PRODUCE SAFETY STANDARDS—RECORDKEEPING AND THIRD PARTY DISCLOSURE REQUIREMENTS
RIN 0910-AG35
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is proposing this regulation under the FD&C Act as amended by the Food Safety Modernization Act (P.L. 111-353) signed into law on January 4, 2011, and the Public Health Service Act (PHS Act).

Section 105 of FSMA, Standards for Produce Safety, amends the FD&C Act to create a new section 419, which mandates rulemaking. Section 419(a)(1)(A) of the FD&C Act requires that the Secretary publish a notice of proposed rulemaking "to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death." Section 419(a)(3) provides specific requirements for the content of this proposed rulemaking, including among other things that the proposed rule "include, with respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water…" (Section 419(a)(3)(B)); that it "consider hazards that occur naturally, may be unintentionally introduced…" (Section 419(a)(3)(C)); and that it "define, for purposes of this section [419], the terms 'small business' and 'very small business'" (Section 419(a)(3)(F)).

Section 419(b) of the FD&C Act requires the Secretary to adopt a final regulation "to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks." Sections 419(b) and (c) of the FD&C Act provide specific requirements for the content of the final regulation, including among other things that the regulation shall "set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally [or] may be unintentionally introduced… into fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act]" (Section 419(c)(1)(A)).

Section 105(c) of FSMA creates a new section 301(vv) in the FD&C Act (21 U.S.C. 331(vv)) to prohibit "[t]he failure to comply with the requirements under section 419 [of the FD&C Act]."

FDA's authority for this proposed rule also derives from sections 402(a)(3), 402(a)(4), and 701(a) of the FD&C Act. Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule includes many requirements that are necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, e.g., regulations to require HACCP systems for fish and fishery products (21 CFR Part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy Salmonella organisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115), and regulations for the production, storage, and transportation of shell eggs (part 118).

In addition to the FD&C Act, FDA's legal authority for the proposed rule derives from the PHS Act. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States … or from one State … into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) The provisions in the proposed rule are necessary to prevent food from being contaminated with human pathogens such as Salmonella, L. monocytogenes, and E. coli O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II of this document, certain practices on farms can lead to the contamination of food with pathogens, increasing the likelihood of foodborne illness. We tentatively conclude that the proposed provisions in this document are necessary to prevent the spread of communicable disease and to prevent food from containing filthy, putrid, or decomposed substances; being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

We are proposing to use our authority under the FD&C Act and the PHS Act to institute certain records requirements as follows:

- For covered produce that is exempted from the requirements of the proposed rule because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance, the identity of the recipient that receives this produce (§ 112.2);

- For alternatives that farms may establish and use for certain requirements of the proposed rule, the scientific data and information used to support such alternatives (§ 112.12).

- Documentation of compliance with certain requirements related to training of personnel (§ 112.30); water monitoring and testing (§ 112.50); biological soil amendments of animal origin (§ 112.60); sanitizing of equipment used in growing operations for sprouts, or for covered harvest, packing, or holding activities (§ 112.140), and sprouts (§ 112.150); and

- General requirements in subpart O that apply to records required to be established and maintained.

2. Purpose and Use of the Information Collection

The proposed recordkeeping requirements are necessary for covered farms to ensure their own compliance with these aspects of the proposed rule and for FDA to ensure that covered farms are complying with the same aspects of the proposed rule. Therefore, these proposed requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both firms and FDA in ensuring that food is not adulterated, and are necessary to prevent the spread of communicable disease because they will aid both firms and FDA in ensuring that food does not become contaminated with human pathogens.

In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the underlying requirements are necessary to minimize the risk of adulteration and the spread of communicable disease, access to records that demonstrate that a firm has followed those requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are

limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

Private Sector: This new collection of information will be performed by growers of covered produce (farms). The records requirements of this proposed rule include records pertaining to: 1) employee training; 2) agricultural water (including documentation of testing results and Certificates of Conformance from public water systems); 3) biological soil amendments of animal origin (including Certificates of Conformance from third party suppliers and process documentation; 4) cleaning and sanitizing equipment (worker tools and machinery); 5) sprout growing (including documentation of testing results, environmental monitoring plans, written sampling plans, and seed documentation) and 6) third-party disclosure for exempt farms.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 80% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

This data collection does not duplicate any other information that is already available to FDA.

