as well as mandatory electronic registration without the option of a waiver

4. Option 4 – This option includes the same requirements as in Option 2 but with the additional implementation of a U.S. Agent Voluntary Identification System (VIS)

1. Option 1 - No Action

We treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of other options. A number of proposed changes to 21 CFR part 1, subpart H that are included in this rulemaking codify provisions of FSMA that were self-implementing and became effective upon enactment of FSMA or became effective in October 2012, when FDA issued a guidance

entitled “Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories” (Ref. 5). Accordingly, Option 1 is not a legally viable option. However, OMB Circular A-4 recommends using a pre-statute baseline when portions of a rule restate self-implementing statutory requirements. The costs and benefits of the pre-FSMA food facility registration requirements would remain unchanged if FDA pursued Option 1. As such, there would be no any additional costs or benefits under Option 1. In examining the costs and benefits of the other options discussed in this preliminary economic impact analysis, all of those options will be measured against the baseline in Option 1. This baseline includes the costs and benefits of the pre-FSMA food facility registration regulation, as estimated in the 2003 economic impact analysis and as further modified by updated assumptions discussed below. The 2003 economic impact analysis estimated annual and first-year costs of requiring food facility registration to both foreign and domestic facilities, as well as costs for future facilities entering the market each year.

The costs to domestic facilities that underlay the 2003 economic impact analysis constituted a four step scenario: (1) the facility becomes aware of the regulation; (2) the facility learns what the requirements are; (3) an administrative worker fills out the form; and (4) the owner, operator, or agent in charge confirms the information is correct (68 FR 58894 at 58939). The costs to foreign facilities stem from two additional steps: finding, and then hiring, a U.S. Agent. The 2003 economic impact analysis estimated that a total of 421,676 facilities (205,405 foreign and 216,271 domestic) would be affected by the interim final rule (68 FR 58894 at 58939).

The costs to FDA identified in the 2003 economic impact analysis included creating and maintaining the registration database, processing paper submissions, and sending annual mailings to registrants (68 FR 58894 at 58947). The 2003 economic impact analysis treated developing and maintaining a database as including automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant (68 FR 5378 at 5397).

For purposes of determining the baseline costs for this preliminary economic impact, we adjusted the cost estimates from the 2003 economic impact analysis in a number of ways, including to reflect 2012 dollars. We also adjusted the cost estimates from the 2003 economic impact analysis to reflect a smaller-than-predicted number of registered facilities. In the 2003 economic impact analysis, we estimated that there would be more than 400,000 registered food facilities (68 FR 58894 at 58938). As of February of 2014, however, there were 81,627 registered domestic and 114,139 registered foreign

facilities in FDA's database. We also updated assumptions regarding Internet usage and the time it would take facilities to complete certain tasks if they are not fluent in English. Specifically, the 2003 economic impact analysis assumed that 31% of foreign and 71% of domestic facilities had internet access (68 FR 58894 at 58948-58949). Given the increased use of electronic registration submissions and access to the Internet discussed in the Conventions section C.4, we change this assumption. In order to calculate the costs of Option 1, we assume that 98 percent of registrants have access to the Internet. We also assume for purposes of Option 1 that facilities with access to the Internet today are sufficiently capable of using FDA's English-language registration module such that it does not take those facilities more or less time to complete certain tasks depending on whether they are fluent in English. We also adjusted certain cost estimates that stem from the application of an administrative worker wage rate. In the 2003 economic impact analysis, we assumed that certain tasks required of foreign facilities would be completed by administrative workers, and therefore applied the administrative worker wage rate in calculating the costs that would result from time spent on those tasks. For domestic facilities, however, we applied different assumptions for those same tasks. In some instances, we assumed that only 75 percent of the time required to complete those tasks would be completed by administrative workers, and that the other 25 percent would be completed by managerial workers. We therefore applied a weighted administrative-managerial wage rate in estimating the costs to domestic facilities. Because we have no reason to believe that different types of workers would complete the same tasks by virtue of being associated with a foreign or domestic food facility, we no longer make that distinction. For purposes of estimating the costs of Option 1, we instead apply the same weighted administrative-managerial wage rate for both domestic and foreign facilities. The tasks for which we now apply a weighted administrative-managerial wage are gathering materials, filing the registration form and reviewing and signing the form for initial registrations, updates and cancellations (68 FR 5378 at 5393). In another instance---estimating the costs associated with researching and learning about the registration requirements---we applied the managerial wage rate in estimating the costs to domestic facilities, but the administrative worker wage rate in estimating the costs to foreign facilities (68 FR 5378 at 5393). We now assume that the managerial wage rate ($70.80 in 2012 dollars) should be applied to foreign facilities, as it was for domestic facilities. Further, the 2003 economic impact analysis applied the U.S. administrative worker wage rate in estimating the costs associated with the time required for a foreign facility to find a U.S. agent (68 FR 58894 at 58949). We now think a managerial wage rate ($70.80 in 2012 dollars) is appropriate. We present these updated costs in table 4.

As stated above, in order to update both first year costs and recurring (annual) costs from the 2003 economic impact analysis, we update the estimated number of domestic and foreign facilities to reflect the number of facilities more recently in FDA's database. In 2003, the agency used the Small Business Administration's (SBA's) estimate that 10 percent of all businesses open each year and about 10 percent close. As explained in the detailed analysis section, the 2003 analysis also estimated that 55 percent of new registrant may incur costs associated with updating their registration during the first year. A more recent SBA report estimates that as many as 12 percent of all firms open each year and as many as 12 percent close (Ref. 6). We apply SBA's updated estimate to food facilities, meaning that we now assume that 12 percent of registered facilities each year constitute new registrations, another 12 percent each year constitute cancellations and that 55 percent of newly registered facilities may have an update during the first year. Thus, baseline recurring costs of initial registrations, updates and cancellations only apply to 12 percent of currently-registered facilities (11,131 domestic and 15,564 foreign facilities).

The estimated total costs in 2012 dollars to domestic and foreign facilities in the first year, include both learning costs and first-time registration costs and the initial recurring costs from updates, cancellations and new registrations. Using our updated assumptions, these updated costs are now approximately $300 million, down from approximately $400 million. The main reason for this significant cost reduction is the decreased number of registered food facilities, compared with the number of registered food facilities we anticipated in 2003. Annual recurring costs after the first year are approximately $101 million. Annualized costs to facilities include annualized first-year costs and annualized recurring costs of approximately $92 million and $108 million per year using a discount rate of 7 percent and 3 percent over a period of 20 years. Annualized recurring costs to FDA were approximately $5 and $8 million using a discount rate of 7 percent and 3 percent, respectively. Under Option 1, our baseline scenario, the total annualized cost is $97 million per year (7 percent over 20 years) and $114 million per year (3 percent over 20 years).

Table 4. —Summary of Updated Costs of 2003 Food Facility Registration Final Rule ($Millions).

	Total One-Time Costs	Annualized Costs (7%)	Annualized Costs (3%)
Domestic Facilities	$ 15	$ 3	$ 3
Foreign Facilities	$ 301	$ 89	$ 104
Subtotal Facilities	**$ 316**	**$ 92**	**$ 108**
Costs to FDA	$ 17	$ 5	$ 6
Total	**$ 333**	**$ 97**	**$ 114**

(2012 U.S. Dollars)

The 2003 economic impact analysis did not quantify the benefits of the 2003 interim final rule. As explained in the preliminary economic analysis that accompanied the 2003 proposed rule, FDA lacked data to estimate the likelihood and resulting costs of a strike on the food supply, which therefore meant that the agency could not quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event. FDA also explained that it lacked data on the number of accidental outbreaks that would be prevented or shortened from the rulemaking. Instead, FDA looked at the relative effectiveness of the various regulatory options considered in the preliminary economic impact analysis, including the option of no action (68 FR 5378 at 5409). Although the 2003 economic impact analysis qualitatively examined the benefits of the current food facility registration regulations, and these benefits therefore constitute the benefits associated with Option 1, we nevertheless keep in mind that FDA has identified several deficiencies with the quality of registration data since 2003. These deficiencies make the pre-FSMA food facility registration system a less reliable tool for FDA than was assumed in 2003.

2. Option 2 - The Proposed Rule

This proposed rule would amend and update FDA's current regulations in 21 CFR part 1, subpart H, regarding registration of food facilities. The proposed rule would do so by codifying certain already-effective provisions authorized by section 102 of FSMA, which added new provisions to the requirements of section 415 of the FD&C Act for the registration of food facilities. The proposed rule would also amend and update FDA's food facility regulations by proposing additional requirements to food facility registrations. This second set of provisions would include certain additional data elements as well as certain verification procedures, thereby enhancing FDA's capabilities with respect to responding to food safety matters and also providing the agency with information that will allow FDA to better use its limited inspectional resources. We estimate costs of this proposed rule in two separate sections:

Section (a): Costs of the already-effective FSMA-related amendments and,

Section (b): Costs of other proposed amendments to the food facility registration regulation

Estimated costs to domestic and foreign facilities from requirements in section (a) began to accrue in 2012, when FDA first implemented biennial registration renewal. Costs in 2012 included learning costs (i.e., the administrative costs incurred by domestic and foreign facilities in order to learn

how to comply with new requirements), first-time biennial registration renewal costs, and recurring costs beginning from the first biennial registration renewal. For purposes of this preliminary economic analysis, we assume that the proposed rule would be finalized in 2016 before October 1, meaning before the start of the biennial registration renewal cycle for 2016. We therefore assume that the proposed rule would be in effect at the time of the 2016 biennial registration renewal cycle. As a result, beginning in 2016, recurring biennial costs would include the costs that result from the requirement for subsequent biennial registration renewal---a requirement that, under the proposed rule, would include the option to submit an abbreviated form of registration renewal in certain specified circumstances. Costs for 2016 also include costs that would result from the mandatory electronic submission requirement, which would also become effective in 2016 and would be a recurring cost for subsequent registration renewal cycles. The costs of mandatory electronic submission are the costs incurred by food facilities that are unable to submit electronic registrations. These facilities would therefore incur costs as a result of requesting a waiver from the electronic submission requirement.

Additional estimated costs of Option 2 (the proposed option) and Options 3 and 4 would be in addition to the estimated costs in section (a). Cost estimates for each of the requirements in section (a) are explained in the detailed cost section of this analysis. During the first biennial registration renewal cycle in 2012, 81,627 domestic facilities and 114,139 foreign facilities submitted registration renewals, thereby incurring costs associated with first-time renewal; we estimate these one-time, first-year costs to be approximately $8 and $11 million, respectively. Table 5 below summarizes the first-year costs incurred in 2012, as well as incremental costs associated with post-2012 biennial registration renewal cycles (beginning in 2014), that domestic and foreign facilities will have incurred as a result of the requirements in section (a).

Table 5. — Summary of One-Time, First-Year and Recurring Biennial Costs ($Millions) to Domestic and Foreign Facilities of Provisions in Section (a) ($Millions)

	Domestic Facilities	Foreign Facilities	Total
Section (a) First Year Costs (2012)	$ 8	$ 11.	$ 19
Section (a) Recurring Biennial Costs (2014)	$ 1.3	$ 1.8	$ 3

Costs from section (b) begin in 2016 and are summarized in table 6. These are costs from meeting the other proposed amendments to the food facility registration regulation in addition to those in section (a), and include, among other things, one-time costs from the proposed requirement to obtain a D-U-N-S ® number.

Table 6.—Summary of One-Time, First Year and Recurring Costs to Domestic and Foreign Facilities of Provisions in Section (b) ($Millions)

	Domestic Facilities	Foreign Facilities	Total
Section (b) First Year Costs (2016)	$ 1.2	$ 2	$ 3.2
Section (b) 2016 Recurring Biennial Costs	$ 1.3	$ 9.6	$ 10.9

Table 7 presents the sum of one-time costs and recurring annual costs to domestic and foreign facilities as they are estimated to accrue in 2012, 2014 and 2016. Costs also include costs to FDA in implementing the provisions in the proposed rule from Table 18 (those costs are contained in the detailed cost analysis section). Table 7 also presents total annualized costs over a 20-year time period using a 7 percent and 3 percent discount rate.

