DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Amendments to Registration of Food Facilities

Docket No. FDA-2002-N-0323

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The food facility registration rule amends 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. Total annualized costs are estimated at $5 million using a seven percent discount rate and $6 million using a three percent discount rate. We expect that the benefits of the final rule will 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.

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Analysis of Economic Impacts

FDA has examined the impacts of the final 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 (Pub. L. 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). The Agency believes that this final rule is not a significant regulatory action under 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. Because the additional costs per entity of this rule are small, we do not believe that this final rule will have a significant economic impact on a substantial number of small entities. However, we have 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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

This final regulatory impact analysis (RIA) estimates costs for the provisions of the final rule by revising the estimated costs set forth in the preliminary regulatory impact analysis (PRIA) for the proposed rule (80 FR 19159, April 9, 2015) (hereinafter referred to as the PRIA). Specifically, estimated costs of this final rule are similar to costs presented under Option 4 in the PRIA (Ref. 1). Option 4 of the PRIA included the cost estimates of all of the provisions of the proposed rule, but with the additional implementation of a U.S. Agent Voluntary Identification System (VIS or the system). In this final rule, we are not finalizing our proposal to shorten the time period for submitting updates and cancellations to 30 calendar days from 60 calendar days. In addition, we are postponing the requirements to submit a unique facility identifier (UFI) and to submit registrations electronically until the year 2020. Thus, as we explain in detail in section IV of this RIA, we revise our cost estimates in Option 4 of the PRIA by removing additional estimated costs associated with updates and also to reflect the discounted present value and annualized costs from postponing the requirements for both the UFI and mandatory electronic registration from 2016 to 2020. For a full explanation of the economic impact analysis of Option 4 of the proposed rule, interested persons are directed to the text of the PRIA, available at http://www.regulations.gov/#!documentDetail;D=FDA-2002-N-0323-0173.

I. Summary of Costs and Benefits

The food facility registration rule amends 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 final rule codifies certain already effective, self-implementing requirements authorized by 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.

The final rule also implements other requirements of section 102 of FSMA, including mandatory electronic registration submissions (which under the final rule will not begin until 2020) and amendments to the retail food establishment definition. In addition, the final rule implements other changes to improve the utility of the food facility registration database. Although FDA is making some generally minor revisions to the final rule, we are finalizing most of the key aspects of the proposed rule and the overall goals of the proposed rule remain unchanged. The following four changes are substantial enough to require us to revise our cost projections: 1) we plan to implement a VIS; 2) we are postponing the requirement to provide a UFI; 3) we are postponing the requirement to submit electronic registrations (a requirement from which facilities may obtain waivers); and 4) we will continue to allow 60 calendar days to submit updates to registrations, instead of shortening the time period to 30 calendar days as we proposed.

At the proposed rule stage, we requested comments on whether to implement a VIS, but we did not settle on plans to do so. As indicated in the preamble to the finale rule, we now plan to implement a VIS. Because the VIS is voluntary, we will implement the VIS through the guidance process in accordance with our Good Guidance Practice regulations in 21 CFR 10.115. Nevertheless, because we have settled on plans to implement the VIS, this final regulatory impact analysis assesses the effect of the VIS on the estimated costs of the final rule.

The second change includes revised estimated costs associated with our proposal to require facilities to include D-U-N-S® numbers in their registrations. In the final rule, we do not require the submission of D-U-N-S® numbers; instead, we require the submission of a unique facility identifier ("UFI") recognized as acceptable by FDA. FDA has not yet recognized any specific facility identifier as acceptable. We anticipate that we will issue guidance specifying which unique facility identifier or identifiers FDA recognizes as acceptable, and we expect to recognize D-U-N-S® numbers as acceptable identifiers. In addition, the final rule postpones the requirement to submit a UFI until 2020. We have revised our estimated costs to account for these changes and to reflect the present value and annualized cost of obtaining a UFI four years in the future or the year 2020.

The third change includes revisions to the costs associated with our proposed requirement for mandatory electronic registration and electronic registration renewals beginning January 4, 2016. In proposing to require electronic submissions, we also proposed to provide the option of a waiver from that requirement under proposed § 1.245. In the final rule, we are postponing the mandatory electronic submission requirement until January 2020. In addition, we are finalizing

our proposal to provide for a waiver from that requirement. In the PRIA, we estimated that registrants would have to submit waiver requests with each biennial cycle, and therefore estimated costs accordingly. However, in the preamble to the final rule, we clarify that if a waiver has been requested and granted, the facility is not required to submit future waiver requests each time the facility submits a renewal or update. Once FDA grants a waiver, we will consider the waiver to be in effect for as long as the reasons for the waiver remain unchanged and the registration has not been cancelled. This final regulatory impact analysis re-assesses the cost of requesting a waiver to reflect the discounted present value of this one-time cost beginning in the year 2020 instead of recurring annual costs beginning in 2016.

