DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

# Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Docket No. FDA-2013-N-1425

## Preliminary Regulatory Impact Analysis

## Preliminary Regulatory Flexibility Analysis

## Preliminary Unfunded Mandates Reform Act Analysis

## Preliminary Paperwork Reduction Act Analysis

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## A. Introduction

The Food and Drug Administration (FDA or we) has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action under Executive Order 12866.

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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We expect this proposed rule may result in a 1-year expenditure that would meet or exceed this amount.

## B. Summary of Costs and Benefits

The proposed rule applies to human food facilities that are required to register and that are part of businesses with more than $10 million in annual sales, with processing steps with significant vulnerabilities and food at a high risk for intentional adulteration caused by acts of terrorism. Almost all of these facilities are engaged in manufacturing or processing of foods, or are warehouses that handle bulk liquid food. Restaurants, farms, animal food facilities, and distributors of raw agricultural commodities are not covered by the rule. Most warehouses, packers, and labelers are not likely to pay any costs as a result of this rule, because these types of facility are unlikely to have the processing steps that create vulnerabilities. The covered facilities must create a food defense plan, identify actionable process steps, implement focused mitigation strategies and related monitoring, corrective actions, and verification activities to protect these steps, train designated employees in food defense, and document these actions. We estimate the annualized costs of these measures to be about $370 million.

The benefits of the actions required by the proposed rule are a reduction in the possibility of illness, death, and economic disruption resulting from intentional adulteration of food. We are unable to quantify these benefits. However, in the Detailed Analysis, 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 18 to 37 attacks per year, depending on the portion of foreign firms' costs that are passed through to U.S. consumers. For attacks causing similar casualties as major historical outbreaks of food-related illness, the breakeven prevention amount would be one or two attacks every year. For catastrophic terrorist attacks causing thousands of fatalities, the breakeven is one attack prevented every 350 to 730 years.

Table 1.—Annualized Cost and Benefit Overview

| All Numbers are USD 2010 (Millions), Annualized over 10 years | | 3% Discount | 7% Discount |
|---|---|---|---|
| Costs | Learning about Rule | $ 3 | $ 3 |
| | Mitigation Costs | $ 59 | $ 63 |
| | Monitoring and Corrective Action | $ 100 | $ 100 |
| | Employee Training | $ 4 | $ 5 |
| | Documentation | $ 6 | $ 6 |
| | **Subtotal (Domestic cost)** | **$ 172** | **$ 177** |
| | Cost to Foreign Firms | $ 185 | $ 190 |
| | **Total** | **$ 357** | **$ 367** |
| Benefits | Lower Chance of Intentional Adulteration | Unquantified | |

## C. Need for Regulation

This regulation is mandated by statute. Sections 103 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 bad 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 bad 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 contamination inflicts on society. In this case, the managers will therefore invest the socially optimal amount (or more) in preventing contamination.

However, the maximum damage that a major contamination 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. Costs and Benefits of the Proposed Rule: Detailed Analysis

FDA is proposing to require domestic and foreign human food facilities to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is proposing these requirements as part of our implementation of FSMA. We expect the proposed rule, if finalized as proposed, would help to protect food from intentional adulteration caused by acts of terrorism.

The subject of the proposed rule is protection of food against intentional adulteration caused by acts of terrorism. The proposed rule would apply 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 proposed rule contains several exemptions:

- The proposed rule would not apply to a qualified facility, except that qualified facilities would be required to provide for official review, upon request, documentation that was relied upon to demonstrate that the facility meets this exemption. As proposed, qualified facilities include very small businesses, those that have less than $10,000,000 in total annual sales of food, adjusted for inflation.
- The proposed rule would not apply to the holding of food, except the holding of food in liquid storage tanks.
- The proposed rule would not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- The proposed rule would not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- The proposed rule would not apply with respect to alcoholic beverages at a facility that meets certain conditions.
- The proposed rule would not apply to the manufacturing, processing, packing or holding of food for animals other than man.

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

- Prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification.
- Identify any actionable process steps, using one of two procedures discussed in the preamble. FDA has determined that the presence of one or more of these key activity types at a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability under section 418 of the FD&C Act and that the food is at high risk of intentional adulteration caused by acts of terrorism under section 420 of the FD&C Act. These key activity types are: Bulk liquid receiving and loading; Liquid storage and handling; Secondary ingredient handling; and Mixing and similar activities. Facilities may identify actionable process steps using the FDA-identified key activity types, or conduct their own facility-specific vulnerability assessments.
- Identify and implement focused 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.
- Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.
- Establish and implement corrective action procedures that must be taken if focused mitigation strategies are not properly implemented.
- Verify that monitoring is being conducted and appropriate decisions about corrective actions are being made; verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities; and conduct a reanalysis of the food defense plan.
- Ensure that personnel and supervisors assigned to actionable process steps receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies.
- Establish and maintain certain records, including the written food defense plan; written identification of actionable process steps and the assessment leading to that identification; written focused mitigation strategies; written procedures for monitoring, corrective actions, and verification; and documentation related to training of personnel.

If companies believe that the FDA-identified key activities type method to identify actionable process steps in the proposed rule is not appropriate to their facilities, they have the option of conducting their own vulnerability assessment. They may do so if they calculate that the costs of conducting their own assessment are lower than the costs of the FDA-identified key activities type method, or if they have already conducted an appropriate vulnerability assessment. To the extent that companies do this, the costs of the proposed rule will be lower than the costs we estimate. We do not know how many firms will choose these different measures, but we believe that the number will be low.