Table 7.—Annual Undiscounted Cost Stream and Annualized Cost Summary of Option 2 – Proposed Option ($ Millions)

Year	Domestic Facilities	Foreign Facilities	FDA	Total
2012	$ 8.0	$ 11.2	$ 3.4	$ 22.6
2013	$ -	$ -	$ 1.5	$ 1.5
2014	$ 0.6	$ 0.9	$ 1.9	$ 3.4
2015	$ 0.6	$ 0.9	$ 1.9	$ 3.4
2016	$ 2.5	$ 7.7	$ 1.9	$ 12
:	:	:	:	:
2031	$ 2.5	$ 7.7	$ 1.9	$ 12.0
Annualized 7%	$ 1.5	$ 3.9	$ 0.9	$ 6.3
Annualized 3%	$ 1.5	$ 4.7	$ 1.2	$ 7.4

A. Costs of the Proposed Rule: Detailed Analysis

Section (a): Costs of the already-effective FSMA-related amendments

The costs analyzed in this section are for provisions of section 102 of FSMA that were self-implementing and have been in effect since FSMA was enacted. These costs consist of learning costs and compliance costs. Learning costs are based on the amount of time required to learn about the new registration requirements such as the requirements for biennial registration renewal. Compliance costs are based on the time spent fulfilling requirements, such as filling out new or additional information in the registration form that was not previously required. We presume that providing information on some items, such as e-mail address information, can take as little as a few seconds to as much as one minute to

enter into the form. But for purposes of estimating the costs of the proposed rule, we use the more conservative estimate that providing data elements such as e-mail address information will require 1 minute of an administrative worker's time. We do not analyze costs to facilities associated with submitting new food facility registrations, as those costs were already accounted for in the 2003 economic impact analysis.

i. Biennial Registration Renewal and Abbreviated Registration Renewal First-Year Costs

At the time of the first biennial registration renewal period in 2012, all food facilities required to register had to learn about the new FSMA-related registration requirements. As explained in the Conventions section of this analysis, we use the estimate that facilities will spend about 1 hour researching the regulation, and treat this as time spent learning. We assume that the owner, operator, or agent in charge will be responsible for this task, and therefore we use the manager wage rate to calculate the costs. For present purposes, we treat the time spent learning as time spent learning about the new FSMA-related requirements prior to submitting registration renewals. We apply this time amount to the 81,627 domestic and 114,139 foreign facilities (195,766 total facilities) that participated in the 2012 biennial registration. Using the manager wage rate of $70.80/ hour, we estimate that these first-year learning costs added up to about $14 million ($5.8 million for domestic food facilities, and $8.1 million for foreign food facilities).[1]

In addition to the first-year learning costs, we also estimate the costs of the 2012 biennial renewal process itself. Even though section 102(a)(3) of FSMA directs FDA to provide an abbreviated renewal process for any registrant that has not had any changes to its registration information since the registrant submitted the preceding registration or registration renewal for the facility, the abbreviated biennial renewal process did not exist for the first biennial renewal registration because all facilities had changes to their preceding registrations in light of the new requirements under section 102 of FSMA.

For facilities that used the online option for biennial renewal in 2012, the already-existing registration information was displayed for review and editing as necessary on online registration forms. Thus, to the extent that a facility's registration information was up-to-date, the only information

[1] 195,766 domestic and foreign facilities x 1 hour learning x $70.80 wage rate = $13,860,194

facilities needed to submit in 2012 was information required by the self-implementing FSMA provisions. We estimate that the time spent submitting 2012 registration renewals ranged from a few minutes to as much as one hour. We assume that the average amount of time required was 30 minutes (0.5 hours), per facility. For purposes of this analysis, we estimate that three quarters of this time (0.75 x 0.50 hours = 22 minutes) were spent by an administrative worker gathering material, logging into the system and entering or updating already-existing information. We estimate that the remaining 8 minutes (0.25 x 0.50 hours) were spent by a manager reviewing and signing the information. Using $31.32/ hour for the administrative worker's wage and $70.80 for the manager's wage, we estimate a weighted average wage of $41.19 for the combined time between the administrative worker and the manager.[2] In total, we estimate that the costs of submitting the form during the first renewal cycle in 2012 were $4.0 million, $1.7 million of which were incurred by domestic facilities and $2.4 million of which were incurred by foreign facilities (Table 8).

ii. Email Address for Domestic Facility's Contact Person and Foreign Facility's U.S. Agent as Required Information

Section 415(a)(2) of the FD&C Act, as amended by section 102(a) of FSMA, requires, among other things, that a registration for a domestic facility contain the email address for the contact person of the facility. This requirement went into effect upon enactment of FSMA. In addition, section 415(a)(2) of the FD&C Act, as amended by section 102(a) of FSMA, requires, among other things, that a registration for a foreign facility contain the email address of the U.S. Agent for the foreign facility. This requirement also went into effect upon enactment of FSMA. For these e-mail address requirements, we assume it will take an administrative worker one minute to add one e-mail address to a form. Table 8 below shows the costs to both domestic and foreign facilities (195,766 facilities x 1/60 x 1= 3,263 (hours) x $31.32 (wage rate) = $102,189). We add these estimated costs to the costs associated with the 2012 registration renewal discussed above. That is, we add the costs associated with the 1 minute required to comply with these e-mail requirements to the costs associated with the 30 minutes required for completing the registration renewal.

[2] (0.75 x $31.32) + (0.25 x $70.80) = $41.19, then $41.19/hour x 195,766 (domestic and foreign facilities) x 0.50 hours = $4,031,768)

iii. Assurance Statement that FDA Will be Permitted to Inspect

Section 415(a)(2) of the FD&C Act, as amended by section 102(b) of FSMA, also requires, among other things, that food facility registrations contain an assurance that the Secretary (and by delegation, FDA) will be permitted to inspect such facility at the times and in the manner permitted by the FD&C Act. This requirement was self-implementing upon enactment of FSMA. Both foreign and domestic facility registrations are required to include a statement in which the owner, operator or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Food facilities include this statement by checking a box on the food facility registration form. We assume that a manager will be required to spend roughly 5 minutes (with an hourly wage of $70.80) every 2 years to read and check the assurance statement (195,766 facilities x 5/60 =16,314 hours x $70.80 = $1,155,016 during the first year (see Table 8)). We request comment on this estimate.

We add these estimated costs to the costs associated with the e-mail address requirement and the costs associated with the 2012 registration renewal form discussed above. That is, we add the costs associated with the 5 minutes required to complete the assurance statement to the costs associated with the one minute estimated as needed to comply with the e-mail address requirement and the 30 minutes estimated as needed for completing the registration renewal. Thus, the total cost of section (a) for the first year is the sum of learning costs, plus the costs of completing the registration renewal, the costs of complying with the e-mail address requirements, and the costs of complying with the assurance statement requirement.

Table 8.— First Year Costs of section (a) to Domestic and Foreign Facilities of the Proposed Amendments to Food Facility Registration

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Costs	Cost/ Facility
Learning Costs	195,766	1.00	1	195,766	$ 70.80	$ 13,860,194	$ 70.80
First Biennial Registration Renewal	195,766	0.50	1	97,883	$ 41.19	$ 4,031,768	$ 20.59
E-mail Address for Contact/U.S. Agent	195,766	0.02	1	3,263	$ 31.32	$ 102,189	$ 0.52
Assurance Statement that FDA will be Permitted to Inspect	195,766	0.08	1	16,314	$ 70.80	$ 1,155,016	$ 5.90
Subtotal First Year	**195,766**	**1.60**	**1**	**313,226**		**$ 19,149,167**	**$ 97.82**

Annual Costs

Under the biennial registration renewal process required by FSMA, food facilities would need to renew their registrations once every two years. For calculation purposes, this translates to an annual frequency of 50 percent. The proposed rule would provide for an abbreviated registration renewal process for registrations that do not have any changes to the information required under 21 CFR 1.232 since the registrant submitted the preceding registration or registration renewal for the facility to FDA. The abbreviated registration renewal process would require a registrant to confirm that no changes have been made to the information required in the registration since the registrant submitted the preceding registration or registration renewal, confirm that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act, and certify that the information submitted is truthful and accurate.

In estimating recurring costs of post-2012 registration renewal cycles, we assume the costs can be as much as the estimated costs for the 2012 first year renewal in section (a), except that now we also factor in the estimated effect of the proposed option to use the abbreviated renewal process. As discussed previously in section (a), we estimate the average amount of time spent submitting the 2012 registration renewals was 30 minutes. As also discussed previously, registrants in 2012 did not have the option of submitting abbreviated registration renewals. For future registration cycles, registrants will have that option. For those that submit non-abbreviated renewals, we estimate that the average amount of time required for such submissions will continue to be 30 minutes. As for abbreviated renewals, we estimate that the average amount of time required for such submissions will be 15 minutes (0.25 hours). Although we cannot know with certainty how many food facilities will use the abbreviated renewal process, we assume that one half of the facilities will take advantage of this option. This results in a weighted average time of 0.375 minutes (0.5 facilities X 0.5 hours) + (0.5 facilities X 0.25 hours) = 0.25 + 0.125 = 0.375 hours, which is 23 minutes. We assume that three quarters of that time was spent by an administrative worker at the administrative worker wage rate ($31.32 /hour) and one quarter of that time was spent by an owner, operator, or agent in charge at the managerial wage rate ($70.80/hour), for a

weighted hourly wage rate of $41.19. Annual costs estimates of Biennial Registration Renewal are estimated to be $1.5 million.[3] The costs are summarized in Table 9 below.

Table 9. —Annual Costs of Biennial Registration Renewal and Abbreviated Renewal -Domestic and Foreign Facilities

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Annual Costs	Cost/ Facility
Domestic Facilities	81,627	0.38	0.5	15,305	$ 41.19	$ 630,410	$ 7.72
Foreign Facilities	114,139	0.38	0.5	21,401	$ 41.19	$ 881,503	$ 7.72
Recurring Costs beginning in 2014	195,766	0.38	0.5	36,706	$ 41.19	$ 1,511,913	$ 7.72

iv. Proposal to Identify and Update Food Product Categories as Identified on FDA Form FDA 3537

Proposed § 1.232(a)(7) would retain the requirement in current § 1.232(g) that food facilities provide information regarding food product categories, but would change that requirement to be consistent with the changes FDA has made to food product categories in response to the FSMA amendments. Current § 1.232(g) provides that food facility registrations include applicable food product categories as defined in 21 CFR § 170.3, unless facilities check either "most/all human food product categories," according to § 1.233(j), or "none of the above mandatory categories" because a facility manufactures, processes, packs, or holds a food that is not identified in § 170.3. Section 102 of FSMA amended section 415(a)(2) of the FD&C Act to now provide, in relevant part, that, when determined necessary by FDA "through guidance," a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in 21 CFR 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. In October 2012, FDA issued a guidance entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (Ref. 7). This guidance represents

[3] For calculation: 81,627 domestic facilities x 0.375 hours x 0.5 annual frequency = 15,305 hours x $41.19 = $630,410 and 114,139 foreign facilities x 0.375 hours x 0.5 annual frequency = 21,401 hours x $41.19 = $881,503.

FDA's conclusion on the necessity of food product categories in food facility registrations and identifies additional food product categories, as provided by section 415(a)(2) of the FD&C Act.

We estimate that no new costs will result from proposed § 1.232(a)(7), as the pre-FSMA food facility registration form already required food product category information and we do not anticipate that the changes FDA has made to the food product category section of the registration form will require registrants to expend any additional time answering. In reaching this tentative conclusion, we also note that the electronic version of the registration form uses a drop-down menu format that we expect will result in a less time-consuming process for registrants to provide food product category information. We also note that there may be some learning costs associated with this provision. Nevertheless, we estimate learning costs for this and all other already-effective, FSMA-related provisions as part of overall learning costs associated with section (a). We therefore assume no net change in time required to fulfill the post-FSMA food product category requirement. Thus, any costs associated with requiring food product category information were already accounted for in the 2003 economic impact analysis.

Total Costs

Total first-year costs and annual costs in section (a) are summarized in Table 10. These costs include only the costs incurred by the already-effective FSMA provisions, as well as other FSMA-related provisions that we assume will go into effect in 2016.

Table 10.—Estimated First Year and Annual Costs of Proposed Amendments in Section (a)

Costs Section (a)	Domestic Facilities	Foreign Facilities	Total
Number of Facilities	**81,627**	**114,139**	**195,766**
First Year Costs			
Learning Costs (2012)	$ 5,779,175	$ 8,081,019	$ 13,860,194
First Biennial Registration Renewal (2012)	$ 1,681,094	$ 2,350,673	$ 4,031,768
E-mail Address for Domestic Facility's Contact and Foreign Facility's U.S. Agent (2012)	$ 42,609	$ 59,580	$ 102,189
Assurance Statement that FDA will be Permitted to Inspect (2012)	$ 481,598	$ 673,418	$ 1,155,016
Identify and Update Food Product Categories	$ -	$ -	$ -

Subtotal First Year	**$ 7,984,476**	**$ 11,164,690**	**$ 19,149,167**
Annual Costs			
Biennial Registration Renewal (2014)	$ 630,410	$ 881,503	$ 1,511,913
Total Costs Section (a)	**$ 8,614,887**	**$12,046,193**	**$ 20,661,079**

Section (b): Costs of other proposed amendments to registration of food facilities

In this section we estimate the marginal costs to domestic and foreign facilities of the proposal to require the following nine additional provisions.

v. U.S. Agent Information Viewing

vi. Verification Procedures for U.S. Agents

vii. Verification Procedures for Registration Submissions not Made by the Owner, Operator, or Agent in Charge

viii. Proposed Requirement for Data Universal Numbering System (D-U-N-S®) Number Submission

ix. Proposal to Require Certain Information in Food Facility Registration that is Currently Optional

x. Proposal to Change the Requirement to Update and Cancel Registration from 60 to 30 Calendar Days

xi. Mandatory Electronic Submission of Food Facility Registration and Registration Renewals

xii. Proposal to Delete the Option for CD ROM Submissions

xiii. Proposal to Require Immediate Updates to Incorrect Information

We estimate the costs for provisions v and vi together.

v. U.S. Agent Information Viewing and

vi. Verification Procedures for U.S. Agents

FDA is proposing to allow U.S. Agents of foreign facilities to view the information submitted in the foreign facility's registration. U.S. Agents could use such information to be in contact with foreign facilities, thereby enabling U.S. Agents to more efficiently and effectively function as communications links between foreign food facilities and FDA. Further, U.S. Agents could use such information to better represent foreign facilities when communicating with FDA.

