July 31, 2014

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. 1204.12

b) Abstract

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (Attachment A) 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)):

> "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.. 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® (*http://www.cspa.org/product-care-product-stewardship/what-is-product-care-.html*). 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.

b) Consultations

As required under 5 CFR 1320.8(d)(1), EPA consulted with a cross-section of pesticide registrants seeking feedback on the adverse effect information reporting requirements and processes, as well as an assessment of the burden estimates associated with this effort. The following companies were asked to participate in the consultation process by responding to a questionnaire:

- Syngenta Crop Protection, Inc. (Nina E. Heard, 336-632-2535)
- Clorox Company (Chandrika Moudgal, 925-368-9031)
- Sysco Corporation (Jason Castroman, 281-584-2847)
- Clean Control Corporation (Cory Hammock, 478-922-5340)
- Bayer CropScience (S. Gerret Van Duyn, 919-549-2914)
- Canberra Corporation (John Wiegand, 419-841-6616)

All registrants contacted provided responses to the questionnaire. Individual responses to the questions are listed in Attachment G. Below is a brief summary of the responses:

Regarding the availability of this information from another source, four of the six registrants agreed that there was no other source other than what they learned themselves.

Regarding frequency of reporting, responses were mixed. Clean Control Corporation felt that the answer to this question was unknown because changing the frequency might result in cost burden for redesigning procedures and retraining employees. Bayer, Syngenta, and Clorox all felt that reporting could be done less frequently and still be effective. Bayer specifically suggested that quarterly reporting would be as effective as the monthly reporting which EPA currently requires for some incidents. Sysco commented that the reporting could perhaps be done less frequently with high risk classes or new registrants reported monthly, major events reported quarterly and minor events collected yearly. Canberra felt that only the EPA could answer this question. EPA will certainly keep these comments under consideration, although the current process distributes the current data entry work load more equitably throughout the year than a less frequent reporting schedule would.

Most respondents indicated that the instructions for reporting adverse effects information are normally clear, however some noted that additional consultation with lawyers and EPA experts was also useful. Canberra and Clorox felt the instructions were for the most part clear.

Syngenta recommended improved content on EPA's Adverse Effects web page including FIFRA 6(a)(2) submissions and a Frequently Asked Questions section. Bayer said that most guidance issues were clear; however they raised some concerns regarding the clarity of the instructions. They believed that the regulation should be updated to cover these issues. EPA will certainly consider those suggestions.

Most respondents retain records and some exceed our record requirements as specified in 40 CFR 169. Most respondents except for Clorox made use of the Voluntary Incident Reporting Forms, and Bayer derives their forms from the Voluntary Incident Reporting Forms. Clorox uses a poison control center to prepare data for submission. (See a copy of the Voluntary Incident Reporting Form in Attachment H.)

The response to questions regarding e-submission of adverse effects information was mixed, though in general the companies are interested in electronic submission. Syngenta and Bayer are currently using the electronic submission process for major active ingredient registration submissions and are willing to work with EPA towards developing new processes for handling adverse effects information. The Agency does encourage electronic reporting for other types of registration-oriented submissions, see Electronic Submissions for Registering Pesticide Products (*http://www.epa.gov/pesticides/regulating/registering/submissions/*). Bayer adds that providing incident reports in an electronic format such as .pdf files would save considerable time and allow for electronic archiving of data as opposed to both electronic and hard copy archiving.

The Agency agrees with many who believe electronic submission, particularly for respondents with large volumes of reporting data, would greatly reduce reporting errors related to formatting and help reduce reporting and archival burdens. However, as noted by industry response, ideas about the type and method of electronic reporting preferences vary significantly. As EPA continues to develop plans for electronic submission, the Agency will continue to consider the needs of industry respondents both large and small.

Regarding burden hours and costs, Canberra and Clorox felt the labor rates were accurate, while Clean Control Corporation said that was unknown with labor rates being cheaper in non-metro southeastern U.S. Syngenta felt the labor rates looked reasonable, but said no attempt was made to verify accuracy. Sysco and Clorox felt that the estimated costs did not cover their contracting costs for incident reporting, since each uses a contractual poison control center to handle incident reporting. Contracting out this service may provide excellent benefits in terms of expert data capture and improved data for trend analysis as well as improved information provided to the government. Nevertheless, contracting is not a requirement of the regulation.

