

**SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

TITLE: Notice of Supplemental Distribution of a Registered Pesticide Product

OMB No.: 2070-0044

EPA No.: 0278.13

1(b) Short Characterization/Abstract

This information collection activity notifies the Environmental Protection Agency (EPA) of supplemental distribution of registered pesticide products. As mandated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is responsible for the regulation of pesticides. Section 3 (e) of FIFRA (7 U.S.C. 136a (e)) allows pesticide products with the same formulation, label claims, and manufacturer as a registered product to be distributed under the same registration as the basic product (see Attachment A). Pesticide registrants may distribute or sell registered pesticides under a different product name in addition to the registered name, or under a different entity's name and address. Such distribution and sale is termed "supplemental distribution" and the product is termed a "distributor product." EPA requires pesticide registrants who enter into supplemental distribution agreements with other companies to submit EPA Form 8570-5, *Notice of Supplemental Distribution of a Registered Pesticide Product* (see Attachment B). Supplemental registrations are only an extension of a currently federally registered pesticide product.

Distributor products must reflect any changes in formulation or labeling made to the basic registered product within the same timeframe imposed on that product. A distributor is considered an agent of the registrant; both the registrant and the distributor may be held liable for violations pertaining to the distributed product. In addition to notifying the Agency, an individual or entity may become a distributor upon meeting the regulatory conditions. Distributor products must be the same as the registered product, and may not be repackaged (must remain in the producer's unopened container); distributor product labels must bear qualifications such as "distributed by," or "sold by;" the labeling must bear the same claims as the basic registered product -- with the exception of deletion of specific claims. In addition, although the distributed product's name may be different from that of the registered product, it may not be misleading. This information collection request (ICR) is a proposed renewal of an existing ICR currently approved by Office of Management and Budget (OMB) that is due to expire on October 31, 2021.

EPA is currently developing a new ICR that will consolidate this and several other approved ICRs. The consolidated ICR will include any updates to the information collection activities covered by this ICR. The renewal of this ICR will ensure there is no lapse in approval of this ICR while the new, consolidated ICR is under development. When the consolidated ICR is approved, EPA plans to discontinue this ICR.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

This information is required to be submitted pursuant to Section 3 (e) of FIFRA, as amended. Regulations pertaining to supplemental distribution of pesticide products are contained in Title 40 CFR Part 152.132 (see Attachment C).

2(b) Practical Utility/Users of the Data

Section 3 (e) of FIFRA requires pesticide registrants to notify the Agency when they enter into an agreement with a second company to distribute the registrant's product under the second company and product's name. The distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. EPA's Office of Pesticide Programs (OPP) is responsible for maintaining information about supplemental distribution agreements.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non duplication

This is the only information collection activity of its kind, performed only once per receipt of a notice of distributor registration. Therefore, the possibility of duplication does not exist.

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

EPA published a notice in the Federal Register announcing a 60-day public notice and comment period on the draft ICR on August 17, 2020 (85 FR 50022). EPA received no public comments in response to this notice, which is available in the docket for this ICR and can be accessed at <http://www.regulations.gov> using the docket identifier EPA-HQ-OPP-2016-0108.

3(c) Consultations

For the previous ICR, as required under 5 CFR 1320.8(d)(1), EPA staff contacted three respondent representatives to seek feedback on the burden estimates in the ICR and the clarity of guidance provided. Two of the representatives responded. In summary, both agreed that our burden estimates and rates were accurate, and they did not suggest changes to our collection process. Both suggested that e-submission would reduce their reporting burden. The Agency is working toward the goal of full electronic submissions, including addressing CBI issues. Our questions and their responses in full are in our docket (Attachment D).

In addition, EPA is currently developing a new ICR that will consolidate this and several other approved ICRs. The consolidated ICR will include any updates to the information collection activities covered by this ICR.

3(d) Effects of Less Frequent Collection

This activity is only conducted once per "event" (one notification is submitted per product); it is not possible to reduce the frequency of the collection. EPA must maintain the current frequency of this collection under FIFRA Section 3 (e).