Section 107 of FSMA authorizes FDA to assess and collect fees from the U.S. Agent for each foreign facility subject to re-inspection to cover re-inspection-related costs (section 743(a)(1)(A) of the FD&C Act [21 U.S.C. 379j-31(a)(1)(A)]). FDA's proposal to allow the U.S. Agent of a foreign facility to view the information submitted in the foreign facility's registration would further enable U.S. Agents to serve this new role.

In addition, FDA is proposing to provide that after a foreign facility completes its registration or updates its U.S. Agent information as part of registration renewal, FDA would email the person identified as the U.S. Agent for the foreign facility, using the email address for the person identified as the U.S. Agent in the facility's registration, to verify that the person has agreed to serve as the facility's U.S. Agent. Under the proposal, FDA would not confirm the foreign facility's registration or registration renewal until that person confirms that the person agreed to serve as the U.S. Agent for the foreign facility. In addition, with respect to initial registrations, FDA would not provide the facility with a registration number until that person confirms that the person agreed to serve as the U.S. Agent for the foreign facility. Further, this verification step would also take place when foreign facilities update U.S. Agent information. For updates to U.S. Agent information, FDA would not provide an update confirmation until that person confirms that the person agreed to serve as the U.S. Agent for the foreign facility.

This verification process would be automated such that when a registrant submits information about its U.S agent, the registration system would send an e-mail to the U.S. Agent to the e-mail address provided by the registrant. The e-mail would include a link that would connect the U.S. Agent to FDA's food facility registration module, allowing the U.S. Agent to either accept or decline assignment with the facility. If the U.S. Agent accepts the assignment, the system would also e-mail the facility informing the facility of the U.S. Agent's acceptance. If, however, a U.S. Agent declines the assignment, the

issuance of the registration number could be delayed. The expedient issuance of a registration number would therefore depend on the already-established agreement between the U.S. Agent and the foreign facility that a U.S. Agent will agree to serve the facility. It would also depend on the registrant providing an accurate e-mail address for the U.S. Agent (Ref. 4).

To calculate the costs associated with these provisions, we begin with the costs that are likely to result from the U.S. Agent verification procedure. We believe this procedure is likely to result in foreign facilities spending time securing the services of a U.S. Agent and/or spending time communicating with the U.S. Agent with whom the facility already established an agreement. Foreign facilities would invest this time to confirm that the U.S. Agent has in fact agreed to serve in that role. Any costs associated with the U.S. Agent's time would likely be recovered in the fees that the U.S. Agent receives. We therefore assign the costs that we anticipate will result from increased communications to foreign facilities, which would have to pay both the costs of U.S. Agents' fees and expend their own time communicating with the U.S. Agents. Because we assume that the facility manager will engage in the communications, we calculate the costs associated with the communications using the manager wage rate. Furthermore, because the proposed rule would allow U.S. Agents to view the registration information for the facilities they represent, we assume that U.S. Agents will in fact spend time viewing this information. We attribute all costs associated with time U.S. Agents spend viewing this information to foreign facilities because, as discussed above, we assume that U.S. Agents will be compensated for their time in the form of increased fees.

We estimate that 30 minutes of labor time will result from both the U.S. Agent verification procedures and U.S. Agent information viewing provision, for a total of 1 hour of time per facility every other year (or 30 minutes (0.5 hours) each year). We estimate the costs that result from this time at the manager wage rate ($70.80/ hour). In total, we estimate that the two proposals will jointly result in annual costs to foreign facilities of $4 million, or $35.40 per facility (Table 11). We seek comments on these cost estimates.

In addition to the costs for which FDA is able to provide quantitative estimates, FDA also estimates that the proposed U.S. Agent verification step could result in additional costs that the agency is not able to quantify. Specifically, FDA estimates that food facilities may incur costs that result from port delays when and if listed U.S. Agents decline the assignment during the verification step during the period of time in which the facilities do not have registration confirmations or registration numbers. These port delays may occur because food from an unregistered foreign facility that is imported or

offered for import into the United States is subject to being held under section 801(l) of the FD&C Act [21 USC 381(l)] and 21 CFR 1.285, and such holds are not resolved until the foreign facility registers with FDA and obtains a registration number. In the 2003 preliminary economic impact analysis and final economic impact analysis, FDA considered qualitatively the potential costs associated with port delays due to foreign facilities not being aware of the registration requirement until their shipment reaches the port. This included costs such as lost value of perishables, storage costs, and transaction costs (68 FR 5397; 68 FR 58940). FDA expects that to the extent there are port delays that result from the U.S. Agent verification step, they typically will include these same costs. In the 2003 preliminary economic impact analysis, FDA estimated that any port delays would typically be experienced by food facilities that ship infrequently to the United States; that delays would be longer and more likely for shipments from facilities that are more distant from the United States or have difficulty communicating with the United States; and that perishables, due to their short shelf life, would more likely be shipped from countries that are geographically close to the United States. For these reasons, FDA expected that costs arising from delays for non-perishable products may be as high as or higher than costs arising from perishable products. FDA has these same expectations with respect to any port delays that may result from this proposed rule. In addition, as with the 2003 preliminary and final economic impact analysis, FDA considers port delay costs qualitatively. FDA requests comments on the length of delay for shipments held while waiting for the U.S. Agent verification step and on the costs of the delay, such as loss of product value, storage costs, and transaction costs. We also seek comments on all other cost estimates regarding verification procedures for U.S. Agents.

Table 11. — Costs to Foreign Facilities from U.S. Agent Information Viewing and Verification Procedures for U.S. Agent

Foreign Facilities	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Costs	Cost/ Facility
U.S. Agent Information Viewing & Verification Procedures for U.S. Agent	114,139	1	0.5	57,070	$70.80	$4,040,509	$ 35.40

vii. Verification Procedures for Registration Submissions Not Made by the Owner, Operator, or Agent in Charge and Related E-mail Address Requirement

Currently, § 1.232(i) provides that if the individual submitting the registration form is not the owner, operator, or agent in charge of the facility, the registration must include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies the name, address, and telephone number of the individual who authorized submission of the registration. The proposed rule would recodify this provision at § 1.232(a)(10), and also add e-mail address to the list of required information identifying the individual who authorized submission of such registrations. In addition, the proposed rule would apply this requirement to registration renewals. Further, the proposed rule would provide that updates and cancellations not submitted by the owner, operator or agent in charge of the facility must include the e-mail address of the owner, operator, or agent in charge who authorized submission of the update.

These requirements would function in connection with a verification step in the proposed rule. Specifically, the proposed rule would provide a verification step for electronic registrations and registration renewals, mail/fax registrations and registration renewals, electronic updates, mail/fax updates, electronic cancellations, and mail/fax cancellations not submitted by the owner, operator or agent in charge of the facility. Under the verification step, FDA would e-mail the individual identified as the owner, operator or agent in charge who authorized the registration submission to verify that the individual in fact authorized the submission on behalf of the facility. Under the proposed rule, FDA would not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration. With respect to registration renewals, the proposed rule would provide that FDA would not provide a confirmation of the registration renewal until the individual confirms that he or she authorized the registration renewal. In addition, FDA would not confirm a registration update until the individual identified as the owner, operator, or agent in charge who authorized the update confirms that he or she in fact authorized the update on behalf of the facility. Further, FDA would not confirm a registration cancellation until the individual identified as the owner, operator, or agent in charge who authorized the cancellation confirms that he or she in fact authorized the cancellation on behalf of the facility. Similar to the proposed verification procedure for U.S. Agents discussed above, this verification process would be automated such that when a registration submission is submitted by an individual other than the owner, operator, or agent in charge, the system would send an e-mail to the e-mail address provided for the individual identified as the owner, operator or agent in charge who authorized the submission. The e-mail would include a link that would connect the owner, operator, or agent in charge to FDA's food facility registration module, allowing the owner, operator, or

agent in charge to either confirm or deny that he or she authorized the registration submission on behalf of the facility (Ref. 8).

Both domestic and foreign facilities are likely to incur costs associated with this provision from the time spent by facilities' owners, operators, or agents in charge in searching, reading and responding to e-mails from FDA in order to confirm whether the facility's registration was in fact submitted by an authorized individual. To estimate the costs associated with the proposed verification step for third party registrations, we begin by looking at the number of existing registrations that were submitted by individuals other than the owner, operator, or agent in charge. About 49 percent of domestic facility registrations (39,992) and 37 percent (42,521) of foreign facility registrations were submitted by individuals other than the owner, operator, or agent in charge of the facility. We then consider the amount of time that owners, operators, or agents in charge are likely to expend on searching, reading, and responding to e-mails from FDA, as well as the time required to enter the email address of the owner, operator, or agent in charge who authorized the submission. We estimate that the total amount of time required for these activities will be 15 minutes. We estimate the costs for this time at the wage rate of $70.80/ hour, and we estimate that facilities will incur these costs once every other year, for a total annual cost of about $730,000.[4]

Table 12. —Facility Costs Associated with Verification Procedures for Registration Submissions Not Made by the Owner, Operator, or Agent in Charge

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Costs	Cost/ Facility
Domestic Facilities	39,992	0.25	0.5	4,999	$70.80	$ 353,926	$ 8.85
Foreign Facilities	42,521	0.25	0.5	5,315	$70.80	$ 376,309	$ 8.85
Total	82,513	0.25	0.5	10,314	$70.80	$ 730,236	$ 8.85

viii. Proposed requirement for Data Universal Numbering System (D-U-N-S®) Number

[4] 82,513 facilities x 0.25 x 0.5= 10,314 hours/year, 10,314 hours/year x $70.80/hour = $730,236.

FDA is proposing to require the D-U-N-S® number of a domestic and foreign facility be included in a facility's registration. A D-U-N-S® number is a nine digit unique facility identifier provided by Dun & Bradstreet Credibility Corp. that can be specific for each site. The site-specific number is a widely recognized business identification tool and serves as a useful resource for FDA in identifying and verifying certain business information submitted by a user. We estimate one-time costs of requiring a D-U-N-S® number in a facility's registration. For first-year costs, food facilities that currently do not have a D-U-N-S ® number will have to obtain one. Based on an FDA analysis of Dun & Bradstreet data, we estimate that about 71 percent of domestic food facilities currently have a D-U-N-S ® number and about 64 percent of foreign food facilities have one, meaning that about 29 percent of domestic food facilities and 36 percent of foreign food facilities that are required to register with FDA would need to obtain a D-U-N-S ® number (Ref. 9). Using these percentages, we estimate that 64,762 facilities will incur one-time costs in order to obtain a D-U-N-S ® number.[5]

Both domestic and foreign food facilities may obtain a D-U-N-S® number free of charge either online or by phone. The type of information required by Dun & Bradstreet in order to get a D-U-N-S® number includes such company information as the name of the business, contact person, e-mail address, physical and mailing address, legal structure, top executive name and title, SIC (Standard Industrial classification code), number of employees, annual revenues and parent company name (if applicable) (Ref. 10) .

Dun & Bradstreet usually requires 30 days to provide a D-U-N-S® number upon receiving a complete request. For businesses that are willing to pay a fee of about $250, Dun & Bradstreet is able to provide a number within 5 days (Ref. 8). We do not know how many facilities will wait 30 days to obtain a D-U-N-S® number for free, or how many will pay $250 for an expedited number. We request comments on this issue.

Regardless of which service facilities choose, we estimate that the time required to request the number would be one hour. We further estimate that 15 minutes (0.25 hours) of that hour would be spent by a manager, and 45 minutes (0.75 hours) would be spent by an administrative worker. In addition, we estimate that the weighted average hourly wage for this labor time would be $41.19. Using

[5](81,627 x 0.29 = 23,672 domestic facilities) + (114,139 x 0.36 = 41,090 foreign facilities).

these estimates, we expect that the one-time cost to food facilities for obtaining a D-U-N-S® number as a result of the proposed rule would be about $2.67 million.[6] First-year costs to both domestic and foreign facilities for obtaining a D-U-N-S® number in response to the proposed rule are summarized in table 13.

Table 13.—First-Year Costs to Domestic and Foreign Facilities for Obtaining a D-U-N-S® Number

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	One-time Costs	Cost/ Facility
Domestic Facilities	23,672	1	1	23,672	$ 41.19	$ 975,035	$ 41.19
Foreign Facilities	41,090	1	1	41,090	$ 41.19	$ 1,692,485	$ 41.19
Total	64,762	1	1	64,762	$ 41.19	$ 2,667,520	$ 41.19

The costs of obtaining a D-U-N-S ® number would not be the only costs associated with the proposed D-U-N-S ® number requirement. We anticipate that the D-U-N-S ® number requirement will also result in costs associated with entering the D-U-N-S ® number onto the food facility registration form. This cost would be incurred by all 195,766 facilities with a D-U-N-S ® number, including those that would be required under the proposed rule to obtain a D-U-N-S ® number for the first time. In estimating these costs, we assume it will take 1 minute of an administrative worker's time (at an hourly wage rate of $31.32) to enter the number onto the registration form, resulting in a total cost of $102,189 ($42,609 of which would be incurred by domestic facilities and $59,580 of which would be incurred by foreign facilities (Table 14)).