Syngenta felt the government's estimated burden hours were lower than their real costs especially for study review and training. Those are priorities for such a large multinational corporation with many employees at several foreign offices. On the other hand, Clean Control Corporation, a smaller company, reported that its 6(a)(2) retraining cost burden was probably lower than in other parts of the country. Syngenta also felt that flagging studies for 6(a)(2) submission required a committee of six to eight scientific and technical experts meeting twice a month. Again, it should be noted that this is a large company which tends to have higher expenditures for 6(a)(2) work given the increased numbers of registrations and the global nature of its research activities. EPA's regulations do require companies to decide which studies to submit to EPA with 6(a)(2) flagging, but we believe the companies still have to review their studies to decide which ones to submit anyway. EPA believes the costs of performing the studies are not significantly different depending on whether they are submitted or not. EPA's

estimates are averages covering many, very small companies as well as a few very large companies. The Agency also believes that it accounts for all activities in estimating burden hours including record keeping, staff training, and legal expertise.

Bayer reported some increases in its per hour costs for 6(a)2 reporting; however, Bayer is a large multinational company with many offices worldwide. Additionally, some of the burden activities Bayer has submitted to EPA are not PRA burdens. The non-PRA burden activities include costs associated with time for investigation of alleged field incidents and large costs for what Bayer considers the capital costs of the data system they use. EPA also suspects that some of the other burden categories Bayer described as capital costs such as their dedicated trend analysis programs, data servers, and truck and transportation expenses with having personnel in the field might also contain an aggregation of 6(a)(2) PRA and non-PRA burden activities.

Bayer also wants to include opportunity costs for the working cost of capital tied to 6(a)2 compliance activities that is unavailable for other possibilities. While EPA agrees that registrants must consider the working cost of capital for all spending, it has never been OPP's practice to add this into paperwork burden costs. For this reason, it would not be appropriate to consider it in this ICR unless that practice was expanded to all ICRs.

It should be noted that Bayer developed a very modern electronic system to capture data fields from the voluntary incident reporting forms. These activities are not mandated by the regulation, though they have been helpful to the company in efficient data capture and reporting. EPA's overhead cost formulas may or may not sufficiently account for global companies with dedicated 6(a)(2) reporting departments, however, based on limitations of the data submitted and a lack of information on the applicability of Bayer data to the broader industry, EPA could not use the Bayer estimates to represent data for the entire industry.

Considering the frequent use of contracting for incident reporting and the assertions from several registrants that some of EPA's previous estimates were low, EPA has decided to raise certain parts of the overall hourly estimates. In Table 2a for Incidents, managerial and technical hours have been raised since consultation. Syngenta wanted to raise training costs since it has trainings for new employees as well as biannual refresher trainings. The majority of companies are much smaller, and training in most companies would be much easier to conduct since not every employee would be expected to receive new incident reports or studies. EPA's previous training estimate is in Table 4 and is based on 10 employees per registrant, and EPA does not have strong enough justification to increase this figure.

c) Public Notice Required Prior to ICR submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA announced the proposed renewal of this information collection activity and a 60-day public comment period in a Federal Register (FR) Notice that published on February 5, 2014 (79 FR 6897). No comments were received during the comment period.

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, 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.

f) 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.

g) 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, according to 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. Beginning in 2010, respondents began submitting enhanced incident data for thousands of domestic animal incidents for almost 100 spot-on flea and tick products. Domestic animal incidents are normally reported statistically without details of breed, age, and circumstances. The Agency felt it was necessary to collect more detailed information about these cases. After meeting with pesticide registrants (Attachment I), 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. (*http://www2.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects*). This enhanced data was analyzed, and new mitigation steps were taken for this type of product. Some of the products have been discontinued by the manufacturers, and other newer products have had additional incident reporting added as a condition of registration. Enhanced data reporting for spot-on flea and tick products will continue so that EPA can monitor incident levels more closely.