5. Impact on Small Businesses or Other Small Entities

The proposed rule reduces the burden on small businesses in part through the use of exemptions: certain small businesses are eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). The proposed rule additionally reduces the burden on small businesses by excluding from the scope of the rule farms with $25,000 or less of average annual monetary value of food sold.

The proposed rule additionally provides all farms flexibility for alternative practices to be used for certain listed requirements with adequate scientific support. The proposed rule also provides for States and foreign countries to submit a request for a variance for one or more requirements of the proposed rule. To be granted, the procedures, processes, and practices to be followed under the variance must be reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of the proposed rule.

Farms defined as small businesses have an additional 2 years to comply with most provisions of the rule after the effective date of FDA's final rule, and farms defined as very small businesses have an additional 3 years, with an additional 2-year compliance period for certain proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)). The extended compliance dates for these specific water quality standards would then be four years from the effective date for small businesses and five years from the effective date for very small businesses.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond on an **occasional** basis**,** as prescribed by the proposed rule. FDA has concluded that recordkeeping is necessary for the success of farming practices and testing procedures. Records of actions taken due to each requirement are essential for manufacturers to implement this rule effectively. Further, records are essential for FDA to be able to determine whether a farm is in compliance with the rule. These burdens are the minimum necessary to meet the requirements of the Food Safety Modernization Act. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of 01/04/2013.

9. Explanation of Any Payment or Gift to Respondents

   There are no payments or gifts to respondents associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

    There is no assurance of confidentiality associated with this collection of information.

11. Justification for Sensitive Questions

    This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

    a. Annualized Hour Burden Estimate

    FDA estimates the burden of this collection in two parts: a recordkeeping burden, in Table 1, and a third-party disclosure burden, in Table 2.

    The estimated average hourly recordkeeping burden is 5,828 one-time hours (2,831 annualized one-time hours), and 617,990.30 annual hours[1]. Furthermore, the estimated one-time third-party disclosure burden is 395,746 hours. FDA estimates the recordkeeping burden for this information collection as follows:

One-Time Hourly Burden						
21 CFR	No. Of	No. of	Total	Average	Total	Operating

[1] The one time burden calculated in the Paperwork Reduction Act analysis is 8,493 hours, and the annual burden is 1,228,959 hours. For the needs of this supporting statement, averages were calculated for proposed provisions of the codified for which there are multiple estimations in the RIA and paperwork analyses, and these are noted in the text.

	Record-keepers	Records	Records	Hourly Burden	Average Hours	Costs (related to testing burdens)
Agricultural Water—Documentation of Scientific Data						
112.50(b)(3)	2,397 (799)	1	2,397 (799)	0.5	1,199 (400)	0
Recordkeeping Related to Soil Amendments						
112.60(b)(4)	238 (79)	1	238 (79)	2	476 (159)	0
112.60(b)(5)	4 (1)	1	4 (1)	2	8 (3)	0
Sprouts-Establishment of Environmental Monitoring Plan						
112.150(b)(2)	95 (32)	1	95 (32)	12	1,140 (380)	0
Sprouts-Establishment of Sampling Plan						
112.150(b)(3), 112.146(a)	285 (95)	1	285 (95)	8	2,280 (760)	0
112.150(b)(5)	1	1	1	5	5	0
Variances						
112.173	6 (2)	1	6	120	720 (240)	0
Total One-Time Hourly Burden					**5,823 (1,947)**	**0**