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 Proposed Rule

The proposed rule generates several new requirements for food facilities required to register. We calculate these separately. In some cases, the actions that the proposed rule requires are already being done (Ref. (2)). For facilities that are already following FDA guidances on food defense, the proposed rule will not impose significant costs, but it will also not generate additional benefits.

We estimated the number of firms, facilities, and employees that the proposed rule would apply to by using facility-level data from Dun & Bradstreet's Global Business Database (Ref. (3)). The

database included 99,800 facilities, and we searched by SIC codes to find facilities that the rule would apply to. We included all human food manufacturers, including bottled water, nonalcoholic beverage, dietary supplement, and food additive manufacturers. We excluded farms and retail because they are not required to register, and warehouses because they are unlikely to have actionable process steps. Some warehouses, such as those storing bulk liquid, may be affected by the proposed rule, and some manufacturers, such as packers and labelers, may not be affected by the proposed rule because they have no actionable process steps. However, we believe that both of these numbers are small. We seek comment on this assumption. We assign all facilities to their parent company, and include all facilities of companies that have more than $10 million in annual sales in the list of facilities that the proposed rule would apply to.

We found 14,260 food production facilities that are part of firms with more than $10 million in annual sales and are estimated to have actionable process steps. The total costs of identifying key activity types, implementing mitigation strategies, monitoring, corrective actions, and verification are based on this number of facilities. We found 47,416 firms with less than $10 million in annual sales and 4,624 firms with more than $10 million in sales. The total costs of learning about the proposed rule, and documenting compliance, are based on these firm numbers. We found about 1.4 million employees in firms that the proposed rule would apply 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 percent of the total sales volume of food produced by registered facilities that are estimated to have actionable process steps, and the qualified facilities produce 3 percent. The proposed rule therefore covers 97 percent of the food market that is vulnerable to terrorist attack that could cause massive casualties; 3 percent of the money that consumers spend on this type of food is spent on food that is not covered by the proposed regulation.

a. Learning About the Proposed Rule and Creating a Food Defense Plan

The 4,600 firms that are covered by the proposed rule will spend time to learn about the proposed rule and how to properly implement it, and to create a food defense plan according to the proposed rule's requirements. We estimate that this will take one individual at the level of an operations manager, and also a legal analyst, between ten and thirty hours, or an average of twenty hours each per business. We request comments on this estimation. For comparison, we estimated that the Preventative

Controls for Human Food proposed rule (Ref. (4)) will take the operations manager and legal analyst 40 hours each to learn about the proposed rule.

The mean hourly wage of an operations manager in the food manufacturing industry is $53.56 (Ref. (5)). We increase this cost by 50 percent to account for benefits and overhead, making the total cost of time $80.34 ($53.56*1.5 = $80.34). The cost of the operations manager's time is about $1,600 per business ($80.34*20 = $1,606.80). The mean hourly wage of a lawyer in the food industry is $65.23 (Ref. (5)), or $97.85 including benefits and overhead ($65.23*1.5 = $97.85). The cost of the lawyer's time is about $2000 per business ($97.85*20 = $1,956.90). The total initial cost per business is about $3,600 ($1,606.80 + $1,956.90 = $3,563.70).

We annualize this cost over ten years at a 7 percent discount rate and calculate average annualized costs of about $510 per business. Because there are about 4,600 firms covered by the proposed rule (Ref. (3)), the total annualized cost to covered firms for learning about the proposed rule and creating food defense plans is about $2.3 million ($507.39*4624 = $2,346,175).

The 47,000 firms that are exempt from the proposed rule because they have less than $10 million in annual sales will each incur a burden to learn enough about the proposed rule to verify that they are exempt. This will not require learning about the entire proposed rule; it will only require learning the exemption criteria and the documentation requirement for qualified facilities. We estimate that this will take one individual at the level of an operations manager between zero and four hours, or an average of two hours, per business. We request comments on this estimation.

At a time cost of $80.34 per hour for the operations manager, the learning cost per exempt business is then about $160 ($80.34*2 = $160.68). We annualize this cost over ten years at a 7 percent discount rate and calculate annualized costs of about $23 per exempt business. Because there are about 47,000 exempt firms (Ref. (3)), the total annualized costs to these firms for learning about the proposed rule will be about $1.1 million ($22.88*47,416 = $1,084,746).

b. Actionable Process Steps and Focused Mitigation Strategies

For each of the 14,260 food production facilities covered by the proposed rule and estimated to have actionable process steps, we estimate that an individual at the level of an operations manager will have to spend five to ten hours, or an average of 7.5 hours, identifying the actionable process steps in that facility.[1] We request comments on this estimation. At a time cost of $80.34 per hour for the operations manager, the cost of identifying actionable process steps is then about $600 per facility ($80.34*7.5 = $602.55).

The proposed rule requires firms to identify and implement focused 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. The proposed rule does not specify a specific number or set of focused mitigation strategies to be implemented. For the purposes of cost estimation, we considered the implementation of the following focused mitigation strategies:[2]

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. 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).

[1] This estimate is for large firms and comes from internal experts who have conducted these kinds of vulnerability studies at many facilities. Once managers learn about vulnerabilities, they can conduct an assessment on their own.

[2] The list was generated with input from internal technical experts who have extensive experience conducting vulnerability assessments and identifying focused mitigation strategies. While focused 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 focused mitigation strategies facilities might employ. The examples provide a range of capital investment and operational changes to illustrate the diversity of potential focused mitigation strategies.

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

Some of the covered facilities are already implementing these mitigation strategies (Ref. (2)). We do not have data on the current adoption rates and costs of these particular 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 it, and we estimate costs where we do not have data.

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:[3] |
|---|---|
| Prohibit after hours key drop deliveries of raw materials | 1,2 |
| Electronic access controls for employees | 4,2 |
| 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.