In the summer of 2011, the Agency received reports from numerous states that E.I. du Pont de Nemours and Company's (DuPont) herbicide, Imprelis, which contains the active ingredient aminocyclopyrachlor, may have caused injury to certain species of evergreen trees, particularly Norway spruce and white pine. DuPont submitted reports for tens of thousands of incidents for this product. The incidents resulted in EPA issuing a stop sale order for the herbicide and EPA requesting extra backup information to help explain circumstances for the incidents of alleged tree and plant damage (Attachment J). The data is still under analysis. (*http://www.epa.gov/pesticides/regulating/imprelis.html*).

Additionally, in 2013, new concerns about neonicotinoid pesticides and the loss of bee colonies led to EPA's request for more documentation from registrants for these products (See Attachment K). 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 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 current 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) analyzing claims of confidentiality and providing appropriate protection; 4) storing the data submitted; and 5) 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 established criteria for voluntary submission of study reports in electronic form (Adobe PDF on CD-ROM), though these studies currently require a registration number for electronic processing. A 6(a)(2) study could be submitted electronically just as easily as a non-6(a)(2) study, but it requires more screening and tracking. Regarding incidents, electronic submission is possible, but would require further database design activity. EPA will work with registrants on 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 master 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 H.

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 (Attachments C and D).

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 FY 2009-2012 were used.

As of May 2014, there were 1,763 registrants with active registrations. The number of registrations held by each registrant ranged from 1 to 512; the average number of product registrations was 10 and the median is two. Seven hundred thirty eight (738) registrants held only one product registration, 1,518 registrants held ten or fewer registrations, 34 registrants held 51-100 product registrations, and 31 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 1,763 respondents assumed for this analysis.

The Agency received an average of 153 studies annually from FY 2009 through FY 2012. For purposes of this analysis, the Agency assumes 153 study-related submissions will be received each year for the duration of this information collection renewal.

From FY 2009 through FY 2012 the Agency received an average of 907 incident-related submissions per year from registrants containing an average of 92,844 incidents per year. Of these, 5,645 incidents were individually reported and 87,199 were reported as aggregate statistics on the yearly average. A total of 222 registrants (13% 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 745 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 92,844 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 17,630 individuals requiring training each year. This estimate is an average; the actual number would range from one person in a small company to several dozen 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*).

Sectors. The specific NAICS code and website for each sector is included in that sector's wage rate table in Attachment F. 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*).

Loaded Wage Rate. Unless stated otherwise, all benefits represent 43% 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 43% 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 2012 data. Attachment F 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 $117.86, $62.64, and $37.37 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. Studies – Respondent Burden and Cost Estimates per Study					
Collection Activities	**Burden Hours by Labor Category**			**Total**	
	Managerial $117.86/hr	Technical $62.64/hr	Clerical $37.37/hr	Burden (hrs)	Costs ($)

Read Instructions	0.10	0.20	0.00	0.30	$24.31
Create Information	0.00	1.00	0.00	1.00	$62.64
Compile and Review	0.10	0.55	0.00	0.65	$46.24
Complete Paperwork	0.00	0.10	0.50	0.60	$24.95
Store and Maintain Data	0.00	0.20	0.50	0.70	$31.21
TOTAL (per study)	**0.20**	**2.05**	**1.00**	**3.25**	**$189.35**

Totals may not sum due to rounding.

Table 1b. Studies – Annual Respondent Burden and Cost Estimates					
Labor Category	**Burden per Request (hrs)**	**Annual Number of Studies**	**Total Annual Hours**	**Labor Rate ($/hr)**	**Annual Costs ($)**
Managerial	0.20	153	31	$117.86	$3,607
Technical	2.05	153	314	$62.64	$19,647
Clerical	1.00	153	153	$37.37	$5,718
TOTAL (per year)	**3.25**	**153**	**497**		**$28,971**

Totals may vary between tables due to rounding.