For the fourth change, we are not finalizing our proposal to shorten the time period for submitting updates to 30 calendar days from the currently-required time period of 60 calendar days. In the PRIA, we estimated incremental costs of the requirement to submit an update within 30 days from 60 days. Since we are not making any changes to the time periods from what is currently required, we remove all costs associated with this requirement from the RIA.

Table 1 presents estimated costs associated with the provisions in this final rule. These costs are similar to what we estimated the proposed rule would cost, but with the additional implementation of a VIS and reduced costs to facilities resulting from postponing the requirements to provide a UFI and to submit registrations electronically. Estimated one-time costs to domestic and foreign facilities are about $27 million. These estimated costs include a small reduction from the estimated one-time costs of provisions in the proposed rule. As explained in the PRIA, one-time costs in the first year stem from the self-implementing FSMA

provisions that are already effective, including 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 requirements for certain data elements in the registration form such as the email address for a domestic facility's contact person and the email address for a foreign facility's U.S. agent. These costs are approximately $20 million. Estimated one-time costs to domestic and foreign facilities for the biennial renewal cycle in 2016, by which time the final rule will be effective, include $46 million in one-time costs for entering additional data elements in the registration form and costs for U.S. agent verification procedures incurred in 2016 without a Voluntary Identification System (VIS). One-time costs in 2020 include the costs for the requirement to obtain a UFI plus the reduced costs associated with the mandatory electronic submission requirement (because the preamble to the final rule clarifies that waivers will not be required with each biennial registration renewal cycle). These costs are approximately $3 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. Recurring costs for 2018 include costs from implementing a VIS. As was the case under Option 4 in the PRIA, these costs are based on the supposition that the U.S. agents for all foreign facilities will choose to use the VIS. In the PRIA (see pages 51 to 53), we estimated that implementing the system by 2018 could reduce estimated costs for the U.S. agent information viewing and verification provisions in the proposed rule by one-half. We estimated that this would result in roughly $2 million of savings

each year or about $4 million every two years. We no longer assess the costs of requiring updates within 30 calendar days because we are not finalizing our proposal to shorten the time period for updates. The final rule does not change the currently-required time periods. Thus, estimated recurring costs of this final rule are now approximately $8.8 million every two years. The $8.8 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 final 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 one-time costs and annualized recurring costs, are approximately $4.7 million and $4.9 million per year ($24 and $25 per facility) 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)

	Total One-time Costs	**Total Annualized Costs 7%**	**Total Annualized Costs 3%**	**Benefits**
Domestic Facilities	$9	$1.4	$1.4	Not Quantified
Foreign Facilities	$18	$3.3	$3.5	
Subtotal Facilities	**$27**	**$4.7**	**$4.9**	
Costs to FDA		$0.9	$1.2	
Total	**$27**	**$5.6**	**$6.1**	

(2015 U.S. Dollars)

This analysis estimates costs and benefits of the provisions in this final rule only, which are in addition to the estimated annual costs already incurred due to the implementation of the provisions in the 2003 interim final rule.[1] Those estimated costs were calculated in an economic impact analysis that accompanied the interim final rule (68 FR 58893 at 58932). 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).[2]

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 final 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. (For a more complete qualitative discussion of the benefits, see the PRIA.) In addition, we updated in this analysis the monetized impact associated with different foodborne outbreak scenarios from the PRIA in order to determine the amount of savings from illness reduction that would be required in order for the final rule to reduce costs that result from foodborne illness by approximately the same amount that the compliance costs the final rule will impose on food facilities. We expect the final rule

[1] The interim final rule implemented section 305 of the Bioterrorism Act, and required domestic and foreign facilities to be registered with FDA by December 12, 2003 (68 FR 58894).
[2] On October 3, 2005, FDA issued a final rule in the Federal Register (70 FR 57505) that confirmed the interim final rule entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

will have additional benefits that we are similarly unable to quantify, including providing for the more efficient use of FDA's inspectional resources.

A. Comments on the PRIA and Responses

(Comment 1) Several comments state that obtaining a D-U-N-S® number will generate costs that we did not capture in our analysis. Specifically, comments state that the requirement will result in delays of registration submissions due to the time required to obtain a D-U-N-S® number once requested.

