SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)

Title of the Information Collection

Title: Recordkeeping Requirements for Producers of Pesticides 40 CFR Part 169
EPA ICR No.: 0143.14
OMB Control No.: 2070–0028
Docket ID No.: EPA-HQ-OECA-2017-0640

Short Characterization/Abstract

This is a renewal of a currently approved Information Collection Request (ICR) that covers the information collection activities under the Recordkeeping Requirements for Producers found at 40 CFR part 169. These regulations issued under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 8 state that the Administrator of the Environmental Protection Agency may prescribe regulations requiring pesticide producers, registrants, and applicants for registration to maintain such records with specifies the records that pesticide producers must keep and how to dispose of them. Under FIFRA section 8, producers must make such records available for inspection and copying.

Producers must maintain records on production data for pesticides, devices, or active ingredients (including pesticides produced pursuant to an experimental use permit); receipt by the producer of pesticides, devices, or active ingredients used in producing pesticides; delivery, moving, or holding of pesticides; inventory; domestic advertising for restricted use pesticides; guarantees; exports; disposal; human testing; and tolerance petitions. These records generally consist of the material produced during the course of ordinary business activity and are maintained in the location, manner, and duration as is generally prudent for such records in the course of ordinary business activity.

Respondents are required to maintain records of receipt, production, shipping, and inventory for two years. Records regarding testing of registered pesticides must be maintained for the life of the pesticide registration, as such data are necessary to support the regulatory decision.

These records are subject to both call-in by EPA and on-site inspection by EPA and its representatives. EPA has not established a regular schedule for the collection of these records, there is no reporting. The businesses subject to the pesticide producer recordkeeping regulations includes producers of any pesticide, device or active ingredient as well as distributors, carriers and pesticide dealers. The records have to be maintained by the owners and operators of such businesses and made available to inspectors to ensure that businesses are in compliance with recordkeeping requirements. These inspections are generally conducted by the states, which enforce FIFRA regulations through cooperative agreements with EPA.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The statutory authority for these collection activities is found in section 8 of FIFRA, 7 U.S.C. 136f. The pesticide producer recordkeeping regulations are contained in Title 40 of the Code of Federal Regulations (CFR) parts 169. See Attachments A and B.2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

EPA or its representative (i.e., the states) will use records that are required to be maintained to verify compliance with the regulations. Although records maintained under the regulations are subject to call-in by EPA, the Agency does not expect to conduct routine call-ins. Instead, the records will be reviewed during routine establishment inspections. These inspections are generally conducted by the states, which enforce FIFRA regulations through cooperative agreements with EPA. In addition, the requirement to keep records may foster regulatory compliance because facilities know they could be inspected and would need to furnish the records.

FIFRA Section 8(a) states that the Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of FIFRA and to make such records available for inspection and copying. FIFRA Section 12(a)(2)(B)(i) provides that it is unlawful for any person to refuse to prepare, maintain, or submit any records required by or under Section 8 of the Act.

EPA must be able to examine and copy records of pesticide producers demonstrating the identity, production, receipt, shipment, inventory, advertisement, and guarantees with respect to all domestically sold or distributed pesticides. This is necessary to determine that such products are in compliance with FIFRA and to support enforcement action against the producers of the products if they are not. EPA must be able to examine and copy records with respect to exported pesticides in order to determine that products that have been exported are in compliance with labeling and foreign purchaser specification and acknowledgment requirements, and to take enforcement action against exporters who do not comply with FIFRA requirements. EPA must be able to examine records of pesticide disposal in order to protect public health and the environment should it be necessary to locate such disposal sites. EPA must be able to access records regarding testing on humans to protect the health and safety of such testing subjects should potential adverse effects become known. EPA must be able to access records regarding testing of registered pesticides to determine the integrity of such information, and the subsequent validity of regulatory decisions based on such information that allow the continued sale and distribution of specific pesticide products. These data may be used by enforcement and compliance officers at the federal and state level, and by regulatory officials at the federal and state level.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

EPA does not collect any information under this information collection request. All information subject to this collection request is to be gathered and maintained by pesticide producers.