[3] 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.

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 focused 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 proposed 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 proposed rule will be lower than our estimate.

The costs of these focused 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.

In addition to these direct costs, and the costs of monitoring and corrective action quantified in the next section, there may be indirect costs related to lost productivity or other side effects from implementing these mitigation strategies. We were unable to quantify these costs, and request comments and data that would help us estimate them in the final Regulatory Impact Analysis.

Because these initial costs involve the purchase of capital equipment (Ref. (6)), they are annualized over the expected seven-year life of the equipment. The equipment will have to be replaced periodically, in contrast to the other initial costs that only occur once and are therefore annualized over the full ten years of the analysis.

The low estimate of the initial capital cost of these focused mitigation strategies is $3,993, the best estimate is $9,039, and the high estimate is $16,616, for an average of about $10,000 per facility

([$3,993+$9,039+$16,616]/3 = $9,882). The low estimate of the recurring costs of the strategies is $583, the best estimate is $1,609, and the high estimate is $4,631, for an average of about $2,300 per facility ([$583+$1,609+$4,631]/3 = $2,274). For costs of each individual strategy, see 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. We request comments on these estimations. The mean hourly wage of a first-line supervisor of production and operating workers in the food industry is $23.32 (Ref. (5)), or $34.98 including benefits and overhead ($23.32*1.5 = $34.98). This means that their time costs will be about $700 per year per facility newly implementing the strategy ($34.98*20=$699.60). The average annual cost per covered facility is then about $210 ($699.60 * 30% = $209.88).

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. At a time cost of $80.34 per hour for the operations manager and $97.85 for the lawyer, the total one-time cost per facility is then about $360 (2*$80.34 + 2*$97.85 = $356.37). The costs of enforcing these procedures are included in the '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 (unintentional adulteration) and sanitation reasons. Alternatively, facilities could require employees to leave most personal items at home or in employees' cars. We assume that there will be no additional costs from these procedures.

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. We request comments on estimating the cost of this focused mitigation strategy.

For the purposes of this cost estimate, we assume that Strategy 9 will not be employed because it would impose a large burden and other focused mitigation strategies are sufficient to control the significant vulnerability. We assume that it is necessary to employ all of the other strategies. To the extent that fewer focused mitigation strategies are necessary to protect the actionable process steps, the costs of the proposed rule will be lower than our estimates.

The total initial cost of identifying key activity types and implementing mitigation strategies is about $11,000 per covered facility ($602.55 + $9,882 + $356.37 = $10,841.29). The annualized cost of these initial costs is about $1,900 per facility. The annualized recurring costs are about $2,500 per facility ($2,274 + $210 = $2,484). The total annualized cost is about $4,400 per facility ($1,926 + $2,484 = $4,410).

Table 3.—Costs of Mitigation

| **Average cost per covered facility** | **Initial** | **Recurring** | **Total Annualized** |
|---|---|---|---|
| Identity key activity types | $ 603 | $ - | $ 107 |
| Prohibit after hours key drop deliveries of raw materials | $ - | $ 1,070 | $ 1,070 |
| Electronic access controls for employees | $ 1,122 | $ 82 | $ 281 |
| Secured storage of finished products | $ 1,999 | $ - | $ 355 |
| Secured storage of raw materials | $ 3,571 | $ - | $ 634 |
| Cameras with video recording in storage rooms | $ 3,144 | $ - | $ 559 |
| Peer monitoring of access to exposed product | $ 47 | $ 1,122 | $ 1,131 |
| Physical inspection of cleaned equipment | $ - | $ 210 | $ 210 |
| Prohibit staff from bringing personal items | $ 356 | $ - | $ 63 |
| **Total** | **$10,841** | **$ 2,484** | **$ 4,411** |

Because there are about 14,300 facilities that are part of firms that must implement focused mitigation strategies (Ref. (3)), the total annualized costs of focused mitigation strategies in these facilities will be about $63 million ($4,410*14,260= $62,886,600).

c. Monitoring and Corrective Action

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

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

Given that the focused mitigation strategies can include relatively frequent activities that employees may wish to bypass, such as keeping equipment and transfer hoses locked when not in use, controlling keys and employee access, and ensuring that employees do not bring personal items into the manufacturing area, we estimate that monitoring and documenting the focused mitigation strategies, and implementing corrective action as needed, will require first-line supervisors and other people responsible for quality control to spend between 100 and 300 hours per year, per facility.[4] We request comments on this estimate.

Given the time cost of $34.98 for first-line supervisors, the costs for monitoring and corrective action will be about $7,000 per year per facility ($34.98*200=$6,996).

Because there are about 14,300 facilities that are part of firms that must implement mitigation strategies (Ref. (3)), the total annual costs of monitoring, corrective action, and verification in these facilities will be about $100 million ($6,996*14,260 = $99,762,960).

d. Training

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 proposed 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. We request comments on these estimations.

[4] This estimate comes from internal food defense experts. This is an estimate for the larger facilities likely to be covered by the rule. Small facilities would take less time, but most of them will be exempt.

The mean hourly wage in the food manufacturing industry is $16.13 (Ref. (5)), or $24.20 including benefits and overhead ($16.13*1.5 = $24.20). This average includes both production workers and supervisors. With one hour of training per worker, the initial training cost is $24.20 per worker receiving training. We annualize this cost over ten years at a 7 percent discount rate and calculate average annualized costs of about $3.40 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. We request comments on this estimation. With a turnover of 33 percent, annual training costs per job will be about $8 per position requiring training ($24.20*0.33=$7.98). Adding the annual training costs to the annualized initial costs yields annual training costs of about $11.43 per job at an actionable process step ($3.44+ $7.98 = $11.43).