Annual Hourly Burden To remain consistent with ICRAS/ROCIS some of the totals in this burden table have been rounded.						
21 CFR	No. of Recordkeep-ers	No of Records	Total Annual Records	Avg. Hourly Burden	Total Hours	Operating Costs
Training						
112.30 (b)	26,384	1	26,384	7.25	191,284	0
Testing Requirements for Agricultural Water						
E.coli Testing						
112.44(a)(1)	37	3	111	0.5	56	$9,690.30
112.44(a)(2), (a)(3), (a)(4)	1,072	2	2,144	0.5	1,072	$187,171
Testing Water Used For Hand Washing						
112.44(a)(5)	14,085	2	28,170	0.5	14,085	$2,459,241
Testing for E. coli when water is directly applicated/Analytical Testing						
112.44c	1,925	9	17,325	.75	12,994	$1,512,473
Recordkeeping Related to Agricultural Water						
Findings of Water System Inspection						
112.50(b)(1)	26,431	6	158,586	0.8	126,869	0
Records of Analytical Test Results						
112.50(b)(2)	264	1	264	0.33	87	0
Documentation of Monitoring Water Treatment						
112.50(b)(4)	4,757	1	4,757	0.98	4,662	0
Testing for E. coli when water is directly applicated/for handwashing/e coli in other water uses						
112.50(b)(5)	2,757	5	13,785	0.33	4,549	0
Recordkeeping Related to Water – Documentation to Support Alternative to Requirements of 112.44(c)						
112.50(b)(6)	1,787	1	1,787	1	1,787	0
Documentation of Certificates of Compliance						
112.50(b)(7)	5,253	1	5,253	0.33	1,733	0
Recordkeeping Related to Soil Amendments						
112.60(b)(1)	41	1	41	0.50	21	0
112.60(b)(2)	4,757	1	4,757	.25	1,189	0
112.60(b)(3)	466	1	466	0.5	233	0
Recordkeeping Related to Cleaning and Sanitation						

112.140(b) Cleaning worker tools/ machinery	14,453	1	14,453	16.5	238,475	0
Testing Requirements for Sprouts						
Testing for E. coli and Salmonella						
112.143(b), 112.146	95	107	10,165	0.5	5,083	0
Testing for Listeria						
112.143(a), 112.144(d)	95	120	11,400	0.15	1,710	0
Recordkeeping Related to Sprouts						
Documentation of Treatment						
112.150(b)(1)	95	108	10,260	0.2	2,052	0
Environmental Monitoring Plan						
112.150(b)(2)	95	2	190	0.15	29	0
Sampling Plan						
112.150(b)(3)	285	1	285	1	285	0
Testing for E.coli and Salmonella/Listeria						
112.150(b)(4)	95	114	10,830	0.17	1625	0
112.150(b)(6)	285	1	285	0.25	71	0
Recordkeeping Related to Corrective Actions						
112.161(b)	4,021	1	4,021	1	4,021	0
Review of Records						
112.161(c)	4,021	1	4,021	1	4,021	
Annual Hourly Burden and Operating Costs					619,940	$4,168,575.30

Section 112.30 (b) requires the establishment and maintenance of records of training documenting required training of personnel, including the date of training, topics covered, and the persons(s) trained. It is estimated that one recordkeeper on each of 26,384 farms will spend an average of 7.25 hours per year on recordkeeping related to training requirements of this proposed rule.

It is estimated that an average of 37 sprout growers would groundwater for irrigation water would sample and test an average of 3 times annually, in accordance with § 112.44(a)(1). In the RIA and Paperwork Reduction Act analysis of this proposed rule, multiple estimations were made for this provision based on estimations of different possible actions of farms. Therefore, these estimations are presented as an average here.

It is estimated that an average of 1,072 produce growers would sample and test an average of 2 times annually, in accordance with § 112.44(a)(2), (a)(3), and (a)(4). In the RIA and Paperwork Reduction Act analysis of this proposed rule, multiple estimations were made for this provision based on estimations of different possible actions of farms. Therefore, these estimations are presented as an average here.

It is estimated that 14,085 of farms that use groundwater sources for hand washing purposes that would sample and test would sample and test 2 times annually, in accordance with § 112.44(a)(5)

It is estimated that an average of 1,925 produce farms would test an average of nine times annually, in accordance with § 112.44(c). In the RIA and Paperwork Reduction Act analysis of this proposed rule, multiple estimations were made for this provision based on estimations of different possible actions of farms. Therefore, these estimations are presented as an average here.

Section § 112.50 outlines recordkeeping requirements related to agricultural water. It is estimated that recordkeeping related to findings of the agricultural water inspection will require one recordkeeper for each of 26,431 farms to maintain a record 6 times a year, in accordance with § 112.50(b)(1).

Section § 112.50(b)(2) requires records of analytical test results for any tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use. It is estimated that 264 percent of farms would need to test their water as part of corrective steps taken because of a determination or reasonable belief that the water is not safe and of adequate sanitary quality for its intended use.

