DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

# Mitigation Strategies to Protect Food Against Intentional Adulteration

Docket No. FDA-2013-N-1425

## Regulatory Impact Analysis

## Regulatory Flexibility Analysis

## Unfunded Mandates Reform Act Analysis

Economics Staff

Office of Regulatory Policy and Social Sciences

Center for Food Safety and Applied Nutrition

## Executive Summary

This rule requires human food facilities that are required to register and that are part of businesses with more than $10 million in annual sales, to create a food defense plan, identify actionable process steps, implement mitigation strategies and related food defense monitoring, corrective actions, and verification activities to protect these steps, train designated employees, and document these actions. We estimate the annualized costs of these measures to food producers to be between $280 and $490 million (annualized over 10 years, at a seven percent discount rate). We were unable to estimate the costs to FDA of enforcing the rule.

The benefits of the actions required by the rule are a reduction in the possibility of illness and death resulting from intentional adulteration of food. We are unable to monetize these benefits; however, for attacks that are similar in impact to acts of intentional adulteration that have happened in the U.S. in the past, the breakeven threshold, counting only producer costs, is 28 to 48 attacks prevented every year. For attacks causing similar casualties as major historical outbreaks of food-related illness, the breakeven threshold is one or two attacks prevented every year. For catastrophic terrorist attacks causing thousands of fatalities, the breakeven threshold is one attack prevented every 270 to 470 years.

Contents

## A. Introduction

The Food and Drug Administration (FDA or we) 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 (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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. The annualized costs per entity due to this rule are about $13,000 for a one-facility firm with 100 employees, and there are about 4,100 small businesses affected by the rule, so we tentatively conclude that the final rule could have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to 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 (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule may result in a 1-year expenditure that would meet or exceed this amount.

## B. Summary of Costs and Benefits

The total cost of the rule to food producers, annualized over 10 years at a 7 percent discount rate, is between $280 and $490 million.[1] The first-year cost is between $680 and $930 million. Counting only domestic firms, the total annualized costs are between $90 and $150 million, with initial costs of between $220 and $300 million. The average annualized cost per covered facility is between $9,000 and $16,000, and the average annualized cost per covered firm is between $27,000 and $47,000. We were unable to estimate the costs to FDA of enforcing the rule, because decisions about the structure and details of the enforcement system have not yet been made.

The benefits of the actions required by the rule are a reduction in the possibility of illness and death resulting from intentional adulteration of food. We monetize the damage that various intentional adulteration scenarios might cause, and present a breakeven analysis showing the number of prevented attacks at which the benefits are larger than the costs. For attacks that are similar in nature to acts of intentional adulteration that have happened in the U.S. in the past, the breakeven is 28 to 48 attacks per year. For attacks causing similar casualties as major historical outbreaks of food-related illness, the breakeven prevention amount is one or two attacks every year. For catastrophic terrorist attacks causing thousands of fatalities, the breakeven is one attack prevented every 270 to 470 years, or a 0.21% to 0.37% annual chance of stopping an attack. These breakeven estimates only include producer costs. When adding FDA enforcement costs, the rule must prevent attacks more often to break even.

[1] With a 3 percent discount rate, the annualized cost is between $270 and $480 million. All numbers used in the text are for a 7 percent rate unless otherwise noted.

Table 1 shows the approximate, rounded, mean values for various cost components of the rule:

Table 1.—Annualized Cost and Benefit Overview

| All Numbers are USD 2014 (Millions), Annualized over 10 years | | 3% Discount | 7% Discount |
|---|---|---|---|
| Costs | Learning about Rule | $ 3 | $ 4 |
| | Creating Food Defense Plans | $ 10 | $ 11 |
| | Mitigation Costs | $ 26 | $ 28 |
| | Monitoring, Corrective Action, Verification | $ 62 | $ 62 |
| | Employee Training | $ 5 | $ 6 |
| | Documentation | $ 9 | $ 9 |
| | **Subtotal (Domestic Producer Cost)** | **$ 115** | **$ 119** |
| | Cost to Foreign Firms | $ 247 | $ 256 |
| | Cost to FDA | Unknown | Unknown |
| | **Total** | **$ 362[2]** | **$ 375[2]** |
| Benefits | Lower Chance of Intentional Adulteration | Unquantified | |

[2] This total does not include costs to FDA of enforcing the rule.

## C. Need for Regulation

This regulation is mandated by statute. Sections 103, 105, and 106 of the FDA Food Safety Modernization Act of 2011 (FSMA) direct the Secretary of Health and Human Services to promulgate regulations to protect against the intentional adulteration of food (Ref. (1)).

The people responsible for managing food production firms make many decisions about what risks to invest in reducing. When doing so, they take into account the probability of the negative event, and the damage the event would cause to their firm. If the probability multiplied by the damage is equal to or greater than the cost of prevention, then they will invest in prevention.

For many negative events, all or most of the damage will be considered. For example, a small adulteration incident that will likely be traced to the company may be expected to cause damage to the company's reputation and sales equal to or greater than the health damage that the adulteration inflicts on society. In this case, the managers will therefore invest the socially optimal amount in preventing adulteration.

However, the maximum damage that a major adulteration event can cause to the owners of the targeted company is the value of the company or the owners' wealth. The social damage that a catastrophic terrorist attack causes is therefore larger than the private damage done to people who could have invested to stop it.

If an attack could cause more damage than the value of the company, then its probability multiplied by the value of the company may be less than the cost of prevention, while its probability multiplied by the total social damage is greater than the cost of prevention. In this case, it is not rational for profit-maximizing managers to invest in prevention, but it is socially optimal. This rule is intended to address these situations.

## D. Description of FDA Action

FDA is requiring domestic and foreign human food facilities to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is promulgating these requirements as

part of our implementation of FSMA. We expect the rule will help to protect food from intentional adulteration when the intent of the adulteration is to cause wide scale public health harm.

The rule applies to both domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act. However, as explained in the preamble, the rule contains several exemptions:

- The rule does not apply to a very small business (i.e., a business, including any subsidiaries or affiliates, averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee), except that the facility must, upon request, provide for official review documentation sufficient to show that the facility meets this exemption.
- The rule does not apply to the holding of food, except the holding of food in liquid storage tanks.
- The rule does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- The rule does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- The rule does not apply with respect to alcoholic beverages at a facility that meets certain conditions.
- The rule does not apply to the manufacturing, processing, packing or holding of food for animals other than man.
- This rule does not apply to on-farm manufacturing, processing, packing, or holding of the certain foods identified as having low-risk production practices.

The rule establishes various food defense measures that an owner, operator, or agent in charge of a facility is required to implement to protect against the intentional adulteration of food. Specifically:

- Prepare and implement a written food defense plan that includes a vulnerability assessment to identify significant vulnerabilities and actionable process steps, mitigation strategies and explanations, and procedures for food defense monitoring, corrective actions, and verification.

- Identify any significant vulnerabilities and actionable process steps by conducting a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility using appropriate methods to evaluate each point, step, or procedure in a food operation.
- Identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. For each mitigation strategy or combination of strategies implemented at each actionable process step, facilities must include a written explanation of how the mitigation strategy(ies) sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.
- Establish and implement mitigation strategies management components, as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of the mitigation strategy and its role in the facility's food defense system.
- Establish and implement food defense monitoring procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system.
- Establish and implement food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy.
- Establish and implement food defense verification activities, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system, to include verification that monitoring is being conducted and appropriate decisions about corrective actions are being made; verification of proper implementation of mitigation strategies and verification of reanalysis.
- Conduct a reanalysis of the food defense plan.
- Ensure certain qualifications of individuals who perform activities under this final rule.
- Establish and maintain certain records, including the written food defense plan; written vulnerability assessment to identify significant vulnerabilities and actionable process steps; written mitigation strategies; written procedures for food defense monitoring, corrective actions, and verification; and documentation related to training of personnel.

All records are subject to certain general recordkeeping, record retention, and public disclosure requirements.

E. Comments on the Preliminary Regulatory Impact Analysis and our Responses

Comment 1) Some comments state that the rule mandates economic and time costs to private businesses that are out of proportion to the benefits of the rule.

Response 1) FDA recognizes that the cost of this rulemaking is not inconsequential. However, the requirements mitigate costs by focusing on only the points, steps, or procedures that are most vulnerable.

Comment 2) Some comments state that the proposed requirements should not be adopted as a final rule so long as FDA is unable to quantify the benefits of this approach and show that they are higher than other possible approaches.

Response 2) This rule is required by statute. We proposed requirements that are based on more than 10 years of collaboration with industry and reflect some industry best practices to be the most effective at protecting the food supply. For details, see the Intentional Adulteration Proposed Rule Federal Register Page 78021 under "B. Interagency Approach to Food Defense", and Page 78023 under "Outreach". We acknowledge that intentional adulteration, where the intent is to cause wide scale public health harm, is a low probability, but potentially very high consequence, event. We also acknowledge that we are somewhat limited due to the lack of real world data related to food defense events associated with wide scale public health harm, and the associated difficulty in making a quantitative comparison of different alternatives. The benefits of any possible approach to the prevention of intentional adulteration, including the proposed requirements and many other possible requirements, are uncertain and cannot be explicitly quantified with real world data related to food defense events associated with wide scale public health harm.

Comment 3) Some comments state that FDA should consider potential costs to the dairy industry and the state agencies that oversee them.

