DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Accreditation of Laboratories to Conduct Food Testing

Docket No. FDA-2019-N-3325

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is not a significant regulatory action as defined by 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. Because a significant number of testing laboratories are small businesses and due to initial one-time costs we find that the proposed rule will 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 $154 million, using the most current (2018) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of costs and benefits

The proposed rule, if finalized, would require that testing of food in certain circumstances be performed by an accredited laboratory (participating lab) accredited to the proposed standards by a recognized accreditation body (participating AB), and for the results to be submitted to us. The costs of the proposed rule, if finalized, would primarily be incurred by participating ABs, participating labs, shell-egg producers, sprouts producers and bottled water manufacturers, and owners and consignees of all human and animal food offered for import covered by the proposed rule. Rarely, certain firms would have participating labs conduct tests for several reasons including as part of a corrective action plan after an order suspending registration, as part of evidence for a hearing prior to issuance of a mandatory recall order, as part of evidence for an appeal of an administrative detention order, and as would be required under a food testing order. We anticipate few of these tests would be conducted and estimate the costs incurred by owners of food subject to these testing requirements would be negligible. We would incur costs to establish and maintain the program for recognizing ABs hoping to participate in our program, assessing participating ABs and participating labs, and for reviewing associated documents and reports. The present value of the costs of the proposed rule, if finalized, would range from $34 million to $78 million when discounted by 7 percent over 10 years and would range from $39 million to $92 million when discounted by 3 percent over 10 years. Annualized costs over 10 years would range from $4.6 million to $9.3 million, with a primary estimate of $6.7 million

when discounted by 7 percent and would range from $4.7 million to $9.3 million, with a primary estimate of $6.8 million when discounted by 3 percent.

The proposed rule, if finalized, would generate some quantified and unquantified benefits. Quantified benefits include cost-savings from the proposed clarifications of the process for compiling, submitting and reviewing analytical reports for human and animal food offered for import covered under the proposed rule, including reduced reporting burden. We anticipate a reduction in the number of foodborne illnesses from fewer false negative test results for all human and animal food offered for import covered under the proposed rule and for shell-eggs, sprouts and bottled water and other food subject to specific testing requirements covered under the proposed rule. There would be less revenue lost from fewer false positive test results for human and animal food offered for import covered under the proposed rule and for tests of shell-eggs, sprouts and bottled water and other food subject to the specific testing requirements covered under the proposed rule. The present value of the quantified benefits of the proposed rule, if finalized, would range from $26 million to $81 million when discounted by 7 percent over 10 years and would range from $32 million to $98 million when discounted by 3 percent over 10 years. Annualized benefits over 10 years would range from $3.7 million to $11.5 million, with a primary estimate of $7.6 million when discounted by 7 percent and would range from $3.7 million to $11.5 million, with a primary estimate of $7.6 million when discounted by 3 percent.

Unquantified benefits could include fewer illnesses from deterring unsafe manufacturing practices by all entities covered by the proposed rule. We expect that specific test reporting

requirements would result in more accurate analytical reports and reporting.[1] We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. In Table 1, we provide the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs Consolidated Information System accounting information.

Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule[1]

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$7.56	$3.71	$11.52	2016	7%	10 years	Cost savings
		$7.56	$3.71	$11.52	2016	3%	10 years	Cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative	Reduced risk of food-related illness from improper test reporting practices for imported human and animal food covered under the proposed rule, and shell-eggs, sprouts and bottled water and other covered tests Reduced risk of food-related illness from unsafe food manufacturing practices						
Costs	Annualized Monetized $millions/year	$6.73	$4.64	$9.27	2016	7%	10 years	
		$6.76	$4.73	$9.28	2016	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized					7%		
						3%		

[1] We note that there are currently no reporting requirements for tests of shell-eggs, sprouts or bottled water.

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year							
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: Potential impacts on laboratories currently not accredited to ISO/IEC 17025 that would participate in the labs program described by the proposed rule. Wages: None Growth: None							

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

In line with Executive Order (EO) 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon.

Table 2: EO 13771 Summary Table (in $ Millions 2016 dollars discounted over an infinite time horizon) [1]

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$100.29	$56.49	$144.54	$216.92	$115.07	$319.32
Present Value of Cost Savings	$101.85	$71.15	$134.87	$237.65	$172.25	$307.92
Present Value of Net Costs	-$1.56	-$57.43	$53.51	-$20.73	-$149.76	$110.77
Annualized Costs	$7.02	$3.95	$10.12	$6.51	$3.45	$9.58
Annualized Cost Savings	$7.13	$5.17	$9.24	$7.13	$5.17	$9.24
Annualized Net Costs	-$0.11	-$3.99	$3.84	-$0.62	-$4.49	$3.32

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

C. Definition of Terms Used in this Analysis

Throughout the analysis we use the following terms. We note that the definitions of these terms only apply to this document.

- We/us/our: used to refer to the Food and Drug Administration.

- ISO/IEC 17025 (ISO/IEC 17025:2017) is the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) standard, an internationally recognized set of management and technical requirements used to evaluate a laboratory's competence to carry out tests or calibrations, including sampling. ISO/IEC 17025 is a voluntary international consensus standard for which labs hold accreditation to be deemed technically competent.

- ISO/IEC 17011(ISO/IEC 17011:2017) is a voluntary international consensus standard that specifies requirements for the competence, consistent operation, and impartiality of accreditation bodies assessing and accrediting testing laboratories and other conformity assessment bodies.

- Accreditation refers to the independent evaluation of a laboratory, against recognized standards, to carry out specific activities that ensure impartiality and competence.

- International Laboratory Accreditation Cooperation (ILAC) is an international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in assessing and accrediting testing laboratories; ILAC's primary purpose is to establish an international arrangement between member accreditation bodies based on peer evaluation and mutual acceptance.

- ILAC Mutual Recognition Arrangement (MRA) is international agreement that provides the technical basis to assess and accredit testing laboratories to ISO/IEC 17025. Accreditation bodies that are signatories to the ILAC MRA have been peer evaluated in accordance with the requirements of ISO/IEC 17011 to demonstrate their competence and agree to recognize each other's results.

- Accreditation Bodies (ABs) is a general term that includes all accreditation bodies that could be affected by the proposed rule if finalized.

- The labs program refers to our proposed laboratory accreditation program as defined by the proposed rule.

- Labs is a general term that includes all laboratories that could be affected by the proposed rule if finalized.

- Participating labs refers to laboratories that would participate in the labs program under the proposed rule, if finalized.

- Participating ABs refers to ABs that would participate in the labs program under the proposed rule, if finalized.

- Import Alerts list products which may be detained after they are imported or offered for import, without physically examining the products, due to their violative history or potential.

- Human or animal food offered for import covered by the proposed rule refers to any food offered for import or potentially offered for import that uses findings from analytical tests performed by a private laboratory to support its admissibility. Food subject to an import alert would typically fall in this category.

- Other testing covered under the proposed rule refers to:

    - as required by FDA in a Food Testing Order
    - to address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing prior to the issuance of a mandatory food recall order, as part of a corrective action plan submitted after an order suspending the registration of a food facility, or as part evidence submitted for an appeal of an administrative detention order;

- Owners and consignees are owners and consignees of human or animal food offered for import covered under the proposed rule.

- Scope refers to the testing methods to which a lab is accredited.

- Specific testing requirements refers to food testing conducted in any of the following circumstances:

    - In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in regulations for the production of sprouts, shell-eggs, and bottled drinking water. Each of these explicit testing requirements refers to a follow-up, or corrective action after a routine test is positive for a pathogen or indicator organism. (See the proposed rule for the specific references.)

- Switching costs refer to the incremental increase in the costs to ship samples to participating labs.

- Proficiency test, according to ISO, is an evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons measures.

- Full analytical report refers to the entire set of information, including test results, that would be sent by a participating lab to us.

- Abridged analytical report refers to a subset of the information that would be required in a full analytical report that would be sent by a participating lab to us.

II. Preliminary Regulatory Impact Analysis

A. Background

On January 4, 2011, President Obama signed the FDA Food Safety Modernization Act (FSMA) into law. FSMA is intended to help FDA to better protect public health by helping ensure the safety and security of the U.S. food supply by focusing on preventing food safety problems rather than primarily reacting to these problems once they surface. FSMA recognized that food testing could perform different roles in supporting a modern food safety system and that food testing can play a role in detecting and responding to food safety problems. FSMA requires that food be tested by accredited laboratories in four circumstances:

- In response to a specific testing requirement (see list of terms above);
- As required by the Secretary to address an identified or suspected food safety problem;
- In support of admission of an article of food offered for import;
- Under an Import Alert that requires successful consecutive tests.

In these circumstances, FSMA requires food testing by accredited laboratories. With one exception, FSMA requires the results of food testing that must be conducted by an accredited laboratory to be sent directly to us.

In recent years we have explored various approaches to improving the quality and consistency of food testing and reporting. On April 29, 2004, we proposed a rule establishing standards for sampling and testing practices that targeted imported food, and for improving the reliability and scientific validity of the test results that we use to make food import admissibility decisions (Ref. 1). That proposed rule would have required that (1) samples of food be properly

identified, collected, and maintained; (2) labs conducting the testing use validated analytical methods; and (3) these labs submit the test results directly to us.

On January 16, 2009, we issued a draft guidance entitled "Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories," in which we recommended a voluntary accreditation program for labs that test to support decisions regarding the admissibility of food offered for import (Ref. 2). The draft guidance noted that oversight of labs by ABs would enhance our confidence in the test results, and the draft guidance recommended that:

- ABs operate in accordance with the standard ISO/IEC 17011:2004 "General requirements for accreditation bodies accrediting conformity assessment bodies"
- ABs be signatories to the ILAC MRA
- Labs accredited by ABs submit all test results directly to us, and
- Importers notify us in advance of which accredited laboratory they intended to use

In addition, the draft guidance suggested a process that would allow labs to submit "abbreviated" analytical reports to us rather than a "full" analytical report. This proposed rule would codify many elements of the 2004 proposed rule and 2009 draft guidance. The proposed rule, if finalized, would require labs be accredited to ISO/IEC 17025 to participate in the labs program, and would define the circumstances under which tests must be conducted by a participating lab, including in support of admission of human or animal food offered for import, and for tests of shell-eggs, sprouts and bottled water subject to specific testing requirements and for food subject to other testing requirements covered by the proposed rule. To fulfill the FSMA mandate and the regulatory purpose of the labs program, we are proposing some requirements beyond those required by ISO/IEC 17025, including certain test verification and validation reporting requirements. In addition, the proposed rule requires some oversight of the sampling process, including by requiring the participating lab to obtain information about the training and

experience of the sampler as well as sampling plans and sampling reports. The proposed rule defines the elements of a "full" analytical report, the process by which participating labs may be allowed to submit "abridged" analytical reports, and the requirements for us to administer the labs program and for ABs and labs to participate in the labs program.

B. Market Failure Requiring Federal Regulatory Action

Lab accreditation to an industry standard is currently voluntary and there is no requirement by us to use an accredited lab. There is evidence that the quality of tests performed by labs accredited to an industry standard is higher than the quality of tests performed by unaccredited labs (Ref. 3). The use of food testing labs that fail to provide reliable and accurate results may have large public health consequences.

Firms may not know the true quality of a lab's tests at the time a lab is selected or may not fully internalize the public health consequences of a lab's failure to provide reliable and accurate test results in certain circumstances important to public health. The combination of these factors creates an externality or market failure when choosing a lab to test human or animal food under certain circumstances. The proposed rule, if finalized, would address this market failure by requiring that certain food testing important to public health be conducted only by participating labs that meet our proposed requirements.

Asymmetric information among human and animal food labs, sample collectors and sample collection entities, and FDA can exacerbate the market failure. The proposed rule includes specific lab reporting requirements that would help address the asymmetric information about testing practices. Finally, the proposed rule fulfills provisions in FSMA that require us to recognize ABs that accredit labs to conduct food testing as part of the labs program and that participating labs adhere to model standards.

C. Purpose of the Proposed Rule

The purpose of the proposed rule is to ensure the quality of tests and reporting in certain situations. The proposed rule would establish a program that recognizes ABs, provides standards that participating labs must meet, and under certain circumstances requires the use of participating labs. ABs that hope to participate in our program would need to apply to us for recognition, maintain recognition status, and accredit labs that hope to participate in the labs program. Participating ABs would tailor their existing program to incorporate the labs program requirements, assess participating labs for adherence to the labs program requirements, maintain current records, and report to us relevant updates regarding changes in the accreditation status of participating labs. Participating ABs would also be periodically assessed by us for adherence to the proposed requirements. We assume that all domestic ABs currently accredited to ISO/IEC 17011 and ILAC MRA signatories would apply to participate in the labs program, and that foreign ABs might also apply as well.

Labs that hope to participate in the labs program would have to become accredited to ISO/IEC 17025 and participate in a proficiency testing program for analytical methods at a prescribed frequency. Under certain circumstances, participating labs would need to validate and verify analytical methods beyond the validation and verification requirements of ISO/IEC 17025. The proposed rule, if finalized, would require that participating labs:

- Be periodically assessed by their AB for adherence to the requirements under the labs program
- Send certain test results directly to us and adhere to format and content requirements for an analytical report
- Provide notices of sampling prior to collecting the sample in certain situations

- Review sample documentation such as a sampling plan, a sample report, and the sampler's credentials
- Ensure the analytical methods required are appropriate for the scope to which it is accredited
- Submit analytical reports, and comply with other documentation recordkeeping requirements

We would recognize and oversee the participating ABs. We would also review test results and reports from participating labs. We would administer the labs program and would have the authority to assess participating labs' performance.

D. Baseline Conditions and the Number of Affected Entities

In this section we describe the number and types of affected entities and the baseline conditions for our analysis. We consider pre-FSMA conditions as the baseline. There had been an upward trend in lab accreditation prior to 2011 (see Background section) and we assume that current rates of lab accreditation are independent of any FSMA requirements. Moreover, our Import Alert program was operational prior to 2011 and we assume that current rates of import alerts are independent of any FSMA requirements.

We use a simulation model to estimate current baseline practices and the number of affected entities. The simulation allows us to account for uncertainty in our estimates. Throughout this document, we report our assumptions about the distribution of the inputs, and report the 5^{th} percentile, mean, and 95^{th} percentile for our simulated outputs. We report the estimated numbers of entities affected by the proposed rule in Table 3. The proposed rule would primarily affect the following entities:

- Eligible ABs seeking recognition by FDA
- Labs that test human and animal food offered for import covered by the proposed rule,

- Labs that test shell-eggs, sprouts and bottled water subject to the specific testing requirements covered by the proposed rule
- Owners and consignees of human and animal food offered for import covered by the proposed rule
- Shell-egg producers, sprouts producers, and bottled water manufacturers
- Owners and consignees of other human and animal food subject to other testing covered by the proposed rule.
- FDA.

We first estimate the number of affected entities and the current accreditation status of labs. We then describe the numbers of analytical reports of tests of human and animal food offered for import covered by the proposed rule, and of tests of shell-eggs, sprouts, bottled water and foods subject to other testing covered by the proposed rule. We also describe the inefficiencies in the current process to submit and review analytical reports of tests of human and animal food offered for import covered by the proposed rule.

1. Number of entities

a. The existing number of ABs and the number of ABs that would participate in our program

ABs that are signatories to the ILAC MRA exist in 70 countries. However, most countries have one national AB. Four countries have more than one AB: the US has five ABs; Thailand, Canada and Japan each have three ABs. The signatory members follow the ISO/IEC 17011 standard and any related ILAC guidance documents. ABs ensure that their accredited labs comply with ISO/IEC 17025, and any related ILAC guidance documents. We estimate that all 5 domestic ABs would participate in the labs program and up to 80 ABs (5 domestic ABs plus 75 foreign ABs) might participate in the labs program.

Several existing ABs already fulfill many of the proposed requirements such as signatory to the ILAC MRA, conforming to the ISO/IEC 17011 standard, and accrediting labs to the ISO/IEC 17025 standard. These ABs would currently perform reviews, audits and assessments of labs' processes and management systems, including self-assessments, at the proposed frequencies. These ABs generally would have the capacity to evaluate labs to determine a lab's ability to meet the proposed requirements. Moreover, existing ABs can place a lab on probation, or revoke, renew, or reduce the scope of a laboratory's accreditation. In addition, ISO/IEC 17011 requires an AB to have a written program like the one in the proposed rule that addresses and protects against potential conflicts of interests with the labs that the AB accredits. In our analysis, we estimate the number of ABs that would participate in the labs program by assuming a Pert[2] distribution between 5 ABs and 80 ABs, with 5 ABs being the most likely number (the number of domestic ABs), and 18 (17.5, rounded up) ABs being the mean of the distribution. We ask for comment on this assumption.

b. The number of labs that would participate in the labs program

We assume that most labs that would choose to participate in the labs program would come from the pool of labs that currently test human or animal food offered for import covered under the proposed rule, and shell-eggs, sprouts, or bottled water subject to specific testing requirements covered under the proposed rule. Moreover, we assume that most of the labs that choose to participate in the labs program would currently be accredited to ISO/IEC 17025. However, some of these labs may decide not to participate in the labs program to avoid the additional costs associated with labs program participation. Furthermore, some labs not currently

[2] A probability distribution defined by three parameters; a minimum, a maximum and a most likely value

accredited to ISO/IEC 17025 may choose to participate in the labs program if their current standards of operation roughly match those required by the proposed rule, if finalized.

Informal communications with labs that test human and animal food offered for import covered under the proposed rule suggest that these labs may differ from the labs used for shell-egg, sprouts, and bottled water subject to specific testing requirements covered under the proposed rule. Labs that test human or animal food offered for import covered under the proposed rule may be located close to ports of entry and specialize in testing protocols for foods based on Import Alerts. Labs that test shell-eggs, sprouts, and bottled water may be more geographically dispersed and specialize in testing and sampling protocols specific to shell-eggs, sprouts and bottled water requirements. For this analysis, we estimate the impacts of the proposed rule on these two types of labs separately. We ask for comment on the numbers, specializations, and geographic locations of labs that test human and animal food offered for import covered under the proposed rule and labs that test shell-eggs, sprouts, and bottled water subject to specific testing requirements covered under the proposed rule.

i. The existing number of labs that test human and animal food offered for import covered under the proposed rule that would participate in the labs program

We estimate the range in the number of labs that would test human and animal food offered for import covered under the proposed rule from the pool of all labs reported in our Private Laboratory Analytical Package System (PLAPS) for January 1, 2016, through December 31, 2017 (Ref. 4). Approximately 106 private labs performed the testing of human and animal food offered for import covered under the proposed rule during this period, with 44 of the labs accredited to ISO/IEC 17025 and 62 of the labs unaccredited for any scope. During this period, accredited labs performed between 92.4 percent and 96.8 percent of all tests, with an average of

97.4 percent. Ten of the labs, owned by four companies, performed between 82 percent and 86 percent of the analyses.

We assume that some labs may decide to forego participation in our program rather than incur the additional costs associated with accreditation. We assume that labs would choose to participate in the labs program if their current standards of operation are roughly comparable to our proposed requirements, or if a significant fraction of their business would include testing covered by this proposed rule, or some combination of these two situations. Because ten labs currently perform a large share of tests of human or animal food offered for import covered under the proposed rule (82 percent to 86 percent) we assume that many labs that currently perform these tests (106 labs in total) would decide not to participate in the labs program. We assume that approximately 25 percent of the total number of labs that test human and animal food offered for import covered under the proposed rule between January 1, 2016 through December 31, 2017, or approximately 25 labs (25 percent x 106 labs = 26.5 labs, rounding to the nearest 5 to acknowledge uncertainty in the estimate) would be an upper bound on the number of labs that would choose to participate in the labs program. We ask for comment on this assumption.

In our analysis, we estimate the range in the number of labs that would test human or animal food offered for import covered under the proposed rule that would participate in the labs program by assuming a Pert distribution between 4 labs (the number of companies that own the ten labs that perform 82 percent to 86 percent of analyses) and 25 labs, with 10 labs being the most likely number (the number of labs that perform 82 percent to 86 percent of analyses), and 12 labs being the mean of the distribution. We ask for comment on the number of labs that test

human or animal food offered for import covered under the proposed rule that would participate in the labs program.

ii. The existing number of labs that test shell-eggs, sprouts, and bottled water subject to specific testing requirements covered under the proposed rule that would participate in the labs program

We lack detailed information on the number of labs that currently test shell-eggs, sprouts, and bottled water subject to specific testing requirements covered under the proposed rule and that might choose to participate in the labs program. However, we have information on the use of labs by the shell-egg industry from an informal survey of members of the Egg Safety Committee of the National Egg Regulatory Officials (NERO). We do not have a reliable source of information on the numbers of labs used by bottled water manufacturers and by sprouts producers; we anticipate few bottled water tests and few sprouts tests would be subject to the specific testing requirements covered by this proposed rule. Therefore, we assume that the labs used by shell-egg producers are also used by bottled water manufacturers and sprouts producers. We ask for comment on this assumption.

