

**SUPPORTING STATEMENT FOR  
AN INFORMATION COLLECTION REQUEST (ICR)**

**1. IDENTIFICATION OF THE INFORMATION COLLECTION**

**a) Title: Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2)**

**ICR Nos.: OMB No. 2070-0039; EPA No. 1204.13**

**Docket ID No.: EPA-HQ-OPP-2017-0687**

**b) Abstract**

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency which may be relevant to the balancing of the risks and benefits of a pesticide product. The statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an *unreasonable* adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, the EPA has limited the scope of factual information that the registrant must submit. The Agency's regulations at 40 CFR part 159 provide a detailed description of the reporting obligations of registrants under FIFRA section 6(a)(2).

**2. NEED FOR AND USE OF THE COLLECTION**

**a) Need/Authority for the Collection**

This information collection stems from a non-discretionary statutory requirement. Submission of information about unreasonable adverse effects is specifically required under FIFRA section 6(a)(2) of (7 U.S.C. 136d(a)(2)) see Attachment A:

"If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator."

The Agency's FIFRA section 6(a)(2) regulations are codified in the Code of Federal Regulations (CFR) at 40 CFR part 159 (Attachment B), and Agency guidance is available in Pesticide Registration (PR) Notice 98-3 (Attachment C).

In terms of scope, please note that in CSMA and NACA v. EPA, 484 F. Supp. 513 (1980), the U.S. District Court for the District of Columbia agreed with EPA that FIFRA section 6(a)(2) covers all information relevant to EPA's determination of whether a pesticide may cause unreasonable adverse effects. The Court agreed that permissible information includes the same type of information as that provided by a registrant as part of an application for registration. The Court specifically rejected the argument that the responsibility for determining what constitutes an unreasonable adverse effect shifts to industry once EPA has granted a registration.

**b) Practical Utility/Users of the Data**

The Office of Pesticide Programs (OPP) is the primary user of the information that registrants submit to the Agency under FIFRA section 6(a)(2). The information submitted is an essential component of the Agency's pesticide registration and registration review programs which also require the submission of important information regarding a pesticide's adverse effects, information which may not have been available at the time of the Agency's initial review of a registration application. Because this information has potentially significant consequences for human health or the environment, the Agency's determination with regard to the registration of the pesticide may have been different if the information had been available earlier. If warranted by the information provided, EPA may seek to amend the registration in order to address the concerns raised by the information.

The adverse effects information submitted under section 6(a)(2) provides an important means of focusing EPA attention on key problem areas regarding the use of a particular pesticide. This information is considered by EPA in conjunction with other information to determine whether pesticide products containing a specific active ingredient should be reregistered, or whether the terms and conditions of registration should be changed. This type of information may also be pertinent to granting emergency exemptions under section 18 of FIFRA.

Registrants perform studies in support of registration applications, in response to data call-ins issued by EPA, or voluntarily for their own purposes. The Agency has the authority to call-in data (a.k.a. DCI "data call-in") under section 3(c)(2)(B) of FIFRA, and the accounting for the burden hours and costs for all OPP program DCIs is documented in the ICR entitled the *Pesticide Data Call-In Program ICR*, OMB #2070-0174; EPA # 2288.02. The outcome of studies, whether they demonstrate known effects or new adverse effects, are carefully analyzed by registrants and presented to the Agency. The 6(a)(2) rule does not impose the requirement to perform studies but merely to identify and promptly submit adverse effects information to the Agency when they are identified.

A number of registrants have indicated that the type of information collected under FIFRA 6(a)(2) is valuable to them as well. Registrants may actively seek unanticipated and/or adverse effects information as part of product stewardship, improving customer relations, minimizing liability, or protecting or expanding market share. According to feedback that EPA has received, registrants acquire and use this information to determine whether actual product use patterns reveal risk issues that did not emerge when the data were developed for the original registration application. These registrants believe that it is an integral part of their product stewardship program and that collecting, analyzing and reacting to adverse effects information is essential to the way in which they conduct business as a routine matter. For example, Consumer Specialty Products Association (CSPA), the trade association for registrants of antimicrobial pesticide products, has a voluntary stewardship program for their members called Product Care® (<https://www.cspa.org/sustainability/product-care-stewardship/>). As noted on the CSPA Product Care® website, Product Care® companies routinely gather marketplace and incident information and evaluate it and make appropriate product changes. However, the stewardship programs are not required by the Paperwork Reduction Act (PRA) and are at the registrant's discretion. Therefore, these programs are not directly related to burden due to the information collection.

### **3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA**

#### **a) Non-Duplication**

The information required to be submitted under this ICR is generally available only from registrants who have opted to secure registration of their pesticide product(s). The only feasible means of collecting the required information is from pesticide registrants because it is either health and safety data that is generated, owned or used by the registrants, or it is submitted to registrants by consumers and other interested parties. This information collection avoids duplication by limiting the submission requirements under FIFRA section 6(a)(2) to information which has not been submitted to the OPP previously. Further, it exempts information submitted under section 8(e) of the Toxic Substances Control Act (TSCA). Information in published articles is generally also exempt from submission.

