DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Laboratory Accreditation for Analyses of Foods (LAAF)

Docket No. FDA-2019-N-3325

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of this rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct 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). We believe that this final 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 the per-entity one-time costs of the rule may exceed one percent of revenues for accreditation bodies and laboratories that choose to participate in the Laboratory Accreditation for Analyses of Foods (LAAF) program, we find that the final 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 issuing "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 $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The rule will require that testing of food in certain circumstances be performed by a laboratory (LAAF-accredited or participating lab) accredited to the new standards established by the final rule by a recognized accreditation body (participating AB), and for the test results to be submitted to us. The costs of the rule will primarily be incurred by participating ABs, participating labs, shell egg producers, sprouts producers, bottled drinking water manufacturers, owners and consignees of import related food, and us. Rarely, certain firms will 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 (FTO) (now referred to as a Directed Food Laboratory Order (DFLO)). We will incur costs to establish and maintain the program for recognizing ABs that apply to participate in our program, evaluating participating ABs and reviewing the performance of participating labs, and for reviewing associated documents and reports. The present value of the costs of the rule ranges from $38 million to $66 million when discounted by 7 percent over 10 years and from $43 million to $77 million when discounted by 3 percent over 10 years. Annualized costs over 10 years range from $5.8 million to $9.6 million when discounted by 7 percent, and from $5.9 million to $9.7 million when discounted by 3 percent.

The rule will generate some quantified and unquantified benefits. Quantified benefits include a reduction in the number of foodborne illnesses from fewer false negative test results for import related food covered under the rule and for shell eggs, sprouts, and bottled drinking water

and other food subject to testing requirements covered under the rule. We anticipate cost savings from the clarifications of the process for compiling, submitting, and reviewing analytical reports for import related food covered under this rule, including reduced reporting burden. There would be less revenue lost from fewer false positive test results for import related food covered under the rule and for tests of shell eggs, sprouts, and bottled drinking water and other food subject to testing requirements covered under the rule. The present value of the benefits of the rule ranges from $46 million to $88 million when discounted at 7 percent over 10 years and range from $56 million to $106 million when discounted at 3 percent over 10 years. Annualized benefits over 10 years range from $6.6 million to $12.5 million when discounted by both 7 and 3 percent.

Unquantified benefits may include fewer illnesses from deterring unsafe manufacturing practices by all entities covered by the rule. We expect that specific test reporting requirements will result in more accurate analytical reports and reporting.[1]

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this rule. In Table 1 we provide the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs Consolidated Information System accounting information.

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

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$9.1	$6.6	$12.5	2020	7%	10 years	Cost savings and avoided QALD losses
		$9.1	$6.6	$12.5	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Reduced risk of food-related illness from improved test performance for covered tests. Cost savings from clarifying reporting requirements and from allowing abridged analytical reports Reduced risk of food-related illness from unsafe food manufacturing practices						
Costs	Annualized Monetized $millions/year	$7.9	$5.8	$9.6	2020	7%	10 years	
		$7.9	$5.9	$9.7	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	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 17025:2017 that would participate in the LAAF program described by this rule. Wages: None Growth: None							

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

C. Definition of Terms Used in the 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/Agency is used to refer to the Food and Drug Administration (FDA).

- ISO/IEC 17025 (ISO/IEC 17025:2017) is the 2017 version of 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 the 2017 version of the 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 assessment 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 an 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 rule.

- LAAF is an acronym for Laboratory Accreditation for Analyses of Foods, which refers to our laboratory accreditation program as established by the rule.

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

- Participating or LAAF-accredited labs refers to laboratories that participate in the LAAF program.

- Participating ABs refers to ABs that participate in the LAAF program.

- Food testing or testing of food means the analysis of food product samples or environmental samples.

- Import Alerts are FDA alerts listing 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.

- Import related food testing refers to the testing of food offered for import or potentially offered for import, where the findings from analytical tests are used to support admissibility of the food. Food testing related to an import alert falls into this category.

- Other testing covered under this rule refers to:

    - testing required by FDA in a directed food laboratory order (DFLO), or

    - testing 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 of evidence submitted for an appeal of an administrative detention order.

- Owners and consignees refer to any person with an ownership or consignment interest in the food product or environment that is the subject of food testing covered by the rule.

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

- Specific testing requirements refer 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.

- Switching costs refer to the incremental costs to send samples to a participating lab instead of a currently used lab that chooses not to participate in the LAAF program.

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

- Full analytical report refers to the entire set of information, including test results, that will be sent by a LAAF-accredited lab to FDA.

- Major Food Testing Discipline refers to the major types of tests for which a participating lab is accredited.
- Abridged analytical report refers to a subset of the information that would be required in a full analytical report that will be sent by a LAAF-accredited lab to FDA.
- Negative means a food test showed no indication of a public health concern.
- Positive means a food test showed some indication of a public health concern (e.g., pathogen).

D. Comments to this Rule

FDA's proposed rule "Laboratory Accreditation for Analyses of Foods" (84 FR 59452) was published on November 4, 2019. The comment period was extended twice – on February 28, 2020 (85 FR 11893) and April 6, 2020 (85 FR 19114) – and closed July 6, 2020. We describe and respond to comments we received on the Preliminary Regulatory Impact Analysis (PRIA) of the proposed rule in the following paragraphs. We have numbered each comment to help distinguish between the different comment themes. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, or the order in which topics were discussed in the comment(s).

(Comment 1) We received comments stating that the assumption that large ISO/IEC 17025:2017 accredited laboratories also adhere to the AOAC/ALACC Guidelines, while small laboratories may not, is incorrect. The comments assert that laboratories that test only animal food (including feed), whether large or small, likely adhere to the AAFCO Guidelines for Feed Laboratories whether these laboratories are accredited to ISO/IEC 17025:2017 or not. These comments recommend that we include cost considerations for laboratories that adhere to the AAFCO Guidelines both singly and jointly with the AOAC/ALACC Guidelines.

(Response 1) We adopt the recommendation provided in the comments that both large and small laboratories accredited to ISO/IEC 17025:2017 are equally likely to adhere to AOAC/ALACC Guidelines, and have revised our estimate of the costs for the proficiency testing requirement (per AOAC Guidelines) accordingly. We assume laboratories that adhere to AOAC Guidelines and AAFCO Guidelines will incur fewer costs to become accredited to ISO/IEC 17025:2017 and we have made that assumption explicit in the Final Regulatory Impact Analysis (FRIA) by adding "...we assume the costs to become accredited to ISO/IEC 17025:2017 for laboratories that adhere to AOAC Guidelines and AAFCO Guidelines would fall in the lower end of the estimated range...."

(Comment 2) Some comments note that the loaded wage, including overhead, used to estimate the costs to generate a sample collection plan, to compile a sample collection report, or to prepare an advance notice of sampling is very high and not representative of the actual wages, including overhead, of laboratory technicians around the world.

(Response 2) We acknowledge that the loaded wage used in the PRIA may not be representative of the wages, including overhead, of laboratory technicians around the world. We have added to the text the caveat "...costs for sample collection plans and reports and advance notices of sampling prepared outside the United States may differ based on the wages of the countries where they are prepared...."

(Comment 3) A small number of comments suggest that only 8-10 accreditation bodies would apply to be recognized, based on commenters' experience with ABs that participate in the Accredited Third-Party Certification Program (ATPCP), and ask that we justify our estimate of 17.5 ABs used in the PRIA.

(Response 3) We concur with the comments' suggestion to use information from the ATPCP to estimate the number of accreditation bodies that will participate in the LAAF program. Currently, there are 4 ABs that participate in the ATPCP. The LAAF Program will cover tests of shell eggs, sprouts, and bottled drinking water, as well as import related food tests. Because accreditation bodies covered by the ATPCP could also oversee laboratories that conduct these tests, we estimate that 4 ABs will participate in the LAAF program – the same number that participate in the ATPCP.

(Comment 4) Some comments disagree with our estimate of the costs for Inter Laboratory Comparisons (ILCs) and proficiency tests. A subset of the comments disagrees with our assumption that ILCs are half the costs of proficiency testing (PT) programs. We understand the comments to suggest that the total cost to a participating laboratory for an ILC would be about the same as that for a PT because the cost for either of those items is just a fraction of the laboratory's total cost of participation; the comments list additional costs including labor and supplies. Another subset of the comments disagrees with our use of $0 as a lower bound on cost for ILCs. These comments suggest that although ILCs may be "free" to a participating lab, the provider still incurs costs such as those associated with providing the test items and issuing reports. Further, these comments note that long-standing ILC series may cost participating laboratories a nominal fee and for shipping, or participating laboratories may rotate the role of provider.

(Response 4) We adopt the recommendation provided in the comments that the total cost for an ILC is about the same as that for a PT. The requirements in the final rule are similar to the AOAC Guidelines for PT and require PT at least once a year for each method within each scope of LAAF-accreditation. This exceeds the requirements for PT in the current ISO/IEC

17025:2017 standard which allows flexibility for laboratories to participate in either ILC or PT at unspecified frequencies. Consequently, we now estimate the costs of the rule from the requirement for PT are the one-time costs for 50 percent of laboratories to incorporate that change into their laboratory management systems. We assume the one-time cost to incorporate changes into management systems from participating in ILCs to performing PTs is negligible.

(Comment 5) Some comments express concern that the PRIA did not consider the costs from the food testing order (FTO, now directed food laboratory order (DFLO) in the final rule) requirements. Some comments suggest that the costs associated with the DFLO outweigh the benefits. In particular, these comments focus on the costs from "test and hold" programs that would be incurred while waiting for the test results. These comments claim that test and hold programs could precipitate disruptions in production schedules. A subset of these comments claims that the requirement to use a LAAF-accredited laboratory and the potential need for us to observe sampling (were we to require an advance notice of sampling), could also cause disruptions to production scheduling.

Some comments note that the PRIA does not estimate the direct costs of the FTO (now DFLO), including the costs of testing, the costs associated with validating specific test methods and matrices, and the cost of maintaining accreditation. A subset of these comments is specifically concerned that we could require firms under FTOs (now DFLOs) to engage in method validation. Other comments note that the use of labs accredited under the LAAF program under circumstances requiring a DFLO could cost more than the use of other available laboratories.

(Response 5) We did not make explicit our estimate of the direct costs of the DFLO or demonstrate quantitatively that the costs outweigh the benefits. We do so here and refer to the

section entitled “Costs for the DFLO and covered tests from other administrative orders covered by the rule” in the FRIA for further details. The DFLO is a new administrative tool requiring the use of a LAAF-accredited lab for analyses in the rare situations when we have reason to question the accuracy and reliability of past or present test results and an identified or suspected food safety problem exists. We intend to issue a DFLO when there is both a validated method and sufficient laboratories LAAF-accredited to that method. Consequently, we do not address costs associated with firms engaging in method validation here.

In the PRIA we estimated the frequency of our use of a DFLO (previously FTO) as the same as our use of other administrative tools with tests covered by this rule; Administrative Detentions (AD), Suspensions of Registrations (SR) and Mandatory Recalls (MR). In the FRIA we make that link quantitative and report our method and estimates here. We required ADs 10 times between 2011 and 2020 and MRs once during that time period (Ref. 1 and 2). We used SRs six times between 2011 and 2020 (Ref. 3). We estimate our annual use of a DFLO will be between 0.1 and 1 (1/10 years and 10/10 years) and report the baseline frequencies of ADs, SRs, and MRs and our estimate for DFLOs in the section entitled “Analytical reports of tests conducted to satisfy Directed Food Laboratory Orders (DFLO), and for tests to satisfy other administrative orders covered by the rule” in the FRIA and in Table 2.

Table 2: Numbers of ADs, SRs, MRs and DFLOs

	Total since 2011	**Annual Frequency**
ADs	10	1
SRs	6	0.6
MRs	1	0.1
DFLOs	N/A	0.1 to 1

A DFLO requires a firm to use a LAAF-accredited lab to conduct the analysis of food product samples or environmental samples and have the results sent directly to us. We do not know the total number of tests and analytical reports that will be subject to a DFLO requirement and use as a guide the rounds of testing ordered in recently adjudicated consent decrees involving food facilities found to be in violation of the FD&C Act.

Many consent decrees have no explicit food product testing requirements. We identified four consent decrees ordered in 2016 that made explicit the testing frequencies (e.g., weekly) and prescribed additional details for finished product testing (e.g., every lot per finished product, one lot from each finished product). We use these four adjudicated consent decrees as the basis for estimating the numbers of tests and analytical reports that will be subject to a DFLO. The first round may require daily product tests over the course of a week's worth of production (5 tests), the second round may require weekly tests over the course of the subsequent month (4 tests), and the third round may require monthly tests over the subsequent year (12 tests). We assume these tests would be analyzed by a LAAF-accredited lab and the results and related analytical report sent directly to us. Consequently, we estimate there will be 21 analytical reports generated for each DFLO.

We estimate the costs of the DFLO requirement using the same methodology we used in the PRIA to estimate costs for other tests that will be subject to the rule. We refer to the section entitled "Costs for the DFLO and other testing covered by the rule related to other administrative orders covered by the rule" section in the FRIA for additional details. We summarize the costs below:

1) generate a sample collection plan ($38.55 to $77.10),
2) compile a sample collection report ($38.55 to $77.10),

3) collect the sample collection report and ensure the analysis and methods fall within the participating LAAF-accredited lab's scope ($12.85 to $25.70),

4) verify analytic methods for specific foods (matrix extensions) ($0.88),

5) switching costs ($72.98),

6) compile and submit an analytic report ($205.98 to $411.98), and

7) our review ($225).

We estimate the annual cost of the DFLO provision is $10,000. We assume the number of tests and analytical reports estimated for a DFLO is the same as the number of tests and analytical reports for the other testing covered by the rule that relates to other administrative orders and estimate the costs of these provisions are about $10,000.

We also estimate the avoided Quality-adjusted Life-day (QALD) losses from the DFLO and covered tests for other administrative orders. In the PRIA we estimated avoided QALD losses from better tests of import related food covered by the rule and for tests of shell eggs, sprouts, and bottled drinking water covered by the rule - treating tests of shell eggs, sprouts, and bottled drinking water as one category without distinguishing between them. In the FRIA, we make explicit our estimate for the avoided QALD losses from the DFLO and tests for other administrative orders covered by the rule. We separately estimate the avoided QALD losses from better tests of shell eggs, sprouts, and bottled drinking water.

In the FRIA, we estimate that more consistently accurate tests required by the DFLO will prevent illnesses at the same rate as those prevented for import related food tests covered by the rule. Moreover, we assume the number of servings of food subject to a DFLO is the same as the number of servings in a shipment of import related food covered by the rule. Consequently, we divide the number of illnesses averted from reducing the number of false negative shipments of import related food (an average of about 322 illnesses) by the number of fewer false negative

tests of that food (an average of about 21 fewer shipments with false negative test results) to obtain the number of illnesses avoided per contaminated shipment of import related food (an average of about 15 illnesses per contaminated shipment). We then multiply by the annual number of DFLO (0.1 to 1.0) to obtain the annual number of illnesses avoided from the DFLO (an average of about 10).

We assume the QALD loss from an illness from food that will now be subject to a DFLO would be the same as the QALD loss from an illness of import related food covered under the rule and obtain the annual average avoided QALD losses from the DFLO of about $69,000. Please see the section entitled "Avoided Quality-adjusted Life-days (QALDs) from fewer contaminated servings on the market" in the FRIA for additional details of this estimate. We make the same assumptions for the avoided QALD losses from the other tests covered under the rule related to other administrative orders, and estimate the annual average avoided QALD losses from those tests combined are about $69,000. We also estimate fewer false positives from more accurate tests of food subject to a DFLO and other administrative orders will result in negligible savings. This is consistent with the small number of tests per year.

We disagree with the comment that any test and hold activities that arise from the FTO (now DFLO) constitute a cost of the rule. Consumers would ordinarily assume the food is safe to consume at the time of purchase and obtain utility from that assumption. If the food is actually unsafe at the time of purchase, the utility obtained from assuming it is safe is misplaced. Rather the consumers' utility of unsafe food at the time of purchase is likely close to zero or even negative. We consider any costs incurred from disruptions in production and shipping schedules as a transfer from producers to consumers from making food safe that would otherwise be unsafe

at the time of purchase. We do not consider transfers to be costs and have added this discussion in the FRIA.

(Comment 6) Some comments state that the PRIA did not clearly define large and small labs.

(Response 6) We disagree that there was no definition of large and small labs in the PRIA. We adopt the definitions of "small" used by the Small Business Administration for the various types of entities affected by the rule, including labs, as described in Section III. A. in the Initial Small Entity Analysis. In the Final Small Entity Analysis, we use the Small Business Administration definitions of "small" and report our estimate that all entities covered by the proposed rule are small.

(Comment 7) Several comments note that the cost estimates are unclear. Some comments express uncertainty regarding whether the PRIA accounted for the time and resources to collect and store the data required by the rule. Some comments contend that the costs may outweigh the benefits. Some comments indicate that the unquantified benefits of the rule contribute to uncertainty.

(Response 72) We try to be clear and transparent with our methods and assumptions for estimating the costs and benefits. We estimate the benefits (about $9.1 million) are greater than the costs (about $7.9 million). We acknowledge there may be some uncertainty from the unquantified benefits but the costs of the activities that generate these benefits is quantified, and the unquantified benefits generated from these activities is greater than zero. We also acknowledge there will be costs for data collection and storage most of which are captured in the costs to become accredited to the ISO/IEC 17025:2017 standard described in the FRIA.

Although the comments did not specify which data or storage costs we failed to capture, we discuss in detail in the FRIA the costs incurred by ABs and LAAF-accredited labs.

E. Other Updates in the FRIA

Eastern Research Group (ERG) completed a profile of the laboratory and analytical testing sector (Profile) affected by the final rule in January 2020 (Ref. 4). Per that Profile, there are 70 to 200 sprouts testing labs[2] and 15 to 38 shell egg testing labs that will be affected by the final rule compared to our estimate of 16 to 50 total shell egg, sprouts, and bottled drinking water testing labs in the PRIA. Moreover, per the Profile, current rates of ISO/IEC 17025:2017 accreditation for shell egg testing labs are lower than those estimated for the PRIA (0.30 - 0.37 compared to 0.51 – 0.95).

We used estimates reported in the Profile to estimate the number of shell egg, sprouts, and bottled drinking water analytical reports that will be submitted, and reviewed by us, per the final rule requirements. ERG derived the number of shell egg tests (144,000 - 187,000) from reports of the annual number of environmental positives obtained from hen houses (720 - 1,400) using an estimated positive rate of 1.1 percent of environmental tests. In the FRIA, we use expert judgment that a majority of shell eggs from molted flocks (50 to 75 percent) will be diverted to the processed egg market following an environmental positive test, with 20 percent of flocks molted (Ref. 5). Consequently, we estimate that 10 to 15 percent of shell eggs will be diverted to the processed egg market to avoid additional shell egg testing (20 percent hens molted x 50 to 75

[2] Throughout the FRIA we use "sprouts testing lab" as a shorthand way of describing labs that conduct the follow-up tests related to sprouts in existing FDA regulations (the Produce Safety Rule), but actually much of that testing is not of sprouts themselves but rather the sprout-growing environment.

percent diversion rate for molted hens = 10 to 15 percent shell eggs diverted following a positive environmental test result) and that 2,520 to 5,023 shell egg analytical reports at 50 test results per report will be submitted, and reviewed by us, annually. We use estimates reported in the Profile that 60 to 480 sprouts analytical reports at 10 test results per report will be submitted to and reviewed by us. The Profile reports that positive bottled drinking water test results that will require the use of a LAAF-accredited lab are rare, and we estimate 0 to 2 analytical reports for bottled drinking water will be submitted to and reviewed by us annually.

Internal data and comments to the proposed rule suggest that most labs that currently test food offered for import covered under the rule are accredited to ISO/IEC 17025:2017. In the PRIA, we estimated that only labs that test import related food currently accredited to ISO/IEC 17025:2017 will participate in the LAAF program and that two to eight labs that perform tests of shell eggs, sprouts, and bottled drinking water covered under the rule that are not accredited to ISO/IEC 17025:2017 will incur costs to become accredited to ISO/IEC 17025:2017 in order to participate in the LAAF program. In the FRIA we refine our estimates of the number of labs from each sector that will choose to participate in the LAAF program and the numbers that will choose not to participate based on the estimated costs to become accredited to ISO/IEC 1725:2017 and the estimated revenue from covered tests for each sector.