Findings from a survey of members of the Egg Safety Committee of the National Egg Regulatory Officials conducted in 2015 indicate that egg producers often use a public university or state lab to test shell-eggs (Ref. 5). We assume these labs would test eggs subject to the specific testing requirements covered by the proposed rule. Responses to the survey from 17 owners who each own several large egg farms suggest that 71 percent of egg farms use a state government lab or in-state public university lab for egg testing. The remaining 29 percent of owners reported that they use a private lab located outside of the state. While there may be biases when applying the 17 responses of the Egg Safety Committee of NERO to the behavior of the

industry overall, the findings suggest the use of public university or state labs by the egg industry for egg testing is likely widespread.

Thus, as an upper bound on the number of participating labs, we estimate that 50 labs (corresponding to 1 lab in each of the 50 states) might test shell-eggs subject to testing requirements covered under the proposed rule. We note that while not all respondents reported using public or state labs for testing shell-eggs, our upper bound estimate assumes that every state would have a private or public participating lab. We assume that one third of the upper bound (16) would be the lower bound on the number of labs that test shell-eggs subject to testing requirements covered under the proposed rule that would participate in the labs program. We ask for comment on the number of labs that test shell-eggs that would participate in the labs program.

We consider it unlikely that labs would participate in the program if tests of sprouts subject to specific testing requirements covered under the proposed rule were the only tests that would be performed by the participating lab. Consequently, we estimate that the number of participating labs that would test sprouts subject to specific testing requirements covered under the proposed rule is smaller than the number of labs that test shell-eggs, and that a subset of the labs that test shell eggs would perform all tests of sprouts subject to specific testing requirements covered under the proposed rule.

We lack detailed information on the number of labs that test bottled water subject to specific testing requirement covered under the proposed rule. We do not have documentation of every instance where bottled water manufacturers were required to test five samples from a sampling site that originally tested positive for *E. coli*. For purposes of this analysis, we estimate that the number of participating labs that would test bottled water subject to specific testing

requirements covered under the proposed rule is smaller than the number of labs that test shell-eggs, and that a subset of the labs that test shell eggs would perform all tests of bottled water subject to specific testing requirements covered under the proposed rule. We request comment on this assumption and information about labs that test bottled water.

iii. The number of labs that would test with accredited labs under other circumstances as required by FDA

The proposed rule, if finalized, would affect labs that test under the following circumstances:

- As part of a corrective action plan after an order suspending registration,
- To submit evidence for a hearing prior to a mandatory recall order,
- To submit evidence for an appeal of an administrative detention order, and
- Under a food testing order.

We lack detailed information on the number of labs that would participate in our labs program for these purposes. Moreover, we assess that these tests would occur infrequently. Note that food testing orders are a new tool we would be implementing via this rulemaking, but we expect the annual number would be quite low. We consider it unlikely that the small number of tests that might be conducted in these situations would support the costs to participate in the labs program if these were the only tests performed by the participating lab. Consequently, we estimate the number of participating labs that would perform these tests would be smaller than the number of labs that test shell-eggs, sprouts or bottled water and that a subset of the labs that test shell eggs, sprouts or bottled water subject to specific testing requirements would perform all tests required for these situations. We ask for comment on this assumption.

c. The number of affected importers of human and animal food offered for import covered under the proposed rule

We assume that importers of human and animal food offered for import covered under the proposed rule would communicate with the United States Customs and Border Patrol and us regarding any testing that might be required. Internal information reports there were 1,219 importers associated with human or animal food offered for import covered under the proposed rule during the 2018 fiscal year. We assume a lower bound of 1,219 importers of human and animal food offered for import covered under the proposed rule that would incur one-time cost to learn about the proposed rule. Because human and animal food offered for import covered under the proposed rule varies from year to year we anticipate that the importers of such human and animal food would also vary from year to year. We assume that three times the lower bound (3,657) would be the upper bound on the total number of importers of human and animal food offered for import covered under the proposed rule that would incur learning costs.

d. The number of shell-egg, sprouts and bottled water manufacturers affected by the proposed rule

We do not know by how much the number of covered shell-egg producers has changed since publication of the Shell-egg final rule in 2009. Consequently, in our analysis we use the number of producers (7,359) published in the Regulatory Impact Analysis of the Shell-egg final rule (Ref. 6). We ask for comment on the use of that number in this analysis. We do not know by how much the number of covered sprouts producers has changed since publication of the FSMA Produce Safety Final rule in 2015. Consequently, in our analysis we use the number of producers (285) published in the Regulatory Impact Analysis of the FSMA Produce Safety final rule (Ref. 7).

Internal inspection data indicate there are 669 domestic bottled water manufacturing establishments that have been inspected between 2002 and 2016 and would be affected by the proposed rule, if finalized. Firms that bottle water and have not yet been inspected would be excluded from this estimate. Firms that exited the industry after being inspected may still be listed in our database. We assume that these numbers off-set each other. We ask for information of the potential number of firms affected by this proposed rule, if finalized.

e. The total number of entities

We estimate that the proposed rule, if finalized, would affect between about 9,600 to about 12,100 entities, including those labs and ABs that choose not to participate in the labs program. We report the estimated numbers of entities by type of entity in Table 3.

Table 3: Number of entities by type of entity affected by the proposed rule, if finalized

	Number affected[1]	Number that would participate (Lower bound)	Number that would participate (Upper bound)
ABs	80	5	80
Labs that test human and animal food offered for import covered under the proposed rule	106	4	25
Labs used for other testing covered under the proposed rule	50	16	50
Importers of human or animal food offered for import covered under the proposed rule	3,657	1,219	3,657
Bottled water manufacturers	669	669	669
Shell-egg producers	7,359	7,359	7,359

Sprouts producers covered by the Produce rule	285	285	285
Total	**12,125**	**9,557**	**12,125**

[1] Includes entities that would choose to participate in the labs program and entities that would choose not to participate in the labs program.

2. The current baseline practices of affected entities

a. Accreditation status of labs that would participate in our program

The proposed rule, if finalized, would require that participating labs be accredited to ISO/IEC 17025 and meet some additional management and technical requirements beyond ISO/IEC 17025.

i. The current accreditation status of labs that would participate to test human and animal food offered for import covered under the proposed rule

Based on our internal study of PLAPS reports from January 1, 2016, through December 31, 2017, we assume that all participating labs that test human and animal food offered for import covered under the proposed rule are currently accredited to ISO/IEC 17025.

ii. The current accreditation status of labs that would participate to test shell eggs, sprouts, bottled water, and other food testing covered under the proposed rule

We conducted an informal survey of our partner state labs and obtained 19 responses from 19 states about their ISO/IEC 17025 accreditation status. Fourteen of the 19 labs responded that they were accredited to ISO/IEC 17025. To estimate a lower bound on the accreditation status of labs that would participate to test food subject to specific testing requirements and other food testing under the proposed rule, we conservatively assume that our survey non-responses represent unaccredited labs and that states with more than one lab would accredit only one of their labs to the ISO/IEC 17025 standard in response to the proposed rule. If we extrapolate our

findings to 50 state labs, we obtain a lower bound of the accreditation status of state labs of 28 percent (= (14 affirmative responses by labs) ÷ (19 responses + 31 non-responses)). If we extrapolate our findings to 50 state labs and assume that all 31 state labs that did not respond to our survey are accredited to ISO/IEC 17025, we obtain an upper bound of the accreditation status of state labs of 90 percent (= (14 affirmative responses by labs + 31 assumed affirmative responses by non-responding labs) / (19 responses + 31 non-responses)).

Information obtained from a sprouts assignment conducted by our investigators in fiscal year 2014-15 indicates that 14 of the 19 labs that sprouts producers reported using, or 73.7 percent, were accredited to ISO/IEC 17025 with the accreditation status of the five remaining labs uncertain. Consequently, we estimate the accreditation status of labs that test sprouts subject to testing requirements ranges between 73.7 percent (=14 accredited labs / 19 total labs) and 100 percent (=19 accredited labs / 19 total labs).

We assume the labs that test bottled water are a subset of the labs that test shell-eggs but do not know the current accreditation status of labs that test bottled water. We assume the accreditation status of participating labs that would test bottled water subject to specific testing requirements is the same as that for participating labs that would test shell-eggs and sprouts subject to the proposed testing requirements. We ask for comment on this assumption.

For this analysis we assume the average of the accreditation status reported above for labs that test shell-eggs and sprouts subject to the requirements of the proposed rule represents the accreditation status of the participating labs that would test shell-eggs, bottled water, sprouts and as part of corrective action plans to support petitions for the reinstatement of registration, as evidence for hearings prior to a mandatory recall, as part of evidence for hearings on administrative detentions, and for food testing orders. The average accreditation status ranges

between 50.9 percent (average of 28 percent and 73.7 percent) and 95 percent (average of 90 percent and 100 percent), with a mean of 72.9 percent. We ask for comment on this assumption.

iii. Summary of the accreditation status of all participating labs

As shown in Table 3, we expect that the number of participating labs would range from 16 labs to 50 labs. Our lower bound estimate of currently accredited labs that would participate in the labs program equals 16 labs x 50.9 percent accreditation status, or approximately 8 accredited labs. This suggests that 8 unaccredited labs also participate to yield the total lower bound of 16 participating labs. Similarly, our upper bound estimate of currently accredited labs that would participate in the labs program equals 50 labs x 95 percent accreditation status, or approximately 48 labs. This suggests that 2 unaccredited labs also participate to yield the total upper bound of 50 participating labs. We report estimates of the accreditation status of participating labs that would be subject to the requirements of the proposed rule in Table 4. Table 5 shows our estimate of the number of currently accredited and unaccredited labs that would participate in the labs program.

Table 4: The accreditation status of all participating labs

	Lower bound	Upper bound
Participating labs that would test human and animal food offered for import covered under the proposed rule	100%	100.0%
Participating labs that would test shell-eggs, sprouts and bottled water and other tests covered under the proposed rule	50.9%	95.0%

Table 5: Estimated number of labs that would participate in the labs program by current accreditation status

	Lower bound	Upper bound

Number of labs currently accredited to ISO/IEC 17025 that would participate in the labs program to test human and animal food offered for import covered under the proposed rule	4	25
Number of labs currently not accredited to ISO/IEC 17025 that would participate in the labs program to test human and animal food offered for import covered under the proposed rule	0	0
Number of labs currently accredited to ISO/IEC 17025 that would participate in the labs program to test eggs, sprouts, bottled and other tests covered under the proposed rule	8	48
Number of labs currently not accredited to ISO/IEC 17025 that would participate in the labs program to test eggs, sprouts, bottled and other tests covered under the propose rule	2	8

Note that the sum of the cells in each column is less than corresponding bound on the number of participating labs reported earlier. However, the lower bound of unaccredited labs plus the upper bound of accredited labs in this table equals the upper bound on the number of participating labs by type reported earlier, and vice versa.

b. The baseline number of analytical reports

i. Analytical reports of tests of human and animal food offered for import covered under the proposed rule

We use information from the Private Laboratory Analytical Packages (PLAPs) dataset to estimate the annual number of analytical reports of tests of human and animal food offered for import covered under the proposed rule. Our practice of grouping individual analytical reports when reporting them in our PLAPs dataset makes it difficult to precisely identify the number of individual analytical reports. We use the results of two internal analyses of PLAPs that cover the period between January 1, 2016, and December 31, 2017. These analyses determined that the annual number of analytical reports submitted to us from private labs ranged between 10,378 and 14,370 reports. (Ref. 4). However, labs currently submit analytical reports to support import admissibility decisions and may not currently submit analytical reports of tests with positive findings. Internal information from PLAPs for 2013-2017 suggests there are between 330 and

740 analytical reports per year with positive findings for tests of human and animal food offered for import covered under the proposed rule. Consequently, we estimate between 10,708 and 15,110 analytical reports would be submitted for tests of human and animal food offered for import covered under the proposed rule (10,378 + 330 = 10,708; and 14,370 + 740 = 15,110).

ii. Analytical reports of tests of shell-eggs subject to specific testing requirements

The proposed rule would require that only participating labs would test shell-eggs subject to certain specific testing requirements described in the Shell-egg Final Rule (Ref. 8). The regulatory impact analysis of the Shell-egg Final Rule does not provide estimates of the number of tests of shell-eggs that would be performed to comply with that rule, only the costs incurred for testing shell-eggs generally. We used this information on the costs for testing shell-eggs to estimate the number of tests of shell-eggs implicit in that analysis. We then use this number as the number of tests of shell-eggs that would be subject to the requirements of this proposed rule.

The regulatory impact analysis of the Shell-egg Final Rule reports total egg testing costs that range from $6,812,000 to $7,319,000 with a 48 percent rate of compliance with the shell-egg testing requirements. We scale these shell-egg testing costs by the estimated compliance rate to estimate the total shell-egg testing costs that we expect would be subject to this proposed rule. Therefore, total shell-egg testing costs range from $14,191,667 to $15,247,917. Using the per sample test costs from the regulatory impact analysis of the shell-egg final rule--$2,169 for sample of 1,000 eggs that includes 50 sub-samples of 20 eggs each--we calculate that labs conduct between 6,543 tests (= $14,191,667 total costs / $2,169 per test) and 7,030 tests (= $15,247,917 total costs / $2,169 per test) annually. Thus, we assume the number of tests of shell-eggs derived from the Regulatory Impact Analysis of the Shell-egg Final Rule represents

the upper bound on the number of shell-egg tests that would be subject to the requirements of the proposed rule.

We assume positive environmental tests that trigger shell-egg tests subject to the specific testing requirements in the proposed rule have declined following implementation of the Shell-egg Final Rule in 2009. Informal discussions with subject matter experts suggest that the fraction of positive findings from environmental tests from shell-egg production facilities is low. For a lower bound, we assume that 20 percent of the number of shell-egg tests derived from the regulatory impact analysis of the Shell-egg Final Rule as the number of shell-egg tests covered under the proposed rule – between 1,309 and 1,406 tests (20 percent x 6,543 = 1,309; and 20 percent x 7,030 = 1,406). We request comment on our assumptions.

As shown in Table 6, the proposed rule, if finalized, would require that participating labs conduct these tests and submit analytical reports directly to us. We ask for comment on our estimates of the number of shell-egg tests that would be subject to the requirements of this proposed rule.

Table 6: Estimated annual number of analytical reports that would be submitted for tests of shell-eggs

	Annual shell-egg testing costs[1]	Annual number of shell-egg tests (Lower bound)	Annual number of shell- egg tests (Upper bound)
Costs of egg tests, row-based sampling	$14,191,667	1,309	6,543
Costs of egg tests, random swab sampling	$15,247,917	1,406	7,030

[1] From Tables 24 and 25 in the Regulatory Impact Analysis of the Shell-egg Final Rule, 74 FR 33029, July 9, 2009

iii. Analytical reports of tests of sprouts and bottled water subject to specific testing requirements covered under the proposed rule

The proposed rule would require that sprout producers have participating labs conduct follow-up tests following a positive finding of *Listeria* species or *L. monocytogenes* from environmental surveillance required under the Produce Safety Final Rule. Sprout producers must conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected, conduct additional testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated, and conduct finished product testing when appropriate.

We use information obtained from the sprouts assignment conducted by our investigators in fiscal year 2014-15 to estimate the number of analytical reports that would be submitted to us for environmental tests and finished product tests of sprouts subject to this proposed rule. From this sprouts assignment, 2 of 186 samples of spent sprout irrigation water, or 1.07 percent, were found to be positive for either members of the genus Salmonella or *Listeria monocytogenes*. We assume that 1.07 percent of sprouts producers or 5 sprout producers (5 sprout producers = 1.07 percent x 285 covered sprouts producers) would conduct one test of a surface and one test of the surrounding area, for an estimate of 10 tests of surfaces and surrounding areas that would be subject to the requirements of the proposed rule. In addition, we assume that each positive environmental test finding would trigger one finished product test that would be subject to the requirements of the proposed rule. Consequently, we estimate there would be a total of 15 tests that would be subject to the requirements of the proposed rule (10 tests of surfaces and the surrounding areas, and 5 tests of the finished product). We ask for comment on the number of environmental and finished product tests of sprouts that would be subject to the requirements of the proposed rule.

The proposed rule would require that the certain bottled water testing required by current bottled water regulations would be subject to testing under the proposed rule. We use the estimates from the regulatory impact analysis of the Bottled Water final rule (Ref. 8) to estimate the number of bottled water tests that would be subject to this proposed rule. The regulatory impact analysis of the Bottled Water final rule predicts that 2 to 3 bottlers per year would have to perform corrective action testing for *E. coli* positive test results from samples taken from a bottler's source water. A water source is considered free of *E. coli* after five consecutive negative sample findings collected over a 24-hour period. The proposed rule would require that these tests be performed by a participating lab and that the lab send the analytical reports directly to us. Consequently, we estimate 25 to 30 tests would be performed annually by participating labs for sprouts producers and water bottlers subject to the requirements of the proposed rule (15 tests related to sprouts + 10 to 15 tests related to bottled water = 25 to 30 tests). We ask for comments on this estimate.

iv. Analytical reports of tests conducted to satisfy other testing covered under the proposed rule

Use of a participating lab may be necessary as part of a corrective action plan after an order suspending registration, to submit evidence for a hearing prior to a mandatory recall order, to submit evidence for an appeal of an administrative detention order, and as required under a food testing order. Because these situations would likely occur infrequently, we estimate the number of samples tested for the purposes discussed in this section would be included within the ranges of the numbers of analytical tests for shell-eggs, sprouts and bottled water subject to specific testing requirements covered under the proposed rule. We report the total number of

analytical reports of tests that we estimate would be compiled by a participating lab in the Table 7.

Table 7: Number of analytical reports that would be compiled by a participating lab

	Lower bound	Upper bound
Human and animal food offered for import	10,708	15,110
Shell-egg final rule	1,309	7,030
Sprouts	15	15
Bottled water rule	10	15
Total number of analytical reports[1]	12,041	22,170

[1] Totals include analytical reports for tests conducted as part of a corrective action plan after an order suspending registration, to submit evidence for a hearing prior to a mandatory recall order, to submit evidence for an appeal of an administrative detention order, and under a food testing order

c. Baseline costs for industry to compile and for us to review an analytical report

The proposed rule would establish clear procedures and expectations for industry to submit analytical reports for tests covered by the proposed rule and for us to review these analytical reports. The current process for reviewing analytical reports of tests of human or animal food offered for import covered under the proposed rule includes an initial check (QC) for completeness upon receipt of the analytical report, a non-technical review of documents to establish a link between the sample and the detained shipment as well as the adequacy of the sample, and a high-level technical review that examines documentation to determine the adequacy of the analytical methods used. We use information from an internal analysis of information from 10 of our regional labs to derive an estimate of the average burden to review an analytical report for tests of human and animal food offered for import covered under the proposed rule. We assume the costs to review an analytical report for tests of eggs, sprouts and bottled water subject to specific testing requirements and other tests would be the same as that for tests of human and animal food offered for import covered under the proposed rule.

We assume the baseline cost for industry to compile an analytical report and for us to review an analytical report include the probability that some analytical reports submitted by industry are initially deficient and returned to industry before resubmitting a deficiency-free analytical report. We use an internal study on the burden incurred by us to review an analytical report and the percent of analytical reports that are deficient at the three stages of the review process: the QC, the non-technical review, and high-level technical review. We assume the extra burden incurred by industry to address a deficient analytical report is proportional to the extra burden incurred by us to review a deficient analytical report.

A deficiency found at the QC stage is returned to industry without going further into the review process. Deficiencies found during the non-technical review may require resampling the lot of human or animal food or require additional information necessary to establish a link between the sample and the lot of human or animal food it represents. A deficiency found during high-level technical review may require us to convene an Expert Panel Task to recommend acceptable remedies and it may require labs to submit additional information to support the analytical methods used for the test. An internal study indicates that approximately 5 percent of analytical reports are found to be deficient at the QC stage, 10 percent at the non-technical review stage, and 60 percent of analytical reports are found to be deficient at the high-level technical review stage.

Experts from our field labs estimate the burdens for each of the review stages: the burden for the QC is 0.08 hours, for the non-technical review is 0.30 hours and the high-level technical review is 1.51 hours, for a total burden to review an analytical report of 1.89 hours (0.08 + 0.30 + 1.51). Consequently, we assume an acceptable analytical report that contains no deficiencies would require a review burden of 1.89 hours. The current baseline burden to review an analytical

report includes the probability of it being deficient. To estimate the current baseline costs that includes the extra review burdens incurred from deficient analytical reports we assume that each deficient analytical report is found to be fully acceptable after the first pass-back to industry. Consequently, we estimate the baseline burden to review an analytical report, including the probability of it being deficient is 2.83 hours (0.08 hours for QC x (1 + 0.05 probability of deficiency) + 0.30 hours for non-technical review x (1 + 0.1 probability of deficiency) + 1.51 hours for a high-level technical review x (1 + 0.6 probability of deficiency) = 2.83 hours).