#### **d) Consultations**

As required under 5 CFR 1320.8(d)(1), EPA sent consultation questionnaires to Canberra Corporation, Clean Control Corporation and Syngenta Corporation seeking feedback on the adverse effect information reporting requirements and processes, as well as an assessment of the burden estimates associated with this effort. EPA did not receive any comments or responses to the questionnaires. A copy of the questionnaire is available in the docket EPA-HQ-OPP-2017-0687. (Attachment D)

#### **c) Public Notice Required Prior to ICR submission to OMB**

As part of the renewal process, EPA published a notice in the **Federal Register** seeking public comment on the renewal ICR and related burden estimates (83 FR 5625, April 4, 2018). During the 60-day comment period, EPA received 28 comments; however, none of the comments provided information about the ICR that would prompt EPA to adjust or revise the estimated burdens in this ICR. Prior to submitting the ICR to OMB, EPA will provide a 30-day comment period to provide an opportunity for additional comments. Pursuant to 5 CFR 1320.8(d), any public comments received will be placed in the EPA docket, EPA-HQ-OPP-2017-0687, for this action.

#### **d) Effect of Less Frequent Collection**

Under FIFRA section 6(a)(2), the information collection activity is a one-time, non-repetitive submission of information. As such, there is no set interval for multiple collections. The information is submitted one time, according to the timeframes described in the rule for various categories of information.

#### **e) General Guidelines**

Section 6(a)(2) regulations do not prescribe specific recordkeeping requirements, but the EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the typical period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that

data other than health, medical or tax records not be required to be retained for more than 3 years will be exceeded for those studies which are required to support registration or registration review under FIFRA section 3, and which show adverse effects that make them reportable under section 6(a)(2). The burdens associated with this recordkeeping requirement have already been approved by OMB under another ICR and are therefore excluded from this ICR.

**e) Confidentiality**

Much of the information submitted pursuant to section 6(a)(2) constitutes FIFRA section 10(d)(1) safety and efficacy information. On September 28, 1999, the Agency issued a class determination that safety and efficacy information submitted under section 6(a)(2) of FIFRA is not entitled to confidential treatment, Attachment E. The determination enables the Agency to respond more quickly and efficiently to requests for information submitted under section 6(a)(2).

Data submitted to the Agency are handled in accordance with the provisions of the FIFRA Confidential Business Information (CBI) Security Manual which provides procedures for protecting information claimed as confidential in accordance with FIFRA section 10. If the information is not protected under FIFRA section 10, and it is not otherwise protected from release under the Freedom of Information Act (FOIA), EPA is obligated to make it available to members of the public upon request under FOIA.

**f) Sensitive Questions**

If information of a sensitive nature is submitted as part of this information collection, the Agency will protect it appropriately, as provided by the Privacy Act or other relevant statutes.

**4. THE RESPONDENTS AND THE INFORMATION REQUESTED**

**a) Respondents/NAICS Codes**

Potential respondents affected by the collection activities under this ICR include anyone who holds or ever held a registration for a pesticide product issued under FIFRA section 3 or 24(c). The North American Industrial Classification System (NAICS) code is 325300 (Pesticide and Other Agricultural Chemical Manufacturing).

**b) Information Requested**

**i) Data Items**

As further defined by the final rule implementing the FIFRA section 6(a)(2) requirements (62 FR 49639), registrants are required to report on:

- (1) Studies showing new or more severe toxicological responses than previously reported of any type in any strain of test organism, (40 CFR 159.165).
- (2) The fact that a study has been discontinued before planned, if submission of information concerning the study is, or would have been, required (40 CFR 159.167).
- (3) Epidemiological or exposure studies of human population groups indicating greater exposure than previously reported (40 CFR 159.170).
- (4) Information on excess residues on food or feed, and residues in surface water, ground water or drinking water (40 CFR 159.178).
- (5) Information on metabolites, degradates, contaminants or impurities which may be of

toxicological concern (40 CFR 159.179).

(6) Incidents involving toxic or adverse effects to human or other non-target organisms (40 CFR 159.184).

(7) Studies, incidents, or other information showing lack of efficacy of certain pesticide products with public-health related uses, plus certain information for any incident of a pest having developed resistance to any pesticide (40 CFR 159.188); and

(8) Other information which may be relevant to risk/benefit determinations of any type (40 CFR 159.195).

In addition, in compliance with 40 CFR 159.160, a former registrant is required to submit information for a period of 5 years after the registration of the pesticide product has been cancelled or transferred to another registrant.

Since the last ICR was approved, the EPA has found it necessary to request additional data in certain subject areas under 40 CFR 159. In 2009, EPA noticed an increase in adverse reaction reports involving the use of spot-on pesticide products for pets. Incidents in pets ranged from skin irritation to death, and several class-action lawsuits were filed against the product producers and registrants. EPA formed a veterinarian team to thoroughly analyze the existing data. EPA also partnered with the Food and Drug Administration's Center for Veterinary Medicine and Health Canada's Pest Management Regulatory Agency, EPA's counterpart agency in Canada, on the review of this analysis. In order to advance the EPA's efforts to mitigate adverse effects from spot-on products used on pets the Agency meet with spot on product manufacturers to discuss product-specific mitigation (<https://www.epa.gov/pets/meetings-registrants-pet-spot-products>). By March 2010, EPA announced the results of the evaluation(<https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects#report>, and after consulting with industry, EPA began requiring more standardized post market surveillance reporting on adverse effects and submission of sales information so the Agency can better evaluate incident rates.). Based on the evaluation, and after receiving over 1100 public comments on the proposed pet spot on analysis and mitigation plan (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0229-0001>, EPA initiated changes to mitigate the adverse effects of spot-on products, which asked companies provide a standardized report for pet incidents, and implement label changes for spot on products for cats and dogs to prevent unreasonable adverse effects and ensure the safety of these products.