Some training required by the proposed rule would be generic and some would be specialized. We are proposing that certain personnel be trained in: (1) food defense awareness and (2) their respective responsibilities in implementing focused mitigation strategies. FDA has published training courses, which are available online and can be used to meet the proposed requirement for food defense awareness training. Training employees in their specific responsibilities in implementing focused mitigation strategies (relevant to the actionable process step to which the employee is assigned) is included in the cost estimates for those strategies. The development of focused mitigation strategies and their required implementation is included in the cost of learning about the rule and creating a food defense plan.

There are about 1.4 million employees in firms covered by the proposed rule (Ref. (3)), so the total annualized costs of the training required by the proposed rule will be about $4.8 million ($11.43*1,386,156*30% = $4,752,785).

e. Annual Documentation and Plan Updating

The 4,600 businesses covered by the proposed rule will also face annual costs to document compliance with the food defense plan and update it as appropriate. 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 will 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 business. We request comments on these estimations.

At a time cost of $80.34 per hour for the operations manager and $97.83 per hour for the lawyer, the recurring annual costs are about $890 per business ($80.34*5 + $97.85*5 = $890.93). Because there are about 4,600 firms covered by the proposed rule (Ref. (3)), the total annualized documentation costs to these firms will be about $6.5 million ($890.93*4,624 = $4,119,637).

Businesses that are exempt from the proposed rule because they are qualified facilities must be prepared to give to FDA inspectors the documentation that was relied upon to demonstrate that the facility meets 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. We request comments on this estimation.

At a time cost of $80.34 per hour, the annual costs of documentation are about $40 ($80.34*.5 = $40.17). Because there are about 47,000 firms that are exempt because they are qualified facilities (Ref. (3)), the total annualized costs to these firms for documenting their exemption will be about $1.9 million ($40.17*47,416 = $1,904,701).

f. Costs to Foreign Firms

There are about 109,000 foreign facilities registered to import food into the U.S. (Ref. (7)). Some of these facilities will also face costs as a result of the rule. We assume 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 proposed rule would apply to is the same. The proposed rule would apply to about 14,300 of 99,800 domestic facilities, so we estimate that it would apply to about 15,600 foreign facilities (14,260/99,800*109,000 = 15,575).

The average annualized cost of the rule for domestic facilities that the rule applies to is about $12,200. 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 the average cost per domestic facility. The total estimated annualized cost to foreign firms is then about $190 million ($12,193*15,575= $189,905,975). The costs are $185 million when annualized at 3%, and the initial costs are $354 million.

g. Total Costs

The total cost of the proposed rule, annualized over 10 years at a 7 percent discount rate, is about $367 million. With a 3 percent discount rate, the annualized cost is about $357 million. The first-year

cost is about $687 million. Counting only domestic firms, the total annualized costs are $177 million at a 7% discount rate and $172 million at a 3% discount rate, with initial costs of $333 million. The average annualized cost of the rule for domestic firms that the rule applies to is about $38,000.

The following table shows, for each component of the proposed 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.—Initial and Annualized Costs

| **Cost ($Millions)** | **Initial** | **Annualized 3%** | **Annualized 7%** |
|---|---|---|---|
| Learning: Exempt Firms | $ 7.6 | $ 0.9 | $ 1.1 |
| Documentation: Exempt Firms | $ 1.9 | $ 1.9 | $ 1.9 |
| **Exempt Domestic Firm Subtotal** | **$ 9.5** | **$ 2.8** | **$ 3.0** |
| *Exempt Firm Average ($)* | *$ 200* | *$ 59* | *$ 63* |
| Learning: Covered Firms | $ 16.5 | $ 1.9 | $ 2.3 |
| Mitigation: Initial Costs | $ 154.6 | $ 23.6 | $ 27.5 |
| Mitigation: Annual Costs | $ 35.4 | $ 35.4 | $ 35.4 |
| Monitoring and Corrective Action | $ 99.8 | $ 99.8 | $ 99.8 |
| Initial Training | $ 10.1 | $ 1.2 | $ 1.4 |
| New Employee Training | $ 3.3 | $ 3.3 | $ 3.3 |
| Documentation: Covered Firms | $ 4.1 | $ 4.1 | $ 4.1 |
| **Covered Domestic Firm Subtotal** | **$ 323.8** | **$ 169.3** | **$ 173.9** |
| *Covered Domestic Firm Average ($)* | *$ 70,000* | *$ 36,600* | *$ 37,600* |
| **Subtotal (Domestic cost)** | **$ 333.3** | **$ 172.1** | **$ 176.9** |
| Cost to Foreign Firms | $ 353.6 | $ 185.0 | $ 189.9 |
| **Total** | **$ 686.9** | **$ 357.1** | **$ 366.8** |

2. Benefits of the Proposed Rule

This proposed 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 at which food defense measures can be applied and are essential to prevent or eliminate a significant vulnerability or reduce such vulnerability to an acceptable level. 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 proposed 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 proposed rule, multiplied by

2) the likelihood that the otherwise successful attack will be prevented as a result of the proposed 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 proposed rule is intended to reduce the possibility of a terrorist successfully using the food supply to harm large numbers of people, the potential benefits of the proposed 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, although these attacks were acts of disgruntled employees rather than acts of terrorism. All of these incidents occurred at the retail level, and none of them resulted in fatalities or widespread illness.[5]

[5] 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 contamination has occurred close to the point of consumption. These events have occurred in a post-manufacturing environment, which is outside the scope of this proposed 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.

Scenario 2 attacks are those that resemble past cases of major outbreaks of foodborne illness in the United States. A successful introduction of a contaminant at an actionable process step would cause, at minimum, a Scenario 2 attack.