Table 14.— Costs to Domestic and Foreign Facilities from Entering a D-U-N-S® Number onto the Food Facility Registration Form

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	One-time Costs	Cost/ Facility
Domestic Facilities	81,627	0.017	1	1,360	$ 31.32	$ 42,609	$ 0.52
Foreign Facilities	114,139	0.017	1	1,902	$ 31.32	$ 59,580	$ 0.52

[6](64,762 facilities needing to obtain a D-U-N-S® number x 1 hour x $41.19/hour wage rate = $2,667,520).

Total	195,766	0.017	1	3,263	$ 31.32	$ 102,189	$ 0.52

Following the submission of a D-U-N-S® number, the proposed rule provides that FDA would initiate a verification step for that number. FDA would not confirm a food facility's registration or registration renewal until FDA verifies the accuracy of the food facility's D-U-N-S® number and verifies that the facility-specific address associated with the D-U-N-S® number is the same address associated with the facility's registration. FDA anticipates that this verification process would use current technology such as an integration manager. For food facilities that provide accurate D-U-N-S® numbers and for which the facility-specific address associated with the D-U-N-S® number is the same as the address associated with the facility's registration, we don't anticipate any delay in FDA verifying the information because the verification process would be fully automated. If, however, the registrant provides incorrect D-U-N-S® number information and/or the address associated with the D-U-N-S® number is not the same as the address associated with the facility's registration, FDA would not be able to immediately provide a confirmation of the registration or registration number. Because food from an unregistered foreign facility that is imported or offered for import into the United States is subject to being held under section 801(l) of the FD&C Act and 21 CFR 1.285, and such holds are not resolved until the foreign facility registers with FDA and obtains a registration number, we anticipate that facilities that do not receive immediate confirmation of the registration or registration number may incur costs that result from port delays during the period of time in which they do not have registration confirmations or registration numbers. As we discussed above in addressing any port delays that would result from the U.S. Agent verification step, we are not able to quantify these costs. Instead, we qualitatively consider such costs and estimate that costs would include lost value of perishables, storage costs, and transaction costs. For the reasons discussed above, FDA further estimates that costs arising from delays for non-perishable products may be as high as or higher than costs arising from perishable products. FDA requests comments on any port delay-related costs. We also seek comments on all other cost estimates regarding the proposed requirements related to D-U-N-S® numbers.

ix. Proposal to Require Certain Information in the Food Facility Registration that is Currently Optional

FDA is proposing to require certain additional information be included in a food facility's registration that is currently optional. Specifically, FDA is proposing to require that domestic and foreign food facilities provide a preferred mailing address if such mailing address is different from the mailing address of the facility. In addition, FDA is proposing to add an email address to the contact information required for the owner, operator or agent in charge of the facility for both domestic and foreign facilities. FDA is further proposing to require food facilities to list the type of activity conducted at the facility for each food product category identified, and to choose among a specified list of activities types. Finally, FDA is proposing to add an email address to the emergency contact information registrants are required to provide for a domestic facility. Because in some cases the emergency contact email address may be the same email address as the email address for the facility contact person required elsewhere in the proposed rule, FDA is proposing to require an emergency contact email address be provided only if that email address is different from the facility contact person email address.

In estimating costs for these requirements, we assume that each of these activities will take an administrative worker one minute to fill in each item (at an hourly wage rate of $31.32). We estimate that one-time costs to domestic and foreign facilities for all of these requirements would be $170,435 and $238,319, respectively (total of $408,754). These costs are summarized in Table 15.

Table 15.— Costs to Domestic and Foreign Facilities from Requiring Certain Information that is Currently Optional

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	One-time Costs	Cost/ Facility
a. Preferred mailing address information	195,766	0.0167	1	3,263	$ 31.32	$ 102,189	$ 0.52
b. Email address for the owner, operator or agent in charge of the facility	195,766	0.0167	1	3,263	$ 31.32	$ 102,189	$ 0.52
c. Type of activity or type of storage conducted at the facility	195,766	0.0167	1	3,263	$ 31.32	$ 102,189	$ 0.52
d. Email address of the emergency contact of all facilities	195,766	0.0167	1	3,263	$ 31.32	$ 102,189	$ 0.52
Subtotal	**195,766**	**0.0667**	**1**		**$31.32**	**$ 408,754**	**$ 2.09**

x. Proposal to Change the Requirement to Update and Cancel Registration from 60 to 30 Calendar Days

Under current § 1.234(a), facilities are required to update their registrations within 60 calendar days of any change to any of the information required in a facility's registration. In addition, under current § 1.235(a), a facility canceling its registration must do so within 60 days of the reason for cancellation (*e.g.*, facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner). The proposed rule would shorten the time period for a food facility to update or cancel its registration from 60 to 30 calendar days.

With respect to the costs of requiring a facility to cancel its registration within 30 calendar days, the 2003 economic impact analysis estimated the costs of registration cancellations. The cost estimate in the 2003 economic impact analysis was based on the requirement that cancellations be submitted within 60 days of the reason for cancellation. Because a registration cancellation need only be submitted one time, we expect that the costs of a 30-day cancellation requirement would be the same as the costs of a 60-day cancellation requirement. That is, the proposed 30-day cancellation requirement would not result in facilities having to make any more or different registration submissions to FDA. For this reason, we don't calculate the costs of cancelling registration again in this analysis, as doing so would result in double counting the costs from the 2003 interim final rule.

With respect to the costs of the 30-day update requirement, we also begin by looking to the 2003 economic impact analysis. In that economic impact analysis, FDA considered the difference in costs of requiring updates within 30 days and 60 days. As detailed in the 2003 economic impact analysis, FDA used the estimate that with a 60-day update requirement, a weighted average of 55 percent of facilities would have a registration update each year (68 FR 58894 at 58941). Although the 2003 analysis did not specifically identify a weighted average for the percent of facilities that would be required to update their registrations each year with a 30-day update requirement, the assumptions the agency relied on in 2003 result in a weighted average of 62.5 percent with a 30-day update requirement.

In estimating the costs of the proposal to implement a 30-day update requirement, we start with the same assumption that 62.5 percent of food facilities under the 2003 interim final rule would be required to update each year. We then also build into our analysis the possibility that the number of annual updates could be affected by other requirements in this proposed rule. For example, the proposed rule may result in registrants having to more frequently update their food product categories, as those

categories that have been updated post-FSMA tend to be more granular. This may make it more likely that food facilities will be required to update their registration information to indicate changes in the type of food handled by the facility. In addition, the proposed requirement to provide information about activity types could also trigger more frequent updates to registrations, as food facilities' activity types may change during the course of a biennial registration renewal cycle, thereby necessitating registration updates. Although we expect that the new data elements may result in facilities having to submit more frequent updates, we do not know whether the proposed requirement for a 30-day update period would have any bearing on the frequency of such updates. To be conservative, however, we assume that an additional 7.5 percent to the 62.5 percent of facilities, or a total of 70 percent of facilities, will report updates each year as a result of the proposed 30-day update requirement and the other requirements in this proposed rule.

We next estimate the time needed by facilities to update their registrations. To do this, we assume that updating a registration would at a minimum take the same amount of time as renewing a registration (23 minutes, as discussed earlier in this preliminary economic impact analysis). Given the variety of proposed new data elements required in the proposed rule, we assume that some updates could require as many as 20 more minutes of additional time, for a maximum update time of 43 minutes. We do not know how many updates will involve updating a minimum number of data elements, and would therefore require 23 minutes, or how many updates will involve updating many data elements, and would therefore require 43 minutes. We therefore assume that the average amount of time required to update a registration will be 33 minutes (0.54 hours), the average of 23 minutes and 43 minutes.

To further calculate the costs of the proposed changes to the update requirement, we return to the fact that the 2003 economic impact analysis assumed that 55 percent of facilities would submit updates each year under the current food facility regulations. That figure is 15 percent fewer than the 70 percent of facilities that we estimated would be required to submit updates each year under the proposed rule.[7] To determine the cost of the proposed rule's changes to the update requirement, we estimate the costs for the 15 percent of facilities that would be newly required to submit updates each year under the

[7] We estimate that instead of 55 percent, 62.5 percent would have updates when facilities have only 30 calendar days to update their registration rather than 60 calendar days when facility information changes. We further increase this 62.5 percent to account for other proposed changes in registration information that may be more granular than what was required in the past, causing the need for an overall increase in updates.

proposed rule. Those costs are the 33 minutes per update discussed above. For domestic and foreign facilities, the estimated recurring annual costs of this requirement are a respective $0.3 and $0.4 million, or a total of $0.7 million.[8]

xi. Mandatory Electronic Submission of Food Facility Registration and Registration Renewals with the Option to Request a Waiver

FDA is proposing that beginning on January 4, 2016, electronic registration will be mandatory, unless a waiver has been granted for the registrant. FDA is also proposing to require electronic registration renewals beginning in the 2016 registration renewal period. We estimate the costs of mandatory electronic submission as the costs of requesting and submitting a request for a waiver from this requirement. Under the proposed rule, registrants would be permitted to request a waiver from the electronic registration requirement by submitting a written request to FDA explaining why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. FDA tentatively concludes that reasons for why it may not be reasonable for a registrant to submit a registration or registration renewal to FDA electronically may include conflicting religious beliefs or where a registrant does not have reasonable access to the Internet. As of February 7, 2014, FDA's Food Facility Registration Module (FFRM) database listed 1,925 domestic and 196 foreign food facility registrations that are active and that were not submitted electronically.

We estimate that each of the 1,925 domestic and 196 foreign facilities will need about 10 minutes (0.167 hours) of a manager's time (hourly wage of $70.80) every other year to prepare and send their request for a waiver. We assume that managers will prepare and send requests for waivers once every other year, in sync with the registration renewal cycle. We consider the number of non-electronic registrations used in this estimate to be an upper-bound estimate, as it is very probable that the number of non-electronic registrations will continue to decline in the future. Costs to domestic and foreign food facilities are summarized in Table 16.[9]

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[8] 195,766 facilities x 0.54 hours per update x 15 percent of additional facilities with annual update x $41.19 hourly wage = 15,906 hours per year x $41.19 = $655,162

[9] 2,121 domestic and foreign facilities x 0.167 hours x 0.50 (annual frequency) = 160 hours/year, then 160.42 hours/year x $70.80 per hour = $12,514/year

Table 16.— Cost to Domestic Facilities of Requesting a Waiver from Mandatory Electronic Submission

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Annual Costs	Cost/ Facility
Domestic Facilities	1,925	0.1667	0.5	160	$ 70.80	$ 11,357	$ 5.90
Foreign Facilities	196	0.1667	0.5	16	$ 70.80	$ 1,156	$ 5.90
Total	**2,121**			**177**		**$ 12,514**	**$ 5.90**

xii. Proposal to Delete the Option for CD-ROM Submissions

FDA is proposing to delete the option to submit, update, and cancel multiple registrations by CD-ROM. Since FDA began requiring registration of food facilities, we have received only 11 CD-ROM submissions. The small number of submissions is likely because this technology is no longer widely used by food facilities. Given the small number of CD-ROM submissions and food facilities' minimal use of CD-ROM technology, we do not associate any new marginal costs with this provision.

xiii. Proposal to Require Immediate Updates to Incorrect Information

FDA is proposing to require food facilities to immediately update any previously submitted registration information that was incorrect at the time of an electronic registration or registration renewal. This proposal is consistent with the current requirement in § 1.231(b)(6) for registration information submitted by mail or fax and § 1.231(c)(10) for registration information submitted by CD-ROM. We assume any costs associated with this provision would be a subset of the cost of submitting an update. Although we do not know how often registrants would submit updates in order to immediately update incorrect information, we expect costs of this provision to be small.

Summary Costs of Section (b)

Table 17 below summarizes total costs for the provisions in section (b). These costs represent the marginal costs of the proposed rule that are in addition to the estimated costs in section (a) from the already-effective, FSMA-related provisions.