Additionally, in 2013, new concerns about neonicotinoid pesticides and the loss of bee colonies and the economic impact on the industry that bee colony collapse creates. EPA requested more documentation from registrants for these products (see Attachment F). In response to numerous bee kills and colony losses worldwide, registrants of certain neonicotinoid products were asked to report honeybee kill incidents quickly and in fuller detail. EPA is concerned about declines in pollinator health and is working to protect bees and other pollinators from pesticide risks through regulatory actions, voluntary changes to pesticide use by registrants and research programs aimed at increasing the understanding of factors associated with declining pollinator health. This information will assist the EPA in its attempt to understand what role pesticides may be playing in pollinator declines.

ii) Respondent Activities

Respondents must:

- (1) read the final rule or instructions;
- (2) plan activities to ensure required information is identified and submitted;
- (3) process, compile, and review information for accuracy and appropriateness;
- (4) complete written instruments to effectuate a submission; and
- (5) submit the information to EPA.

Under FIFRA section 6(a)(2), as implemented by the regulations in 40 CFR part 159, pesticide registrants have no obligation to create or seek out adverse effects information. Such activities may be conducted by the registrant in support of pesticide registration under FIFRA section 3 and registration review under section 3(g). The burden for these activities is approved by OMB under separate ICRs. Registrants may collect adverse effects information in the normal course of business, such as following up on consumer complaints to gather more information. Regardless of how the information comes into the possession of the registrant, once the registrant acquires information subject to submission under section 6(a)(2), as defined by the regulations, the registrant must submit it to EPA.

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

### **a) Agency Activities**

The Agency will continue the following activities with regard to the FIFRA section 6(a)(2) program: 1) answering questions and providing guidance to respondents; 2) receiving and recording data submissions; 3) storing the data submitted; and 4) screening and analyzing the information for significance.

### **b) Collection Methodology and Management**

The regulation allows flexibility in the method or format for the required submission. In essence, the regulation specifies the types of data that should be reported to the extent the information is available and the reporting time-frames. For incident information (but not studies), these vary according to the significance of the information.

Scientific studies containing 6(a)(2) information are assigned Master Record Identifier Numbers (MRIDs), as are all other pesticide studies submitted to OPP. Preliminary notification letters for 6(a)(2) science studies are assigned sequential tracking numbers in a separate series. Adverse effects incident reports are entered into a computerized database which can track incidents by chemical, submitter, type of incident, location, date of submission, and other parameters. All 6(a)(2) submissions are screened by subject matter experts throughout the pesticide program. Data are forwarded to and reviewed by pesticide product managers and science reviewers for relevance to the regulatory status of the pesticide product(s) to which the submitted information pertains. The public may access the data by making a request under FOIA.

OPP has created a CDX portal for the submission of studies. A 6(a)(2) study may be submitted electronically just as easily as a non-6(a)(2) study, but it requires more screening and tracking. Electronic incident submissions through the CDX portal is now possible, but it requires further database design. EPA will continue to work with registrants to improve fields and methods to support electronic submission. The submission technique would need to comply with the Agency's electronic submission standards.

Finally, OPP has been working to integrate its existing databases into its Office of Pesticide Programs Information Network (OPPIN) system. The current Incident Data System has been partially integrated with the Office of Pesticide Programs Information System. It draws on live chemical, product, and registration number data from OPPIN in cataloging new incidents. That development was seen as an essential precursor to electronic submission of incident data.

It should be noted that at the time the final regulations went into effect in 1998 and at the request of the regulated community, OPP staff worked with industry representatives and trade associations on voluntary forms for incident reporting. This was done by the trade associations as a service for their members. The Agency accepts incident reports using the voluntary forms as well as incidents formatted in other ways. The voluntary forms may well serve as the foundation for standardized forms, see Attachment G.

**c) Small Entity Flexibility**

Regardless of the size of the registrant, the 6(a)(2) regulations provide simplified reporting and extended reporting time-frames for most incident reports. At the present time there is no standard reporting format prescribed in the regulations, so the submitters can use a format of their choosing for incidents. While the Agency does not mandate a specific format for the required submission, as noted above, EPA has worked with industry to provide one to facilitate submissions. To further simplify compliance, EPA has issued detailed guidance (Attachment C).

The requirements of FIFRA section 6(a)(2) related to studies fall largely on basic producers, i.e., registrants that produce the active ingredient from raw materials, because they are the registrants most likely to generate and possess data subject to the information collection. Formulators (companies that do not manufacture active ingredients) are exempt from generating most health effects data required to support registration except for product-specific acute toxicity studies.

