

**SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY**

1. Identification of the Information Collection

1(a) Title of the Information Collection

Pesticide Establishment Application, Notification of Registration and Pesticide Production Report for Pesticide-Producing and Device-Producing Establishments (40 CFR Part 167) (Renewal). EPA ICR Number: 0160.11, OMB Control Number 2070-0078.

1(b) Short Characterization/Abstract

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 7(a) requires that any person who produces pesticides or active ingredients subject to the Act must register with the Administrator of EPA the establishment in which the pesticide is produced. This Section further requires that the application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such an establishment. EPA Form 3540-8, Application for Registration of Pesticide-Producing and Device-Producing Establishments, is used to collect the establishment registration information required by this Section.

FIFRA Section 7(c) requires that any producer operating an establishment registered under Section 7 report to the Administrator within 30 days after it is registered, and annually thereafter by March 1st for certain pesticide/device production and sales/distribution information. The producers must report which types and amounts of pesticides, active ingredients, or devices are currently being produced, were produced during the past year, sold or distributed in the past year. The supporting regulations at 40 CFR Part 167 provides the requirements and time schedules for submitting production information. EPA Form 3540-16, Pesticide Reports for Pesticide-Producing and Device-Producing Establishments, is used to collect the pesticide production information required by Section 7(c) of FIFRA.

Establishment registration information, collected on EPA Form 3540-8, is a one-time requirement for all pesticide-producing and device-producing establishments. Pesticide and device production information, reported on EPA Form 3540-16, is required to be submitted within 30 days of receipt of the Notification of Registration of Pesticide-Producing and Device-Producing Establishments, and annually thereafter on or before March 1.

Attached are copies of: (1) Forms 3540-8 and 3540-16; (2) instructions for their completion; (3) Section 7 of FIFRA; and (4) 40 CFR Part 167 (1998), to further explain the establishment registration and reporting requirements.

During January 2016, an option has been added to allow pesticide establishment producers to electronically enter and submit their establishment registration information and pesticide production information through EPA's Central Data Exchange (CDX). Further explanation is detailed in Section 5(b).

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

FIFRA Section 7 states that required pesticide production information be reported annually as required under regulations (40 CFR 167) as the Administrator may prescribe.

2(b) Practical Utility/Users of the Data

The purpose of this reporting requirement is to obtain pesticide production information. The EPA requires this information in order to maintain current and complete records of the locations of all pesticide-producing and device-producing establishments. This information provides an overview of establishments engaged in pesticide activities and allows the Agency to target establishments for inspections with optimal utilization of limited inspection resources. Such production information permits EPA to trace ineffective, contaminated or otherwise violative products to their source, and minimizes any adverse environmental impact that might arise from the production or distribution of violative products. If this information were not collected, the Agency would be unable to meet the statutory requirements of FIFRA.

The Office of Compliance (OC) in the Office of Enforcement and Compliance Assurance (OECA) collects the establishment and pesticide production information for compliance purposes and risk assessment. This information is used by EPA Regional pesticide enforcement and compliance staffs, the OC, the Office of Civil Enforcement (OCE), and the Office of Pesticide Programs (OPP) within the Office of Chemical Safety & Pollution Prevention (OCSPP), as well as the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), other Federal agencies, States under Cooperative Enforcement Agreements, and the public.

EPA Headquarters, Regions and the States use the data for targeting inspection activities, compliance and outreach, and enforcement actions. Establishment registration and production data are used to: identify where specific pesticides are made; target inspections in response to tips or complaints of producer violations; determine where violative products found in the marketplace were produced, thus facilitating recalls of problem products; facilitate the issuance of Stop Sale, Use, or Removal Orders for violative products; help locate production sites of canceled or suspended products; and assist in notifying producers of regulatory actions or requirements.

3. Non-duplication, Consultations and Other Collection Criteria

3(a) Non-duplication

No agency besides EPA, nor any other program within EPA, requests this information. The Agency, under Section 29 of FIFRA, does collect a subset of production data for conditionally registered pesticides only. However, this production data for conditionally registered pesticides does not fulfill the requirements of Section 7 of FIFRA. Therefore, no duplication exists.