Table 17.— Costs of Section (b) Other Proposed Amendments to Registration of Food Facilities

	Domestic	Foreign	Total
Number of Facilities	81,627	114,139	195,766
One Time Costs			
Obtaining D-U-N-S ® Number	$ 975,035	$ 1,692,485	$ 2,667,520
Entering the D-U-N-S ® Number	$ 42,609	$ 59,580	$ 102,189
a. Preferred mailing address information	$ 42,609	$ 59,580	$ 102,189
b. Email address for the owner, operator or agent in charge of the facility	$ 42,609	$ 59,580	$ 102,189
c. Type of activity or type of storage conducted at the facility	$ 42,609	$ 59,580	$ 102,189
d. Email address of the emergency contact of a domestic facility	$ 42,609	$ 59,580	$ 102,189
Subtotal One Time Costs	**$ 1,188,079**	**$ 1,990,384**	**$ 3,178,463**
Annual Costs			
Change update requirements from 60 to 30 days	$ 273,178	$ 381,984	$ 655,162
Verification procedures for registration submissions not made by the owner, operator, or agent in charge.	$ 353,926	$ 376,309	$ 730,236
U.S. Agent information viewing	*NA*	$ 2,020,255	$ 2,020,255
Verification procedures for U.S. Agents	*NA*	$ 2,020,255	$ 2,020,255
Subtotal Annual Costs (2014)	**$ 627,104**	**$ 4,798,803**	**$ 5,425,907**
Cost of requesting a waiver from electronic submission (2016)	$ 11,357	$ 1,156	$ 12,514
Subtotal Annual Costs	**$ 638,462**	**$ 4,799,960**	**$ 5,438,421**

Costs to FDA

We estimate the costs to FDA for sections (a) and (b) together. Such costs include modifying and maintaining a database to implement the provisions of the proposed rule, including those FSMA-related provisions that are already effective. Some of those costs were incurred in 2012, the first year in which the already-effective, FSMA-related provisions of the proposed rule were implemented. First-year development and maintenance activities included making modifications and enhancements to the Food Facility Registration Module (FFRM) required by FSMA. Some of the modifications in 2012 included allowing food facilities to renew their registrations every two years, modifying information

fields, and generating notifications to facilities for when registration information is created or changed. Other enhancements in the FFRM allowed adding new product category columns and creating updates to online help files. Continued modifications in 2013 were made to include marking registrations that failed to renew with an invalid reason code stating "failed to renew for period 2012." First-year development and maintenance costs also included rebuilding the FFRM's aging architecture, which involved development costs, hardware costs, licensing costs, maintenance costs, and support costs. FDA estimates that three full time equivalent employees (FTEs) would be needed to oversee the modifications and maintenance of the database that would be necessary in order to implement Option 2 (Ref.11). We present costs for the first 5 years of developing and maintaining the system in table 18 below. Annual costs are discounted at 7 percent and 3 percent.

We present these same costs in the analysis of FDA's estimated costs for implementing Options 3 and 4. We repeat these costs in the discussion of those options because we do not have sufficient data and information to more precisely identify how FDA's costs in implementing Options 3 and 4 would differ from the costs of implementing Option 2, and any difference in the cost to FDA for implementing those options is likely to be small.

Table 18.— FDA Costs of Implementing FSMA Modifications to the Food Facility Registration Module

	2011	2012	2013	2014	2015
Development/Modifications/ Enhancements (DME)	$ 2,250,000	$ 225,000	$ 594,000	$ 476,111	$ 100,000
Operational Maintenance (O & M)	$ 148,830	$ 148,830	$ 106,555	$ 237,184	$ 249,043
Number of FTE's	3	3	3	3	3
Cost per FTE	$ 250,000	$ 250,000	$ 250,000	$ 250,000	$ 250,000
Food Facility Response Team	$ 241,000	$ 353,000	$ 377,000	$ 382,000	$ 388,000
Mailing Costs	$ 35,000	$ 35,000	$ 35,000	$ 40,000	$ 40,000
Total	**$ 3,424,830**	**$ 1,511,830**	**$ 1,862,555**	**$ 1,885,295**	**$1,527,043**
7% Discounted Total	$ 3,424,830	$ 1,412,925	$ 1,626,828	$ 1,538,962	$1,164,974
3% Discounted Total	$ 3,424,830	$ 1,467,796	$ 1,755,637	$ 1,725,312	$1,356,758

B. Benefits of the Proposed Rule

We expect that this proposed rule would increase the utility of FDA's registration database, thereby enabling the agency to more effectively and efficiently respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. We also expect that the proposed rule would allow the agency to use its inspectional resources more efficiently. At the time of the 2003 interim final rule, FDA identified four ways in which the interim final rule requiring food facility registration would aid in deterring and limiting the effects of foodborne outbreaks: (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 compliance and regulatory resources and better able to identify facilities affected by future FDA actions (including possible regulations); and (4) FDA inspectors would be better able to identify shipments for inspection.

Although food facility registration has improved FDA's ability to deter and limit the effects of foodborne outbreak, many of the benefits the agency projected in 2003 were premised on the assumption that the food facility registration database would contain accurate information about facilities. Since FDA implemented the registration requirement in 2003, however, the agency has identified a number of inaccuracies in the registration database. One particular accuracy-related problem FDA has encountered is that of duplicate registrations, where multiple registrations exist for a single facility. Too many duplicate registrations could be an indication that the database includes inactive facilities, or that facilities have gone out of business or moved. Such inaccuracies make the database less reliable as a tool for responding to food-related emergencies, as well as for deploying the agency's compliance and regulatory resources efficiently and for being better able to identify shipments for inspection.

The already-effective, FSMA-related provisions in this proposed rule do much to address the accuracy and reliability concerns with the food facility registration data. Since the 2012 registration renewal period concluded, for instance, the number of domestic and foreign registered food facilities decreased by 57 percent, to about 194,000 facilities. We interpret this decrease in the number of registered facilities to indicate that biennial registration renewal had the effect of removing many out-of-date registrations from the registration system. The already-effective, FSMA-related provisions do not, however, fully prevent facilities from having multiple registrations. For instance, duplicate registrations for facilities could be created within any given renewal period and languish in the registration database

during the two-year period between registration renewal cycles. In addition, it is possible that registration submissions could include other inaccurate data. Further, biennial registration does not prevent unauthorized third parties from submitting registrations on behalf of facilities.

The proposed rule would enhance the ability of registration renewal to rid the registration database of outdated registrations by also specifying that FDA will consider a registration for a food facility to be expired if the registration is not renewed and cancel a registration that is expired for failure to renew if the facility has failed to renew its registration in accordance with the renewal requirements. Thus, the proposed rule would provide a better mechanism by which FDA could use the registration renewal process to help remove outdated registrations from the registration database.

We expect that additional provisions in the proposed rule would further increase the accuracy and reliability of the food facility registration database. Specifically, we expect that several of the other proposed requirements would allow FDA to verify key registration information. Such information includes address information, which FDA would be able to verify by requiring registrants to submit D-U-N-S® numbers and then verifying both the accuracy of the food facility's D-U-N-S® number and that the facility-specific address associated with the D-U-N-S® number is the same address associated with the facility's registration. FDA is also proposing to verify U.S. Agent information submitted as part of initial registrations, registration renewals, and updates. Finally, for registrations, registration renewals, and updates to registrations submitted by individuals other than the owner, operator, or agent in charge, FDA is proposing to email the person identified as the owner, operator, or agent in charge to verify that the individual in fact authorized the submission on the facility's behalf. We expect that these proposed provisions would result in registration data being entered more accurately.

In addition to improving the accuracy of the registration database through the use of verification procedures, we also expect that other proposed requirements would further ensure that registration information is accurate and up-to-date. The proposed requirement that electronic registrants immediately update any previously-submitted incorrect information would impose an obligation on registrants to ensure the accuracy of their registration information, regardless of whether their registrations were submitted electronically or by paper or fax. Under the current registration regulations, the requirement to immediately update incorrect registration information only applies to registrations submitted by CD-ROM or by mail or fax, but does not apply to registrations submitted electronically. The proposal to shorten the time period for a food facility to update or cancel its registration from 60 calendar days to 30 calendar days would also have accuracy-related benefits, as more timely information

ensures that the information contained in the registration database is not outdated. In addition, we expect more accurate registration information to result from the proposal that FDA cancel a registration if the agency independently verifies that the facility is not required to register, if information about the facility's address was not updated in a timely manner, or if the registration was submitted to the agency by a person not authorized to submit the registration. More accurate registration information would allow FDA to use the registration database more effectively and efficiently to deter and limit the effects of foodborne outbreak.

We expect that the proposed rule would further improve the agency's ability to respond to foodborne outbreaks and other threats by requiring additional facility contact information. Specifically, the proposed rule would codify the already-effective requirements under FSMA that registrants provide the email address for the contact person of a domestic facility and the email address for U.S. Agents of foreign facilities. In addition, the proposed rule would require domestic and foreign food facilities to provide a preferred mailing address if such mailing address is different from the mailing address of the facility. It would also add an email address to the contact information required for the owner, operator or agent in charge of the facility (for both domestic and foreign facilities), and would add an email address to the emergency contact information registrants are required to provide for a domestic facility. This contact information would allow FDA to communicate with facilities in a quick manner in the event of a threatened or actual terrorist attack, an outbreak of foodborne illness, or other food-related emergency.

We expect that benefits from this proposed rule would be from allowing FDA to more efficiently and effectively deploy the agency's limited inspectional resources. Such increased efficiency is likely to result from provisions in the proposed rule that would increase the accuracy of facility address information. Specifically, we anticipate that the proposed requirement to include D-U-N-S® numbers and for FDA to verify the facility-specific address associated with those numbers would increase the accuracy of the address information contained in FDA's food facility registration database. We also anticipate that the proposal to cancel registrations when information about the facility's address was not updated in a timely manner would result in improved facility location information. We expect this same result from the proposal to shorten the period for providing updates from 60 calendar days to 30 calendar days. Should these provisions become effective, we expect that FDA investigators would be able to more efficiently and effectively identify and locate facilities for inspection. Accurate address information is critical to scheduling inspections efficiently, and without it FDA often faces the problem

of "inspectional washouts," where an FDA investigator arrives for an unannounced inspection at a listed address only to find that the facility has gone out of business or is otherwise not located at the listed address. FDA estimates that the cost of a washout inspection is about $400 per incident. As a result, FDA maintains a multi-year contract with Dun & Bradstreet (at a cost of $25,000) to help address the issue of inspectional washouts. In a recent study, FDA used Dun & Bradstreet to help identify future food facility locations for inspection that had a high likelihood of resulting in an inspectional washout. The results from the study showed that verifying 10,000 inspectional candidates identified 850 (8.5 %) addresses that were out of business or inactive. Avoiding initiating inspections for those 850 inspectional candidates would amount to approximately $339,000 in savings for FDA. Thus, to the extent that improved biennial reporting has the effect of removing out-of-date registrations from FDA's database, we can expect the number of potential inspectional candidates resulting in a washout inspection to decrease and further save FDA the costs associated with washout inspections. As a result, FDA could make more efficient use of its compliance and regulatory resources.

We expect that the proposed rule would also improve the use of the agency's inspectional resources by allowing the agency to have more information about the activities performed by food facilities. Specifically, the proposed rule would require registrants to identify the type of activity conducted at the facility for each food product category identified. Information about the types of activities performed at a facility would allow the agency to prepare investigators for inspections and assign appropriate investigators. Sending appropriate, well-prepared investigators would help ensure that inspections are thorough and meaningful, thereby allowing for the more efficient use of FDA's inspectional authority. Furthermore, information about a facility's activity type would allow FDA to better assess the facility's potential impact in cases of bioterrorist incidents or other food-related emergencies. It would also assist FDA in implementing FSMA's mandate to determine inspectional frequency based on safety risks. In addition, the activity type information would allow FDA to communicate more quickly and efficiently on various non-emergency issues, such as new regulatory requirements or policies.

We expect that the proposed rule will have additional efficiency benefits. By requiring mandatory electronic registration submissions in 2016, FDA anticipates that that the timeliness and accuracy of submissions would improve. The electronic transmission of information would be easier and more efficient for both industry and FDA than the use of paper forms. For example, a registrant would receive on-screen feedback if the information submitted was not complete, reducing errors and

time and cost of communicating with FDA. Similarly, electronic transmission of the information would reduce significantly the time and cost associated with processing paper forms and communicating with industry concerning errors on those forms. Information search and retrieval time would be reduced, allowing quicker access to the information in the database. Electronic registration also enables a facility to be registered more quickly than if registering by mail. Registration by mail can take several weeks to several months, depending on the efficiency of the mail system, the number of paper registrations that FDA would need to enter manually into the system, whether the agency would have to return an incomplete or illegible form to a registrant, and because FDA would have to subsequently mail the registration number and receipt of registration to the registrant.

The public health benefits of a regulation that would prevent the consumption of contaminated food arise from non-events. That is, the public health benefits arise when illnesses that would otherwise occur in the absence of the regulation do not occur. To assess these benefits, we must therefore place a value on risk reduction and health-related costs for illnesses that we anticipate will not take place. The conjectural nature of the risk reduction suggests that any estimate of health benefits from preventing the consumption of contaminated food shipments is more art than science. As a first step towards measuring these benefits, we monetize the impact of several different scenarios.

For this proposed rule to break even as measured by cost savings from fewer illnesses, the rule would have to result in about $6.8 million to $8.2 million in savings each year. By breaking even in terms of cost savings from fewer illnesses, we mean that the proposed rule would reduce costs that result from foodborne illness by approximately the same amount as the compliance costs the proposed rule would impose on food facilities. (We anticipate that the proposed rule would have additional benefits such as the more efficient deployment of FDA inspectional resources, but we do not consider such benefits in analyzing the narrower question of when the proposed rule would break even in terms of cost savings from fewer illnesses.) We lack sufficient data to determine whether the proposed rule would achieve health-related cost savings sufficient to break even with the cost that the proposed rule would impose on food facilities. But to understand what kind of health savings would be required to achieve that break-even point, we examine the cost of several foodborne illnesses.