Both basic producers and formulators, however, may register and market end use products and receive incident reports from distributors and users of their products as well as other sources such as state regulatory agencies. The number of incident reports associated with a pesticide product depends on such variables as the volume of sales of that product and whether it is sold to the general public or is restricted to experienced and trained applicators. Some registrants put toll-free telephone numbers on their labels making it easy for consumers to contact them with incident reports. Other registrants, however, do not. Thus, it is difficult to generalize about the relative burden of incident reporting in terms of small versus large companies.

**d) Collection Schedule**

The information required to be submitted under FIFRA section 6(a)(2) is not based on any schedule because the information is non-repetitive in nature. As such, the information required to be submitted by respondents is generally on an "as received basis." The regulations establish time-frames within which reportable information received by registrants must be submitted to EPA. The reporting time-frames vary according to the organism exposed and the relative severity or rarity of the alleged effects. Allegations of human deaths must be reported individually by registrants within 15 days of acquiring the information. Other serious and rare incidents are reported individually. Generally, they may be accumulated for one month and

submitted by the end of the month following the accumulation period. Minor or common incidents are reported as aggregate counts of incidents and effects for each product registration number or active ingredient. They may be accumulated for three months and submitted by the end of the second month following the accumulation period.

## **6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

### **a) Estimating Respondent Burden**

To estimate the respondent burden, the Agency is using updated current statistics on the number of registrants of active products. For burden estimates related to study and incident data submissions, actual statistics for fiscal year (FY) 2013-2015 were used.

As of October 2017, there were 1,452 registrants with active registrations. The total number of registrations were 18,028 and the number of registrations held by each registrant ranged from 1 to 834. The average number of registrations was 12 and the median was 2. 644 registrants held only 1 registration, 216 registrants held 2 registrations, 294 registrants held between 3 and 5 registrations, 126 registrants held between 6 and 10 registrations, 120 registrants held between 11 and 50 registrations, 19 registrants held between 51 and 100 registrations and 33 registrants held more than 100 registrations.

Former registrants have an obligation to report adverse effects information for 1 year after the cancellation or transfer of their product so long as the former registrant holds no active registrations. Since stocks of the formerly registered products diminish, it is unlikely these former registrants would acquire or submit much adverse effects information to the Agency. Former registrants, therefore, are not included in the estimated 1,452 respondents assumed for this analysis.

The Agency received an average of 237 studies annually from FY 2013 through FY 2015. For purposes of this analysis, the Agency assumes 237 study-related submissions will be received each year for the duration of this information collection renewal.

From FY 2013 through FY 2015 the Agency received an average of 891 incident-related submissions per year from registrants containing an average of 107,798 incidents per year. Of these, 6,858 incidents were individually reported and 100,940 were reported as aggregate statistics on the yearly average. A total of 202 registrants (14% of current registrants) submitted incident reports during this time period. Registrants may report for themselves alone or they may report for themselves and related entities such as their divisions or subsidiaries. Registrant task forces such as the (DEET) Issues Task Force or the Metam Task Force may report specific types of incidents or studies for their member registrants.

A small number of incidents, an average of 717 per year, were reported by parties other than registrants. These include states, EPA regional offices, and private groups and individuals. These parties are not required to report adverse effects information to the Agency, but their reports are received and processed in the same way as registrant-submitted information.

For purposes of this ICR renewal, the Agency estimates that it will continue to receive 107,798 incident reports from the regulated community each year. It is the estimated number of incidents that drives the burden estimates in this analysis, not the total number of registrants or number of registrants represented by current incident reporting.

The level of registrant reporting would be substantially higher had it not been for action taken by the Agency to eliminate certain types of incident reports. The final regulations included the following as a condition for reporting incidents:

40 CFR 159.184(a)(2) - The registrant is aware or has been informed that the person or non-target organism suffered a toxic or adverse effect or *may suffer* a delayed or chronic adverse effect in the future. (*Emphasis added*)

A literal interpretation of the italicized language above could have resulted in registrants reporting all asymptomatic exposures. Those are cases in which someone alleges exposure to a pesticide, but is experiencing no symptoms. Or someone may call a registrant to ask if they may get sick after an exposure or to express concern that they may get sick in the future as a result of an exposure. (These were referred to as 'may suffer' incidents.) OPP consulted with a major poison control center to determine the volume of asymptomatic exposure calls they receive. According to the poison control center's statistics for a major pesticide company, nearly half the calls they handled were asymptomatic exposures. In order to focus resources, both the Agency's and registrants', on a manageable volume of useful incident reports, the Agency eliminated the requirement to report most 'may suffer' incidents. This was accomplished in PR Notice 98-4 (Attachment D), which referenced the Agency's authority under part 159.155 of the FIFRA 6(a) (2) regulations to eliminate specified requirements by written notice to registrants. Elimination of the requirement is still in effect.

Another aspect of the respondents' burden is ongoing employee training on compliance with 6(a)(2) reporting requirements. New employees would require training and experienced employees are likely to receive refresher training. Each company would plan training and track the status of training efforts. For purposes of determining the number of employees that need to be trained on adverse effects information reporting, EPA assumed an average of 10 employees per registrant or 17,500 individuals requiring training each year. This estimate is an average; the actual number would range from one person in a small company to several dozens in a large company. The Agency does not believe that a high proportion of people in any company need detailed training in 6(a)(2) requirements. Most employees who are likely to receive information concerning the effects of pesticide products are simply made aware of the need to pass information along to an appropriate individual or unit within the company that evaluates reports and prepares submissions to the Agency.