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

The Federal Register notice required by 5 CFR 1320.8(d) was published February 3, 2016 at 81 FR 5749-5750.

3(c) Consultations

There were no comments received in response to the Federal Register Notice.

3(d) Effects of Less Frequent Collection

EPA Form 3540-8 is a one-time requirement for information used to register pesticide-producing and device-producing establishments. EPA Form 3540-16 must be submitted by all establishments subject to Section 7 of FIFRA, 30 days after notification of the initial assignment of an establishment registration number, and thereafter on an annual basis. The statute dictates the time schedule in which reporting must occur. Therefore, EPA could not carry out the requirements of the statute if EPA collected such data on a less frequent reporting schedule.

Additionally, if the information were not submitted, the EPA would be unable to fulfill its statutory responsibilities relative to the review and registration of pesticides and the protection of human health and the environment.

3(e) General Guidelines

None of the reporting or record keeping requirements contained in 40 CFR 167 or otherwise pertinent to this request violate any of the regulations established by OMB in 5 CFR 1320.6.

3(f) Confidentiality

The information collected on EPA Form 3540-8 does not involve any confidentiality concerns or sensitive questions. However, pesticide and device producers must report certain confidential business information (CBI) on EPA Form 3540-16, including the amounts of pesticides/devices produced, sold, and distributed, under FIFRA Section 7 requirements. EPA safeguards trade secrets in accordance with FIFRA Sections 7(d) and 10. The Agency's copies of individual firms' reports are stored in secure file cabinets within CBI security areas. Confidential business information pertaining to specific data on any one firm cannot be released to the public.

3(g) Sensitive questions

This information collection activity does not involve any questions of a sensitive nature.

4. The Respondents and the Information Requested

4(a) Respondents NAICS Codes

Establishments producing pesticide products, pesticide chemical ingredients, and devices are subject to FIFRA. The six-digit sector/sub-sector United States North American Industry Classification System (NAICS) Codes assigned to the businesses and other institutions participating in this program include primarily Manufacturing, Sectors 31-33; and Agricultural, Forestry, Fishing & Hunting, Sector 11.

4(b) Information Requested

(i) Data Items

All data in this ICR that is recorded is required by Section 7 of FIFRA and the supporting regulations at 40 CFR 167. Under this requirement producers of pesticides and devices must report to the Agency annually the amounts of pesticides and devices produced, repackaged, relabeled; the amount sold or distributed in U.S. markets; the amount sold or distributed in Foreign markets; and the amount anticipated to be produced in the following year.

(ii) Respondent Activities

- Read instructions (provided with each EPA Form)
- Plan the reporting activity
- Gather information
- Plan and review information for accuracy
- Store, file and maintain the information
- One-time CDX registration

During the course of normal business operations, a producer would plan and maintain the information required to comply with this information collection activity, arrange for the collection, review the information for accuracy, and arrange to maintain or store the information. The information required to be reported is information that the producer would generally maintain as prudent business practices. The Agency does not specify in the regulation how the data to be gathered must be organized; however, the Agency does supply a reporting form, which provides for the reporting of the required information in a consistent manner.

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

5(a) Agency Activities

In this collection the Agency will: 1) answer companies' and producers' questions; 2) will review the data collected; 3) provide appropriate protection of confidential business information; and 4) store collected data both electronically and in paper file system.

5(b) Collection Methodology and Management

Producers determine how to best comply with the requirements for record keeping under FIFRA Section 7. They may collect and store the required data electronically or by paper copy.

The Agency in turn annually provides forms for pesticide-producing and device-producing establishments to report their collected and stored information. As of January 2, 2016, EPA also launched an optional electronic reporting option.

EPA's Office of Enforcement and Compliance Assurance, Office of Pesticide Programs and Office of Environmental Information partnered to deploy electronic reporting (eReporting) of establishment registration information (EPA Form 3540-8) and pesticide production information (EPA Form 3540-16) into the Section Seven Tracking System (SSTS). eReporting will allow producers who operate pesticide-producing or device-producing establishments to electronically enter and submit their establishment registration information and pesticide production information by way of EPA's Central Data Exchange (CDX). CDX provides a suite of services to support data collection and exchange with external partners and stakeholders such as states, tribes, localities, industry, federal agencies and other organizations or countries. This new process is an option, it is not mandatory. This process has a one-time registration requirement.