Based on information contained in the Profile we estimate the total revenue to labs from covered tests of shell eggs, sprouts, and bottled drinking water, and assume the costs to participate in the LAAF program will be lower for labs already accredited to ISO/IEC 17025:2017 and that currently conduct covered tests. We assume the covered tests for shell eggs, sprouts, and bottled drinking water currently conducted by labs are distributed uniformly across all labs in each sector, including those that are accredited to ISO/IEC 17025:2017 and those that

are not accredited to ISO/IEC 17025:2017. We estimate the number of labs that may incur the one-time and annual costs to become accredited to ISO/IEC 17025:2017 due to the rule based on the revenue from covered tests that remains after labs already accredited to ISO/IEC 17025:2017 participate in the LAAF program. In the FRIA we estimate that for covered tests of import related food, sprouts, and bottled drinking water only labs that are currently accredited to ISO/IEC 17025:2017 and conduct those tests will participate in the LAAF program. We estimate that revenues from covered tests for import related food, sprouts, and bottled drinking that are left over after labs that are already accredited to ISO/IEC 17025:2017 have chosen to participate in the LAAF program are insufficient to cover the costs of becoming accredited to ISO/IEC 17025:2017. Consequently, we estimate that 10 to 44 labs that conduct covered tests of import related food, 60 to 190 labs that conduct covered tests of sprouts, and 0 to 1 labs that conduct covered tests of bottled drinking water will participate in the LAAF program. We estimate that labs that currently conduct covered tests of import related food, sprouts, and bottled drinking water and that are not accredited to ISO/IEC 17025:2017 are not likely to participate in the LAAF program.

We estimate there will be sufficient revenue left over from covered tests of shell eggs once labs currently accredited to ISO/IEC 17025:2017 participate in the LAAF program to cover the costs for some labs to become accredited to ISO/IEC 17025:2017 that are currently not accredited to that standard. We estimate that 7 to 10 labs that conduct covered tests of shell eggs may incur one-time and annual costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program and that a total of 15 to 21 labs that conduct covered tests of shell eggs will participate in the LAAF program.

There will be switching costs – costs to switch to a participating lab – added to the costs of those tests currently performed by labs that choose not to participate in the LAAF program. We estimate switching costs as the additional costs to ship a sample to a LAAF-accredited lab that may be located further away than the lab that otherwise would have been selected. We acknowledge the possibility that when switching costs are high or costs to become accredited to ISO/IEC 17025:2017 are low, additional labs may choose to participate in the LAAF program. We did not estimate the number of such labs that would choose to participate in the LAAF program because of high switching costs or low costs to become accredited to ISO/IEC 17025:2017. Rather, we assume switching costs and the costs for these labs to become accredited to ISO/IEC 17025 are offsetting.

We note there is uncertainty about the number of labs that will participate in the LAAF program, and the Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for testing ensures there will be enough lab capacity in the LAAF program for any tests that are required. The stepwise approach to implementation and giving a 6-month notice to owners and consignees prior to requiring the use of LAAF-accredited laboratories affects the timing of costs incurred for tests covered by the rule. We estimate that the benefits and costs will be incurred for import related food covered by the rule one to two years following publication of the final rule. We believe that timeframe is realistic because import related owners and consignees, and labs conducting import related tests, are already used to sending analytical reports to FDA, and because comments assert there is currently sufficient lab capacity to conduct at least all import related tests covered by the rule. For tests of shell eggs, sprouts, and bottled drinking water covered by the rule, we estimate benefits and costs will be incurred two to three years following publication of the rule. Those

industries and laboratories do not currently submit analytical reports to FDA in connection with the tests covered by the rule, so we anticipate that it will take longer to attain sufficient lab capacity for such tests. We discount public health benefits from better tests of food covered by the rule by three percent and the costs and cost savings by seven percent. We report a summary of the updates based on estimates from the Profile as well as from public comments in Table 3, Table 4, and Table 5.

Table 3: Summary of substantive changes in the FRIA based on public comments, clarifications, and updates

	PRIA	FRIA
Labs that currently test shell eggs, sprouts, and bottled drinking water[1]	16 – 50 labs	215 – 418 labs
Labs that would incur costs to become ISO/IEC 17025:2017 accredited	2 – 8 labs	7 – 10 labs
Rates of ISO/IEC 17025:2017 accreditation of labs that test shell eggs	51 – 95 percent	30 – 37 percent
The annual number of analytical reports for tests of import related food covered by the rule	10,708 – 15,110	11,648
The annual number of analytical reports: shell eggs, sprouts, and bottled drinking water	1,334 – 7,060	2,640 – 5,985
Number of full analytical reports prior to gaining permission to submit abridged analytical reports	10 full analytical reports representative of the lab's major food testing disciplines	5 full analytical reports per major food testing discipline. 1 to 3 major food testing disciplines per lab.
Number of ABs that will apply to be recognized	5 – 80, with a mean of 17.5 ABs	4, the current number of ATPCP-approved ABs
Number of labs that test import related food covered under the rule that will participate in the LAAF program	4 – 25	10 – 44
Number of labs that test shell eggs subject to specific testing requirements that will	15 – 50	15 – 21

	PRIA	FRIA
participate in the LAAF program		
Number of labs that test sprouts subject to specific testing requirements that will participate in the LAAF program	Included in the number of labs that test shell eggs and bottled drinking water	60 – 190
Number of verification and validation studies evaluated by ABs for purposes of the LAAF program	1 – 10 studies per lab	0
Annual frequencies of Administrative Detentions, Mandatory Recalls and Suspensions of Registrations	Infrequent Negligible number of analytical reports	0.1 to 1 per year 2.1 to 21 analytical reports annually
Annual frequencies of the FTO (now DFLO)	Infrequent Negligible number of analytical reports	0.1 to 1 per year 2.1. to 21 analytical reports annually
Benefits and costs of the FTO (now DFLO)	We did not separately estimate benefits and costs of the FTO	Benefits: $69,000 Costs: $10,000
Benefits and costs of tests of other administrative orders covered by the rule	We did not separately estimate benefits and costs of the tests from other administrative orders covered by the rule	Benefits: $69,000 Costs: $10,000
Estimate of the effect of the improved laboratory performance on the number of shipments.	Applied the improved performance rate to the baseline rates of test findings	Obtained the number of false test results from the rule and subtracted from the baseline number of false test results to obtain the number of fewer false test results from the rule
Benefits of covered tests of sprouts and bottled drinking water	Benefits estimated jointly with those of covered tests of shell eggs	Benefits of covered tests of shell eggs, sprouts, and bottled drinking water estimated separately
Fully loaded wages	Microbiologist: $75.38 Natural Science Manager: $128.52 Food Scientist and Technologist: $69.22 Lawyer: $136.44 FDA/ORA: $116.75	Microbiologist: $88.30 Natural Science Manager: $148.89 Food Scientist and Technologist: $77.10 Lawyer: $143.18 FDA/ORA wage: $119.08 Acknowledge in the FRIA that the loaded wage used in the PRIA may not be representative of the wages, including overhead, of laboratory technicians around the world.

	PRIA	FRIA
Estimates of QALD losses per illness from import related food, shell eggs, sprouts, and bottled drinking water updated	QALD loss per illness of imported food is the average QALD loss per illness reported in Minor, et al. (about $1,100) updated to 2016 levels.	QALD loss per illness of imported food estimated using Gould, et al. illnesses from imports, Scallan, et al. underreporting multipliers and Minor, et al. QALD loss estimates, updated to 2020 values.
Switching cost occurrence by testing category	0 - 5 percent of samples of import related food, and 5 - 49 percent of samples of shell eggs, sprouts, and bottled drinking water.	3.2 - 7.5 percent of samples of import related food, 5 -15 percent of sprouts samples and bottled drinking water samples and 63 to 70 percent of shell egg samples.
Timing of costs and benefits (the effect of the stepwise approach to implementation and the 6-month FR notice provision)	All costs and benefits would be incurred in the first year following publication of the rule	Costs and benefits for tests of import related food covered by the rule will be incurred one to two years following publication of the rule. Costs and benefits for tests of shell eggs, sprouts, and bottled drinking water will be incurred two to three years following publication of the rule.

[1] Final estimate includes 70 - 200 sprouts testing labs and 15 - 38 shell egg testing labs in the pool of labs potentially affected by the rule per ERG report.

Table 4: Summary of changes in the cost estimates

Categories of costs	PRIA primary estimate	FRIA primary estimate
AB costs	$203,257	$175,166
Costs incurred at the lab level	$2,148,893	$3,527,536
Costs incurred by test	$2,296,107	$1,589,601
Cost incurred from fewer false negatives	$2,561	$4,206
Learning costs	$769,098	$1,030,784
Government costs	$1,308,178	$1,569,189
Total annualized costs of this rule	$6,728,094	$7,896,481

Table 5: Summary of changes in the benefits estimates

Categories of benefits	PRIA primary estimate	FRIA primary estimate
Cost savings from clarifications of the processes for compiling and reviewing analytical reports of tests of import related food covered by the rule	$2,426,228	$1,892,655
Cost savings from allowing abridged analytical reporting of tests of import related food covered by the rule	$4,629,879	$3,969,236
Cost savings from management systems upgrade	$148,096	$131,260
Cost savings from fewer false positives - import related food	$2,954	$5,249
Cost savings from fewer false positives - Shell Eggs	$20,317	$70,161
Cost savings from fewer false positives - Sprouts	Not estimated	$2,802
Cost savings from fewer false positives - Bottled Drinking Water	Not estimated	$0
Avoided QALD losses from fewer servings of contaminated imported food	$317,377	$2,689,678
Avoided QALD losses from fewer servings of contaminated Shell Eggs	$108,254	$153,177
Avoided QALD losses from fewer servings of contaminated Sprouts	Not estimated	$1,699
Avoided QALD losses from fewer servings of contaminated Bottled Drinking Water	Not estimated	$209
Avoided QALD losses from DFLO	Not estimated	$68,966
Avoided QALD losses from covered tests from other administrative orders	Not estimated	$68,966
Total annualized benefits of this rule	$7,555,215	$9,054,057

II. Final 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. Section 202

of FSMA requires that food be tested by laboratories accredited to standards established by FDA 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; and
- under an Import Alert that requires successful consecutive tests.

In these circumstances, FSMA requires the results of food testing that must be conducted by a LAAF-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 (never finalized) 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. 6). 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. 7). 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 rule codifies many elements of the 2004 proposed rule and 2009 draft guidance. For instance, the rule requires labs to be accredited to ISO/IEC 17025:2017 in order to participate in the LAAF program. The rule also defines the circumstances under which tests must be conducted by a participating lab, including in support of admission of import related food, and for tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements and for food subject to other testing requirements covered by the rule. To fulfill the FSMA mandate and the regulatory purpose of the LAAF program, the rule codifies some laboratory requirements beyond those required by ISO/IEC 17025:2017, including certain test method verification and validation reporting requirements. In addition, the rule provides for 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 sample collection reports. The rule also 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 LAAF program and for ABs and labs to participate in the LAAF program.

B. Need for Federal Regulatory Action

The rule implements provisions in FSMA that require us to establish a program for the testing of food by accredited labs, including the recognition of accreditation bodies and the

development of model standards that labs must meet to be LAAF-accredited to conduct testing under this rule.

There are several sources of asymmetric information between the owner or consignee, the testing laboratory, and us that create a need for federal regulatory action. Food owners and consignees may not know the true quality of a lab's tests at the time a lab is selected or even after the lab has reported the test result if they assume tests from a lab not accredited to the industry standard are as accurate as tests from a lab accredited to the industry standard. For some tests, FDA may not know the true quality of the lab results even after the food is tested if they are not currently reported to us.

Food contamination is often difficult to detect without the assistance of sophisticated laboratory techniques performed by trained technicians and analysts. Food owners and consignees depend on lab results to confirm the safety of their food. Consumers rely on owners and consignees to provide safe food which otherwise would not be consumed. Unsafe food that has been identified by a poor-quality laboratory as safe is able to enter commerce and may cause illness among the unsuspecting public. Had the owners or consignees known the food was unsafe they might have withdrawn it from commerce prior to it causing illness among unsuspecting consumers. Had we known the food was unsafe we would have better targeted our enforcement resources to prevent illness from occurring.

There is evidence that these sources of information asymmetry occur and have an impact on public health outcomes. For instance, unsafe imported food continues to cause illness among unsuspecting consumers – possibly even after the unsafe food has been tested, found to be safe, and the test results sent to us. Also, unsafe food subject to other FDA monitoring regulations

such as shell eggs, sprouts, and bottled drinking water, continues to cause illness among unsuspecting consumers.

This rule addresses these sources of asymmetric information and the resulting public health risk. Owners or consignees of food subject to the tests covered under the rule will now know they are hiring a high-quality lab as there will be a public registry of labs that participate in the LAAF program. In addition, owners or consignees of food subject to the tests covered under the rule will know that the quality of the tests performed by the participating labs will conform to the standards established in the final rule, including that the labs be assessed by recognized accreditation bodies (ABs) and have their performance reviewed by us to ensure that the tests more consistently reveal the true safety of the food. Consequently, owners or consignees will be better able to withdraw unsafe food from commerce, we will more accurately target our enforcement resources to prevent illness among the unsuspecting public, and consumers will have greater assurance that the food they purchase is safe.

C. Purpose of the Rule

The purpose of the rule is to better protect public health by helping ensure the quality of tests and reporting in certain situations. The rule establishes a program (the LAAF program) that recognizes ABs, provides standards that participating ABs and labs must meet, and under certain circumstances requires the use of LAAF-accredited labs. ABs may apply to us for recognition, maintain recognition status, and accredit labs to the LAAF standards defined by the rule. Participating ABs will incorporate the LAAF program requirements, assess participating labs for adherence to the LAAF program requirements, maintain current records, and report to us relevant updates regarding changes in the accreditation status of participating labs. Participating

ABs will be periodically evaluated by us for adherence to the LAAF requirements. We assume that all ABs that currently participate in our ATPCP will apply for recognition from the LAAF program.

Labs participating in the LAAF program will be accredited to ISO/IEC 17025:2017 and participate in a proficiency testing program for analytical methods at a prescribed frequency. Under certain circumstances, LAAF-accredited labs will validate and verify analytical methods beyond the validation and verification requirements of ISO/IEC 17025:2017. The rule requires, among other things, that LAAF-participating labs:

- be periodically assessed by their AB for adherence to the requirements under the LAAF program;
- send certain test results directly to us and adhere to format and content requirements for an analytical report;
- provide advance notice of sampling prior to collecting the sample in certain situations;
- submit to FDA sample documentation such as a sampling plan, a collection report, and the sampler's credentials; and
- ensure the analytical methods required are appropriate for the scope to which it is LAAF-accredited.

We will recognize and oversee the participating ABs. We will also review test results and reports from participating labs. We will administer the LAAF program and have the authority to review the performance of participating labs.

D. Baseline Conditions

In this section we describe the number and types of affected entities and the baseline conditions for our analysis. We use a simulation model to estimate current baseline practices.

This 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 fifth percentile, mean, and 95th percentile for our simulated outputs. The rule will primarily affect the following entities:

- eligible ABs seeking recognition by FDA;
- labs that conduct import related food testing covered by the rule;
- labs that conduct testing on shell eggs, sprouts, and bottled drinking water covered by the rule;
- owners and consignees; and
- FDA.

We estimate the number of affected entities and the current ISO 17025:2017 accreditation status of labs. We then describe the numbers of analytical reports we expect to receive under the rule. We also describe the inefficiencies in the current process to submit and review analytical reports of import related food testing that will be covered by the rule.

1. Number of entities

a. The pool of ABs potentially affected by the rule

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 U.S. has five ABs; Thailand, Canada, and Japan each have three ABs. The signatory members follow the ISO/IEC 17011:2017 standard and any related ILAC guidance documents. ABs ensure that their accredited labs comply with ISO/IEC 17025:2017 and any related ILAC guidance documents.

Several existing ABs already fulfill many of the rule's requirements such as signatory to the ILAC MRA, conforming to the ISO/IEC 17011:2017 standard, and accrediting labs to the ISO/IEC 17025:2017 standard. These ABs currently perform assessments of labs' processes and management systems, at the frequencies specified in the ISO/IEC 17025:2017 standard and generally have the capacity to assess labs to determine a lab's ability to meet the LAAF-accreditation requirements. Moreover, existing ABs can place a lab on suspension, or withdraw, renew, or reduce the scope of a laboratory's accreditation to the LAAF standard. In addition, ISO/IEC 17011 requires an AB to have a written program that addresses and protects against potential conflicts of interest with the labs that the AB accredits. Consequently, we estimate that between 5 domestic ABs and 80 ABs (5 domestic ABs + 75 foreign ABs) are in the pool of ABs that could potentially be affected by the rule.

b. The pool of labs potentially affected by the rule

We assume that all labs that choose to participate in the LAAF program will come from the pool of labs that currently conduct the testing that will be covered under this rule. We estimate that some labs from the pool may decide not to participate in the LAAF program to avoid the additional costs associated with LAAF program participation. We estimate that labs from the pool will decide to participate in the LAAF program if performing the covered tests constitutes a significant share of their business, if the costs for becoming LAAF-accredited are low, or a combination of these factors.

Labs that perform covered tests of import related food differ from the labs that perform covered tests of shell eggs, sprouts, and bottled drinking water. Labs that test import related food are 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 drinking water are more geographically dispersed to account for proximity as a factor determining lab use. In addition, according to the Profile their use tends to be sector specific, with labs that perform tests for one sector tending to be different than those that perform tests for the others.

i. The pool of labs that perform covered tests of import related food potentially affected by the rule

We estimate the pool of labs that will test import related food covered under the 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. 8). Approximately 106 private labs performed the covered tests of import related food during this period, with 44 of the labs accredited to ISO/IEC 17025.

ii. The pool of labs that test shell eggs, sprouts, and bottled drinking water subject to specific testing requirements and labs that conduct other tests covered under the rule potentially affected by the rule

Our contractor, ERG, completed a profile in January 2020 of the laboratory and analytical testing sector (Profile) that will be affected by the final rule (Ref. 4). Information from the Profile indicates that there are 70 to 200 sprouts testing labs, 15 to 38 shell egg testing labs, and 130 to 180 bottled drinking water testing labs that may be affected by the final rule compared to a total of 16 to 50 shell egg, sprouts, and bottled drinking water testing labs estimated in the PRIA. Moreover, the final rule will 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 DFLO.

We estimate in a later section that these latter tests will occur infrequently, 0.1 to 1 time annually as part of a corrective action plan to reinstate a registration, prior to a mandatory recall, and appealing an administrative detention order; and 0.1 to 1 time annually for a DFLO. We consider it unlikely that the small number of tests that might be conducted in these situations will support the costs to participate in the LAAF program if these were the only tests performed by the lab. Consequently, we estimate the number of participating labs that test shell eggs, sprouts, and bottled drinking water as a subset of the pool of labs potentially affected by the rule.

c. The number of affected owners or consignees of import related food the tests of which are covered under this rule

There were 1,219 food importers during the 2018 fiscal year. We assume the number of food importers is the same as the number of owners or consignees of import related food covered by the rule. Consequently, we assume a lower bound of 1,219 owners or consignees of import related food covered by the rule will incur a one-time cost to read and understand the rule. We anticipate that the number of owners or consignees of import related food covered by the rule will vary from year to year. We assume that three times the lower bound (3,657) will be the upper bound on the total number of owners or consignees of import related food covered by the rule that will incur one-time costs to read and understand the rule.

d. The number of shell egg, sprouts, and bottled drinking water manufacturers affected by this rule

We do not know by how much the number of covered shell egg producers has changed since that number was estimated in relation to the shell egg safety rule published in 2009 (Ref. 9). Consequently, we use the number of producers (7,359) published in the Regulatory Impact Analysis of the shell egg safety rule in our analysis. We do not know by how much the number of covered sprouts producers has changed since the number was estimated in relation to the Produce Safety Rule published in 2015 (Ref. 10). Consequently, we use the number of producers (285) published in the Regulatory Impact Analysis of the Produce Safety Rule in our analysis.

There were 669 domestic bottled drinking water manufacturing establishments inspected between 2002 and 2016 that will be affected by this rule. Manufacturing establishments that bottle drinking water and have not yet been inspected will be excluded from this estimate. Manufacturing establishments that exited the industry after being inspected may still be listed in our database. We assume that these numbers offset each other.

e. The total number of entities affected by the rule

We estimate that the final rule will affect between about 9,800 to about 12,500 entities, including certain labs and ABs that choose to participate in the LAAF program, and owners or consignees of import related food subject to tests covered under the rule and food subject to specific testing requirements. We report the estimated numbers of entities by type of entity in Table 6.