Table 8: Average burden to review an analytical report including the probability of it being deficient

Review stage	Burden to review a fully acceptable report (hours)	Probability of being deficient by review stage	Baseline burden to review an analytical report (hours)
QC	0.08	0.05	0.08
Non-technical review	0.30	0.10	0.33
High-level technical review	1.51	0.60	2.42
Total	1.89		2.83

We obtain the average extra burden of 0.94 hours for us to review an analytical report that includes the probability of it being deficient (2.83 hours burden to review an analytical report, including the probability if it being deficient – 1.89 hours to review a fully acceptable analytical report = 0.94 hours). We assume the average extra burden for industry to compile an analytical report that includes the probability of it being deficient is proportional to the average extra burden incurred by us to review an analytical report. We do not have information on the current baseline burden incurred by industry to compile an analytical report. We estimate the current burden to compile an analytical report of between four hours and eight hours, which includes the probability of it being deficient. We obtain the extra burden per analytical report incurred by industry of between 1.3 hour (4 hours x 0.94 hours extra review burden / 2.83 review

burden) and 2.7 hours (8 hours x 0.94 hours extra review burden / 2.83 hours average review burden). We report the parameters used to estimate the extra burden per analytical report for industry and us in Tables 9a and 9b.

Table 9a: Extra burden to review an analytical report incurred by us

	Burden estimate (hours)
FDA current burden to review an analytical report that includes the probability of being deficient	2.83
FDA burden to review a fully acceptable analytical report	1.89
Extra review burden per report due to deficiencies	0.94

Table 9b: Extra burden to compile an analytical per report incurred by industry

	Lower estimate (hours)	Upper estimate (hours)
Current baseline burden for industry to compile an analytical report that includes the probability of being deficient	4.0	8.0
Extra burden per report for industry due to deficiencies	1.3	2.7

We multiply the fully loaded hourly wage for an ORA reviewer of $116.75, derived from the FY2018 annual fully loaded salary for ORA personnel used by FDA for budgeting purposes, to obtain the cost for us to review an analytical report of about $330 (2.83 hours x $116.75 = $330.40) and an extra burden to review a deficient analytical report of about $110 (0.94 hours x $116.75 = $109.74). We multiply by the fully loaded wage of a Food Scientist and Technologist of $69.22 to obtain the baseline cost for industry to compile an analytical report of between about $277 (4 hours x $69.22 = $276.88) and $554 (8 hours x $69.22 = $553.76), with an extra review burden of between about $92 (1.3 hours x $69.22 = $91.97) and $184 (2.7 hours x

$69.222 = $183.94). We report the current baseline costs and extra burdens for us to review an analytical report and for industry to compile an analytical report in Tables 10a and 10b.

Table 10a: Baseline costs and extra burdens for us to review an analytical report

	Average burden (hours)	Wage	Total cost
Baseline costs for us to review an analytical report	2.83	$116.75	$330.40
Cost of the extra review burden due to deficiencies	0.94	$116.75	$109.74

Table 10b: Baseline costs and extra burdens for industry to compile an analytical report

	Low burden (hours)	High burden (Hours)	Low cost	High cost
Baseline costs to compile an analytical report	4.0	8.0	$276.88	$553.76
Cost of the extra burden to compile an analytical report due to deficiencies	1.3	2.7	$91.97	$183.93

E. Benefits of the Proposed Rule

There are quantified and unquantified benefits from the proposed rule. Quantified benefits include (1) cost savings from specifying the requirements for tests and analytical reports that would reduce the extra burdens incurred by us and industry to review and compile analytical reports of tests of human or animal food offered for import covered under the proposed rule, and (2) cost savings from allowing participating labs to submit abridged analytical reports for tests of human or animal food offered for import covered under the proposed rule following the successful submission of 10 consecutive fully acceptable analytical reports. In addition, improvements to our management systems required for establishing the labs program would

reduce the amount of time we spend to review an analytical report. Quantified benefits also include the reduction in the numbers of false negative and false positive results for all tests covered by the proposed rule. Fewer false negatives would result in fewer illnesses and QALD losses stemming from contaminated shipments of human or animal food, and fewer false positives would result in fewer revenue losses from shipments of safe human or animal food.

Unquantified benefits include increased deterrence of unsafe food manufacturing practices by all covered entities due to improved test performance. Test reporting and sample collection oversight requirements may deter improper test reporting practices and improve sample collection practices. Better test reporting practices may result in fewer false negative test results (if current practices encourage the intentional reporting of negative test results) while better sample collection practices may result in tests of samples that better represent the shipment of human or animal food. Both proposed improvements may add to the deterrence of unsafe food manufacturing practices.

1. Annual cost savings from specifying requirements for tests and analytical reports for human and animal food offered for import covered under the proposed rule

We currently don't receive analytical reports for tests of shell eggs, bottled water, sprouts, and other food subject to specific testing requirements covered under the proposed rule. Thus, in this section and the subsequent section we calculate cost savings from tests and analytical reports for human or animal food offered for import covered under the proposed rule.

Some analytical reports may be deficient for many reasons, including failures to include data necessary to replicate test results, to verify and validate methods, to include names of analysts, and other reasons. By clarifying our expectations for the content required in an analytical report of tests of human and animal food offered for import covered under the

proposed rule and by specifying the requirements for tests and analytical reports we anticipate that the proposed rule, if finalized, would generate cost-savings for us and industry. We would spend less time reviewing deficient analytical reports before returning them to industry to address the deficiencies, and industry would spend less time addressing deficiencies, and would submit fully acceptable analytical reports the first time.

We assume the proposed clarifications would reduce the extra review burden incurred by us by between 20 percent (assume some reduction in the extra review burden) and 100 percent, and the extra burden incurred by industry by between 20 percent and 100 percent. We ask for comment on the extent to which the proposed clarifications would reduce the extra burden for preparing and submitting an analytical report.

To obtain the upper bound of cost savings accrued to us we multiply 100 percent of the upper bound number of analytical reports of tests of human and animal food offered for import covered under the proposed rule (15,110) by the extra review burden due to deficiencies from Table 10a ($109.74). Thus the upper bound on the potential cost-savings from the clarifications in the proposed rule equals $1,658,233. To obtain the lower bound on the cost savings accrued to us we multiply 20 percent of the lower bound of analytical reports of tests of human and animal food offered for import covered under the proposed rule (10,708) by the extra review burden due to deficiencies from Table 10a ($109.74). The lower bound on potential cost-savings from clarifications in the proposed rule equals $235,017. We assume the estimate of the cost-savings accrued to us would be uniformly distributed between the lower and upper bounds.

To obtain the upper bound of cost savings accrued to industry we multiply 100 percent of the upper bound number of analytical reports of tests of human and animal food offered for import covered under the proposed rule (15,110) by the extra burden to compile an analytical

report from Table 10b ($183.93). Thus the upper bound of potential cost-savings for industry equals $2,779,249. To obtain the lower bound on the cost savings accrued to industry we multiply 20 percent of the lower bound number of analytical reports of tests of human and animal food offered for import covered under the proposed rule (10,708) by the extra burden to compile an analytical report from Table 10b ($183.93) Thus the lower bound of potential cost-savings from clarifications in the proposed rule equals $196,948. We assume the estimate of the cost-savings accrued to industry would be uniformly distributed between the lower and upper bounds. In Table 11, we report the cost savings for industry and us from clarifying expectations of tests of human and animal food offered for import covered under the proposed rule.

Table 11: Annual cost-savings to industry and us from clarifying expectations for compiling and reviewing analytical reports of tests of human and animal food offered for import covered under the proposed rule

	Lower bound	Upper bound
Industry cost savings	$196,948	$2,779,249
FDA cost savings	$235,017	$1,658,233

We assume a uniform distribution of the cost savings to us and industry and use a Monte Carlo simulation to obtain the 5 percent, mean and 95 percent estimates. We report these estimates in Table 12.

Table 12: Annual cost-savings to industry and us from clarifying expectations for compiling and reviewing analytical reports of tests of human and animal food offered for import covered by the proposed rule

	5th percentile estimate	**Mean estimate**	**95th percentile estimate**
Industry cost savings	$324,560	$1,488,098	$2,648,679
FDA cost savings	$305,954	$946,625	$1,586,931

2. Cost savings from abridged analytical reports for tests of human and animal food offered for import covered under the proposed rule

We propose to reduce the quantity of information required in an analytical report once participating labs have successfully submitted 10 consecutive full analytical reports. Participating labs that successfully submit 10 consecutive full analytical reports will then be permitted to comply with the abridged analytical report requirements. We currently require a full analytical report to contain detailed and substantive documentation that allows us to confirm the analysis was performed correctly. Moreover, information in a full analytical report would allow us to review each analytical step in the test and confirm the test results, if necessary. The abridged analytical report would include a fraction of the amount of information required in a full analytical report. We assume the burdens to compile and to review an abridged analytical report to be between 25 percent and 33 percent of the burdens to compile and review a full analytical report. Participating labs subject to abridged analytical report requirements would still be required to maintain records of all information required in a full analytical report. As a check of participating labs subject to abridged analytical report requirements, we would occasionally audit information required in a full analytical report.

All cost-savings from allowing abridged analytical reports would come from analytical reports of tests of human and animal food offered for import covered under the proposed rule, because testing results are often submitted as part of testimony for foods under DWPE. There would be no cost-savings generated from abridged analytical reports for tests of shell eggs, sprouts, bottled water or other food subject to specific testing requirements because there is no current requirement to submit these analytical reports.

We use the burden estimates for industry to compile a full analytical report assuming the efficiency gains from the proposed rule's clarifying requirements have been realized. Thus, the time to compile a full analytical report would fall from 4 hours to 2.7 hours in the lower bound and fall from 8 hours to 5.3 hours in the upper bound. We multiply the fully loaded wage of a Food Scientist and Technologist of $69.22 to obtain the cost to compile a full analytical report of between about $185 (2.7 hours x $69.22 = $184.91) and $370 (5.3 hours x $69.22 = $369.83). Similarly, we use the burden estimates for us to review a full analytical report assuming the efficiency gains from the proposed rule's clarifying requirements have been realized. Thus, the time we spend reviewing a full analytical report would fall from 2.83 hours to 1.89 hours. We multiply by the fully loaded hourly wage for an ORA reviewer of $116.75 and obtain the cost to review a full analytical report of about $221 (1.89 hours x $116.75 = $220.66).

We assume the cost to compile an abridged analytical report and the cost to review an abridged analytical report ranges between 25 percent and 33 percent of the cost to compile and the cost to review a full analytical report. Consequently, we estimate the costs for industry to compile an abridged analytical report would be between about $46 (25 percent x $184.91 = $46.23) and $122 (33 percent x $369.83 = $122.04), and costs for us to review an abridged analytical report would be between about $55 (25 percent x $220.66 = $55.16) and $73 (33 percent x $220.66 = $72.82). In Tables 13a and 13b we report the costs to compile and review a full analytical report and an abridged analytical report, both incorporating the cost-savings from the proposed rule's clarification discussed in the previous section.

Table 13a: Cost for industry to compile an abridged analytical report - net of the efficiency gains from the proposed rule's clarifications

	Lower bound	Upper bound

Cost to compile a full analytical report (net of efficiency gains from clarifications)	$184.91	$369.83
Cost to compile an abridged analytical report	$46.23	$122.04

Table 13b: Cost for us to review an abridged analytical report – net of the efficiency gains from the proposed rule's clarifications

	Lower bound	Upper bound
Cost for us to review a full analytical report (net of efficiency gains from clarifications)	$220.66	$220.66
Cost for us to review an abridged analytical report	$55.16	$72.82

3. Total Cost-savings from allowing abridged reporting

We estimate the annual cost-savings for industry to compile abridged analytical reports and for us to review abridged analytical reports as the difference between the costs to compile between 10,708 and 15,110 full analytical reports at between $184.91 and $369.83 per report and the costs to compile between 10,708 and 15,110 abridged analytical reports at between $46.23 and $122.04 per report, less the costs to compile 10 consecutive successful full analytical reports at the cost of a full analytical report for between 4 and 25 participating labs that we expect would qualify for abridged reporting. We report the 5th percentile, mean and 95th percentile estimates of the cost-savings for us and industry from allowing abridged reporting in Table 14.

Table 14: Cost savings from allowing abridged reporting

	5th percentile estimate	Mean estimate	95th percentile estimate
Annual cost savings accrued to industry from compiling abridged reports for tests food offered for import covered under the proposed rule	$1,287,201	$2,500,718	$3,814,052
Annual cost savings accrued to us from reviewing abridged reports for tests of	$1,717,446	$2,027,155	$2,375,194

food offered for import covered under the proposed rule			

4. Cost-savings from reduced burdens to review analytical reports of tests of human and animal food offered for import covered under the proposed rule due to improvements to the current management systems

We would improve upon current management systems to administer the requirements of the program. Improvements in the management systems would expedite our processes for creating work assignments, including identifying technical lead panels, routing analytical reports to the labs most appropriate for reviews, notifying labs and reviewers of new work activities, identifying and convening expert panel assignments and for closing out and reopening reviews of analytical reports. In addition, improvements in current management systems would facilitate retrieval of information on participating labs from previous analytical reports, including validation and verification studies, and other relevant information on the participating labs' qualifications. Once these improvements have become operational we expect a reduction in the amount of time required to review an analytical report. While this would not be a cost-savings attributable to requirements of the proposed rule per se, we adjust current baseline analytical report review times by the new lower review times that would results from the one-time costs of establishing the labs program, discussed later in the analysis.

We expect the proposed rule, if finalized, would reduce the time to review an abridged analytical report uniformly by between 10 percent and 25 percent. We apply the estimated percent reduction in review time to the costs of reviewing abridged analytical reports of tests of human and animal percent food offered for import covered under the proposed rule in a Monte Carlo simulation to obtain the 5 percent, mean and 95 percent estimates of the annual cost-

savings from improvements in the management systems. These cost savings are reporting in Table 15.

Table 15: Cost savings to review analytical reports of tests of human and animal food offered for import covered under the proposed rule with the labs program's improved management systems

5th percentile estimate	Mean estimate	95th percentile estimate
$83,542	$143,716	$212,649

5. Total cost-savings from the proposed rule

We use a Monte Carlo simulation to add together the cost-savings to industry and FDA from clarifying submission and review processes, allowing abridged reporting, and improvements in the management systems with the establishment of the labs program to obtain estimates of the 5th percentile, mean and 95th percentile of the cost-savings accrued to industry and to us. We report the total cost savings from the proposed rule in Table 16.

Table 16 Total cost-savings from the proposed rule

	5th percentile estimate	**Mean estimate**	**95th percentile estimate**
Total industry cost savings	$2,202,588	$3,988,816	$5,834,263
Total FDA cost savings	$2,362,103	$3,117,496	$3,870,013
Total cost savings	$5,128,894	$7,106,313	$9,180,785

6. Improved Test Performance

The proposed requirements to maintain accreditation to the ISO/IEC 17025 standard for proficiency testing, and for verifying and validating methods may provide quality assurance for

testing methods. Evidence of a positive effect of lab accreditation on proficiency testing (PT) performance is somewhat mixed. For example, in a statistical analysis of 50 randomly selected sets of PT for food analysis conducted in 2006, Thompson, et al. (2009) found no statistical effect of a methods' accreditation status on PT performance (Ref. 9). However, in a later study of Canadian labs, Middlebrook (2017) did find evidence that accredited labs outperform non-accredited labs when comparing randomly selected PT results for the two groups. Middlebrook found that the percentage of Questionable and Unsatisfactory performance was higher for non-accredited labs than for accredited labs (Ref. 3). For example, Middlebrook reports that 3.42 percent of PT outcomes were Unsatisfactory for accredited labs while 6.19 percent of outcomes were Unsatisfactory for unaccredited labs, where Unsatisfactory was defined as greater than 3 standard deviations from the mean. Moreover, Middlebrook reports that 4.91 percent of outcomes were Questionable for accredited labs while 6.12 percent of outcomes were Questionable for unaccredited labs, where Questionable was defined as between 2 and 3 standard deviations from the mean. Diagnostic statistics indicate the differences reported in the PT performance outcomes for accredited and unaccredited labs are statistically significant.

Unlike previous studies, Middlebrook controls for experience with PT participation and found evidence that some (but not all) of the difference in PT performance could be explained by labs' familiarity with PT. Middlebrook attributes findings from other studies that find no statistically significant differences between the PT performances of accredited and unaccredited labs to inability to control for familiarity with the PT scheme. We assume there is no difference between the performance of accredited and unaccredited labs in the US and in Canada and use Middlebrook findings of better PT performance by accredited labs compared to unaccredited labs to estimate the reduced number of false negatives and false positives from tests of human and

animal food subject to the proposed rule. Specifically, we assume the rate of false negatives and false positives for accredited labs is distributed uniformly between the lower bound of 3.42 percent and upper bound of 8.33 percent (3.42 percent Unsatisfactory + 4.91 percent Questionable = 8.33 percent), while that for unaccredited labs is distributed uniformly between the lower bound of 6.19 percent and the upper bound of 12.31 percent (6.19 percent Unsatisfactory + 6.12 percent Questionable = 12.31 percent).

To estimate the baseline performance rate for tests of human and animal food covered under the proposed rule we multiply the weighted percentages of uniformly distributed Unsatisfactory and Questionable outcomes obtained from accredited and unaccredited labs, by the corresponding uniformly distributed shares of tests performed by those labs (accredited labs perform between 94.8 percent and 100 percent of tests of human and animal food offered for import covered under the proposed rule). Similarly, we estimate the baseline performance for tests of shell-eggs, sprouts and bottled water subject to specific testing requirements covered under the proposed rule by multiplying the weighted percentage of uniformly distributed Unsatisfactory and Questionable outcomes obtained from accredited and unaccredited labs, by the corresponding uniformly distributed shares of tests performed by those labs (accredited labs perform between 50.9 percent and 95.0 percent of tests for shell-eggs, sprouts and bottled water subject to specific testing requirements covered under the proposed rule).

Because we estimate that only a small number of tests of sprouts and bottled water subject to testing requirements would require the use of a participating lab (15 tests of sprouts per year, and 10 to 15 tests of bottled water per year), and the number of tests of other foods subject to testing are covered under the proposed rule is expected to be small, for the remainder of the benefits analysis we assume the results obtained for tests of shell-eggs subject to specific

testing requirements would also cover all other tests of human or animal food subject to testing covered under the proposed rule.

We report the baseline test performance rate variables and the expected test performance rate variables under the proposed rule, if finalized, that we use to estimate improved test performance in Tables 17a and 17b. We request comment on these assumptions.

Table 17a: Variables used to estimate improved test performance for tests of human and animal food offered for import covered under the proposed rule

	Lower bound	Middle estimate	Upper bound
Rate of unsatisfactory and questionable tests performed by labs accredited to ISO/IEC 17025	3.42%	5.88%	8.33%
Rate of unsatisfactory and questionable tests performed by labs not accredited to ISO/IEC 17025	6.19%	9.25%	12.31%
Share of tests of food offered for import currently performed by labs not accredited to ISO/IEC 17025	0.00%	3.7%	5.20%
Baseline test performance rate	**3.42%**	**5.98%**	**8.54%**
Test performance rate with the proposed rule	**3.42%**	**5.88%**	**8.33%**

Table 17b: Variables used to estimate improved test performance for tests of shell-eggs, bottled water, sprouts and other foods subject to specific testing requirements covered under the proposed rule[1]

	Lower bound	Middle estimate	Upper bound
Rate of unsatisfactory and questionable tests performed by labs accredited to ISO/IEC 17025	3.42%	5.88%	8.33%
Rate of unsatisfactory and questionable tests performed by labs not accredited to ISO/IEC 17025	6.19%	9.25%	12.31%
Share of tests of shell-eggs and bottled water subject to specific testing requirements currently performed by labs not accredited to ISO/IEC 17025	4.0%	17.5%	31.0%
Baseline test performance rate	**3.53%**	**6.55%**	**9.56%**
Test performance rate with the proposed rule	**3.42%**	**5.88%**	**8.33%**

[1] We assume the results obtained for tests of shell-eggs subject to specific testing requirements would also cover tests of sprouts and bottled water and other food subject to specific testing requirements.

We apply Monte Carlo methods to subtract the baseline performance from the expected performance with the proposed rule reported in Tables 17a and 17b to simulate the means, 5th percentile estimates, and 95th percentile estimates of the increase in test performance from the proposed rule. We assume uniform distributions between the upper and lower bounds for the variables reported in Tables 17a and 17b and estimate the change in test performance following the proposed rule to be between -3.29 percent and 3.44 percent, with an average of 0.10 percent for tests of human and animal food offered for import covered under the proposed rule, and between -3.02 percent and 4.43 percent, with an average of 0.67 percent increase in test performance for tests of shell-eggs, sprouts, bottled water and other food subject to testing covered under the proposed rule. We report estimates of the potential changes in test performance following publication of the proposed rule, if finalized, in Table 18. While the mean estimate of test performance reported in Table 18 is consistent with the effect of the proposed rule, there may be some variation as reported in the five percent and 95 percent estimates attributable to accredited lab test performance, independent of the effect of the proposed rule. We request comment on these estimates.