3(e) General Guidelines

Long-term recordkeeping: The only PRA-imposed guideline in 5 CFR 1320.6 that may be exceeded in this collection is the record-keeping retention period. The registrant and the distributor are expected to maintain copies of their distribution agreement (EPA Form 8570-5) as long as the registration is valid or until the parties notify EPA that they have voluntarily dissolved the distribution agreement. Registrations are valid unless they are voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration as a result of the Registration Review Program or an adverse finding by the Agency.

Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA-imposed guideline indicating that data, other than health, medical, or tax records need not be retained for more than 3 years generally will be exceeded in this program.

Electronic submissions: OMB regulations require agencies to provide a statement indicating whether the proposed 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 an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). At this time, OPP is not offering a fully electronic submission option but will soon be offering the option to submit via the Agency's Central Data Exchange (CDX) Portal. As this information collection request indicates, both the basic product registrant and the distributor must sign the required notification. While EPA Form 8570-5 is available and fillable online, the form currently needs to be printed out to be signed. Once the 8570-5 form is signed by both parties, it may be mailed or submitted as a pdf via the CDX Portal.

The CDX Portal is the Agency's way to extend full electronic submission options in keeping with the June 22, 2012 OMB memo on "Reducing Reporting and Paperwork Burdens" and other related policy and guidance. Electronic submission via the CDX Portal should reduce the time needed to complete the form and the activities described in Sections 4 and 5 of this ICR while improving the overall quality of submissions.

3(f) Confidentiality

Product distributorship data submitted by basic product registrants under FIFRA Section 3(e) are considered by OPP to contain no confidential business information (CBI).

3(g) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, this information collection activity complies with

provisions of the Privacy Act of 1974 and OMB Circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

Potential respondents are individuals or firms engaged in registration and distribution of pesticide products. The North American Industrial Classification System (NAICS) code for businesses participating in this program is **325320** (Pesticide and other Agricultural Chemical Manufacturing).

4(b) Information Requested

(i) Data Items, Including Record Keeping Requirements

Pursuant to 40 CFR 152.132, supplemental distribution of a registered pesticide is permitted if the registrant meets all of the conditions and submits a completed and signed EPA Form 8570-5, *Notice of Supplemental Distribution of a Registered Pesticide Product*. Sub-section 152.132 (a) requires the registrant to furnish the following information:

- EPA registration number of the product to be distributed;
- EPA-assigned distributor company number;
- Name of the registered product to be distributed;
- Name and address of the basic product registrant;
- Name to be used on the distributed product;
- Name and address of the distributor;
- Signature and title of the distributor and date signed; and
- Signature and title of the basic product registrant and date signed.

(ii) Respondent Activities

For each distributor product, the basic product registrant must send to EPA a completed Form 8570-5, signed by both the basic product registrant and the distributor (see Attachment E for instructions and EPA’s requirements). Responsibility for regulatory compliance rests primarily with the basic product registrant. However, both the registrant and the distributor may be held liable for any violation of FIFRA.

A registrant wishing to distribute a registered product under a different name or through a different company goes through the process summarized below:

Summary of Steps to Notify EPA of Supplemental Distribution Agreement

Read	Read form and instructions;
Request	If necessary, obtain an EPA company number for the supplemental distributor;
Compile	Assemble information; review for accuracy and completeness;

Submit	Submit EPA Form 8570-5 to the Agency;
Store	File or otherwise maintain the information.

Before distribution and sale of EPA-registered pesticides, a company must have an EPA-assigned company number. If the distributor company is different from the registrant of the product and has not previously obtained an EPA company number, the company needs to obtain one before submitting the form to EPA (see Attachment F for instructions on how to obtain an EPA company number).

The Agency estimates that one-third of the responses submitted to EPA on Form 8570-5 are completed using newly-assigned company numbers. This is a conservative estimate because the number of entities submitting requests to EPA for company number assignment as part of the process for a supplemental distribution agreement is often very low compared to the total number of forms that use newly-assigned distributor company numbers. The primary reason for such a discrepancy is that companies often establish multiple distribution agreements for multiple products, either with the same or with different registrants, and notifications for all of those products get submitted around the same time period. The exact number of company number requests that are submitted specifically for the purposes of becoming a distributor cannot be determined at this time, and EPA has used a larger estimate of one-third.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

Upon receipt of Notices of Supplemental Distribution of a Registered Pesticide Product, EPA Form 8570-5, the front-end process involves the following activities:

- receive distribution notices;
- pin-punch forms with date of receipt;
- make copies of the forms;
- screen forms for completeness of information; contact the registrant when needed;
- send letters of receipt to the registrants, including copies of the pin-punched forms;
- if items need to be corrected, include a correction checklist with the letter;
- send forms for review and follow up by product teams where the original product was registered;
- enter information from reviewed forms in database under the basic registration file; and,
- scan original forms into an electronic filing system.