Table 6: The pool of entities potentially affected by the rule by entity type

	Low	High
Accreditation bodies (ABs)	5	80
Labs that test import related food	106	106
Labs that test shell eggs covered by the rule	15	38
Labs that test sprouts covered by the rule	70	200
Labs that test bottled drinking water covered by the rule	130	180
Owners or consignees of import related food the tests of which are covered by the rule	1,219	3,657
Shell egg producers	7,359	7,359
Sprouts producers	285	285
Bottled drinking water manufacturers	669	669
Total	**9,858**	**12,569**

2. The current baseline practices of affected entities

a. The current accreditation status of labs that perform tests that will be covered by the rule

The final rule will require that participating labs be accredited to ISO/IEC 17025:2017 and meet some additional management and technical requirements beyond ISO/IEC 17025:2017. In the PRIA, we used information from an internal study of PLAPS reports from January 1, 2016, through December 31, 2017, to estimate that 44 labs in the pool of 106 labs that conduct covered tests of import related food are accredited to ISO/IEC 17025 (41.5 percent) and that these labs perform between 92.47 percent and 96.78 percent of all covered tests of import related food (Ref. 8).

Information from the Profile indicates that the current rate of ISO/IEC 17025:2017 accreditation for shell egg testing labs is 30 to 37 percent and 85 to 95 percent for sprouts testing labs. Because we estimate the number of covered tests of bottled drinking water is so small, for purposes of this analysis we assume the accreditation status of labs that perform covered tests of bottled drinking water is the same as that for sprouts tests. We do not have information on the

rates at which covered tests of shell eggs, sprouts, and bottled drinking water are performed by ISO/IEC 17025:2017 accredited labs, and assume they are the same as the accreditation rates of labs that conduct covered tests of shell eggs, sprouts, and bottled drinking water. Table 7 shows current rates of accreditation to ISO 17025:2017 for labs and the percent of covered tests they perform.

Table 7: Current rates of accreditation to ISO 17025:2017 by labs and the percent of tests they perform that will be covered by the rule

	Low	High
To comply with import related food testing requirements	41.5 percent of labs (92.5 percent of tests)	41.5 percent of labs (96.8 percent of tests)
To comply with shell egg testing requirements	30.0 percent of labs (assume 30 percent of tests)	37.0 percent of labs (assume 37 percent of tests)
To comply with sprouts testing requirements	85.0 percent of labs (assume 85 percent of tests)	95.0 percent of labs (assume 95 percent of tests)
To comply with bottled drinking water testing requirements	85.0 percent of labs (assume 85 percent of tests)	95.0 percent of labs (assume 95 percent of tests

b. The baseline number of analytical reports

i. Analytical reports of import related food testing covered under this rule

We use information from the Private Laboratory Analytical Packages (PLAPs) dataset to estimate the annual number of analytical reports of import related food testing covered under this rule. Our information indicates there were 11,648 PLAPs submitted to support import admissibility decisions in 2019 and that for the years 2018 and 2019 approximately 4.63 percent report positive test findings.

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

We used estimates reported in the Profile of the number of analytical reports of shell egg, sprouts, and bottled drinking water tests that will be submitted to us per the final rule

requirements. The Profile derives 144,000 to 187,000 shell egg tests based on an estimated 720 to 1,400 environmental positives, obtained using an estimated positive rate of 1.1 percent of environmental tests. We adjust the number of covered shell egg tests to account for the probability that shell eggs will be diverted to the processed egg market following an environmental positive. We use expert judgment (Ref. 7) that most shell eggs (50 to 75 percent) obtained from molted flocks will be diverted to the processed egg market following an environmental positive test and that 20 percent of flocks are molted (Ref. 8). Consequently, we estimate that 10 to 15 percent of shell eggs will be diverted to the processed egg market to avoid additional shell egg testing costs (20 percent hens molted x 50 to 75 percent diversion rate for molted hens = 10 to 15 percent shell eggs diverted following a positive environmental test result) and that 2,520 – 5,023 shell egg analytical reports, at 50 test results per report, will be submitted to and reviewed by us annually.

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

This rule will 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 Rule (Ref. 10). 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 estimates reported in the Profile that between 60 – 480 sprouts analytical reports at 10 test results per report will be submitted to and reviewed by us annually.

This rule will require certain bottled drinking water testing required by the Bottled Water Final Rule (Ref. 11) to be subject to testing under this rule. The Profile reports that positive bottled drinking water test results that will require the use of a LAAF-accredited lab are rare, and we estimate 0 - 2 analytical reports for bottled water at 5 results per report will be submitted to and reviewed by us annually.

iv. Analytical reports of tests conducted to satisfy Directed Food Laboratory Orders (DFLO), and for tests to satisfy other administrative orders covered by the rule

Use of a LAAF-accredited lab may be necessary as part of a corrective action plan after an order suspending registration (SR), to submit evidence for a hearing prior to a mandatory recall order (MR), to submit evidence for an appeal of an administrative detention order (AD), and as required under a Directed Food Laboratory Order (DFLO). We required ADs 10 times and MRs once between 2011 and 2020 (Ref. 1 and 2). In addition, we used SRs six times between 2011 and 2020 (Ref. 3). We assume we will require the use of a participating lab under these circumstances at the same frequencies.

The DFLO is a new administrative tool requiring the use of a LAAF-accredited lab for analyses in the rare situations when we have reason to question the accuracy and reliability of past or present test results, and an identified or suspected food safety problem exists. In the PRIA, we estimated the frequency of our use of a DFLO (previously FTO) as the same as our use of other administrative tools with tests covered by this rule (ADs, SRs, and MRs). In the FRIA, we make that link quantitative and report our method and estimates here. We estimate our annual use of a DFLO will be between 0.1 and 1 (1/10 years and 10/10 years) and report the baseline frequencies of ADs, SRs, and MRs, and our estimate for DFLOs in Table 8.

Table 8: Numbers of ADs, SRs, and MRs and DFLOs

	Total since 2011	Annual Frequency
ADs	10	1
SRs	6	0.6
MRs	1	0.1
DFLOs	N/A	0.1 to 1

A DFLO requires a firm to use a participating LAAF-accredited lab to conduct environmental tests or food product tests and have the results sent directly to us. We do not know the total number of tests and analytical reports that will be subject to a DFLO requirement. We use as a guide the rounds of testing ordered in recently adjudicated consent decrees involving food facilities found to be in violation of the FD&C Act.

Many consent decrees have no explicit product testing requirements. We identified four consent decrees ordered in 2016 that made explicit the testing frequencies (e.g., weekly) and prescribed additional details for finished product testing (e.g., every lot per finished product, one lot from each finished product, etc.) for finished product testing. We use these four adjudicated consent decrees as examples for estimating the numbers of tests and analytical reports that will be subject to a DFLO. The first round may require daily product tests over the course of a week's worth of production (5 tests), the second round may require weekly tests over the course of the subsequent month (4 tests), and the third round may require monthly tests over the subsequent year (12 tests). We assume these tests would be analyzed by a participating LAAF-accredited lab and the results compiled into an analytical report and sent directly to us. Consequently, we estimate there will be 21 analytical reports generated for each DFLO. We report the total number of analytical reports of tests that we estimate will be compiled by a LAAF-accredited lab in Table 9.

Table 9: Number of analytical reports that will be compiled by a LAAF-accredited lab and submitted to us

Regulatory effort	Lower value	Mean	Upper value
Import related food	11,648	11,648	11,648
Shell eggs	2,520	3,771	5,023
Sprouts	60	270	480
Bottled drinking water	0	1.0	2
ADs, SRs, and MRs	2.1	11.6	21
DFLOs	2.1	11.6	21
Total number of analytical packages	**14,232**	**15,713**	**17,195**

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

This rule will establish clear procedures and expectations for industry to submit analytical reports for tests covered by this rule and for FDA to review these analytical reports. The current process for reviewing analytical reports of tests of human or animal food offered for import covered under this rule includes an initial check (IC) 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 import related food covered under this rule. We assume the costs to review an analytical report for tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements and other tests covered by the rule will be the same as that for reports of import related food covered under this rule.

We assume the baseline cost for industry to compile an analytical report and for us to review an analytical report includes 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 IC, 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 IC 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 a panel of Technical Leads, or field scientists who are recognized within FDA as able to provide recommendations on technical matters. The Technical Leads 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 IC 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 IC 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 will 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

include 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 IC 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). We present the results in Table 10.

Table 10: 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)
IC	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 of 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 hours (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 us and industry in Table 11a and Table 11b.

Table 11a: 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 11b: Extra burden to compile an analytical 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 burden to FDA to review an analytical report by the fully loaded hourly wage for an ORA reviewer of $119.08, derived from the FY2020 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 $337 (2.83 hours x $119.08 = $337) and an extra burden to review a deficient analytical report of about $112 (0.94 hours x $119.08 = $111.94). We multiply burden for industry to compile an analytical report by the fully loaded wage of a Food Scientist and Technologist of $77.10 to obtain the baseline cost for industry to compile an analytical report of between about $308 (4 hours x $77.10 = $308.40) and $617 (8 hours x $77.10 = $616.80), with an extra review burden of between about $102 (1.3 hours x $77.10 = $102.44) and $205 (2.7 hours x $77.10 = $204.87). 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 Table 12a and Table 12b.

Table 12a: 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	$119.08	$337.01
Cost of the extra review burden due to deficiencies	0.94	$119.08	$111.94

Table 12b: 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	$308.40	$616.80
Cost of the extra burden to compile an analytical report due to deficiencies	1.3	2.7	$102.44	$204.87

E. Benefits of this Rule

There are quantified and unquantified benefits from the rule. Quantified benefits include the reduction in the number of false negative and false positive results for all tests covered by this rule. Fewer false negatives would result in fewer illnesses and QALD losses stemming from contaminated shipments of food. Fewer false positives would result in fewer revenue losses from shipments of safe food. Quantified benefits also 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 import related food covered under this rule and (2) cost savings from allowing participating labs to submit abridged analytical reports for tests of import related food covered under this rule following the successful submission of five consecutive fully acceptable analytical reports per major food testing

discipline. In addition, improvements to our management systems required for establishing the LAAF program would reduce the amount of time we spend to review an analytical report.

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. Improved test reporting practices may result in fewer false negative test results (if current practices allow for the intentional reporting of false negative test results) while the requirement to develop sample collection reports may result in better sample collection practices resulting in samples that better represent the lot or shipment of human or animal food. These improvements may add to the deterrence of unsafe food manufacturing practices.

We note that there is uncertainty about the number of labs that will participate in the LAAF program; however, the Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for the testing ensures there will be enough lab capacity in the LAAF program for any tests that are required. The stepwise approach to implementation and giving a 6-month notice to owners and consignees prior to requiring them to comply with the final rule affects the timing of costs and benefits of the rule. We estimate that the benefits will be incurred for import related food covered by the rule one to two years following publication of the final rule. We believe that timeframe is realistic because import related owners and consignees and labs conducting import related tests are already used to sending analytical reports to FDA, and because comments assert there is currently sufficient lab capacity to conduct at least all import related tests covered by the rule. For tests of shell eggs, sprouts, and bottled drinking water covered by the rule, we estimate benefits will be incurred two to three years following publication of the rule. Those industries

and laboratories do not currently submit analytical reports to FDA in connection with the tests covered by the rule, so we anticipate that it will take longer to attain sufficient lab capacity for such tests. We discount public health benefits from better tests of food covered by the rule by three percent and cost savings by seven percent.

We currently do not receive analytical reports for the tests of shell eggs, sprouts, and bottled drinking water that are covered under this rule. Thus, in this section and the subsequent section we calculate cost savings from tests and analytical reports for import related food covered under this 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 specifying the requirements for tests and analytical reports, we anticipate that this rule 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. Likewise, industry would spend less time addressing deficiencies and would submit fully acceptable analytical reports the first time. We assume the clarifications from this rule would reduce the extra review burden incurred by us by between 20 percent (assuming some reduction in the extra review burden) and 100 percent, and the extra burden incurred by industry by between 20 percent and 100 percent.

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 import related food covered under this rule (11,648) by the extra review burden due to deficiencies from Table 11a ($111.94). Thus, the upper bound on the potential cost savings from the clarifications in the rule equals $1,303,866. To obtain the lower bound on the cost savings accrued to us we multiply this by 20 percent to

obtain $260,773. 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 import related food covered under this rule (11,648) by the extra burden to compile an analytical report from Table 11b ($204.87). Thus, the upper bound of potential cost savings for industry equals $2,386,367. To obtain the lower bound on the cost savings accrued to industry we multiply this by 20 percent to obtain the lower bound of potential cost savings from clarifications in the rule, which equals $238,637. We assume the estimate of the cost savings accrued to industry would be uniformly distributed between the lower and upper bounds. In Table 13, we report the cost savings for industry and us from clarifying expectations of tests of import related food covered under this rule.

Table 13: Annual cost savings to industry and us from clarifying expectations for compiling and reviewing analytical reports of import related food covered under this rule

	Lower bound	Medium value	Upper bound
Cost savings for industry from clarifications	$238,637	$1,312,502	$2,386,367
Cost savings for us from clarifying expectations	$260,773	$782,320	$1,303,866

We assume a uniform distribution of the cost savings to us and industry and use a Monte Carlo simulation to obtain the fifth percentile, mean, and 95th percentile estimates. We report these estimates in Table 14.

Table 14: Annual cost savings to industry and us from clarifying expectations for compiling and reviewing analytical reports of tests of import related food covered by this rule

	5th percentile	Mean	95th percentile
Industry cost savings	$345,283	$1,312,502	$2,278,419
FDA cost savings	$312,627	$782,320	$1,251,592

Total cost savings	$1,001,762	$2,094,821	$3,226,529

1. Cost savings from abridged analytical reports for tests of import related food covered under this rule

We propose to reduce the quantity of information required in an analytical report once participating labs have successfully submitted five consecutive full analytical reports per major food testing discipline. Participating labs that successfully submit five consecutive full analytical reports per major food testing discipline can request permission to submit abridged analytical reports. 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 will allow us to review each analytical step in the test and confirm the test results, if necessary. Participating labs permitted to submit abridged analytical report will submit 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 permitted to submit abridged analytical reports will still be required to maintain records of all information required in a full analytical report. As a check of participating labs permitted to submit abridged analytical reports, we will occasionally audit information required in a full analytical report.

All cost savings from allowing abridged analytical reports will come from analytical reports of tests of import related food covered under this rule, because those are the only laboratory analytical reports we currently receive and review. There will be no cost savings generated from abridged analytical reports for tests of shell eggs, sprouts, bottled drinking 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 this rule's clarifying requirements have been realized. Thus, the time to compile and submit a full analytical report will 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 this time by the fully loaded wage of a Food Scientist and Technologist of $77.10 to obtain the cost to compile a full analytical report of between about $206 (2.7 hours x $77.10 = $205.96) and $412 (5.3 hours x $77.10 = $411.93). Similarly, we use the burden estimates for us to review a full analytical report assuming the efficiency gains from this rule's clarifying requirements have been realized. Thus, the time we spend reviewing a full analytical report will fall from 2.83 hours to 1.89 hours. We multiply this time by the fully loaded hourly wage for an ORA reviewer of $119.08 and obtain the cost to review a full analytical report of about $225 (1.89 hours x $119.08 = $225.07).

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 and submit an abridged analytical report will be between about $51 (25 percent x $205.96 = $51.49) and $136 (33 percent x $411.93 = $135.94), and costs for us to review an abridged analytical report will be between about $56 (25 percent x $225.07 = $56.27) and $74 (33 percent x $225.07 = $74.27). In Table 15a and Table 15b we report the costs to compile and review a full analytical report and an abridged analytical report, both incorporating the cost savings from this rule's clarification discussed in the previous section.

Table 15a: Cost for industry to compile an abridged analytical report – net of the efficiency gains from this rule's clarifications

	Lower bound	Upper bound
Cost to compile and submit a full analytical report (net of efficiency gains from clarifications)	$205.96	$411.93
Cost to compile and submit an abridged analytical report	$51.49	$135.94

Table 15b: Cost for us to review an abridged analytical report – net of the efficiency gains from this rule's clarifications

	Lower bound	Upper bound
Cost for us to review a full analytical report (net of efficiency gains from clarifications)	$225.07	$225.07
Cost for us to review an abridged analytical report	$56.27	$74.27

2. Total cost savings from allowing abridged analytical reports

We estimate the annual cost savings for industry to compile and submit abridged analytical reports and for us to review abridged analytical reports as the difference between the costs to compile and submit 11,648 full analytical reports at between $205.96 and $411.93 per report and the costs to compile and submit 11,648 abridged analytical reports at between $56.27 and $135.94 per report, less the costs to compile and submit five consecutive successful full analytical reports per major food testing discipline, assuming 1 to 3 major food testing disciplines, at the cost of a full analytical report for 10 to 44 participating labs (see Section II.F.2.a for the estimate of the number of participating labs that test import related food covered by the rule) that we expect would qualify for abridged analytical reports. We report the fifth percentile, mean, and 95th percentile estimates of the cost savings for us and industry from allowing abridged analytical reports in Table 16.

Table 16: Cost savings from allowing abridged analytical reports

	5th percentile estimate	Mean estimate	95th percentile estimate

Annual cost savings accrued to industry from abridged analytical reports for tests of import related food covered under this rule	$1,309,286	$2,521,671	$3,726,613
Annual cost savings accrued to us from reviewing abridged analytical reports for tests of import related food covered under this rule	$1,779,409	$1,871,545	$1,963,278

3. Cost savings from reduced burdens to review analytical reports of tests of import related food covered under this rule due to improvements to the current management systems

The rule will improve upon current management systems to administer the requirements of the program. Improvements in the management systems will expedite our processes for creating work assignments, including identifying and convening technical lead panels, routing analytical reports to the labs most appropriate for reviews, notifying labs and reviewers of new work activities and for closing out and reopening reviews of analytical reports. In addition, improvements in current management systems will 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 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 this rule per se, we adjust current baseline analytical report review times by the new lower review times that will result from the one-time costs of establishing the LAAF program, discussed later in the analysis.

We expect this rule will 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 import related food covered under this rule in a Monte Carlo simulation to obtain the fifth percentile, mean, and 95th percentile

estimates of the annual cost savings from improvements in the management systems. These cost savings are reported in Table 17.

Table 17: Cost savings to review analytical reports of tests of import related food covered under this rule because of the LAAF program's improved management systems

5th percentile estimate	Mean estimate	95th percentile estimate
$78,534	$131,260	$185,759

4. Total cost savings from this 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 LAAF program to obtain estimates of the fifth percentile, mean, and 95th percentile of the cost savings accrued to industry and to us. We report the total cost savings from this rule in Table 18.

Table 18: Total cost savings from this rule

	5th percentile estimate	Mean estimate	95th percentile estimate
Total industry cost savings	$2,263,556	$3,834,173	$5,482,578
Total FDA cost savings	$2,318,658	$2,785,125	$3,260,652
Total cost savings	$4,976,793	$6,619,298	$8,330,334

5. Improved test performance

We expect that the requirements to maintain accreditation to the ISO/IEC 17025:2017 standard, for annual proficiency testing (PT) or a comparison program, and for verifying and validating methods, will provide quality assurance for testing methods. Evidence of a positive effect of lab accreditation on 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 method's accreditation status on PT performance (Ref. 12). 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. 13). 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 United States and in Canada and use Middlebrook's 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 import related food covered by this rule. Specifically, we assume the rate of false negatives and false positives for accredited labs is between 3.42 percent and 8.33 percent (3.42 percent Unsatisfactory + 4.91 percent Questionable = 8.33 percent), while that for unaccredited labs is

between 6.19 percent and 12.31 percent (6.19 percent Unsatisfactory + 6.12 percent Questionable = 12.31 percent).

To estimate the baseline performance rate for food testing covered under this rule we add the weighted percentages of Unsatisfactory and Questionable outcomes obtained from accredited and unaccredited labs, with the corresponding shares of tests performed by those labs as the weights (accredited labs perform between 95 percent and 100 percent of tests of import related food covered under this rule). Similarly, we estimate the baseline performance for tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements covered under this rule by adding the weighted percentage of Unsatisfactory and Questionable outcomes obtained from accredited and unaccredited labs - with the corresponding shares of tests performed by accredited labs as the weights. Accredited labs perform between 30 percent and 37 percent of tests covered under this rule for shell eggs, and between 85 percent and 95 percent of tests covered under this rule for sprouts. We assume the baseline accreditation rates for tests of bottled drinking water covered under this rule are the same as those for tests of sprouts covered under the rule, and that those for the DFLO and tests for other covered administrative orders are the same as those for tests of import related food covered by the rule. For purposes of this analysis we assume the performance of "accredited labs" referred to in Middlebrook refers to the ISO/IEC 17025:2017 standard. We report the baseline test performance rate variables and the expected test performance rate variables under this rule that we use to estimate improved test performance in Table 19a, Table 19b, and Table 19c.