We start by estimating the costs of a single outbreak. To do this, we use the estimated average number of illnesses per outbreak, using numbers from the Centers for Disease Control and Prevention (CDC) (Ref.12). We adjust these estimates to account for potential under-reporting and underdiagnoses using factors from Scallan, et al, (2011), in which the authors used data from active and passive

surveillance and other sources to estimate the number of foodborne illness episodes caused by 31 major pathogens in the United States (Ref. 13). This allows us to account not only for identified illnesses, but also for those illnesses that are never reported or missed by health officials. We then multiply the total number of illnesses from a single outbreak by the individual cost per illness. For the individual cost per illness, we use the amount identified by FDA in Appendix A to the January 2013 proposed rule for Preventive Controls for Human Food (78 FR 3646)) (Ref. 14). We use this estimate because it represents a recent and thorough FDA analysis of the burden of foodborne illness. Whereas Appendix A to the January 2013 proposed rule for Preventive Controls for Human Food estimates the costs of various foodborne illnesses, we focus our analysis on three different pathogens(*E. coli* (non-O157 STEC), *Salmonella* spp. (non-typhoid) and *Listeria monocytogenes*), and the estimated average cost per illness for those pathogens. Table 19 summarizes the cost of an average outbreak based on the estimated average number of illnesses per outbreak.

Table 19.--Estimated Average Illnesses per Foodborne Outbreak and Costs per Outbreak Associated with three Pathogens

Pathogen	Average Illnesses/ Outbreak	Under Reporting	Under Diagnosis	Illnesses/ Outbreak	Cost/ Case	Total Cost/ Outbreak
Salmonella	19.28	1	26.1	503	$8,510	$ 4,282,300
E. Coli	19.28	1	29.3	565	$4,717	$ 2,664,652
Listeria	19.28	1	2.1	40	$1,410,385	$ 57,103,668

We estimate the average costs per illness due to *Salmonella spp.* (non-typhoid) to be about $4,717 (Ref. 12). Reducing the cost of illness by $7 million (i.e. the lower-end estimate for compliance costs of this proposed rule) based on this pathogen alone would require reducing the number of illnesses attributed to *Salmonella* spp. (non-typhoid) by at least 1,488 illnesses each year, which is roughly equivalent to 2 outbreaks per year. In a similar manner, we estimate the costs of a case of foodborne illness caused by *E. coli* non-O157 STEC to be about $8,510 (Ref. 12). Breaking even with compliance costs for this proposed rule based on reductions in *E. coli* non-O157 STEC alone would require reducing the number of cases due to this pathogen by 856 illnesses, or by 2 average-sized outbreaks per year. Outbreaks due to the pathogen *Listeria monocytogenes* cause, on average, 40 illnesses. The annual cost for each foodborne outbreak from listeriosis is about $57 million, or $1.4 million per case. For compliance costs to break even based on a reduction in listeriosis alone, the proposed rule would have to reduce about one tenth (0.10) of a single listeriosis outbreak, or about 5 cases per year. FDA does not have enough information to determine whether the proposed rule would reduce foodborne illnesses such

that the compliance costs of the proposed rule would be equal to or less than the costs of those foodborne illnesses.

3. Option 3 - Promulgate Only the Already-Effective FSMA Provisions, as well as Mandatory Electronic Registration Without a Waiver

Under this option, the proposed rule would only codify the self-implementing FSMA provisions that are already effective, and would also codify the requirement for mandatory electronic registration in 2016 (but would do so without providing for the option of a waiver from that requirement). A portion of the costs for these provisions are estimated in section (a) of Option 2. The other portion of these costs is the cost of mandatory electronic registration without the option of a waiver. In that way, the cost estimates concerning mandatory electronic waiver for Option 3 differ from the cost estimates concerning mandatory electronic waiver in section (b) of Option 2, because the analysis in section (b) of Option 2 accounted for the availability of a waiver. To estimate the costs of requiring electronic registration without the availability of a waiver, we start with the assumption that the 1,925 domestic and 196 foreign facilities with current non-electronic registrations have made a private decision that electronic submission is more costly than non-electronic submission. In estimating the costs of not allowing a waiver option, we start by considering how long it would take to access the Internet. FDA lacks data on exactly how much time it takes to find access to the Internet. For purposes of this analysis, we assume it would take 1.5 hours. These 1.5 hours of required time would be in addition to the estimated time we expect facilities to spend to comply with the proposals discussed in section (a) of Option 2. We assume that all current, non-electronic registrants will spend this additional 1.5 hours to find Internet access. We use the assumption that two thirds of that time (1 hour) will be spent by an administrative work ($31.32 hourly wage) and one third of that time (30 minutes) will be spent by a manager ($70.80 hourly wage). The total cost of this additional extra time then is about $66,000.[10]

We use the same assumptions for both domestic and foreign facilities who currently submit non-electronic registrations. The estimated costs for requiring electronic registrations without providing for the availability of a waiver are summarized in Table 20. We request comments on these cost estimates.

[10] 2,121 paper registrants x 1.5 hours x 0.5 annual frequency = 1,591 hours/ year. Subsequently, 1,591 hours/year x [(1/3 x $70.80) + (2/3 x $31.32)] = 1,591 hours per year x $41.19 hourly wage = $65,522)

This estimate represents an upper bound cost estimate, as the number of registrants without access to the Internet is likely to decline over time.

Table 20.—Costs of Mandatory Electronic Submission of Food Facility Registration without the Option to Request a Waiver

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Annual Costs	Cost/ Facility
Costs to Domestic Facilities	1,925	1.5	0.5	1,444	$ 41.19	$59,468	$ 30.89
Costs to Foreign Facilities	196	1.5	0.5	147	$ 41.19	$ 6,055	$ 30.89
Total	2,121			1,591		$65,522	$ 30.89

The total costs of Option 3 would be the sum of costs from section (a) of Option 2 plus the costs of complying with the mandatory electronic registration requirement without the availability of a waiver.

Table 21 presents the sum of one-time costs and recurring costs to domestic and foreign facilities as they begin to accrue in 2012, 2014, and in 2016. Costs also include costs to FDA of implementing the provisions of this Option from table 18 in the detailed costs analysis section for Option 2. As costs vary until 2016, Table 21 also presents annualized costs over a 20-year time period using a 7 percent and 3 percent discount rate.

Table 21. — Annual Undiscounted Cost Stream and Annualized Cost Summary of Option 3 ($Millions)

Year	Domestic Facilities	Foreign Facilities	FDA	Total
2012	$ 7.98	$ 11.16	$ 3.42	$ 22.57
2013	$ -	$ -	$ 1.51	$ 1.51
2014	$ 0.63	$ 0.89	$ 1.86	$ 3.44
2015	$ 0.63	$ 0.89	$ 1.89	$ 3.46
2016	$ 0.69	$ 0.89	$ 1.89	$ 3.53
:	:	:	:	:
2031	$ 0.69	$ 0.89	$ 1.89	$ 3.53
Annualized 7%	$ 1.07	$ 1.47	$ 0.86	$ 3.41
Annualized 3%	$ 0.99	$ 1.34	$ 1.21	$ 3.54

Benefits

The potential benefits of Option 3 are from improved accuracy and reliability of the food facility registration data. We expect that these benefits would be achieved due to the electronic registration requirement and biennial renewal requirement for the reasons discussed under Option 2. We also expect that this Option would have benefits with regard to improving the agency's ability to respond to foodborne outbreaks and other threats by requiring that registrants provide the email address for the contact person of a domestic facility and the email address for U.S. Agents of foreign facilities, thereby improving FDA's ability to communicate with food facilities. However, we do not expect that Option 3 would result in the same level of benefits, as we anticipate that many of the proposed provisions under Option 2 that would not be implemented under Option 3 would go a long way toward improving the utility of the food facility registration database and allowing the agency to effectively respond to food-related emergencies and plan for inspections. Although we do not quantify benefits of Option 2, any expected benefits from Option 3 would be less than the expected benefits from the proposed rule under Option 2.

4. Option 4 – The Proposed Rule with the Additional Implementation of Voluntary U.S. Agent Identification (VIS)

Option 4 includes the same provisions as those in sections (a) and (b) from Option 2, but with the additional implementation of a Voluntary U.S. Agent Identification System (VIS or the system).

In the preamble to the proposed rule, we are requesting comment on whether we should issue a future guidance document to provide for the creation of a VIS, or otherwise provide for the creation of such a system. As currently envisioned, the system would be designed to ensure the accuracy of U.S. Agent information and enable U.S. Agents to independently identify the facility or facilities for which the agent has agreed to serve. Specifically, the system would allow a U.S. Agent to directly provide their contact information (that is, the same contact information required for foreign food facility registration) and the name of the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. Agent contact information through foreign food facility registrations, many of which are created and updated by the facility, rather than the U.S. Agent for the facility. The system would allow agents to provide their name, full mailing address, phone number, email address, and an emergency contact phone number, as well as the name of the facility or facilities for which the agent agrees to serve. After a U.S. Agent provides this information, FDA would provide the agent with an identification number that the agent could provide to foreign facilities it has agreed to represent as a U.S. Agent. If a foreign facility uses a U.S. Agent identified in the system, the facility would have the option

of providing the name and identification number for the U.S. Agent in its registration rather than the specific U.S. Agent's contact information required for food facility registrations (e.g., address, email address, phone number). After using the identification number, and if the foreign facility name matches a facility name the U.S. Agent identified in the system, the U.S. Agent contact information in the system would then be linked and automatically populated in the foreign facility registration. When the confirmation copy of a foreign facility registration is sent to the U.S. Agent, it would be sent to the contact information provided by the U.S. Agent to ensure that the U.S. Agent is aware of the connection with each foreign facility registration.

Having such a system in place would allow FDA to use the U.S. Agent identification number to automatically populate the U.S. Agent information in the foreign facility registration if the foreign facility name matches a facility name the U.S. Agent identified in the system. The use of the U.S. Agent identification number for a registered U.S. Agent would also constitute a verification of U.S. Agent information for purposes of the proposed U.S. Agent verification step discussed under Option 2 if the name of the facility matches the facility name the agent has identified.

By providing U.S. Agents with more control over the U.S. Agent information that is required for food facility registration, we anticipate that a VIS would reduce the time foreign facilities spend corresponding with U.S. Agents as a result of the proposed U.S. Agent information viewing provision described in Option 2. We expect that a VIS would also reduce the costs associated with the U.S. Agent verification procedures that are also described in Option 2.

Assuming that the U.S. Agents for all foreign facilities use the VIS, we estimate that implementing the system could reduce the costs we estimated for the U.S. Agent information viewing and verification provisions by one-half. This would result in roughly $2 million of savings each year. For example, without a VIS, if a facility enters U.S. Agent information onto its registration form, the facility would have to expend time ensuring that its U.S. Agent has accepted the assignment. Some facility managers would possibly check their e-mail accounts several times. We expect that a VIS would also reduce the number of data elements that a food facility would need to enter in the registration form, thereby reducing the likelihood of incorrect submissions and mistakes. Such incorrect information could result in delays associated with the U.S. Agent verification step, and could cause the facility to expend time trying to correct the error and contacting the U.S. Agent. Table 22 below summarizes the difference between the costs of the U.S. Agent information viewing and verification requirements with and without a VIS. We request comment on these cost estimates.

Table 22.— Difference in Costs to Foreign Facilities of U.S. Agent Information Viewing and Verification Procedures with and without a Voluntary U.S. Agent Identification System (VIS)

	Facilities	Time (Hours)	Frequency	Hours/ Year	Wage	Costs	Cost/ Facility
U.S. Agent Information Viewing & Verification Procedures for U.S. Agent With a VIS	114,139	1.00	0.5	57,070	$ 70.80	$4,040,509	$ 35.40
U.S. Agent Information Viewing & Verification Procedures for U.S. Agent Without VIS	114,139	0.50	0.5	28,535	$ 70.80	$2,020,255	$ 17.70
Difference		**0.50**		**28,535**		**$2,020,255**	**$ 17.70**

Table 23 summarizes total costs for the provisions in section (b) of Option 2 along with the costs of implementing a VIS. These are the estimated costs of Option 4.

Table 23.—Costs of Option 4 (which include costs of section (b) under Option 2 and Costs of Implementing a U.S. Agent VIS

	Domestic	Foreign	Total
Number of Facilities	**81,627**	**114,139**	**195,766**
One Time Costs			
Facilities Obtaining D-U-N-S ® Number	$ 975,035	$ 1,692,485	$ 2,667,520
Entering the D-U-N-S ® Number	$ 42,609	$ 59,580	$ 102,189
a. Preferred mailing address information	$ 42,609	$ 59,580	$ 102,189
b. Email address for the owner, operator or agent in charge of the facility	$ 42,609	$ 59,580	$ 102,189
c. Type of activity or type of storage conducted at the facility	$ 42,609	$ 59,580	$ 102,189
d. Email address of the emergency contact of a domestic facility	$ 42,609	$ 59,580	$ 102,189
Subtotal One Time Costs	**$ 1,188,079**	**$ 1,990,384**	**$ 3,178,463**
Annual Costs			
Change Update Requirements from 60 to 30 days	$ 273,178	$ 381,984	$ 655,162

Verification procedures for registration submissions not made by the owner, operator, or agent in charge	$ 353,926	$ 376,309	$ 730,236
U.S. Agent Information Viewing with VIS	*NA*	$ 1,010,127	$ 1,010,127
Verification Procedures between Facility and U.S. Agents with VIS	*NA*	$ 1,010,127	$ 1,010,127
Subtotal Annual Costs	**$ 627,104**	**$ 2,778,549**	**$ 3,405,653**
Cost of requesting a waiver from electronic submission	$ 11,357	$ 1,156	$ 12,514
Total Annual Costs	**$ 638,462**	**$ 2,779,705**	**$ 3,418,167**

Under Option 4, we expect that foreign facilities would incur annual costs of $1.3 million less each year (or about $18 less per facility) compared to the costs that we estimate foreign facilities would incur under Option 2 (the proposed rule).