Response 3) This final rule imposes no requirements on dairy farms. For our plans regarding dairy farms, see the preamble of the final rule.

Comment 4) Some comments state that FDA should consider the costs and benefits of addressing economically motivated adulteration, or food fraud.

Response 4) Provisions for preventing economically motivated adulteration of human food are in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation, and their costs and benefits are detailed in the Regulatory Impact Analysis for that regulation.

Comment 5) Several comments state that some mitigation strategies may be more costly for some facilities than our estimates indicated.

Response 5) Our presented cost estimates are averages across the spectrum of facilities covered by this rule. We acknowledge that implementing this rule may be more costly at some facilities. In particular, we expect that the costs for the largest food facilities with the most actionable process steps could be higher than the estimated average costs, even if they already have a food defense program, simply because they have so many more actionable process steps than smaller producers. The average cost estimates include the thousands of smaller food producers also covered by the rule, as shown in the 'Costs of the Rule' section of the RIA.

Comment 6) Some comments state that FDA failed to account for the cost of implementing several costly focused mitigation strategies when calculating industry's anticipated costs to implement this rule. Instead, FDA calculated the initial and recurring costs incurred by industry using relatively inexpensive mitigation strategies.

Response 6) The rule is written to allow facilities the flexibility to implement whichever set of mitigation strategies is most appropriate to their facility. Producers do not need to use all strategies; they can choose which mitigation strategies to employ at their facilities. We expect that facilities will implement the most cost effective mitigation strategies that address their significant vulnerabilities, and not implement strategies that would be prohibitively expensive when others would suffice.

Comment 7) Some comments state that FDA incorrectly asserts that there will be no additional costs for food facilities that are already implementing the food defense measures contained in existing FDA guidances.

Response 7) We apologize for the lack of clarity. The statement was meant to refer only to the mitigation costs. We know that many facilities are already implementing several mitigation strategies that satisfy the mitigation strategy requirement of the rule. When we calculate the average cost per covered facility of implementing mitigation strategies, we account for the percentage of facilities that

already have such strategies. However, as shown in the RIA, all of our estimates for learning about the rule, conducting vulnerability assessments, training, monitoring and corrective action, verification, and documentation assume that all covered facilities will bear these additional costs.

Comment 8) Some comments state that an alternate approach of loosely protecting the entire facility rather than focusing on the most vulnerable production steps would minimize implementation costs for industry, because many leading companies have already implemented the measures that would be required by this alternate approach.

Response 8) We agree that different approaches may have lower costs for a subset of the industry; however, an approach that loosely protects the entire facility would not significantly minimize, or prevent, intentional adulteration of food at the points, steps, or procedures at highest risk of intentional adulteration because it would not address the highest risk scenario in which an attacker has legitimate access to a facility (see discussion in section V.C. of the rule). We have a duty to provide adequate protection for the public while minimizing overall costs of the rule. While our approach may impose more costs on companies producing more food, we believe it imposes fewer costs on smaller companies. In particular, we expect that the costs of our approach for the largest food facilities with the most actionable process steps may be higher than the estimated average costs, even if they already have a food defense program, simply because they have so many more actionable process steps than smaller producers. An alternate approach focused on facility protection would impose more equal per-facility costs on all producers, which would lower the cost for these few hundred large producers while raising it for the several thousand smaller producers.

Comment 9) One comment asserts that the Institute of Food Technologists / Research Triangle Institute (RTI) model upon which the PRIA relies heavily was incomplete and did not encompass a broad segment of the food industry.

Response 9) We agree that the model does not have all the data we would like. However, it is the best data currently available. It includes a representative sample of food production facilities, chosen to give data on a wide variety of food production. While it does not include the costs of all possible mitigation strategies, it does include the costs of a suite of mitigation strategies that we believe would be sufficient to comply with the mitigation strategy requirements of the rule for most facilities. To the extent that there are other possible mitigation strategies with no or lower costs compared to the ones in the model, this will only decrease the average expected costs of the rule, because companies could

choose to use those other, possibly cheaper, strategies instead of the ones for which we have estimated cost.

Comment 10) One comment notes that the PRIA assumes facilities with sales less than $10 million per year will be exempt from the rule's requirements, and the cost estimates in the PRIA would not be accurate if a different portion of the food industry is subject to the rule.

Response 10) In Table 6 of the RIA, we include cost estimates for other possible facility exemptions. However, the final regulation provides an exemption for all facilities with sales less than $10 million per year. Thus the estimated costs accurately represent the effects of this rulemaking.

Comment 11) One comment states that FDA has produced a standard market failure justification for the regulation focused on externalities, does not provide evidence that food companies have in fact underinvested in preventing terrorist attacks, and does not discuss whether or not these externalities are "inframarginal."

Response 11) The 'Need for Regulation' section of the RIA assumes that managers will internalize the social costs of many negative events, and invest the socially optimum amount in preventing them. The regulation focuses on events that cause more damage than the value of the company. We have observed that larger firms invest substantially more in preventing intentional adulteration incidents than smaller firms, suggesting that our model is accurate; managers invest more in prevention as the larger value of their company causes them to internalize more costs. We believe that these larger investments may be closer to the social optimum, and that our regulation will cause more companies to make targeted investments in reducing the probability of catastrophic attacks that it would not be individually rational for them to make. Under current conditions, unpriced risk reduces the social value of the last (marginal) food product from a company that has underinvested in food defense relative to its market value, meaning that the externality is not inframarginal and regulation may be justified.

Comment 12) One comment asserts that FDA has failed to show in the PRIA precisely which industry categories (NAICS or, as the FDA uses, the older SIC codes) will be affected by this rule. The comment goes on to state that this leaves a number of questions, including what types of foods are covered, how many facilities are exempted by the $10 million cut-off, and how many firms will not have actionable process steps.

Response 12) The final RIA includes a footnote showing the SIC and NAICS codes used in the cost calculations. It also includes more information on how many facilities will be covered and exempted. However, facilities are not covered based on industry category; facilities are required to comply with the rule if they are required to register with FDA, per section 415 of the FD&C Act, and if they are not exempted as described in the Exemptions section of the final rule. Some facilities in the listed codes will not be covered, and some facilities on other codes will be covered, but we believe that both of these numbers are small.

Comment 13) One comment notes that the Analysis of Uncertainty does not specify the probability distributions used.

Response 13) The introduction to the Detailed Analysis section describes the probability distributions used in the analysis.

Comment 14) Some comments state that FDA should use existing estimates for the costs of conducting vulnerability assessments, including those in different industries, rather than basing costs on the estimated time.

Response 14) In the PRIA, we requested information on costs of the various requirements in the proposed rule, including the cost of conducting vulnerability assessments. However, we did not receive any comments providing such information. To our knowledge, there are no existing studies of the cost of doing many things required by this regulation, including conducting vulnerability assessments. Different industries have very different standards for vulnerability assessments; in many cases the processes have little in common except the name. The best way of calculating all administrative costs of this rule's specific requirements is to use the estimated time to do the specific things we require.

Comment 15) One comment notes that, if FDA wants to annualize costs (a practice allowed by OMB), it ought to also discuss total first-year costs and recurring costs.

Response 15) In Table 4 in the PRIA, we included both initial and annualized costs, and each section of the cost analysis included a discussion of initial costs. In Table 4 of the final RIA, we use the same format in reporting of costs.

Comment 16) One comment asks whether the 70 percent average adoption rate for facilities with 100 or more employees for already complying with the mitigation strategies in the Research Triangle Institute model is an assumption or based on data.

Response 16) The referenced documentation for the RTI model includes adoption rate data for all mitigation strategies in the study. Surveys of food producers show an average of 70 percent adoption of the relevant food defense strategies.

Comment 17) Some comments state that the Benefits section of the PRIA is based on many uncertain assumptions.

Response 17) We agree that little data is available regarding benefits, and we were forced to make assumptions. We are trying to prevent a situation that has never happened before, and it is impossible to use standard statistical methods on an event that has never been observed. We believe the assumptions are reasonable. In particular, the assumption that some of the attacks prevented will reduce likelihood of attacks elsewhere is reasonable because in some cases, the strategies mandated by this rule will result in the perpetrators being caught in the act, which will result in their incarceration and subsequent inability to attack other targets.

Comment 18) Some comments state that the Benefits section of the PRIA uses casualty estimates for a terrorist attack that are unreasonably high in light of past natural outbreaks.

Response 18) The casualty estimate for a Scenario 2 attack is based on past natural outbreaks. The estimates for a Scenario 3 attack, one designed by a sophisticated attacker to be more deadly than any natural outbreak, come from peer-reviewed research cited in the PRIA.

Comment 19) Many comments state that the rule imposes a high burden of costs in the form of producing and maintaining records.

Response 19) The annual documentation costs are between $300 and $1,400 per covered facility, with an average of about $800.

## F. Costs and Benefits of the Rule: Detailed Analysis

There is a large degree of uncertainty inherent in this analysis. To reflect this uncertainty, we define many inputs as probability distributions. In this section, we illustrate the analysis with the mean value of each probability distribution, rounding in the text for ease of reading but using the unrounded point estimate in the example calculation to avoid introducing rounding errors. In the Analysis of Uncertainty, we generate low and high estimates for the total costs with a Monte Carlo simulation that draws values at random from the probability distributions.