Table 19a: Variables used to estimate improved test performance for tests of import related food covered under this rule and for DFLO and from other covered tests from administrative orders under this rule

	Lower bound	Medium value	Upper bound
Rate of unsatisfactory and questionable tests performed by labs accredited to ISO/IEC 17025:2017	3.42%	5.88%	8.33%
Rate of unsatisfactory and questionable tests performed by labs not accredited to ISO/IEC 17025:2017	6.19%	9.25%	12.31%
Share of tests of import related food currently performed by labs not accredited to ISO/IEC 17025:2017	3.20%	5.35%	7.50%
Baseline test performance rate	3.51%	6.06%	8.63%
Test performance rate with this rule	3.42%	5.88%	8.33%

Table 19b: Variables used to estimate improved test performance for tests of shell eggs subject to specific testing requirements covered under this rule

	Lower bound	Medium value	Upper bound
Rate of unsatisfactory and questionable tests performed by labs accredited to ISO/IEC 17025:2017	3.42%	5.88%	8.33%
Rate of unsatisfactory and questionable tests performed by labs not accredited to ISO/IEC 17025:2017	6.19%	9.25%	12.31%
Share of tests of shell eggs subject to specific testing requirements currently performed by labs not accredited to ISO/IEC 17025:2017	63.00%	66.50%	70.00%
Baseline test performance rate	5.17%	8.12%	11.12%
Test performance rate with this rule	3.42%	5.88%	8.33%

Table 19c: Variables used to estimate improved test performance for tests of sprouts and bottled drinking water subject to specific testing requirements covered under this rule

Rates of false negatives for sprouts requirements under scenarios of the baseline and proposed rule	Lower bound	Medium value	Upper bound
Rate of false negatives for tests performed by labs accredited to ISO/IEC 17025:2017	3.42%	5.88%	8.33%
Rate of false negatives for tests performed by labs not accredited to ISO/IEC 17025:2017	6.19%	9.25%	12.31%
Share of tests currently performed by labs not accredited to ISO/IEC 17025:2017 to support sprouts and bottled drinking water testing requirements	5.00%	10.00%	15.00%
Baseline scenario: Rate of false negatives for tests performed by labs under baseline accreditation status	3.56%	6.21%	8.93%
Test performance rate with this rule	3.42%	5.88%	8.33%

a. Fewer false negative results for tests covered under this rule

We apply Monte Carlo methods and assume the variables for the improved rates of test performance from this rule and from the current baseline are uniformly distributed. We estimate the improved number of false negative findings from tests of import related food by multiplying the number of negative findings by the improved rate of test performance from the rule. We then obtain the baseline number of false negative findings from tests of import related food by multiplying the baseline number of negative findings by the baseline rate of test performance. We then subtract the improved number of false negative findings from the baseline number of false negative findings to obtain the number of fewer false negative findings from the rule. We consider that each test, even if environmental, applies to an entire shipment or lot of the corresponding human or animal food. We refer to quantities of import related food in terms of "lines" of human or animal food, with the line reflecting the quantity of import related food covered under this rule that will be represented by a test result.

We estimate that, on average, there will be 21 fewer lines per year of import related food covered under the rule with false negative test results as a result of this rule. We estimate that, on average, there will be 85 fewer shipments per year of shell eggs with false negative test results as a result of this rule and less than one fewer shipment each of sprouts and bottled drinking water per year with false negative test results as a result of this rule. We estimate the baseline and improved rates of test performance for a DFLO and tests for other administrative orders covered by the rule are the same as those for tests of import related food covered by the rule. We report the fifth percentile estimate, mean, and 95th percentile estimate of the reduction in false negative lines of import related food and shipments of shell eggs, sprouts, and bottled drinking water covered under the rule in Table 20.

Table 20: The estimated fewer number of false negative findings from shipments of import related food, shell eggs, sprouts, and bottled drinking water[1]

	5th percentile	Mean	95th percentile
The fewer number of false negative lines of import related food covered under this rule	0	21	49
The fewer number of false negative shipments of shell eggs subject to specific testing requirements	0	85	189
The fewer number of false negative shipments of sprouts subject to specific testing requirements	0	0.9	3
The fewer number of false negative shipments of bottled drinking water subject to specific testing requirements	0	0.002	0.006

[1] We report the fifth percentile as zero when the simulated value obtained is a negative number.

i. Consumer exposure to fewer contaminated servings of import related food the tests of which are covered under this rule

We apply the reduction in the number of false negative tests of import related food covered under this 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 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. 14). 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 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 overstated quantities 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 were 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.

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 import related food covered under this rule is uniformly distributed between the lower and upper bounds reported earlier. Consequently, we estimate an annual average of about 6,903,011 contaminated servings will be avoided from fewer false negative covered tests of import related food. In Table 21 we report the variables used to estimate the number of contaminated servings avoided from fewer false negative tests of import related food covered under this rule.

Table 21: The variables used and estimates of the number of contaminated servings avoided from fewer false negative tests of import related food offered covered under this rule[1]

	Lower bound	Medium Value	Upper Bound
The number of lines with negative findings from tests of import related food	11,648	11,648	11,648
The baseline number of lines with false negative findings	459	705	948
The fewer number of false negative lines (shipments) from the rule	0	21	49
Average number of servings per line	583	1,312,864	3,172,534
Probability of a serving being contaminated given that the composite sample from the shipment tests positive		0.25	
Number of contaminated servings avoided from better tests of import related food	0	6,903,011	18,857,179

[1] We report the lower bound as zero when the fifth percentile is used and is a negative number.

ii. Consumer exposure to fewer contaminated servings of shell eggs, sprouts and bottled drinking water the tests of which are covered under this rule

We assume that the number of shell eggs contained in an egg shipment has not changed since publication of the shell egg 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 final regulatory impact analysis of the shell egg rule. The shell egg rule reports that approximately 3,328 egg farms subject to testing requirements produce about 72,113,000 eggs per year, or approximately 21,668,570 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 53,678 shell eggs (26,839 eggs per hen house daily x 2 days = 53,678 eggs). We assume one shell 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.

We estimate the improved number of false negative findings from tests of shell eggs by multiplying the number of negative findings by the improved rate of test performance from the rule. We then obtain the baseline number of false negative findings from tests of shell eggs by multiplying the baseline number of negative findings by the baseline rate of test performance. We then subtract the improved number of false negative findings from the baseline number of false negative findings to obtain the number of fewer false negative findings from the rule.

We apply Monte Carlo methods to multiply the number of servings of shell eggs in a shipment (between 26,839 and 53,678 shell eggs per shipment) to the reduction in the number of false negative test results of shell eggs. 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 is uniformly distributed between the fifth 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 an annual average of about

852,000 fewer contaminated servings of shell eggs subject to specific testing requirements from fewer false negative test results. We report the variables used to obtain the number of contaminated servings of shell eggs subject to specific testing requirements that will be avoided in Table 22.

Table 22: The variables used and estimates of the number of contaminated servings avoided from fewer false negative test results of shell eggs subject to specific testing requirements[1]

	Lower Bound	Medium Value	Upper Bound
The number of negative findings from covered tests of shell eggs	2,520	3,771	5,023
The baseline number of tests with false negative findings	197	306	433
The fewer number of false negative findings from the rule	0	85	187
Average number of servings per shipment represented by the test	26,839	40,259	53,678
Probability that a serving from the corresponding shipment would test positive given that the composite sample tests positive		0.25	
Number of contaminated servings avoided from better tests of shell eggs	0	851,891	2,019,383

[1] We report the lower bound as zero when the fifth percentile is used and is a negative number.

We use the findings reported in the ERG Profile to estimate the size of a shipment of sprouts represented by a test covered under this rule (400 – 1,400 lbs. per shipment) and divide by the serving size for seeds and nuts obtained from the Serving Size rule (approximately 0.066 lbs. per serving) to obtain the number of servings contained in a shipment of sprouts (6,061 – 212,121 servings). We apply Monte Carlo methods to multiply the number of servings of sprouts in a shipment by the reduction in number of false negative test results of sprouts subject to specific test requirements covered under this rule. We adjust by the probability that a serving of sprouts in a shipment is contaminated given the composite sample tests positive (0.25). We assume the reduction in the number of false negative test results is uniformly distributed between the upper and lower bounds. Consequently, we estimate that an annual average of about 25,000

fewer contaminated servings of sprouts subject to specific testing requirements from fewer false negative test results. We report the variables used to obtain the reduction in the number of contaminated servings of sprouts subject to specific testing requirements from the rule in Table 23.

Table 23: The variables used and estimates of the number of contaminated servings avoided from fewer false negative test results for sprouts subject to specific testing requirements[1]

	Lower Bound	Medium Value	Upper Bound
The number of negative findings from covered tests of sprouts	60	270	480
The baseline number of shipments with false negative findings	5	17	32
The fewer number of false negative findings from the rule	0	0.9	3
Average number of servings per shipment represented by the test	6,061	109,091	212,121
Probability that a serving from the corresponding shipment would test positive given that the composite sample tests positive		0.25	
Number of contaminated servings avoided from better tests of sprouts	0	24,852	80,988

[1] We report the lower bound as zero when the fifth percentile is used and is a negative number.

We use findings from the Profile that weekly source water testing for bottled drinking water is typically conducted per tanker load and that the amount of source water represented by a sample is around 6,300 gallons, which is the typical amount of water that a tanker holds. We estimate that a sample of source water used for bottled drinking water represents between 5,500 and 6,500 gallons of bottled drinking water. We multiply by 3.7854 liters per gallon and again by six servings per liter to obtain between 1,249,185 and 1,476,310 servings of bottled drinking water represented by a sample of source water. We apply Monte Carlo methods to multiply the number of servings of bottled drinking water in a shipment by the reduction in number of false negative test results of bottled drinking water subject to specific test requirements covered by the rule. We adjust by the probability that a serving of bottled drinking water in a shipment is contaminated given the composite sample tests positive (0.25). We assume the reduction in the

number of false negative test results is uniformly distributed between the upper and lower bounds. Consequently, we estimate that an annual average of 615 fewer contaminated servings of bottled drinking water subject to specific testing requirements will reach consumer as a result of this rule. We report the variables used to obtain the reduction in the number of contaminated servings of bottled drinking water subject to specific testing requirements from the rule in Table 24.

Table 24: The variables used and estimates of the number of contaminated servings avoided from fewer false negative test results for bottled drinking water subject to specific testing requirements[1]

	Lower Bound	Medium Value	Upper Bound
The number of negative findings from tests of bottled drinking water	0	1	2
The baseline number of lines with false negative findings	0.005	0.061	0.129
The fewer number of false negative findings from the rule	0	0.002	0.005
Average number of servings per shipment represented by the test	1,249,185	1,362,748	1,476,310
Probability that a serving from the corresponding shipment would test positive given that the composite sample tests positive		0.25	
Number of contaminated servings avoided from better tests of bottled drinking water	0	615	1,729

[1] We report the lower bound as zero when the fifth percentile is used and is a negative number.

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 will 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 will be avoided from this rule (Ref. 15). 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 import related food covered under this rule is distributed uniformly across all seven food categories used in the model and that each serving is contaminated with a probability of one. In simulations using endpoints of the range of the number of avoided contaminated servings of shell eggs subject to covered testing, we assume each serving is contaminated with *Salmonella* with a probability of one. 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 import related food covered under this rule upon import and by contaminated shell eggs subject to covered tests upon production.

a. Illnesses avoided from fewer contaminated servings of import related food, sprouts, and bottled water covered by the rule

We first estimate the illnesses avoided from import related food covered by the rule using FHPM. We define parameters in the FHPM to estimate the probability that a serving of food contaminated at the source will cause an illness. It is less straightforward for the FHPM to estimate the probability that a serving of bottled drinking water or a serving of sprouts will cause an illness. Consequently, we estimate illnesses avoided from contaminated servings of sprouts and bottled drinking water covered under the rule by prorating the illnesses avoided from better tests of import related food by the fractions of contaminated servings of sprouts and bottled drinking water subject to specific testing covered by the rule.

The fifth percentile estimate of the number of illnesses from import related food computed by FHPM using the fifth percentile estimate of contaminated servings of import

related food covered under this rule is zero. When we input the mean number of contaminated servings of import related food covered under this rule, the FHPM calculates between about 259 and 316 illnesses will be avoided annually from this rule. When we input the 95th percentile estimate of the number of avoided contaminated servings of import related food covered under this rule, the FHPM calculates between about 737 and 831 illnesses will be avoided annually.

We incorporate these ranges into a Monte Carlo simulation model and assume the number of illnesses avoided is distributed as a Pert, with the lower value equal to the number of illnesses avoided when using the fifth percentile 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 95th percentile estimate of contaminated servings. For estimates of illnesses avoided from fewer contaminated servings of import related food we assume the mean and upper values are themselves uniformly distributed between the fifth percentile and 95th percentile estimates of those numbers reported above. We estimate about 322 fewer illnesses from fewer contaminated servings of import related food covered by the rule.

We prorate the fifth percentile, mean, and 95th percentile estimates of the number of illnesses avoided from import related food covered by the rule by the fractions of fewer contaminated servings from sprouts and bottled drinking water to obtain the fifth percentile, mean, and 95th percentile estimates of the number of illnesses avoided from fewer false negatives from covered tests of sprouts and bottled drinking water. We assume the illnesses avoided from fewer contaminated servings of sprouts and bottled drinking water are the corresponding means of these estimates distributed uniformly between the fifth percentiles and 95th percentiles. We report the annual numbers of illnesses avoided from fewer contaminated

servings of import related food covered under the rule and from sprouts and bottled drinking water subject to specific testing covered under the rule in Table 25a, Table 25b, and Table 25c.

Table 25a: Annual illnesses avoided from fewer contaminated servings of import related food being consumed

	5th percentile	Mean	95th percentile
Illnesses estimated by the FHPM assuming the fifth percentile estimate of the number of avoided contaminated servings of import related food covered under this rule	0	0	0
Illnesses estimated by the FHPM assuming the mean estimate of the number of avoided contaminated servings of import related food covered under this rule	259	287	316
Illnesses estimated by the FHPM assuming the 95th percentile estimate of the number of avoided contaminated servings of import related food covered under this rule	737	783	831
Total illnesses avoided from fewer false negatives distributed as a Pert[1]	97	322	575

[1] Total avoided illnesses from fewer contaminated servings of import related food are distributed as a Pert, with a lower value, most likely value, and upper value distributed uniformly between the fifth percentile and 95th percentile estimates reported in the first three rows of this table.

Table 25b: Annual illnesses avoided from fewer contaminated servings of sprouts being consumed[1]

	5th percentile	Mean	95th percentile
Illnesses assuming the fifth percentile estimate of the number of contaminated servings	0	0	0
Illnesses assuming the mean estimate of the number of contaminated servings	0.9	1.0	1.1
Illnesses assuming the 95th percentile estimate of the number of contaminated servings	2.7	2.8	3.0

[1]We assume the illnesses avoided from fewer contaminated servings of sprouts is the mean of these estimates distributed uniformly between the fifth percentile and 95th percentile.

Table 25c: Annual illnesses avoided from fewer contaminated servings of bottled drinking water being consumed[1]

	5th percentile	Mean	95th percentile
Illnesses avoided assuming the fifth percent estimate of the number of contaminated servings	0	0	0
Illnesses avoided assuming the mean estimate of the number of contaminated servings	0.02	0.03	0.03
Illnesses avoided assuming the 95th percent estimate of the number of contaminated servings	0.07	0.07	0.07

[1]We assume the illnesses avoided from fewer contaminated servings of bottled drinking water is the mean of these estimates distributed uniformly between the fifth percentile and 95th percentile.

b. Illnesses avoided from fewer contaminated servings of shell eggs covered by the rule

We estimate the illnesses avoided from fewer contaminated servings of shell eggs from the rule using the FHPM which specifically identifies eggs as a food category. The estimated average number of illnesses avoided when the fifth percentile estimate of the number of contaminated servings of shell eggs is used as an input in the FHPM is zero. When we input the mean number of contaminated servings of shell eggs into the FHPM we obtain an average of about 22 illnesses avoided. When we input the 95th percentile estimate of the number of contaminated servings of shell eggs avoided into the FHPM we obtain an average of about 51 illnesses avoided.

We assume the number of illnesses avoided is distributed as a Pert, with the lower value equal to the number of illnesses avoided when we use the fifth percentile estimate of contaminated servings of shell 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 shell eggs avoided, and the upper value equals the number of illnesses avoided when we use the 95th percentile estimate of the number of contaminated servings of shell 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 fifth 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 average number of illnesses avoided from improvements in tests of shell eggs will be about 23. We report the results of the simulation in Table 26.

Table 26: Annual illnesses avoided from fewer contaminated servings of shell eggs consumed

	5th percentile	Mean	95th percentile
Illnesses estimated by the FHPM assuming the fifth percentile estimate of the number of contaminated servings	0	0	0
Illnesses estimated by the FHPM assuming the mean estimate of the number of contaminated servings	14	22	30
Illnesses estimated by the FHPM assuming the 95th percentile estimate of the number of contaminated servings	39	51	63
Total annual illnesses avoided[1]	8	23	39

[1] Total avoided illnesses are distributed as a Pert, with a lower value, most likely value, and upper value distributed uniformly between the fifth percentiles and 95th percentiles reported in the first three rows of this table.

c. Illnesses avoided from fewer contaminated servings of food subject to a DFLO and covered tests from other administrative orders

We assume a contaminated serving of food that will now be subject to a DFLO would result in an illness with the same probability as a contaminated serving of import related food covered by the rule. Moreover, we assume the number of servings of food subject to a DFLO is the same as the number of servings in a shipment of import related food covered by the rule. Consequently, we divide the number of illnesses avoided from reducing the number of false negative shipments of import related food (about 322) by the number of fewer false negative tests of that food (about 21) to obtain the number of illnesses avoided per contaminated shipment of import related food (about 15). We then multiply by the annual number of DFLO (0.1 to 1.0) to obtain the annual number of illnesses avoided from the DFLO (an average of about 8). We make the same assumptions for calculating the number of illnesses avoided from covered tests of food subject to other administrative orders covered under the rule. We report in Table 27a the fifth percentile, mean, and 95th percentile illnesses avoided from better tests subject to DFLO when the fifth percentile, mean, and 95th percentile of the avoided number of contaminated servings of food subject to a DFLO are input into the FHPM. We report in Table 27b the fifth

percentile, mean, and 95th percentile illnesses avoided from better covered tests from other administrative orders covered by the rule.

Table 27a: Annual illnesses avoided from fewer contaminated servings of food subject to a DFLO

	5th percentile	Mean	95th percentile
Illnesses avoided assuming the fifth percentile estimate of the number of contaminated servings	0	0	0
Illnesses avoided assuming the mean estimate of the number of contaminated servings	0	8	47
Illnesses avoided assuming the 95th percentile estimate of the number of contaminated servings	0	20	127
Average illnesses avoided from fewer false negatives distributed uniformly across the mean estimates, fifth percentile estimates and 95th percentile estimates	1	10	68

Table 27b: Annual illnesses avoided from fewer contaminated servings of food subject to other administrative orders covered under the rule

	5th percentile	Mean	95th percentile
Illnesses avoided assuming the fifth percentile estimate of the number of contaminated servings	0	0	0
Illnesses avoided assuming the mean estimate of the number of contaminated servings	0	8	47
Illnesses avoided assuming the 95th percentile estimate of the number of contaminated servings	0	20	127
Average illnesses avoided from fewer false negatives distributed uniformly across the mean estimates, fifth percentile estimates and 95th percentile estimates	1	10	68

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

We estimate the range in the value of illnesses avoided from improved tests of import related food, shell eggs, sprouts, and bottled drinking water covered under this rule using QALDs. The QALDs are derived from the 2019 value of a statistical life (VSL) of $5 million, $10 million, and $16.2 million and inflated to 2020 values using Department of Health and

Human Services Guidance. We use findings of the numbers of outbreaks and illnesses by pathogen associated with imported food reported in Gould, et al., to estimate the average QALD loss from an illness associated with imported food (Ref. 16). We then apply illness multipliers by pathogen found in Scallan, et al. (Ref. 17) and Pennotti and Scallan (Ref. 18) to account for underreporting and underdiagnosing and apply the QALD loss estimates by pathogen reported in Minor, et al. (Ref. 19) to obtain the QALD loss per case from imported food. We report the total number of illnesses and outbreaks reported in Gould, et al., adjusted to account for underreporting and underdiagnosing in Table 28.