Table 18: The estimated change in test performance

	5 percent estimate	**Mean**	**95 percent estimate**
Tests of human and animal food offered for import covered under the proposed rule	-3.29%	0.10%	3.44%
Tests of shell-eggs, sprouts and bottled water subject to specific testing requirements[1]	-3.02%	0.67%	4.43%

[1] We assume the results obtained for tests of shell-eggs subject to specific testing requirements would also include tests of sprouts and bottled water and other food subject to specific testing requirements.

a. Fewer false negative results for tests of human and animal food subject to the proposed rule

We apply Monte Carlo methods and assume the variables for the increase in test performance from the proposed rule and the current baseline number of negative findings are uniformly distributed between the upper and lower bounds. We consider that each test applies to an entire shipment of the corresponding human or animal food. We refer to quantities of human or animal food offered for import in terms of "lines" of human or animal food, with the line reflecting the quantity of human or animal food offered for import covered under the proposed rule that would be represented by a test result. We estimate the reduction in the number of lines of human or animal food offered for import covered under the proposed rule with false negative test results would range from -419 to about 420, with a mean reduction of 13, and the reduction in the number of shipments of shell-eggs, sprouts, and bottled water and other food subject to testing covered under the proposed rule with false negative test results would range from -132 to 217, with a mean of 28.

i. Fewer contaminated servings of human and animal food offered for import covered under the proposed rule that would reach the consumer

We apply the reduction in the number of false negative tests of human and animal food offered for import covered under the proposed rule to the estimated number of food servings in a line of imported food. We estimate the number of servings in a line of imported food using internal 2016 Operational and Administrative System for Import Support (OASIS) data on the number of kilograms in a line by industry code. We convert the number of kilograms to servings by applying estimates of the Reference Amounts Customarily Consumed reported in the Serving Size regulations for the food category that closely corresponds to the industry code reported in the OASIS data (Ref. 10). We then apply an estimate of the probability that a serving from a line is contaminated given the composite sample from the corresponding line tests positive to

estimate the number of contaminated servings in a line of imported food with false negative test results.

We obtain the mean numbers of kilograms in an imported line for each of 26 industry codes reported in OASIS for 2016. The 26 industry codes represent most of all the imported food; we include in the data only those industry codes with a large fraction of lines measured in kilograms and exclude a small number of industry codes where the lines are measured in a unit other than kilograms (for example, beverage categories may be reported by volume, such as liters). After an initial cleaning of the data to account for lines reported with $0 value or with 0 kg quantity, we use two criteria to eliminate outliers that would have quantities overstated because of observed systematic input errors. We then calculate the values per kg for each line and either 1.) eliminate lines with values per kg that lie outside the interval $0.01 and $100, or 2.) eliminate lines with values per kg that lie outside the interval $0.001 and $1,000. We sampled the eliminated data to determine if they were likely candidates for systematic input error and found that to be the case. There are between about 8.5 and 8.7 million lines of imported human and animal food in the remaining data, depending on the cleaning criterion.

We apply the average Reference Amount Customarily Consumed for the food categories reported in the serving size regulations to the mean number of kilograms found for the closely corresponding industry code from the OASIS data and compute an average number of servings in a line for each industry code. We then aggregate across all industry codes and compute the weighted average number of servings in an imported line using the industry code's share of the total lines as the weights for each data set.

We assume the sample collected is randomly selected and representative of the imported line. We adjust the average number of servings in a line to account for the probability that a

serving from a line is contaminated given that a composite sample of that line tests positive. Guidance recommends collecting up to 60 sub-samples per sample, depending on the analysis of interest. If just one of the sub-samples is contaminated, the composite sample may test positive – even if the remaining sub-samples are free of contamination. Without additional information, we assume that 50 percent of sub-samples contain some contaminated servings given the composite sample tests positive. We request comment on the estimated distribution of contamination in sub-samples given a composite sample tests positive.

Not all servings in a contaminated sub-sample of food are necessarily contaminated. For example, a sub-sample weighing 1 Kg would contain approximately 36 servings of food with an average serving size of 60 grams (1,000 grams / 60 grams per serving = approximately 36 servings). Without additional information, we assume that 50 percent of servings in a sub-sample are contaminated given a contaminated sub-sample. We multiply the probabilities together and estimate that 25 percent of servings in a line are contaminated when a composite sample of that line tests positive (50 percent of sub-samples are contaminated x 50 percent of servings in a sub-sample that are contaminated = 25 percent).

We apply Monte Carlo methods to multiply the average number of servings in an imported line to the reduction in the number of lines with false negative test results and adjust by the probability that a serving in a line is contaminated given that the composite sample tests positive. We assume the number of servings in a line is lognormally distributed with the mean and standard deviation themselves uniformly distributed between the means and standard deviations obtained using the different data cleaning criteria. We assume the reduction in the number of false negative results of tests of human and animal food offered for import covered under the proposed rule is uniformly distributed between the lower and upper bounds reported

earlier. Consequently, as shown in Table 19, we estimate that between -61,867,944 and 69,420,307 contaminated servings, with a mean of 4,202,254 servings would be avoided from improved tests of human and animal food offered for import covered under the proposed rule. In Table 19 we report the variables used to estimate the number of contaminated servings avoided from improved tests of human and animal food offered for import covered under the proposed rule.

Table 19: The variables used to estimate the number of contaminated servings avoided from improved tests of human and animal food offered for import covered under the proposed rule

	Lower bound	Mean	Upper bound
The total number of lines with negative findings from tests of human and animal food offered for import covered under the proposed rule	9,967	12,373	14,779
The reduced number of false negative lines	-419	13	420
Average number of servings per line	582.85	1,312,864	3,172,534
Probability that a serving in a line is contaminated given that a composite sample tests positive		0.25	
Number of contaminated servings avoided from improved tests of human and animal food offered for import covered under the proposed rule	-67,906,409	4,202,254	63,001,990

ii. Fewer contaminated servings of shell-eggs, sprouts and bottled water and other food subject to testing covered under the proposed rule

We assume that the number of eggs contained in an egg shipment has not changed since publication of the Shell egg Final rule in 2009. We estimate the number of servings of shell-eggs in a shipment represented by a test result from information contained in the regulatory impact analysis of shell-egg final rule. The shell-egg final rule reports that approximately 3,328 egg farms subject to testing requirements produce about 72,113,000 thousand eggs per year, or approximately 21,668.57 thousand eggs per farm. We use information from Table 6 of the shell-egg final rule to estimate a weighted average of approximately 39,785 hens per farm subject to shell-egg test requirements. We obtain an average annual production per hen of approximately 545 eggs (21,668,570 eggs per farm per year / 39,785 hens per farm = 545 eggs per hen) for daily production of a hen of about 1.49 eggs (545 eggs / 365 days). Multiplying the daily production per hen by the number of hens per farm (39,785) we estimate an average of 59,366 eggs produced daily per farm. We then divide by the weighted average number of hen houses per farm of 2.21, derived from Table 6 in the final shell-egg rule, to obtain 26,839 eggs per house produced daily.

We assume a range of between 1 and 2 days-worth of egg production would be represented by a sample of shell-eggs subject to testing requirements. Consequently, we estimate that the size of a shipment of shell-eggs represented by a test is between 26,839 (26,839 eggs per hen house daily x 1 day = 26,839 eggs), and 53,679 shell eggs (26,839 eggs per hen house daily x 2 days = 53,679 eggs). We assume one egg per serving and apply the probability that a serving in a shipment of shell-eggs is contaminated given the composite sample tests positive (0.25) described earlier. Because of the estimated small numbers of tests of bottled water, sprouts and other food subject to specific testing requirements we assume the number of servings in a

shipment of these foods is the same as the number of servings in a shipment of shell-eggs. We ask for comment on this assumption.

We apply Monte Carlo methods to multiply the number of servings of shell-eggs in a shipment (between 26,839 and 53,679 shell eggs per shipment) to the reduction in the number of false negative test results of shell-eggs (between -132 and 217 shipments). We adjust by the probability that a serving of shell-eggs in a shipment is contaminated given the composite sample tests positive (0.25). We assume the reduction in the number of false negative results of tests of shell-eggs and bottled water subject to testing requirements is uniformly distributed between the 5th percentile and 95th percentile estimates reported earlier, and that the number of servings of shell-eggs in a shipment is uniformly distributed between the one and two days-worth of production for a hen house. Consequently, we estimate that between -1,361,365 and 2,174,758 contaminated servings of shell-eggs subject to specific testing requirements with a mean of 283,975 would be avoided from improved test performance. We report the variables used to obtain the number of contaminated servings of shell-eggs subject to specific testing requirements that would be avoided in Table 20.

Table 20: The variables used to estimate the number of contaminated servings avoided from better tests of shell-eggs, sprouts and bottled water and other food subject to specific testing requirements

	Lower bound	Mean	Upper bound
The total number of negative findings for shell-eggs, sprouts and bottled water subject to test requirements	1,334	4,197	7,060
The reduced number of false negative findings	-132	28	217

Average number of servings of shell-eggs per shipment represented by a test	26,839	40,259	53,679
Probability that a serving from the corresponding shipment would test positive given the composite sample tests positive		0.25	
Number of contaminated servings avoided from better test performance of shell-eggs, sprouts and bottled water and other food subject to covered testing	-1,361,365	283,975	2,174,758

[1]We assume the results obtained for tests of shell-eggs subject to test requirements would also cover tests of sprouts and bottled water and other food subject to covered testing requirements.

iii. Fewer illnesses from fewer contaminated servings on the market

We use the endpoints of the range of the estimated number of contaminated servings that would be avoided as inputs into separate runs of FDA's Food Handling Practices Model (FHPM) to estimate the range in the number of illnesses that would be avoided from the proposed rule, if finalized (Ref. 11). The FHPM allows for food contaminated at the source to either be eliminated prior to consumption or to grow and become even more of a hazard. We modified the baseline scenario in the FHPM, which is calibrated to reproduce the number of foodborne illnesses reported in Scallan, et al., by assuming that each endpoint of the range of the number of contaminated servings of human and animal food offered for import covered under the proposed rule is distributed uniformly across all seven food categories used in the model and that each serving is contaminated with probability 1. In simulations using endpoints of the range of the number of avoided contaminated servings of shell-eggs, sprouts and bottled water and other food subject to testing covered under the proposed rule, we assume each serving is contaminated with Salmonella with probability 1. We adjust the baseline probabilities of being contaminated at

retail and household levels to be zero so that the outputs contain only the number of illnesses caused by contaminated servings of human and animal food offered for import covered under the proposed rule upon import, and by contaminated shell-eggs, sprouts and bottled water and other food subject to testing covered under the proposed rules upon production.

The five percent estimate of the number of illness computed by FHPM using the 5 percent estimate of contaminated servings of human and animal food offered for import covered under the proposed rule is between about -4,408 to -4,199. When we input the mean number of contaminated servings of human and animal food offered for import covered under the proposed rule, the FHPM calculates between 264 and 321 illnesses would be avoided annually from the proposed rule. When we input the 95 percent estimate of the number of avoided contaminated servings of human and animal food offered for import covered under the proposed rule, the FHPM calculates between 7,713 and 4,938 illnesses would be avoided annually from better tests of human and animal food offered for import covered under the proposed rule.

We assume the number of illnesses avoided is distributed as a Pert, with the lower value equal to the number of illness avoided when using the 5 percent estimate of contaminated servings as an input into the FHPM, the most likely value equals the number of illnesses avoided when we use the mean estimate of contaminated servings, and the upper value equal to the number of illnesses avoided when we use the 95 percent estimate of contaminated servings. We assume the lower value, mean and upper value are themselves uniformly distributed between the 5 percent and 95 percent estimates of those numbers reported above. We then apply Monte Carlo methods to simulate the number of illnesses avoided from the proposed rule to range from -2,559 and 3,114, with a mean of 282 avoided illnesses from better tests of human and animal food offered for import covered under the proposed rule.

The estimated number of illnesses avoided when the five percent estimate of the number of contaminated servings of shell-eggs, sprouts and bottled water is used as an input in the FHPM is between -111 to -80, with a mean of -96. When we input the mean number of contaminated servings of shell-eggs into the FHPM we obtain between 13 and 28 illnesses avoided, with a mean of 21 illness avoided. When we input the 95 percent estimate of the number of contaminated servings of shell eggs avoided into the FHPM we obtain between 128and 170, with a mean of 149 illnesses avoided from improved test performance.

We assume the number of illnesses avoided is distributed as a Pert, with the lower value equal to the number of illness avoided when we use the 5 percent estimate of contaminated servings of eggs avoided, the most likely value equal to the number of illnesses avoided when we use the mean estimate of the number of contaminated servings of eggs avoided, and the upper value equals the number of illnesses avoided when we use the 95 percent estimate of the number of contaminated servings of eggs avoided as an input into the FHPM. We assume the lower value, mean and upper value in the Pert distributions are themselves uniformly distributed between the 5th percentile and 95th percentile estimates reported earlier, with a most likely value as the mean number of illnesses avoided. We apply Monte Carlo methods to estimate the number of illnesses avoided from improvements in tests of shell-eggs would range from -52 to 99, with an average number of 23. We report the results of the simulation in Tables 21a and 21b.

Table 21a: Annual illnesses avoided from improved tests of human and animal food offered for import covered under the proposed rule

	5th percentile estimate	Mean estimate	95th percentile estimate
Illnesses estimated by the FHPM assuming the 5 percent estimate of the number of avoided	(4,408)	(4,304)	(4,199)

contaminated servings of food offered for import covered under the proposed rule			
Illnesses estimated by the FHPM assuming the mean estimate of the number of avoided contaminated servings of food offered for import covered under the proposed rule	264	293	321
Illnesses estimated by the FHPM assuming the 95 percent estimate of the number of avoided contaminated servings of food offered for import covered under the proposed rule	4,713	4,826	4,938
Total annual illnesses avoided[1]	(2,559)	282	3,114

[1] Total avoid illnesses are distributed as a Pert, with a lower value, most likely value, and upper value distributed uniformly between the 5 percent and 95 percent estimates reported in the first three rows of this table

Table 21b: Annual illnesses avoided from improved tests of shell-eggs, sprouts and bottled water and other food subject to test requirements

	5th percentile estimate	Mean estimate	95th percentile estimate
Illnesses estimated by the FHPM assuming the 5 percent estimate of the number of contaminated servings	(111)	(96)	(80)
Illnesses estimated by the FHPM assuming the mean estimate of the number of contaminated servings	13	21	28
Illnesses estimated by the FHPM assuming the 95 percent estimate of the number of contaminated servings	128	149	170
Total annual illnesses avoided[1]	(52)	23	99

[1] Total avoid illnesses are distributed as a Pert, with a lower value, most likely value, and upper value distributed uniformly between the 5 percent and 95 percent estimates reported in the first three rows of this table

iv. Avoided Quality-adjusted Life-day (QALDs) from fewer contaminated servings on the market

We estimate the range in the value of illnesses avoided from improved tests of human and animal food offered for import covered under the proposed rule from the proposed rule using QALDs. The QALDs are derived from the value of a statistical life (VSL) of $4.6 million, $9.9

million and $15.0 million. We inflate to 2016 dollars the mean value of a QALD (one that is derived from a VSL of $9.9 million) from a case of a foodborne illness reported in Minor, et al. of $1,113 (Ref. 12), consistent with Department of Health and Human Services Guidelines and obtain a QALD of $1,137. We estimate a lower bound by assuming a VSL of $4.6 million and then scaling the mean value reported above (4.6 million / 9.9 million x $1,137) to obtain a QALD of $528 per foodborne illness. We estimate an upper bound by assuming a VSL of $15 million and then scaling the mean value reported above ($15.0 million / $9.9 million x $1,137) to obtain a QALD of $1,723 per foodborne illness. We use this range to estimate the value of illnesses avoided from improved tests of human and animal food offered for import covered under the proposed rule.

We use the value of a QALD from a case of Salmonellosis obtained from Minor et al (Ref.12) to estimate the value of illnesses avoided from improved tests of shell-eggs subject to testing requirements. We inflate to 2016 dollars the mean value of a QALD (one that is based on a VSL of $9.9 million) from a case of a Salmonellosis reported in Minor, et al. of $6,196, consistent with Department of Health and Human Services Guidelines, to obtain a QALD of $6,329. We estimate a lower bound by assuming a VSL of $4.6 million and then scaling the mean value reported above (4.6 million / 9.9 million x $6,329) to obtain a QALD of $2,941 per case of Salmonellosis. We estimate an upper bound by assuming a VSL of $15 million and then scaling the mean value reported above ($15.0 million / $9.9 million x $6,329) to obtain a QALD of $9,590 per case of Salmonellosis.

We use the mean value of $1,592 for a QALD of an illness attributable to contaminated sprouts obtained from the Regulatory Impact of Analysis of Produce Safety Final Rule to estimate the value of illnesses avoided from improved tests of sprouts subject to testing

requirements. We inflate to 2016 dollars, consistent with Department of Health and Human Services Guidelines, to obtain a QALD of $1,626 per illness attributable to sprouts. We estimate a lower bound by assuming a VSL of $4.6 million and then scaling the mean value reported above (4.6 million / 9.9 million x $1,626) to obtain a QALD of $756 per illness attributable to sprouts. We estimate an upper bound by assuming a VSL of $15 million and then scaling the mean value reported above ($15.0 million / $9.9 million x $1,626) to obtain a QALD of $2,464 per illness attributable to sprouts. We assume the value of a QALD from an illness attributable to bottled water would fall within the ranges of those used for a case of Salmonellosis and for an illness attributable to sprouts. We report the ranges in the values of a QALD from improved tests in Table 22.

Table 22: The value of a QALD per illness from human and animal food offered for import covered under the proposed rule and from shell-eggs, sprouts, and bottled water subject to specific testing requirements

	Lower bound	Middle estimate	Upper bound
QALD per illness from human and animal food offered for import covered under the proposed rule[1]	$528	$1,137	$1,723
QALD per case of Salmonellosis from shell-eggs subject to test requirements[2]	$2,941	$6,329	$9,590
QALD per illness attributable to sprouts subject to test requirements[3]	$756	$1,626	$2,464

[1] Mean QALD per illness from Minor et al and inflated to 2016 dollars per DHHS Guidance

[2] Mean QALD per case of Salmonellosis from Minor, et al and inflated to 2016 dollars per DHHS Guidance

[3] Mean case of illness attributable to sprouts obtained from the Produce Safety Final Rule and inflated to 2016 dollars per DHHS Guidance

We multiply the values of QALD by the numbers of illnesses avoided from improved tests of human and animal food offered for import covered under the proposed rule and from shell-eggs, sprouts, and bottled water and other food subject to testing covered under the

proposed rule using Monte Carlo methods and estimate the mean, 5 percent, and 95 percent estimates of the total avoided QALDs. We obtain the avoided QALD from improved tests of human and animal food offered for import covered under the proposed rule and from shell-eggs, sprouts and bottled water and other food subject to testing covered under the proposed rule and add them together to obtain the total avoided QALDs from fewer false negative test results. We report the means, 5 percent estimates and 95 percent estimates in the Table 23.

Table 23: Annual avoided QALDs from improved tests

	5th percentile estimate	Mean estimate	95th percentile estimate
Avoided QALDs from improved tests of human and animal food offered for import covered under the proposed rule	($3,035,888)	$317,377	$3,820,837
Avoided QALDs from improved tests of shell-eggs, sprouts, and bottled water and other food subject to covered testing	($273,057)	$108,254	$503,521
Total avoided QALDs from improved tests from the proposed rule	($2,875,483)	$425,631	$3,923,682

b. Avoided revenue losses from fewer false positive test results

The proposed rule may also result in fewer false positive test results for human and animal food offered for import covered under the proposed rule and shell-eggs, sprouts, and bottled water and food subject to testing covered under the proposed rule. A false positive test result for human and animal food offered for import covered under the proposed rule would result in refusing entry into the US market of uncontaminated human and animal food. A false positive test result for shell-eggs, sprouts and bottled water and other food subject to testing covered under the proposed rule would prevent uncontaminated shell-eggs, sprouts and bottled

water and other food from entering the market and could also set in motion a range of corrective actions required by shell-egg, sprouts and bottled water producers.

We assume the upper bound on the cost of a false positive test result would be the full wholesale value of the corresponding shipment of human or animal food offered for import covered under the proposed rule or shell-eggs, sprouts or bottled water subject to specific test requirements. The full wholesale value of the shipment may overstate the loss to the extent that the shipment can be reconditioned and resold. We assume the cost of reconditioning a shipment of human or animal food offered for import covered under the proposed rule is between $500 and $1,500, and the cost savings from fewer false positives is uniformly distributed between the wholesale value the shipment and the cost of reconditioning the shipment. We ask for comment on these assumptions.

i. Avoided revenue losses from fewer false positive test results for human and animal food offered for import covered under the proposed rule

Internal records from PLAPs for 2013-2017 indicate the annual numbers of private lab-confirmed positive test results for human and animal food offered for import covered under the proposed rule from 2013 through 2017 is between 331 and 741. We assume the rate of improved test performance from the proposed rule discussed earlier would reduce the number of false positive test results for tests of human and animal food offered for import covered under the proposed rule by the same rate. We use 2016 OASIS data from our Office of Regulatory Affairs to obtain the means and standard deviations of the wholesale values of imported lines for 26 categories of food cleaned using the two criteria discussed above to estimate the wholesale loss from a false positive result from tests of human and animal food offered for import covered by the proposed rule.