5(c) Small Entity Flexibility

The information collected under this ICR does not significantly impact small businesses, since the information being reported is that which their records would be considered as "customary and usual business activities." 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 record keeping and reporting requirements are the same for small and large 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

The collection schedule established in the regulations at 40 CFR 167.85(d) requires that each producer report pesticide and device production information within 30 days of receipt of the notification of assignment of their establishment number from the Agency; thereafter, each producer is required to report their pesticide production information by March 1st annually. The Agency will mail out notifications each December reminding producers of the March 1 reporting deadline and providing them with the link where they can obtain the forms online. The notification will also include a phone number for producers to call to request the Agency to mail them the forms, but it is expected that the majority of producers will print out the required forms from the website.

6. Estimating the Burden and Cost of the Collection

6(a) Estimating Respondent Burden

The estimates for EPA Form 3540-8 are based on discussions with the industry. The one-time submission of information is of such a nature as to demand no research of company records or calculations; it is easily completed by clerical personnel; and reviewed and signed by a company officer. The completion of the application rarely exceeds the estimated hourly rate. See Table 1 for respondent burden estimates.

Burden estimates for EPA Form 3540-16 are based on the results of interviews with a cross-section of industry respondents. We asked six industry representatives of the respondent universe -- small businesses, firms with multiple establishments, and repackagers -- to estimate the amount of time they typically spent gathering, compiling and filling out information for the report.

From these interviews we learned that, generally, the information is already assembled and compiled so filling out the form involves little burden. See Table 2 for the respondent burden estimates for EPA Form 3540-16.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

Since the regulation and associated information collection has a minor economic impact on respondents, a regulatory impact analysis was not conducted. 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 2015 National Industry-Specific Occupational Employment and Wage Estimates for the industry NAICS code 325300 (Pesticide, Fertilizer and other Agricultural Chemical Manufacturing), which is presumed to dominate this sector. The mean hourly wage rates for NAICS code 325300 were: management, \$57.78; technical (engineering), \$43.24; and clerical (administrative), \$19.62. A factor of 1.00 was added to adjust for benefit costs, resulting in respective total wage costs of \$115.56, \$86.48, and \$39.24.

Application for Registration of Pesticide-Producing and Device-Producing Establishments (EPA Form 3540-8):

Public reporting burden for this collection of information is estimated to average 0.30 hours (18 minutes) per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing the review and collection of information. Optional CDX registration is a one-time activity estimated to take 30 minutes per respondent.

Pesticide Report for Pesticide-Producing Establishments (EPA Form 3540-16)

Public reporting burden for this collection of information is estimated to average 1.43 hour (1 hour and 26 minutes) per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the review and collection of information. Optional CDX registration is a one-time activity estimated to take 30 minutes per respondent.

See Tables 1 and 2 for the respondent cost estimates for EPA Forms 3540-8 and 3540-16, respectively.

(ii) Estimating Capital and Operations and Maintenance Costs

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

6(c) Estimate of Agency Burden and Costs

The cost to the Government for the Application for Registration of Pesticide-Producing and Device-Producing Establishments (EPA Form 3540-8) is based on one work-year to review and process applications. Other direct costs are limited to printing costs for instructions and reporting forms, review of the data, mailing costs, etc. The number of respondents (700) are estimated based on the average annual number of applicants registering establishments over past three year periods. See Table 3 for Agency burden and cost estimates.

The cost to the Government for the Pesticide Report for Pesticide-Producing and Device-Producing Establishments (EPA Form 3540-16) is based on one work-year to review and process production reports. Other direct costs are limited to printing costs for instructions and reporting forms. The number of respondents is the number of active pesticide-producing and device-producing establishments registered with EPA (14,730). See Table 4 for Agency burden and cost estimates.

This ICR consolidated all government labor costs to that of a GS-12 step 1, as the bulk of the work is performed at this level. The minor shares of burden carried by management and clerical staff have been judged approximately equal and thus balance out if the entire burden is estimated at the GS-12/1 level.