For some parameters, we have a low and high estimate. In these cases, we draw the parameter from a uniform distribution. The low estimate is the minimum value of the distribution and the high estimate is the maximum value of the distribution. For other parameters, we have a low estimate, a high estimate, and a best estimate. In this case, we draw the parameter from a triangular distribution. The low estimate is the minimum value of the distribution, the best estimate is the peak of the distribution, and the high estimate is the maximum value of the distribution. The mean of a triangular distribution is the average of the three estimates used to generate the distribution.

When explaining the calculations, we show example calculations with the 7 percent discount rate. Both 7 percent and 3 percent discount rates are reported in the summary tables.

### 1. Costs of the Rule

We estimated the number of firms, facilities, and employees that the rule applies to by using facility-level data from Dun & Bradstreet's Global Business Database (Ref. (2)). We used both SIC and NAICS codes[3] to find facilities that the rule applies to. We counted all human food manufacturers, including bottled water, nonalcoholic beverage, dietary supplement, and food additive manufacturers. We did not count farms or retail establishments because they are not required to register. We did not count warehouses because most will be exempt. Some warehouses, such as those storing food in liquid storage tanks, may be affected by the rule, and some manufacturers, such as packers and labelers, may not be affected by the rule because they qualify for the exemption. However, we believe that both of these numbers are small.

[3] SIC codes > = 20000000 and < 22000000; NAICS codes > = 310000 and < 320000

To determine the number of facilities covered under this rule, we first matched each facility to its parent firm. Next we added up the sales for all the facilities in each firm to determine the total sales for that firm. Firms that have more than $10 million in annual sales are covered under this rule, and the facilities covered are those that fall under those firms. We found 18,080 firms with less than $10 million in annual sales and 3,247 firms with more than $10 million in sales. The total costs of learning about the rule are based on these firm numbers. We found 9,759 food production facilities that are part of firms with more than $10 million in annual sales and are estimated to be covered by this rule. The total costs of identifying actionable process steps, implementing mitigation strategies, food defense monitoring, corrective actions, and verification are based on this number of facilities. We found about 1.2 million employees that the rule applies to. The total costs of training are based on this employee number.

The facilities that are part of firms with more than $10 million in sales produce 97-98 percent of the total sales volume of manufactured packaged food, and the very small businesses produce two percent. The rule therefore covers 98 percent of the food market that is vulnerable to terrorist attack that could cause massive casualties; two percent of the money that consumers spend on this type of food is spent on food that is not covered by the regulation (Ref. (2)).

The rule generates several new requirements for food facilities required to register. We calculate these separately. In some cases, the actions that the rule requires are already being done (Ref. (3)).

a. Learning About the Rule

The 3,200 firms that are fully covered by the rule will spend time to learn about the rule and how to properly implement it, and to develop a general corporate approach and strategy for complying with the rule's requirements. We estimate that this will take one individual at the level of an operations manager between 20 and 40 hours, or an average of 30 hours, per business. We also estimate that this will require a legal analyst to spend between 10 and 30 hours, or 20 hours per business.

The mean hourly wage of an operations manager in the food manufacturing industry is $55.59 (Ref. (4)). We double this cost to account for benefits and overhead, making the total cost of time $111.18. The cost of the operations manager's time is about $3,300 per firm ($111.18 * 30 = $3,335). The mean hourly wage of legal analysts in the food industry is $74.99 (Ref. (4)), or $149.98 including benefits and overhead. The cost of legal time is about $3,000 per business ($149.98 * 20 = $2,999). The total initial cost per business is about $6,300. We annualize this cost over ten years at a 7 percent discount rate and calculate average annualized costs of about $900 per business. Because there are about

3,200 firms covered by the rule, the total annualized costs to covered firms for learning about the rule will be about $2.9 million ($902 * 3,247 = $2,928,794).

The 18,000 firms that are exempt from the rule because they have less than $10 million in annual sales will each incur a burden to learn enough about the rule to verify that they are exempt. This will not require learning about the entire rule; it will only require learning the exemption criteria and the documentation requirement for very small businesses. We estimate that this will take one individual at the level of an operations manager between zero and five hours, or an average of 2.5 hours, per business.

At a time cost of $111.18 per hour for the operations manager, the learning cost per exempt business is then about $280 ($111.18 * 2.5 = $277.95). We annualize this cost over ten years at a 7 percent discount rate and calculate annualized costs of about $40 per exempt business. Because there are about 18,000 exempt firms (Ref. (2)), the total annualized costs to these firms for learning about the rule will be about $720,000 ($39.57 * 18,080 = $715,495).

b. Developing a Food Defense Plan

Developing a food defense plan requires the following actions:

- Conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps.
- Identify the mitigation strategies to be used at the actionable process steps.
- Write procedures for food defense monitoring, corrective actions, and verification at the actionable process steps.

A food defense plan must be developed for each covered facility. We estimate that between 60% and 90% (average 75%) of facilities will conduct a vulnerability assessment using the Key Activity Types method described in the preamble of the proposed rule [4], and that the rest will use some other method after training their managers in that method. Solely for the purposes of this economic analysis, we assume that operations managers will do all of the work of creating a food defense plan. To the

[4] For a description of Key Activity Types and their use to identify actionable process steps, see the Intentional Adulteration Proposed Rule FR Page 78039-78042.

extent that they designate work to other individuals, as the rule allows, the cost of the rule will be lower than what we estimate here.

For the facilities that use the Key Activity Types method, we estimate that employees will spend 8 to 18 hours, or an average of 13 hours, training in the use of the method and developing the food defense plan (Ref. (5)). At a time cost of $111.18 per hour for operations managers, the initial cost of developing a food defense plan for these facilities is then about $1,400 per facility ($111.18 * 13 = $1,445).

In order to conduct a vulnerability assessment using another method, employees must receive more extensive training. For those employees who do not choose to utilize the Key Activity Type guidance to conduct a vulnerability assessment and have little prior knowledge or expertise in conducting assessments, we estimate that this training will require one or two (average 1.5) employees per facility to spend three days (24 hours) in training. At a time cost of $111.18 per hour, the training cost per facility is about $4,000 ($111.18 * 1.5 * 24 = $4,002).

For the facilities that do not use the Key Activity Types method, we estimate that employees will have to spend 27 to 55 hours, or an average of 41 hours, developing the food defense plan (Ref. (5)). At a time cost of $111.18 per hour for operations managers, the initial cost of developing a food defense plan for these facilities is then about $4,600 per facility ($111.18 * 41 = $4,558).

Given our assumption that about 75% of facilities will use the Key Activity Types method of conducting a vulnerability assessment, the average initial costs per covered facility of creating a food defense plan are about $3,200 [$1,445 * 75% + ($4,002 + $4,558) * 25% = $3,224]. At a seven percent discount rate, the annualized costs are about $460 per covered facility.

At a minimum, facilities must conduct a reanalysis of the food defense plans at least once every three years. We estimate that this required reanalysis will cost 40% of the initial cost of making the plan, and that it will be done every two to three years (average 2.5), for an average of 16% of the initial cost per year. Additionally, plans must be reanalyzed whenever there are significant changes at the facility that may increase vulnerabilities associated with points, steps, or procedures. We estimate that this will happen at 20% of facilities annually, and will cost 20% of the initial cost when it does happen, for an

average of 4% of initial plan costs per facility. Therefore, we estimate an annual cost of 20% (16% + 4%) of the initial cost of making a food defense plan. This annual cost of reanalysis is then about $640 per facility (3,224 * .02 = $644.84)[5].

We add the annualized initial costs to the annual reanalysis costs to calculate total annualized costs of about $1,100 per facility ($459 + 645 = $1,104). Because there are about 9,759 facilities covered by the rule (Ref. (2)), the total annualized cost to covered facilities for creating food defense plans and reanalyzing these plans is about $11 million ($1,104 * 9,759 = $10,772,964).

c. Mitigation Strategies

The rule requires firms to identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated.[6] The rule does not specify a specific number or set of mitigation strategies to be implemented. The rule gives operators the flexibility to choose the most appropriate mitigation strategies for their facility.

For the purposes of cost estimation, we considered the implementation of the eight least expensive of the following ten mitigation strategies:[7]

1. Establish check-in and shipment verification procedures, such as seals and associated documentation.
2. Restrict movement of delivery drivers once they are in the facility.
3. Secure transfer hoses in locked cabinets.
4. Establish key check-in/check-out procedures.

[5] We include the cost of vulnerability assessment training here to account for manager turnover.

[6] For discussion of how the proposed mitigation strategies will reduce the probability of catastrophic food adulteration events, see the "Proposed § 121.135 – Focused mitigation strategies for actionable process steps" section of the preamble.

[7] The list was generated with input from internal technical experts who have extensive experience conducting vulnerability assessments and identifying mitigation strategies. While mitigation strategies are facility-specific and are tailored to address vulnerabilities associated with a facility's processing environment, we believe the list is a reasonable approximation of what facilities might do and serves as a representative sampling of mitigation strategies facilities might employ. The examples provide a range of capital investment and operational changes to illustrate the diversity of potential mitigation strategies.

5. Install locks on tanks.
6. Physically inspect cleaned equipment.
7. Prohibit staff from bringing personal items into manufacturing areas.
8. Ensure clear line of sight to actionable process steps (e.g., store stacks of pallets in less obstructive location).
9. Reduce staging time of ingredients.
10. Retrofit equipment to reduce accessibility (e.g., install lids on open mixers).