Table 24 presents the sum of one-time costs and recurring costs to domestic and foreign facilities as they begin to accrue in 2012, 2014, and in 2016 under Option 4. Costs also include costs to FDA for implementing the provisions of this Option. These costs are the same as the costs to FDA under Option 2, as we do not expect that the VIS would add to FDA's costs in any significant way. As costs vary until 2016, table 24 also presents annualized costs over a 20-year time period using a 7 percent and 3 percent discount rate.

Table 24 .— Annual Undiscounted Cost Stream and Annualized Cost Summary of Option 4 ($Millions)

Year	Domestic Facilities	Foreign Facilities	FDA	Total
2012	$ 7.98	$ 11.16	$ 3.42	$ 22.57
2013	$ -	$ -	$ 1.51	$ 1.51
2014	$ 0.63	$ 0.88	$ 1.86	$ 9.96
2015	$ 0.63	$ 0.88	$ 1.89	$ 6.80
2016	$ 2.46	$ 5.65	$ 1.89	$ 6.82
:	**:**	**:**	:	:
2031	$ 1.27	$ 3.66	$ 1.89	$ 6.82
Annualized 7%	**$ 1.47**	**$ 2.97**	$ 0.86	$ 5.30
Annualized 3%	**$ 1.47**	**$ 3.34**	$ 1.21	$ 6.01

Benefits

Expected benefits from Option 4 are almost the same as in Option 2 (the proposed rule). Although we do not quantify these benefits, any expected benefits under Option 2 would be achieved at a higher cost to foreign facilities than under Option 4. Although we do not quantify benefits of either Option 2 (the proposed rule) or Option 4, we expect that the benefits from Option 2 (the proposed rule) would potentially be less than the benefits from Option 4. We request comment on these potential benefits.

5. Comparison of Options

Table 25 provides a side-by-side summary of the sum of one-time annualized costs and recurring annualized costs to domestic and foreign facilities and to FDA under all four options, presented in descending order of costs. All costs are discounted for 20 years using a 7 percent and 3 percent discount rate. Total annualized costs include annualized costs to facilities and annualized costs to FDA.

Table 25.—Annualized Cost Summary of Options 2, 4, 3 and 1 ($Millions)

Options Considered	Domestic Facilities	Foreign Facilities	FDA	Subtotal Facilities	Total
7% Discount Rate					
Option 2- The Proposed Rule	$ 1.47	$ 3.92	$ 0.86	$ 5.39	$ 6.25
Option 4- The Proposed Rule with implementation of a VIS	$ 1.47	$ 2.97	$ 0.86	$ 4.44	$ 5.30
Option 3- Already Effective FSMA Provisions Only	$ 1.07	$ 1.47	$ 0.86	$ 2.54	$ 3.41
Option 1- No action	$ -	$ -	$ 0.86	$ -	$ -
3% Discount Rate					
Option 2- The Proposed Rule	$ 1.47	$ 4.69	$ 1.21	$ 6.16	$ 7.36
Option 4- The Proposed Rule with implementation of a VIS	$ 1.47	$ 3.34	$ 1.21	$ 4.81	$ 6.01

Option 3- Already Effective FSMA Provisions Only	$ 0.99	$ 1.34	$ 1.21	$ 2.33	$ 3.54
Option 1- No action	$ -	$ -	$ 1.21	$ -	$ -

II. Preliminary Regulatory Flexibility Analysis

A. Introduction

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We expect compliance costs generated by this proposed rule to be small, but are nevertheless unsure whether this proposed rule would have a significant economic impact on a substantial number of small entities. We have analyzed various regulatory options to examine the impact on small entities.

B. Economic Effects on Small Entities

The Small Business Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Small entities have fewer resources to devote to regulatory compliance and, therefore, may be more affected by regulatory compliance costs. The agency is unsure whether the proposed rule will have a significant economic impact on a substantial number of small entities.

a. Number of small entities affected

The Small Business Administration (SBA) publishes size standards for small businesses. The SBA defines food manufacturers as "small" according to their number of employees. For the most part, food manufacturers employing 500 or fewer persons are considered small businesses. However, there are some particular food manufacturing industry segments where the employee maximum is higher (750 or 1,000 employees). For purposes of this analysis, FDA has defined a small business as a business having 500 or fewer employees, consistent with the SBA definition for most food manufacturers. About 99.5 percent of all food manufacturers, warehouses, and wholesalers that are covered by the proposed rule employ 500 employees or less and are therefore considered small businesses for purposes of this

analysis. Of the approximately 81,627 domestic facilities affected by this rule, about 99.5 percent (81,228) employ 500 or fewer employees.

The number of facilities in Table 2 represents a snapshot in time as of February 2014 of all active registrations in FDA's food facility registration database. Because this figure only captures those facilities that took the step to register with FDA, the number of facilities in the database could be an underestimate of the number of food facilities that are in fact required to register. Also, the food industry has traditionally been characterized by substantial entry of small businesses and also by substantial exit. As a result, over time we can expect the number of future food facility registrations to vary.

b. Costs to small entities

FDA estimates that the proposed rule would result in total one-time costs to domestic facilities of approximately $9 million, which is about $112 per facility. Total domestic (one-time and recurring) annualized costs is about $1.47 million (using a 7 and 3 percent discount rate over 20 years), which translates to about $18 in annualized costs per facility. Total foreign annualized one-time costs and recurring costs range from $3.9 million (7 percent over 20 years) to $4.7 million (3 percent over 20 years), which translates to a $34 to $41 in annualized costs per facility. Table 26 shows the total average annualized costs per facility (both domestic and foreign) in increasing order of costs for Option 2 (the proposed rule), Option 3 and Option 4 as costs begin to accrue in addition to the baseline costs. The incremental costs associated with the provisions in this proposed rule are very small in comparison to estimated costs calculated as part of the 2003 economic impact analysis. Total annualized costs from either Option 2 (the proposed rule) or from Options 3 and 4 contribute to less than 6 percent of annualized costs associated with meeting the requirements under the 2003 food facility regulations.

Table 26.—Annualized Costs per Facility of Options 2, 3 and 4[1]

Options	Total Annualized Costs/Facility (7%)	Total Annualized Costs/Facility (3%)
Option 3- Already Effective FSMA Provisions Only	$ 13	$ 12
Option 4- The Proposed Rule with VIS	$ 23	$ 25

Option 2- The Proposed Rule	$ 28	$ 31

[1]All costs are in USD 2012 and discounted over 20 years.

Because such a large percentage of domestic food facilities are small businesses, the options considered in the Cost and Benefits Analysis in section I.E of this document analyze regulatory options that would lessen the economic effect of the rule on small entities. The expected burden of the proposed rule on small entities under Option 1 is the least of all options. Under Option 1, we would take no new regulatory action, and small entities would not incur any new costs. Because Option 1 serves as the baseline for determining the costs of all of the other analyzed options, Table 26 does not show estimations for the costs to small entities associated with Option 1. FDA is not proposing this option because it is not legally viable. A number of proposed changes to 21 CFR part 1, subpart H that are included in this rulemaking codify provisions of FSMA that were self-implementing and became effective upon enactment of FSMA or became effective in October 2012, when FDA issued a guidance entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories." Additionally, we believe that the proposed rule is necessary to improve the utility of FDA's food facility registration database, thereby enabling FDA to more effectively and efficiently respond to outbreaks from food-related emergencies and use the agency's inspectional resources more efficiently.

The next least-costly option is Option 3, under which FDA would codify only the already-effective, self-implementing FSMA provisions of the proposed rule, and would also implement mandatory electronic registration without the availability of a waiver. Under this option, FDA would not implement Congress's direction in section 102(c) of FSMA to amend the definition of retail food establishment or take any additional steps to improve the utility of the food facility registration database. FDA is not proposing to follow Option 3 because we tentatively conclude that doing so would be inconsistent with Congress's direction in section 102(c) of FSMA with regards to amending the definition of retail food establishments. We also tentatively conclude that the additional proposed requirements in the proposed rule are important tools for increasing the accuracy of FDA's food facility registration database and improving the agency's ability to respond to foodborne outbreaks and other threats. Further, we tentatively conclude that the proposed rule would allow FDA to more efficiently prepare for and pursue inspections.

Option 4 is more costly than Option 3, but less costly than Option 2 (the proposed rule). Under Option 4, FDA would propose all of the requirements proposed under Option 2 but with the additional implementation of a U.S. Agent Voluntary Identification System (VIS). We expect that the VIS would save foreign facilities time and money in connection with U.S. Agent communications. Although we expect that a VIS would lessen the economic effects of the proposed rule on small entities, we are not proposing a VIS at this time because we are seeking additional information about whether such a system is likely to increase the accuracy of U.S. Agent contact information and reduce the number of unauthorized or fraudulent U.S. Agent listings. We are therefore seeking comment on the merits of a U.S. Agent Voluntary Identification System.

As for Option 2 (the proposed rule), the expected burden on facilities is low, between $28 (7 percent discount rate) and $31 (3 percent discount rate) per facility.

In developing the proposed rule, FDA considered several options for reducing the small business regulatory burden. First, FDA is proposing to modify the retail food establishment definition, as required by section 102(c) of FSMA, and we expect that such modifications would expand the number of establishments that meet that definition. We anticipate that this would reduce the burden on small business because it would expand the number of establishments that are exempt from the food facility registration requirements and many of these establishments are likely small businesses. As described in Section D of this document, the proposed rule would amend the definition of a retail food establishment in ways that we expect would expand the number of establishments that meet that definition, and would therefore be exempt from the food facility registration requirements.

Specifically, the proposed rule would address off-farm sales by an establishment located on a farm, providing that sales from manufacturing/processing operations need not be made on-farm for that operation to qualify as a retail food establishment. Rather, in determining the primary function of an establishment or a retail food establishment, the sale of food directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment would include: (1) the sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture (CSA) program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by FDA. In so doing, the proposed rule clarifies that all sales by an on-farm establishment do not have to be on the farm by specifically addressing how off-farm sales directly to

consumers are to be counted in determining whether the on-farm establishment is a retail food establishment---and therefore exempt from the food facility registration requirements.

According to data from USDA ERS, and in table 3 in Section D of this document, there are about 70,000 farms that only use Direct to Consumer Marketing (DTC) channels such as farmers markets, road side stands, and Community Supported Agriculture (CSA's), all of which the USDA describes as small to medium-sized based on revenue. A subset of these 70,000 establishments would probably meet FDA's proposed definition of a retail food establishment and would be exempt from registration under the proposed rule. We do not know how many of these farms would be exempt from registration under the proposed rule that are currently required to register. We request comment on this issue.

In addition, we note that the existing food facility registration regulation has considerable flexibility for small businesses---flexibility that was built into the food facility registration system by the Bioterrorism Act. In particular, the Bioterrorism Act exempts retail food establishments and farms from food facility registration requirements. Many retail food establishments and farms are small entities.

We have tentatively concluded that other options, besides the proposed option, that would lessen the economic effect of the rule on small entities would not be appropriate. For instance, we have tentatively concluded that it would not be legally viable to exempt small entities from the proposed requirements of the rule. In addition, we have tentatively concluded that it would be inconsistent with the Bioterrorism Act and FSMA to provide small entities with a staggered compliance date. In enacting the Bioterrorism Act, it appeared that Congress intended for all food facilities to be subject to food facility registration requirements and the registration deadline established in section 305 of the Bioterrorism Act. Indeed, although the recordkeeping provision of the Bioterrorism Act directed FDA to take into account the size of a business when issuing implementing regulations, the registration provision contained no such language. Accordingly, FDA concluded that it would be inconsistent with section 305 of the Bioterrorism Act to allow small entities more time to register (68 FR 5413). In enacting FSMA, Congress included a number of provisions to reduce the burden on small businesses that are food facilities.

With regards to the rulemaking for preventive controls for human food authorized by section 103 of FSMA, Congress provided for modifications and exemptions for facilities engaged only in specific types of on-farm activities that involve foods determined to be low risk (§ 103(c)(1)(D) of FSMA). In addition, Congress provided that small businesses would have an additional six months to comply (§ 103(i) of FSMA)

and very small businesses would have an additional 18 months. Further, Congress provided that very small businesses could be deemed "qualified" and therefore qualify for the exemptions from many of the provisions of the regulations (§ 418(l)(1)(B)) of the FD&C Act.

The registration provisions of FSMA, however, contain no such provisions. Further, exempting small entities from the proposed rule or providing them with a staggered compliance date would thwart many of the key objectives of the proposed rule. Those objectives include providing FDA with the tools to respond efficiently and effectively to food-related emergencies and plan efficiently for inspections. To achieve those objectives, FDA requires complete and up-to-date information about food facilities that manufacture, process, pack or hold food for consumption in the United States. An exemption for small entities or a staggered compliance date would mean that FDA's food facility registration database would be neither complete nor up-to-date. FDA requests comment on the effect of this proposed rule on small entities.