**b) Estimating Respondent Costs**

**i) Estimating Labor 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 employing publicly-available data to provide more accurate estimates and allow easy replication of the calculations.

*Methodology.* The methodology uses publicly available wage data for each sector and labor type for an *Unloaded wage rate* (hourly wage rate) and calculates the *Loaded wage rate* (unloaded wage rate + benefits) and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate the Agency's staffing costs.

*Unloaded Wage Rate.* Wages are estimated for labor types (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). (see [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)).

Sectors. The specific NAICS code and website for each sector is included in that sector's wage rate table in Attachment H. 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](http://www.bls.gov/oes/current/oes_stru.htm)).

*Loaded Wage Rate.* Unless stated otherwise, all benefits represent 46.4% of unloaded wage rates, based on benefits for all civilian non-farm workers, from <http://www.bls.gov/news.release/ecec.t01.htm>. However, if other sectors are listed for which 46.4% is not applicable, the applicable percentage will be stated.

*Fully Loaded Wage Rate.* The fully loaded wages include benefits and overhead costs. The loaded wage rate is multiplied by 50% (EPA guidelines 20-70%) to get overhead costs. Costs are indexed to 2016 data. Attachment H contains worksheets providing the breakout of these costs for respondents and the Federal Government.

Using these data and methodology, Agency economists estimated the wages for the management, technical, and clerical labor categories. The fully loaded wage rates used to calculate the respondent costs for this renewal are \$124.81, \$67.19, and \$43.74 per hour for managerial, technical, and clerical labor hour costs, respectively.

Tables 1 - 5 summarize the annual burden hours and costs to registrants for compliance with the section 6(a)(2) requirements. The estimates include the paperwork burden costs of submitting studies and incident reports (calculated separately) and the costs of employee 6(a)(2) training. Tables 1 (a and b) and 2 (a and b) present per study and per incident estimates of respondent burden and costs along with the annual totals for each category.

| Table 1a. Respondent Burden and Cost Estimates per Submission - STUDIES |  |             |             |             |                 |
|---|--|-------------|-------------|-------------|-----------------|
| Collection Activities   | Burden Hours (per study) by Labor Type |             |             | Total       |                 |
|   | Managerial                             | Technical   | Clerical    | Hours       | Costs (\$)      |
|   | \$124.81                               | \$67.19     | \$43.74     |             |                 |
| Read Instructions   | 0.10                                   | 0.20        | 0.00        | 0.30        | \$25.92         |
| Create Information  | 0.00                                   | 1.00        | 0.00        | 1.00        | \$67.19         |
| Compile and Review  | 0.10                                   | 0.55        | 0.00        | 0.65        | \$49.44         |
| Complete Paperwork  | 0.00                                   | 0.10        | 0.50        | 0.60        | \$28.59         |
| Store and Maintain Data   | 0.00                                   | 0.20        | 0.50        | 0.70        | \$35.31         |
| <b>Total (per study)</b>  | <b>0.20</b>                            | <b>2.05</b> | <b>1.00</b> | <b>3.25</b> | <b>\$206.45</b> |

Totals may not sum due to rounding.

| Table 1b. Annual Respondent Burden and Cost Estimates - STUDIES |                          |                       |                    |                    |            |
|---|--------------------------|-----------------------|--------------------|--------------------|------------|
| Labor Category  | Burden Hours per Request | Number of Submissions | Total Annual Hours | Labor Rate (\$/hr) | Costs (\$) |
| Managerial  | 0.20                     | 237                   | 47                 | \$124.81           | \$5,916    |
| Technical   | 2.05                     | 237                   | 486                | \$67.19            | \$32,646   |

|                         |             |            |            |         |                 |
|-------------------------|-------------|------------|------------|---------|-----------------|
| Clerical                | 1.00        | 237        | 237        | \$43.74 | \$10,367        |
| <b>TOTAL (per year)</b> | <b>3.25</b> | <b>237</b> | <b>770</b> |         | <b>\$48,929</b> |

Totals may vary between tables due to rounding.

| Table 2a. Respondent Burden and Cost Estimates per Submission - INCIDENTS |  |             |             |             |                 |
|---|--|-------------|-------------|-------------|-----------------|
| Collection Activities   | Burden Hours (per study) by Labor Category |             |             | Total       |                 |
|   | Managerial                                 | Technical   | Clerical    | Hours       | Costs (\$)      |
|   | \$124.81                                   | \$67.19     | \$43.74     |             |                 |
| Read Instructions   | 0.00                                       | 0.10        | 0.00        | 0.10        | \$6.72          |
| Create Information  | 0.00                                       | 0.55        | 0.00        | 0.55        | \$36.96         |
| Compile and Review  | 0.25                                       | 0.60        | 0.00        | 0.85        | \$71.52         |
| Complete Paperwork  | 0.00                                       | 0.00        | 0.55        | 0.55        | \$24.06         |
| Store and Maintain Data   | 0.00                                       | 0.12        | 0.20        | 0.32        | \$16.81         |
| <b>Total (per incident)</b>   | <b>0.25</b>                                | <b>1.37</b> | <b>0.75</b> | <b>2.37</b> | <b>\$156.06</b> |