We do not require a specific set of mitigation strategies to be applied. Rather, we expect facilities to identify and implement those mitigation strategies that are necessary and relevant for each actionable process step in their operation. The mitigation strategies used to estimate costs serve as examples of mitigation strategies that a facility may identify as suitable for their operation. We expect that the mitigation strategies a facility employs will be sufficient to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, but under this rule the determination of which mitigation strategies to implement rests with the facility.

Some of the covered facilities are already implementing these mitigation strategies (Ref. (3)). We do not have data on the current adoption rates and costs of these exact mitigation strategies, but we do have data on the adoption rates and costs of many similar strategies. Where we have data on a similar strategy, we use the published data, and we estimate new costs where no data exists.

RTI International and the Institute of Food Technologists supplied FDA with data on food defense practices from industry interviews and a literature review (Ref. (6)). The following table shows the practices for which they provided cost estimates, and the strategy or strategies on our list that are equivalent or accomplish the same function:

Table 2.—Mitigation Strategies with Cost Estimates

| Strategy with RTI Cost Estimate: | Equivalent to:[8] |
|---|---|
| Prohibit after hours key drop deliveries of raw materials | 1,2 |
| Electronic access controls for employees | 4,2 |

[8] By "equivalent," we mean that these strategies serve the same function and provide an equivalent risk reduction. To the extent that a cheaper strategy can be used, the costs of the rule will be lower than these estimates.

| | |
|---|---|
| Secured storage of finished products | 3,5,10 |
| Secured storage of raw materials | 3,5,10 |
| Cameras with video recording in storage rooms | 8 |
| Peer monitoring of access to exposed product | 8 |

This leaves strategies 6, 7, and 9 without estimates of cost or adoption rates.

RTI used their data to create a prototype food defense cost model. We use this model to estimate the average cost per facility of implementing all of the mitigation strategies in the table above for facilities with 100 or more employees that did not currently employ them. When calculating the costs of each strategy, zero costs are assigned to facilities currently implementing that strategy. The average adoption rate for these strategies is 70 percent. The model does not take into account potential cost savings from implementing multiple strategies simultaneously. To the extent that cost savings can be realized by doing this, the costs of the rule will be lower than our estimate. It is also likely that companies will not need to implement all of the strategies we considered here for cost estimation purposes. To the extent that they need to implement fewer strategies, the costs of the rule will be lower than our estimate.

The costs of these mitigation strategies are a mix of initial capital costs and annual personnel costs. The costs of prohibiting after-hours key drop deliveries are the labor hours that would likely be necessary to supervise all raw materials deliveries during the plant's operating hours. The costs for electronic access control systems include the initial costs of installing readers on doors in the facility and setting up the initial cards for each employee in the plant, and annual costs for additional cards (purchase costs and labor costs to program the cards for each employee). The costs of secured storage of finished products and raw materials are the costs of installing electronic access controls on the doors to the rooms with those products. The costs of surveillance cameras with video recording in storage rooms are primarily the costs of purchasing and installing the cameras. The costs of peer monitoring are the costs

of annual training and posting signs with reminders and numbers to call.[9] All initial capital costs are annualized over ten years. The costs of these strategies, annualized at 7%, are in Table 3.

We estimate that physical inspection of cleaned equipment (Strategy 6) will require first-line supervisors and other people responsible for quality control to spend about six minutes per inspection, and that there will be 100 to 300 inspections per year, resulting in a time cost of between 10 and 30 hours per year, per facility, or an average of 20 hours. We estimate that about 70 percent of facilities already employ this mitigation strategy, so this cost will be borne by 30 percent of facilities. The mean hourly wage of a first-line supervisor of production and operating workers in the food industry is $25.27 (Ref. (4)), or $50.54 including benefits and overhead. This means that their time costs will be about $1,000 per year per facility newly implementing the strategy ($50.54 * 20 = $1,010.80). The average annual cost per covered facility is then about $300 ($1,010.80 * 30% = 303.24).

We estimate that establishing procedures to prohibit staff from bringing personal items into manufacturing areas (Strategy 7) will require one individual at the level of an operations manager, and also a legal analyst, between one and three hours, or an average of two hours each, per facility. We estimate that about 70 percent of facilities already employ this mitigation strategy, so this cost will be borne by 30 percent of facilities. At a time cost of $111.18 per hour for the operations manager and $149.98 for the lawyer, the total one-time cost per facility newly implementing this strategy is then about $520 (2 * $111.18 + 2 * $149.98 = $522.32). The average cost per covered facility is then about $160 ($522.32 * 30% = $156.70). The costs of enforcing these procedures are included in the 'Food Defense Monitoring and Corrective Action' section below.

Facilities may need to provide secure areas to store personal items that cannot be brought to the manufacturing area. However, many facilities already provide employee lockers, break rooms, or other areas where personal items can be kept away from processing areas because it is common practice to restrict personal items from processing areas due to food safety and sanitation reasons. Alternatively, facilities could require employees to leave most personal items at home or in employees' cars. We believe that there will be no additional costs from these procedures.

---

[9] We believe that producers will only use peer monitoring if there are many people already working who can see each other, and that they will not hire someone just to watch a few people. If producers have people working alone, they will use video monitoring instead of peer monitoring.

We are unable to estimate the cost of reducing the staging time of ingredients (Strategy 9) because decisions about the flow of raw materials through a production plant can have a wide variety of effects on productivity, personnel costs, and production planning. For the purposes of this cost estimate, we assume that Strategy 9 will be more expensive than the other ones, and therefore will not be chosen. In some facilities, Strategy 9 may be cheaper, and may be chosen. To the extent that this happens, the costs of the rule will be lower than our estimates.

Based on experience in working with facilities to implement mitigation strategies (see footnote 4), we believe that it is likely that facilities would employ all but one of the strategies other than reducing the staging time of ingredients, and that the strategy not employed would be peer monitoring, the one with the highest average annualized cost. To the extent that fewer mitigation strategies are necessary to protect the actionable process steps, the costs of the rule will be lower than our estimates.

The total initial cost of implementing mitigation strategies is about $10,000 per covered facility. The annualized cost of these initial costs is about $1,400 per facility. The annualized recurring costs are about $1,500 per facility. The total annualized cost is about $2,900 per facility:

Table 3.—Costs of Mitigation

| **Average cost per covered facility** | **Initial** | **Recurring** | **Total Annualized** |
|---|---|---|---|
| Prohibit after hours key drop deliveries of raw materials | $ - | $ 1,070 | $ 1,070 |
| Electronic access controls for employees | $ 1,122 | $ 82 | $ 242 |
| Secured storage of finished products | $ 1,999 | $ - | $ 285 |
| Secured storage of raw materials | $ 3,571 | $ - | $ 508 |
| Cameras with video recording in storage rooms | $ 3,144 | $ - | $ 448 |
| *Peer monitoring of access to exposed product (not used)* | *$ 47* | *$ 1,122* | *$ 1,129* |
| Physical inspection of cleaned equipment | $ - | $ 303 | $ 303 |
| Prohibit staff from bringing personal items | $ 157 | $ - | $ 22 |
| **Total** | **$ 9,993** | **$ 1,455** | **$ 2,878** |

Because there are about 9,800 facilities that are part of firms that must implement mitigation strategies (Ref. (2)), the total annualized costs of mitigation strategies in these facilities will be about $28 million ($2,878 * 9,759 = $28,086,159).

d. Food Defense Monitoring, Corrective Action, and Verification

The rule requires that facilities establish and implement procedures for monitoring the mitigation strategies, and for taking corrective action if mitigation strategies are not properly implemented.

It also requires that facilities verify that food defense monitoring is being conducted, appropriate decisions about corrective actions are being made; and that the mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities.

We conducted an expert elicitation to determine the per-facility amount of time required by these three activities, and what percentage of the activities could be done by production workers and what percentage must be done by line supervisors (Ref. (5)). We report the average values given by the experts here, and in the Monte Carlo simulation, we choose one value in each simulation run.

We estimate that monitoring activities will take an average of 114 hours per facility, and that 78% of monitoring hours can be done by production workers, for an average of 88 hours of worker time and 26 hours of supervisor time.

We estimate that corrective actions will take an average of 22 hours per facility, and that 39% of corrective action hours can be done by production workers, for an average of 8 hours of worker time and 13 hours of supervisor time.

We estimate that verification activities will take an average of 39 hours per facility, and that 14% of verification hours can be done by production workers, for an average of 5 hours of worker time and 34 hours of supervisor time.

The total time required of line production workers by these three activities is 102 hours. The mean hourly wage of a line production worker in the food manufacturing industry is $12.87 (Ref. (4)). We double this cost to account for benefits and overhead, making the total cost of time $25.74. The average cost of worker time is then about $2600 per year per facility (102 * $25.74 = $2,625).

The average total time required of first-line supervisors by these three activities is about 73 hours. Given the time cost of $50.54 for first-line supervisors, the average cost of supervisor time is then about $3,700 per year per facility (73.05 * 50.54 = $3,692).

We add up these labor costs to calculate that the costs for food defense monitoring, corrective action, and verification will be about $6,300 per year per facility ($2,624 + $3,692 = $ 6,316).