Section 112.50(b)(3) requires documentation of scientific data relied on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1). It is estimated that one recordkeeper for each of 2,397 farms will spend .5 hour one-time on this documentation.

Section 112.50(b)(4) requires documentation of the results of monitoring water treatment under § 112.43(c)(2). It is estimated that one recordkeeper for each of 4,757 farms will maintain records of these activities 1 time annually.

Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. It is estimated that, on average, 2,757 farms will maintain records an average of five times annually. In the RIA and Paperwork Reduction Act analysis of this proposed rule, multiple estimations were made for this provision based on estimations of different possible testing purposes and actions of farms. Therefore, these estimations are presented as an average here.

Proposed § 112.50(b)(6) requires documentation of scientific data or information relied on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method.

It is estimated that 1,787 farms that use a direct application method will seek some alternative to the requirements in § 112.44(c) and each farm will work 1 hour annually to fulfill this proposed requirement.

Proposed § 112.50(b)(7) requires documentation of certificates of compliance. It is estimated that 5,253 farms will spend 1 hour annually to fulfill this proposed requirement.

Section 112.60(b)(1) requires growers of covered produce to document the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest from that growing area. It is estimated that one recordkeeper for each of 41 farms will spend .5 hour annually to meet this requirement.

Section 112.60(b)(2) requires documentation (such as a Certificate of Conformance) for a treated biological soil amendment of animal origin received from a third party. It is estimated that one recordkeeper for each of 4,757 farms will spend .25 hour annually to meet this requirement.

Section 112.60(b)(3) requires growers of covered produce to document, for a treated biological soil amendment of animal origin produced for a grower's covered farms, documentation that process controls (for example, time, temperature, and turnings) were achieved. It is estimated that one recordkeeper for each of the 466 farms will spend .5 hour annually on this requirement.

Sections 112.60(b)(4) and 112.60(b)(5) require that growers of covered produce keep scientific data or information relied on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54 (c)(3) and scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b). It is estimated that one recordkeeper for each of a total of 242 farms will spend two hours to search for information on alternative composting processes or minimum application interval and this represents a one-time burden.

Section 112.140(b) requires the establishment and maintenance of records documenting the date and method of cleaning and sanitizing of equipment used in:
(1) Growing operations for sprouts; and (2) Covered harvesting, packing, or holding activities. Hourly burdens for these requirements are estimated for two activities: cleaning worker tools and cleaning machinery and these estimations vary across farm size in the RIA and Paperwork Reduction Analysis. For the purposes of this supporting statement, these estimations are combined and averaged. It is estimated that one recordkeeper for each of an average of 14,453 farms will have to spend an average of 16.5 hours annually on recordkeeping related to cleaning worker tools and machinery.

Section 112.143 outlines certain requirements related to sprout farming. Sections § 112.143(b) and § 112.146 outline requirements related to testing spent sprout irrigation

water for *E. coli* O157: H7 and *Salmonella*. This testing requirement is considered an information collection; however, the burden is estimated to vary across farm size in the RIA and Paperwork Reduction Act analysis. Therefore, for the purposes of this supporting statement, burdens are presented as an average for this proposed provision of the codified. It is estimated that the collection burden associated with testing is an average of .5 hour per test. It is estimated that an average of 107 batches of sprouts will be tested annually by each of an average of 95 farms to comply with § 112.143(b) and § 112.146.

Sections 112.143(a) and 144(d) outlines testing requirements for testing the sprout growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*. This testing requirement is considered an information collection; however, the burden is estimated to vary across farm size in the RIA and Paperwork Reduction Act analysis. Therefore, for the purposes of this supporting statement, burdens are presented as an average for this proposed provision of the codified. It is estimated that the collection burden associated with testing is .15 hour to collect each sample. It is estimated thatone recordkeeper from an average of 95 will collect an average of 120 samples per year. Therefore, 120 samples per year x 95 farms = 11,400 total samples, and 11,400 x .15 hour = 1,170 average annual hours §§ 112.43(a) and 112.144(d).