(Response 1) This final rule no longer requires facilities to use D-U-N-S® numbers. Instead, the final rule requires the use of a unique facility identifier recognized as acceptable by FDA. Because FDA has not yet recognized any specific facility identifier as acceptable, it is not possible to estimate whether this change in the final rule will affect costs. However, as stated in the preamble to the final rule, we plan to issue guidance that will recognize a unique facility identifier or identifiers as acceptable, and we anticipate that the guidance will recognize D-U-N-S® numbers as acceptable. Because we anticipate that our guidance will recognize D-U-N-S® numbers as acceptable, for purposes of estimating costs in the RIA, we estimate the costs of obtaining a UFI as the costs of obtaining a D-U-N-S® number. 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 24,000 or 29 percent of domestic food facilities and about 41,000 or 36 percent of foreign

food facilities that are required to register with FDA would need to obtain a D-U-N-S® number (Ref. 2). In the PRIA, we expressed the cost of obtaining and using a D-U-N-S® number in Table 13, First Year Costs to Domestic and Foreign Facilities of Obtaining a D-U-N-S® Number under the Proposed Rule, as well as in Table 14, Costs to Domestic and Foreign Facilities from Entering a D-U-N-S® Number onto the Food Facility Registration Form (Ref. 1). As reflected in the PRIA, we estimate that during the first year, the time required to request a D-U-N-S® number would be one hour, and that the time required to enter the number onto the registration form would be 1 minute, at an estimated cost of $3 Million. There is no fee to obtain a D-U-N-S® number unless an expedited service is requested. We also noted that 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. 3). In the PRIA, we stated that we did 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.

Although comments did not provide an estimate of the number of facilities likely to pay $250 for the expedited service, we believe that the PRIA did not adequately account for the possibility that, under the proposed rule, at least some facilities would have been likely to pay for the expedited service. We believe that this would have been likely under the proposed rule in part because of the narrow window of time between when this rule would have been finalized and when facilities would have been required under the proposed rule to provide a D-U-N-S® number for their registrations. As explained in section IV. B of this analysis, we revise our original premise in the PRIA that, under the proposed rule, facilities would not pay the $250 fee

for expedited service. Instead, we estimate that, under the proposed rule, all (41,000) foreign facilities and half (12,000) of domestic facilities (or a total of 53,000 facilities) that currently do not have a D-U-N-S® number would choose to pay the $250 fee to expedite receiving their D-U-N-S® number. This is a conservative estimate. Based on this revised premise for the proposed rule, we adjust our one-time cost of obtaining a D-U-N-S® number under the proposed rule from $3 to $16 million, which represents $13 million in costs in addition to the estimated costs in the PRIA.[3]

However, as stated in the preamble of this final rule, in response to the comments, we are delaying the requirement to submit a UFI recognized as acceptable to FDA until the registration renewal period beginning October 1, 2020. By postponing this requirement by 4 years, facilities will be allowed significantly more time to obtain a UFI. With this additional time provided under the final rule, we believe that facilities will be less likely to pay the fee to expedite obtaining a D-U-N-S® number. We therefore do not incorporate the $16 million upward adjustment of the one-time cost of obtaining a D-U-N-S® number under the proposed rule into the cost of the final rule. The upward adjustment to $16 million is only an upward adjustment for the costs of the proposed rule. Given that the final rule delays the UFI requirement until 2020, for the final rule we do not estimate that facilities will need to pay fees for expedited service.

[3] 53,000 facilities x $250 (expedited fee) = $13,250,000.
Total costs = $ 3 million from PRIA + $ 13 million in fees = $16 million.

Therefore, our estimated one-time (undiscounted) cost of obtaining a D-U-N-S® number is $3 million.

Since $3 million represents a cost as if incurred in 2016, we revise this cost to reflect the present value of the estimated $3 million as incurred 4 years in the future or otherwise 2020. We revise our one-time cost using a discount rate of 7 and 3 percent over 20 years to calculate a present value cost of obtaining a D-U-N-S ® to a respective $2 to $2.5 million.

(Comment 2) Comments express concern that public health benefits from this rule are not commensurate with the costs of this rule. Other comments expressed concern over the uncertainty about benefits.

(Response 2) FDA does not have the data to quantify the benefits of the final rule, and we therefore discuss the benefits qualitatively. Although we are unable to quantify the benefits, we believe that they are substantial and that the benefits of the final rule justify the costs. We expect that the final rule will increase the utility of FDA's registration database, enabling the agency to more effectively and efficiently respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. The requirements in the final rule will make registration information more accurate and more up-to-date. More accurate registration information will allow FDA to use the registration database more effectively and efficiently, including to deter and limit the effects of foodborne outbreaks. In addition, certain new information required by the final rule, including activity type information, will assist FDA in more efficiently and effectively deploying the agency's limited inspectional resources.