We estimate the lower and upper bounds of the wholesale values of an imported line by assuming a lognormal distribution, with mean and standard deviation themselves random variables distributed uniformly between the means and standard deviations obtained using the two data cleaning criteria discussed earlier. We report the 5 percent and 95 percent estimates of the wholesale value of the lognormal distribution described above obtained using Monte Carlo methods. We report the upper and lower bounds and medium values of the variables used to estimate the avoided retail loss from fewer false positive test results for human and animal food offered for import covered under the proposed rule in Table 24.

Table 24: Variables used to estimate revenue losses avoided from fewer false positive test results for human and animal food offered for import covered under the proposed rule

	Lower bound	Medium value	Upper bound
The number of lines of human or animal food offered for import covered under the proposed rule that test positive	331	536	741
The number of fewer false positives for lines of human and animal food offered for import covered under the proposed rule	-18	0.55	20
Wholesale value per line of imported human and animal food	$130	$9,653	$37,232

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ii. Avoided revenue losses from fewer false positive test results for shell-eggs, sprouts and bottled water subject to testing requirements

We assume the current baseline rate of positive test results for shell-eggs, sprouts, and bottled water and other food subject to testing requirements under the proposed rule is the same as the current baseline rate of positive test results for human and animal food offered for import covered under the proposed rule. We request comment on this assumption. Using the values from Table 24, we estimate the rate of positive test results for shell-eggs, sprouts and bottled water

ranges from 3.21 percent to 4.77 percent of all tests (1 – (741 positive test results / (15,520) total test results = 3.21 percent; and 1 – (331 positive test results / (10,298)) total test results = 4.77 percent). We multiply the rates of positive test results by the total number of tests of shell eggs, sprouts and bottled water subject to testing requirements shown in Table 20 to estimate the annual number of positive findings for shell-eggs to range from 43 to 337 (3.21 percent x 1,334 total tests of shell eggs = 43; and 4.77 x 7,060 total tests of shell eggs = 337). We then multiply by the estimated rate of improved test performance due the proposed rule to obtain the reduction in the number of false positives from the proposed rule. We assume uniform distributions for the total number of positive test results and for the rate of improved test performance from the proposed rule, if finalized, and report the mean reduction in false positive test results (about 1 test), the lower bound reduction in false positive test results represented by the 5 percent level (-6 tests), and the upper bound reduction in false positive test results represented by the 95 percent level (9 tests) in Table 25.

We obtain the wholesale value of a shipment that corresponds to a test of shell-eggs subject to specific testing requirements by multiplying the number of shell-eggs in a shipment, from Table 20, by the price per egg received by the egg farm. We obtain average monthly farm prices received for a dozen eggs from the USDA Farm Price Received report for 2016 (Ref. 13). We find the mean monthly farm price received for a dozen eggs for 2016 to be about $0.77, with a standard deviation of about $0.26. We assume a lognormal distribution of the farm price received for a dozen eggs, divide by 12 to obtain the price per egg and multiply by the number of eggs in a shipment to obtain the wholesale value of a shipment of shell-eggs. We do not know the wholesale values of shipments of sprouts and bottled water and assume they are the same as the wholesale value of a shipment of shell-eggs. We ask for comment on this assumption. We

report the mean wholesale value of a shipment (about $32,000), the lower bound represented by the 5 percent level (about $20,500), and the upper bound represented by the 95 percent level (about $41,000) in Table 25.

Table 25: Variables used to estimate the avoided revenue losses from fewer false positive test results for shell-eggs, sprouts, bottled water and other food subject to covered testing[1]

	Lower bound	Medium estimate	Upper bound
The number of shipments subject to shell-eggs, sprouts and bottled water testing requirements that test positive	43	190	337
Reduction in false positives for shipments of shell-eggs, sprouts and bottled water subject to testing requirements	(6)	1	9
Wholesale value per shipment of shell-eggs, sprouts and bottled water subject to testing requirements	$20,543	$30,815	$41,087

[1] Because the estimated number of tests of shell-eggs subject to specific testing requirements covered under the proposed rule is so much larger than the estimated number of tests of sprouts, bottled water and other food subject to testing covered under the proposed rule we assume the variables used to estimate the latter are included in the variables to estimate the former.

iii. Total avoided revenue losses

We apply Monte Carlo methods to the random variables reported in the tables above to simulate the 5th percentile, mean and 95th percentile estimates of the total avoided retail loss from the reduction in false positive test results due to the proposed rule. We assume uniform distributions between the lower and upper bounds for the number of positive test results and the reduction in the numbers of false positive test results reported in the tables above. We assume the wholesale values of a shipment of shell-eggs and human and animal food offered for import covered under the proposed rule are distributed lognormally with the means and standard deviations reported earlier. We add together the avoided revenue losses from tests of human and animal food offered for import covered under the proposed rule and from shell-eggs, sprouts, bottled water and other food subject to specific testing requirements to obtain the total avoided

revenue losses from fewer false positives. We report the means, 5th percentile estimates and 95th percentile estimates in Table 26.

Table 26: Estimated annual avoided revenue losses from fewer false positive test results

	5th percentile estimate	Mean estimate	95th percentile estimate
Avoided revenue losses from fewer false positive test results for human and animal food offered for import covered under the proposed rule	-$114,279	$2,954	$134,983
Avoided revenue losses from fewer false positive test results for shell-eggs, sprouts, bottled water and other food subject to testing requirements	-$100,739	$20,317	$179,530
Total avoided revenue losses from fewer false positive tests from to the proposed rule	-$188,821	$23,270.93	$253,449

7. Deterrence of unsafe food manufacturing practices due to better expected test performance

The possibility of more positive test findings from more accurate testing by participating labs may deter human and animal food suppliers from unsafe manufacturing practices if the additional cost of being caught with contaminated food is greater than the additional cost of providing safer food. The cost of a positive test finding includes any required corrective actions, such as reconditioning, combined with the value of the lost shipment. The deterrence of unsafe food manufacturing practices from the threat of a positive test finding is greater as the probability of false findings decline.

When safe food practices are prevalent, we would expect a high prevalence of contaminant-free food and the probability of a negative test finding to be high if tests are accurate. That describes the current situation with the estimated share of negative findings from tests of human and animal food offered for import covered under the proposed rule to be between 96 percent and 98 percent, indicating a high prevalence of food safety practices. Consequently,

under current conditions and assuming diminishing marginal returns we would expect the additional costs required to increase food safety practices by manufacturers to be comparatively high.

When baseline rates of test performance are high, we would expect the rates of false negative and false positive test results to be low. That describes our assessment of current baseline conditions for which we estimated rates of false positives and false negatives to be between 3.4 percent and 8.3 percent (see the earlier discussion on improved test performance). Consequently, we expect the additional commercial losses from even fewer false negative test findings to be low.

With the assumed current high prevalence of food safety practices and the current high rates of test performance, the additional costs that would be incurred by manufacturers to provide even safer human or animal food potentially subject to more accurate testing may be close to, or even greater than, the additional costs to the manufacturer from the greater likelihood that contaminated food would be caught. We assume the additional costs to the manufacturer from the lost commercial value due to fewer false negative test findings is greater than the additional cost of providing even safer human or animal food potentially subject to even more accurate testing, and there would be some deterrence of unsafe practices by all manufacturers affected by the proposed rule from improved test performance.

8. Improved test reporting practices from test reporting requirements

The proposed requirement to send all analytical reports to us if they participate in the labs program may deter possible selective reporting behavior designed to increase the likelihood of reporting false negative test results. Selective reporting includes such practices as “testing into compliance” (testing multiple samples and reporting the results for only those that are found to

be negative) and "banking negative test results" (saving negative analytic findings for later use). Evidence from a 2009 outbreak involving peanut butter suggests the existence of behavior of selectively reporting false negative test results (Ref. 14). We request comment on the assumption that the requirement to send all analytical reports to us and other reporting requirements, if finalized, will deter improper reporting of test results.

10. Total benefits of the proposed rule

We apply Monte Carlo methods to obtain the 5th percentile, mean and 95th percentile estimates for the total cost-savings from clarifying analytical report submission and review processes, from abridged reporting and management systems improvements and the total avoided QALD losses and revenue losses from better tests. We report the means, 5th percentile estimates and 95th percentile estimates of these variables and the total benefits of the proposed rule in Table 27.

Table 27: Total benefits from the proposed rule

	5th percentile estimate	Mean estimate	95th percentile estimate
Cost-savings from clarifications of the processes for compiling and reviewing analytical reports of tests of human and animal food offered for import covered under the proposed rule	$1,043,082	$2,426,228	$3,809,375
Cost savings from allowing abridged analytical reporting of tests of human and animal food offered for import covered under the proposed rule	$3,219,481	$4,629,879	$6,040,277
Cost savings from management systems improvements	$83,542	$148,096	$212,649
Cost-savings from fewer false positives	-$188,821	$23,270.93	$253,449
Avoided QALD losses from fewer servings of contaminated food available	-$2,875,483	$425,631	$3,923,682

Total quantified benefits	$3,708,852	$7,555,215	$11,524,072
Deterrence of unsafe manufacturing practices by all human and animal food suppliers affected by the proposed rule		Unquantified	
Deterrence of improper test reporting practices due to the proposed test reporting requirements		Unquantified	

F. Costs of the Proposed Rule

1. Costs incurred by participating ABs

The proposed rule includes requirements for ABs to apply for recognition by FDA and to renew that recognition periodically. The proposed rule, if finalized, would require that recognized ABs be members of ILAC and signatories of the ILAC MRA, conform to the ISO/IEC 17011 standard, and to renew recognition at least every 5 years. All ABs currently considered as potential applicants already satisfy the requirements of the ISO standards and are monitored and evaluated on an on-going basis. Additional costs that recognized ABs would incur under the proposed rule, if finalized, include;

- modifying existing programs and standard operating procedures for accrediting labs to the proposed requirements and,
- maintaining and submitting reports and other records to us.

We estimate between 5 and 80 ABs would participate in the labs program and assume a Pert distribution with the minimum (5) as the most likely number of ABs. This yields a mean of 17.5 ABs that would participate in the labs program. The upper and lower bound cost estimates reported in this section can be replicated by using 17.5 as the number of ABs that would incur these costs. For estimates of the labor costs incurred by ABs and other entities described in the

following sections we use the mean hourly wage of a Microbiologist, a Natural Science Manager and a Lawyer reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation codes 19-1022, 11-9121 and 23-1011 (ref. 15). We multiply these wages by two to account of overhead to obtain fully loaded hourly wages of $75.38 for a Microbiologist, $128.52 for a Natural Sciences Manager, and $136.44 for a Lawyer.

a. Costs for initial applications for recognition

The proposed rule, if finalized, would require ABs that wish to be recognized to submit an application that demonstrates their qualifications to accredit labs to meet the proposed requirements. We assume that this process would be overseen by a lawyer and a natural science manager and estimate that it would take a total of between 40 and 80 hours to compile all the relevant information, prepare for an assessment and complete the initial application process. Consequently, we estimate the cost incurred by ABs for submitting applications for recognition to range from about $92,736 (40 hours x ($136.44 per hour + $128.52 per hour) / 2) x 17.5 ABs = $92,736) to about $185,472 (80 hours x $136.44 per hour + $128.52 per hour) / 2) x 17.5 ABs = $185,472). We estimate the annualized costs for initial recognition discounted at seven percent over 10 years to range from $12,340 to $24, 679. When we assume a three percent discount rate over 10 years the annualized costs range from $10,555 to $21,109.

b. Costs for applications for renewal and maintenance of recognition

The proposed rule, if finalized, would require an AB to apply for renewal of recognition at the end of their term of recognition, which for purposes of this analysis we assume will be the maximum duration of recognition (five years). We ask for comment on this assumption. We assume that application for renewal would take less time than the initial application for recognition as the information will have been mostly already compiled. We assume that the

renewal application would be overseen by a lawyer and a natural science manager and estimate that it would take between 20 and 40 hours. We assume renewal costs would be incurred every five years, or twice over a 10-year period, and add the discounted present value of the renewal costs incurred during year 5 to the discounted present value of the renewal costs incurred during year 10 to obtain the total renewal costs. We assume discount rates of seven percent for the lower bound estimate and three percent for the upper bound estimate. Consequently, we estimate cost to submit applications for renewal over 10 years would range from $56,631 (17.5 ABs x 20 hours x the average of $128.52 per hour and $136.44 per hour divided by 1.07 raised to the 5^{th} power + 17.5 ABs x 20 hours x the average of $128.52 per hour + $136.44 per hour divided by 1.07 raised to the 10^{th} power = $56,631) to $148,999 (17.5 ABs x 80 hours x the average of $128.52 per hour and $136.44 per hour per hour divided by 1.03 raised to the 5th power + 17.5 ABs x 40 hours x the average of $128.52 per hour and $136.44 per hour per hour per hour divided by 1.03 raised to the 10th power = $148,999). We estimate the annualized renewal cost discounted at seven percent over 10 years would range from $7,535.48 to $19,826.29. The annualized costs discounted by 3 percent over five years would range from $6,445.50 to $16,958.49.

c. Costs to modify existing programs to accredit labs to the proposed standards

ABs would incur one-time costs to modify their existing program for accrediting labs to the requirements of the proposed rule, if finalized. Activities for establishing a program could include modifying

- a strategic plan for accrediting labs to the proposed standards,
- implementation plans for assuring that quality standards are met,

- quality management system procedures (QMSPs) for defining policies,
- standard operating procedures (SOPs) for auditing and inspecting labs against the proposed standards, and
- training auditors and inspectors to monitor the performance of member labs.

We assume managers and scientists in each AB would spend time to modify existing programs for participating labs to meet the requirements of the proposed rule, if finalized. We assume that each activity would require between 20 hours and 40 hours for a manager and between 20 hours and 40 hours for a scientist. We apply the fully loaded wages for a manager ($128.52) and a scientist ($75.38) to these hourly burdens and multiply by the number of ABs to obtain a total one-time cost to the industry of between about $214,095 and about $428,190 for modifying existing programs for accrediting labs to the proposed standards. We report the one-time costs to establish a program to accredit labs to the proposed standards are reported in Table 28.

Table 28: One-time costs for participating ABs to modify existing programs to accredit labs to the proposed standards

	Manager hourly burden (lower bound)	Manager hourly burden (upper bound)	Scientist hourly burden (lower bound)	Scientist hourly burden (upper bound)	Total industry costs (lower bound) [1]	Total industry costs (upper bound) [1]
Strategic and Action Plans	20	40	20	40		
QMSPs and SOPs	20	40	20	40		
Training	20	40	20	40		
Total Industry Cost					**$214,095**	**$428,190**

[1] We estimate the number of ABs using a Pert distribution with the minimum (5) as the most likely number. This yields a mean of 17.5 ABs that would participate in the labs program. The upper and lower bounds of total one-time industry costs can be replicated by using the 17.5 mean.

We divide the upper and lower bounds for the total industry costs by the average number of participating ABs (17.5) to obtain the range on the one-time costs per AB to establish a

program of between $12,234 and $24,468. The annualized cost for all participating ABs to modify existing programs to accredit labs discounted at seven percent over 10 years range from $28,488 to $56,976. The annualized costs discounted by three percent over 10 years range from $24,367 to $48,735.

d. Costs to periodically assess participating labs

There would be costs incurred by participating ABs to periodically assess participating labs for compliance with the proposed standards. These costs would be incurred over and above those required to accredit labs to the ISO/IEC 17025 standard, which we include in the estimated costs incurred by participating labs to maintain accreditation to that standard. The proposed rule, if finalized, would require a participating AB to conduct an onsite assessment of a participating lab every two years. Certain assessment activities may be conducted remotely. We assume that each assessment would take between 16 and 24 hours, including for preparation, travel and for any follow-up reporting and correspondence. Consequently, we estimate monitoring and assessing costs incurred by ABs annually to be between about $12,061 (16 hours x $75.38 per hour x 20 participating labs x 0.5 inspections per year = $12,060.80) and about $67,842 (24 hours x $75.38 per hour x 75 participating labs x 0.5 inspections per year = $67,842.00).

e. Recordkeeping and reporting costs

The proposed rule, if finalized, would require a participating AB to maintain records of participating lab accreditation activities for five years after the date of the creation of the record, including any changes to the scopes of accreditation. ILAC requires that ABs maintain these records, although ILAC does not specify the number of years. We do not have information on the number of years that ABs keep records. For our analysis, we assume that ABs keep records at

least 5 years after the date of creation and that no additional recordkeeping costs would be incurred. We request comment on this assumption.

The proposed rule, if finalized, would require a participating AB to report to us any significant changes affecting its accreditation program or the accreditation status of participating labs it accredits. The proposed rule, if finalized, would require participating ABs to provide us with access to records and other resources, including self-assessments by ABs and participating labs, records related to a participating lab's or AB's accreditation status, investigations of participating labs or ABs, and information on the AB's qualifications, resources, quality assurance programs, recordkeeping, reporting, monitoring procedures. The participating AB would also incur costs for making records available electronically to us. The amount of time the AB must devote to these activities will depend in part on the number of participating labs that it has accredited.

We estimate that participating ABs would incur one hour per month, or 12 hours per year submitting reports and notifications to us. We assume this task would be undertaken by an employee at the level of microbiologist. Consequently, we estimate the annual cost to participating ABs to be about $15,830 (12 hours x $75.38 per hour x 17.5 ABs = $15,829.80).

f. Costs to ensure verification studies submitted by participating labs are evaluated properly

Under the proposed rule, the first validation or verification study for a method would go to the participating AB, so that the AB can evaluate whether to add the method to the participating lab's scope of accreditation. All subsequent validation and verification studies would be submitted to us. This requirement would not affect the total number of validation and verification studies conducted and evaluated but would distribute to participating ABs the responsibility to

evaluate some studies. We assume this responsibility would lie outside the ABs' current purview. We assume ABs would contract with a scientist from an outside organization on an as-needed basis, and that ABs would incur some administrative costs to ensure that the studies are evaluated properly. We assume that each study submitted to an AB would require 4 to 6 hours to ensure proper evaluation by a microbiologist at a fully loaded hourly wage of $75.38, and that each participating lab would submit 1 to 10 validation and verification studies per year for ABs to evaluate. We report the parameters used to estimate the costs to ensure that validation and verification studies are evaluated properly in Table 29.

Table 29: Parameters used to estimate the costs incurred by participating ABs to ensure validation and verification studies are properly evaluated

	Lower bound	Upper bound
Hourly burden to ensure that each validation or verification study is properly evaluated	4	8
Fully loaded wage	$75.38	$75.38
Number of participating labs[1]	20	75
Number of validation and verification studies per lab required to be properly evaluated by an ABs	1	10
Total cost to ensure verification studies are evaluated properly	$6,030.40	$452,280.00

[1] Includes the estimated number participating labs that test human and animal food offered for import covered under the proposed rule and the estimated number of participating labs that test shell eggs, sprouts, bottled water, and other food subject to specific testing requirements covered under the proposed rule.

g. Summary of costs incurred by ABs

We report the costs of the proposed rule that would be incurred by participating ABs by cost category and frequency with which they would occur in Table 30. For the one-time costs of the initial application for recognition and for modifying existing programs we discount over 10 years at seven percent and at three percent. For the costs for application renewal we assume costs

are incurred at year five and year 10. The present value of these costs are discounted over 10 years at seven percent and three percent**.**

Table 30: Summary of the costs and frequencies incurred by ABs by cost category

Task	Lower bound	Upper bound	Frequency
Costs for initial application for recognition	$92,736	$185,472	One-time
Costs for application renewal	$56,631	$148,999	Every 5 years
Modify existing programs for accrediting labs	$214,095	$428,190	One-time
Periodically assess participating labs	$7,761	$67,842	Annual
Recordkeeping and reporting costs	$15,830	$15,830	Annual
Costs to ensure verification studies are evaluated properly	$6,030	$452,280	Annual

We use a Monte Carlo simulation to estimate total annualized costs and the present values of costs incurred by participating ABs. We assume uniform distributions for annualized cost estimates that range between the lower bound and upper bound described in each cost category. We report the simulation results for the total present values and annualized costs incurred by ABs discounted by seven percent and three percent over 10 years in Table 31.