Because there are about 9,800 facilities that are part of firms that must implement mitigation strategies (Ref. (2)), the total annual costs of food defense monitoring, corrective action, and verification in these facilities will be about $62 million ($6,316 * 9,759 = $61,639,588).

e. Training

Some training required by the rule is generic and some is specialized. The rule requires that certain personnel be trained in: (1) food defense awareness and (2) their respective responsibilities in implementing mitigation strategies. FDA has published training courses, which are available online and can be used to meet the requirement for food defense awareness training. Training employees in their specific responsibilities in implementing mitigation strategies (relevant to the actionable process step to which the employee is assigned) is included in the cost estimates for those strategies. The cost of training associated with development of the food defense plan, choosing and explaining mitigation strategies, and performing a reanalysis of the plan is included in the cost of learning about the rule. The cost of training associated with performing or overseeing the performance of a vulnerability assessment is included in the cost of mitigation strategies and actionable process steps.

All supervisors and employees assigned to actionable process steps in covered facilities must receive appropriate training in food defense awareness, and this training must be documented. We estimate that the training and documentation will require between zero and two hours, or an average of one hour, per employee when the rule takes effect or when a new employee is hired. We also estimate that between 10 percent and 50 percent, or an average of 30 percent, of all workers and supervisors in covered facilities are assigned to work at actionable process steps.

The mean hourly wage in the food manufacturing industry is $16.67 (Ref. (4)), or $33.34 including benefits and overhead. This average includes both production workers and supervisors. With one hour of training per worker, the initial training cost is $33.34 per worker receiving training. We annualize this cost over ten years at a 7 percent discount rate and calculate average annualized costs of about $4.75 per employee receiving training. Employee turnover in the food manufacturing industry is high, so we estimate that turnover is about 33 percent for the covered facilities. With a turnover of 33 percent, annual training costs per job will be about $11 per position requiring training. Adding the annual training costs to the annualized initial costs yields annual training costs of about $15.75 per job at an actionable process step ($4.75 + $11.00 = $15.75).

There are about 1.2 million employees in firms covered by the rule (Ref. (2)), so the total annualized costs of the training required by the rule will be about $5.8 million ($15.75 * 1,224,011 * 30% = $5,783,109).

f. Annual Documentation

The facilities covered by the rule will also incur annual costs to document compliance with the food defense plan. These costs are in addition to the per-employee costs of documenting that employee's training, calculated in the previous section. We estimate that the overall documentation would, without any existing records that can be used, take one individual at the level of an operations manager, and also a legal analyst, between zero and ten hours, or an average of five hours each per facility. However, facilities may use existing documentation to satisfy the requirements of this rule. Many mitigation strategies are already used by 70% of facilities, and we estimate that about 50% of facilities using these strategies will already be producing documentation that will satisfy the requirements of this rule. So, on average, 35% of the documentation is already completed, and this rule will require an average of 3.25 hours each per facility.

At a time cost of $111.18 per hour for the operations manager and $149.98 per hour for the legal analyst, the recurring annual costs are about $850 per facility ($111.18 * 3.25 + $149.98 * 3.25 = $ 848.77). Because there are about 9,800 facilities covered by the rule (Ref. (2)), the total annualized documentation costs to these firms will be about $8.3 million ($848.77 * 9,759 = $8,283,146).

Businesses that are exempt from the rule because they are very small businesses must be able to demonstrate to FDA with documentation that the facility qualifies for the exemption. We estimate that this preparation and updating of files will take one individual at the level of an operations manager between zero and one hour, with a mean estimate of 30 minutes, each year.

At a time cost of $111.18 per hour, the annual costs of documentation are about $56 ($111.18 * .5 = $55.59). Because there are about 18,000 firms that are exempt because they are very small businesses (Ref. (2)), the total annualized costs to these firms for documenting their exemption will be about $1.0 million ($55.59 * 18,080 = $1,005,067).

g. Costs to Foreign Firms

There are about 61,000 foreign food manufacturers registered to import food into the U.S. (Ref (7)). Some of these facilities will also incur costs as a result of the rule. We estimate that the distribution

of foreign facilities is similar to that of domestic facilities in ownership structure, size, and type. In that case, the proportion of domestic and foreign facilities that the rule applies to is the same. Because we lack survey data about baseline foreign facility food defense practices and the likely costs to incorporate all the changes to comply with the rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic facilities; they will have the same proportion of baseline practices and the same proportion of covered and exempt facilities. Foreign facilities are likely to have lower labor costs, but also lower adoption rates, so our best estimate of the average cost per foreign facility is that it would be the same as the average cost per domestic facility.

Because about 9,800 of the 28,000 domestic manufacturing facilities have more than $10 million in annual sales and are covered by this rule, we estimate that the rule also applies to about 21,000 foreign facilities (9,759/28,000 * 61,000 = 21,261).

The average annualized cost of the rule for domestic facilities that the rule applies to is about $12,000 ($117,493,636 / 9,549 = $12,040). The total estimated annualized cost to foreign firms is then about $260 million ($12,040 * 21,261 = $255,968,278 ). The costs are $250 million when annualized at 3%, and the initial costs are $550 million.

h. Costs to FDA

FDA will incur costs to enforce this rule. These costs include setting up an inspection system, training inspectors, conducting regular inspections of food defense activities, and taking action against producers who are not complying with the rule. While we are currently in the process of developing a comprehensive compliance program in order to implement this rule, we were unable to estimate these costs. We do not know what the inspection system will be, how many food defense inspectors will be trained, how many food defense inspections FDA will undertake, or what the probability of enforcement action is.

i. Total Costs

The total cost of the rule to producers, annualized over 10 years at a 7 percent discount rate, is about $380 million. With a 3 percent discount rate, the annualized cost is about $360 million. The first-year cost is about $800 million. Counting only domestic firms, the total annualized costs are $120 million, with initial costs of $260 million. The average annualized cost per covered facility is $12,000, and the average annualized cost per covered firm is about $36,000.

The following table shows, for each component of the rule, the total first-year cost and the annualized cost at 3 percent and 7 percent discount rates. It also shows the average costs per exempt and covered firms. Totals are in millions of dollars, and averages are in dollars:

Table 4.—Annual, Initial, and Annualized Costs

| **Cost ($Millions)** | **First Year** | **Annualized 3%** | **Annualized 7%** |
|---|---|---|---|
| Exempt Firms Learning: One Time | $ 5 | $ 1 | $ 1 |
| Exempt Firms Documentation: Annual | $ 1 | $ 1 | $ 1 |
| **Exempt Domestic Firm Subtotal** | **$ 6** | **$ 2** | **$ 2** |
| *Exempt Firm Average ($)* | *$334* | *$ 88* | *$ 95* |
| Covered Firms Learning: One Time | $ 21 | $ 2 | $ 3 |
| Creating Food Defense Plan: One Time | $ 31 | $ 4 | $ 4 |
| Updating Food Defense Plan: Annual | $ - | $ 6 | $ 6 |
| Initial Mitigation: One Time | $ 98 | $ 11 | $ 14 |
| Mitigation: Annual | $ 14 | $ 14 | $ 14 |
| Monitoring, Corrective Action, Verification: Annual | $ 62 | $ 62 | $ 62 |
| Initial Training: One Time | $ 12 | $ 1 | $ 2 |
| New Employee Training: Annual | $ 4 | $ 4 | $ 4 |
| Covered Facilities Documentation: Annual | $ 8 | $ 8 | $ 8 |
| **Covered Domestic Firm Subtotal** | **$ 250** | **$ 113** | **$ 117** |
| *Covered Domestic Firm Average ($)* | *$77,000* | *$35,000* | *$36,000* |
| **Subtotal (Domestic Industry Cost)** | **$ 256** | **$ 115** | **$ 120** |
| Cost to Foreign Firms | $ 545 | $ 247 | $ 256 |
| Cost to FDA | Unknown | Unknown | Unknown |
| **Total** | **$ 801[10]** | **$ 362[10]** | **$ 375[10]** |

[10] This total does not include costs to FDA of enforcing the rule.

2. Benefits of the Rule

This rule is focused on reducing the potential for intentional adulteration of food at an actionable process step, i.e., a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent a significant vulnerability. This reduction can be from detecting the perpetrators as they attempt the act, or from deterring an attack because the food supply is known to be harder to contaminate. Deterring an attack may cause perpetrators to choose an alternate target (Ref. (8)), so the benefit of the rule is based on the difference in damage between the attack on a large food production facility that is prevented and the alternate attack on some other target that is conducted instead.

a. General Model

The expected annual benefits of preventing intentional adulteration of food are:

1) the annual likelihood of an attempted attack that will succeed without the rule; multiplied by

2) the likelihood that the otherwise successful attack will be prevented as a result of the rule; multiplied by

3) the expected damage that the attack would do if it was successful; minus the damage, if any, of an alternate attack that happens as a result of the perpetrator choosing a different target.

A successful attack is one that is not detected until after the adulterated food has harmed consumers. Although the rule is intended to reduce the possibility of individuals or groups successfully using the food supply to harm large numbers of people, the potential benefits of the rule come from preventing various attack scenarios. Solely for the purpose of this analysis, we define three attack scenarios and estimate the harm caused in each scenario.

Scenario 1 attacks are those that resemble previous acts of intentional adulteration in the United States. There have been several documented cases (Ref. (9)) of intentional adulteration of food for

reasons other than profit in the United States, but all of these incidents occurred at the retail level, and none of them resulted in fatalities or widespread illness.[11]

Scenario 2 attacks are those that resemble past cases of major outbreaks of foodborne illness in the United States.