Totals may not sum due to rounding.

| Table 2b. Annual Respondent Burden and Cost Estimates - INCIDENTS |                          |                       |                    |                    |                     |
|---|--------------------------|-----------------------|--------------------|--------------------|---------------------|
| Labor Category  | Burden Hours per Request | Number of Submissions | Total Annual Hours | Labor Rate (\$/hr) | Costs (\$)          |
| Managerial  | 0.25                     | 107,798               | 26,950             | \$124.81           | \$3,363,625         |
| Technical   | 1.37                     | 107,798               | 147,683            | \$67.19            | \$9,923,286         |
| Clerical  | 0.75                     | 107,798               | 80,849             | \$43.74            | \$3,536,422         |
| <b>TOTAL (per year)</b>   | <b>2.37</b>              | <b>107,798</b>        | <b>255,481</b>     |                    | <b>\$16,823,333</b> |

Totals may vary between tables due to rounding.

Table 3. exhibits the estimated annual respondent burden and costs estimates for all studies and incidents under this information collection.

| Table 3. Total Annual Respondent Burden and Cost Estimates for Studies and Incidents |                          |            |                                     |                |                     |
|--|--------------------------|------------|-------------------------------------|----------------|---------------------|
|  | Per Submission Estimates |            | Total Submissions Expected per Year | Totals         |                     |
|  | Burden Hours             | Costs (\$) |                                     | Burden Hours   | Costs (\$)          |
| Studies  | 3.25                     | \$206.45   | 237                                 | 770            | \$48,929            |
| Incidents  | 2.37                     | \$156.06   | 107,798                             | 255,481        | \$16,823,333        |
| <b>TOTAL</b>   |                          |            | <b>108,035</b>                      | <b>256,252</b> | <b>\$16,872,261</b> |

Totals may vary between tables due to rounding.

Table 4. presents the respondent burden and cost estimates for training activities.

| Table 4. Registrant Burden and Cost Estimates for Training Activities |                                |           |          |                      |            |                               |                               |
|---|--------------------------------|-----------|----------|----------------------|------------|-------------------------------|-------------------------------|
|   | Burden Hours by Labor Category |           |          | Total (per activity) |            | Expected Activities each Year | Total Annual Burden and Costs |
|   | Managerial                     | Technical | Clerical | Hours                | Costs (\$) |                               |                               |
| Training Activity   | \$124.81                       | \$67.19   | \$43.74  |                      |            |                               |                               |
| Plan Training   | 0.50                           | 0.10      | 0.00     | 0.60                 | \$69.13    | 1,452                         | 871                           |
| Conduct Employee Training   | 0.50                           | 1.50      | 1.00     | 3.00                 | \$206.94   | 14,520                        | 43,560                        |
| Follow-up,  | 0.00                           | 0.10      | 0.20     | 0.30                 | \$15.47    | 1,452                         | 436                           |
|   |                                |           |          |                      |            |                               |                               |
|   |                                |           |          |                      |            |                               |                               |

|                         |  |  |  |  |               |               |                    |
|-------------------------|--|--|--|--|---------------|---------------|--------------------|
| Tracking                |  |  |  |  |               |               |                    |
| <b>Total (per year)</b> |  |  |  |  | <b>17,424</b> | <b>44,867</b> | <b>\$3,127,554</b> |

Totals may not sum due to rounding.

Table 5. exhibits the estimated total annual respondent burden and costs for all activities, including study and incident reporting and training activities.

| Table 5. Studies + Incidents + Training - Total Annual Respondent Burden and Cost for Respondents |   |                |                     |
|---|---|----------------|---------------------|
| Submission Type or Activity   | Total Submissions or Activities each Year | TOTALS         |                     |
|   |   | Hours          | Costs (\$)          |
| Studies   | 237                                       | 770            | \$48,929            |
| Incidents   | 107,798                                   | 255,481        | \$16,823,333        |
| Training Activities   | 17,424                                    | 44,867         | \$3,127,554         |
| <b>TOTAL (per year)</b>   | <b>125,459</b>                            | <b>301,118</b> | <b>\$19,999,815</b> |

Totals may not sum due to rounding.

## ii) Estimating Capital, and Operations and Maintenance Costs

There are no capital expenditures or operation and maintenance costs associated with this information collection activity.

### c) Estimating Agency Burden and Cost

Agency activities include: screening 6(a)(2) submissions by subject matter experts to determine the significance of the information; information management activities to record, file, and track the submissions; communicating with registrants, providing guidance on the requirements; and management and oversight of the process.

The EPA fully loaded employee costs for this renewal for managerial, technical, and clerical rates are estimated at \$127.07, \$83.40, and \$47.14 per hour, respectively. The fully loaded wage rates for EPA employees were calculated using the same method that was used for the respondent wage rates; the calculation of wage rates is in Attachment H. Screening and managing submitted information involves a mixture of technical and clerical skills; no managerial labor time is involved in these tasks.

The Agency burden estimate does not include the effort to fully review a 6(a)(2) study or to prepare the resulting documents. Nor does the burden estimate include the effort to take regulatory action that may result from 6(a)(2) adverse effects information. The burden associated with those activities is covered under other ICRs. This ICR does include the costs of subject matter experts reviewing incident reporting.