Table 31: Present values and total annualized costs incurred by ABs discounted at 7 percent and 3 percent over 10 years

	5th percentile estimate	Mean estimate	95th percentile estimate
Annualized costs at 7 percent	$105,457	$203,257	$341,244
Annualized costs at 3 percent	$100,668	$192,420	$317,123
Present value at 7 percent	$651,707	$1,457,703	$2,648,382
Present value at 3 percent	$760,239	$1,671,666	$2,993,175

2. Costs incurred at the lab level

Labs currently used by the human and animal food industries may incur the costs of accreditation to the proposed standards, if finalized. The proposed rule incorporates by reference, subject to certain exceptions, the management requirements and technical requirements in the ISO/IEC 17025 standard. Consequently, labs would have to become accredited to the ISO/IEC 17025 standard to participate in the labs program. There would be costs over and above those required to maintain accreditation to the ISO/IEC 17025 standard to participate in the labs program, such as costs:

- To be periodically assessed against the proposed standards by the AB,
- To meet requirements to participate in a proficiency testing program,
- When necessary, to validate an analytical method

Labs would also incur costs at the analysis level. These include costs related To the sampling process, verifying analytical methods and compiling and submitting analytical reports to us. The costs of the proposed requirements for the oversight of sampling include:

- obtaining a sample collection plan and sample collection report
- one-time costs to obtain sampler's applicable qualifications by training and experience.

To estimate the costs incurred at the lab level we use the fully loaded wage of $69.22 for a Food Scientist and Technologist, code 11-9121, obtained from the Occupation Employment and Wages, May 2017 report.

a. Costs to attain and maintain accreditation to the ISO/IEC 17025

The Association of Public Health Laboratories (APHL) reported the results of a survey administered to 30 accredited labs associated with FDA cooperative agreements (FDA's ISO cooperative agreement, the FDA Animal Food Regulatory Program Standards cooperative

agreement, and accredited labs that receive assistance through the FDA Associations Cooperative Agreement) regarding the costs to attain and maintain accreditation to the ISO/IEC 17025 standard (Ref. 16). Representatives from eighteen labs responded to the survey, for a response rate of 60 percent. A limitation of the survey was that the information obtained depended on the respondents' ability to recall the costs, which may have been incurred several years prior to responding. The respondents did not specify the number of scopes to which their cost estimates would apply. We assume the range in scopes implied from the survey responses corresponds to the same range in scopes that would be accredited due to the proposed rule.

According to the survey, the average one-time costs to attain and maintain accreditation to ISO/IEC 17025 range from $100 to $700,676, with a median response of $75,642. These include costs for training and consultants, supplies and equipment, and software and monitoring systems. We assume these are one-time costs. The annual costs to maintain accreditation range from $2,541 to $811,315, with median response of $246,292. These include assessment fees, calibration costs, preventive maintenance, proficiency testing costs and annual salaries for additional employees that were needed to perform analytical, quality control and administrative responsibilities which we assume would be incurred annually. We report the ranges in one-time costs and annual costs for a participating lab to attain and maintain accreditation to the ISO/IEC 17025 standard in Table 32.

Table 32: One-time and annual costs to attain and maintain accreditation to the ISO/IEC 17025 standard per lab[1]

	Lower bound	Median	Upper bound
One-time costs to attain and maintain accreditation to ISO/IEC 17025	$100	$75,642	$700,676
Annual costs to attain and maintain accreditation to ISO/IEC 17025	$2,541	$246,292	$811,315

[1]Association of Public Health Laboratories, "Laboratory Costs of ISO/IEC 17025 Accreditation: A 2017 Survey Report." February 2018.

We apply the costs reported in Table 32 to all participating labs that are currently not accredited to ISO/IEC 17025. We estimate that all participating labs that would test human or animal food offered for import covered under the proposed rule are currently accredited to ISO/IEC 17025 and would not incur additional costs from this requirement. To estimate the costs that would be incurred by participating labs not currently accredited to ISO/IEC 17025 that test shell-eggs, sprouts and bottled water and other food subject to specific testing requirements under the proposed rule, we multiply the number of these labs reported in Table 5 by the one-time and annual costs per lab reported in Table 32. We report the total one-time costs and annual costs for all participating labs not currently accredited to ISO/IEC 17025 that would test shell-eggs, sprouts and bottled water subject to testing requirements in Table 33.

Table 33: Total one-time and annual costs for ISO/IEC 17025 accreditation for participating labs that would test shell-eggs, sprouts and bottled water and other food subject to covered testing

	Lower bound	Upper bound
Number of participating labs currently not accredited to ISO/IEC 17025	2	8
Total one-time costs for accreditation to ISO/IEC 17025	$200	$5,605,408
Total annual costs for accreditation to ISO/IEC 17025	$5,082	$6,490,520

b. Costs for participating labs to be assessed by us and ABs

The proposed rule, if finalized, would allow us to assess participating labs to determine whether they are complying with the proposed requirements. We may review any records pertaining to the labs program and may conduct an on-site assessment at any time, with or

without the presence of a representative from the participating AB that accredited the participating lab. Moreover, the proposed rule, if finalized, would require participating ABs to conduct an on-site assessment of participating labs every two years to maintain accreditation status of participating labs. We estimate that we would conduct an on-site assessment once every four years. We assume that these costs would be over and above those incurred for maintaining accreditation to the ISO/IEC 17025 standard.

We estimate that a participating lab would spend an additional 4 to 8 hours once every two years preparing for and following up with these assessment activities. Assuming a fully loaded wage for a Food Scientist and Technologist of $69.22, we estimate the annual costs to be assessed by ABs and FDA range between about $4,153 and about $31,149. We report the annual costs for participating labs to be assessed by us and ABs in Table 34. We ask for comment on the additional costs for incurred by participating labs to be assessed from the proposed rule.

Table 34: Costs for participating labs to be assessed by us and ABs

Lower bound	Upper bound
$4,153.20	$31,149.00

c. Costs to participate in a proficiency testing program

The requirements in the proposed rule follow the Association of Analytical Chemists (AOAC) guidelines for proficiency testing which requires proficiency testing at least once a year for each method within each scope of accreditation. This exceeds the requirements for proficiency testing in the current ISO/IEC 17025 standard. The current ISO standard allows flexibility for labs to participate in either inter-laboratory comparisons or proficiency testing programs at unspecified frequencies. We assume that the largest labs adhere to AOAC guidelines while the smallest labs may not adhere to the guidelines. We ask for comments on this assumption.

We use the ISO/IEC 17025 standard as the baseline for the smallest labs. We assume participation in an inter-laboratory comparison program costs about half the cost to participate in a proficiency testing program. We also assume that half of the smallest labs would participate in inter-laboratory comparisons for each accredited method and the other half would participate in a proficiency testing program for each accredited method.

We use the results on the per lab-costs for proficiency testing found from the APHL survey (Ref.16) to estimate the additional cost to industry of the requirement to participate annually in a proficiency testing program. The APHL survey found that proficiency testing cost between $0 and $9,000, with a median per-lab cost of $3,327. We use our estimate of between 20 and 75 participating labs reported from information contained in Table 3 and apply the costs for proficiency testing to 50 percent of the number of participating labs and multiply again by 50 percent to account for the lower cost of inter-laboratory comparisons. We estimate the total annual costs to comply with the proposed proficiency testing program range between $0 and $168,750, with a medium estimate of $27,586.

d. Costs to validate testing methodology

The proposed rule would require participating labs to use validated methodologies. Because the ISO/IEC 17025 standard requires that non-standard methods be validated, we assume that our estimates of the recurring costs to maintain accreditation to the ISO/IEC 17025 standard include these costs. We ask for comment on this assumption. Moreover, any additional costs that may be incurred to verify methods that have not been validated for specific foods are discussed in a following section on costs incurred by test.

e. One-time costs to compile 10 consecutive successful full analytical reports per lab prior to qualifying for abridged reporting

Each participating lab would be required to provide 10 consecutive full analytical reports prior to qualifying for abridged analytical reporting. For purposes of this analysis, we assume that each participating lab would be accredited by a participating AB to two disciplines within the scope of its accreditation. We multiply the cost to review a full analytical report by 10 consecutive successes (assuming the two disciplines are included in the 10 consecutive successes), and finally by the number of participating labs (between four and 25 participating labs that test human and animal food offered for import covered under the proposed rule, with a mean of 12; plus between 16 and 50 participating labs that test shell eggs, sprouts, bottled water and for other covered testing, with a mean of 21). We use Monte Carlo simulation methods to obtain the 5 percent, mean and 95 percent estimates of the one-time cost to industry from this requirement and report them in Table 35.

Table 35: One-time costs for industry to compile 10 full analytical reports per lab prior to qualifying for abridged reporting

5th percentile estimate	Mean estimate	95th percentile
$50,216.93	$80,899.35	$121,535

a. Total costs incurred at the participating lab level

We report the upper and lower bounds for the annualized costs incurred at the lab level by cost category discounted at seven percent and three percent over 10 years in Tables 36a and 36b.

Table 36a: Annualized costs incurred at the participating lab level by cost category discounted at 7 percent over 10 years

	Lower bound	Upper bound

Costs for labs to attain and maintain accreditation to ISO/IEC 17025 for a testing scope	$5,109	$7,236,393
Costs for labs to be assessed by FDA and AB	$4,153	$31,149
Costs for labs to participate in a proficiency testing program	$0	$168,750
Costs for labs to submit 10 successful full analytical reports each prior to abridged reporting	$6,652	$18,973

Table 36b: Annualized costs incurred at the participating lab level by cost category discounted at 3 percent over 10 years

	Lower bound	Upper bound
Costs for labs to attain and maintain accreditation to ISO/IEC 17025 for a testing scope	$5,105	$7,128,505
Costs for labs to be assessed by FDA and AB	$4,153	$31,149
Costs for labs to participate in a proficiency testing program	$0	$168,750
Costs for labs to submit 10 successful full analytical reports each prior to abridged reporting	$5,477	$15,622

We also used a Monte Carlo simulation to simulate total annualized costs and the present values of costs incurred at the participating lab level. We assume Pert distributions for the annualized costs to attain and maintain accreditation to ISO/IEC 17025 and to participate in a proficiency testing program with the median values found in the AHPL survey as the most likely values. We assume a uniform distribution for the costs to be assessed by us and ABs and the costs to submit 10 successful full analytical reports between the reported lower and upper bounds. We report the 5 percent, means and 95 percent estimates of the total costs annualized over 10 years at seven percent and three percent and present values of costs discounted at seven percent and three percent over 10 years in Table 37.

Table 37: Annualized costs and present values of costs incurred industry-wide at the lab level, discounted by 7 percent and 3 percent over 10 years

	5th percentile estimate	Mean estimate	95th percentile estimate
Annualized costs at 7 percent	$461,085	$2,148,893	$4,448,946
Annualized costs at 3 percent	$482,816	$2,150,116	$4,412,324
Present value at 7 percent	$3,091,077	$26,082,378	$49,130,735
Present value at 3 percent	$3,674,121	$31,058,702	$58,510,396

3. Costs incurred for each test

There would be costs incurred by test. These include costs to comply with standards related to sampling, including notices of sampling in limited circumstances, test results, verifying analytic methods, and the costs of compiling and submitting an analytical report which are incurred each time a test is performed. In addition, costs may be incurred for switching from a conveniently located lab to an appropriately accredited participating lab for each test performed. Costs to comply with the standards related to sampling include the costs to obtain relevant documentation of samplers' training and experience. Moreover, participating labs would also incur the cost to ensure that methods required for each test fall within their scope of accreditation, and a sample collection plan and a sample collection report.

We use the mean hourly wage for Food Scientists and Technologists, Occupation Code 19-1012, Occupational Employment and Wages May 2017, and multiply by 2 to account for overhead to obtain a fully loaded wage of $69.22 for estimates of the labor costs incurred at the analysis level. From information reported in the baseline conditions section there would be between 10,708 and 15,110 analytical reports submitted for tests of human or animal food offered for import covered under the proposed rule, and between 1,309 and 7,030 analytical reports of tests of shell-eggs subject to specific testing requirements, and between 25 and 30

analytical reports of tests of bottled water, sprouts and other tests subject to testing covered under the proposed rule.

a. Costs of the notice of sampling

The proposed rule provides that in certain circumstances we may require the participating lab to submit a notice of sampling to the appropriate FDA Division, modified as appropriate, 48 hours prior to when the sampling would occur. This would allow us the option to observe the sampling process. The notice of sampling would require a unique identifier of the sample, the name and address of the sampler, the name of the corresponding participating lab that would test the sample, a primary contact from the sampler, the reason the food is to be sampled, the location where the sample would be collected, applicable entry line numbers and product codes, and the date and approximate time the sampling would begin.

We assume that it would take a lab analyst between 1 and 2 hours to compile the required information and submit the notice of sampling to us. The intent of this requirement is to allow us the option to observe the sample collection process on an occasional and random basis. We assume that between 1 percent and 5 percent of all analyses submitted annually would be subject to the notice of sampling requirement. We use a fully loaded wage of a Food Scientist and Technologist ($69.22) to find the cost of the notice of sampling requirement to range between about $8,335 (1-hour x $69.22 hourly wage x 1 percent x 12,041 samples = $8,334.84) and about $153,460 (2 hours x $69.22 hourly wage x 5 percent x 22,170 samples = $153,460.25).

b. Costs to generate a sample collection plan and to compile a sample collection report

The proposed rule would require each participating lab to submit to us appropriate documentation of the sampler's credentials, a sample collection plan and sample collection

report to ensure the representational nature of the sampling does not impact the validity of the subsequent testing. A sample collection report must include

- a product code,
- dates of sampling,
- size,
- identity,
- quantity of samples,
- sampling procedures and sampling techniques,
- and documentation of the chain of custody of the sample.

Participating labs would be required to submit sample collection plans and sample collection reports with analytical reports of tests covered by the proposed rule. We do not know the number of sampling plans and collection reports affected by the proposed rule or the extent to which current sampling plans for tests of food offered for import covered under the proposed rule already conform to the requirements in the proposed rule. We assume that all samples collected for tests covered by the proposed rule would have some sample collection reports and that some may be deficient in their sample collection plans and reports. In the earlier section describing cost-savings from the proposed rule we assume that assume that 10 percent of analytical reports submitted for tests of human or animal food offered for import covered under the proposed rule may currently be deficient in requirements to satisfy the non-technical review and may result in some cost-savings from the clarifications of the proposed rule. Because we do not interact with entities that collect samples of shell-eggs, bottled water or sprouts at the time of the collection, we assume that all sample collection plans and sample collection reports that would be submitted with analytical reports for tests of shell-eggs, sprouts, or bottled water

subject to specific testing requirements do not currently conform to the same format and information required by the proposed rule and would all be deficient. We ask for comment on this assumption.

We assume that an additional 1/2 hour to 1 hour would be spent to generate the additional information required in a sample collection plan, and 1/2 hour and 1 hour to compile the additional information required for a sample collection report. We multiply by the fully loaded wage of $69.22 to obtain the lower and upper bound cost estimates of between $34.61 and $69.22 to generate the additional information required for a sample collection plan, and the same additional amount to compile a sample collection report. We multiply by the number of analytical reports of shell-eggs, sprouts, and bottled water subject to specific testing requirements to obtain the total range of sample collection reports and sample collection plans affected by these requirements. As shown in Table 38a, industry would incur costs that range from about $46,156 to $488,688 to generate a sample collection plan. As shown in Table 38b, industry would incur costs that range from $46,156 to $488,688 to compile a sample collection report. We request comments on the costs to generate a sample collection plan and to compile a sample collection report.

Table 38a: Costs to generate a sample collection plan

	Fully loaded wage	Hours to generate a plan	Cost per sample collection plan	Cost for industry
Lower bound	$69.22	0.5	$34.61	$46,155.58
Upper bound	$69.22	1.0	$69.22	$488,688.31

Table 38b: Costs to compile a sample collection report

	Fully loaded wage	Hours to compile a report	Cost per sample collection report	Cost for industry

Lower bound	$69.22	0.5	$34.61	$46,155.58
Upper bound	$69.22	1.0	$69.22	$488,688.31

c. Costs for participating labs to collect sampler credentials, sample collection plans and reports and to confirm accreditation status for methods of testing that they conduct

The proposed rule would not require sampling entities to follow standards but would require participating labs to obtain or develop records related to sampling. Specifically, the proposed rule would require a participating lab to obtain a sample collection plan, a sample collection report and appropriate sampler credentials for inclusion in the analytical report submitted to us. Moreover, the participating lab would have to confirm that the methods to be used and analysis to be performed fall within its scope of accreditation.

We assume a participating lab would take between 10 minutes (0.17 hours) and 20 minutes (0.34 hours) to collect the sampling plan and the sampler's credentials for inclusion in the analytical report, and to confirm a match between the scope to which they are accredited and the test they would perform. Using the fully loaded wage of $69.22, we estimate that participating labs would spend between $11.54 and $23.07 per sample collection report. We multiply the cost per sample collection report by the total annual number of reports to obtain a total cost of these requirements. We estimate the participating labs would incur costs that range from about $138,914 to about $511,534. We report the costs to review collection plans and reports and to confirm the lab is accredited to the appropriate scope in Table 39.

Table 39: Costs for participating labs to collect sampler credentials, sample collection plans and reports and to confirm a match between the test and the scope of accreditation

	Fully loaded wage	Hours	Cost per report	Number of sample collection reports	Total costs
Lower bound	$69.22	0.17	$11.54	23.568	$138,914.05
Upper bound	$69.22	0.33	$23.07	26,060	$511,534.17

d. Costs to report results from validation and verification studies

The proposed rule, if finalized, would require the participating lab to submit verification and validation studies to us as part of an analytical report, or to an AB as a prerequisite for participation in the labs program. Additional studies may include information to verify that a method previously validated for a specific food item is also valid for a different food item, in what is called a 'matrix extension.' Internal experts suggest that between 5 percent and 30 percent of analytical reports currently submitted for tests of human and animal food offered for import covered under the proposed rule require verification studies such as matrix extensions, and that it requires less time to perform a matrix extension than to validate a method. We estimate the burden for a matrix extension is 75 percent of the burden to validate a method.

The ISO/IEC 17025 standard requires the use of validated methods for testing foods. We included this burden in the estimated costs of maintaining accreditation. However, the proposed rule, if finalized, would require additional verification studies over and above the requirements in ISO/IEC 17025 such as matrix extensions. We estimate the cost of requiring participating labs to submit these additional verification studies to be between 1 percent and 5 percent of the costs for verification and validation activities required to maintain accreditation to ISO/IEC 17025. We ask for comment on this assumption.

Because there is only one food item and contaminant combination that would be subject to the specific testing requirements for shell-eggs, sprouts and bottled water, we assume these tests would not require matrix extensions. While we acknowledge that verification studies might also be extended to include new contaminants, we assume that methods used to test shell-eggs, sprouts and bottle water would have been validated, and the costs to do so would have been included in the costs to maintain accreditation to the ISO/IEC 17025 standard. Consequently, we assume that shell-eggs, sprouts and bottled water producers would incur no additional costs from this requirement.

We estimate the costs to perform a matrix extension from responses to an internal survey of representatives from 13 state labs with which we have cooperative agreements regarding the burden incurred to verify an analytical method. The average low response was 27.3 hours and the average high response was 59.1 hours. We multiply by 0.75 to obtain the lower burden for conducting a matrix extension of between about 22 (27.3 hours x 0.75 for a matrix extension = about 22 hours) and about 46 hours (59.1 hours x 0.75 = about 46 hours). We use the fully loaded wage for a food scientist and technologist of $69.22 to obtain the cost of a matrix extension of between about $1,521 ($69.22 per hour x 22 hours = $1,521.11) and about $3,167 ($69.22 per hour x 46 hours = $3,166.82).

Finally, to estimate the number of analytical reports that would require matrix extensions, we multiply by the share of analytical reports submitted to us for tests of human or animal food offered for import covered under the proposed rule that would require matrix extensions (between 5 percent and 30 percent based on our experts), by the total number of analytical reports for tests of human and animal food offered for import covered under the proposed rule (between 10,708 and 15,110 analytical reports). To obtain the cost of the matrix extensions, we

multiply the number of affected analytical reports by our estimated cost to verify each matrix extension. The total cost to industry to verify analytical methods would apply to specific food items ranges from about $8,144 to about $1,053,121. We report the additional costs from the proposed rule for labs to verify analytical methods in Table 40.

Table 40: Cost to report results from validation and verification studies for matrix extensions

	Fully loaded wage	Hours for lab to verify an analytical method	Cost per sample to verify an analytical method	Percent analytical reports requiring verification	Percent of costs over and above ISO/IEC 17025	Total costs
Lower bound	$69.22	22	$1,521.11	5%	1%	$8,143.64
Upper bound	$69.22	46	$3,166.82	30%	5%	$1,053,120.97

a. **Costs to compile an analytical report with test results**

The proposed rule, if finalized, would require each participating lab to submit to us a full analytical report with test results, unless they can submit abridged reports. As described in the cost-savings section, we propose to reduce the quantity of information required in an analytical report once participating labs have submitted 10 consecutive successful full analytical reports. Participating labs that submit these 10 consecutive successful full analytical reports would then be allowed to submit abridged analytical reports for the disciplines included in the 10 consecutive analytical reports thereafter.