Table 2a. Incidents – Respondent Burden and Cost Estimates per Incident					
Collection Activities	**Burden Hours by Labor Category**			**Total**	
	Managerial $117.86/hr	Technical $62.64/hr	Clerical $37.37/hr	Burden (hrs)	Costs ($)
Read Instructions	0.00	0.10	0.00	0.10	$6.26
Create Information	0.00	0.55	0.00	0.55	$34.45
Compile and Review	0.25	0.60	0.00	0.85	$67.05
Complete Paperwork	0.00	0.00	0.55	0.55	$20.55
Store and Maintain Data	0.00	0.12	0.20	0.32	$14.99
TOTAL (per incident)	**0.25**	**1.37**	**0.75**	**2.37**	**$143.31**

Totals may not sum due to rounding.

Table 2b. INCIDENTS – Annual Respondent Burden and Cost Estimates					
Labor Category	**Burden per Request (hrs)**	**Annual Number of Incidents**	**Total Annual Burden Hours**	**Labor Rate ($/hr)**	**Costs ($)**
Managerial	0.25	92,844	23,211	$117.86	$2,735,648
Technical	1.37	92,844	127,196	$62.64	$7,967,575
Clerical	0.75	92,844	69,633	$37.37	$2,602,185
TOTAL (per year)	**2.37**	**92,844**	**220,040**		**$13,305,409**

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. Studies + Incidents - Total Annual Respondent Burden and Cost Estimates for Studies and Incidents					
	Estimates per Study/Incident		**Studies/Incidents Expected each Year**	**Annual Estimates**	
	Burden (hrs)	Costs ($)		Burden (hrs)	Costs ($)
Studies	3.25	$189.35	153	497	$28,971
Incidents	2.37	$143.31	92,844	220,040	$13,305,409
TOTAL (per year)			**92,997**	**220,538**	**$13,334,380**

Totals may vary between tables due to rounding.

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

Table 4. Training – Respondent Burden and Cost Estimates for Training Activities								
Training Activity	**Burden Hours by Labor Category**			**Total (per activity)**		**Expected Activities each Year**	**Total Annual Burden and Costs**	
	Managerial $117.86/hr	Technical $62.64/hr	Clerical $37.37/hr	Burden (hrs)	Costs ($)		Burden (hrs)	Costs ($)
Plan training	0.50	0.10	0.00	0.60	$65.19	1,763	1,058	$114,937
Conduct employee training	0.50	1.50	1.00	3.00	$190.26	17,630	52,890	$3,354,284
Follow-up, tracking	0.00	0.10	0.20	0.30	$13.74	1,763	529	$24,220
TOTAL (per year)						**21,156**	**54,477**	**$3,493,441**

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 Activities - Total Annual Burden and Cost for Respondents			
Study, Incident, or Training Activity	**Studies/Incidents/Training Activities each Year**	**Totals**	
		Burden (hrs)	Costs ($)
Studies	153	497	$28,971
Incidents	92,844	220,040	$13,305,409
Training Activities	21,156	54,477	$3,493,441
TOTAL (per year)	**114,153**	**275,014**	**$16,827,821**

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 $120.73, $78.32, and $44.66 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 F. 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. Studies – Agency Burden and Cost Estimates per Study

Collection Activities	Burden Hours by Labor Category			Total	
	Managerial $120.73/hr	Technical $78.32/hr	Clerical $44.66/hr	Burden (hrs)	Costs ($)
Screen submitted information	0.00	2.00	0.00	2.00	$156.64
Record, file, and track submissions	0.00	3.60	0.90	4.50	$322.15
TOTAL (per study)	**0.00**	**5.60**	**0.90**	**6.50**	**$478.79**

Totals may not sum due to rounding.

Table 6b. Studies – Annual Agency Burden and Cost Estimates

Labor Category	Burden per Request (hrs)	Annual Number of Studies	Total Annual Hours	Labor Rate ($/hr)	Costs ($)
Managerial	0.00	153	0.00	$120.73	$0
Technical	5.60	153	857	$78.32	$67,105
Clerical	0.90	153	138	$44.66	$6,150
TOTAL (per year)	**6.50**	**153**	**995**		**$73,254**

Totals may vary between tables due to rounding.