Scenario 3 attacks are those that could be caused by skilled terrorists 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. An example of such a large-scale attack is modeled by Liu and Wein (Ref. (10)).

The benefits of the proposed 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 proposed rule will reduce the chances that each attack is successful. This means that we are unable to quantify the benefits of the proposed 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 proposed rule prevents an attack. We then compare that number to the annual cost of the proposed rule. This yields the annual reduction in the odds of a successful attack at which the benefits of the proposed rule outweigh the costs.

We conduct this analysis separately for each attack scenario, presenting the breakeven point for the proposed rule assuming that it only prevented attacks of that type. It is possible that the proposed rule may prevent 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 proposed rule is not intended to cover such attacks, the food defense awareness training required by the proposed 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. (4)), 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 for 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. 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 proposed rule to domestic firms are $177 million. If no foreign costs were passed on to Americans, and if the actions undertaken as a result of this proposed rule only prevented Scenario 1 attacks, they would have to prevent 18 or more Scenario 1 attacks per year for the benefits to be larger than the costs ($177/$10.1 = 17.5). If all costs to foreign firms were passed on to Americans, then the annualized costs would be $367 million and the rule would have to prevent 37 or more Scenario 1 attacks per year for the benefits to be larger than the costs ($367/$10.1 = 36.3).

c. Scenario 2 Attacks

A Scenario 2 attack, the successful introduction of a contaminant at an actionable process step, would likely produce 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 $8.1 million, the monetized value of the deaths is $81 million ($8.1*10 = $81). 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 $283 million. ($2+$81+$200 = $283). 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 proposed 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 $212 million ($283*(1-(0.5*0.5)) = $212.25).

If the actions undertaken as a result of this proposed rule only prevented Scenario 2 attacks, and no foreign costs are passed on to Americans, they would have to prevent one attack every year for the benefits of the proposed rule to outweigh the costs ($177/$212.25 = 0.6). If all foreign costs were passed on, the rule would have to prevent two attacks per year for the benefits to be larger than the costs ($367/$212.25 = 1.73).

d. Scenario 3 Attacks

The hypothetical Scenario 3 attack modeled by Liu and Wein (Ref. (10)) resulted in about 100,000 illnesses and 5,000 fatalities. Other agents introduced at an actionable process step for a widely distributed food might cause similar casualty figures. 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. (4) and (10)). 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 $41 billion (8.1*5,000 = 40,500), for a total health damage of $46 billion ($5+$40.5 = $45.5). 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 $34 billion. (45.5*(1-(0.5*0.5)) = 34.3).

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. (13)). The cumulative damages 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. (13)). 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 $129 billion. ($34+$95 = $129).

If the actions undertaken as a result of this proposed rule only prevented Scenario 3 attacks, and no foreign costs are passed on to Americans, they would have to prevent one attack every 730 years for the benefits of the proposed rule to outweigh the costs ($129,000/$177 = 730). If all foreign costs were passed on, the rule would have to prevent one attack every 350 years for the benefits of the proposed rule to outweigh the costs ($129,000/$367 = 352).

Counting only the health effects and not the economic disruption, and counting domestic costs only, the actions undertaken as a result of this proposed rule would have to prevent one Scenario 3 attack every 200 years for the benefits to outweigh the costs ($34,300/$177 = 194). With foreign costs, the rule would have to prevent one attack every hundred years for the benefits of the proposed rule to outweigh the costs ($34,300/$367 = 93).

3. Analysis of Uncertainty

In Table 4 of this document and elsewhere we present the expected costs of the proposed rule as point estimates. While this is a convenient way to summarize the costs of the proposed 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 proposed 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

| | 5th Percentile | Mean | 95th Percentile |
|---|---|---|---|
| Initial Cost ($Mil) | $ 521 | $ 687 | $ 860 |
| Annualized 3% ($Mil) | $ 251 | $ 357 | $ 464 |
| Annualized 7% ($Mil) | $ 260 | $ 367 | $ 474 |

## E. Analysis of Regulatory Alternatives

We have identified six regulatory alternatives:

1. No action;

2. The proposed rule;

3. The proposed rule, but with a different definition of very small business;

4. The proposed rule, with an additional requirement that dairy farms limit access to milk storage;

5. The proposed rule, with an additional requirement that all registered food facilities conduct vulnerability assessments and act according to those assessments; and

6. The proposed rule, with additional requirements designed to prevent economically motivated adulteration of foods that could cause a food safety hazard.

### 1. No Action

Under this option, FDA would rely on

- current FDA guidances for industry (Ref. (14)),
- voluntary adoption of some or all provisions of the proposed 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 proposed 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 safety hazards, including serious adverse health consequences or death from intentional adulteration of food. 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 Proposed Rule

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

3. A Different Very Small Business Size than the Proposed Rule

One 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 proposed 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 total cost to domestic firms at a 7 percent discount rate, of the actions required by the proposed rule at various definitions of very small businesses. 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. (3)), as described in the Detailed Analysis:

Table 6.—Other Facility Exemptions

| Cutoff ($Mil) | Facilities Covered | Firms Covered | Total Cost ($Mil) | Share Covered |
|---|---|---|---|---|
| 5 | 16,700 | 6,600 | $ 208 | 98% |
| 10 | 14,300 | 4,600 | $ 177 | 97% |
| 20 | 12,000 | 3,100 | $ 149 | 95% |
| 30 | 10,500 | 2,300 | $ 130 | 93% |
| 40 | 9,700 | 1,900 | $ 120 | 92% |
| 50 | 9,200 | 1,700 | $ 115 | 91% |

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.

