

SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY
RECORDKEEPING REQUIREMENTS FOR PRODUCERS OF PESTICIDES
40 CFR PART 169

1. Identification of the Information Collection

1(a) Title of the Information Collection

Recordkeeping Requirements for Producers, Registrants and Applicants of Pesticides and Pesticide Devices under Section 8 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); EPA ICR Number 0143.13

1(b) Short Characterization/Abstract

FIFRA Section 8 states that the Administrator of the Environmental Protection Agency may prescribe regulations requiring pesticide producers, registrants and applicants for registration to maintain such records with respect to their operations and the effective enforcement of this Act and to make such records available for inspection and copying as specified in the statute. The regulations at 40 CFR Part 169 (Books and Records of Pesticide Production and Distribution) specify the following records that producers must keep and the disposition of those records.

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. Additionally, Section 8 gives the Agency inspectional authority to monitor the validity of research data (including raw data), developed in accordance with Good Laboratory Practice Standards, and used to support pesticide registration. 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.

Approximately 28,566 respondents are currently subject to this requirement, and it is estimated that no additional respondents per year will become subject to this requirement in the next three years. The estimate of number of respondents is based on the number of pesticide producers who have responded to the latest mandatory annual reporting response under FIFRA Section 7, 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 three years. The estimated cost per producer has been estimated to consist entirely of the cost of preparing records for inspection, as the recordkeeping itself consists of activities that are considered to be customary business practices.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

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 1 2(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.

2(b) PRACTICAL UTILITY/USERS OF THE DATA

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.

3. Nonduplication, Consultations, and Other Collection Criteria

3(a) Nonduplication

The records required to be maintained are normal business records and as such are only created upon the occurrence of a discrete activity. 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. Since it applies to the original records, no duplication exists.

3(b) Public Notice Required Prior to ICR Submission to OMB

An announcement of a public comment period for the renewal of this ICR was published in the Federal Register on February 13, 2018 (83 FR 6176).

3(c) Consultations

Three comments were received in response to the Federal Register Notice. However, EPA is unable to respond to the comments as they are not relevant to this specific ICR.

3(d) Effects of Less Frequent Collection

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.

3(e) General Guidelines

None of the reporting or recordkeeping requirements contained in 40 CFR Part 169 or otherwise pertinent to this request violate any of the regulations established by OMB in 5 CFR 1320.6.

3(f) Confidentiality

The required information consists of emissions data and other information that have been determined not to be private. However, any information submitted to the agency for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in Title 40, Chapter 1, Part 2, Subpart B - Confidentiality of Business Information (see 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979).

3(g) Sensitive Questions

None of the reporting or recordkeeping requirements contained in 40 CFR Part 169 or otherwise pertinent to this request contain sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The three-digit Standard Industrial Classification codes assigned to pesticide producers are 286 and 287.

4(b) INFORMATION REQUESTED

(i) Data Items

All data in this ICR that is recorded is required by 40 CFR Part 169. Under this requirement producers of pesticides must maintain:

(A) In a current status:

Inventory records with respect to types and amounts of pesticides and active ingredients or quantities of devices in stock. These records may be discarded when updated with more current records. (169.2(e))

(B) For one (1) year:

- copies of all guarantees given pursuant to Section 1 2(a)(2)(C) of the Act. (169.2(g))

(C) For two (2) years:

- Records showing the product name, EPA registration number, experimental use permit number, amounts per batch and batch identification numbers of pesticides produced.
- Records showing the brand names and quantities of pesticides produced. (169.2(b))
- Records showing the following information regarding receipt by the producer of pesticides, devices, and active ingredients: brand name of pesticide or device or common/chemical name of active ingredient; name and address of shipper; name of delivering carrier; date received; and quantities received. (169.2(c))
- Records showing the following information regarding shipment by the producer of pesticides, devices, and active ingredients: brand name of pesticide or device or common/chemical name of active ingredient; name and address of consignee; in the case of pesticides produced pursuant to Sections 5, 18, or 24 of the Act, the information required under these sections and any regulations promulgated thereto regarding the distribution of such pesticides; name of originating carrier; date shipped or delivered for shipment; and quantities shipped or delivered for shipment. (169.2(d))
- Copies of all domestic advertising of the restricted uses of any restricted use pesticide that the producer caused to have prepared. (169.2(f))
- In the case of pesticides, devices, and active ingredients used in producing pesticides intended solely for export: copies of specifications or directions of the foreign purchaser for production of such pesticides, devices, and active ingredients; copies of labels or labeling required to comply with Section 17(a)(1) of the Act; and for any pesticide not registered under Section 3 or sold under Section 6(a)(1) of the Act, a copy of the statement from the foreign purchaser acknowledging that the foreign purchaser is aware that the product is not registered in the United States and cannot be sold for use in the United States. (169.2(h))

(D) For twenty (20) years, or forwarded after three (3) years to EPA for maintenance:

- Records of the method of disposal, data or dates of disposal, location of disposal sites, and types and amounts of pesticides or pesticide active ingredients disposed of by the producer or contractor, deviations from normal practice, and records on disposal of pesticides, active ingredients, or containers specified pursuant to Section 19 of the Act or regulations promulgated thereto. (169.2(i))

- Records of any tests conducted on human beings whether conducted by or paid for by the producer, including: the names and addresses of subjects tested, dates and types of tests; written consent of subjects to test; instructions to subjects regarding purpose, nature, foreseeable health consequences of the tests; and any records of adverse effects either before or after the tests. (169.2(j))

(E) For as long as a registration is valid and the producer is in business:

- Records containing research data relating to registered pesticides including data submitted to the EPA in support of a registration or tolerance petition, and all underlying raw data. (169.2(k))

This period of retention is necessary to allow the agency to evaluate the validity of data used to support pesticide registrations at any time during the period that the product is registered. Without these data the Agency would not be able to support its regulatory decision allowing the product to be registered.