Scenario 3 attacks are those that could be caused by skilled inside attackers with advanced knowledge of contaminants and the food supply, and the intention to kill as many people as possible. Such an attack would cause tens or hundreds of thousands of illness cases, and potentially thousands of deaths.

This rule is designed to prevent Scenario 3 attacks.[12] While it is not intended to prevent Scenario 1 or 2 attacks, there may be collateral benefits in preventing some such attacks.

The benefits of the rule are a reduction in the chances of these attacks being attempted and the success of the attacks if attempted. We do not have enough information to calculate this reduction in probability. We have very limited information on the expected number of attempted attacks per year, and no numerical estimate of how this rule will reduce the chances that each attack is successful. This means that, for the purposes of this analysis, we are unable to monetize the benefits of the rule.

Therefore, we present a breakeven analysis. We calculate the dollar value of the damage that the average attack might cause, and subtract the damage multiplied by the probability of an alternate attack, to find the expected monetized benefit if the rule prevents an attack. We then compare that number to the annual cost of the rule. This yields the annual reduction in the odds of a successful attack at which the benefits of the rule outweigh the costs.

We conduct this analysis separately for each attack scenario, presenting the breakeven point for the rule assuming that it only prevented attacks of that type. It is possible that the rule may prevent

---

[11] While there have been many acts of intentional adulteration outside of the U.S. that have resulted in fatalities, in all cases that we are aware of, the point of adulteration has occurred close to the point of consumption. These events have occurred in a post-manufacturing environment, which is outside the scope of this rule. Specifically, there are many reported examples of fatalities occurring due to post-manufacturing adulteration of food in China where restaurant owners or operators intentionally adulterated competitors' food.

[12] For discussion of how this rule would prevent these attacks, see our responses to Comments 1 and 6 in the preamble, which describe the overall framework for the rule and how the requirements within the framework work as a system to significantly minimize or prevent significant vulnerabilities at actionable process steps.

attacks of all three types, but we do not have the information required to adjust the breakeven points to reflect this.

b. Scenario 1 Attacks

There have been several documented attacks on the U.S. food supply (Ref. (9)), although none of them occurred at an actionable process step in a covered facility. The recorded attacks on the food supply in the U.S. have each resulted in several dozen to a hundred illnesses and no fatalities. Future attacks that also did not occur at actionable process steps would likely cause harm of similar magnitude. Although the rule is not intended to cover such attacks, the food defense awareness training required by the rule might result in the prevention of these attacks in covered facilities.

Based on this data (Ref. (9)), we estimate that the average Scenario 1 attack would cause 50 cases of illness, and that each case would cost about $2,000 (Ref. (10)), so that the average health damage per attack is $100,000 ($2,000 * 50 = $100,000).

We believe that such an attack would cause a recall of the affected food. The average cost of a small or medium recall is about $10 million, as described by research by the Grocery Manufacturers' Association (Ref. (11)). If a Scenario 1 attack is prevented, then there would be no alternate attack, because the attack would be either one of convenience or motivated by a desire to harm one specific company, and would not be intended to cause wide scale public health harm. Therefore, the benefits per prevented Scenario 1 attack are about $10 million ($10 + 0.1 = $10.1). Note that the casualty estimates are based on cases where there was a recall; in the absence of detection and recall, casualties would likely have been higher and there may have been fatalities.

The annualized costs of the rule are about $380 million. If the actions undertaken as a result of this rule only prevented Scenario 1 attacks, they would have to prevent 37 or more Scenario 1 attacks per year for the benefits to be larger than the costs ($376 / $10.1 = 37.25).

c. Scenario 2 Attacks

A Scenario 2 attack is one that produces casualties equivalent to a major outbreak of food-related illness due to unintentional contamination at a production facility. We estimate that the average Scenario 2 attack would result in about a thousand illnesses and ten fatalities, based on the history of major outbreaks described in the FDA’s Risk Assessment for Food Terrorism (Ref. (12)). Note that this is a

mean, not a median; most major outbreaks cause around a hundred illnesses but public health estimates for some outbreaks indicated more than 100,000 illnesses (Ref. (12)).

The monetized value of illness from such an attack is about $2 million ($2,000 * 1,000 = $2,000,000). With a Value of a Statistical Life of $9 million, the monetized value of the deaths is $90 million ($9 * 10 = $90). Such an attack would also likely prompt a major recall of the affected food, and major recalls are much more expensive than small or medium recalls, costing about $200 million (Ref. (11)). The total cost of an attack is then $292 million. ($2 + $90 + $200 = $292). Again, the casualties would likely be higher without the recall.

We do not know the probability of an alternate attack, so we model it as a uniform distribution with minimum zero and maximum one, with an average estimate that 50 percent of Scenario 2 attacks on the food supply prevented by this rule will result in an alternate attack on some other target. We do not know how much damage this alternate attack would cause, but we know that it is expected to cause at least some damage, and slightly less damage than an attack on the food supply. If an alternate attack was expected to cause more damage for the same amount of terrorist effort, it would have been chosen as the target instead of the food supply. Therefore, we estimate the damage caused by the alternate attack as a uniform distribution with minimum slightly more than zero and a maximum slightly less than the expected damage of an attack on the food supply, with an average estimate of 50 percent of the expected damage.

Therefore, the average expected benefits of preventing a Scenario 2 attack on the food supply are about $220 million ($292 * (1- (0.5 * 0.5)) = $219).

If the actions undertaken as a result of this rule only prevented Scenario 2 attacks, they would have to prevent 1.7 attacks every year for the benefits of the rule to outweigh the costs ($376 / $219 = 1.72). While the rule is not designed to specifically address all acts of intentional adulteration that may be possible, we do believe that if an act of intentional adulteration were attempted at an actionable process step, the mitigation strategies would likely detect or foil the attempt, regardless of the intent of the adulteration.

d. Scenario 3 Attacks

The hypothetical Scenario 3 is based on an act of intentional adulteration resulting in wide scale public health harm. FDA has conducted many vulnerability assessments which, among other things,

evaluate the potential public health impact of an act of intentional adulteration. We have analyzed a wide variety of food production scenarios in these assessments, representing a broad cross-section of the food industry. These assessments resulted in a wide range of public health impact estimates, with some resulting in significant public health impact estimates. These findings are classified and not available for inclusion in this document. The open source research by Wein and Liu (Ref. (13)) serve as an appropriate proxy for evaluating potential public health impact of an intentional adulteration of food when the intent of the adulteration is to cause public health harm. Consequently, the Wein and Liu findings serve as an appropriate basis for the Scenario 3 breakeven analysis.

We therefore estimate the damages caused by an attack that causes 5,000 fatalities and 100,000 illnesses. The advanced techniques that would cause a Scenario 3 attack would likely generate average illness costs higher than the other two scenarios; we estimate that each nonfatal case of illness would have a cost of about $50,000 (Refs. (10) and (13)). The monetized value of the illnesses is about $5 billion ($50,000 * 100,000 = $5,000,000,000) and the monetized value of the deaths is about $45 billion (9 * 5,000 = 45,000), for a total health damage of $50 billion ($5 + $45 = $50). As with the Scenario 2 attack, there may be an alternative attack, so the expected health benefit of preventing a large-scale attack is about $38 billion. (50 * (1 - (0.5 * 0.5)) = 37.7).

There are many expected economic damages from a catastrophic terrorist attack in addition to the lives lost and illnesses caused. Catastrophic terrorist attacks cause reductions in investment and consumer confidence, leading to reductions in GDP growth (Ref. (14)). The cumulative damage due to these indirect effects of terrorism are estimated to be $190 billion, most of which comes from a recession and a reduction in the growth rate of the economy (Ref. (14)). If the Scenario 3 attack is prevented, these damages will be prevented, but if an alternate attack of comparable magnitude is conducted, they will not be, so the expected benefit of preventing indirect damages is about $95 billion ($190 * (1 - 0.5) = $95). The total benefit from preventing a Scenario 3 attack is then about $133 billion. ($38 + $95 = $133).

If the actions undertaken as a result of this rule only prevented Scenario 3 attacks, they would have to prevent one attack every 350 years for the benefits of the rule to outweigh the costs ($133,000 / $376 = 353). This is equivalent to the benefits of this rule being greater than the costs if it has a 0.28% or better annual chance of preventing a Scenario 3 attack ($376 / $133,000 = 0.0028).

Counting only the health effects and not the economic damages, the actions undertaken as a result of this rule would have to prevent one Scenario 3 attack every 100 years for the benefits to outweigh the costs ($37,700 / $376 = 100).

3. Analysis of Uncertainty

In Table 4 of this document and elsewhere we present the expected costs of the rule as point estimates. While this is a convenient way to summarize the costs of the rule and explain our calculation, the use of point estimates neglects the large degree of uncertainty intrinsic to the underlying analysis. In Table 5 of this document, we present the results of a Monte Carlo simulation of uncertainty for the eventual annual costs of the rule.