Section 112.150 of this proposed rule outlines recordkeeping requirements related to sprout farming. Section 112.150(b)(1) requires documentation of treatment of seeds or beans. This burden is expected to vary across farms; however, for the purposes of this supporting statement, this burden is presented as an average and this documentation burden is estimated to be .2 hour per activity. It is estimated that one recordkeeper for each of an average of 95 farms an average of 108 times annually.

Section 112.150(b)(2) requires sprout growers to establish and keep a written environmental monitoring plan in accordance with § 112.144. There is a one-time burden estimated for the establishment of this plan and an annual burden estimated for the maintenance of this plan. While the burden of this proposed requirement is estimated to vary across farm size, for the purpose of this supporting statement, the burden is presented as an average. For an average of 95 it is estimated that the establishment of this record is an average one-time burden of 12 hours. As with the one-time burden, the annual burden is presented as an average. An average of 95 farms will update this records an average of two times annually.

Section 112.150(b)(3) requires the documentation of the written sampling plan for irrigation water in accordance with § 112.146(a). It is estimated that there is a one-time burden to establish this record and an annual burden to maintain this record. For each of 285 farms it is estimated that the one-time burden to establish a written sampling plan is 8 hours. The annual burden of § 112.150(b)(3) is based on the estimation that each record will take 1 hour to update annually, and that each of 285 farms will do so.

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144. To comply with this, records for

environmental testing results and spent irrigation results will be kept, and it is estimated that each record will represents a burden of .17 hour, but the number of records will vary across farm sizes, as estimated in the RIA and Paperwork Reduction Act analysis. For the purposes of this supporting statement, this burden will be presented as an average. For an average of 95 farms, it is estimated that an average total of 11,400 records will be kept annually. Therefore, 11,400 records x .17 hour per record = 1,938 average total annual hours for farms to comply with § 112.150(b)(4).

Proposed § 112.150(b)(5) requires sprout growers to have documentation of any analytical methods used in lieu of the methods that are incorporated by reference in § 112.52. It is not known how many sprout growers will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement.

Proposed § 112.150(b)(6) requires sprout growers to document the testing method used in accordance with the requirements of § 112.146(b). It is estimated that sprout growers will each spend 15 minutes on this requirement annually. Therefore, 285 total sprout growers x .25 hour annually = 71.25 annual hours to meet the requirement of § 112.146(b).

Proposed § 112.161(b) requires farms to maintain records related to corrective actions. It is estimated that 4,021 will spend one hour annually to maintain such records.

Proposed § 112.161(c) requires farms to review records. It is estimated that 4,021 farms will spend one hour annually to perform such review.

Table 2- Estimated Third Party Disclosure Burden[1]					
One Time Third Party Disclosure Burden					
20 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
112.6(b)(2) Documentation	13,542 (4,514)	1	13,542	.08	1,083 (361)
Total One-Time Burden					1,083 (361)
Annual Third Party Disclosure Burden					
20 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
112.6(b)(2) Posting signage	3,333	24	79,992	1	79,992

112.31(b)(2)	8,663	1	8,663	.08 (5 minutes)	722
112.33(b)	39.379	1	39,379	8	315,032
Total annual burden hours					395,746

Under § 112.6 qualified exempt farms must comply with certain food labeling or disclosure requirements.

It is estimated that it will take the farm operator approximately 1 hour to buy and prepare one poster board. It is also estimated that the operator will buy posters bi-weekly. The total annual time required to buy and prepare a poster board is 24Therefore, 3,333 farms x 24 annual hours = 79,992 annual hours for these farms to comply with the requirement of § 112.6(b)(2).

It is estimated that farms with other marketing channels will provide their name and complete business address on an invoice or receipt that accompanies their product. We estimate that 95 percent of very small, 98 percent of small, and 99 percent of large farms will have to provide an invoice or receipt. Multiplying the percentages by the number of farms required to label, we obtain 11,216 very small farms (.95 x 11,816), 1,727 small farms (.98 x 1,763), and 133 large farms (.99 x 134), for a total of 13,542 farms. It is estimated that these farms already provide an invoice that accompanies their product, but that it does not include the full information required by the proposed rule. It is estimated that it will take a farm operator 5 minutes (.08 hour) to change this template for new invoices, and that this is a one-time burden. Therefore, 13,542 x .08 hour = about 1,083 hours (361 annualized one-time hours) to comply with § 112.6 (b)(2).