Producers determine how best to comply with the requirements for recordkeeping under 40 CFR

part 169. They may collect and store the required data electronically. The Agency, through State, headquarters or EPA Regional inspectors, may periodically audit or review the data at sites chosen by individual producers. Other than review during periodic inspections, those records will generally not be submitted to the Agency unless the Agency requests them for a specific reason, such as a need to review research data supporting a registration or in the preparation of an enforcement case.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Duplication is not an issue because these records are generally unique to the requirements of the federal pesticide law (FIFRA) and to specific pesticide products. EPA is the primary Federal Agency that regulates pesticide producers. To the extent that companies may already retain these records as part of its management practices, any potential duplication will facilitate their compliance with the regulation. These records may be reproduced at the time of an inspection, but EPA does not require a producer to submit these records to the Agency. Therefore, there is no duplication of effort.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information to be recorded is straightforward and can be maintained by facilities in the manner they see fit, as long as the records are available for review during routine establishment inspections by EPA or the states. The information collected under this ICR does not negatively impact small businesses, because the records required to be maintained are those which qualify as "customary and usual business activity." To the extent that larger businesses can use economies of scale to reduce their burden, the overall burden will be reduced. However, even though the recordkeeping and reporting requirements are the same for small and larger businesses, the Agency considers these requirements the minimum needed to ensure compliance and, therefore, cannot reduce them further for small businesses.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Not applicable. There is no collection activity. Records are generated when certain activities take place, related to the production and distribution of pesticides and pesticidal devices, and, if necessary, information will be collected periodically without a set schedule for compliance assurance.

EPA must be able to examine and copy records at pesticide producers demonstrating the identity, production, receipt, shipment, inventory, advertisement, and guarantees with respect to all domestically sold or distributed pesticides. This is necessary to determine that such products are in compliance with FIFRA and to support enforcement action against the products producers if they are not. EPA must be able to examine and copy records with respect to exported pesticides in order to determine that products that have been exported are in compliance with labeling and foreign purchaser specification and acknowledgment requirements, and to take enforcement action against exporters who do not comply with FIFRA requirements. EPA must be able to

examine records of pesticide disposal in order to protect public health and the environment should it be necessary to locate such disposal sites. EPA must be able to access records regarding testing on humans to protect the health and safety of such testing subjects should potential adverse effects become known. EPA must be able to access records regarding testing of registered pesticides to determine the integrity of such information, and the subsequent validity of regulatory decisions based on such information that allow the continued sale and distribution of specific pesticide products. These data may be used by enforcement and compliance officers at the federal and state level, and by regulatory officials at the federal and state level.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The only guideline established under the Paperwork Reduction Act (PRA) that may be exceeded in this collection is the time period for retaining records. The PRA guidelines specify that an Agency must provide justification when requiring data other than health, medical or tax records be retained for more than three years. This is discussed below.

Each record required relates to a separate, discrete business activity. Each record is generated only once in the course of each activity. It would not be possible to reduce the collection frequency without removing certain activities from compliance altogether.

8. If applicable, provide a copy and identify the date and page number of publications in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping,

disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Prior to submission to OMB, this ICR was made available to the public for comment through a Federal Register notice. The public had 60 days to provide comments. EPA did receive one comment in response to the previously provided public review opportunity issued in the Federal Register on September 7, 2022 (87 FR 54,687).

Under 5 CFR 1320.8(d)(1) OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an original or renewal ICR to OMB for review and approval. In accordance with this regulation, EPA pursued additional consultations with interested parties during the development of the renewal of this collection.

EPA contacted the following pesticide companies with questions regarding the ICR:

- Kimberly York, Syngenta Crop Protection, LLC
- Tami Jones-Jefferson, Corteva Agriscience LLC
- Amanda Burwell, Stepan Company
- Dr. Nina Ellen Jenkins, Conidio Tec
- Jeff Stroburg, Southern States Cooperative, Inc.

The questions EPA asked included:

1. As part of this ICR renewal, EPA reassessed who typically preforms the activities necessary to comply with 40 CFR part 169. In previous ICR burden analysis, EPA assumed that most of the recordkeeping activities were performed by managers and clerical staff. For this renewal, EPA recognized that there may be four different types of employees involved in meeting the recordkeeping requirements. EPA assumes that Managers, Compliance Officers, Computer Technicians, and Data Entry staff help pesticide producers and distributors comply with 40 CFR part 169. What categories of staff help your company comply with 40 CFR part 169?
2. On the following activities, how long did you or staff spend on completing each of the following aspects associated with complying with 40 CFR part 169—Books and Records of Pesticide Production and Distribution?
3. Are there activities EPA is missing?
4. Would you like to mention anything specific to this issue in your experience, which was not asked in the survey?

EPA did not receive responses to the questions posed.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This question is not applicable to this ICR.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a system of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

In some cases, the pesticide producer records may contain confidential business information (CBI) as defined in FIFRA, but the other records do not contain CBI. If the producers submit CBI, such information is protected from disclosure under FIFRA Section 10. CBI data submitted to the EPA is handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual.