Table 28: Outbreaks and Illnesses reported in Gould, et al., adjusted for underreporting and underdiagnosing

	Outbreaks		**Illnesses**		**Illnesses per outbreak**	
	Number	**Percent**	**Number**	**Percent**	**Reported**	**Adjusted to account for underreporting and undiagnosing[1]**
Scombroid toxin	57	0.31	192	0.02	3	33
Salmonella	52	0.28	4,421	0.42	85	2,491
Ciguatoxin	18	0.1	76	0.007	4	42
Cyclospora	11	0.06	3,533	0.33	321	26,690
Norovirus	10	0.05	131	0.01	13	384
Escherichia coli O157	6	0.03	116	0.01	19	505
Shigella sonnei	5	0.03	625	0.06	125	33
Vibrio parahaemolyticus	5	0.03	243	0.02	49	7,613
Listeria monocytogenes	4	0.02	67	0.006	17	35
Hepatitis A virus	4	0.02	1,150	0.11	288	2,878
Brucella	3	0.02	11	0.001	4	61
Other	9	0.05	38	0.004	4	85
Unspecified						

[1] Scallan, et al. (Ref. 17)

We apply the QALD loss per case from Minor, et al. to the pathogens from imported foods found by Gould, et al., and weigh each by the percent of outbreaks associated with each

pathogen. We report the mean QALD loss associated with each pathogen from Minor et al. and the weighted mean in Table 29.

We estimate the lower bound, medium value, and upper bound of the weighted average QALD loss from an illness from import related food the tests for which are covered under the rule based on 2019 VSL and inflated to 2020 VSL values. We use the value of a QALD loss from a case of Salmonellosis obtained from Minor, et al. (Ref. 19) to estimate the value of illnesses avoided from better tests of shell eggs subject to testing requirements. We inflate to 2020 dollars the mean value of a QALD loss from a case of a Salmonellosis from the 2019 VSL values reported earlier. We scale the mean value by the lower and upper bounds of the 2019 VSL and inflate those to 2020 VSL values to obtain the lower and upper bounds of a QALD loss attributable to contaminated shell eggs.

Table 29: Mean QALD loss per case by pathogen with weights for computing the weighted average

	Mean QALD loss per case[1]	Mean QALD loss per case weighted by the percent of outbreaks from imported food
Scombroid toxin	$1,374	$426
Salmonella	$5,337	$1,494
Ciguatoxin	$26,610	$2,661
Cyclospora	$3,252	$195
Norovirus	$363	$18
Escherichia coli O157	$10,274	$308
Shigella sonnei	$2,800	$84
Vibrio parahaemolyticus	$1,904	$57
Listeria monocytogenes	$1,456,676	$29,134
Hepatitis A virus	$42,780	$856
Brucella	$14,627	$293
Other	$3,488	$174

[1]Minor, et al. (Ref. 19)

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

estimate the value of illnesses avoided from improved tests of sprouts subject to testing requirements. We inflate to 2020 dollars to obtain a mean QALD loss of $1,829 per illness attributable to sprouts. We assume the value of a QALD loss from an illness attributable to bottled drinking water is the same as that from imported food, and the QALD loss from food subject to a DFLO or other covered tests from administrative orders covered under the rule is the average of the values of all other QALD losses covered by the rule. We report the QALD losses used for this analysis in Table 30.

Table 30: QALD loss per case

	Lower bound	Mean	Upper bound
QALD loss per case from imported food[1]	$4,114	$8,998	$13,883
QALD loss per case from *Salmonella* in shell eggs[2]	$3,296	$7,119	$10,942
QALD loss per case from sprouts contamination[3]	$847	$1,829	$2,811
QALD loss per case from bottled drinking water contamination	$4,114	$8,998	$13,883
QALD loss per case from facilities subject to a DFLO and other administrative orders covered under the rule	$3,093	$6,736	$10,380

[1] Mean QALD per illness from Minor, et al. and inflated to 2020 dollars.
[2] Mean QALD per case of Salmonellosis from Minor, et al. and inflated to 2020 dollars.
[3] Mean case of illness attributable to sprouts obtained from the Produce Safety Final Rule and inflated to 2020 dollars.

We multiply the values of a QALD loss by the numbers of illnesses avoided from improved tests of import related food covered under this rule and from shell eggs, sprouts, bottled drinking water, and DFLO and other administrative orders subject to testing covered under this rule using Monte Carlo methods and estimate the fifth percentile, mean, and 95th percentile estimates of the total avoided QALD losses. We obtain the avoided QALD losses from improved tests of import related food covered under this rule and from shell eggs, sprouts, bottled drinking water, and DFLO and other administrative orders subject to testing covered

under this rule and add them together to obtain the total avoided QALDs from fewer false negative test results. We report the means, fifth percentile and 95th percentile estimates in Table 31.

Table 31: Annual avoided QALDs from improved tests

	5th percentile	Mean	95th percentile
QALD loss avoided from better covered tests of imported related food	$756,353	$2,895,966	$5,819,669
QALD loss avoided from better tests of shell eggs	$42,823	$164,925	$326,774
QALD loss avoided from better tests of sprouts	$938	$1,829	$2,772
QALD loss avoided from better tests of bottled drinking water	$112	$225	$351
QALD loss avoided from DFLO	$4,291	$68,966	$391,202
QALD loss avoided from better tests for other administrative tools	$4,291	$68,966	$391,202
Total	$1,018,505	$3,200,876	$6,543,439

b. Avoided revenue losses from fewer false positive test results

This rule may also result in fewer false positive test results for import related food covered under the rule and shell eggs, sprouts, and bottled drinking water and other food subject to testing covered under the rule. A false positive test result for import related food covered under this rule will result in refusing entry into the U.S. market of uncontaminated human and animal food. A false positive test result for shell eggs, sprouts, and bottled drinking water and other food subject to testing covered under this rule will prevent uncontaminated shell eggs, sprouts, and bottled drinking water and other food from entering the market and could also set into motion a range of unnecessary corrective actions by shell egg, sprouts, bottled drinking water, and other, producers.

We assume the upper bound on the cost of a false positive test result will be the full wholesale value of the corresponding shipment of human or animal food offered for import

covered under this rule or shell eggs, sprouts, or bottled drinking 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 import related food covered under this rule is between $500 and $1,500 and the cost savings from fewer false positives is uniformly distributed between the wholesale value of the shipment and the cost of reconditioning the shipment.

i. Avoided revenue losses from fewer false positive test results for import related food the tests of which are covered under this rule

Internal records from PLAPs for all countrywide import alerts 2018-2019 indicate that the annual rate of private lab-confirmed positive test results for human and animal food offered for import covered under this rule is about 4.6 percent. We assume the rate of improved test performance from this rule discussed earlier will reduce the number of false positive test results for tests of import related food covered under this rule by the same rate. We use 2016 OASIS data from our Office of Regulatory Affairs, updated to 2020 values using the Consumer Price Index, 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 import related food covered by this rule.

We estimate the improved number of false negative findings from tests of shell eggs by multiplying the number of negative findings by the improved rate of test performance from the rule. We then obtain the baseline number of false negative findings from tests of shell eggs by multiplying the baseline number of positive findings by the baseline rate of test performance. We then subtract the improved number of false positive findings from the baseline number of false

positive findings to obtain the number of fewer false positive findings from the 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 assume the wholesale values of a shipment of food subject to a DFLO or testing for other administrative orders covered by the rule is the same as that for food offered for import covered by the rule. 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 import related food covered under this rule in Table 32.

Table 32: Variables used to estimate revenue losses avoided from fewer false positive test results for import related food covered under this rule and from the DFLO

	Lower Bound	Medium Value	Upper Bound
The number of lines of import related food that test positive	566	566	566
The baseline number of false positive lines	22	34	46
The number of fewer false positive lines	0	1.02	2
Average $ wholesale value per shipment	$130	$10,377	$37,232

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

We assume the current baseline rate of positive test results for shell eggs, sprouts, and bottled drinking water is the same as the current baseline rate of positive test results for import related food covered under this rule. We estimate an average of 183 shipments of shell eggs subject to covered testing currently test positive annually, 13 shipments of sprouts subject to tests covered by the rule test positive annually, and 0.05 shipments of bottled drinking water subject to covered tests covered by the rule test positive annually. We assume the same baseline performance for sprouts and bottled drinking water tests covered by the rule as for covered tests

of shell eggs. We estimate the improved number of false positive findings from tests of shell eggs, sprouts, and bottled drinking water by multiplying the baseline numbers of positive findings by the improved rates of test performance from the rule. We then obtain the baseline number of false positive findings from tests of shell eggs, sprouts, and bottled drinking water by multiplying the baseline numbers of positive findings by the baseline rates of test performance. We then subtract the improved numbers of false positive findings from the baseline numbers of false positive findings to obtain the numbers of fewer false positive findings of shell eggs, sprouts, and bottled drinking water under the rule. We assume uniform distributions for the baseline test performance and improved test performance from this rule and estimate an average of about four fewer false positive test results for shipments of shell eggs, 0.4 fewer false positives for sprouts shipments, and a negligible number of false positive shipments of bottled drinking water annually.

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 22, by the price per shell egg received by the egg farm. We obtain average monthly farm prices received for a dozen shell eggs from the USDA Farm Price Received report for 2020 (Ref. 20). We find the mean monthly farm price received for a dozen shell eggs for 2020 to be about $0.91, with a standard deviation of about $0.28. We assume a lognormal distribution of the farm price received for a dozen shell eggs, divide by 12 to obtain the price per shell egg and multiply by the number of shell eggs in a shipment to obtain the wholesale value of a shipment of shell eggs. We use the wholesale values of shipments of sprouts and bottled drinking water as a finished product reported in the ERG Profile and report the lower bound, medium value, and

upper bound wholesale values of shipments of shell eggs, sprouts, and bottled drinking water in Table 33a, Table 33b, and Table 33c.

Table 33a: Variables used to estimate the avoided revenue losses from fewer false positive test results for shell eggs subject to covered testing

	Lower Bound	Medium Value	Upper Bound
The total number of shipments of shell eggs that test positive	122	183	244
The baseline number of false positive shipments	9	15	22
The number of fewer false positives from the rule	0	4.1	9
Average $ wholesale value per shipment of shell eggs	$24,524	$36,787	$49,049

Table 33b: Variables used to estimate the avoided revenue losses from fewer false positive test results for sprouts subject to covered testing

	Lower Bound	Medium Value	Upper Bound
The total number of shipments of sprouts that test positive	3	13	23
The baseline number of false positive shipments	0	1	2
The number of fewer false positives from the rule	0.00	0.04	0.12
Average $ wholesale value per shipment of sprouts	$160	$70,080	$140,000

Table 33c: Variables used to estimate the avoided revenue losses from fewer false positive test results for bottled drinking water subject to covered testing

	Lower Bound	Medium Value	Upper Bound
The total number of shipments of bottled water that test positive	0.000	0.049	0.097
The baseline number of false positives	0	0	0
The number of fewer false positives from the rule	0.00	0.00	0.00
Average $ wholesale value per shipment of bottled water	$900	$2,250	$3,600

iii. Total avoided revenue losses

We apply Monte Carlo methods to the random variables reported in the tables above to simulate the fifth percentile, mean, and 95th percentile estimates of the total avoided retail loss from the reduction in false positive test results due to this 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

value of a shipment of import related food covered under this rule is distributed lognormally with the means and standard deviations reported earlier. To estimate the savings from false positives for shipments subject to DFLO and testing required from other administrative orders covered under the rule we obtain the difference between the baseline number of false positives and the number of false positives from this rule and multiply by the annual frequency of a DFLO (0.1 to 1) to obtain a negligible savings from fewer false positives from the DFLO. We report the means, fifth percentile estimates, and 95th percentile estimates of the cost savings from fewer false positives from the rule in Table 34.

Table 34: Estimated annual avoided revenue losses from fewer false positive test results

	5th percentile[1]	Mean	95th percentile
Avoided revenue losses from fewer false positives of import related food	$0	$5,810	$24,919
Avoided revenue losses from fewer false positives of shell eggs subject to testing requirements	$0	$77,655	$199,679
Avoided revenue losses from fewer false positives of sprouts subject to covered testing requirements	$0	$3,101	$9,980
Avoided revenue losses from fewer false positives of bottled drinking water subject to covered testing requirements	$0	$0.20	$1
Avoided revenue losses from fewer false positives for DFLO subject to covered testing requirements	$0	$0	$0
Avoided revenue losses from fewer false positive test results for other administrative orders subject to covered testing requirements	$0	$0	$0

[1] We report the lower bound as zero when the estimate is reported as a negative number.

6. 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 safe 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 declines.

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 this 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 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 will be incurred by manufacturers to provide even further assurances of safe 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 will 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 further assurances of safe human or animal food potentially subject to even

more accurate testing, and that there will be some deterrence of unsafe practices by all manufacturers affected by this rule from improved test performance.

7. Improved test reporting practices from test reporting requirements

The requirement for LAAF-accredited labs to send all test results and analytical reports to us if they participate in the LAAF 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) and "laboratory shopping" (a practice where an owner or consignee sends samples to several laboratories in hopes that one will return results indicating the sample complies with FDA requirements; the owner or consignee would then submit only that result to us). Evidence from a 2009 outbreak involving peanut butter suggests the existence of behavior of selectively reporting false negative test results (Ref. 21).

8. Total benefits of this rule

We apply Monte Carlo methods to obtain the fifth 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, fifth percentile estimates and 95th percentile estimates of these variables and the total benefits of this rule in Table 35.

Table 35: Total benefits from this rule[1]

Total benefits	5th percentile	Mean	95th percentile
Cost savings from clarifications of the processes for compiling and reviewing analytical reports of tests of import related food covered by the rule	$903,648	$1,892,655	$2,916,164
Cost savings from allowing abridged analytical reports of tests of import related food covered by the rule	$2,871,042	$3,969,236	$5,060,875
Cost savings from management systems upgrade	$78,534	$131,260	$185,759
Cost savings from fewer false positives – import related food covered by the rule	$0	$5,249	$25,343
Cost savings from fewer false positives – Shell eggs	$0	$70,161	$221,540
Cost savings from fewer false positives – Sprouts	$0	$2,802	$9,754
Cost savings from fewer false positives – Bottled Drinking Water	$0	$0	$1
Avoided QALD losses from fewer servings of contaminated imported food	$749,095	$2,689,678	$5,714,506
Avoided QALD losses from fewer servings of contaminated shell eggs	$42,494	$153,177	$299,416
Avoided QALD losses from fewer servings of contaminated sprouts	$869	$1,699	$2,530
Avoided QALD losses from fewer servings of contaminated bottled drinking water	$105	$209	$334
Avoided QALD losses from DFLO	$3,926	$68,966	$375,818
Avoided QALD losses from MR, AD and SR provisions	$3,926	$68,966	$375,818
Total quantified benefits	$6,604,454	$9,054,057	$12,461,223

[1] We report the lower bound as zero when the estimate is reported as a negative number.

F. Costs of this Rule

We note that there is uncertainty about the number of labs that will participate in the LAAF program; however, the Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for the testing ensures there will be enough lab capacity in the LAAF program for any tests that are required. The stepwise approach to implementation and giving a 6-month notice to owners and consignees prior to requiring them to comply with the final rule affects the timing of costs and benefits of the rule. We estimate that the costs will be incurred for import related food covered by the rule one to two years following publication of the final rule. We believe that timeframe is realistic

because import related owners and consignees and labs conducting import related tests are already used to sending analytical reports to FDA, and because comments assert there is currently sufficient lab capacity to conduct at least all import related tests covered by the rule. For tests of shell eggs, sprouts, and bottled drinking water covered by the rule, we estimate costs will be incurred two to three years following publication of the rule. Those industries and laboratories do not currently submit analytical reports to FDA in connection with the tests covered by the rule, so we anticipate that it will take longer to attain sufficient lab capacity for such tests. We discount costs of the rule by seven percent.

1. Costs incurred by participating ABs

The final rule includes requirements for ABs to apply for recognition by FDA and to renew that recognition periodically. The final rule will require recognized ABs to be members of ILAC and signatories of the ILAC MRA, to conform to the ISO/IEC 17011:2017 standard, and to renew recognition at least every 5 years. All ABs currently considered 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 will incur include:

- modifying existing programs and standard operating procedures for accrediting labs to the requirements established by this rule and
- maintaining and submitting reports and other records to us.

Consistent with comments we received on the PRIA, we use information from our ATPCP to estimate the number of ABs that will participate in the LAAF program. Currently, there are 4 ABs that participate in the ATPCP. We assume the ABs that accredit labs for testing foods offered for import are the same ABs that will accredit labs for testing shell eggs, sprouts,

and bottled drinking water. Consequently, we estimate that 4 ABs will apply to be recognized and incur costs of the rule.

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 2020 National Occupational Survey under occupation codes 19-1022, 11-9121 and 23-1011 (Ref. 22). We multiply these wages by two to account for overhead to obtain fully loaded hourly wages of $88.30 for a microbiologist, $148.98 for a natural sciences manager, and $143.18 for a lawyer.

a. Costs for initial applications for recognition

This rule will require ABs that wish to be recognized to submit an application that demonstrates their qualifications to accredit labs to meet the requirements established by this rule. We assume that this process will be overseen by a lawyer and a natural science manager and estimate that it will 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. This may overstate the burden to the extent that ABs applying for recognition are already subject to FDA oversight through other programs. We estimate the cost incurred by ABs for submitting applications for recognition to range from about $23,373 (40 hours x ($143.18 per hour + $148.98 per hour) / 2) x 4 ABs = $23,373 to about $46,746 (80 hours x $143.18 per hour + $148.98 per hour) / 2) x 4 ABs = $46,746). We estimate the annualized costs for initial recognition discounted at seven percent over 10 years to range from $3,110 to $6,220. When we assume a three percent discount rate over 10 years the annualized costs range from $2,660 to $5,320.

b. Costs for applications for renewal of recognition

This rule will 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 assume that application for renewal of recognition will take less time than the initial application for recognition as the information already will have been mostly compiled. We assume that the renewal application will be overseen by a lawyer and a natural science manager and estimate that it will take between 20 and 40 hours. We assume renewal costs will 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 will range from $14,273 (4 ABs x 20 hours x the average of $148.98 per hour and $143.18 per hour divided by 1.07 raised to the 5^{th} power + 4 ABs x 20 hours x the average of $148.98 per hour + $143.18 per hour divided by 1.07 raised to the 10^{th} power = $14,273) to $37,553 (4 ABs x 40 hours x the average of $143.18 per hour and $148.98 per hour per hour divided by 1.03 raised to the 5^{th} power + 4 ABs x 40 hours x the average of $148.98 per hour and $143.18 per hour per hour per hour divided by 1.03 raised to the 10^{th} power = $37,553). We estimate the annualized renewal cost discounted at seven percent over 10 years will range from $1,899 to $4,997. The annualized costs discounted by 3 percent over five years will range from $1,625 to $4,274.

c. Costs to modify existing programs to accredit labs to the standards established by this rule

ABs will incur one-time costs to modify their existing program for accrediting labs to the requirements of this rule. Activities for establishing a program could include modifying

- a strategic plan for accrediting labs to the standards established by this rule,
- implementation plans for assuring that quality standards are met,
- quality management system procedures (QMSPs) for defining policies,
- standard operating procedures (SOPs) for assessing labs against the LAAF standards, and
- training of assessors to monitor the performance of LAAF-accredited labs.

We assume managers and scientists in each AB will spend time to modify existing programs for participating labs to meet the requirements of this rule. We assume that each activity will 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 ($148.98) and a scientist ($88.30) to these hourly burdens and multiply by the number of ABs to obtain a total one-time cost to the industry of between about $56,947 and about $113,894 for modifying existing programs for accrediting labs to the new standards. We report the one-time costs to establish a program to accredit labs to the standards established by this rule in Table 36.

Table 36: One-time costs for participating ABs to modify existing programs to accredit labs to the standards established by this rule

	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					$56,947.20	$113,894.40

[1] We estimate 4 ABs will participate in the LAAF program.