Under § 112.31(b)(2), covered farms are required to instruct personnel to notify their supervisor(s) if they are have, or if there is a reasonable possibility that they have an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea). It is estimated that one worker from each of 8,663 farms will spend 5 minutes annually to comply with § 112.31(b)(2), which will consist of the employer giving verbal instructions to employees. Therefore, 8,663 x 5 minutes = 722 hours to comply with § 112.31(b)(2).

Under § 112.33(b), covered farms must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. We estimate that it will take 8 hours annually for the operator to inform visitors of the farm policies, including showing them where the restrooms are, and to take reasonable steps to ensure their compliance, such as monitoring visitors to ensure they are following the policies and procedures and it is estimated that 39,379 farms will need to do so. Therefore, 39,379 farms x 8 hours per farm = 315,032 annual hours to comply with § 112.33(b). We ask for comment on these estimations.

b. Annualized Cost Burden Estimate

We measure costs based on the best available information from government, industry, and academic sources. We list some common conventions used throughout the cost analysis here.

- All wage rates used come from the Bureau of Labor Statistics, Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 11 – Agriculture, Forestry, Fishing, and Hunting (http://bls.gov/oes/current/naics2_11.htm). Wages are increased by 50 percent to account for overhead.

    a. Farm Operator or Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for a farm operator or manager is $47.40 including fringe benefits and other overhead. Farm operators are the persons who have completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate for Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry as shown in NAICS code 11, Agriculture, Forestry, Fishing, and Hunting in 2010 (http://bls.gov/oes/current/naics2_11.htm) of $31.60 and we add 50 percent for fringe benefits and other overhead costs ($15.80) for a total estimate of $47.40.

    b. Farm Supervisor Mean Wage Rate: Our estimate for the mean hourly wage rate for farm supervisors is $30.26 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate for First-Line Supervisors/Managers as shown in NAICS code 11, Agriculture, Forestry, Fishing, and Hunting in 2010 (http://bls.gov/oes/current/naics2_11.htm) of $20.17 and we add 50 percent for fringe benefits and other overhead costs ($10.09) for a total estimate of $30.26.

    c. Farm Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for farm workers (nonsupervisory) is $14.00 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate for Farmworkers and Laborers, Crop, Nursery, and Greenhouse as shown in NAICS code 11, Agriculture, Forestry, Fishing, and Hunting in 2010 (http://bls.gov/oes/current/naics2_11.htm) of $9.33 and we add 50 percent for fringe benefits and other overhead costs ($4.67) for a total estimate of $14.00.

    d. Biological Technician: Using the mean hourly wage of $20.07 for a biological technician, and multiplying by 1.5 to account for overhead expenses, we estimate the labor cost for in-house sample collection to be $30.10 per hour.

First Year Only			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent**

			Costs
Farm Operator	242	$47.40	$11,471
Farm Supervisor	1,683	$30.26	$50,928
Total			$373,722 ($124,574 annualized)

Annual Costs			
Farm Operator	200,768.8	$47.40	$9,516,439
Farm Supervisor/Manager	141,680	$30.26	$4,287,237
Biological Technician	162,522.4	$30.10	$4,891,923
Farm Worker	789,509	$14	$11,053,126
Total*			$30,122,447

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs associated with this information collection. However, there are operating costs associated with this information collection. The burden of testing to comply with requirements of this proposed rule also extends to operating costs above any labor hours spent collecting for the test (laboratory analysis, shipping and collection supplies, and any laboratory travel). This additional operating cost is an average of $87.30 per test. Please note that the totals here are based on the estimated burdens in the RIA and Paperwork Reduction Act analysis and do not reflect simplified burdens.

21 CFR	Total Annual Records	Operating Costs ($87.30 per test)
112.42(d)	264	23,047
112.44(a)(1)	185	$16,151
112.44(a)(2)	6,432	$561,514
112.44(a)(5)	28,170	$2,459,241
112.44(c)	114,625	$10,006,763
112.143(b)	40,249	$3,513,738
112.143(a)	38,820	$3,388,986
Total		$19,969,439

14. Annualized Cost to the Federal Government

These activities will be covered by existing resource allocations, therefore for this information collection we are estimating zero costs to the Federal government.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval to not display the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.