Consistent with labeling regulation [40 CFR 156.10](#), starting in 2010, a product team reviews the product information submitted on the form. The team verifies the registered product information and ensures that the distributor product name is in compliance with labeling as well as

supplemental distribution regulations. If needed, EPA staff follows up with the registrant through the OPP division where the original product is registered. After product team review, the information is entered in an electronic database under the original registration of the product. The pin-punched forms are maintained in electronic records.

Summary of Steps for Reviewing and Recording Notification Information

Assign	Assign an EPA company number to the supplemental distributor if the company does not already have one.
Verify	Verify the regulatory status of the primary registration that is to be supplementally distributed;
Acknowledge receipt	Provide receipt of the supplemental distribution notice by mailing a copy of it to the distributor company;
Product information review	Check distributor product information; if necessary, follow-up with registrant; make decisions.
Process information	Enter information from EPA Form 8570-5 (Notice of Supplemental Distribution of a Registered Pesticide Product) into an electronic "Distributor File," a part of the Office of Pesticide Programs Integrated Network (OPPIN);
File and maintain information	Electronically file date-stamped form in the regulatory file of the parent Section 3 registration. This file is maintained by OPP at the Information Services Center.

5(b) Collection Methodology and Management

Registrants voluntarily enter into agreements with distributors. They are required, under FIFRA, to notify the Agency of these agreements. EPA maintains the original notifications in the regulatory file of the parent Section 3 registration at the OPP Information Services Center.

5(c) Small Entity Flexibility

Most of the companies participating in this program would qualify as small entities. The Agency closely examined potential burdens to small entities and instituted changes to this program in 1984. At that time, OMB approved the changes. The Agency also re-evaluated the general burden categories in 1986. The Agency believes that the burden imposed by this activity has been minimized to what is believed to be the minimal level at which this program can effectively function under the requirements specified in the FIFRA and the regulations for the enforcement of FIFRA.

5(d) Collection Schedule

Not applicable. This activity is conducted only once per "event" when the registrant submits a Notice of Supplemental Distribution of a Registered Pesticide Product, to the Agency. Therefore, there is no set schedule for collection of this information.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

The burden associated with this collection of information is estimated to be approximately 19 minutes per response. To complete Form 8570-5, a distributor’s EPA-assigned company number must be included. Distributors without an EPA company number must send a formal request letter on company letter-head to the Agency to get one assigned (Attachment F). EPA estimates that one-third of the responses submitted to EPA on Form 8570-5 are completed using newly-assigned company numbers. This is a conservative estimate; the actual number may be much lower because companies often enter into distributor agreements to distribute two or more registered products. The number of entities submitting requests to EPA for company number assignment during the reporting period is far fewer than the total number of forms that use newly-assigned distributor company numbers.

Due to an overall increase in the number of supplemental distribution notifications received by the Agency over the last several years, the total burden hours has increased. Whereas EPA had expected to receive about 1,451 notice submissions annually over the past 3 years, based on the actual number of submissions received annually over that period (1,904 in FY2012, 1,822 in FY2013, and 1,930 in FY2014), the Agency now expects to receive about 1,885 notice submissions annually over the next 3 years. Given this change, EPA estimates the total annual burden associated with the notice of supplemental distribution of a registered pesticide product to be 603 hours, as shown below:

$$\begin{aligned}
 & \textit{Total annual notification burden for forms} \\
 & = \text{ number of ALL responses per year } \times \text{ time to complete notification} \\
 & = 1,885 \times 0.32 \text{ hours} \\
 & = 603.2 \text{ hours}
 \end{aligned}$$

*Total annual respondent burden is estimated to be = **603 hours***

6(b) Estimating Respondent Costs

Consistent with recent ICR renewals, OPP is using labor cost estimates from Agency economists with respect to wages, benefits and overhead for all labor categories for affected industries, state government, and EPA employees. This approach uses a transparent and consistent methodology and current publicly-available data to provide more accurate estimates and allow easy replication of the estimates.