We divide the upper and lower bounds for the total industry costs by 4 participating ABs to obtain the range on the one-time costs per AB to establish a program of between $14,237 and $28,474. The annualized costs for all participating ABs to modify existing programs to accredit labs discounted at seven percent over 10 years range from $7,577 to $15,155. The annualized costs discounted by three percent over 10 years range from $6,482 to $12,963.

d. Costs to periodically assess participating labs

There will be costs incurred by participating ABs to periodically assess participating labs for compliance with the LAAF standard. Because ISO/IEC 17011:2017 requires the AB to reassess a sample of a lab's scope at least every two years, although not necessarily on-site, we assume that only some of the costs to periodically assess participating labs for compliance with LAAF will be incurred over and above those required to accredit labs to the ISO/IEC 17025:2017 standard. This rule will require a participating AB to conduct an on-site assessment of a participating lab every two years. Certain assessment activities may be conducted remotely. We assume that each assessment will take between 16 and 24 hours, including for preparation, travel, and any follow-up reporting and correspondence. Consequently, we estimate the additional monitoring and assessing costs incurred by ABs annually due to the rule to be between about $50,797 (16 hours x $88.30 per hour x 75 participating labs that test shell eggs, sprouts, and bottled drinking water after 4 to 6 years and 10 labs that test import related food covered by the rule after one to two years x 0.5 inspections per year = $50,797) and about $230,907 (24

hours x $88.30 per hour x 212 participating labs that test shell eggs, sprouts, and bottled drinking water after 4 to 6 years and 44 labs that test import related food covered by the rule after one to two years x 0.5 inspections per year = $230,907).

e. Recordkeeping and reporting costs

This rule will 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 five years after the date of creation and that no additional recordkeeping costs will be incurred.

This rule will require a participating AB to report to us any significant changes affecting its recognition or the accreditation status of participating labs it accredits. This rule will 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 accreditation status or AB's recognition, assessments of participating labs or evaluations of ABs, and information on the AB's qualifications, resources, quality assurance programs, recordkeeping, reporting, monitoring procedures. The participating AB will 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.

In the PRIA, we estimate that participating ABs will incur one hour per month, or 12 hours per year submitting reports and notifications to us. We scale the burden per AB estimated in the PRIA to account for the large number of participating labs estimated in this analysis to

obtain a burden per AB of 42 hours. We assume this task will be undertaken by an employee at the level of microbiologist. Consequently, we estimate the annual cost to participating ABs to be about $14,834 (42 hours x $88.30 per hour x 4 ABs = $14,834).

f. Summary of costs incurred by ABs

We report the costs of this rule that will be incurred by participating ABs by cost category and frequency with which they will occur in Table 37. 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 5 and year 10. The present value of these costs is discounted over 10 years at seven percent and three percent**.**

Table 37: Summary of the costs and frequencies incurred by ABs by cost category

Task	Lower bound	Upper bound	Frequency
Costs for initial application for recognition	$23,373	$46,746	One-time
Costs for application for renewal of recognition	$14,273	$37,553	Every 5 years
Modify existing programs for accrediting labs	$56,947	$113,894	One-time
Periodically assess participating labs	$51,990	$230,907	Annual
Recordkeeping and reporting costs	$14,834	$14,834	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 38.

Table 38: Present values and total annualized costs incurred by ABs discounted at 7 percent and 3 percent over 10 years

	5th percentile	Mean	95th percentile
Annualized costs at 7 percent	$94,770	$175,762	$257,132
Annualized costs at 3 percent	$92,431	$172,944	$253,274
Present value at 7 percent	$649,970	$1,242,361	$1,830,190
Present value at 3 percent	$769,981	$1,483,015	$2,190,828

2. Costs incurred at the lab level

Labs currently used for tests covered by the rule may incur the costs of accreditation to the standards established by this rule. This rule incorporates by reference the ISO/IEC 17025:2017 standard. Consequently, labs will have to be accredited to the ISO/IEC 17025:2017 standard to participate in the LAAF program. There will be costs over and above those required to maintain accreditation to the ISO/IEC 17025:2017 standard to participate in the LAAF program, such as costs:

- to be periodically assessed against the LAAF program standards by the AB,
- to meet requirements to participate in a proficiency testing program, and
- when necessary, to validate an analytical method.

Labs will 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 these requirements for the oversight of sampling include:

- developing or obtaining a sample collection plan and sample collection report and
- one-time costs to develop or 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 $77.10 for a food scientist and technologist, code 11-9121, obtained from the Occupation Employment and Wages, May 2020 report.

a. Costs to attain and maintain accreditation to the ISO/IEC 17025:2017 standard

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. 23). Representatives from 18 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 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 will participate in the LAAF program.

The costs to become accredited to ISO/IEC 17025:2017 were incurred over a number of years. We report the lower bounds, medians, and upper bounds for the one-time costs and annual costs to obtain accreditation to ISO/IEC 17025 found by the survey in Table 39. We assume triangle distributions using the lower bounds, medians, and upper bounds as the parameters and use the @RISK software to obtain the average one-time costs of $237,137 and the average annual costs of $374,655 to become accredited to ISO/IEC 17025. Consistent with public comments, we assume the costs to become accredited to ISO 17025:2017 for labs that adhere to

AOAC Guidelines and AAFCO Guidelines will fall in the lower end of the estimated range. We assume these costs would be incurred by any lab that conducts tests covered by the rule, that is currently not accredited to ISO/IEC 17025, and that chooses to participate in the LAAF program.

Table 39: One-time and annual costs to attain and maintain accreditation to the ISO/IEC 17025:2017 standard per lab[1]

	Lower bound	Median	Upper bound
Training costs	$0	$12,715	$155,600
Recurring assessment fees	$1,300	$6,000	$17,201
Consultant costs	$0	$3,000	$35,500
Supplies and equipment	$100	$15,300	$49,576
Calibration	$1,241	$10,927	$41,650
Preventive maintenance	$0	$60,788	$300,857
Proficiency testing	$0	$3,327	$9,000
Software and monitoring systems	$0	$44,627	$460,000
Annual salaries	$0	$164,000	$442,697

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

Labs that currently conduct tests covered by the rule will participate in the LAAF program if the costs of doing so are less than the revenues from conducting the covered tests. We assume that only labs that are in the pools of labs that currently conduct covered tests of import related food, shell eggs, sprouts, and bottled drinking water may participate in the LAAF program. The costs for labs to participate in the LAAF program are lower for labs that are currently accredited to ISO/IEC 17025, and we assume that labs that conduct covered tests of import related food, shell eggs, sprouts, and bottled drinking water that are already accredited to ISO/IEC 17025:2017 would participate in the LAAF program if the revenues from LAAF participation exceed the costs. If there is sufficient revenue from covered tests remaining to cover the costs to become accredited to ISO/IEC 17025:2017, there may be labs not currently

accredited to ISO/IEC 17025:2017 in the pool of labs affected by the rule that may choose to incur these costs in order to participate in the LAAF program.

Data from the 2017 PLAPs indicates that 10 labs that test import related food covered by the rule conduct between 82 percent and 86 percent of the covered tests of import related food, and that these labs are currently accredited to ISO /IEC 17025:2017. We assume 10 labs is the lower bound on the number of labs that conduct covered tests of import related food that will participate in the LAAF program. The data also indicates that between 93 percent and 96 percent of all covered tests of import related food are conducted by labs accredited to ISO/IEC 17025:2017 and that 44 labs of the 106 labs in the pool of labs that conduct covered tests of import related food are accredited to ISO/IEC 17025:2017. We estimate that the remaining revenue from four percent to seven percent (100 percent – 96 percent, and 100 percent – 93 percent) of tests of import related food is insufficient to cover the costs for labs to become accredited to ISO/IEC 17025 to participate in the LAAF program. Consequently, we estimate between 10 and 44 labs that conduct covered tests of import related food and that are already accredited to ISO/IEC 17025:2017 will participate in the LAAF program.

Because no labs that test import related food will incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program, we assume the four percent to seven percent of the covered tests of import related food currently conducted by labs not accredited to ISO/IEC 17025:2017 will now be conducted by a LAAF participating lab. These tests may be subject to some costs from switching to labs that participate in the LAAF program.

We use information reported in the Profile to estimate the number of labs that conduct covered tests of shell eggs that will participate in the LAAF program and information from Section II.D.2.b.ii to obtain between 126,000 and 251,125 tests of shell eggs (287,000 tests of

shell eggs reported in the Profile - 12.5 percent of shell eggs that will be diverted to the processed market upon receipt of a positive environmental test finding) that will be covered by the rule. We do not know the percent of these tests that are currently performed by labs already accredited to ISO/IEC 17025 and assume they are uniformly distributed among the 15 to 38 labs in the pool of labs that conduct the covered tests of shell eggs. The Profile reports that labs charge between $26 and $30 per test. Consequently, we estimate the average total revenue from all covered tests of shell eggs is $5,279,750, and the average revenue per lab is $199,238 for each of the 15 to 38 labs in the pool of labs that conduct covered tests of shell eggs.

Labs in the pool of labs that conduct covered tests of shell eggs and that are currently accredited to ISO/IEC 17025:2017 will have a cost advantage for participating in the LAAF program over labs not accredited to ISO/IEC 17025:2017. We assume that labs currently accredited to ISO/IEC 17025:2017 that conduct covered tests of shell eggs will be the first to participate in the LAAF program. Labs that currently conduct the covered tests of shell eggs but that are not accredited to ISO/IEC 17025:2017 will participate in the LAAF program only if there is sufficient revenue left over to warrant incurring the costs to become accredited to ISO/IEC 17025:2017. We estimate that between 4.5 and 14.06 labs that conduct covered tests of shell eggs are accredited to ISO/IEC 17025:2017 (30 percent accredited to ISO/IEC 17025 x 15 labs = 4.5 labs; and 37 percent accredited to ISO/IEC 17025:2017 x 38 total labs = 14.06 labs.) We multiply the $199,238 average revenue per lab by the number of labs that conduct covered tests of shell eggs that are already accredited to ISO/IEC 17025:2017 to obtain a total revenue of between $896,561.32 and $2,801,256.04 for labs that conduct covered tests of shell eggs that are already accredited to ISO/IEC 17025:2017.

Labs not already accredited to ISO/IEC 17025:2017 that conduct covered tests of shell eggs may incur the costs to become accredited to ISO/IEC 17025:2017 in order to participate in the LAAF program if the remaining revenues from the covered tests exceed the annual costs to become accredited to ISO/IEC 17025:2017. To estimate the number of labs that conduct covered tests of shell eggs that are not currently accredited to ISO/IEC 17025:2017 that will incur costs to become accredited ISO/IEC 17025:2017 to participate in the LAAF program, we divide the total revenue remaining for labs that conduct covered tests of shell eggs and that are not accredited to ISO/IEC 17025:2017 by the annual costs to maintain accreditation to ISO/IEC 17025:2017. Consequently, we estimate that between 6.6 and 11.7 labs that are not currently accredited to ISO/IEC 17025:2017 may incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program (($5,279,750 total revenue from all tests - $2,801,256 revenue for 14.06 labs already accredited to ISO/IEC 17025:2017) / $374,655 annual costs to become accredited = 6.6 labs; and ($5,279,750 total revenue from all tests - $2,801,256 revenue for 4.5 labs already accredited to ISO/IEC 17025:2017) / $374,655 annual costs to become accredited = 11.7 labs).

We derive the estimate of 7 labs (6.6 rounded to the nearest integer) that may incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program when we assume there are 38 labs in the pool that conduct covered tests of shell eggs - 14 (14.06 rounded to the nearest integer) of which are already accredited to ISO/IEC 17025:2017 and 24 of which are not accredited to ISO/IEC 17025:2017. We derive the estimate of 12 labs (11.7 rounded to the nearest integer) that may incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program when we assume there are 15 labs in the pool that conduct covered tests of shell eggs - 5 (4.5 rounded to the nearest integer) of which are already accredited

to ISO/IEC 17025:2017 and 10 of which are not accredited to ISO/IEC 17025:2017. Because the 12-lab estimate exceeds the number of labs remaining in the pool of 15 labs that conduct covered tests of shell eggs and that are not accredited to ISO/IEC17025:2017 (10), we assume that 10 labs rather than 12 labs that conduct covered tests of shell eggs may incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program.

The number of labs that conduct covered tests of shell eggs that will incur costs to become accredited to ISO/IEC 17025:2017 in order to participate in the LAAF program will depend on the number of labs that conduct covered tests of shell eggs that are already accredited to ISO/IEC 17025. We estimate that 10 labs that conduct covered tests of shell eggs and that are not already accredited to ISO/IEC 1705:2017 will incur costs to become accredited to ISO/IEC 17025:2017 when there are five labs that conduct covered tests of shell eggs and that are already accredited to ISO/IEC 17025:2017. We estimate that 7 labs not already accredited to ISO/IEC 17025:2017 will incur costs to become accredited to ISO/IEC 17025:2017 when there are 14 labs that conduct covered tests of shell eggs already accredited to ISO/IEC 17025:2017. Consequently, we estimate that between 15 labs and 21 labs that conduct covered tests of shell eggs will participate in the LAAF program (10 labs that conduct covered tests of shell eggs that are currently not accredited to ISO/IEC 17025:2017 + 5 labs that conduct covered tests of shell eggs and that are currently accredited to ISO/IEC 17025:2017 = 15 labs; and 7 labs that conduct covered tests of shell eggs that are currently not accredited to ISO/IEC 17025:2017 + 14 labs that conduct covered tests of shell eggs and that are currently accredited to ISO/IEC 17025:2017 = 21 labs)).

We do not know the number of labs that conduct covered tests of sprouts that will participate in the LAAF program. We assume that labs currently accredited to ISO/IEC

17025:2017 that conduct covered tests of sprouts will be the first to participate in the LAAF program and that labs that currently conduct the covered tests of sprouts that are currently not accredited to ISO/IEC 17025:2017 will participate in the LAAF program only if there is sufficient revenue left over to warrant incurring the costs to become accredited to ISO/IEC:2017 17025:2017.

We obtain from Section II.D.2.b and the Profile that there are between 60 and 480 analytical reports of sprouts tests, with each report containing the results of 10 tests. Consequently, we estimate between 600 and 4,800 tests of sprouts will be covered by the rule. We do not know the percent of these tests that are currently performed by labs already accredited to ISO/IEC 17025:2017 and assume they are uniformly distributed among the 70 to 200 labs in the pool of labs that conduct covered tests of sprouts. The Profile reports that labs charge about $40 per covered test of sprouts. Consequently, we estimate the average total revenue from all covered tests of sprouts is $108,000, and an average revenue of $800 per lab that conducts tests of covered sprouts. Because the annual costs that would be incurred to become accredited to ISO/IEC 17025:2017 for labs that are not already accredited to that standard are so much greater than the average revenue per lab from covered tests of sprouts, and that between 85 and 95 percent of labs that conduct covered tests of sprouts are already accredited to ISO /IEC 17025:2017 we estimate that only labs that conduct covered tests of sprouts and that are already accredited to ISO/IEC 17025:2017 will participate in the LAAF program. Consequently, we estimate that between 60 and 190 labs that conduct covered tests of sprouts will participate in the LAAF program. We estimate covered tests of bottled drinking water will be rare and that any covered tests of bottled drinking water will be performed by labs that participate in the LAAF program but primarily conduct covered tests for import related food, shell eggs, or sprouts.

We estimate that any tests currently performed by labs not accredited to ISO/IEC 17025:2017 and that choose not to participate in the LAAF program will result in costs to switch to a LAAF-accredited lab. We estimate switching costs as the additional costs to ship a sample to a LAAF-accredited lab that may be located further away than the lab that otherwise would have been selected. We acknowledge the possibility that when switching costs are high or costs to become accredited to ISO/IEC 17025:2017 are low, labs that do not currently conduct covered tests may choose to participate in the LAAF program. We did not estimate the number of such labs that would choose to participate in the LAAF program because of high switching costs or low costs to become accredited to ISO/IEC 17025:2017 and assume switching costs and the costs for these labs to become accredited to ISO/IEC 17025 are offsetting. However, we acknowledge that if labs incur costs to become accredited to ISO/IEC 17025:2017 because of high switching costs or low costs to become accredited to ISO/IEC 17025, we may underestimate the number of labs that will participate in the LAAF program. We estimate switching costs in Section II.F.3.f below.

We report the number of labs that we estimate will participate in the LAAF program in Table 40a and the one-time and annual costs incurred for labs that conduct covered tests of shell eggs to become accredited to ISO/IEC 17025:2017 in order to participate in the LAAF program in Table 40b.

Table 40a: The number of labs that will participate in the LAAF program

	Lower bound	Medium value	Upper bound
The number of labs that test import related food covered by the rule that will participate in the LAAF program	10	27	44
The number of labs that test shell eggs covered by the rule that will participate in the LAAF program	15	18	21

The number of labs that test sprouts and bottled drinking water covered by the rule that will participate in the LAAF program	60	125	190

Table 40b: One-time and annual costs incurred for labs that conduct covered tests of shell eggs to become accredited to ISO/IEC 17025 to participate in the LAAF program

	Lower bound	Medium value	Upper bound
One-time costs incurred for labs that conduct covered tests of shell eggs to become accredited to ISO/IEC 17025	$1,660,031.33	$2,015,752.33	$2,371,473.33
Annual costs incurred for labs that conduct covered tests of shell eggs to become accredited to ISO/IEC 17025	$2,625,289.33	$3,187,851.33	$3,750,413.33

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

This rule will allow us to review the performance of participating labs to determine whether they are complying with the requirements established by the rule. We may review any records pertaining to the LAAF program and may conduct an on-site review at any time, with or without the presence of a representative from the participating AB that LAAF-accredited the participating lab. Moreover, this rule will require participating ABs to conduct an on-site review of participating labs every two years to maintain accreditation status of participating labs. We estimate that we will conduct an on-site review once every four years. We assume some of these costs will be over and above those incurred for maintaining accreditation to the ISO/IEC 17025:2017 standard.

We estimate that a participating lab will 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 $77.10, we estimate the annual costs to be assessed by ABs and FDA to range from about $17,332 to about $101,278. We report the annual costs for participating labs to be assessed by us and ABs in Table 41.

Table 41: Costs for participating labs to be assessed by us and ABs

Lower bound	Upper bound
$17,332.26	$101,278.02

c. Costs to participate in a proficiency testing program

The proficiency testing (PT) requirements in this rule are similar to those in the Association of Analytical Chemists (AOAC) Guidelines; the rule requires PTs (or a comparison program if no proficiency testing program is available or practicable) at least once a year for each method within the scope of LAAF-accreditation. This exceeds the requirements for PTs in the current ISO/IEC 17025:2017 standard. The current ISO standard allows flexibility for labs to participate in either ILCs or PT programs at unspecified frequencies.

We assume that 50 percent of participating labs will change from participating in ILCs to performing PTs instead. We adopt the suggestion in the comments that the costs of ILCs are about the same as for PT. Consequently, the costs of the final rule from the requirement for PTs are the one-time costs for 50 percent of labs to incorporate that change into their laboratory management systems. We assume the one-time cost to incorporate changes into management systems from participating in ILCs to performing PTs is negligible.

d. Costs to validate testing methodology

This rule will require participating labs to use validated methodologies. Because the ISO/IEC 17025:2017 standard requires that non-standard methods be validated, we assume that our estimates of the recurring costs to maintain accreditation to the ISO/IEC 17025:2017 standard include these costs. 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 and submit five consecutive successful full analytical reports per major food testing discipline prior to requesting permission to submit abridged analytical reports

We will review the last five full analytical reports submitted for a major food testing discipline to determine whether the lab will be permitted to submit abridged analytical reports for the major food testing discipline. If the full analytical reports contain no shortcomings which call into question the validity of the results and the lab is not on probation, we will grant permission to submit abridged analytical reports for the major food testing discipline requested. For purposes of this analysis, we assume that each participating lab will be accredited by a recognized AB for scopes covering one to three major food testing disciplines. We multiply the cost to review a full analytical report by five for each major food testing discipline for which the lab wishes to submit abridged analytical reports and finally by the number of participating labs. We use Monte Carlo simulation methods to obtain the fifth percentile, mean, and 95th percentile estimates of the one-time cost to industry from this requirement and report them in Table 42.

Table 42: One-time costs for participating labs to compile and submit five full analytical reports per major food testing discipline prior to requesting permission to submit abridged analytical reports

5th percentile	Mean	95th percentile
$41,580.83	$85,385.46	$144,410

f. 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 Table 43a and Table 43b.

Table 43a: 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 17025 for a testing scope	$2,846,178	$4,065,969
Costs for labs to be assessed by AB and reviewed by FDA	$17,332	$101,278
Costs for labs to submit five successful full analytical reports per major food testing discipline prior to abridged analytical reports	$5,575	$21,343

Table 43b: 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 17025 for a testing scope	$2,814,228	$4,020,325
Costs for labs to be assessed by AB and reviewed by FDA	$17,332	$101,278
Costs for labs to submit five successful full analytical reports per major food testing discipline prior to abridged analytical reports	$4,590	$17,573

We also used Monte Carlo methods to simulate total annualized costs and the present values of costs incurred at the participating lab level. We assume a uniform distribution for the costs to be assessed by ABs, to be reviewed by FDA, and the costs to submit five successful full analytical reports per major food testing discipline between the reported lower and upper bounds. We report the fifth percentile, mean, and 95th percentile 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 44.

