UNITED STATES FOOD & DRUG ADMINISTRATION

Standards for the Growing, Harvesting, Packaging, and

Holding of Produce for Human Consumption

OMB Control No. 0910-0816; RIN 0910-AI49 –

Final Rule

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the agency rulemaking entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” RIN 0910-AI49), (0910-AI49) Agency regulations in 21 CFR part 112 establish procedures, processes, and practices intended to 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 are revising certain agricultural water provisions of the produce safety regulation in light of recent science, findings from investigations of several produce-related outbreaks, and feedback from an array of stakeholders on the previous requirements, and making corresponding changes to the associated recordkeeping provisions. Specifically, we are removing the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) and establishing provisions for systems-based pre-harvest agricultural water assessments. We are also establishing requirements for expedited mitigation for hazards related to certain activities associated with adjacent and nearby lands, in light of findings from several recent produce outbreak investigations.

We are therefore requesting approval of the information collection provisions found in 21 CFR part 112 as revised by the subject rulemaking and discussed in this supporting statement.

1. Purpose and Use of the Information Collection

The revised regulations establish requirements for systems-based pre-harvest agricultural water assessments and appropriate measures and FDA intends to use the information collected to determine compliance with the requirements to better ensure that produce entering the marketplace is reasonably unlikely to be associated with foodborne illness.

*Description of Respondents:* Respondents to the collection of information are farms that grow, harvest, pack, or hold produce for human consumption, meaning fruits and vegetables such as berries, tree nuts, and herbs, and who use pre-harvest agricultural water for non-sprout covered produce. Respondents are from the private sector (for-profit businesses).

1. Use of Improved Information Technology and Burden Reduction

While it does not so require, we believe the majority of respondents affected by this collection will rely on information technology to store, retrieve, and otherwise comply with data collection requirements. FDA may collect records from covered farms in paper or electronic (e.g. documents sent via email) format. FDA will use existing systems—including the Electronic Inspection System (eNSpect) and, when appropriate, the Compliance Management System (CMS)—to collect and store records.

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

1. Impact on Small Businesses or Other Small Entities

The recordkeeping requirements for pre-harvest agricultural water assessments apply to covered farms of all sizes. We are providing for staggered compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce based on farm size, beginning with large farms. The purpose of staggered compliance dates is to give businesses of various sizes time to come into compliance with the requirements technically, financially, and operationally. In light of practical considerations for small and very small businesses, we consider that additional time for small and very small farms to come into compliance with the pre-harvest agricultural water requirements, including the recordkeeping requirements for agricultural water assessments, is warranted.

We also provide small business assistance on our website at <https://www.fda.gov/industry/small-business-assistance>.

1. Consequences of Collecting the Information Less Frequently

Information collection is consistent with statutory and regulatory requirements. There are no legal obstacles to reducing burden.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the *Federal Register* on December 6, 2021 (86 FR 69120). Comments received in response to the rulemaking are discussed in section IX of the final rule. All comments may be found in the agency Docket (FDA-2021-N-0471).

As discussed in section IX of the final rule, we received one comment suggesting that the recordkeeping time burden in the proposed rule may have been underestimated if activities such as reassessments were not included. We also received a few comments suggesting that the estimates for assessment recordkeeping in the proposed rule, which ranged from 4-9 hours depending on farm size, may have been too low, since some farms may face various challenges in conducting agricultural water assessments. In response to these comments, we explain that reassessments are included in the recordkeeping estimates. We also explain that the Final Regulatory Impact Analysis (FRIA) provides low, most likely, and high estimates for recordkeeping based on farm size in the recognition that the time it takes covered farms to conduct recordkeeping for agricultural water assessments is likely to range for a variety of reasons; and that for the purposes of estimating the burden of information collection associated with agricultural water assessment recordkeeping, we use the “most likely” values from the FRIA.

As comments did not provide data or information suggesting recordkeeping estimates that would be more applicable across the diversity that exists in industry in agricultural water systems, operations, and conditions, we are not revising our estimates for information collection burden in response to comments. However, as discussed in section 12, we are revising some of our estimates to account for more recent data sources on covered farm counts.