(ii) Respondent Activities

- Read instructions- 40 CFR Part 169 regulations
- Plan activities- CBP
- Gather information- CBP
- Plan and review information for accuracy- CBP
- Store, file, and maintain the information- CBP
- CBP- “Customary and Usual Business Practice”

During the course of normal and prudent business operations, a producer would plan his and his staffs’ information collection activities, arrange for the collection, review or have staff review the information for accuracy, and arrange to maintain or store the information detailed under 3(b). The information required to be kept is generally information that prudent businesses would maintain. The Agency does not specify in the regulation how the data to be gathered must be organized. Therefore, producers can continue to gather the required data in a manner consistent with their customary and usual business practices.

5. The Information Collected -- Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

In this collection the Agency: 1) will answer producers’ questions; 2) may audit or review data collected; 3) will provide appropriate protection of confidential business information; and 4) will store long-term data, if requested.

5(b) Collection Methodology and Management

Producers determine how best to comply with the requirements for recordkeeping under FIFRA Section 8. 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.

Those records pertaining to disposal of pesticide and human testing, which are required to be retained for 20 years, may be turned over to the Agency for storage after 3 years. The Agency then stores those records in the form in which they are submitted. If a producer submits Section 8 records to the Agency, that portion of the records which are not classified as Confidential Business Information (CBI) could be accessed by the public through the Freedom of Information Act.

5(c) Small Entity Flexibility

The information collected under this ICR does not negatively impact small businesses, since 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.

5(d) Collection Schedule

There is no specified collection schedule. Production of records for Agency review occurs at the time of routine inspection, which occurs approximately every two to three years, or when a specific need arises to evaluate the compliance of a producer. For the purposes of estimation, this is assumed to be annual, which overstates the actual collection burden.

6. Estimating the Burden and Cost of the Collection

The records that must be maintained for purposes of FIFRA Section 8 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 two hours per year. The burden is due, therefore, less to the actual recordkeeping requirement itself than to the burden placed upon the record keeper in locating and presenting these records to an inspector. While the actual burden that falls upon a company undergoing an inspection may be greater than the estimated two hours, a given company will undergo an inspection no more often than once every two to three years, if that frequently. EPA estimates that approximately one hour is spent by management employees in the planning and reviewing of the records for presentation to an EPA inspector and one hour by a clerical employee in the planning, gathering, and maintenance of the information.

The table in Section 6(e) documents the computation of individual burdens for each of the recordkeeping and reporting requirements applicable to the industry. The individual burdens are expressed under standardized headings believed to be consistent with the concept of burden under the Paperwork Reduction Act. Where appropriate, specific tasks and major assumptions have been identified.

Responses to this information collection are mandatory, as required at FIFRA Sections 8 and 12(a)(2)(B). The Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

6(a) Estimating Respondent Burden

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated at two (2) person-hours. These hours are based on Agency knowledge and experience with the pesticides program, the previously approved ICR, and any comments received about time to prepare reports.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

This ICR uses labor rates of \$132.07 per hour for the Managerial workers, based on \$62.89 per hour + 110% overhead. These rates were from the United States Department of Labor, Bureau of Labor Statistics, May 2017, National Industry-Specific Occupational Employment and Wage Estimates.

(ii) Estimating Capital and Operations and Maintenance Costs

The only type of industry costs associated with the information collection activity in the standards are labor costs.

(iii) Capital/Start-up vs. Operating and Maintenance (O&M) Costs

This is not applicable as there are no capital/start-up costs.

6(c) Estimating Agency Burden and Cost

There is no agency burden or cost because these recordkeeping requirements do not require agency action other than reviews that may be incidental to routine inspections.

6(d) Estimating the Respondent Universe and Total Burden and Costs

The total number of respondents subject to 40 CFR Part 169 is 28,566, which is an adjustment reflecting fluctuations in the numbers of respondents. The total annual labor costs are \$7,545,424 and total annual capital and O&M costs to the regulated entity are \$0 dollars. Details upon which this estimate is based appear in the table below.

6(e) Bottom Line Burden Hours and Cost

ANNUAL BURDEN OF REPORTING AND RECORDKEEPING REQUIREMENTS FOR PESTICIDE PRODUCERS, 40 CFR PART 169

Recordkeeping requirements	(A) Occurrences /hours per occurrence	(B) Hours! respondent /year	(C=AXB) Respondent /year	(D) Respondents per year	(E=CXD) Hours per year	(F) Cost/ year, \$
A. Read Instructions	1	0.5	0.5	28,566	14,283	\$1,886,356
B. Plan Activities	1	0.5	0.5	28,566	14,283	\$1,886,356
C. Implement Activities	1	1.0	1.0	28,566	28,566	\$3,772,712
D. Develop Record System	-	-		N/A		
E. Time to Enter Information	-	-		N/A		
F. Audits	-	-		N/A		
TOTAL ANNUAL BURDEN	-	-			57,132	\$7,545,424

For lines D and E, assume this is in accordance with customary business practices with no additional burden to the respondent.

For line F, burden for audits is included in activities A-C

6(f) Reasons for Change in Burden

There is an increase of 28,238 hours in the total annual burden from the previously approved ICR. This is an adjustment due to the growth in the number of respondents since the last ICR.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OECA-2017-0640, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Use <http://www.regulations.gov> to view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the docket ID number identified in this document.