Table 7a. INCIDENTS – Agency Burden and Cost Estimates per Incident

Collection Activities	Burden Hours by Labor Category			Total	
	Managerial $120.73/hr	Technical $78.32/hr	Clerical $44.66/hr	Burden (hrs)	Costs ($)
Screen submitted information	0.000	0.135	0.000	0.135	$10.57
Record, file, and track submissions	0.000	0.023	0.033	0.056	$3.28
Communications, guidance	0.000	0.025	0.000	0.025	$1.96
TOTAL (per incident)	**0.000**	**0.183**	**0.033**	**0.216**	**$15.81**

Totals may not sum due to rounding.

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

LABOR CATEGORY	Burden Hours per Request	Annual Number of Incidents	Total Annual Hours	Labor Rate ($/hr)	Costs ($)
Managerial	0.000	92,844	0	$120.73	$0
Technical	0.183	92,844	16,990	$78.32	$1,330,692
Clerical	0.033	92,844	3,064	$44.66	$136,832
TOTAL (per year)	**0.216**	**92,844**	**20,054**		**$1,467,524**

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 for Studies and Incidents					
	Per Study/Incident Estimate		Studies/Incidents Expected each Year	Total	
	Burden (hrs)	Costs ($)		Hours	Costs ($)
Studies	6.50	$478.80	153	995	$73,254
Incidents	0.216	$15.81	92,844	20,054	$1,467,524
TOTAL (per year)				**21,049**	**$1,540,778**

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.

Table 9. MASTER TABLE	TOTAL	
	Hours	Costs ($)
Annual Respondent Burden and Cost Estimates	275,014	$16,827,821
Annual Agency Burden and Cost Estimates	21,049	$1,540,778
TOTAL	**296,063**	**$18,368,599**

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 275,014 hours. The average per respondent burden is 156 hours (275,014 total hours ÷ 1,763 total potential respondents), and the average cost is $9,545 per respondent ($16,827,821 total cost ÷ 1,763 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 71,778 hours from 203,236 hours to 275,014 hours, with an expected increase in estimated costs from $11,793,027 to $16,827,821. The increase in burden hours and cost is primarily due to the expected increase in the number of responses, as discussed further below. It also reflects a small increase in the number of registrants of active products (1,763 versus 1,733) which resulted in a small increase in the additional employees being trained. Total burden hour estimates associated with studies are reduced because the estimated annual number of study submissions decreased from 183 studies to 153.

The number of responses is expected to increase by 31% from 71,000 in the last ICR approval to approximately 93,000 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 275,014 hours, with an average potential per respondent burden of 156 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-2013-0742, 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-2013-0742 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*. 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-2013-0742** 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 136d), *http://www.law.cornell.edu/uscode/7/usc_sec_07_00000136---d000-.html.*

ATTACHMENT B:
FIFRA Section 6(a)(2) Reporting Requirements - Codified as 40 CFR part 159.
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

ATTACHMENT C:
PR Notice 98-3 **-** Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants
http://www.epa.gov/PR_Notices/.

ATTACHMENT D:
PR Notice 98-4 - Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants (w/Attachment)
http://www.epa.gov/PR_Notices/.

ATTACHMENT E:
Class Determination Regarding Confidentiality of 6(a)(2) Information
http://www.epa.gov/EPA-PEST/1999/December/Day-15/p32185.htm.

ATTACHMENT F:
Worksheet for Estimating OPP ICR Wage Rates for Respondent and Agency Labor Costs

ATTACHMENT G:
Reserved – Record of Consultations

ATTACHMENT H:
Industry's Voluntary 6(a)(2) Incident Reporting Forms & Guidance Documents see
http://www.epa.gov/pesticides/fifra6a2/.

ATTACHMENT I:
Meeting with Registrants on Spot-On Flea and Tick Pesticide Products
http://www2.epa.gov/sites/production/files/documents/spot-on-meeting-may2009.pdf.

ATTACHMENT J:
Letter to Dupont on Stop Sale, Use or Removal Order
http://www.epa.gov/pesticides/regulating/imprelis-stopsale-letter.pdf.

ATTACHMENT K:
Pollinator Protection Letter to Registrants
http://www.epa.gov/opp00001/ecosystem/pollinator/bee-july2013-letter.pdf.