As we explained in the introduction to the Detailed Analysis, many parameters are defined as probability distributions. In our Monte Carlo simulation, we use samples from the probability distributions rather than using the mean values. The randomly chosen numbers are used to form a final estimate. This procedure is repeated 10,000 times, and the results are ranked from lowest to highest. We report the 5th percentile, mean, and 95th percentile of the simulated results:

Table 5.—Low, Mean, and High Total Cost Estimates and Breakeven Numbers

| | 5th Percentile | Mean | 95th Percentile |
|---|---|---|---|
| Initial Cost ($Mil) | $ 683 | $ 802 | $ 933 |
| Annualized 3% ($Mil) | $ 267 | $ 363 | $ 475 |
| Annualized 7% ($Mil) | $ 280 | $ 376 | $ 488 |
| Scenario 1 Attacks per Year | 28 | 37 | 48 |
| Scenario 2 Attacks per Year | 1.3 | 1.7 | 2.2 |
| Scenario 3 Years per attack | 474 | 353 | 272 |
| Scenario 3 Annual Reduction | 0.21% | 0.28% | 0.37% |

Tables 6 and 7 show the low and high estimates, respectively, for all numbers in Table 4. All numbers in these tables are from simulation runs. The subtotals and totals are not the sum of the individual cost numbers. Any total obtained by adding up the $5^{th}$ or $95^{th}$ percentile in each cost category would be an extremely low-probability number.

Table 6.—Annual, Initial, and Annualized Costs, 5th Percentile

| Cost ($Millions) | First Year | 3% | 7% |
|---|---|---|---|
| Exempt Firms Learning: One Time | $ 1 | $ 0 | $ 0 |
| Exempt Firms Documentation: Annual | $ 0 | $ 0 | $ 0 |
| **Exempt Domestic Firm Subtotal** | **$ 1** | **$ 0** | **$ 1** |
| *Exempt Firm Average ($)* | *$ 78* | *$ 27* | *$ 30* |
| Covered Firms Learning: One Time | $ 15 | $ 2 | $ 2 |
| Creating Food Defense Plan: One Time | $ 22 | $ 3 | $ 3 |
| Updating Food Defense Plan: Annual | $ - | $ 4 | $ 4 |
| Initial Mitigation: One Time | $ 97 | $ 11 | $ 14 |
| Mitigation: Annual | $ 13 | $ 13 | $ 13 |
| Monitoring, Corrective Action, Verification: Annual | $ 34 | $ 34 | $ 34 |
| Initial Training: One Time | $ 1 | $ 0 | $ 0 |
| New Employee Training: Annual | $ 0 | $ 0 | $ 0 |
| Covered Facilities Documentation: Annual | $ 3 | $ 3 | $ 3 |
| **Covered Domestic Firm Subtotal** | **$ 213** | **$ 83** | **$ 87** |
| *Covered Domestic Firm Average ($)* | *$ 66,000* | *$ 26,000* | *$ 27,000* |
| **Subtotal (Domestic Industry Cost)** | **$ 219** | **$ 85** | **$ 89** |
| Cost to Foreign Firms | $ 464 | $ 182 | $ 190 |
| Cost to FDA | Unknown | Unknown | Unknown |
| **Total** | **$ 683** | **$ 267** | **$ 280** |

Table 7.— Annual, Initial, and Annualized Costs, 95th Percentile

| Cost ($Millions) | First Year | 3% | 7% |
|---|---|---|---|
| Exempt Firms Learning: One Time | $ 10 | $ 1 | $ 1 |
| Exempt Firms Documentation: Annual | $ 2 | $ 2 | $ 2 |
| **Exempt Domestic Firm Subtotal** | **$ 11** | **$ 3** | **$ 3** |
| *Exempt Firm Average ($)* | *$ 589* | *$ 150* | *$ 161* |
| Covered Firms Learning: One Time | $ 26 | $ 3 | $ 4 |
| Creating Food Defense Plan: One Time | $ 42 | $ 5 | $ 6 |
| Updating Food Defense Plan: Annual | $ - | $ 9 | $ 9 |
| Initial Mitigation: One Time | $ 98 | $ 11 | $ 14 |
| Mitigation: Annual | $ 16 | $ 16 | $ 16 |
| Monitoring, Corrective Action, Verification: Annual | $ 96 | $ 96 | $ 96 |
| Initial Training: One Time | $ 30 | $ 3 | $ 4 |
| New Employee Training: Annual | $ 10 | $ 10 | $ 10 |
| Covered Facilities Documentation: Annual | $ 14 | $ 14 | $ 14 |
| **Covered Domestic Firm Subtotal** | **$ 291** | **$ 149** | **$ 153** |
| *Covered Domestic Firm Average ($)* | *$ 90,000* | *$ 46,000* | *$ 47,000* |
| **Subtotal (Domestic Industry Cost)** | **$ 297** | **$ 151** | **$ 155** |
| Cost to Foreign Firms | $ 635 | $ 324 | $ 334 |
| Cost to FDA | Unknown | Unknown | Unknown |
| **Total** | **$ 932** | **$ 475** | **$ 489** |

## G. Analysis of Regulatory Alternatives

We have identified five regulatory alternatives:

1. No action;

2. The rule;

3. The rule, with requirements for dairy farms;

4. The rule, but with a different definition of very small business; and

5. Prescribing a simpler and less flexible rule.

### 1. No Action

Under this option, FDA would rely on

- current FDA guidances for industry (Ref. (15)),
- voluntary adoption of some or all provisions of the regulation,
- new State and local enforcement activity to bring about a reduction of potential harm from adulterated foods, or
- the tort system, with litigation or the threat of litigation serving to bring about the goals of the rule.

This option is not legally viable because Sections 103 and 106 of FSMA require us to establish regulations to protect against the intentional adulteration of food. Moreover, we believe that this option would not minimize the risk of food-related illnesses, including serious adverse health consequences or death from intentional adulteration of food. As explained in the 'Need for Regulation' section, using the tort system will fail to induce optimal investment, because the damages are larger than the value of the company. The advantage of this option is that there would be no costs to food producers, but the disadvantage is that there would also be no benefits to society.

### 2. The Rule

The costs and benefits of the actions required by the rule are described in the Detailed Analysis section above.

### 3. The Rule with Dairy Farm Requirements

One alternative is adding requirements for dairy farms to the rule. We have identified significant vulnerabilities on dairy farms. Any potential requirement to address these vulnerabilities would generate additional costs, and also the additional benefit of protecting the milk supply on the farm. We estimate the potential costs in this section, and present a breakeven analysis. The example calculations assume that all of the approximately 49,000 dairy farms that are licensed to sell milk would be covered, and the summary table shows how costs would change with rule coverage based on different herd sizes.

As discussed in the rule, at this time there are no strategies that limit access to milk that are appropriate and practical to require for all farms. However, for the purposes of this regulatory alternative, we estimate that the primary cost of any such strategy would be to cause a loss in productivity. Farm workers, milk truck drivers, veterinarians, and state milk inspectors (in some states) would need to spend time complying with the required mitigation strategies.

It is likely that several mitigation strategies would be needed to limit access to milk while it is on the farm because solely locking the bulk tank is ineffective in preventing access to the milk. We present a cost estimate for one, very simple mitigation strategy (adding a lock on the milk tank) below. Other mitigation strategies would cost several times as much in both capital costs and lost productivity. Therefore, these cost estimates should be considered a minimum; the actual cost would be several times as much as we estimate below.

We estimate that a mitigation strategy to address a potential vulnerability at dairy farms will result in, on average, fifteen minutes of lost productivity per day on each farm affected by the alternative. Dairy farms operate every day of the year. Fifteen minutes lost per day means 91 hours lost per year (15*365/60 = 91.25). The mean hourly wage in the agricultural industry is $12.94 (Ref. (16)), and we double this to account for benefits and overhead, to value the time lost at $25.88 per hour ($12.94*2 = $25.88). This means that the value of the total time lost would be about $2400 per farm ($25.88 *91.27 = $2,362).

In addition to this lost productivity, we estimate average initial costs of about $5,000 per dairy as a result of this alternative for startup costs, such as education and training, and/or the purchase and installation of capital equipment (Ref. (6)). This results in annualized costs of about $700 per business. We then add the productivity and capital costs to estimate an average annual cost per dairy farm of about $3,100 ($2,362 + $712 = $3,073).

There are about 49,000 dairy farms licensed to ship milk commercially (Ref. (17)), so the total annual cost of a dairy farm requirement would be about $150 million ($3,073 * 49,331 = $151,615,746).

The alternative might apply to all dairy farms, or only to dairy farms with more than a certain number of milk-producing cows. The following table shows the cost of a dairy farm provision at various herd size exemptions:

Table 8.—Dairy Farm Rule Costs by Coverage

| Rule Coverage | Farms Covered | Cost ($Mil) |
|---|---|---|
| All Farms | 58,000 | $ 170 |
| Licensed to sell | 49,000 | $ 150 |
| 30 or more cows | 39,200 | $ 120 |
| 50 or more cows | 29,500 | $ 91 |
| 100 or more cows | 15,000 | $ 46 |
| 200 or more cows | 7,100 | $ 22 |

If there were strategies that limit access to milk that were also appropriate and practical to require for all farms at this time, the benefits of requiring these strategies to be implemented on farms would come from a reduction in the chances of public health harm as a result of contamination of the milk supply on farms. As with the implemented provisions for manufacturers and processors, we do not know how many instances of intentional adulteration there will be in the future. Therefore, we present a breakeven analysis. For descriptions of the scenarios, see the Detailed Analysis.

If this provision only prevented Scenario 1 attacks, which would have an average benefit of about $10 million per prevented attack, it would have to prevent fifteen attacks every year on the milk supply at dairy farms for the benefits to outweigh the costs ($152 / $10 = 15.2).

If this provision only prevented Scenario 2 attacks, which would have an average benefit of about $220 million per prevented attack, then it would have to prevent 0.7 attacks per year on the milk supply at dairy farms for the benefits to outweigh the costs ($152 / $220 = 0.69).