As stated before, the Agency is also collecting additional incident data for spot-on pet products, one herbicide, and neonicotinoids related to effects on pollinators. These data were required in order to investigate the higher than expected incident numbers. Thus, the Agency is receiving and needing to analyze extra data and thus has an increased burden of information for analysis. To account for this, Agency burden hours have been adjusted upwards for this renewal. Tables 6 through 8 illustrate the estimated Agency burden and costs. Tables 6 (a and b) and 7 (a and b) below present per study and per incident Agency burden and costs.

Table 6a. Agency Burden and Cost Estimates per Submission - STUDIES

| Collection Activities               | Burden Hours per Submission by Labor Category |             |             | Total       |                 |
|-------------------------------------|---|-------------|-------------|-------------|-----------------|
|                                     | Managerial                                    | Technical   | Clerical    | Hours       | Costs (\$)      |
|                                     | \$127.07                                      | \$83.40     | \$47.14     |             |                 |
| Screen submitted information        | 0.00  | 2.00        | 0.00        | 2.00        | \$166.80        |
| Record, file, and track submissions | 0.00  | 3.60        | 0.90        | 4.50        | \$342.66        |
| <b>Total (per study)</b>            | <b>0.00</b>                                   | <b>5.60</b> | <b>0.90</b> | <b>6.50</b> | <b>\$509.46</b> |

Totals may not sum due to rounding.

Table 6b. Annual Agency Burden and Cost Estimates - STUDIES

| Labor Category          | Burden Hours per Request | Number of Submissions | Total Annual Hours | Labor Rate (\$/hr) | Costs (\$)       |
|-------------------------|--------------------------|-----------------------|--------------------|--------------------|------------------|
| Managerial              | 0.00                     | 237                   | 0                  | \$127.07           | \$0              |
| Technical               | 5.60                     | 237                   | 1,327              | \$83.40            | \$110,686        |
| Clerical                | 0.90                     | 237                   | 213                | \$47.14            | \$10,056         |
| <b>TOTAL (per year)</b> | <b>6.50</b>              | <b>237</b>            | <b>1,541</b>       |                    | <b>\$120,742</b> |

Totals may vary between tables due to rounding.

Table 7a. Agency Burden and Cost Estimates per Submission - INCIDENTS

| Collection Activities              | Burden Hours per Submission by Labor Category |              |              | Total        |                |
|------------------------------------|---|--------------|--------------|--------------|----------------|
|                                    | Managerial                                    | Technical    | Clerical     | Hours        | Costs (\$)     |
|                                    | \$127.07                                      | \$83.40      | \$47.14      |              |                |
| Screen Submitted Information       | 0.000   | 0.135        | 0.000        | 0.135        | \$11.26        |
| Record, File and Track Submissions | 0.000   | 0.023        | 0.033        | 0.056        | \$3.47         |
| Communications, Guidance           | 0.000   | 0.025        | 0.000        | 0.025        | \$2.08         |
| <b>Total (per incident)</b>        | <b>0.000</b>                                  | <b>0.183</b> | <b>0.033</b> | <b>0.216</b> | <b>\$16.82</b> |

Totals may not sum due to rounding.

Table 7b. Annual Agency Burden and Cost Estimates - INCIDENTS

| Labor Category          | Burden Hours per Request | Number of Submissions | Total Annual Hours | Labor Rate (\$/hr) | Costs (\$)         |
|-------------------------|--------------------------|-----------------------|--------------------|--------------------|--------------------|
| Managerial              | 0.000                    | 107,798               | 0                  | \$127.07           | \$0                |
| Technical               | 0.183                    | 107,798               | 19,727             | \$83.40            | \$1,645,203        |
| Clerical                | 0.033                    | 107,798               | 3,557              | \$47.14            | \$167,710          |
| <b>TOTAL (per year)</b> | <b>0.216</b>             | <b>107,798</b>        | <b>23,284</b>      |                    | <b>\$1,812,913</b> |

Totals may vary between tables due to rounding.

Table 8. presents the combined total annual Agency burden and costs estimates for studies and incidents.

Table 8. Total Annual Agency Burden and Cost Estimates

|                         | Per Submission Estimates |            | Total Submissions Expected per Year | Totals        |                    |
|-------------------------|--------------------------|------------|-------------------------------------|---------------|--------------------|
|                         | Hours                    | Costs (\$) |                                     | Burden Hours  | Costs (\$)         |
| Studies                 | 6.50                     | \$509.46   | 237                                 | 1,541         | \$120,742          |
| Incidents               | 0.216                    | \$16.82    | 107,798                             | 23,284        | \$1,812,913        |
| <b>TOTAL (per year)</b> |                          |            | <b>108,035</b>                      | <b>24,825</b> | <b>\$1,933,656</b> |

Totals may vary between tables due to rounding

#### **d) Bottom Line Hours and Costs Tables**

Table 9. displays the total burden hours and costs of FIFRA section 6(a)(2) requirements for respondents and the Agency from Tables 1 – 8.