Each submission would contain:

- Test results
- Sampling plans, sample collection reports, and the sampler's qualifications
- When a validation study required, the documentation required by 17025
- When a verification study required, documentation such as results and supporting analytical data

- Either a full or abridged analytical report (see below)
- Certification that the test results and reports are true and accurate, and that they include the results of all tests conducted under this program on the product at issue.

In the cost-savings section we estimated the cost to compile an abridged analytical report to be between 25 percent and 33 percent of the costs to compile a full analytical report.

Participating labs allowed to submit to abridged analytical reports would still be required to maintain records of all information required in a full analytical report. We anticipate reviewing the records of information required in a full analytical report of participating labs allowed to submit abridged analytical reports one to three times per year per participating lab.

Analytical reports are currently submitted for tests of human and animal food offered for import covered under the proposed rule and, as discussed in the cost-savings section, would accrue cost-savings from clarifications of the reporting requirements, and those who qualify for abridged reporting (and incur the costs of compiling 10 successful full analytical reports), would accrue additional cost-savings. Because we currently do not receive analytical reports for tests of shell-eggs, sprouts and bottled water subject to specific testing requirements, we assume they are currently not generated with the same information as would be required by the proposed rule. We assume that all tests of shell-eggs, sprouts and bottled water subject to specific testing requirements would result in costs from compiling analytical reports from the proposed rule – first, 10 consecutive successful full analytical reports per participating lab, then abridged analytical reporting thereafter. We ask for comment on these assumptions.

We estimated the costs for participating labs to qualify for abridged reporting in the section on lab level costs. As reported in Table 12 in the cost-savings section, we estimate the cost to compile an abridged analytical report of between $46.23 and $122.04, and multiply by the

annual number of tests of shell eggs, sprouts and bottled water subject to specific testing requirements (between 1,309 and 7,030) and obtain the lower and upper bounds for compiling abridged analytical reports. We report the costs to compile abridged analytical reports in Table 41.

Table 41: Costs to compile and submit abridged analytical reports

	Cost to compile an abridged analytical report	Numbers of tests of shell-eggs, sprouts, bottled water, and other tests	Total cost to compile abridged analytical reports
Lower bound	$46.23	1,309	$61,649.50
Upper bound	$122.04	7,030	$861,611.02

e. Costs for switching to participating labs accredited to the appropriate scope

The proposed rule may result in switching costs if owners and consignees must switch from their current conveniently located lab to a participating lab that is accredited to the appropriate scope that may not be as conveniently located. We assume there may be switching costs for a fraction of samples to be tested that would equal the increment to costs to ship these samples for analysis to participating labs accredited to the appropriate scope located at a greater distance than the current lab. We assume that switching costs would be net of the costs of any current transfers between labs. We also assume for tests that would be subject to switching costs the current location of the lab is the primary factor for determining which to choose.

Without additional information, we assume the shipping cost to a participating lab accredited to the appropriate scope is between 0 and 25 percent more than the shipping cost to the current lab, net of any current costs of inter lab transfers. We estimate the ranges for the increased shipping costs using internal documents regarding the numbers and weights of sub-

samples recommended to be collected for each food category and the shipping costs published on UPS website (Ref. 17). A sample may be comprised of several sub-samples, with each sub-sample weighing between 2 and 3 pounds. FDA's internal Compliance Program Guidance Manual recommends collecting 10 sub-samples per sample of imported food in the absence of specific sample collection instructions when testing food with no identified pathogen (Ref. 18). We use 10 sub-samples as the lower bound in the range of sub-samples that would be shipped to a participating lab.

When testing for pathogens such as *Salmonella* and other specified microbes that might be consumed by vulnerable populations (infants, elderly, immune-compromised, etc.), The Bacteriological Analytical Manual (BAM), Chapter 1, calls for 60 sub-samples per sample for foods that would not normally be subjected to a process lethal to the microbe of interest (Category I foods) (Ref. 19). We use 60 sub-samples as the upper bound in the range of sub-samples that would be shipped to a participating lab. Because our internal experts judge that 10 sub-samples represents the most-likely number to comprise a full sample, we assume a Pert distribution, with 10 as the most likely value for the number of sub-samples in a full sample.

We use the weight of 2.5 pounds per sub-sample obtained from internal guidance, the weight of the packaging materials distributed uniformly between 1 and 10 pounds, and shipping costs based on retail rates published by UPS, distributed uniformly between $2.30 per pound and $7.67 per pound (Ref. 17). We assume that switching costs would be incurred for the number of samples currently not analyzed by labs accredited to the ISO/IEC 17025. Consequently, we estimate that between 0 percent and about 5.2 percent of all analytical reports submitted for tests of human and animal food offered for import covered under the proposed rule (100 percent – 100

percent of reports analyzed by an accredited lab = 0 percent; and 100 percent – 94.8 percent = 5.2 percent).

We do not have information on the accreditation status of labs that perform tests for shell-eggs, bottled water and sprouts subject to specific testing requirements that would be covered by the proposed rule, if finalized. Nor do we have information on the accreditation status of labs that perform tests used for corrective action plans after an order suspending registration, evidence for a hearings prior to a mandatory recall order, evidence for an appeal of an administrative detention order, or under a food testing order. We assume the accreditation status of these tests is the weighted average of the accreditation status of participating labs discussed earlier in the Baseline Conditions section and that between 10 percent and 72 percent of all analytical reports submitted to support shell-egg, sprouts and bottled water testing requirements (100 percent – 90 percent of labs currently accredited to ISO/IEC 17025 = 10 percent; and 100 percent – 28 percent labs currently accredited to ISO/IEC 17025 = 72 percent) would be subject to switching costs. Adding together the analytical reports submitted for tests of human and animal food offered for import covered under the proposed rule with those submitted for tests of shell-eggs, sprouts and bottled water and other tests covered under the proposed rule we obtain a total number of analytical reports subject to switching costs uniformly distributed between 133 and 5,869. We report the switching costs from the proposed rule in Table 42.

Table 42: Incremental costs to switch to participating labs accredited to the appropriate scope

	Lower bound	Upper bound
Number of sub-samples collected	10	60
Incremental shipping costs[1]	$8.66	$487.26
Total number of samples subject to switching costs	133	5,869
Total switching costs[2]	$14,955.25	$1,627,305.84

[1] Costs range from $2.30 per pound to $7.67 per pound. We assume each sample weighs 2.5 pounds and packing materials weigh from 1 pound to 10 pounds.

[2] We assume switching costs range 0 and 25 percent from current baseline costs.

f. Summary of costs incurred by test

We report summary of the costs incurred by test by sub- category and their annual frequencies in Table 43.

Table 43: Summary of costs incurred by test and their annual frequencies

	Lower bound	Upper bound	Frequency
Costs of the notice of sampling	$8,335	$153,460	Annual
Costs to generate a sample collection plan	$46,156	$488,688	Annual
Costs to compile a sample collection report	$46,156	$488,688	Annual
Costs for labs to confirm accreditation to the appropriate scope	$138,914	$511,534	Annual
Costs to include results from validation and verification studies	$8,144	$1,053,121	Annual
Costs to compile an analytical report with test results	$61,649	$861,611	Annual
Costs for switching to a lab accredited to the appropriate scope	$14,955	$1,627,306	Annual

We use Monte Carlo methods to simulate total annualized costs and the present values incurred by test. In Table 44 we report the simulated 5th percentile, mean and 95th percentile estimates of the annual and present value of costs by test discounted at seven percent and three percent over 10 years.

Table 44: Total annual costs and present value of costs incurred by test discounted over 10 years at seven percent and three percent

	5th percentile estimate	Mean estimate	95th percentile estimate
Annual costs	$1,394,555	$2,296,107	$3,569,163
Annualized costs at 3 percent	$1,371,870	$2,296,107	$3,541,175
Present value of costs at 7 percent	$9,625,868	$16,126,894	$25,775,326
Present value of costs at 3 percent	$11,690,703	$19,586,257	$31,304,365

4. Cost of fewer false negative test findings

The cost of fewer false negative test findings from better tests would include the cost of salvaging any shipments of human or animal food offered for import subject to the proposed rule that would now test positive. We assume consumers would not pay for human or animal food if they knew it to be contaminated, and that the consumer surplus gained by knowing the food is contaminated is at least as high as the lost wholesale value of the contaminated human or animal food incurred by the supplier. We consider this private transfer from supplier to consumer separately from the public health benefit of reducing foodborne illness.

There might be some portion of shipments of human or animal food offered for import covered under the proposed rule that currently test negative but would test positive under the proposed rule that could be salvaged by reconditioning. We estimate a cost for reconditioning of between $500 and $1,500 per line for 20 percent of shipments of human and animal food offered for import covered under the proposed rule from fewer false negative test findings. We assume that shipments of shell-eggs, bottled water, sprouts and other food subject to specific testing requirements would either be discarded or diverted to another use if a sample were to test positive. We assume zero costs for discarding contaminated shell-eggs, bottled water, and sprouts subject to specific testing requirements, and that any diversion of these products to a

lower value use is a reduction in the private transfer from producer to the consumer discussed above.

We use Monte Carlo methods to estimate that 20 percent of between -419 and 420 shipments, with a mean of 13 shipments of human and animal food offered for import covered under the proposed rule would incur a reconditioning cost of between $500 and $1,500 per shipment. We report the 5 percent, mean and 95 percent estimates for the cost of false negatives and the present value of the cost discounted at seven percent and three percent over 10 years in Table 45.

Table 45: Annual and present value of costs to recondition human and animal food offered for import covered under the proposed rule with fewer false negatives, discounted at seven percent three percent over 10 years

	5th Percentile Estimate	Mean estimate	95th Percentile estimate
Annualized cost at 7 percent	-$84,668	$2,561	$89,535
Annualized cost at 3 percent	-$84,668	$2,561	$89,535
Present value of costs at 7 percent	-$594,675	$17,985	$628,857
Present value of costs at 3 percent	-$722,238	$21,843	$763,753

5. One-time costs to learn the rule

We model the one-time learning costs as the time required by regulatory affairs personnel from human and animal food importers, laboratory accreditation bodies, private and public laboratories, shell egg producers, bottled water producers, sprouts producers and other entities to access and read the rule, if finalized. We estimate that a regulatory affairs expert would incur a burden of between 15 minutes and 30 minutes to access the rule and would read the preamble and codified provisions at a rate of 200 to 250 words per minute. The preamble has approximately 50,000 words and the codified has approximately 15,500 words, and we estimate that it would take between 4.36 and 5.45 hours for a regulatory affairs expert to read the

preamble and codified.

We estimate the mean hourly wage of a regulatory affairs expert using wages reported in the Bureau of Labor Statistics, Occupation Employment Statistics, May 2017 National Industry-Specific Occupational Employment Estimates for a Lawyer, which are doubled to account for overhead ($136.44). Applying the fully loaded mean hourly wage to the hourly burdens described above, we obtain a one-time cost of between $597.15 and $743.71 for a regulatory affairs expert to access and read the final rule (between 0.25 hours and 0.5 hours to access the rule + between 4.36 and 5.45 hours to read the rule x $136.44 per hour). The total access and learning costs for all affected entities, including importers, ABs, labs, and shell egg, sprouts and bottled water producers, would equal between $5,693,648 (for 9,557 entities) and $9,029,912 (for 12,125 entities) if incurred the first year following publication of the rule. However, we assume that entities would incur one-time access and learning costs uniformly over 5 years following publication of the rule. The present value of learning costs distributed uniformly over 5 years at a discount rate of 7 percent is between $4,470,161 and $7,089,508, with annualized costs between $594,813 and $943,352. When access and learning costs are assumed distributed uniformly over 5 years at a discount rate of 3 percent, the present value is between $5,087,381 and $8,068,395, with annualized costs between $676,943 and $1,073,606. We request comment about our assumption that these costs would occur over 5 years.

6. FDA Costs

FDA currently does not have a process to officially recognize ABs for the accreditation of labs. Costs to FDA from the proposed rule would include the one-time costs to establish a process and program to recognize ABs that include the one-time costs for training and

investments in information technology. We would also incur recurring costs to evaluate initial applications for AB recognition, the renewal of recognition, and the costs to monitor recognized participating ABs and labs. In addition, there would be costs to maintain websites with current contact information and recognition status of recognized ABs, and the scopes of accreditation, contact information and accreditation status of participating labs. We would incur costs to review and maintain records of analytic reports submitted for tests subject to testing requirements and to review notifications of intents to analyze. For estimating the costs reported in this section we use the fully loaded hourly wage of $116.75, which is derived from the 2018 annual fully loaded salary for ORA personnel of $242,838 used by FDA for budgeting purposes.

a. Costs for management systems upgrades, maintenance and training

Implementation of the proposed rule would require expansion and modification of FDA's existing management systems to enable the processing of AB applications for initial recognition and periodic renewal, the maintenance of databases of recognized ABs and participating labs, and for processing analytical reports submitted by participating labs. FDA experts estimate the one-time costs for improving the management systems for the labs program, including information technology improvements, hardware, software, training and associated labor costs to be about $3.0 million; and the annual maintenance costs of the improved management systems to be about $0.5 million. The annualized costs to establish and maintain the improved management systems to support the proposed rule discounted at seven percent over 10 years equal $899,189. With a three percent discount rate over 10 years, the establishment and maintenance costs equal $841,448.

b. Costs to evaluate the initial applications for recognition

The proposed rule requires us to review any completed application for recognition by an AB to determine whether the applicant meets all requirements specified in the rule. Applications would be submitted electronically and will initially go through an automated screening. They would then be reviewed and evaluated, and the applicants will be notified whether the application has been approved or denied. Approvals may be accompanied by requests for further information and denials will state the basis for the decision and provide instructions for requesting reconsideration.

The total estimated costs to review the initial application include the costs to review of the outcome of the automated screening, any follow-up requests for information and informing the applicant of the outcome. We estimate the initial review of an AB's application for recognition would take between 40 and 80 hours. The cost for reviewing an application from an AB would range from about $4,670 ($116.75 per hour x 40 hours = $4,669.96) to about $9,340 ($116.75 per hour x 80 hours = $9,339.92). Based on our simulation, we estimate a mean of 17.5 ABs would apply to be recognized and that the total one-time cost of reviewing applications would range from about $81,724 ($4,669.96 per AB x 17.5 ABs = $181,724.33) to about $163,449 ($9,339.92 per AB x 17.5 ABs = $163,448.65). We estimate the annualized costs to review an initial application would range from $10,874.49 to $21,748.98 when discounted by seven percent over 10 years, and between $9,301.54 and $18,603.08 when discounted by three percent over 10 years.

c. Costs to evaluate applications for renewal

The proposed rule provides that FDA may grant recognition to an AB for up to five years, and upon application for renewal. Evaluations of applications for renewal can include

reviews of one or more of the following: (1) AB's self-assessments; (2) reviews, accreditations, audits and investigations of labs; and (3) documents or other relevant information concerning the ABs authority, qualifications, resources, quality assurance program, and recordkeeping, reporting, notification and monitoring procedures. We estimate the burden for our evaluation of an application for renewal would be equal to that for an initial review, or between 40 hours and 80 hours per application for renewal.

We assume renewal costs would be incurred every five years, or twice over a 10-year period, and add the discounted present value of the renewal costs incurred during year 5 to the discounted present value of the renewal costs incurred during year 10 to obtain the total renewal costs. We assume discount rates of seven percent for the lower bound estimate and three percent for the upper bound estimate. Consequently, we estimate cost to review renewals over 10 years would range from about $99,813 (17.5 ABs x 40 hours x $116.75 per hour divided by 1.07 raised to the 5^{th} power + 17.5 ABs x 40 hours x $116.75 per hour divided by 1.07 raised to the 10^{th} power = $99,812.82) to about $262,613 (17.5 ABs x 80 hours x $116.75 per hour divided by 1.03 raised to the 5th power + 17.5 ABs x 40 hours x $116.75 per hour divided by 1.03 raised to the 10th power = $262,613.39). We estimate the annualized renewal cost discounted at seven percent over 10 years would range from $14,211.10to $37,390.24. The annualized costs discounted by 3 percent over five years would range from $11,701.11 to $30,786.30.

d. Costs to maintain website registry with information on ABs and labs

The proposed rule, if finalized, would require us to provide information on our website on all ABs, including those that have been placed on probation or whose recognition has been revoked, or whose application for recognition has been denied. In addition, the proposed rule

would require us to provide information on participating labs including scopes of accreditation, contact information and their program participation status, including those that have been placed on probation or had their accreditation revoked. We anticipate an annual burden for maintaining a website with information on ABs to be one hour per AB, and for maintaining a website with information on participating labs to be one hour per participating lab. Consequently, based on our simulation, we estimate the annual costs to maintain website information on ABs to be about $2,043 (1-hour x $116.75 per hour x 17.5 ABs = $2,043.11), and the annual costs to maintain website information on participating labs to range between about $2,335 (1-hour x $116.75 per hour x 20 labs = $2,334.98) and $8,756 (1 hour x 75 labs = $8,756.18).

e. One-time costs to review 10 consecutive successful full analytical reports per lab prior to qualifying for abridged reporting

Each participating lab would be required to provide 10 consecutive full analytical reports, prior to qualifying for abridged reporting. For purposes of this analysis, we assume that each participating lab would be accredited by a participating AB to two test methods of different disciplines. We multiply the cost to review a full analytical report of $220.66 by 75 percent and 90 percent to account for cost savings from management systems improvements, assume 10 consecutive successes and that the two relevant disciplines are included in the 10 consecutive successes, and multiply by the number of participating labs (between four and 25 participating labs that test human and animal food offered for import covered under the proposed rule, with a mean of 12, plus between 16 and 50 participating labs that test shell eggs, sprouts, bottled water and for other tests subject to testing covered under the proposed rule, with a mean of 21). We report the one-time costs for us to review 10 full analytical reports per lab and scope in Table 46.

Table 46: One-time per lab cost for us to review full analytical reports to qualify for abridged reporting

5th Percentile estimate	Mean estimate	95th percentile estimate
$43,738	$73,726.58	$103,667

f. Costs to review analytical reports

The proposed rule, if finalized, would require us to review analytical reports submitted by participating labs for adherence to the proposed requirements and to notify the participating lab of our findings. The current process for reviewing analytical reports of tests of human or animal food offered for import covered under the proposed rule includes an initial check for completeness upon receipt of the analytical report, a non-technical review of documents to establish a link between the sample and the detained shipment as well as the adequacy of the sample, and a high-level technical review that examines documentation to determine the adequacy of the analytical methods used. We may require resampling of the shipment during the non-technical review if the evidence suggests deficiencies on the sample collection. Moreover, a reviewer may convene an expert panel to address any concerns about the analytical package that may arise during the high-level technical review.

We assume that all participating labs would submit abridged analytical reports once they have qualified to do so. Moreover, we assume between 10 percent and 25 percent time saved to review an analytical report due to improvements in the management systems required for us to implement the labs program. Consequently, we estimate the cost for us to review an abridged analytical report including time saved from management systems improvements is between $41.37 and $65.53 (from Table 12b review costs are between $55.16 and $72.82 per analytical

report, multiplied by between 10 percent and 25 percent review time saved from management system improvements).

We assume we would incur costs to review all analytical reports of tests of shell-eggs, sprouts and bottled water subject to specific testing and for other testing requirements from the proposed rule. We assume we would not incur additional costs to review analytical reports submitted for tests of human and animal food offered for import covered under the proposed rule because that is the current baseline practice. Consequently, we estimate the costs for us to review analytical reports from the proposed rule is between about $55,175 ($41.37 per analytical report x [1,309 shell egg tests + 15 sprouts tests + 10 bottled water packages] x 75 percent due to cost-savings from management systems improvements = $55,174.57) and about $385,559 ($65.53 per analytical report x [7,030 shell egg tests + 15 sprouts tests + 15 bottled water packages] x 90 percent due to cost-savings from management systems improvements = $385,558.85. We assume costs for us to review analytical reports of tests for other food subject to testing covered under the proposed rule are included within this range).

g. Costs to assess participating labs

FDA may assess a participating lab to determine whether it complies with the proposed requirements. We may review a participating lab's records, conduct an on-site assessment, and obtain any other related information. We assume that we would assess each participating lab once every three to four years and that an assessment would take an assessor between 40 and 80 hours to complete. We multiply the hourly burden by the fully loaded wage of $116.75 to obtain a cost of between about $23,350 (40 hours x $116.75 per hour x 20 participating labs / 4 years = $23,349.81) and about $233,498 (80 hours x $116.75 per hour x 75 participating labs / 3 years =

$233,498.08) for FDA to assess each accredited lab once every three to four years, with an average cost of about $128,424.

h. Summary of FDA costs

We report upper and lower bounds and annual frequencies of the costs to us from the proposed rule by cost category in Tables 47.