The estimates for Agency costs for EPA Forms 3540-8 and 3540-16 are shown in Tables 3 and 4, respectively.

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

As of December 2015, there were 14,730 active pesticide-producing and device-producing establishments registered with EPA. While the actual number of registered establishments fluctuates somewhat, the average over the past three year period has appeared to stabilize approximately at the present level. For purposes of this ICR, EPA assumes that the number of newly registered establishments in any period of time will approximately equal the number of currently registered establishments going out of business. The total annual respondent burden is 24,079 hours (560 + 23,519) and the total annual labor costs are \$1,964,005.55 (\$52,271.52 + \$1,911,734.03). Details upon which these estimates are based appear in Tables 1 and 2: Respondent Burden.

6(e) Bottom Line Burden Hours and Cost Tables

Table 1

Respondent Burden Hours and Costs for
Application for Registration of Pesticide-Producing Establishments
(EPA Form 3540-8)

ACTIVITIES	ANNUAL BURDEN HOURS			TOTAL HOURS	TOTAL COST \$
	Management	Technical	Clerical		
	\$115.56	\$86.48	\$39.24		
a. Read or Hear Any Instructions	14	21	0	35	\$3,433.92
b. Plan Activities	0	0	0	0	\$0
c. Create Information	0	0	0	0	\$0
d. Gather Information	0	0	0	0	\$0
e. Process, Compile, and Review the Information	0	35	0	35	\$3,026.80
f. Complete Form(s)	0	70	0	70	\$6,053.60
g. Record, Disclose, Display, or Report the Information	0	35	0	35	\$3,026.80
h. Store, File, or Maintain the Information	0	0	35	35	\$1,373.40
i. One-time CDX Registration	175	175	0	350	\$35,357.00
TOTAL	189	336	35	560	\$52,271.52

Annual Burden Hour total = 560*

Annual Cost total = \$52,271.52*

* assumes 700 responses annually

*****NOTE: Numbers in the Tables (1-4) may vary slightly due to rounding**

Table 2

Respondent Burden Hours and Costs for
Pesticide Report for Pesticide-Producing Establishments
(EPA Form 3540-16)

ACTIVITIES	ANNUAL BURDEN HOURS			TOTAL HOURS	TOTAL COST \$
	Management	Technical	Clerical		
	\$115.56	\$86.48	\$39.24		
a. Read or Hear Any Instructions	$(14730 \times .10) = 1473 \text{ hours}$ $(\$115.56 \times 1473) = \$170,219.88$	$(14730 \times .15) = 2209.50 \text{ hours}$ $(\$86.48 \times 2209.50) = \$191,077.56$	0	3,682.50	$(\$170,219.88 + 191,077.56) = \$361,297.44$
b. Plan Activities	$(14730 \times .10) = 1473 \text{ hours}$ $(\$115.56 \times 1473) = \$170,219.88$	$(14730 \times .15) = 2209.50 \text{ hours}$ $(\$86.48 \times 2209.50) = \$191,077.56$	0	3,682.50	$(\$170,219.88 + 191,077.56) = \$361,297.44$
c. Create Information	0	0	0	0	\$0
d. Gather Information	0	$(14730 \times .16) = 2356.80 \text{ hours}$ $(\$86.48 \times 2356.80) = \$203,816.06$	0	2,356.80	\$203,816.06
e. Process, Compile, and Review the Information	0	$(14730 \times .17) = 2504.10 \text{ hours}$ $(\$86.48 \times 2504.10) = \$216,554.57$	0	2,504.10	\$216,554.57
f. Complete Written Form(s)	0	$(14730 \times .25) = 3682.50 \text{ hours}$ $(\$86.48 \times 3682.50) = \$318,462.60$	0	3,682.50	\$318,462.60
g. Photocopying Form(s)	0	0	$(14730 \times .10) = 1473 \text{ hours}$ $(\$39.24 \times 1473) = \$57,800.52$	1,473.00	\$57,800.52
h. Record, Disclose, Display, or Report the Information	0	0	$(14730 \times .17) = 2504.10 \text{ hours}$ $(\$39.24 \times 2504.10) = \$98,260.88$	2,504.10	\$98,260.88
i. Store, File, or Maintain the Information	0	0	$(14730 \times .08) = 1178.40 \text{ hours}$ $(\$39.24 \times 1178.40) = \$46,240.42$	1,178.40	\$46,240.42
i. One-time CDX Registration	$(4,910 \times .25) = 1,227.50 \text{ hours}$ $(\$115.56 \times 1,227.50) = \$141,849.90$	$(4,910 \times .25) = 1,227.50 \text{ hours}$ $(\$86.48 \times 1,227.50) = \$106,154.20$	0	2,455.00	\$248,004.10