Table 44: 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	Mean	95th percentile
Annualized costs at 7 percent	$1,588,728	$3,527,536	$5,260,086
Annualized costs at 3 percent	$1,471,424	$3,486,591	$5,204,149
Present value at 7 percent	$8,895,695	$24,711,273	$38,080,547
Present value at 3 percent	$10,678,751	$29,561,350	$45,439,281

3. Costs incurred for each test

There will be costs incurred by test. These include costs to comply with standards related to sampling, including advance notices of sampling in limited circumstances, submitting test results, verifying analytical 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 the current 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, a sample collection plan, and a sample collection report. Moreover, participating labs will also incur the cost to ensure that methods required for each test fall within their scope of accreditation.

We use the mean hourly wage for food scientists and technologists, Occupation Code 19-1012, Occupational Employment and Wages May from 2020 and multiply by 2 to account for overhead to obtain a fully loaded wage of $77.10 for estimates of the labor costs incurred at the analysis level. Consistent with public comments we assume that costs for sample collection plans and reports, and advance notices of sampling prepared outside the United States, may differ based on the wages of the countries where they are prepared. From information reported in the baseline conditions section there will be 11,648 analytical reports submitted for tests of import related food covered under this rule, between 2,520 and 5,023 analytical reports of tests of shell eggs subject to specific testing requirements, between 60 and 480 analytical reports of tests of

sprouts, and between 0 and 2 tests of bottled drinking water a subject to testing covered under this rule. The cost estimates assume there will be sufficient participation by labs that test shell eggs, sprouts, and bottled drinking water two to three years following publication of the rule and by labs that test import related food one to two years following publication of the rule.

a. Costs of the advance notice of sampling

This rule provides that in certain circumstances we may require the participating lab to submit an advance notice of sampling to us, 48 hours prior to when the sampling will occur. This will allow us the option to observe the sampling process. The advance notice of sampling will require a unique identification code, the name of the LAAF-accredited lab that will test the sample, the name and street address of the sampling firm, a primary contact for the sampling firm, the reason the food product or environment is to be sampled, the location of the food product or environment that will be sampled, applicable entry line numbers and product codes or a description of the environment, and the date and approximate time the sampling will begin.

We assume that it will take a lab analyst between 1 and 2 hours to compile the required information and submit the advance 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 we may require advance notice of sampling for 1 percent to 5 percent of all analyses submitted annually. We use a fully loaded wage of a food scientist and technologist to estimate the cost of the advance notice of sampling requirement to range from about $10,973 (1 hour x $77.10 hourly wage x 1 percent x 14,232 samples = $10,973.03) to about $132,570 (2 hours x $77.10 hourly wage x 5 percent x 17,195 samples = $132,569.60).

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

This rule will 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 sampling does not impact the validity of the subsequent testing, including controlling for the representational nature of the sample. A sample collection report must include:

- the product code of the food product or the location of the environment to be sampled,
- the date of sampling,
- the lot number, size, identity, and quantity of the sample,
- documentation of the sample collection procedures and sample preparation techniques, and
- documentation of the chain of custody of the sample and of measures taken to ensure the validity of the subsequent analytical testing.

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

drinking water at the time of the collection, we assume that all sample collection plans and sample collection reports that will be submitted with analytical reports for tests of shell eggs, sprouts, or bottled drinking water subject to specific testing requirements do not currently conform to the same format and information required by this rule and will all be deficient.

We assume that an additional 1/2 hour to 1 hour will 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 $77.10 to obtain the lower and upper bound cost estimates of between $38.55 and $77.10 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 drinking 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 45a, industry will incur costs from $84,118.41 to $361,088.74 to generate a sample collection plan. As shown in Table 45b, industry will incur costs from $84,118.41 to $361,088.74 to compile a sample collection report. These results assume labs that test import related food covered under the rule will participate in the LAAF program one to two years following publication of the rule, and that labs that test shell eggs, sprouts, and bottled water will participate in the LAAF program two to three years following publication of the rule.

Table 45a: 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	$77.10	0.5	$38.55	$84,118.41
Upper bound	$77.10	1.0	$7.10	$361,088.74

Table 45b: 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	$77.10	0.5	$38.55	$84,118.41
Upper bound	$77.10	1.0	$77.10	$361,088.74

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

This rule will not require accreditation of samplers but will require participating labs to obtain or develop records related to sampling. Specifically, this rule will require a participating lab to obtain or develop a sample collection plan, a sample collection report, and appropriate sampler credentials to be submitted to us with the analytical report. Moreover, the participating lab will have to confirm that the methods to be used and analysis to be performed fall within its scope of LAAF-accreditation.

We assume a participating lab will 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 test method and the scope of LAAF-accreditation. Using the fully loaded wage of $77.10, we estimate that participating labs will spend between $12.85 and $25.70 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 report the costs to review collection plans and reports and to confirm the lab is LAAF-accredited to the appropriate scope in Table 46. These results assume labs that test import

related food covered under the rule will participate in the LAAF program one to two years following publication of the rule, and that labs that test shell eggs, sprouts, and bottled drinking water will participate in the LAAF program two to three years following publication of the rule.

Table 46: Costs for participating labs to collect sampler credentials, sample collection plans, and reports and to confirm a match between the test method and the scope of accreditation

	Fully loaded wage	Hours	Cost per report	Number of sample collection reports	Total costs
Lower bound	$77.10	0.17	$12.85	14,232	$163,271.27
Upper bound	$77.10	0.33	$25.70	17,195	$390,826.51

d. Costs to report results from validation and verification studies

This rule will sometimes require the participating lab to submit verification and validation studies to us with an analytical report. 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 import related food covered under this 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 17025:2017 standard requires the use of validated methods for testing foods. We included this burden in the estimated costs of maintaining accreditation. However, this rule will require additional verification studies over and above the requirements in ISO/IEC 17025:2017 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 17025:2017.

Because foods subject to specific testing requirements covered by the rule are each subject to being tested for only one or two pathogens (*Salmonella enteritidis* for shell eggs; *Listeria, sp.* or *Listeria monocytogenes* for sprouts; and *E. coli* for bottled drinking water), we assume these tests will 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 bottled drinking water will have been validated, and the costs to do so will have been included in the costs to maintain accreditation to the ISO/IEC 17025:2017 standard. Consequently, we assume that shell eggs, sprouts, and bottled drinking water producers will 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 hours (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 $77.10 to obtain the cost of a matrix extension of between about $1,694 ($77.10 per hour x 22 hours = $1,694.27) and about $3,527 ($77.10 per hour x 46 hours = $3,527.33).

Finally, to estimate the number of analytical reports containing the results of tests requiring matrix extensions, we multiply the share of analytical reports submitted to us containing the results of tests of import related food covered under this rule that will require matrix extensions (between 5 percent and 30 percent based on our experts), by the total number of analytical reports containing the results of tests of import related food covered under this rule

(11,648 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 that analytical methods will apply to specific food items ranges from $8,915.16 to $556,816.93. We report the additional costs from this rule for labs to verify analytical methods in Table 47. These results assume labs that test import related food covered under the rule will participate in the LAAF program one to two years following publication of the rule, and that labs that test shell eggs, sprouts, and bottled drinking water will participate in the LAAF program two to three years following publication of the rule.

Table 47: 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 17025:2017	Total costs
Lower bound	$77.10	22	$1,694.27	5%	1%	$8,915.16
Upper bound	$77.10	46	$3,527.33	30%	5%	$556,816.93

e. Costs to compile an analytical report with test results

This rule will require each participating lab to submit to us a full analytical report with test results, unless they can submit abridged analytical 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 five consecutive successful full analytical reports per major food testing discipline. Participating labs that submit these five consecutive successful full analytical reports per major food testing discipline will then be allowed to submit abridged analytical reports for the methods included in major food testing discipline thereafter.

Each submission will contain:

- test results;
- sampling plans, sample collection reports, and if not previously submitted, the sampler's qualifications;
- when a validation study is required, the documentation required by ISO/IEC 17025:2017;
- when a verification study is required, documentation such as results and supporting analytical data;
- either a full or abridged analytical report (see below); and
- 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 abridged analytical reports will still be required to maintain records of all information required in a full analytical report. We anticipate occasionally reviewing the records of information required in a full analytical report of participating labs allowed to submit abridged analytical reports.

Analytical reports are currently submitted for tests of import related food covered under this rule and, as discussed in the cost savings section, will accrue cost savings from clarifications of the reporting requirements, and those who qualify for abridged analytical reports (and incur the costs of compiling five successful full analytical reports per major food testing discipline), will accrue additional cost savings. Because we currently do not receive analytical reports for tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements, we assume they are currently not generated with the same information as will be required by this rule. We assume that all tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements will result in costs from compiling analytical reports from this rule – the

first five consecutive successful full analytical reports per major food testing discipline, and then abridged analytical reports thereafter.

We estimated the costs for participating labs to qualify for abridged analytical reports in the section on lab level costs. As reported in the cost savings section, we estimate the cost to compile an abridged analytical report of between $51.49 and $135.94, and multiply by the annual number of tests of shell eggs, sprouts, and bottled drinking water subject to specific testing requirements (between 2,580 and 5,503) and obtain the lower and upper bounds for compiling abridged analytical reports. We report the costs to compile abridged analytical reports in Table 48. These results assume labs that test shell eggs, sprouts, and bottled drinking water will participate in the LAAF program two to three years following publication of the rule.

Table 48: Costs to compile and submit abridged analytical reports

	Cost to compile an abridged analytical report	Numbers of tests of shell eggs, sprouts, bottled drinking water, and other tests	Total cost to compile abridged analytical reports
Lower bound	$51.49	2,580	$112,173.43
Upper bound	$135.94	5,503	$631,588.60

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

This rule may result in switching costs if owners and consignees must switch from their current lab to a participating lab that is accredited to the appropriate scope that may not be as conveniently located or may otherwise be a higher cost lab. We estimate that any tests currently performed by labs not accredited to ISO/IEC 17025:2017 and that choose not to participate in the LAAF program will result in costs to switch to a LAAF-accredited lab. We define switching costs as the increase in costs to ship food samples to participating labs that are located further away than the labs currently used that choose not to participate in the LAAF program.

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 for tests of import related food covered by the rule and all other tests covered by the rule except shell eggs using internal documents regarding the numbers and weights of sub-samples recommended to be collected for each food category and the 2017 shipping costs published on the UPS website (Ref. 24) and inflated to 2020 dollars. A sample may be comprised of several sub-samples, with each sub-sample weighing an average of 2.5 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. 25). We use 10 sub-samples as the lower bound in the range of sub-samples that will 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 will not normally be subjected to a process lethal to the microbe of interest (Category I foods) (Ref. 26). We use 60 sub-samples as the upper bound in the range of sub-samples that will be shipped to a participating lab and 35 sub-samples as the average number that comprise a sample. For shell eggs we assume a shell egg weighs 1.5 oz. to 2.5 oz., or 0.094 lbs. to 0.156 lbs., and that 1,080 shell eggs are shipped in one sample.

We use the weight of 2.5 pounds per sub-sample obtained from internal guidance, an average weight of 7.5 pounds for packaging materials, and shipping costs based on retail rates published by UPS, distributed uniformly between $2.30 per pound and $7.67 per pound of

import related food samples and sprouts samples inflated to 2020 values. We assume that switching costs will be incurred for the number of samples currently not analyzed by labs accredited to ISO/IEC 17025:2017. Consequently, we estimate that between 3.2 percent and about 7.5 percent of all tests of import related food covered under this rule (100 percent – 96.8 percent of reports analyzed by an accredited lab = 3.2 percent and 100 percent – 92.5 percent = 7.5 percent), between 5 percent and 15 percent of tests of sprouts subject to specific testing requirements covered by the rule, and between 63 percent and 70 percent of shell eggs subject to specific testing requirements covered by the rule will be switched to a different lab. We adjust the tests of shell eggs that will be subject to switching costs to account for labs that test shell eggs that will incur costs to become accredited to ISO/IEC 17025:2017 to participate in the LAAF program. Consequently, we adjust the number of tests of shell eggs that will be subject to switching costs by between 0 percent (100 percent – [10 labs that will incur costs to become accredited to ISO/IEC 17025:2017 /10 labs currently not accredited to ISO/IEC 17025:2017] = 0 percent) and 70 percent (100 percent – [7 labs that will incur the costs to become accredited to ISO/IEC 17025:2017 / 24 labs currently not accredited to ISO/IEC 17025:2017]) = 70 percent). We estimate switching costs for tests of bottled drinking water will be negligible. Consequently, we estimate that on average about 623 covered tests of import related food, 27 covered tests of sprouts, and 1,245 covered tests of shell eggs will be subject to switching costs. We report the switching costs from this rule in Table 49.

Table 49: Incremental costs to switch to participating labs accredited to the appropriate scope

	Lower Bound	Medium Value	Upper Bound
Number of sub-samples collected (low for filth, high for Category 1 *Salmonella*)	10	35	60
Lbs. of eggs per samples, 1 sample of shell eggs = 1,000 eggs	101	135	169
Extra shipping cost of samples of import related food and sprouts: 0.25 x (@$2.30 - $7.67 per lb.; Assume 2.5 lbs. packaging costs, 2.5 lbs. per sub, gross weight)	$3.90	$59.54	$149.53
Extra shipping cost of samples of eggs. 0.25 x (@$2.30 - $7.67 per lb.; Assume 5-10 lbs. packaging costs)[1]	$9.29	$94.27	$188.14
Total number of samples of import related food and that will be subject to switching costs.	373	623	874
Total number of samples of egg shipments that will be subject to switching costs	0	1,245	2,490
Total number of samples of sprouts and bottled drinking water that will be subject to switching costs	3	27	72
Total cost to switch to testing entities LAAF-accredited to the appropriate scope	$8,570.98	$133,988.38	$354,946.39

[1] A sample comprises 1,000 shell eggs – 50 pools at 20 eggs per pool. We estimate shipping costs for an extra 80 shell eggs to account for the possibility of breakage.

g. Costs for the DFLO and covered tests from other administrative orders covered by the rule

The DFLO is a new administrative tool requiring the use of a LAAF-accredited lab for analyses in the rare situations when we have reason to question the accuracy and reliability of past or present test results, and an identified or suspected food safety problem exists. In the PRIA we estimated the frequency of our use of a DFLO (previously FTO) as the same as our use of other administrative tools with tests covered by this rule: Administrative Detentions (AD), Suspensions of Registrations (SR), and Mandatory Recalls (MR). In this analysis, we make that link quantitative and report our method and estimates here. We required ADs 10 times and MRs once between 2011 and 2020 (Ref. 1 and 2). Internal records indicate we used SRs six times

between 2011 and 2020 (Ref. 3). We estimate our annual use of a DFLO will be between 0.1 and 1 (1/10 years and 10/10 years).

A DFLO requires a firm to use a participating LAAF-accredited lab to conduct environmental tests or food product tests and have the results sent directly to us. We do not know the total number of tests and analytical reports that will be subject to a DFLO requirement and use as a guide the rounds of testing ordered in recently adjudicated consent decrees involving food facilities found to be in violation of the FD&C Act.

Many consent decrees have no explicit product testing requirements. We identified four consent decrees ordered in 2016 that made explicit the frequencies (e.g., weekly) and scopes (e.g., every lot per finished product, one lot from each finished product, etc.) for product testing. We use these four adjudicated consent decrees as examples for estimating the numbers of tests and analytical reports that will be subject to a DFLO. The first round may require daily product tests over the course of a week's worth of production (we assume 5 tests), the second round may require weekly tests over the course of the subsequent month (we assume 4 tests), and the third round may require monthly tests over the subsequent year (we assume 12 tests). We assume these tests would be analyzed by a LAAF-accredited lab and the results submitted with an analytical report and sent directly to us. Consequently, we estimate there will be 21 analytical reports generated for each DFLO. We make the same assumptions for the costs of covered tests for other administrative orders covered by the rule. We estimate the costs of submitting and reviewing an analytical report generated by a DFLO requirement as well as covered tests of other administrative requirements covered by the rule using the same methodology that we used for estimating the costs of submitting and reviewing all other analytical reports subject to the rule.

h. Summary of costs incurred by test

We report a summary of the costs incurred by test by sub-category and their frequencies in Table 50.

Table 50: Summary of costs incurred annually by test

	Lower bound	Upper bound
Costs of the advance notice of sampling	$10,973	$132,570
Costs to generate a sample collection plan	$84,118	$361,089
Costs to compile a sample collection report	$84,118	$361,089
Costs for labs to confirm accreditation to the appropriate scope	$163,271	$390,827
Costs to include results from validation and verification studies	$8,915	$556,817
Costs to compile an analytical report with test results	$112,173	$631,589
Costs for switching to a lab accredited to the appropriate scope	$8,571	$354,946

We use Monte Carlo methods to simulate total annualized costs and the present values incurred by test. In Table 51 we report the simulated fifth 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 51: Total annual costs and present value of costs incurred by test discounted over 10 years at seven percent and three percent

	5^{th} percentile	Mean	95^{th} percentile
Annualized costs at 7 percent	$1,173,560	$1,589,601	$2,041,812
Annualized costs at 3 percent	$1,150,422	$1,589,601	$2,040,799
Present value of costs at 7 percent	$8,167,071	$11,164,689	$14,290,130
Present value of costs at 3 percent	$9,918,982	$13,559,615	$17,355,492

4. Cost of fewer false negative test findings

The cost of fewer false negative test findings from better tests will include the cost of salvaging any shipments of import related food covered by this rule that will 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 import related food covered under this rule that currently test negative but will instead test positive under this 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 import related food covered under this rule from fewer false negative test findings. We assume that shipments of shell eggs, sprouts, and bottled drinking water, and other food subject to specific testing requirements will either be discarded or diverted to another use if a sample were to test positive. We assume zero costs for discarding contaminated shell eggs, sprouts, and bottled drinking water 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 shipments of human and animal food offered for import covered under this rule will incur a reconditioning cost of between $500 and $1,500 per shipment. We report the five 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 52.

Table 52: Annual and present value of costs to recondition import related food covered under this rule with fewer false negatives, discounted at seven percent and three percent over 10 years[1]

	5th percentile	Mean	95th percentile
Annualized cost at 7 percent	$0	$4,206.38	$10,441
Annualized cost at 3 percent	$0	$4,206.38	$10,441
Present value of costs at 7 percent	$0	$29,544	$73,330
Present value of costs at 3 percent	$0	$35,881	$89,060

[1] We report $0 as the lower bound when the fifth percentile is less than or equal to $0.

5. One-time costs to read and understand the rule

We model the one-time learning costs to read and understand the rule as the time required by regulatory affairs personnel from human and animal food importers, ABs, private and public laboratories, shell egg producers, sprouts producers, and bottled drinking water producers, and other entities to access and read the rule. We estimate that a regulatory affairs expert will incur a burden of between 15 minutes and 30 minutes to access the rule and will read the preamble and codified provisions at a rate of 200 to 250 words per minute. The preamble and codified text have approximately 83,000 words. We estimate that it will take between 5.53 and 6.92 hours for a regulatory affairs expert to read and understand the preamble and codified text.

We estimate the mean hourly wage of a regulatory affairs expert using wages reported in the Bureau of Labor Statistics, Occupation Employment Statistics, May 2020 National Industry-Specific Occupational Employment Estimates for a lawyer, which are doubled to account for overhead ($143.18). Applying the fully loaded mean hourly wage to the hourly burdens described above, we obtain a one-time cost of between $792.26 and $891.30 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 $143.18 per hour). The total access and learning costs for all affected entities, including importers, ABs, labs, shell egg, sprouts, and bottled drinking water producers, will equal between $7,621,934.46 (for 9,620 entities) and

$12,111,715.52 (for 12,230 entities) if incurred in the first year following publication of the rule. However, we assume that entities will 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 $5,984,085.67 and $9,509,074.59, with annualized costs between $796,260.91 and $1,265,306.82.