One type of registration information that we think will be more accurate as a result of the requirements in the final rule is information about the location of food facilities. We expect that this will enable us to better locate food facilities for inspections. In some cases, this should help us more efficiently enforce certain other requirements that apply to food facilities that are required to register under section 415 of the FD&C Act, such as the preventive controls requirements for human and animal food. *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (80 FR 55908, September 17, 2015); and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (80 FR 56170, September 17, 2015).

II. Need for Regulation

We have not revised the need for regulation from the PRIA. For a detailed discussion of the need for regulation, see the PRIA (Ref. 1).

III. Regulatory Alternatives

We have not revised the regulatory alternatives from the PRIA. For a detailed discussion of the feasible regulatory alternatives, see the PRIA.

IV. Costs of the Rule

In this section we provide a detailed description of the estimated cost revisions of this rule. These costs differ from the PRIA as a result of the four changes in the final rule discussed above that are substantial enough to require us to revise our cost projections.

A. Costs of Implementing a VIS

In the preamble to the proposed rule, we requested comments 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. In the PRIA we estimated the costs of the provisions in the proposed rule with the additional implementation of a VIS under option 4 of the analysis. As stated in the preamble to the final rule, we now plan to implement a VIS through guidance. As we envision the VIS, the system will enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. We also expect that the system will 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 they agree to serve. 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 will reduce the time that we anticipate foreign facilities will spend corresponding with U.S. agents as a result of the provision in the final revised § 1.227 specifying that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. In addition, we expect that a VIS would also

reduce the costs that we estimate in association with the U.S. agent verification procedures in final §§ 1.231(a) (5) and (b) (7).

As explained in the PRIA, we estimate that implementing the system could reduce the costs to foreign facilities that we estimated for the U.S. agent information viewing and verification provisions in the PRIA by one-half, resulting in roughly $2 million of (undiscounted) savings each year. Table 2 below summarizes the difference between the costs of the U.S. agent information viewing and verification procedures with and without a VIS.

Table 2.—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
Without VIS	114,139	1.00	0.5	57,070	$ 72.86	$ 4,157,909	$ 36.43
With VIS	114,139	0.50	0.5	28,535	$ 72.86	$ 2,078,954	$ 18.21
Difference		**0.50**		**28,535**		**$ 2,078,954**	**$ 18.21**

(2015 U.S. Dollars)

B. Costs of a UFI

In the PRIA, we explained that there is no cost to obtain a D-U-N-S® number (a data element that the proposed rule would have required) and that Dun & Bradstreet usually requires 30 days to provide a D-U-N-S® number upon receiving a complete request. As reflected in the PRIA, we estimate that during the first year, the time required to request a D-U-N-S® number would be one hour, and that the time required to enter the number onto the registration form

would be 1 minute, at an estimated cost of $3 Million. We also explained that, for businesses that are willing to pay a fee of about $250, Dun & Bradstreet is able to provide a D-U-N-S® number within 5 days (Ref. 2). In our original cost estimate, we estimated that facilities would choose not to pay the fee to expedite receipt of their D-U-N-S® number. Consequently, the PRIA does not account for costs associated with such fees under the proposed rule. In the PRIA, we requested comments on the number of facilities who would most likely wait 30 days to obtain a D-U-N-S® number for free, and on how many would pay $250 for an expedited number. Although comments did not specifically estimate the number of facilities that might choose to pay the expedited fee, we agree with comments that this requirement, as proposed, would generate costs that we did not capture in the PRIA. In the PRIA, we did not adequately account for the possibility that, under the proposed rule, at least some facilities would have been likely to pay for the expedited service. We believe that this would have been likely under the proposed rule in part because of the narrow window of time between when this rule would have been finalized and when facilities would have been required under the proposed rule to provide a D-U-N-S® number for their registrations.

As the time between requesting a D-U-N-S® number and receiving the D-U-N-S® number approaches the time the registration renewal period ends, the risk that a facility might miss the deadline to submit a complete registration renewal is greater. If a facility fails to complete a registration or registration renewal, the facility may incur costs related to an invalid registration, such as shipments from the facility being delayed at the port (for foreign facilities).

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. Potential costs associated with port delays include costs such as lost value of perishables, storage costs, lost revenue in sales and other transaction costs. Given the incentive in such cases for food facilities to complete the registration or registration renewal process promptly, we now believe that, under the proposed rule, most facilities that currently do not have a D-U-N-S ® would opt for paying the $250 fee to expedite receipt of their number.

If this requirement as proposed became final, we conservatively estimate that 12,000 of 24,000 domestic facilities that currently do not have a D-U-N-S® number would choose to pay the $250 fee to expedite obtaining their D-U-N-S® number in order to comply with the requirement by 2016, for a total of $3 million. In a similar manner, we also estimate that, under the proposed rule, all of the 41,000 foreign facilities that currently do not have a D-U-N-S®, would also choose to pay the fee in order to comply with the requirement by 2016, totaling $10 million. We adjust one-time costs of this proposed requirement from $3 million, as set forth in the PRIA, to $16 million (approximately a $13 million more than originally estimated in the PRIA).