4. The Proposed Rule with Dairy Farm Requirements

We have identified the fluid milk storage tank as a potentially significant vulnerability at a dairy farm, and are considering whether and how access to fluid milk storage and loading in bulk tanks at dairy farms can be limited. A requirement to limit access to the fluid milk storage tank 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.

We do not know what mitigation strategies would be required by this option, but we estimate that the primary cost of any such strategy would be to cause a loss in productivity. Farm workers, milk truck drivers, and state milk inspectors would need to spend time gaining access to the fluid milk, and then securing the tank or building when they leave. For example, if locks and keys are used for access control, this will require unlocking and relocking the storage tanks and/or the building containing fluid milk. Farm operators would have to manage and coordinate the distribution and control of keys. Additional time would be lost if keys are lost or forgotten. Because state milk inspectors routinely access fluid milk, and limiting access will likely make this more difficult, some costs of this option may be borne by state milk inspection agencies.

We estimate that limiting access to milk storage tanks will result in, on average, fifteen minutes of lost productivity per day on each farm affected by the proposed rule.[6] We request comments on this estimation. To the extent that mitigation strategies can be found that generate less loss in productivity, the costs of this option will be lower than the costs we estimate here.

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 $12.47 (Ref. (15)), and we increase this by 50 percent to account for benefits and overhead, to value the time lost at $18.71 per hour ($12.17*1.5 = $18.71). We request comments on the suitability of this value of time estimate to dairy farms. This means that the value of the total time lost would be about $1700 per farm ($18.71*91.27 = $1,707).

In addition to this lost productivity, we estimate average initial costs of about $5,000 per dairy as a result of this proposed rule for startup costs, such as education and training, and/or the purchase and

[6] This number is based on discussions with FDA experts. We recently obtained data on the number of storage tanks at dairy farms of different sizes, and will use that data to generate more precise estimates for the final Regulatory Impact Analysis based on any requirements established in the final rule on this issue.

installation of capital equipment (Ref. (6)). We request comments on this estimation. 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 $2,400 ($1,707+$712 = $2,419).

There are about 49,000 dairy farms licensed to ship milk commercially (Ref. (16)), so the total annual cost of a dairy farm requirement would be about $119 million ($2,419 * 49,331 = $119,317,815).

Alternatively, the proposed rule 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 7.—Dairy Farm Rule Costs by Coverage

| Rule Coverage | Farms Covered | Cost ($Mil) |
|---|---|---|
| All Farms | 58,000 | $ 140 |
| Licensed to sell | 49,000 | $ 119 |
| 30 or more cows | 39,200 | $ 95 |
| 50 or more cows | 29,500 | $ 71 |
| 100 or more cows | 15,000 | $ 36 |
| 200 or more cows | 7,100 | $ 17 |

The benefits of this option would come from a reduction in the chances of public health harm as a result of terrorist attacks on the milk supply. As with the proposed rule, we do not know how many instances of intentional adulteration there will be in the future, or how effective the requirements would be at stopping them. 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 twelve attacks every year for the benefits to outweigh the costs ($119/$10 = 11.9).

If this provision only prevented Scenario 2 attacks, which would have an average benefit of about $212 million per prevented attack, then it would have to prevent such an event every 1.8 years for the benefits to outweigh the costs ($212/$119 = 1.8).

If this provision only prevented Scenario 3 attacks, which would have an average benefit of about $129 billion per prevented attack, then it would have to prevent one such event every thousand years for the benefits to outweigh the costs ($129,000/$119 = 1,081).

5. Vulnerability Assessment Requirement

Another alternative would be to require all registered food facilities to conduct their own vulnerability assessments and craft a food defense plan according to the results of that vulnerability assessment. This alternative would have all of the costs and benefits of the proposed rule, as well as additional costs and benefits.

Our experience is that the most challenging part of developing a system of controls for intentional adulteration related to terrorism is identifying the points in the food operation that are most vulnerable to attack by performing a vulnerability assessment. Conducting vulnerability assessments is expensive and requires the time of personnel or consultants with specialized knowledge and training. For this option, companies may incur significant cost.

We estimate that conducting a vulnerability assessment for the average facility covered by the proposed rule would take 40 hours by people at the level of an operations manager, and that learning how to conduct the vulnerability assessment would require an additional 20 hours, for a total time cost of 60 hours.

The mean hourly wage of an operations manager in the food manufacturing industry is $53.56 (Ref. (5)). We increase this cost by 50 percent to account for benefits and overhead, making the total cost of time $80.34 ($53.56*1.5 = $80.34). This results in a cost of about $4,800 per facility ($80.34*60 = $4,820). There are about 14,300 facilities covered by the proposed rule, so the total up-front cost would be about $69 million ($4,820*14,300= $68,733,200). This results in annualized costs of about $12 million per year at a seven percent discount rate.

The additional benefit of this alternative is that it may provide more thorough and specialized coverage of the vulnerabilities at each food manufacturing plant. We are unable to quantify these benefits, and we believe that they are small relative to the costs. As explained in the preamble to the proposed rule, FDA has conducted extensive vulnerability assessments and as a result, we determined that the presence of one or more of four key activity types at a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability and that the food is at high

risk of intentional adulteration caused by acts of terrorism. We do not believe that requiring individual facility-specific vulnerability assessments will cause significant changes in the mitigation strategies chosen or the effectiveness of those strategies, so therefore we believe that the additional costs of this option outweigh the additional benefits. We request comments on this conclusion.

If producers expect that conducting individualized, facility-specific vulnerability assessments would result in less costly and/or more effective measures than the ones required by the proposed rule, they would have the option of doing this under the proposed rule. Therefore, the proposed rule already incorporates any benefits from flexibility that this option would generate.