Table 47: Summary of costs incurred by FDA

	Lower bound	Upper bound	Frequency
Management systems upgrade	$3,000,000	$3,000,000	One-time
Management systems maintenance costs	$500,000	$500,000	Annual
Recognizing ABs	$81,724	$163,449	One-time
Renewing recognition of ABs	$99,812.82	$262,613.39	Every 5 years
Maintain our website with information on participating ABs and participating labs	$4,378	$10,799	Annual
Review of 10 full analytical reports per lab	$44,131	$165,492	One-time
Review notifications and analytical reports	$55,175	$385,559	Annual
Assess participating labs	$23,350	$233,498	Annual

We use Monte Carlo methods to simulate the total annualized and present values of the costs incurred by us. In Table 48, we present our estimate assuming uniform distributions between the lower and upper bounds reported earlier in the section for each cost category. We report the 5 percent estimates, 95 percent estimates, and means estimates of the total annualized costs that would be incurred by us discounted at seven percent and three percent over 10 years.

Table 48: Estimated total annualized and present value of costs to FDA at discount rates of 7 percent and 3 percent over 10 years

	5^{th} percentile estimate	Mean estimate	95^{th} percentile estimate

Annualized costs at 7 percent	$1,118,524	$1,308,178	$1,500,061
Annualized costs at 3 percent	$1,043,243	$1,241,666	$1,437,150
Present value of costs at 7 percent	$4,057,503	$5,863,161	$7,755,387
Present value of costs at 3 percent	$4,262,688	$6,435,223	$8,698,536

7. Summary of total annualized and present value of costs of the proposed rule discounted at seven percent and at three percent over 10 years

We add together the costs incurred by ABs, costs incurred at the participating lab level, costs incurred on a per test basis, costs incurred with fewer false negatives, learning costs, and government costs in a Monte Carlo simulation model to estimate the 5 percent, mean and 95 percent range of the total annualized costs of the proposed rule. We report the estimated range of total annualized costs from the proposed rule discounted over 10 years at seven percent and at three percent in Tables 49a and 49b. We report the present values of the benefits and costs from the proposed rule discounted by seven percent and by three percent over 10 years in Table 50.

Table 49a: Summary of total costs of the proposed rule annualized at seven percent over 10 years

	5th percentile estimate	**Mean estimate**	**95th percentile estimate**
AB costs	$105,457	$203,257	$341,244
Costs incurred at the lab level	$461,085	$2,148,893	$4,448,946
Costs incurred by test	$1,394,555	$2,296,107	$3,569,163
Cost incurred from fewer false negatives	($84,668)	$2,561	$89,535
Learning costs	$594,845	$769,098	$943,352
Government costs	$1,118,524	$1,308,178	$1,500,061
Total annualized costs	$4,642,380	$6,728,094	$9,268,399

Table 49b: Summary of total costs of the proposed rule annualized at three percent over 10 years

	5th percentile estimate	Mean estimate	95th percentile estimate
AB costs	$100,668	$192,420	$317,123
Costs incurred at the lab level	$482,816	$2,150,116	$4,412,324
Costs incurred by test	$1,371,870	$2,296,107	$3,541,175
Costs incurred from fewer false negatives	($84,668)	$2,561	$89,535
Learning costs	$676,978	$875,292	$1,073,606
Government costs	$1,043,243	$1,241,666	$1,437,150
Total annualized costs	$4,726,930	$6,758,162	$9,283,088

Table 50: Present value of the benefits and costs of the proposed rule discounted at 7 percent and 3 percent over 10 years

	5th percentile estimate	Mean estimate	95th percentile estimate
Present value of costs at 7 percent	$34,161,713	$55,817,516	$77,986,344
Present value of costs at 3 percent	$38,735,842	$65,043,088	$91,655,772
Present value of benefits at 7 percent	$26,049,427	$53,064,669	$80,940,262
Present value of benefits at 3 percent	$31,637,263	$64,447,516	$98,302,675

We use a Monte Carlo simulation to subtract the total annualized costs of the proposed rule reported from the total annualized benefits reported earlier. When discounted by seven percent over 10 years, the annualized net benefits range between -$4,166,998and $5,566,821, with a mean annualized net benefit of $827,121. When discounted by three percent over 10 years, the annualized net benefits range between -$3,477,558and $5,259,903 with a mean annualized net benefit of $797,053. We report the annualized net benefits in Table 51.

Table 51: Annualized Net Benefits of the Proposed Rule Over 10 Years

	5th percentile estimate	Mean estimate	95th percentile estimate
Annualized net benefits at 7 percent	-$4,166,998	$827,121	$5,566,821

Annualized net benefits at 3 percent	-$3,477,558	$797,053	$5,259,903

a. Distributional Effects

The proposed, if finalized, rule would affect the distribution of revenues from tests of food offered for import covered under the proposed rule and from tests of shell-eggs, bottled water and other foods subject to testing covered under the proposed rule. requirements. Participating labs may incur between $52 thousand and $553 thousand in one-time costs to participate in our program if they are not currently accredited to ISO/IEC 17025. Labs may participate in our program if tests of food subject to DWPE and tests of shell-eggs and bottled water subject to testing requirements comprise a significant share of their business, or if they largely already meet the standards required for program participation, or a combination of both. We expect there to be some laboratories that currently test human or animal food offered for import covered under the proposed rule or test shell-eggs, sprouts and bottled water subject to specific testing requirements that would forego that business rather than incur the one-time costs associated with program participation. We expect the total revenue from testing human and animal food covered under the proposed rule and from testing shell-eggs, sprouts and bottled water subject to specific testing requirements to remain unchanged (or slightly higher if the price of a test increases) from the proposed rule, but that it would become concentrated in a smaller number of participating labs. We assume labs that would forego revenue from testing activities covered by the proposed rule would not exit the industry but would continue to function as businesses with slightly reduced revenues. We ask for comment on this assumption.

The proposed rule, if finalized, would also affect the distribution of revenue for ABs that accredit laboratories that test human and animal food offered for import covered under the

proposed rule and that test shell-eggs, sprouts bottled water and tests of other food subject to testing covered under the proposed rule An AB may incur up to between 19 thousand and $28 thousand in one-time costs to participate in our program. ABs may not participate in our program if few of its member labs would participate in our program. If an AB were not to participate in our program, the labs they currently accredit would need to switch to a different AB if they would participate in our program. We expect the proposed rule, if finalized, to result in fewer than the current number of labs that test human and animal food offered for import covered under the proposed rule or that test shell-eggs, sprouts and bottled water subject to specific testing requirements. We expect that total revenue from accreditation fees paid by participating and non-participating labs would remain unchanged (or slightly higher if the fees to accredit in the labs program increase) from the proposed rule, if finalized. A small number of labs that would participate in the labs program may switch to a participating AB if their current AB does not participate in the labs program. We expect that all domestic ABs would participate in the labs program. We assume that ABs that do not participate in our program would continue to function as businesses but with slightly reduced revenues. We request comment on these assumptions.

b. International Effects

We expect the effects from the proposed rule, if finalized, on the level of international trade to be small since the current share of tests of human and animal food offered for import covered under the proposed rule conducted by international labs is small. We also expect the effects of the proposed rule, if finalized, on the composition of international trade to be small. There may be a slight redistribution of international ABs and labs that perform the tests of human and animal food offered for import covered under the proposed rule across countries, depending on the amount of food exported to the US. International labs and ABs from countries

that export small amounts of human and animal food to the US may relinquish any business from testing human and animal food offered for import covered under the proposed rule to a competitor, likely located in a different country, rather than incur the one-time costs to participate in the labs program.

c. Uncertainty and Sensitivity Analysis

We obtained 5 percent estimates, means and 95 percent estimates of the benefits, costs and net benefits using Monte Carlo simulation methods. The means obtained using Monte Carlo simulation methods are not different than the means that would be obtained using non-simulation methods. However, Monte Carlo simulation methods provide 5 percent estimates and 95 percent estimates that quantify the degree of uncertainty in the outputs (costs, benefits and net benefits). Moreover, Monte Carlo simulation methods allow us to weigh the importance that the estimate of each input contributes to the uncertainty in the corresponding output.

We estimate net benefits would range from -$4.2 million to $5.6 million, with a mean of $0.83 million. The three most important sources of uncertainty in the estimate of the net benefits include (1) uncertainty in the estimates of the percent fewer false negatives and false positives from better tests of human and animal food offered for import covered under the proposed rule, (2) uncertainty in the costs for labs to attain and maintain accreditation to ISO/IEC 17025, and (3) industry cost-savings. Uncertainty in the estimate of the percent fewer false negatives and fewer false positives from better tests of human or animal food offered for import covered under the proposed rule adds between -$2.7 million and $4.0 million to the uncertainty in the net benefits estimate. Uncertainty in the estimate of the costs to attain and maintain accreditation to ISO/IEC 17025 contributes to between -$1.9 million and $2.6 million in uncertainty in the net benefits estimate. Finally, uncertainty in the estimate of industry cost savings contributes to

between $0.38 million and $2.3 million in uncertainty in the net benefits estimate. We report the three main sources of uncertainty in Table 52.

Table 52: Three primary sources of uncertainty in the net benefits estimate (mean net benefit = $0.83 million)

Source of uncertainty	Contribution to uncertainty (Lower bound)	Contribution to uncertainty (Upper bound)
Better tests of human and animal food offered for import covered under the proposed rule	-2.7 million	$4.0 million
Costs to attain and maintain accreditation to ISO/IEC 17025	-$1.9 million	$2.6 million
Industry cost savings	-0.38 million	$2.3 million

G. Analysis of Regulatory Alternatives to the Proposed Rule

1. Do not allow abridged reporting

Following 10 successful full analytical reports, a participating lab would thereafter be allowed to submit abridged analytical reports. Abridged analytical reports would contain information that would meet the ISO/IEC 17025 standard for reporting, but less than that needed for us to replicate the test results. All information contained in a full analytical report would be available to us on an as-needed basis. We estimated cost savings from compiling and reviewing abridged analytical reports of tests of human and animal food offered for import covered under the proposed rule as well as a reduced cost for compiling and reviewing analytical reports of tests of shell-eggs, sprouts and bottled water and tests of other food subject to specific testing covered under the proposed rule. By not allowing abridged reporting we estimate the mean net benefits from the proposed rule would fall from $0.83 million to -$10.2 million.

2. Cover only tests of human and animal food offered for import covered under the proposed rule

When only tests of human and animal food offered for import covered under the proposed rule are subject to the proposed requirements, if finalized, labs that test shell-eggs, sprouts, and bottled water would not be affected by the rule and analyses of shell-eggs, sprouts, and bottled water would not be subject to the requirements of the proposed rule, if finalized. This regulatory alternative is most consistent with current baseline practices for reporting test results since currently only analytical reports of tests of human and animal food offered for import covered under the proposed rule are regularly submitted to us. By not covering tests of shell-eggs, sprouts, bottled water and other tests subject to specific testing requirements the mean net benefits of the rule would increase from $0.83 million to $2.7 million.

3. Prohibit in-house testing

Internal information indicates between 3.3 percent and 7.5 percent of all tests of human and animal food offered for import covered under the proposed rule currently may be performed by in-house labs. We assume this range also applies to tests of shell-eggs, sprouts and bottled water subject to specific testing requirements. We ask for comment on the percent of tests of shell-eggs, sprouts and bottled water subject to specific testing requirements that are performed by in-house labs. Consequently, prohibiting in-house testing may result in switching costs for up to an additional 3.3 percent to 7.5 percent of all tests covered under the proposed rule – or up to an additional 397 to 1,633 tests.

The switching costs estimated earlier for the proposed rule were from between 133 and 5,869 tests currently performed by labs not accredited to ISO/IEC 17025. We assume between 0 and 100 percent of in-house labs that perform tests covered under the proposed rule are also not

accredited to ISO/IEC 17025 and shouldn't be counted in the estimate of the additional switching costs incurred from this regulatory alternative. Consequently, we estimate the additional switching costs incurred from this option would be between $1,722 and $284,221, with a mean of $80,900.

Table 53: A comparison of regulatory alternatives with the proposed rule

Regulatory alternative	**Comparison with the proposed rule**	**Reason not selected**
Do not allow abridged reporting	Mean net benefits fall from $0.83 million to -$10.2 million	Too costly
Cover only tests of human and animal food offered for import covered under the proposed rule	Mean net benefits increase from $0.83 million to $2.7 million	Inconsistent with Statute
Prohibit in-house testing	Total switching costs increase by between $1,722 and $284,221, with a mean increase of $80,900.	Too costly

III. Initial Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because the costs of the proposed rule may have a significant impact on a substantial number of small entities, we consider the possibility of extended compliance dates for those labs not currently accredited to ISO/IEC 17025 to participate in the program.

A. **Description and Number of Affected Small Entities**

The primary impact of this rule will be on accreditation bodies and testing laboratories. Importers, shell-egg producers, sprouts producers and bottled water producers and other food manufacturers would also be affected by the proposed rule. The Small Business Administration (SBA) reports size standards for industry categories defined by North American Industry Classification System (NAICS) codes (Ref 20). Using the SBA's standards, testing laboratories (NAICS 54138) are considered small if they earn $15 million revenue or less, chicken-egg producers (NAICS code 112320) are considered small if they earn $15 million in revenues or less, and bottled water manufacturers (NAICS 312112) are considered small if they have fewer than 1,000 employees. We assume the SBA standard of small for Perishable Prepared Food Manufacturing (NAICS 311991) of 500 or fewer employees applies to sprouts producers and importers, and we assume the SBA standard of small for All Other Professional, Scientific and Technical Services (NAICS 541990) of $15 million or less would apply to accreditation bodies.

We apply data from the Economic Census by NAICS code to determine the numbers of accreditation bodies, testing labs, shell egg producers, bottled water producers and sprouts producers and importers that are small by the SBA standards. The 2012 Economic Census reports that over 95 percent of all testing laboratories under NAICS code 54138 have annual revenues below $15 million, over 95 percent of bottled water manufacturers under NAICS 312112 have fewer than 1,000 employees (Ref. 21) and over 85 percent of establishments under NAICS 311991 (including sprouts manufacturing establishments) have fewer than 100 employees. We assume that the number of sprouts growers with more than 100 employees is distributed uniformly between 100 employees and more than 500 employees, by increments of 100, so that fewer than 3 percent of sprouts manufacturing establishments have more than 500

employees. Moreover, consistent with the regulatory impact analysis of the Final shell-egg rule, over 99 percent of shell-egg producers (NAICS code 112320) covered by this proposed rule would be considered small as well. For purposes of this analysis, we assume that 100 percent of ABs, labs, shell-egg producers, and sprouts, importers and bottled water manufacturers affected by this proposed rule are small.

We compare the costs per entity from the proposed rule with the average revenue per establishment by NAICS code obtained from the 2012 Economic Census. We obtain the average revenue per establishment by dividing the total revenue reported in the 2012 Economic Census for each NAICS code by the total number of establishments reported for the corresponding NAICS code. We obtain the average revenue per testing laboratory of $2,502,209, the average revenue per accreditation body of $904,257, the average revenue per sprouts producer of $14,468,090 and the average revenue per bottled water manufacturer of $19,520,408. We derive the average revenue per shell-egg producer ($1,022,458) from information reported in Table 39 of the Regulatory Flexibility Analysis for the Shell-egg final rule. We report the NAICS codes, SBA thresholds, the numbers of entities, and the average revenue per entity covered by the proposed rule in Table 54.

Table 54: Entities affected by the proposed rule

	Number of Establishments [1]	Annual Revenue ($ million)[1]	Revenue per Establishment ($ thousand)	SBA Size Standard
Testing laboratories, NAICS 541381	6,045	$15,125.86	$2,502.21	$15 million
Accreditation bodies, (All Other Professional, Scientific and Technical Services) NAICS 5419909	12,294	$11,116.93	$904.26	$15 million
Sprouts producers and importers (Perishable Prepared	702	$10,156.60	$14,468.09	500 employees

Food Manufacturing), NAICS 311991				
Bottled water manufacturers, NAICS 312112	294	$5,739.00	$19,520.41	1,000 employees
Shell-egg producers, NAICS code 112310 [2]	7,359	$7,524.27	$1,022.46	$15 million

[1] No. of Establishments and Annual Revenue reported in the 2012 Economic Census

[2] No of Establishments and Revenue per Establishment derived from figures reported in Table 39 of the Regulatory Flexibility Act for the Shell-egg Final rule

B. Description of the Potential Impacts of the Rule on Small Entities

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. In the Preliminary Regulatory Impact Analysis, we estimate the one-time and annual costs for accreditation bodies, testing laboratories, shell-egg, sprouts, importers and bottled water producers. We use a Monte Carlo simulation to estimate the 5 percent, mean and 95 percent levels of one-time costs per entity using the distributional assumptions discussed in the Regulatory Impact Analysis. ABs that choose to participate in our program would incur one-time costs to apply for recognition, establish an accreditation program, as well as to learn about the rule equaling between about $19,000 and $28,000 per entity. Participating labs would incur one-time costs to become accredited to ISO/IEC 17025 and to learn about the rule. One-time costs for labs already accredited to ISO/IEC 17025 would equal between about $600 and about $740 per lab. One-time costs for labs that choose to participate in the labs program but are not accredited to ISO/IEC 17025 would equal between about $52,000 and about $553,000. Shell-egg producers, sprouts producers, importers and bottled water manufacturers would incur one-time costs to learn about the rule equaling between about $600 to about $737. Importers would incur costs to learn about the rule. We report the one-time costs per entity from this proposed rule in Table 55.

Table 55: One-time per entity costs of the proposed rule

	5th percentile estimate	Mean estimate	95th percentile estimate
ABs that choose to participate	$19,301.02	$23,544.06	$27,677.50
Labs that choose to participate that are currently accredited to ISO/IEC 17025	$603.17	$670.26	$737.24
Labs that choose to participate that are currently not accredited to ISO/IEC 17025	$52,126.08	$259,476.26	$553,164.33
Bottled water manufacturers	$603.17	$670.26	$737.24
Shell-egg producers	$603.17	$670.26	$737.24
Sprouts producers and importers	$603.17	$670.26	$737.24

The range in one-time costs for ABs that choose to participate in our program is between 2.1 percent and 3.1 percent of average revenue per entity. We report the range in one-time costs for labs that choose to participate in our program for labs that are already accredited to ISO/IEC 17025 and those that are not yet accredited to ISO/IEC 17025. Labs that would participate in the labs program and are currently accredited to ISO/IEC 17025 would incur one-time costs of between 0.024 percent and 0.029 percent of the average revenue per entity. Labs that would participate in the labs program but are currently not accredited to ISO/IEC 17025 would incur one-time costs of between 10.4 percent and 22.1 percent of the average revenue per entity. The range in one-time costs for bottled water manufacturers is between 0.003 percent and 0.004 percent of the average revenue per entity, the one-time costs for shell-egg producers is between 0.065 percent and 0.072 percent of the average revenue per entity, and the one-time costs for sprouts producers and importers is between 0.005 percent and 0.005 percent of the average revenue per entity. We report the costs per entity as a percent of average revenue per entity, for all entities affected by the proposed rule are reported in Table 56.

Table 56: One-time per entity costs as a percent of average per entity revenue

	Costs as a percent of revenue (lower bound)	Costs as a percent of revenue (mean estimate)	Costs as a percent of revenue (upper bound)
ABs participating in the program	2.1345%	2.6037%	3.0608%
Labs participating in the program currently accredited to ISO/IEC 17025	0.0241%	0.0268%	0.0295%
Labs participating in the program not currently accredited to ISO/IEC 17025	2.0832%	10.3699%	22.1070%
Bottled water manufacturers	0.0031%	0.0034%	0.0038%
Shell-egg producers	0.0590%	0.0656%	0.0721%
Sprouts producers and importers	0.0042%	0.0046%	0.0051%

We consider costs per entity over and above one percent of annual revenues to be a substantial impact. All estimates of the costs per entity for labs not currently accredited to ISO/IEC 17025 exceed one percent of annual revenues. The largest share of one-time costs incurred by these entities would be from becoming accredited to ISO/IEC 17025. We ask for comment on the number of labs that are currently not accredited to ISO/IEC 17025 that would participate in the labs program.

We do not know the number of labs that would participate in the labs program and assume that those that would choose not to participate currently earn only small share of their business from tests that would now require a participating lab. Consequently, we assume that any lab that currently performs tests referred to in this proposed rule and chooses not to participate in the labs program would not forgo enough business as to cease its operations. Rather, we assume

that labs that choose not to participate in the labs program would continue operating as labs but with slightly reduced incomes. We ask for comment on this assumption.

C. Alternatives to Minimize the Burden on Small Entities

As a regulatory option to minimize the burden on small entities we consider extending compliance dates for ABs and corresponding labs that currently perform analyses covered in this proposed rule but are not accredited to ISO/IEC 17025 so that they can continue performing these analyses while taking steps to acquire ISO accreditation. The one-time costs incurred by labs that choose to participate in our program could be between $52 thousand and $553 thousand if they are not yet accredited to ISO/IEC 17025. This option would prevent a loss of business for these labs (and ABs) in the short term while enhancing the supply of participating labs that could perform the analyses required in the proposed rule. We request comment on the number of ABs accrediting these labs and the number of labs that currently perform tests covered by the proposed rule but are not accredited to the ISO/IEC 17025 but would continue to perform these tests following publication of a final rule if we were to extend compliance dates.

IV. References

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