Table 1. Methodology Used to Calculate Labor Costs

Labor Cost Approach	Description
<i>Methodology:</i>	The methodology uses data on each sector and labor type for an <i>Unloaded wage rate</i> (hourly wage rate), and calculates the <i>Loaded wage rate</i> (unloaded wage rate + benefits), and the <i>Fully loaded wage rate</i> (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses data from 2014,

	which is the most recent.
<i>Unloaded Wage Rate:</i>	Wages are estimated for occupations (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm .
<i>Sectors:</i>	The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).
<i>Loaded Wage Rate:</i>	Benefits represent 46.3% of unloaded wage rates, based on benefits for all civilian non-farm workers, from http://www.bls.gov/news.release/ecec.t01.htm .
<i>Fully Loaded Wage Rate:</i>	The loaded wage rate is multiplied by 50% (EPA guidelines 20-70%) to get overhead costs.

A copy of the formula work sheets used to estimate the labor rates and to derive the registrants' fully loaded rates and overhead costs for this renewal are listed in *Attachment G*.

Table 2. Estimated Respondent Burden/Cost per Supplemental Distribution Application

REGISTRANT	HOURS, RATES			TOTAL	
	<i>Mgmt, \$/hr</i>	<i>Technical, \$/hr</i>	<i>Clerical, \$/hr</i>	Hours	Costs
Collection Activities	\$135.39	\$69.33	\$45.19		
Read instructions	0.08	-	-	0.08	\$10.83
Process, compile, review information for accuracy and appropriateness	0.05	-	-	0.05	\$6.77
If necessary, obtain an EPA company number for the supplemental distributor	-	-	0.08	0.08	\$3.62
Complete and submit EPA Form 8570-5	0.03	-	-	0.03	\$4.06
Store, file, or maintain information	-	-	0.08	0.08	\$3.62
Total	0.16	0	0.16	0.32	\$28.89

ANNUAL BURDEN: **603 Hours** (= 0.32hrs X 1,885 responses)

ANNUAL COSTS: **\$54,463** (=0.32hrs X \$28.89 average hourly wage rate)

6(c) Estimating Agency Burden and Cost

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of labor rates for the North American Industry Classification System code for the Federal Executive Branch (NAICS 999100). Historical Submissions

Table 3 summarizes the Agency process in reviewing the supplemental distribution applications, with associated hours and costs for each task. A copy of the formula work sheets used to estimate the labor rates and to derive the Agency's fully loaded rates and overhead costs for this renewal are listed in *Attachment H*.

Table 3. Estimated Agency Burden/Cost per Supplemental Distribution Application

AGENCY	HOURS, RATES *			TOTAL	
	Mgmt, \$/hr	Technical, \$/hr	Clerical, \$/hr	Hours	Costs
Collection Activities	\$124.09	\$81.53	\$46.42		
If necessary, assign an EPA company number to the supplemental distributor. ¹	-	-	0.08	0.08	\$3.71 ¹
Verify, acknowledge receipt ²	-	-	0.03	0.03	\$1.39
• Initial product screening ³	-	0.36	-	0.36	\$29.35
• Product review meeting ³	0.63	-	-	0.63	\$78.18
• Process disapproved product distribution information ³	-	0.42	-	0.42	\$34.24
Process: Enter form information into electronic file in OPPIN	-	0.5	-	0.5	\$40.77
File and maintain information	-	0.02	-	0.02	\$1.63
Total	0.63	1.3	0.11	2.04	\$59.20⁴

* U.S. Department of Labor, Bureau of Labor Statistics. (2014) *May 2014 National Industry-Specific Occupational Employment and Wage Estimates; NAICS 999100 – Federal Executive Branch (OES Designation)*. Available from BLS Web site at http://www.bls.gov/oes/current/naics4_999100.htm

¹This step is only necessary in a third of cases based on conservative estimates from historical data. In the calculations the maximum time was used, but the expected cost \$1.24 (1/3 * \$3.71) was used for total.