6. Economically Motivated Adulteration Requirements

Under this option, FDA would add provisions to this rule to prevent the profit-motivated addition of substances that could cause a food safety hazard, like melamine, to foods.[7] We are unsure what mitigation strategies these provisions would require, but they would likely result in companies testing certain raw ingredients for these contaminants. This option would have all of the costs and benefits of the proposed rule, along with additional costs and benefits.

Our current thinking, as described in the preamble, is that provisions to prevent economically motivated adulteration will be added to other rules. The cost estimates in this section should not be applied to those other rules, because the number of facilities covered, and the potential provisions, would be different. The estimate below is intended to be an illustrative example of what costs might be if economically motivated adulteration was addressed in this rule.

We do not know how many contaminants would be tested for or how many firms would be testing for them. We also do not know how frequently the tests would be conducted, or how often these tests are currently being conducted by the industry. As an illustrative example of possible costs, we assume that this option would require about half of the covered facilities to conduct an average of 20 additional diagnostic tests per year on incoming lots of ingredients, and that the tests would cost an average of $100, which is the approximate current price of melamine testing (Ref. (17)). This would

[7] By "economically motivated adulteration" we mean intentional adulteration that is not intended to harm consumers. Profit-motivated intentional adulteration that *is* intended to harm consumers (for example, one firm attempting to contaminate a competitor's product) is considered terrorism and is one of the targets of this proposed regulation.

result in per-facility annual costs of $1,000 (20*0.5*$100 = $1,000). There are about 14,300 facilities covered by the proposed rule, so the additional annual costs of this option would be about $14.3 million ($1,000*14,300 = $14,300,000).

The benefits of this option would come from a reduction in the chances of public health harm as a result of profit-motivated adulteration. As with the proposed rule, we do not know how many instances of intentional adulteration there will be in the future, or how effective the requirements would be at stopping them. Since we have only presented an illustrative example of possible costs of such a set of requirements, we do not conduct a breakeven analysis here.

## Preliminary 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 proposed 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 proposed 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 4,107 firms with more than $10 million in sales, and less than 500 employees, that would be covered by this proposed rule (Ref. (3)). We also find that there are 47,416 firms that have less than $10 million in sales, and are exempt from the proposed rule, but would have to learn about the proposed rule and be prepared to document their exemption.

The facilities that are part of firms with more than $10 million in sales produce 97 percent of the total sales volume of food produced by registered facilities that are estimated to have actionable process steps, and the qualified facilities produce 3 percent. The proposed rule therefore covers 97 percent of the food market that is vulnerable to terrorist attack; 3 percent of the money that consumers spend on this type of food is spent on food that is not covered by the proposed regulation.

### 2. Costs to Small Entities

The annualized costs per entity due to this proposed rule for a firm affected by the rule are about $13,000 for a one-facility firm with 100 employees. This includes learning and documentation costs of about $1,400 per firm; actionable process steps, mitigation, monitoring, corrective action, and verification costs of about $11,400 per facility, and worker training costs of about $340. 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 $63 per firm. This includes an annualized cost of about $23 to learn about the rule, and an annual cost of about $40 to maintain documentation that was relied upon to demonstrate that the facility meets the qualified facility exemption. For more information about these numbers, see the appropriate sections of the Detailed Analysis.

3. Regulatory Flexibility Options

FDA is proposing that the final rule would be 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. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA.

Therefore, as proposed, facilities, other than small and very small businesses, that are subject to part 121 would have 1 year after the effective date to comply with proposed part 121. Small businesses would have 2 years after the effective date to comply with proposed part 121 (see section V.A of the proposed rule preamble for a discussion of the proposed definition of a "small business"). With respect to very small businesses, as discussed in section V.B of the preamble, we are proposing to exempt qualified facilities, which include very small businesses, from the requirements of proposed part 121, except that such facilities must, upon request, provide for official review documentation that was relied upon to demonstrate that the facility meets this exemption. Very small businesses then would have 3 years after the effective date to comply with proposed §121.5(a) (see section V.A of the preamble for a discussion of the proposed definition of a "very small business").

Allowing small businesses more time to comply with the requirements of the proposed 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 proposed rule. Documentation must be established and kept for the certain purposes described in the proposed 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 $141million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this proposed 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 proposed rule is a major rule for the purpose of Congressional review.

## Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A description of these provisions is given in the Detailed Analysis section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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

Title: Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Description: The Food and Drug Administration (FDA or we) is proposing to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is proposing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). We expect the proposed rule, if finalized as proposed, would help to protect food from intentional adulteration caused by acts of terrorism.

Description of Respondents: We found 14,260 food production facilities that are part of 4,624 firms with more than $10 million in annual sales and are estimated to have actionable process steps and thus will need to comply with this proposed rule. We found 47,416 firms with less than $10 million in annual sales that may need to show documentation of exemption.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Reporting Burden

*Exemption for Food Produced by Qualified Facilities*

The proposed rule would not apply to a qualified facility, except that qualified facilities would be required to provide for official review, upon request, documentation that was relied upon to demonstrate that the facility meets this exemption. We do not know how often facilities will need to show this information to inspectors on an annual basis. Therefore, we do not estimate a reporting burden here. However, we do estimate a recordkeeping burden associated with the collection and retention of this information (see discussion of Recordkeeping Burden).

Recordkeeping Burden

*Requirements for Food Defense Plan*

The proposed rule under § 121.126 requires that the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan.

The food defense plan must include:

(1) The written identification of actionable process steps as required by § 121.130;

(2) The written focused mitigation strategies as required by § 121.135(b);

(3) The written procedures for monitoring as required by § 121.140(a);

(4) The written corrective action procedures as required by § 121.145(a)(1); and

(5) The written verification procedures as required by § 121.150(e).

