Standards for the Growing, Harvesting, Packing,
and Holding of Produce for Human Consumption

OMB Control No. 0910-NEW
RIN: 0910-AG35
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) has established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. This rulemaking is part of our implementation of the FDA Food Safety and Modernization Act. The standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this regulations. The rulemaking sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated because of such hazards. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.

2. Purpose and Use of the Information Collection

   The regulations promulgated by FDA establish procedures, processes, and practices including setting forth monitoring and sampling plans, documenting data and training, and ensuring disclosure that produce for human consumption meets these requirements. The regulations also provide for certain exemptions and variances to qualified respondents. The agency will use the information collection to verify that the standards established by the rulemaking are followed such that produce entering the marketplace is reasonable assured to be safe.

3. Use of Improved Information Technology and Burden Reduction

   We believe the information collection associated with the rulemaking imposes minimum burden. While the regulations do not so require, we believe respondents will rely on information technology to store, retrieve, and otherwise comply with data collection requirements.

4. Efforts to Identify Duplication and Use of Similar Information

   The rulemaking underlying this information collection establishes regulations regarding safety standards for produce for human consumption. We are unaware of regulations that duplicate the information collection.

5. Impact on Small Businesses or Other Small Entities

The statutory requirements promulgated by the rulemaking apply to both domestic and imported produce. At the same time, the rule does not apply to specified produce rarely consumed raw, nor to produce used for personal or on-farm consumption. Also, the rule provides for exemptions for produce that receives commercial processing thus adequately reducing the presence of microorganisms of public health significance. These exemptions must be disclosed. Finally, the rule provides for modified requirements for farms meeting specific criteria.

6. Consequences of Collecting the Information Less Frequently

Information collection occurs consistent with statutory requirements.

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 on January 16, 2013 (78 FR 45781) and again in its supplemental proposed rule on September 29, 2014 (79 FR 58433). Comments received in response to the rulemaking are discussed in the agency's final rule that published in the Federal Register on November 27, 2015 (80 FR 74354). All comments may be found in the agency Docket (FDA-2011-N-0921).

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The rulemaking does not specify confidentiality. Records that may be reviewed by FDA are subject to FDA regulations on the release of information found in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with sections 5 U.S.C. 552(a) and (b) and by 21 CFR part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to the collection include farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. We estimate there are 37,404 such farms and approximately 285 sprouting operations covered by the rulemaking.

12 a. Annualized Hour Burden Estimate

Recordkeeping Burden

The regulations established at 21 CFR Part 112 provide for specific records under subparts A (General Provisions); B (General Requirements); C (Personnel Qualifications and Training); D (Health and Hygiene); E (Agricultural Water); F (Biological Soil Amendments of Animal Origin and Human Waste); K (Growing, Harvesting, Packing and Holding Activities); L (Equipment, Tools, Buildings, and Sanitation); M (Sprouts); N (Analytical Methods); O (Records); and P (variances) where a summary of estimates for both one-time and annual recordkeeping burden is shown below.

Estimated One-Time Recordkeeping Burden

Activity in 21 CFR Part 112	No. of Recordkeepers	No. of Records per Recordkeeper[1]	Total One-Time Records	Avg. Burden per Recordkeeping (in hours)[1]	Total Hours
Agricultural water; documentation of scientific data	26,649	1.137	30,310	0.50	15,158
Sprouts; establishment of environmental monitoring and sampling plans	354	1	354	10.658	3,773
Sprouts; documentation of data and variances	185	1.951	361	4.299	1,552
TOTAL	27,188		31,025		20,483

1. Numbers rounded to nearest 1/1000

Estimated Annual (Recurring) Recordkeeping Burden

Activity in 21 CFR Part 112	No. of Recordkeepers	No. of Records per Recordkeeper[1]	Total Annual Records	Avg. Burden per Recordkeeping (in hours)[1]	Total Hours
Exemptions under §112.7	3,285	1	3,285	0.500	1,643
Training under §112.30	24,420	1	24,420	7.250	177,045
Testing requirements for agricultural water under §§112.44 and 112.45	48,361	2.989	144,599	0.825	119,314
Records related to agricultural water	160,605	2.242	360,030	2.161	777,913

Activity in 21 CFR Part 112	No. of Recordkeepers	No. of Records per Recordkeeper[1]	Total Annual Records	Avg. Burden per Recordkeeping (in hours)[1]	Total Hours
Testing requirements for sprouts under §§112.144, 112.145, and 112.147	256	245.660	62,889	0.403	25,331
Records related to sprouts	1,023	62.061	63,488	0.174	11,033
Documentation supporting compliance w/§112.2	4,568	1	4,568	0.079	365
TOTAL	242,518		663,279		1,112,644

1. Numbers rounded to nearest 1/1000

Third Party Disclosure

The regulations established at 21 CFR Part 112 provide for specific disclosures under subpart A (general provisions), subpart D (health and hygiene), and subpart M (sprouts). Individual provisions are discussed more fully in the preamble to the final rule (80 FR at 74538) where a summary of estimates for both one-time and annual disclosure burden is shown below.

Estimated One-Time Disclosure Burden[1]

21 CFR Part 112	No. of Respondents	No. of Disclosures per Respondent	Total one-time Disclosure	Avg. Burden per Disclosure (in hours)	Total Hours
Disclosure under §112.6(b)	3,083	1	3,083	0.08	247

[1] There are no operating or maintenance costs associated with one-time reporting.

Estimated Annual (Recurring) Disclosure Burden[1]

21 CFR Part 112	No. of Respondents	No. of Disclosure per Respondent	Total Disclosures	Avg. Burden per Disclosure (in hours)	Total Hours
Disclosures under §§112.2, 112.6, 112.31, 112.33, and 112.142	77,165	3.459	266,928	1.422	379,705

[1] There are no operating or maintenance costs associated with annual disclosure

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden to farms covered by the rulemaking as follows:

Recording activity	**Very Small**	**Small**	**Large**	**Total**
Qualified exempt farms labeling and documentation	$5,239	$469	$0	$5,709
Agricultural water (§ 112.50)	$4,510	$829	$1,043	$6,382
Biological soil amendments of animal origin (§ 112.60)	$184	$32	$40	$256
Equipment, tools, buildings, and sanitation (§ 112.140)	$4,829	$2,620	$5,492	$12,941
Sprouting operations (§ 112.150)	$108	$109	$484	$702
Training (§ 112.30)	$1,069	$186	$227	$1,482
Documentation relating to commercial processing	$13	$3	$3	$18
Total cost (annual in thousands)	**$15,95**	**$4,249**	**$7,290**	**$27,490**

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

Recordkeeping costs associated with the rulemaking are estimated to be $27.5 million. These costs are detailed in the agency's Final Regulatory Impact Analysis (FRIA), Section II.F.9 (at p. 97), and found in the agency's Docket.

14. Annualized Cost to the Federal Government

These activities will be covered by existing resource allocations. Therefore, we are estimating zero cost to the Federal government as a result of this rulemaking.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of data resulting from this information collection is planned or anticipated.

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

We are not seeking approval not to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.