Annual Burden Hour total = 23,518.90*

Annual Cost total = \$1,911,734.03*

* assumes 14,730 responses annually, and one-time CDX registration (annualized over 3 years)

*****NOTE: Numbers in the Tables (1-4) may vary slightly because of a rounding factor.**

Table 3

Annual Agency Burden/Cost Estimates for
Application and Notification for Pesticide-Producing Establishments
(EPA Form 3540-8)

[2016 GS-12/1 hourly rate is \$29.76 + \$29.76 (29.76 x 2.00 (benefits cost) = \$59.52]

ACTIVITIES	ANNUAL BURDEN HOURS	TOTAL COSTS \$
a. Respond to Inquiries	(1120 x \$59.52) = 1120	\$66,662.40
b. Review Information for Accuracy	(520 x \$59.52) = 520	\$30,950.40
c. Record Form Submission and Assign Establishment Number	(185 x \$59.52) = 185	\$11,011.20
d. Store and Maintain Data	(140 x \$59.52) = 140	\$8,322.80
e. Prepare Notification	(195 x \$59.52) = 195	\$11,606.40
TOTAL	2160	\$128,553.20

***NOTE: Numbers in the Tables (1-4) may vary slightly because of a rounding factor.

Table 4

Annual Agency Burden Cost Estimates for
Pesticide Report for Pesticide-Producing Establishments
(EPA Form 3540-16)

[2016 GS-12/1 hourly rate is \$29.76 + \$29.76 (29.76 x 1.00 (benefits cost) = \$59.52]

ACTIVITIES	ANNUAL BURDEN HOURS	ANNUAL COST
a. Preparation of Notification	(90 x \$59.52) = 90	\$5,356.80
b. Respond to Inquiries	(1375 x \$59.52) = 1,375	\$81,840.00
c. Review Information for Accuracy	(1050 x \$59.52) = 1,050	\$62,496.00
d. Record and Enter Data into Electronic Database	(1060 x \$59.52) = 1,060	\$63,091.20
e. Store and Maintain Data	(430 x \$59.52) = 430	\$25,593.60
f. Prepare Annual Solicitation/Mailings	(80 x \$59.52) = 80	\$4,761.60
TOTAL	4,085	\$243,139.20

Other Annual Agency Costs associated with Table 4:

1. Printing of Notification \$ 2,580.90
2. Postage Mailing Costs \$ 838.04

Other Annual Agency Costs \$ 3,418.94

*(Cost is from the 2014 Annual Reporting Notification on EPA Form 1335-21 01-08-2015)

Burden Cost + Other Costs are: \$243,139.20 + 3,418.94 = \$246,588.14

\$128,553.20 (Table #3) + \$246,588.14 (Table #4) = \$393,141.34

COMBINED AGENCY BURDEN COSTS FOR THIS ICR = \$393,141

*****NOTE: Numbers in the Tables (1-4) may vary slightly due to rounding.**

6(f) Program Changes and Adjustments to Burden

There is an increase of 2,805 hours in burden due to the new CDX registration option for electronic submission. This one-time burden is a program change. All other adjustments to the burden estimates resulted from (1) adjustments in the salary computation for industry to reflect current wage scales, (2) adjustments in the salary computation for Agency personnel to reflect current wage scales, (3) adjustments for inflation, and (4) adjustment to the number of respondents.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1.45 hours per response, plus 30 minutes for respondents who are first-time CDX registrants. 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, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OECA-2011-0824, which is available for online viewing at www.regulations.gov, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566-1752. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public 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 above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OECA-2011-0824 and OMB Control Number 2070-0078 in any correspondence.

Part B of the Supporting Statement

This part is not applicable to this collection.