| <b>Table 9. MASTER TABLE</b>                | <b>TOTAL</b>   |                     |
|---|----------------|---------------------|
|   | Hours          | Costs (\$)          |
| Annual Respondent Burden and Cost Estimates | 301,118        | \$19,999,815        |
| Annual Agency Burden and Cost Estimates     | 24,825         | \$1,933,656         |
| <b>TOTAL</b>                                | <b>325,943</b> | <b>\$21,933,471</b> |

The average respondent burden is 3.25 hours per study and 2.37 hours per incident (average 2.81 hours per response), and the total annual respondent burden is 301,118 hours. The average per respondent burden is 207 hours (301,118 total hours ÷ 1,452 total potential respondents), and the average cost is \$13,774 per respondent (\$19,999,815 total cost ÷ 1,452 total potential respondents). Not all of the potential respondents are likely to submit information each year. This calculation is a simple average of the burden and does not reflect the more likely potential respondent burden which is characterized by the type of submission, the number of registrations held, and the number of incidents that need to be reported.

#### **e) Reasons for Change in Burden**

The estimated total respondent burden is expected to increase by 26,104 hours from 275,014 hours to 301,118 hours, with an expected increase in estimated costs from \$16,827,821 to \$19,999,815. The increase in burden hours and cost is primarily due to the expected increase in the number of responses, as discussed further below. Total burden hour estimates associated with studies are increased because the estimated annual number of study submissions increased from 153 studies to 237.

The number of responses is expected to increase by 16% from 93,000 in the last ICR approval to approximately 108,000 for this ICR renewal. The increase is due to EPA's revised expectations regarding the number of incident reports that will be submitted to the Agency, which reflects historical information on the number of responses received. The increase in the number of incident reports has also prompted the need for additional information discussed in section 4 of this supporting statement. Since the last ICR was approved, the EPA has found it necessary to request additional data in certain subject areas under 40 CFR 159. First, due to a significant increase in the number of adverse incidents for spot-on domestic animal pet products from several registrants, EPA began requiring more standardized post-market surveillance reporting on adverse effects and submission of sales information, so the Agency can better evaluate incident rates. Second, the Agency requested additional information from the registrant of an herbicide to help explain circumstances for incidents of alleged tree and plant damage. Finally, new concerns about neonicotinoid pesticides and the loss of bee colonies led to EPA's request for more documentation from registrants for these products.

Calculations of labor rates and related burden costs have changed for both EPA and respondents due to changes in the base wages and an increase in the percentage of benefits. For this renewal, the Agency updated the fully loaded wage rates for all labor categories for both Agency employees and respondents. The Agency burden has increased, which reflects an increase in the number of incident submissions and more communication relating to incident

data.

**f) Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2.81 hours per response. The total annual "respondent" (applicant) burden is estimated to be 301,118 hours, with an average potential per respondent burden of 207 hours. "Burden" is defined in 5 CFR 1320.3(b). The Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to the PRA unless it displays a currently valid OMB control number. The OMB control numbers for certain regulations in Title 40, after initial display in the Federal Register, are listed in 40 CFR part 9, and may appear on the information collection instrument as applicable, i.e., form or instructions, and in the Federal Register.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2017-0687, which is available for online viewing at <http://www.regulations.gov>, or in person viewing at the EPA Docket Center-Public Reading Room, EPA West Building, in Rm. S-3334, 1301 Constitution Avenue, NW, Washington, DC. This docket facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The docket telephone number is (202) 566-1744. You may submit comments regarding 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.

Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0687 and OMB control number 2070-0039, to both EPA and OMB as follows:

- To EPA online using <http://www.regulations.gov> (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.
- To OMB via email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**7. LIST OF ATTACHMENTS**

All of the attachments listed below can be found in the docket for this ICR, which is 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-2017-0687** 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:**

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) – Section 6(a)(2) (7 USC 136(d)(2))

<https://www.gpo.gov/fdsys/pkg/USCODE-2016-title7/pdf/USCODE-2016-title7-chap6-subchapII-sec136d.pdf>

**ATTACHMENT B:**

FIFRA Section 6(a)(2) Reporting Requirements - Codified as 40 CFR part 159 subpart D. Reporting Requirements for Risk/Benefit Information

<https://www.gpo.gov/fdsys/pkg/CFR-2016-title40-vol26/pdf/CFR-2016-title40-vol26-part159-subpartD.pdf>

**ATTACHMENT C:**

PR Notice 1998-3 - Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product

<https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year>

see also PR Notice 1998-4 - Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants)

<https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year>

**ATTACHMENT D:**

Copy of the 6(a)(2) Consultation Questionnaire is available in the Docket **EPA-HQ-OPP-2017-0687**.

**ATTACHMENT E:**

Class Determination Regarding Confidentiality of 6(a)(2) Information

<https://archive.epa.gov/ogc/documents/web/pdf/1-99.pdf>

**ATTACHMENT F:**

Pollinator Protection Letter to Registrants

<https://www.epa.gov/sites/production/files/2013-11/documents/bee-july2013-letter.pdf>

**ATTACHMENT G:**

Industry's Voluntary 6(a)(2) Incident Reporting Forms & Guidance Documents see

<https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants>

**ATTACHMENT H:**

Worksheet for Estimating OPP ICR Wage Rates for Respondent and Agency Labor Costs are available as an attachment to Docket **EPA-HQ-OPP-2017-0687**.