1. Explanation of Any Payment or Gift to Respondents

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

1. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected may include farm point of contact, farm address, and farm phone number. FDA determined that although PII is collected and stored in a Privacy Act system, eNSpect, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

1. Justification for Sensitive Questions

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

1. Estimates of Annualized Burden Hours and Costs

*12a. Annualized Hour Burden Estimate*

Table 1.--Cumulative Average Recordkeeping Annual Burden, Covered Farms of All Sizes

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 21 CFR 112 subpart E: Requirements that apply regarding records | Total No. of Respondents | No. of Records per Respondent | Total Annual Records | Average Burden per Farm (in hours) | Total Hours |
| Agricultural Water Assessment and Records Maintenance--Very small, covered farms (§ 112.50(b)(2)) | 9911 | 1.1 | 10902 | 4 | 43608 |
| Agricultural Water Assessment and Records Maintenance--Small covered farms (§ 112.50(b)(2)) | 2057 | 1.1 | 2263 | 8 | 18102 |
| Agricultural Water Assessment and Records Maintenance--All other (Large) Covered Farms (§ 112.50(b)(2)) | 5392 | 1.1 | 5931 | 9 | 53381 |
| Cumulative totals for covered farms of all sizes | **17360** |  | **19096** |  | **115091** |
| Cumulative average 7.0 burden hours per covered farm annually | | | | | |

Section 112.50(b)(2) requires covered farms using pre-harvest agricultural water for non-sprout covered produce to prepare and maintain records of their agricultural water assessments unless exempt under § 112.43(b). We estimate that a total of 17,360 covered farms (9,911 very small farms, 2,057 small farms, and 5,392 other (large) covered farms) will be subject to information collection requirements, consistent with figures in our FRIA and informed by a 2018 USDA survey of covered farms’ irrigation practices[[1]](#footnote-2). The change in these numbers compared to estimates provided in the proposed rule are a result of updates to covered farm counts between the Preliminary Regulatory Impact Analysis (PRIA)[[2]](#footnote-3) and the FRIA. The PRIA relied on farm counts based on 2012 NASS Census of Agriculture data, whereas the FRIA relies on 2017 NASS Census of Agriculture data (the most recent available).

Consistent with the FRIA, we assume affected farms will conduct approximately 1.1 assessments annually, in accordance with the requirement to conduct assessments annually and whenever a significant change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces.

To account for a range in the amount of time recordkeeping for agricultural water assessments may take, in the FRIA, we provide low, most likely, and high estimates based on farm size (see tables 31-33 in that document). To estimate the burden of information collection associated with the requirements for pre-harvest agricultural water assessments, we use the “most likely” values in the FRIA for each farm size. Thus, we are assuming a range of burden: 4 hours of burden for very small farms, 8 hours of burden for small farms, and 9 hours for other (large) farms, based on estimates of the amount of time in hours to conduct recordkeeping for pre-harvest agricultural water assessments. These numbers are consistent with that used in the proposed rule as well as the PRIA and the FRIA.

For very small farms, for example, 9,911 farms x 1.1 records per farm = 10,902 total annual records; and 10,902 total annual records x 4 hours of average burden = 43,608 hours to meet the recordkeeping requirements of § 112.50(b)(2).

*12b. Annualized Cost Burden Estimate*

As detailed in the FRIA, we estimate the annualized cost burden to farms covered by the collection of information:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Table 2.--Estimated Annual Cost to Farms (Millions) | | | | |
| **Recording activity** | **Very Small** | **Small** | **Large** | **Total** |
| Agricultural Water Assessment and Records Maintenance (§ 112.50(b)(2)) | $4.0 | $1.3 | $2.8 | $8.1 |

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

There are no other costs associated with the information collection.

1. Annualized Cost to the Federal Government

Our review of agricultural water assessment records would occur as part of inspection activities. If we devoted approximately 0.5 hours per inspection to the inspection of assessment records, we estimate the cost to the Federal government for the review of records retained by a firm to be $26.84 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be $53.67 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023. $53.67 per hour multiplied by 0.5 hours equals $26.84. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $53.67 per review. If FDA inspected 200 farms that prepare agricultural water assessments annually, we estimate that the total annual cost to the Federal government would be $10,734 ($53.67 x 200).

1. Explanation for Program Changes or Adjustments

The information collection is associated with new regulatory requirements for pre-harvest agricultural water assessments for non-sprout covered produce. As discussed more fully in Q-12, we modified our estimate from what we proposed originally to reflect updates to covered farm counts. The result is a decrease by **340,980** responses and **662,674** hours annually to the information collection.

1. Plans for Tabulation and Publication and Project Time Schedule

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

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

Consistent with 5 CFR 1320.5(b)(2)(ii)(C), the information collection will be published in the CFR.

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

1. Astill, G., T. Minor, L. Calvin, et al., “Before Implementation of the Food Safety Modernization Act’s Produce Rule: A Survey of U.S. Produce Growers,” 2018. Available at: https://www.ers.usda.gov/publications/pub-details/?pubid=89720. [↑](#footnote-ref-2)
2. FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,” 2021. Available at: https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations. [↑](#footnote-ref-3)