Since EPA does not anticipate a collection or call-in of the retained records covered by this ICR, the information in those records would not leave the possession of the affected businesses.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Not applicable. No information of a sensitive or private nature is requested in this information collection activity.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government.'**

The regulated community affected by the producer recordkeeping regulations includes businesses that produce, sell or distribute pesticide products or devices. The affected businesses are pesticide producers, classified as North American Industry Classification System (NAICS) AICS 3250A1 - Chemical Manufacturing (3251, 3252, 3253, and 3259 only),

The records that must be maintained for purposes of 40 CFR part 169 are generally those that a responsible company would maintain as good business practice. It is estimated that the burden for a producer to prepare for the possibility of an on-site EPA inspection of those records, is 1.75 hours per year. While an additional burden will fall upon a company undergoing an inspection to locate and present the records, a given company is unlikely to undergo an inspection more often than once every two to three years.

Approximately 19,027 respondents are currently subject to this requirement, and it is estimated that 808 additional respondents per year will become subject to this requirement in the next three years. The estimate of the number of respondents is based on the number of registered active pesticide producers, which defines the entire universe of legal producers of pesticides for sale or distribution in the United States. The estimated change is based on extrapolation from trends in the number of reported producers over the last five years. EPA considers the activities under this ICR to be customary business practices. EPA estimated the costs based on the limited activities needed to understand the regulations at 40 CFR part 169 and their integration into the producer's customary business practices.

The regulated community affected by the producer recordkeeping regulations includes businesses that produce, sell or distribute pesticide products or devices. This ICR uses estimates of labor rates and associated costs based on Department of Commerce Bureau of Labor Statistics estimates. Specifically, this ICR uses the May 2021 National Industry-Specific Occupational Employment and Wage Estimates for the North American Industry Classification System (NAICS) AICS 3250A1 — Chemical Manufacturing (3251, 3252, 3253, and 3259 only). The mean hourly wage rates for NAICS code 3250A1 were: management, $69.64; compliance officer, $38.31; computer and mathematical operations, $44.71; and data entry and information processing workers, $17.30. A factor of 1.6 was added to adjust for benefit costs, resulting in respective total labor costs of $111.42, $61.30, 71.54, and $27.68.

Activity	Management (11-000) Hours Per Response	Total Management Hours	Management Costs at loaded hourly rate of: $ 111.42	Compliance Officer (13-1041) Hours Per Response	Total Compliance Officer Hours	Compliance Officer Costs at loaded hourly rate of: $ 61.30	Computer (15-000) Hours Per Response	Total Computer Hours	Computer Costs at loaded hourly rate of: $ 71.54	Data Entry (43-9020) Hours Per Response	Total Data Hours	Data Entry Costs at loaded hourly rate of: $ 27.68	**Total Hours**	**Total Costs**
a. Read regulation Respondents: 19,027	0.1	1,903	$ 212,006	0.40	7,611	$ 466,512	0	0	$ -	0	0	$ -	**9,513.50**	**$ 678,518**
b. Develop recordkeeping system and procedures Respondents: 808	0.05	40	$ 4,502	0.20	162	$ 9,905	0.75	606	$ 43,351	0	0	$ -	**808.00**	**$ 57,758**
c. Store, File, or Maintain the Information Respondents: 19,027	0	0	$ -	0	0	$ -	0.05	951	$ 68,056	0.2	3,805	$ 105,333	**4,756.75**	**$ 173,389**
Total:	0.15	1,943	$ 216,508	0.60	7,772	$ 476,417	0.80	1,557	$ 111,407	0.20	3,805	$ 105,333	**15,078**	**$ 909,665**

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The only type of industry costs associated with complying with the ICR activity are labor costs. There are no capital/start-up or O&M costs.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

There is no direct cost to EPA. EPA or duly authorized state inspectors only collects this information as part of an inspection or other compliance monitoring activity. EPA does not anticipate collecting or calling-in the records retained to comply with the producer recordkeeping regulations. The data maintained by pesticide producers will be available for review by EPA or its designee to ensure compliance with the regulations during an inspection.

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet (in hour or cost burden.)

There is a decrease of 42,054 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is a result of our reassessment of the assumptions used to estimate the burden of this ICR. Adjustments resulted from corrections of clerical or computational errors in the previous ICR renewal supporting statement. Further

adjustments to the burden estimates resulted from (1) adjustments in the salary computation for industry to reflect current wage scales; (2) adjustments for inflation; and (3) adjustment to the number of respondents.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Not applicable. The activity is conducted only as needed by EPA or state inspections, or upon the determination of the respondent. There is no set schedule for the collection of this information.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

This question is not applicable to this ICR.

18.Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

EPA does not request an exception to the certification of this information collection.

List of Attachments for this Supporting Statement

7 USC 136f
40 CFR 169
87 FR 54,687