If this provision only prevented Scenario 3 attacks, which would have an average benefit of about $133 billion per prevented attack, then it would have to prevent one such attack on the milk supply at dairy farms every 870 years for the benefits to outweigh the costs ($133,000/$152 = 873).

4. A Different Very Small Business Size Threshold than the Rule's $10 Million

Another alternative is to choose some level other than $10 million in annual sales for the definition of very small businesses. Choosing a higher cutoff would lower the number of facilities required to implement the rule, which would lower costs, but would result in a larger percentage of food being produced by businesses that are not required to implement the regulation.

The following table shows the estimated number of domestic firms and facilities covered and the total cost to domestic firms at a 7 percent discount rate for the actions required by the rule at various cutoffs for very small business. It also shows the share that would be covered by the regulation, where the total is defined as food produced domestically by registered facilities that are estimated to have actionable process steps. The table was generated by using facility-level data from Dun & Bradstreet's Global Business Database (Ref. (2)), as described in the Detailed Analysis:

Table 9.—Other Facility Exemptions

| Cutoff ($Mil) | Facilities Covered | Firms Covered | Domestic Cost ($Mil) | Share Covered |
|---|---|---|---|---|
| 5 | 11,353 | 4,678 | $ 139 | 99.0% |
| 10 | 9,759 | 3,247 | $ 120 | 98.3% |
| 20 | 8,972 | 2,592 | $ 110 | 97.7% |
| 30 | 8,440 | 2,151 | $ 103 | 97.2% |
| 40 | 8,021 | 1,832 | $ 98 | 96.7% |
| 50 | 7,646 | 1,563 | $ 93 | 96.2% |

All cost numbers are produced using the same procedures described in the Detailed Analysis below. We do not have similar data on foreign firms, but we estimate that the number of firms and facilities, and the total costs, would be roughly doubled if foreign firms were included.

Individuals or groups intending to cause harm would likely target the product of relatively large facilities, especially firms whose brand is nationally or internationally recognizable. However, if facilities were attacked at random, then the benefits of this rule would be proportional to the share covered. Going down to a $5 million sales cutoff would increase domestic costs by $19 million a year while increasing coverage by 0.7%. Going up to a $20 million sales cutoff would decrease costs by $10 million a year while decreasing coverage by 0.6.

5. Prescribing a Simpler and Less Flexible Rule

Another alternative would be the provisions as originally proposed, which reduces complexity and learning costs by prescribing a simpler and less flexible rule. This alternative would have reduced the costs to learn about the rule and generate a food defense plan. However, it increases costs because the alternative does not allow facilities to take into account some existing mitigation strategies when identifying actionable process steps. Additionally, this alternative reduces flexibility for food defense monitoring, corrective actions, and verification activities.

We estimate that this alternative would have the following effects:

1. The average time for the operations manager in covered firms to learn about the rule would decrease from 30 to 20 hours.
2. The average time for exempt firms to learn about the rule would decrease from 2.5 to 2 hours.
3. The average time to identify actionable process steps would decrease from 20 to 15 hours.
4. Facilities would need to use the nine least costly mitigation strategies of the ten analyzed above, instead of the eight least costly strategies, because this alternative did not allow facilities to take into account existing mitigation strategies when identifying actionable process steps.
5. The average time supervisors spend on monitoring and corrective action would increase from 175 to 200 hours, because more mitigation strategies would be required and facilities would have less flexibility in choosing what strategies to use.

Given these effects, this alternative would increase the annualized domestic costs of the rule by about $22 million and foreign costs by about $47 million, for a total cost increase of about $69 million. We believe that this alternative does not provide enough benefits to justify these costs.

## Regulatory Flexibility Analysis

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 believes that the rule will have a significant economic impact on a substantial number of small entities.

### 1. Number of Small Entities Affected

The Small Business Administration 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 the purposes of this rule-making, we have defined a very small business as having annual sales of less than $10 million on an annual basis, and a small business as a business employing fewer than 500 persons.

We find that there are 2,887 firms with more than $10 million in sales, and less than 500 employees, that are covered by this rule (Ref. (2)). We also find that there are 18,080 firms that have less than $10 million in sales, and are exempt from the rule, but will have to learn about the rule and be prepared to document their exemption.

The facilities that are part of firms with more than $10 million in sales produce 98 percent of the total sales volume of manufactured packaged food, and the exempt facilities produce two percent. Two percent of the money that consumers spend on manufactured packaged food is spent on food that is not covered by the regulation.

### 2. Costs to Small Entities

The annualized costs per entity due to this rule for a firm affected by the rule are about $13,000 for a one-facility firm with 100 employees. This includes learning costs of about $900 per firm; food defense plan, mitigation, food defense monitoring, corrective action, and verification, and documentation costs of about $11,200 per facility, and worker training costs of about $500. For more information about these numbers, see the appropriate sections of the Detailed Analysis.

The annualized costs for a very small business affected by the rule but exempted from its provisions are about $95 per firm. This includes an annualized cost of about $40 to learn about the rule,

and an annual cost of about $56 to maintain documentation that was relied upon to demonstrate that the facility meets the very small business exemption. For more information about these numbers, see the appropriate sections of the Detailed Analysis.

3. Regulatory Flexibility Options

This rule is effective 60 days after publication in the Federal Register, with staggered compliance dates. We recognize that businesses of all sizes may need more time to comply with the new requirements established under FSMA. Therefore, facilities, other than small and very small businesses, that are subject to part 121 will have 3 years after the effective date to comply with part 121. Small businesses will have 4 years after the effective date to comply with part 121 (see section IV.B of the rule preamble for a discussion of the definition of a "small business"). With respect to very small businesses as discussed in section IV.E of the preamble, we are exempting very small businesses from the requirements of part 121, except that such businesses must, upon request, provide for official review documentation that was relied upon to demonstrate that the facility meets this exemption. Very small businesses will have 5 years after the effective date to comply with §121.5(a) (see section IV.B of the preamble for a discussion of the definition of a "very small business").

Allowing small businesses more time to comply with the requirements of the rule would save them money, but we do not know what the cost savings would be and we do not know how this would affect the risk of an attack on the food supply.

4. Description of Recordkeeping and Recording Requirements.

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this rule. Documentation must be established and kept for the certain purposes described in the rule. Discussion of the costs of recordkeeping, record creation, and reporting can be found in corresponding sections of the analysis.

## Unfunded Mandates

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 (2014) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Reform Act of 1995 include assessing the rule's effects on:

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and
- Exports.

We have determined that this rule will not have a significant impact on any of these variables.

## Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this rule is a major rule for the purpose of Congressional review.

References

1. **FDA Food Safety Modernization Act of 2011.** Pub. L. No. 111-353 §§ 103, 105, 106. 2011.

2. **Dun & Bradstreet.** Dun & Bradstreet Global Business Database. 2014.

3. *Agroterrorism: Where Are We in the Ongoing War on Terrorism?* **Tamara M Crutchley, et al.** s.l. : Journal of Food Protection, 2007.

4. **Bureau of Labor Statistics.** May 2014 National Industry-Specific Occupational Employment and Wage Estimates. *NAICS 311000 - Food Manufacturing.* [Online] http://www.bls.gov/oes/current/naics3_311000.htm.

5. **FDA CFSAN.** Expert Elicitation on Food Defense Time Costs. 2016.

6. **Institute of Food Technologists.** Modeling the Costs of Food Defense Practices: Prototype Model. 2011.

7. **Food and Drug Administration.** *Food Facility Registration Module.*

8. *Adversarial Risk Analysis for Counterterrorism Modeling.* **Rios, Jesus and Insua, David Rios.** s.l. : Risk Analysis, 2012.

9. *Risk Analysis of Chemical, Biological, or Radionuclear Threats: Implications for Food Security.* **Mohtadi, Hamid and Murshid, Antu.** 2009, Risk Analysis.

10. **Food and Drug Administration.** Preventative Controls for Human Food Regulatory Impact Analysis.

11. **Grocery Manufacturers' Association.** Capturing Recall Costs: Measuring and Recovering the Losses. [Online] http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf.

12. **FDA Center for Food Safety and Applied Nutrition.** Risk Assessment for Food Terrorism and Other Food Safety Concerns. 2003.

13. *Analyzing a bioterror attack on the food supply: The case of botulinum toxin in milk.* **Wein, Lawrence M. and Liu, Yifan.** 2005, PNAS.

14. **Stinson, Thomas.** The National Economic Impacts of a Food Terrorism Event: Preliminary Estimates. [Online] 2005. http://www.ift.org/knowledge-center/read-ift-publications/science-reports/conference-papers/~/media/Knowledge%20Center/Science%20Reports/Conference%20Papers/3Stinson.pdf.

15. **Food and Drug Administration.** Food Defense Guidance. [Online] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/default.htm.

16. **Bureau of Labor Statistics.** May 2014 National Industry-Specific Occupational Employment and Wage Estimates. *Sector 11 - Agriculture, Forestry, Fishing and Hunting.* [Online] http://www.bls.gov/oes/current/naics2_11.htm.

17. **USDA National Agricultural Statistics Service.** Farms, Land in Farms, and Livestock Operations 2012 Summary. [Online] http://usda01.library.cornell.edu/usda/current/FarmLandIn/FarmLandIn-02-19-2013.pdf.