

**SUPPORTING STATEMENT  
ENVIRONMENTAL PROTECTION AGENCY**

**Pesticide Establishment Application, Notification of Registration and Pesticide Production Report for Pesticide-Producing and Device-Producing Establishments (40 CFR Part 167) (Renewal)**

**1. Identification of the Information Collection**

**1(a) Title of the Information Collection**

Application for Registration of Pesticide-Producing and Device-Producing Establishments (EPA Form 3540-8); Notification of Registration of Pesticide-Producing and Device-Producing Establishments and Pesticide Report for Pesticide-Producing and Device-Producing Establishments (EPA Form 3540-16). EPA ICR Number: 0160.10 (Renewal).

**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 1<sup>st</sup> 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.

## **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 November 29, 2011 at 76 FR 73620-73622.

### **3(c) Consultations**

One comment was received in response to the Federal Register Notice. However, EPA was unable to respond promptly to the commenter since the representative did not provide any contact information. The comment was submitted by a regulatory compliance consulting company affected by this ICR. This comment is addressed below.

The private consulting company, Lighthouse Product Services (LPS), submitted a comment directed toward the application process for requesting and receiving an EPA establishment registration number. LPS stated that filing an initial report 30 days after the assignment of the establishment registration number is an unnecessary burden of time, when production reports must be filed yearly by March 1<sup>st</sup>. This concern is directly answered in Sections' 1(b), 2, 3(a) and (d) of this Supporting Statement that details the need and use of the data collected under this ICR.

### **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

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.

### **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 1<sup>st</sup> 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 2010 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, \$55.84; technical (engineering), \$38.78; and clerical (administrative), \$17.23. A factor of 1.14 was added to adjust for benefit costs, resulting in respective total wage costs of \$119.50, \$82.99, and \$36.87.

#### 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.

#### 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.

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.

**(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) 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 (13,830) 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 November 2011, there were 13,830 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 labor costs are  $\$16,395 + \$1,528,709 = \$1,545,104$ . Details upon which this estimate is based appear in Tables 1 & 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		
	\$119.50	\$82.99	\$38.87		
a. Read or Hear Any Instructions	14	21	0	35	\$3,415.79
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	\$2,904.65
f. Complete Form(s)	0	70	0	70	\$5,809.3
g. Record, Disclose, Display, or Report the Information	0	35	0	35	\$2,904.65
h. Store, File, or Maintain the Information	0	0	35	35	\$1,360.45
<b>TOTAL</b>	<b>14</b>	<b>161</b>	<b>35</b>	<b>210</b>	<b>\$16,394.84</b>

Annual Burden Hour total = 210\*

Annual Cost total = \$16,395\*

\* assumes 700 responses annually

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

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		
	\$119.50	\$82.99	\$38.87		
a. Read or Hear Any Instructions	1383	2074.5	0	3457.5	\$337,431.26
b. Plan Activities	1383	2074.5	0	3457.5	\$337,431.26
c. Create Information	0	0	0	0	\$0
d. Gather Information	0	2212.8	0	2212.8	\$183,640.27
e. Process, Compile, and Review the Information	0	2351.1	0	2351.1	\$195,117.79
f. Complete Written Form(s)	0	3457.5	0	3457.5	\$286,937.93
g. Photocopying Form(s)	0	0	1383	1383	\$53,757.21
h. Record, Disclose, Display, or Report the Information	0	0	2351.1	2351.1	\$91,387.26
i. Store, File, or Maintain the Information	0	0	1106.4	1106.4	\$43,005.77
TOTAL	2766	12170.4	4840.5	19,776.9	\$1,528,708.75

Annual Burden Hour total = 19,776.9\*

Annual Cost total = \$1,528,709\*

\* assumes 13,830 responses annually

**\*\*\*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)

ACTIVITIES	ANNUAL BURDEN HOURS	TOTAL COSTS \$
a. Respond to Inquiries	1120	\$69,440
b. Review Information for Accuracy	520	\$32,240
c. Record Form Submission and Assign Establishment Number	185	\$11,470
d. Store and Maintain Data	140	\$8,680
e. Prepare Notification	195	\$12,090
TOTAL	2160	\$133,920

Other Annual Agency Costs associated with Table 3:

- Postal Mailing Costs . . . . . \$ 590  
Other Annual Total Costs . . . . . \$ 590

Burden Cost + Other costs are: \$133,920+ \$590 = \$134,510

**\*\*\*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)

ACTIVITIES	ANNUAL BURDEN HOURS	ANNUAL COST
a. Preparation of Notification	90	\$5,580
b. Respond to Inquiries	1375	\$85,250
c. Review Information for Accuracy	1050	\$65,100
d. Record and Enter Data into Electronic Database	1060	\$65,720
e. Store and Maintain Data	430	\$26,660
f. Prepare Annual Solicitation/Mailings	80	\$4,960
TOTAL	4085	\$253,270

Other Annual Agency Costs associated with Table 4:

1. Printing of Notification . . . . . \$ 4,250
2. Postage Mailing Costs . . . . . \$ 4,438

Other Annual Agency Costs . . . . . \$ 8,688

Burden Cost + Other Costs are: \$253,270 + \$8,688 = \$261,958

\$134,510 (Table #3) + \$261,958 (Table #4) = \$396,468

**COMBINED AGENCY BURDEN COSTS FOR THIS ICR = \$396,468**

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

### **6(f) Program Changes and Adjustments**

No program changes occurred affecting the burden estimates of this ICR. Adjustments to the burden estimates per response 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. 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](http://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](http://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.