However, as stated in section II, FDA is postponing the requirement for providing a UFI from 2016 to 2020. By allowing 4 more years for facilities to obtain a UFI in the final rule, we estimate that, under the final rule, no facilities will choose to expedite the process of obtaining a

D-U-N-S® number in order to meet the requirements of this rule. Thus, for the final rule, we do not believe that there will be costs associated with expediting D-U-N-S® numbers. The upward adjustment to $16 million is only applicable to the proposed rule, because the proposed rule did not provide for any delay in the proposed D-U-N-S® number requirement.

For the final rule, our estimated one-time (undiscounted) cost of obtaining a D-U-N-S® number is $3 million. This $3 million cost estimate is the same as originally estimated in the PRIA (i.e., without the $13 million cost adjustment from fees that we now believe would have resulted from paying fees to expedite D-U-N-S® numbers in order to meet the requirements in the proposed rule)).

Table 3 below summarizes the difference between adjusted one-time cost to facilities of obtaining a D-U-N-S® beginning in 2016, and the present value of the one-time cost of the UFI provision in the final rule beginning in 2020. By postponing the requirement to obtain a UFI to the year 2020 in the final rule, the reduction in costs to facilities of this requirement ranges between $14 and $13 million (using a discount rate of 7 and 3 percent respectively).

Table 3.—Difference in One-time Costs to Facilities in Obtaining a UFI in 2016 and in 2020 ($ Millions)

Year	7%	3%
PRIA (2016) plus fees	$ 16	$ 16
RIA (2020)	$ 2.2	$ 2.5
Difference	$ 14	$ 13

(2015 U.S. Dollars)

C. Costs Associated with the Electronic Submission Requirement and Waiver from Electronic Submission Requirement

Under the proposed rule, registrants would be required to submit registrations and registration renewals electronically beginning January 4, 2016, absent the granting of a waiver under proposed § 1.245. The proposed rule would have also required the electronic submission of updates and cancellations beginning January 4, 2016. The proposed rule proposed that facilities 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 to submit a registration or registration renewal electronically to FDA. FDA tentatively concluded 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 (80 FR at 19177-78).

As of February 7, 2014, FDA's Food Facility Registration Module (FFRM) database listed 1,925 domestic and 196 foreign food facility registrations that were active and that were not submitted electronically. In the PRIA, the costs of mandatory electronic submission are the costs of requesting and submitting a request for a waiver from this requirement. The PRIA estimated that 1,925 domestic and 196 foreign food facility managers will prepare and send requests for waivers once every other year, during the registration renewal cycle. We estimated annual costs of submitting a waiver to be $12,500 per year, or $25,000 every biennial cycle.

In the preamble of the proposed rule, we requested comment on the proposed requirements for mandatory electronic registration and registration renewals to begin in the year 2016 and the proposal to allow for a waiver from these requirements. We also requested comment and data on the number of facilities that believe they would be unable to register or renew their registrations electronically, and the reasons for such belief. Although comments did not provide data on the number of affected facilities, one comment stated that small overseas facilities may not be able to submit registrations electronically by 2016 because there might not be reliable nationwide Internet. The comment also requested that paper registrations remain an option. In the final rule, we make a number of changes to the requirements related to electronic submissions. First, we are delaying the electronic submission requirement to January 2020. The January 2020 date applies to electronic registrations, registration renewals, updates, and cancellations. In addition, we are also revising § 1.245 of the final rule to provide that a waiver is available not only from the requirement to submit registrations and registration renewals electronically, but also from the requirement to submit updates and cancellations electronically and certain other electronic requirements such as certain e-mail address requirements. In addition, the preamble to the final rule clarifies that if a waiver has been requested and granted, the facility is not required to submit future waiver requests each time the facility submits a renewal or update. Once FDA grants a waiver, we will consider the waiver to be in effect for as long as the reasons for the waiver remain unchanged and the registration has not been cancelled. As stated in the PRIA, in 2014 about 2,000 facilities submitted paper registrations. We therefore estimated that 2,000 facilities would incur about $25,000 in recurring biennial costs requesting waivers, or $12 per facility that requests a waiver, every two years, for annualized costs of $7,000 to $10,000 ($3 to $5 per facility) over 20 years using a 7 and 3 percent discount rate. By

delaying the electronic submission requirement until January 2020 and by further clarifying that facilities may need only request a waiver one-time, we revise our cost estimate to a one-time cost of $26,000, or $12 per facility that requests a waiver. Using a discount rate of 7 and 3 percent over 20 years, we revise estimated annualized costs of this requirement as $2,000 to $1,500 ($1 per facility).