There are 4,624 firms that will need to create a food defense plan. We estimate that it will take a one-time burden of 40 hours to create such a plan. We annualize this estimate and present the burden in Table 8 row 1 ((40 x 4,624)/3).

*Actionable Process Steps*

In addition to the creation of the food defense plan at the firm level, each of the 14,260 food production facilities covered by the proposed rule are estimated to have actionable process steps, for which they must spend time identifying and specifying under § 121.130 for the food defense plan. We estimate that an individual at the level of an operations manager will have a one-time burden of an average of 7.5 hours identifying the actionable process steps in that facility. We annualize this one-time burden and present it in Table 8 row 2 ((14,260 x 7.5 hours)/3).

*Mitigation Strategies*

The proposed rule requires firms to identify and implement focused 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. The proposed rule does not specify a specific number or set of focused mitigation strategies to be implemented. Some of the covered facilities are already implementing these mitigation strategies. The costs of these focused mitigation strategies are a mix of initial capital costs and annual personnel costs. The average initial capital cost of these focused mitigation strategies is about $10,000 per facility. We annualize these costs and add them to the average annual capital costs associated with these strategies of about $2,300 per facility. We take into account that about 70 percent of facilities already have mitigation strategies implemented. Therefore, of the 14,260 total food

facilities, only 30 percent of these, or 4,278 will need to incur this burden. The annualized capital costs associated with focused mitigation strategies are then presented in Table 8 row 3 [($10,000/3) + $2,300) x 4,278].

We estimate that physical inspection of cleaned equipment as a mitigation strategy 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. We also estimate a one-time burden associated with establishing procedures to prohibit staff from bringing personal items into the manufacturing area as a mitigation strategy. This one time burden will require one individual at the level of an operations manager and one legal analyst, between one and three hours, or an average of two hours each, per facility. We annualize this burden. Table 8 row 3 shows the total burden of creating and implementing mitigation strategies ((20 hours + 4 hours/3) x 4,278).

*Monitoring and Corrective Actions*

We estimate that monitoring and documenting the focused mitigation strategies, and implementing corrective action as needed, will require first-line supervisors and other people responsible for quality control to spend between 100 and 300 hours per year (average 200 hours), per facility. Table 8 row 4 shows this burden estimate (200 hours x 14,260).

*Training*

Personnel and supervisors assigned to actionable process steps must receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies under proposed § 121.160. All training received in accordance with this section must be

documented in records. We estimate that the training and documentation will require between zero and two hours, or an average of one hour, per employee when the proposed 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. We annualize the one hour initial burden for training per worker assigned to actionable process steps (60 minutes / 3). In addition, 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, the annual training burden per job will be about 20 minutes per position requiring training (60 minutes x 0.33= 19.8 minutes). Adding the annual training burden to the annualized initial burden yields an annual training burden of 40 minutes per job at an actionable process step (20 minutes + 20 minutes = 40 minutes). There are about 1.4 million employees in firms covered by the proposed rule so the total annualized burden of the training required by the proposed rule will be about $4.8 million (40 minutes x 1,386,156 x 30% = 16,633,872 minutes or 277,231 hours). We show this burden in Table 8 row 5.

*Maintaining Records*

The 4,624 firms covered by the proposed rule will also face an annual burden to document compliance with the food defense plan and update it as appropriate under proposed §§ 121.305 and 121.310. We estimate that the overall documentation will 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 firm. We show this burden in Table 8 row 6 (5 hours x 4,624).

*Exemption for Food Produced by Qualified Facilities*

Businesses that are exempt from the proposed rule because they are qualified facilities must be prepared to give to FDA inspectors the documentation that was relied upon to demonstrate that the facility meets the exemption. We found 47,416 firms with less than $10 million in annual sales;

exempting them from the proposed rule. It is these facilities that may need to show documentation upon request to verify their exempt or qualified facility status under proposed § 121.5 Exemptions. 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 for a total annual burden of 23,708 hours (30 minutes x 47,416). We show this burden in Table 8 row 6.

Table 8.—Estimated Annual Recordkeeping Burden

| 21 CFR Section | No. of Record-keepers | No. of Records per Record-keeper | Total Annual Records | Average Burden per Record-keeping | Total Hours* | Total Capital Costs* |
|---|---|---|---|---|---|---|
| Food Defense Plan § 121.126 | 1,541 | 1 | 1,541 | 40 | 61,640 | |
| Actionable Process Steps § 121.130 | 4,753 | 1 | 4,753 | 7.5 | 35,648 | |
| Focused Mitigation Strategies § 121.135(b) | 4,278 | 1 | 4,278 | 21.33 | 91,250 | $24,097,974 |
| Monitoring and Corrective Actions § 121.140(a), § 121.145(a)(1) | 14,260 | 1 | 14,260 | 200 | 2,852,000 | |
| Training § 121.160 | 415,847 | 1 | 415,847 | 0.67 (40 minutes) | 277,231 | |
| Records § 121.305, § 121.310 | 4,624 | 1 | 4,624 | 5 | 23,120 | |
| Exemption for Food from Qualified facilities § 121.5 | 47,416 | 1 | 47,416 | 0.5 (30 minutes) | 23,708 | |
| Total | | | | | 3,364,597 | $24,097,974 |

*There are no operating and maintenance costs associated with this collection of information.

Third Party Disclosure Burden

We have not identified any Third Party Disclosure burdens as a result of this proposed rule-making.

In compliance with the Paperwork Reduction Act of 1995 (44. U.S.C. 3407(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by March 31, 2014 to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title, "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration."

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