6. FDA costs

FDA currently does not have a process to officially recognize ABs for the accreditation of labs. Costs to FDA from this rule will 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 will also incur recurring costs to evaluate initial applications for AB recognition, to evaluate the renewal of recognition and to evaluate recognized ABs and review the performance of participating labs. In addition, there will be costs to maintain a website with the public registry with current contact information and recognition status of recognized ABs and the scopes of accreditation, contact information, and accreditation status of participating labs. We will incur costs to review and maintain records of analytical reports submitted for tests subject to the rule and to review advance notices of sampling. For estimating the costs reported in this section we use the fully loaded hourly wage of $119.08, which is derived from the 2020 annual fully loaded salary for ORA personnel of $247,695 used by FDA for budgeting purposes.

We note there is uncertainty about the number of labs that will participate in the LAAF program, and the Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for the testing ensures there will be enough lab capacity in the LAAF program for any tests that are required. The stepwise approach

to implementation and giving a 6-month notice to owners and consignees prior to requiring them to comply with the final rule affects the timing of costs and benefits of the rule. We estimate that costs will be incurred for tests of import related food covered by the rule one to two years (discounted at seven percent) following publication of the final rule based on comments that assert there is currently sufficient lab capacity for this to be the case. For tests of shell eggs, sprouts, and bottled drinking water covered by the rule, we estimate costs will be incurred two to three years (discounted at seven percent) following publication of the rule, after we have determined that sufficient lab capacity exists for covered tests of shell eggs, sprouts, and bottled drinking water.

a. Costs for management systems upgrades, maintenance, and training

Implementation of this rule will require expansion and modification of FDA's existing management systems to enable the processing of AB applications for initial recognition and renewal of recognition, 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 LAAF 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 this 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

This 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 will be submitted electronically and will initially go through an automated screening. They will 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 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 will take between 40 and 80 hours. The cost for reviewing an application from an AB will range from about $4,763 ($119.08 per hour x 40 hours = $4,763.37) to about $9,527 ($119.08 per hour x 80 hours = $9,526.73). We estimate 4 ABs will apply to be recognized and that the total one-time cost of reviewing applications will range from $19,053.46 ($4,763.37 per AB x 4 ABs = $19,053.46) to $38,106.92 ($9,527.73 per AB x 4 ABs = $38,106.92). We estimate the annualized costs to review an initial application will range from $2,535.31 to $5,070.62 when discounted by seven percent over 10 years and between $2,168.59 and $4,337.18 when discounted by three percent over 10 years.

c. Costs to evaluate applications for renewal

This rule provides that FDA may grant recognition to an AB for up to five years, after which ABs must submit an application for renewal of recognition up to another five years.

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 AB's 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 of recognition will be equal to that for a review of an initial application for recognition, or between 40 hours and 80 hours per application for renewal of recognition.

We assume renewal costs will 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 the cost to review renewals over 10 years will range from about $5,817.67 (4 ABs x 40 hours x $119.08 per hour divided by 1.07 raised to the 5^{th} power + 4 ABs x 40 hours x $119.08 per hour divided by 1.07 raised to the 10^{th} power = $5,817.67) to about $15,306.62 (4 ABs x 80 hours x $119.08 per hour divided by 1.03 raised to the 5^{th} power + 4 ABs x 40 hours x $119.08 per hour divided by 1.03 raised to the 10^{th} power = $15,306.62). We estimate the annualized renewal cost discounted at seven percent over 10 years will range from $3,313.22 to $8,717.28. The annualized costs discounted by 3 percent over five years will range from $2,728.03 to $7,177.61.

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

This rule will require us to provide information on our website on all ABs, including ABs who have been placed on probation, whose recognition has been revoked, or whose application

for recognition has been denied. In addition, this rule will require us to provide information on participating labs, including scopes of accreditation, contact information and their program participation status, and including those that have been suspended or had their accreditation withdrawn or their scope of LAAF-accreditation reduced. 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, we estimate the annual costs to maintain website information on ABs to be about $476.34 (1 hour x $119.08 per hour x 4 ABs = $476.34) and the annual costs to maintain website information on participating labs to range between $10,296.49 (1 hour x $119.08 per hour x 85 labs = $10,058.32) and $30,366.45 (1 hour x $119.08 per hour x 255 labs = $30,366.45). We assume labs that test shell eggs, sprouts, and bottled drinking water will participate in the LAAF program two to three years following publication of the rule and labs that test import related food will participate in the LAAF program one to two years following publication of the rule.

e. One-time costs to review five consecutive successful full analytical reports per major food testing discipline per lab prior to qualifying for abridged analytical reports

Each participating lab will be required to provide five consecutive full analytical reports per major food testing discipline prior to qualifying to submit abridged analytical reports. For purposes of this analysis, we assume that each participating lab will be accredited by a participating AB to scopes represented by one to three major food testing disciplines. We multiply the cost to review a full analytical report of $225.07 by 75 percent and 90 percent to account for cost savings from management systems improvements. We assume five consecutive successes for each of one to three major food testing disciplines and multiply by the number of

participating labs (between 85 and 256 participating labs). We report the one-time costs for us to review five full analytical reports per lab for each major food testing discipline in Table 53.

Table 53: One-time per lab cost for us to review full analytical reports to qualify for abridged analytical reports

5th Percentile	Mean	95th percentile
$32,967	$62,457.21	$99,408

f. Costs to review analytical reports

This rule will require us to review analytical reports submitted by participating labs for adherence to the requirements established by this rule 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 this 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 a panel of Technical Leads, as described in section II.D.2.c. to address any concerns about the analytical package that may arise during the high-level technical review.

Subject to a few exceptions, we assume that all participating labs will 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 LAAF program. Consequently, we estimate the cost for us to review an abridged analytical report including time saved from management systems

improvements is between $42.20 and $66.85 (from Table 15b review costs are between $56.27 and $74.27 per analytical report, multiplied by between 10 percent and 25 percent review time saved from management systems improvements).

We assume we will incur costs to review all analytical reports of tests of shell eggs, sprouts, and bottled drinking water subject to specific testing and for other testing requirements from this rule. We assume we will not incur additional costs to review analytical reports submitted for tests of import related food covered under this rule because that is the current baseline practice. Consequently, we estimate the costs for us to review analytical reports from this rule is between $91,934.23 ($56.27 per analytical report x [2,520 shell egg tests + 60 sprouts tests + 0 bottled drinking water test] x 75 percent due to cost savings from management systems improvements = $91,934.23) and $258,910.31 ($74.27 per analytical report x [5,023 shell egg tests + 480 sprouts tests + 2 bottled drinking water tests] x 90 percent due to cost savings from management systems improvements = $258,910.31), assuming labs that test shell eggs, sprouts, and bottled drinking water participate in the LAAF program in two to three years following publication of the rule.

g. Costs to review the performance of participating labs

FDA may review the performance of a participating lab to determine whether it complies with the new requirements. We may review a participating lab's records, conduct an on-site evaluation, and obtain any other related information. We assume that we will evaluate each participating lab once every three to four years and that an evaluation will take between 40 and 80 hours to complete. We multiply the hourly burden by the fully loaded wage of $119.08 to obtain a cost of between $100,583.22 (40 hours x $119.08 per hour x 85 participating labs / 4

years = $100,583.22) and $809,772.12 (80 hours x $119.08 per hour x 256 participating labs / 3 years = $809,772.12) for FDA to evaluate each participating lab once every three to four years, and assuming labs that test shell eggs, sprouts, and bottled drinking water participate in the LAAF program in two to three years following publication of the rule.

h. Summary of FDA costs

We report upper and lower bounds and annual frequencies of the costs to us from this rule by cost category in Table 54.

Table 54: 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
Costs of recognizing ABs	$19,053	$38,107	One-time
Costs of renewing recognition of ABs	$23,271	$61,226	Every 5 years
Costs to maintain website registry with information on ABs and labs	$10,535	$30,843	Annual
Reviewing notifications and lab packages	$91,934	$258,910	Annual
Costs to review participating labs' performance	$100,583	$809,772	Annual
Costs to review five successful full analytical reports per lab and scope prior to abridged reporting	$56,186	$146,295	One-time

We use Monte Carlo methods to simulate the total annualized and present values of the costs incurred by us. In Table 55, 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 fifth percentile, 95th percentile, and mean estimates of the total annualized costs that will be incurred by us discounted at seven percent and three percent over 10 years.

Table 55: Estimated total annualized and present value of costs to FDA at discount rates of 7 percent and 3 percent over 10 years

	5th percentile	Mean	95th percentile

Annualized costs at 7 percent	$1,235,891	$1,569,189	$1,904,776
Annualized costs at 3 percent	$1,185,176	$1,508,264	$1,840,658
Present value of costs at 7 percent	$4,764,682	$7,570,720	$10,355,675
Present value of costs at 3 percent	$5,130,303	$8,531,652	$11,906,236

7. Summary of total annualized and present value of costs of this 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 fifth percentile, mean, and 95th percentile range of the total annualized costs of this rule. We report the estimated range of total annualized costs from this rule discounted over 10 years at seven percent and at three percent in Table 56a and Table 56b. We report the present values of the benefits and costs from this rule discounted by seven percent and by three percent over 10 years in Table 57.

Table 56a: Summary of total costs of this rule annualized at seven percent over 10 years

	5th percentile	Mean	95th percentile
AB costs	$93,875	$175,166	$256,805
Costs incurred at the lab level	$1,588,728	$3,527,536	$5,260,086
Costs incurred by test	$1,173,560	$1,589,601	$2,041,812
Cost incurred from fewer false negatives[1]	$0	$4,206	$10,441
Learning costs	$796,261	$1,030,784	$1,265,307
Government costs	$1,235,891	$1,569,189	$1,904,776
Total annualized costs	$5,783,823	$7,896,481	$9,646,508

[1] We report $0 as the lower bound when the fifth percentile is less than or equal to $0.

Table 56b: Summary of total costs of this rule annualized at three percent over 10 years

	5th percentile	Mean	95th percentile
AB costs	$91,298	$172,348	$252,802
Costs incurred at the lab level	$1,471,424	$3,486,591	$5,204,149
Costs incurred by test	$1,150,422	$1,589,601	$2,040,799
Costs incurred from fewer false negatives[1]	$0	$4,206	$10,441
Learning costs	$906,205	$1,173,110	$1,440,015
Government costs	$1,185,176	$1,508,264	$1,840,658
Total annualized costs	$5,866,735	$7,934,120	$9,693,149

[1] We report $0 as the lower bound when the fifth percentile is less than or equal to $0.

Table 57: Present value of the benefits and costs of this rule discounted at 7 percent and 3 percent over 10 years

	5th percentile	Mean	95th percentile
Present value of costs at 7 percent	$37,976,705	$53,105,904	$66,095,251
Present value of costs at 3 percent	$43,375,955	$61,555,452	$76,973,885
Present value of benefits at 7 percent	$46,386,921	$63,591,906	$87,522,413
Present value of benefits at 3 percent	$56,337,332	$77,232,941	$106,296,756

We use a Monte Carlo simulation to subtract the total annualized costs of this rule reported from the total annualized benefits reported earlier. We report the annualized net benefits discounted by seven percent and three percent in Table 58.

Table 58: Annualized Net Benefits of this Rule Over 10 Years

	5th percentile	Mean	95th percentile
Annualized net benefits at 7 percent	-$2,075,396	$1,157,576	$5,721,795
Annualized net benefits at 3 percent	-$1,948,935	$1,119,937	$5,719,000

a. Distributional effects

This rule will affect the distribution of revenues from tests of import related food covered under this rule and from tests of shell eggs, sprouts, and bottled drinking water and other foods subject to testing covered under this rule's requirements. We quantify the distributional effects as switching costs – the costs to switch from labs that currently perform the tests required under this rule but choose not to participate in the LAAF program to labs that choose to participate in the LAAF program. In Table 49 in the earlier section entitled "Costs for switching to participating labs accredited to the appropriate scope" we reported the average switching costs will be about $0.134 million.

b. International effects

We expect the effects from this rule on the level of international trade to be small since the current share of tests of import related food covered under this rule conducted by international labs is small. We also expect the effects of this rule 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 import related food covered under this rule across countries, depending on the amount of food exported to the U.S. Some international labs and ABs from countries that export small amounts of human and animal food to the U.S. may relinquish any business from tests of import related food covered under this rule to a competitor, likely located in a different country, if the one-time costs to participate in the LAAF program are too high.

c. Uncertainty and sensitivity analysis

We obtained fifth percentile, mean, and 95th percentile 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 will be obtained using non-simulation methods; however, Monte Carlo simulation methods provide fifth percentile estimates and 95th percentile 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 will range from -$2.0 million to $5.7.2 million with a mean of $1.2 million. The main source of uncertainty is from the estimate of the rates of false negatives for tests currently performed by labs not accredited to the ISO/IEC 17025:2017 standard (6.2 percent to 12.3

percent). Uncertainty in this estimate accounts for about 60.5 percent of the variance in the net benefits.

G. Analysis of Regulatory Alternatives to this Rule

1. Do not allow abridged analytical reports

Following five successful full analytical reports per major food testing discipline, a participating lab will thereafter be allowed to submit abridged analytical reports. Abridged analytical reports will contain information that will meet the ISO/IEC 17025:2017 standard for reporting, but less than that needed for us to replicate the test results. All information contained in a full analytical report will be available to us on an as-needed basis. We estimated cost savings from compiling and reviewing abridged analytical reports of tests of import related food covered under this rule, as well as a reduced cost for compiling and reviewing analytical reports of tests of shell eggs, sprouts, and bottled drinking water. For the regulatory alternative that does not allow abridged analytical reports the mean net benefits from this rule would fall from about $1.2 million to about -$2.8 million.

2. Cover only tests of import related food covered under this rule

When only tests of import related food covered under this rule are subject to the new requirements, labs that test shell eggs, sprouts, and bottled drinking water will not be affected by the rule, and analyses of shell eggs, sprouts, and bottled drinking water will not be subject to the requirements of this rule. This regulatory alternative is most consistent with current baseline practices for reporting test results since currently only analytical reports of tests of import related

food covered under this rule are regularly submitted to us. By not covering tests of shell eggs, sprouts, and bottled drinking water, the mean net benefits of the rule would increase from about $1.2 million to about $3.6 million.

3. Exclude the DFLO and requirements to use a participating lab for other administrative orders covered under this rule

The DFLO is a new administrative tool requiring the use of a LAAF-accredited lab for analyses in the rare situations when we have reason to question the accuracy and reliability of past or present test results, and an identified or suspected food safety problem exists. In the FRIA, we estimated our use of a DFLO will be between 0.1 and 1 per year. A DFLO requires a firm to use a participating LAAF-accredited lab to conduct environmental tests or food product tests and have the results sent directly to us. In the FRIA, we estimate the annual costs of the DFLO to be about $12,000 and the annual avoided QALD losses from the DFLO to be about $65,000. Consequently, we estimate the mean annual cost savings from the regulatory alternative of excluding the DFLO requirement is about $10,000 and the mean annual avoided QALD losses would decrease by about $69,000. Table 59 presents a comparison of the regulatory alternatives discussed.

Table 59: A comparison of regulatory alternatives to this rule

Regulatory alternative	Comparison to this rule	Reason not selected
Do not allow abridged analytical reports	Mean net benefits fall from $1.2 million to -$2.8 million	Too costly
Cover only tests of import related food	Mean net benefits increase from $1.2 million to $3.6 million	Inconsistent with Statute
Exclude the DFLO provisions of the rule	Average cost saving of about $10,000 and an average reduction in avoided QALD losses of about $69,000.	Too costly

III. Final Small Entity Analysis

FDA has examined the economic implications of this final 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. The Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for the testing may lessen the burden on small entities while ensuring there will be enough lab capacity in the LAAF program for any tests that are required.

A. Description and Number of Affected Small Entities

The primary impact of this rule will be on ABs and testing laboratories. Importers, shell egg producers, sprouts producers, and bottled drinking water producers and other food manufacturers will also be affected by this rule. The Small Business Administration (SBA) reports size standards for industry categories defined by North American Industry Classification System (NAICS) codes (Ref. 27). 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 112310) are considered small if they earn $15 million in revenues or less, and bottled drinking 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 will apply to ABs.

We apply data from the Economic Census by NAICS code to determine the numbers of ABs, testing labs, shell egg producers, sprouts producers, and bottled drinking water 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. 28), 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 producers 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 final rule will be considered small as well. For purposes of this analysis, we assume that 100 percent of ABs, labs, shell egg producers, and sprouts producers, importers and bottled drinking water manufacturers affected by this final rule are small.

We compare the costs per entity from this 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 60 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 this rule in Table 60.

Table 60: Entities affected by this 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 541990	12,294	$11,116.93	$904.26	$15 million
Sprouts producers and importers (Perishable Prepared Food Manufacturing), NAICS 311991	702	$10,156.60	$14,468.09	500 employees
Bottled drinking 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 FRIA, we estimate the one-time and annual costs for ABs, testing laboratories, shell egg, sprouts, importers, and bottled drinking water producers. We use a Monte Carlo simulation to estimate the fifth percentile, mean, and 95th percentile levels of one-time costs per entity using the distributional assumptions

discussed in the Regulatory Impact Analysis. ABs that choose to participate in the LAAF program may incur costs to become accredited to ISO/IEC 17025:2017 and will incur one-time costs to apply for recognition, establish an accreditation program, as well as to read and learn about the rule equaling between about $22,000 and $33,000 per entity. Labs that currently perform tests that will be subject to the rule but choose not to participate in the LAAF program will incur one-time costs of about $30,000 to about $164,000 per entity. Labs that currently perform tests that will be subject to the rule but choose not to participate in the LAAF program will no longer perform those tests. Using information from the FRIA, we estimate that about 250 labs that test import related food covered by the rule and shell eggs, sprouts, and bottled drinking water subject to specific testing requirements will choose not to participate in the LAAF program. In the FRIA, we estimate the costs to switch from these labs to a LAAF-accredited lab will be about $460 per affected lab. Shell egg producers, sprouts producers, importers, and bottled drinking water manufacturers will incur one-time costs to read and understand the rule equaling between about $800 to about $980 per entity. Importers will incur one-time costs to learn about the rule. We report the one-time costs per entity from this final rule in Table 61.

Table 61: One-time per entity costs of this rule

	5th percentile	**Mean**	**95th percentile**
ABs that choose to participate	$22,387.91	$27,544.50	$32,733.44
Labs that choose to participate in the LAAF program	$29,839.27	$96,683	$163,526.62
Labs that choose not to participate in the LAAF program	$32.05	$459.25	$1,115.24
Bottled drinking water manufacturers	$802.15	$891.30	$980.41
Shell egg producers	$802.15	$891.30	$980.41
Sprouts producers and importers	$802.15	$891.30	$980.41

The range in one-time costs for ABs that choose to participate in our program is between about 2.5 percent and 3.6 percent of average revenue per entity. Labs that will participate in the

LAAF program will incur one-time costs of between 1 percent and 6 percent of the average revenue per entity. Labs that choose not to participate in the LAAF program will incur a loss of between 0.003 percent and 0.02 percent of the average revenue per entity from lost business. The range in one-time costs for bottled drinking water manufacturers is between 0.004 percent and 0.005 percent of the average revenue per entity, the one-time costs for shell egg producers is between 0.078 percent and 0.096 percent of the average revenue per entity, and the one-time costs for sprouts producers and importers is between about 0.006 percent and 0.007 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 this rule in Table 62.

Table 62: 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	2.476%	3.046%	3.620%
Labs that choose to participate in the LAAF program	1.135%	1.135%	6.143%
Labs that choose not to participate in the LAAF program	0.003%	0.037%	0.082%
Bottled drinking water manufacturers	0.004%	0.005%	0.005%
Shell egg producers	0.078%	0.087%	0.096%
Sprouts producers and importers	0.006%	0.006%	0.007%

We consider costs per entity over and above one percent of annual revenues to be a substantial impact. Because the mean estimates of the costs per entity for ABs that choose to participate in the LAAF program and for labs that choose to participate in the LAAF program exceed one percent of annual revenues, we certify that this rule will have a substantial impact on a significant number of small entities.

C. Alternatives to Minimize the Burden on Small Entities

The Agency's plan to issue a *Federal Register* notice 6 months prior to requiring owners and consignees to use a LAAF-accredited laboratory for the testing ensures there will be enough lab capacity in the LAAF program for any tests that are required. The stepwise approach to implementation and giving a 6-month notice to owners and consignees prior to requiring them to comply with the final rule affects the timing of costs and benefits of the rule. We estimate that costs will be incurred for tests of import related food covered by the rule one to two years (discounted at seven percent) following publication of the final rule based on comments that assert there is currently sufficient lab capacity for this to be the case. For tests of shell eggs, sprouts, and bottled drinking water covered by the rule, we estimate costs will be incurred two to three years (discounted at seven percent) following publication of the rule, after we have determined that sufficient lab capacity exists for covered tests of shell eggs, sprouts, and bottled drinking water.

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