D. Costs of the Requirement to Update Facility Registrations within 60 Calendar Days

In the PRIA, we estimated incremental costs associated with our proposal to shorten the time period for updating registrations. Specifically, we proposed to shorten the time period from the 60 calendar days allowed in the current registration regulation to 30 calendar days. Since we are not finalizing the proposal to shorten the time period, the final rule will keep the current 60-day requirement unchanged. As a result, cost estimates of this final rule no longer include costs associated with this proposed requirement.

E. Summary of Costs

Total annualized costs of this final rule include revisions to estimated costs for implementing a VIS. The revised costs also reflect our decision to postpone the requirements for providing a UFI and for mandatory electronic registration. We further revise our cost estimates for requesting a waiver as a one-time cost (once a waiver is granted) instead of a recurring cost every biennial registration cycle. Finally, we no longer include costs associated with the

proposed requirement to shorten the time period to update registrations. The changes made in this final rule will result in a reduction of annualized costs to facilities of about $2.3 to $2.5 million each year using a respective discount rate of 7 and 3 percent.

Table 4 compares total annualized costs (at 3% and 7%) of both the proposed rule (as revised to include fees in the costs of obtaining a D-U-N-S®) and the final rule.

Table 4.—Comparison of Summary Costs of Proposed and Final Food Facility Registration Rule ($ Millions)

		Domestic Facilities	**Foreign Facilities**	**Costs to FDA**	**Total**
Proposed Rule (Revised)	Costs discounted at 3%	$ 1.8	$ 5.6	$ 1.2	$ 8.6
	Costs discounted at 7%	$ 1.9	$ 5.1	$ 0.9	$ 7.8
Final Rule	Costs discounted at 3%	$ 1.4	$ 3.5	$ 1.2	$ 6.1
	Costs discounted at 7%	$ 1.4	$ 3.3	$ 0.9	$ 5.6
Difference	Costs discounted at 3%	$ 0.4	$ 2.1	$ -	$ 2.5
	Costs discounted at 7%	$ 0.5	$ 1.8	$ -	$ 2.3

(2015 U.S. dollars)

V. Benefits of the Rule

As stated in the PRIA, we expect that the benefits of the final rule will include aiding FDA's ability to deter and limit the effects of foodborne outbreaks and other food-related emergencies and will help us respond to such emergencies efficiently.

As explained in more depth in the PRIA, we also expect that the rule will allow the agency to use its inspectional resources more efficiently. The already-effective, FSMA-related

provisions in the final rule do much to address the accuracy and reliability concerns with the food facility registration data. We expect that the new requirements in the final rule will further enhance the ability of registration renewal to rid the registration database of outdated registrations and will further increase the accuracy and reliability of the food facility registration database. One means by which we expect the final rule to accomplish this is through 21 CFR 1.241(b), which specifies 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. We also believe the UFI requirement and associated verification process will increase the accuracy of registrations, as will the process for verifying certain U.S. agent information and registration submissions not made by the owner, operator, or agent in charge. The database is also likely to become more accurate and up-to-date as a result of the requirement to immediately update any previously-submitted incorrect information and the provision that FDA will 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 and up-to-date registration information will allow FDA to use the registration database more effectively and efficiently, including responding to outbreaks and other food-related emergencies. We also expect that the new facility contact information required in the final rule will allow us to more efficiently and effectively respond to such emergencies. Further, we anticipate that the requirement for electronic registration will have additional efficiency benefits, improving the timeliness and accuracy of submissions and making the transmission of information easier and more efficient.

Although we are unable to quantify these and other benefits, we discuss the expected benefits qualitatively in more depth in the PRIA.

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 final rule to reduce costs that result from foodborne illness by approximately the same amount that the compliance costs the final rule would impose on food facilities (i.e. a breakeven analysis).

Since the publication of the proposed rule, new studies on the valuation of foodborne illness and the value of statistical life have published. We revise our break even analysis in the PRIA to include this new information. We update our analysis with the most current information available.