²Approximately 90% of forms received by EPA are completed correctly and undergo standard processing, requiring only clerical and technical labor types.

³The rest of the forms (approximately 10%) require review by the Agency's product review team, requiring all three types of labor. In the calculations the maximum time was used, but the expected cost \$14.18 [10% * \$141.77 (29.35+78.18+34.24)] was used for total.

⁴\$1.24 (footnote 1) + \$1.39 + \$14.18 (footnote 3) + \$40.77 + \$1.63 = \$59.20

The total annual Agency burden associated with the notice of supplemental distribution of a registered pesticide product is 1,260 hours. The tasks marked by the superscript 2 represent the review process in which some of the product information must be reviewed by the Agency to determine that supplemental distributed product names are consistent with [40 CFR 156.10 \(5\)](#) and are not “misleading.” The annual total Agency cost is \$111,592 an increase from \$76,589 of the 2012 ICR due to the increase in the average amount of submissions (2011-1,451 to 2014-1,885), and the wage rate.

6(d) Bottom Line Burden Hours and Cost Tables**Total Annual Respondent and Agency Burden and Costs**

	Total	
	Hours	Costs
Annual Respondent Burden/Cost Estimates	603	\$54,463
Annual Agency Burden/Cost Estimates	1260	\$111,592

6(e) Reasons for Change in Burden

The total annual respondent burden associated with the notice of supplemental distribution of a registered pesticide product is 603 hours, a 216 hour increase from 387 hours estimated in the ICR from 2012. This increase is an adjustment based on the average number of supplemental registrations received by the EPA over the last three years which was approximately 1,885 responses per year (1,904 in FY2012, 1,822 in FY2013, and 1,930 in FY2014). Based on these numbers, the Agency estimates that it will receive an average of 1,885 supplemental registrations annually for the next three years.

6(f) Burden Statement

The total estimated annual respondent paperwork burden to comply with this information collection activity is 603 hours, or about 19 minutes per response. This estimate includes the time needed to review instructions; 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 respond to a collection of information; search existing 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 in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable (see Attachment I).

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2016-0108, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Room 3334, 1301 Constitution Ave, NW, Washington, DC 20460. The 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 Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

Comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden may be submitted to EPA electronically through <http://www.regulations.gov> or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C.

20460. You can also send comments to the Office of Information and Regulatory Affairs, of the Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Include docket ID No. EPA-HQ-OPP-2016-0108 and OMB number 2070-0044 in any correspondence. Follow the online instructions for submitting comments online. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

ATTACHMENTS LIST

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted), accessible electronically through <http://www.Regulations.gov> On the main page, select **Advanced Search** from the menu bar at the top and select **Docket Search**. Enter the Docket ID Number, EPA-HQ-OPP-2016-0108, in the **Docket ID** field. Click on the **Submit button**. From the results page, you will be able to link to the docket view or directly open select documents found in the docket.

Attachment A	7 U.S.C. 136a – Section 3 of FIFRA. Also available at online at the US House of Representatives' US Code website .
Attachment B	EPA Form 8570-5 - Notice of Supplemental Distribution of a Registered Pesticide Product Also online at http://www.epa.gov/opprd001/forms/8570-5.pdf
Attachment C	40 CFR Part 152.132 - Obligations and Rights of Registrants - Supplemental Distribution. Also available online at the National Archives and Records Administration's Electronic CFR Website .
Attachment D	Consultations: List of Standard Questions and Industry Responses
Attachment E	Requirements for Approval of Supplemental Distribution Also available at: http://www.epa.gov/opprd001/registrationmanual/chapter9.html
Attachment F	How to Obtain an EPA Company Number http://www.epa.gov/pesticides/registrationkit/company-num_addr-chg.pdf
Attachment G	Work Sheets used to Calculate Registrant & EPA Wage Rates
Attachment H	Display Related to OMB Control #2070-0044 – Listings of Related Regulations in 40 CFR 9.1 Also available online at the National Archives and Records Administration's Electronic CFR Website .