III. 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 Description section of this document with an estimate of the annual reporting burden. Included in the burden 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 comment on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will 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 (OMB Control No. 0910-0502) -- Revision

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

Description: FDA is proposing to amend its regulations governing food facility registration. We are proposing to codify the requirements of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA. In addition, we are proposing to implement other requirements of section 102 of FSMA, as discussed above, including mandatory electronic registration submissions beginning in 2016 and amendments to the retail food establishment definition. Lastly, we are proposing other changes to improve the utility of the food facility registration database. As discussed in the preamble to the proposed rule, FDA has the authority to issue this proposed rule under section 305(d) of the Bioterrorism Act, sections 102 and 107 of FSMA, and sections 301(dd), 415, 421, 701(a) 704 and 801(l) of the FD&C Act.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act to require, among other things, that registrants for food facilities renew registrations biennially (section 415(a)(3) of the FD&C Act (21 U.S.C. 350d(a)(3)). FSMA also amended section 415 of the FD&C Act to require that food facility registrations include the e-mail address for the contact person of a domestic facility and the e-mail address of the United States agent for a foreign facility, as well as an assurance that FDA will be permitted to inspect the facility (section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)). These requirements went into effect upon enactment of FSMA. In addition, section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)), as amended by FSMA, also provides that, when determined necessary by FDA "through guidance," a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed or held at such facility, as determined appropriate by FDA, including by guidance. FDA issued a guidance document entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" in October 2012.

To comply with the statutory deadline under the provisions of FSMA, FDA initially obtained a 6-month OMB approval of these self-implementing FSMA reporting burdens under the emergency processing provisions of the Paperwork Reduction Act (the PRA), and subsequently obtained a 3-year approval of these requirements under the same assigned OMB Control No. 0910–0502. OMB extended the approval for an additional three years in 2013. The current expiration date of the information collection is August 31, 2016.

The proposed rule would require food facilities to submit additional registration information to FDA with initial registrations, updates and biennial renewals. The proposed rule would make the

submission of the following currently optional information mandatory: a) Preferred mailing address, b) e-mail address for the owner operator or agent in charge, c) type of activity conducted at the facility, and d) e-mail address of the emergency contact of a domestic facility. In addition, the proposed rule would require food facilities to submit a D-U-N-S Number and, for registrations submitted by individuals other than the owner, operator, or agent in charge, the e-mail address for the owner, operator, or agent in charge who authorized the registration submission on behalf of the facility. The proposed rule would also require mandatory electronic registration submissions beginning in 2016, which we estimate would cause some food facilities to submit a request for a waiver from that requirement. Finally, the proposed rule would establish a verification procedure for registration submissions made by individuals other than the owner, operator, or agent in charge, as well as a verification procedure for U.S. Agents.

Registration is one of several tools implemented under the Bioterrorism Act that enables FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. Further, in the event of an outbreak of food-borne illness, such information helps FDA determine the source and cause of the event. In addition, registration information enables FDA to quickly notify food facilities that might be affected by an outbreak, terrorist attack, threat, or other emergency. The proposed amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

The currently-approved reporting burden for food facility registration under OMB Control No. 0910-0502 is 468,117 hours. The estimated reporting burden for food facility registration under the proposed rule is 413,153 hours, a decrease of 54,964 hours. This decrease is due in large part to a reduction in the number of registered food facilities, which we believe is reflective of the fact that the 2012 biennial registration renewal cycle appears to have had the effect of removing many out-of-date registrations from the registration system. We are proposing to make additional changes to the currently-approved reporting burden as well. Since obtaining the FSMA-related emergency OMB approval and subsequent 3-year approval, we have refined our estimates for the time required to comply with the self-implementing FSMA provisions. As we explain in detail in the preliminary economic impact analysis, this is in part because we no longer assume that it will take domestic and foreign facilities different amounts of time to comply with the provisions of the proposed rule. It is also in part

because the option to submit abbreviated registration renewals did not previously exist, and in part because we have revised additional assumptions.

FDA revises its estimate of the one-time burden of the FSMA-related provisions of the proposed rule on registered facilities as follows:

Table 27.-- Estimated One time Reporting Burden[1]

Activity/ 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
All facility registrations (1.230-1.233)	172,274	1	172,274	0.18 (11 mins)	31,584

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

To determine the number of facilities in the above table, we assume that some of the participants in the 2012 biennial registration renewal cycle were new registrants. We do not consider those new registrations in estimating the total burden associated with the FSMA requirements. FDA used the Small Business Administration's (SBA's) estimate that 12 percent of all businesses are new. Although SBA's estimate does not necessarily mean that 12 percent of all food facilities are new, we nevertheless find the SBA's estimate sufficiently relevant to apply to food facilities. We therefore estimate that 12 percent of currently-registered food facilities were not registered at the time of the 2012 registration renewal cycle. As such, we estimate that 88 percent of currently-registered food facilities, or 172,274 facilities, were registered in 2012.

Using our updated estimates for the time required to comply with the self-implementing FSMA provisions, we now estimate that the requirement for an email address for a domestic facility's contact person and a foreign facility's U.S. Agent will take 1 minute. We also now estimate that the assurance statement required by FSMA will take 5 minutes to provide, and that the post-FSMA changes to food product categories will not result in any additional burden for facilities.

We also estimate the one-time burden from the new data elements in the proposed rule. We estimate that the average burden per response would be increased by the new data elements in the proposed rule. FDA believes that the new information will be readily available to the firms. We estimate that entering the four additional pieces of information that are currently optional would require, on average, an additional minute for each new data element per response. The four additional pieces of information that are currently optional are: 1) Preferred mailing address, 2) e-mail address for the owner opperator or agent in charge, 3) type of activity or type of storage conducted at the facility, and 4) e-mail

address of the emergency contact of a domestic facilitiy. In addition, we estimate that entering a D-U-N-S® Number, would require, on average, an additional minute per response. Thus, we estimate that these five proposed new data elements will require a total of five additional minutes. We estimate that the submission of the FSMA data elements and proposed new data elements would jointly increase the one-time burden from those activities by a total of eleven minutes (0.18 hour). The estimated one-time burden for currently-registered facilities is therefore 172,274 facilities x 0.18 hours = 31,584 hours.

FDA estimates the annual burden of the proposed rule's revision of this information collection as follows:

Table 28.-- Estimated Annual Reporting Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total
New domestic facility registrations (1.230-1.233)	9,795	1	9,795	2.7	26,447
New foreign facility registrations (1.230-1.233)	13,697	1	13,697	8.7	119,164
Updates (1.234)	68,518	1	68,518	1.5	102,777
Cancellations (1.235)	6,390	1	6,390	1	6,390
Biennial renewals (1.235)	97,883	1	97,883	0.38	37,196
Waiver requests (1.245)	1,061	1	1,061	0.17	180
Third party registration verification procedure	41,256	1	41,256	0.25	10,314
U.S. Agent verification procedure	57,070	1	57,070	0.5	28,535
Total Hours					**331,002**

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

The currently approved annual reporting burden for food facility registration under OMB Control No. 0910-0502 is 468,117 hours. The estimated reporting burden for food facility registration under the proposed rule is 331,002 hours, a decrease of 137,115 hours. This decrease is due to the recently reduced number of active registrations in the food facility registration database.

Our estimates of the number of facilities that will submit new facility registrations are based on estimates by SBA that 12 percent of all businesses each year are new. As such, we estimate that 12 percent of registrations (or 23,500 registrations) are from new facilities entering the market. We are proposing to make additional changes to the currently-approved reporting burden as well. As discussed

above, FDA obtained a 6-month emergency OMB approval of the self-implementing FSMA reporting burdens, and subsequently obtained a 3-year approval of these requirements. As described in the preliminary economic impact analysis, we estimate that 68,518 respondents will file updates, a decrease from the estimated number of 118,530 respondents reported in the 2013 request for extension, and we estimate that 97,883 respondents will file biennial renewals, a decrease from the estimated number of 224,930 respondents reported in the 2013 request for extension. These decreases are due to recent reductions in the number of active registrations in the food facility registration database.

Prior to FSMA, FDA estimated that the average burden associated with new domestic and foreign facility registrations was a respective 2.5 and 8.5 hours. (See 75 FR 30033.) We expect that the proposed rule would add an additional 11 minutes to that burden as a result of the proposed new data elements. Based on estimates by SBA that 12 percent of all businesses are new, we estimate that all new facilities each year will be equal to 12 percent of the total number of registered facilities. Thus, we estimate that each year there will be 9,795 new domestic and 13,697 new foreign facility registrations, and that the average burden for those new registrations will be of 2.7 hours (2.5 hours plus 11 minutes) for new domestic facility registrations and 8.7 hours (8.5 hours plus 11 minutes) for new foreign facility registrations, as reported in table 28, rows 1 and 2.

The proposed rule would also shorten the time period for updates from 60 calendar days to 30 calendar days. The average burden per response for updates would increase from 1.2 hours to 1.54 hours (difference of 0.34 hours, or about 20 minutes), as reported in table 28 row 3.

This proposed rule would also establish an abbreviated renewal process, which modifies our previous estimate that on average it would take 0.5 hours per renewal. With the option for an abbreviated renewal process, we estimate that half the facilities will take 15 minutes per renewal using the abbreviated renewal process and that half of facilities will take 30 minutes. This alters our previous estimate of 0.5 hours to submit a renewal to an average of 0.38 hours (23 minutes) to submit a renewal, as reported in table 28, row 5. This estimate takes into account that some registered firms would be able to take advantage of the abbreviated renewal process, while other firms would take more time to prepare and submit the renewal, as discussed in the preliminary economic impact analysis. We have not changed our estimate of the average burden per response for cancellations because the proposed rule does not add new data elements for cancellations.

If the rule is finalized as proposed, it would mandate the electronic submission of food facility registrations, while also allowing respondents to submit a request for waiver of the requirement to electronically submit their registration. As described in the preliminary economic impact analysis, we estimate that, on average, 1,061 facilities will seek a waiver each year. We also estimate that it would take a respondent ten minutes to prepare the proposed waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the total annual burden of submitting waiver requests is estimated to be 180 hours (1,061 x 0.17 hours), as reported in table 28, row 6.

If the rule is finalized as proposed, it would establish a verification procedure for registrations submitted by individuals other than the owner, operator, or agent in charge (third party registrations), as well as a verification procedure for U.S. Agents. To verify third-party registrations, FDA would send an e-mail to the owner, operator or agent in charge with a link allowing the owner, operator, or agent in charge to either confirm or deny that he or she authorized the registration submission on behalf of the facility. In connection with requiring his verification process, the proposed rule would add e-mail address to the list of required information identifying the individual who authorized submission of registrations submitted by individuals other than the owner, operator, or agent in charge. As described in the preliminary economic impact analysis, we estimate that it would take an owner, operator, or agent in charge fifteen minutes (0.25 hour) to participate in FDA's verification procedure. This estimate includes the time required to enter the e-mail address of the owner, operator, or agent in charge who authorized the submission. We further estimate that 82,513 registrations would be affected once every other year, or 41,257 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours (41,257 x 0.25 hour = 10,314 hours), as reported in table 28, row 7.

To verify the U.S. Agent, FDA would send an e-mail to the U.S. Agent at the e-mail address provided by the registrant. The e-mail address would include a link that would connect the U.S. Agent to FDA's food facility registration module, allowing the U.S. Agent to either accept or decline assignment with the facility. If the U.S. Agent accepts the assignment, FDA would also e-mail the facility of the U.S. Agent's acceptance. If, however, a U.S. Agent declines the assignment, the issuance of the registration number could be delayed. We estimate that the burden that will result from the verification procedure would be about 30 minutes (0.5 hours). We also estimate that 114,139 registrations would be affected once every two years, or 57,070 facility registrations annually. Thus, the total annual burden of these verifications is estimated to be 28,535 hours (57,070 x 0.5 hour = 28,535 hours), as reported in table 28, row 8.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(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 by [insert date 30 days after date of publication in the FEDERAL REGISTER] to the Office of Information and Regulatory Affairs, OMB.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the title "Registration of Food Facilities." These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

IV. References

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8. Memorandum to file Subject: Verification Steps for Certain Proposed Provisions, April 24, 2014 from Erwin Miller, Branch chief Compliance Information Branch, Office of Compliance, CFSAN, FDA.

9. Memorandum to file Subject: D-U-N-S ® and Registered Facilities. July, 9th, 2014 from John Gardner, MD, MPH Senior Technical Advisor, Medical Informatics, Office of Informatics and Technology Innovation, Office of Information Management and Technology, Office of Operations, U.S. Food and Drug Administration.

10. D& B website. http://www.dnb.com/get-a-duns-number.html viewed on 2/19/2014.

11. Memorandum to file Subject: Costs to FDA to Update Food Facility Registration Module. March 14, 2014 from Erwin Miller, Branch chief Compliance Information Branch, Office of Compliance, CFSAN, FDA.

12. Centers for Disease Control (CDC) and Prevention – Tracking and Reporting Foodborne Disease Outbreaks- http://www.cdc.gov/features/dsfoodborneoutbreaks/ viewed on 3/12/2014.

13. Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. (2011) "Foodborne illness acquired in the United States—major pathogens" Emerg Infect Dis, Vol. 17, No. 1.

14. Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food – Appendix A (PDF - 1.4MB) http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334117.pdf viewed on 2/14/ 2014.