For this rule to break even as measured by cost savings from fewer illnesses, the rule would have to result in about $5 million in savings each year. By breaking even in terms of cost savings from fewer illnesses, we mean that the rule would reduce costs that result from foodborne illness by approximately the same amount as the compliance costs the rule would impose on food facilities. (We anticipate that the rule will 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 rule would break even in terms of cost savings from fewer illnesses). We lack sufficient data to determine whether the rule will achieve health-

related cost savings sufficient to break even with the cost that the rule will impose on food facilities. But to understand what kind of health savings will 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.4). 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. 5). This allows us to account not only for identified illnesses, but also for those illnesses that are never reported or were 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 Minor, et al (2015) (Ref. 6). We use this estimate because it represents a pathogen specific estimate of dollar burden a typical case of this particular foodborne illness places on an individual. Although the authors estimate the costs of various foodborne illnesses, we focus this 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. We also revise this cost per illness estimate to reflect a more recent Value of Statistical Life (VSL) of $9 million, and a higher Quality Adjusted Life Day (QALD) estimate of $1,260, for all

pathogens (Ref. 7). Table 5 summarizes the updated average cost per illness based on the estimated average number of illnesses per outbreak. [4]

Table 5.—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	21.09	1	26.1	550	$6,190	$ 3,406,345
E. Coli	21.09	1	29.3	618	$2,318	$ 1,432,324
Listeria	21.09	1	2.1	44	$1,620,423	$ 71,749902

(2015 U.S. Dollars)

We estimate the average costs per illness due to *Salmonella spp.* (non-typhoid) to be about $6,190 (Ref. 7). Reducing the cost of illness by $6 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 750 illnesses each year, which is roughly about 1 outbreak 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 $2,318 (Ref. 7). Breaking even with compliance costs for this rule based on reductions in *E. coli* non-O157 STEC alone would require reducing the number of cases due to this pathogen by 2,004 illnesses, or by 3 average-sized outbreaks per year. Outbreaks due to the pathogen *Listeria monocytogenes* cause, on average, 44 illnesses. The annual cost for each foodborne outbreak from listeriosis is about $72 million, or $1.6 million per case. For compliance costs to break even based on a

[4] The updated values for illnesses are updated from the article in Minor, et al (2015) (Ref. 6) using a QALD= $603 and a VSL of $8.1 Million to a QALD=$1,260 and a VSL of $9 Million from Robinson, et al (Ref.7).

reduction in listeriosis alone, the rule would have to reduce about 6 percent of a single listeriosis outbreak, or about 3 cases per year.

In Table 6, we provide CDC estimates for the number of foodborne outbreaks of *E. coli* (non-O157 STEC), *Salmonella* spp. (non-typhoid) and *Listeria monocytogenes* for 2014 alongside the number of foodborne outbreaks for each of the three pathogens that would have to be prevented in order to break even with the costs of this final rule (Ref. 8) due to a reduction in outbreaks caused by each pathogen alone. For example, in 2014 there were 149 foodborne outbreaks caused by *Salmonella spp.* (non-typhoid). Reducing the cost of illness by $5 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 750 illnesses each year, which is roughly about 1 outbreak per year of 149 outbreaks. In a similar manner for E- Coli (non-O157 STEC), the cost of illness reduction in 2014 needed in order to break even with compliance costs of this rule would be equivalent to 4 out of 24 outbreaks per year, and the CDC estimates that there are 24 outbreaks caused by this pathogen each year. Finally for *Listeria monocytogenes*, the costs of illness reduction needed in order to break even with compliance costs would be about one half of an outbreak per year, or one outbreak every other year. The CDC estimates that there are 9 outbreaks caused by this pathogen per year.

Table 6. —Foodborne outbreaks required for breaking even with compliance costs

Pathogen	Number of Outbreaks in 2014	Number of Outbreaks Needed to be Prevented to Break Even, Annually	Percent of 2014 Outbreaks Needed to be Prevented to Break even, Annually
Salmonella spp.	149	1	1%
E. Coli (non-O157 STEC)	24	4	15%
Listeria monocytogenes	9	0.4	4%

VI. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. At an average annualized cost per facility of about $24 and $25 (using a respective 7 and 3 percent discount rate over 20 years), we believe the costs to all businesses, including small businesses, will be insignificant. Because average costs per facility are small, we believe that the final rule will not have a significant economic impact on a substantial number of small entities. However, we have analyzed various regulatory options to examine the impact on small entities. The following analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis under the Regulatory Flexibility Act.

A. 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. This final rule will impact a substantial number of small businesses, but because costs per facility of this final rule are small, we believe that this final rule will not have a significant economic impact on a substantial number of small entities. However, we have analyzed various regulatory options to examine the impact on small entities.

B. 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 an estimated 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 (Table 7). Of the approximately 81,627 domestic facilities affected by this rule, we estimate that about 99.5 percent (81,228) employ 500 or fewer employees. In a similar manner, we estimate that 99.5 percent of 114,139 (or 113,581) foreign facilities employ 500 or fewer employees.

Table 7.—Number of Registered Facilities and Number of Registered Facilities with 500 or Fewer Employees

	Registered facilities	**Facilities with 500 employees or less**
Domestic Facilities	81,627	81,228
Foreign Facilities	114,139	113,581
Total	195,766	194,810

The number of facilities in Table 7 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.

C. Costs to Small Entities

FDA estimates that this final rule will result in total one-time costs to domestic facilities of approximately $9 million, which is about $116 per facility. Total domestic (one-time and recurring) annualized costs are about $1.4 million (using a 7 and 3 percent discount rate over 20 years), which translates to about $17 in annualized costs per facility. Total foreign annualized one-time costs and recurring costs are about $ 3.3 and 3.5 million (7 and 3 percent over 20

years), or $29 to $31 in annualized costs per facility. Table 8 shows the total average annualized costs for both domestic and foreign facilities.

Table 8.—Average One-time and Average Annualized Costs per Facility

	One-time Costs per Facility	Annualized Costs per Facility (7%)	Annualized Costs per Facility (3%)
Domestic Facilities	$ 116	$ 17	$ 17
Foreign Facilities	$ 155	$ 29	$ 31
Total Facilities	**$ 139**	**$ 24**	**$ 25**

(2015 U.S. Dollars)

Because such a large percentage of domestic food facilities are small businesses, we considered options that would lessen the economic effect of the rule on small entities in the Cost and Benefits Analysis in section I.E of the PRIA analysis of regulatory options. In the PRIA, we considered the option of taking no new regulatory action (Option 1) as the least burdensome of all options so that small entities would not incur any new costs (Ref. 1). FDA did not pursue 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."

The next least-costly option identified in the PRIA was 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 have implemented 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 did not pursue Option 3 because doing so would have been inconsistent with Congress's direction in section 102(c) of FSMA with regards to amending the definition of retail food establishments. In addition, we believe that the additional requirements in the final rule are important tools for increasing the accuracy of FDA's food facility registration database and will improve the agency's ability to respond to foodborne outbreaks and other threats. Further, we believe that the final rule will allow FDA to more efficiently prepare for and conduct inspections.

FDA is finalizing and implementing most of the proposals under Option 4, which is more costly than Option 3 but less costly than the proposed rule (Option 2). Under this final rule, FDA has made final most of the requirements in Option 2 of the proposed rule but with the additional implementation of a U.S. agent Voluntary Identification System (VIS). In addition to implementing the VIS, we are postponing the requirements to provide a UFI and to make registration submissions electronically (or otherwise request a waiver). We are also clarifying that waivers may only need to be sought and obtained a single time. Finally, we are not finalizing our proposal to shorten time periods for submitting updates from 60 calendar days to 30 calendar days.

As discussed in Option 4 in the PRIA (Ref.1), we estimated that the VIS would save foreign facilities time and money in connection with U.S. agent communications (about $1

million in annualized costs (discounted for 20 years at 7% and 3%). As such, we estimated that the VIS would lessen the economic effects of the rule on small entities

Another way FDA is reducing the burden on small entities is by postponing the requirements for providing a UFI and for making registration submissions electronically (or otherwise requesting a waiver). We provide a detailed discussion for the reasons for these changes in the preamble to the final rule.

In addition, our clarification that facilities may need to only request a waiver from the electronic submission requirement once should also reduce the burden of the final rule on small entities.

Finally, FDA is reducing the burden on small entities by amending the retail food establishment definition. As we stated in the preliminary regulatory flexibility analysis, we expected that our proposed amendment, which would have addressed off-farm sales by establishments located on a farm, would expand the number of establishments that meet that definition and that would therefore be exempt from the requirements of food facility registration. However, we were not able to quantify the number of establishments that we anticipated would be affected by the proposed amendment to the retail food establishment definition. According to data from USDA ERS, 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. We noted that 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 proposal.

The final rule expands on our proposed definition by also addressing direct-to-consumer sales by establishments not located on farms. Specifically, we are changing the final rule to also address direct-to-consumer sales by "farm-operated businesses." By "farm-operated business," we mean a business that is managed by one or more farms and that conducts manufacturing/processing off of the farm(s). As such, the final rule addresses sales by establishments that are either (1) located on farms, or (2) similar to farms because they are managed by one or more farms. Under the final rule, both categories of establishments may consider sales directly to consumers at farmers' markets, roadside stands, CSAs, and other such direct-to-consumer platforms in determining their primary function and whether they would meet the requirements to be considered retail food establishments.

We anticipate that our changes in the final rule will further reduce the burden on small business because it will further expand the number of establishments that are exempt from the food facility registration requirements. We expect that many of these establishments are likely small businesses. We do not have sufficient data on how many establishments will be affected because we do not have data on how establishments manufacture/process RACs grown, harvested, raised, packed, or held by a farm under the same management.

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 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 concluded that it would not be legally viable to exempt small entities from the requirements of the rule. In addition, we have 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 rule or providing them with a staggered compliance date would thwart many of the key objectives of the 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.

VII. References

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