# 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. 1204.11**

### b) Abstract

This Information Collection Request (ICR) is a renewal of an existing ICR that is currently approved by OMB and is due to expire October 31, 2010. Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), see 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 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 section 6(a)(2) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) (7 USC 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 Notice 98-3, see 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 submissible 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 possible significant consequences for human health or the environment, had the information been available earlier, the Agency's determination with regard to the registration of the pesticide may well have been different. If warranted by the information provided, EPA may seek to amend the registration in order to address the concerns raised by the information.

In essence, this information provides an important means of focusing EPA attention on key problem areas regarding the use of the pesticide in question. The adverse effects information submitted under section 6(a)(2) is considered by EPA in conjunction with other information to determine whether pesticides 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 authority to call-in data (a.k.a. DCI "data call-in") is found in 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 # 2288.01. 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 adverse effects information is valuable to them as well. Registrants who actively seek 6(a)(2) information justify their actions as part of product stewardship, customer relations, minimizing liability, and protecting or expanding market share. According to feedback that EPA has received, registrants acquire and use this information as a way of determining whether actual product use circumstances reveal new 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, the trade association for registrants of antimicrobial pesticide products, has a voluntary program for their members called Product Care. Among their principles is the need for members to provide information to their customers and the need to have a system in place to minimize adverse effects when product related incidents occur.

## 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 generated, owned or used by the registrants, or 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 part of preparation of this ICR renewal, EPA contacted representatives of 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:

- Syngenta CropProtection, Inc. (Dennis Hackett, 336-632-2535)
- Clorox Services Company (Myranda Hanstedt, 925-425-6860)
- Sysco Corporation (Richard Cottrell, 281-584-1793
- Sunburst Chemicals, Inc. (Bill Scepanski, 952-886-3684)
- Bayer CropScience (S. Gerret Van Duyn, 919-549-2914)
- Canberra Corporation (John Wiegand, 419-841-6616)

All companies provided comments except for Sunburst Chemical. Individual responses are listed in Attachment G.

Regarding the availability for this information from another source, all but one company agreed that there was no other source other than what they learned themselves. Bayer commented that some incident data from universities is available to the EPA upon request. EPA would respond that universities have no responsibility to report under 6(a)(2), since they are not normally registrants. But, EPA would need to know which university department was holding the information in order to direct a request to gather it. EPA would not normally have this information.

Bayer also added that state poison control centers and administrative departments also stored incident data. Some of the state data is available publicly, and EPA does gather some of this data for its incident collections. States often only summarize the details and sometimes do not even report the exact products involved, which limits the usefulness of some of this data.

Regarding frequency of reporting there was mixed response. Some companies, such as Bayer, felt that those incidents required to be reported on a monthly basis could be as effectively reported quarterly. Syngenta and Clorox felt that reporting could be done less frequently and still be effective. Sysco commented that the reporting could perhaps be done less frequently but

that the current reporting frequency was not particularly burdensome to them. Canberra felt that the current schedule was acceptable. EPA will certainly take these comments under consideration.

Most respondents indicated that the instructions for reporting adverse effects information are normally clear, however some noted that additional consultation with lawyers, outside consultants and EPA experts was also useful. Canberra and Clorox felt the instructions were clear. Syngenta recommended improved content on EPA's Adverse Effects web page including FIFRA 6(a)(2) submissions and a Frequently Asked Questions section. EPA will certainly consider those suggestions.

Bayer raised three issues regarding the clarity of the instructions, which relate more to interpretation of the regulations than discussion directly pertinent to the Paperwork Reduction Act (PRA) burden of the Information Collection Request. EPA has responded to Bayer directly on these issues and a copy of the agency response has been placed in docket # EPA-HQ-OPP-2009-0886 for this action.

All respondents were clear that they needed to retain records. Canberra and Clorox felt the instructions were clear. All respondents except for Clorox made use of the Voluntary Incident Reporting Forms. Sysco Corporation commented that they used the forms "developed by PROSAR Corporation," a private company providing poison control center services and adverse event reporting for 6(a)(2) registrants. EPA would like to clarify this to say that a representative of PROSAR did work with the industry work group that developed the Voluntary Incident Reporting forms, and it makes use of them today. (See a copy of the Voluntary Incident Reporting Form in Attachment H.

The response to questions regarding e-submission of adverse effects information was decidedly mixed. 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. Correspondence about adverse effects information within Syngenta is usually handled through email, and they are moving towards a Documentum based document management system as a supplement to their paper records storage system. At present they are more inclined to submit CBI on paper rather than on diskette, CD, DVD, or via the web. Clorox thinks electronic reporting options should be pursued, and they are handling their documents in both .pdf and .doc formats. They are interested in real time instantaneous submission of documents including CBI over "secure web based transmission." Sysco is inclined to submit .pdf documents via web based email. Canberra Corporation indicates that they keep their information in Word document format, and they have not been successful using XML schema on other EPA e-submissions for labeling. They would prefer to submit CBI data on CD to the Agency as opposed to sending it via the web. Sysco Corporation also mentioned the cost of sending information to the Agency via certified mail.

Bayer commented that they understand that EPA's ePRISM program for electronic study submission is not meant for 6(a)(2) study submission, and they have consequently not been using it for that reason. Bayer is correct in stating that EPA's web site has not yet encouraged using electronic submission methods for 6(a)(2) submissions, however the Agency is working towards this goal. 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 they support the use of electronic submission in terms of direct data stream in order to avoid formatting and data entry errors due to rekeying of data. They also commented 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 in industry that believe electronic submission, particularly for respondents with large volumes of reporting data, would greatly reduce a number of reporting errors related to formatting and help reduce reporting and archival burdens. However, as noted by industry response, consensus on the type and method of electronic reporting preferences vary greatly. As EPA continues to develop new electronic submission protocols to accommodate a broader spectrum of pesticide activities, the Agency will continue to plan for the development of infrastructure to accommodate electronic reporting to support the needs of industry respondents both large and small.

Regarding burden hours and costs, Canberra and Clorox felt the rates were accurate. Sysco did not comment on the labor rates. Syngenta felt the labor rates were fairly accurately reflected. Syngenta felt the burden hours were low, especially for training, and that is a priority for such a large multinational corporation with many employees at several foreign offices. 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. 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 registrant 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 relatively small number of 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 Corporation, a large multinational company with many offices worldwide, felt that the EPA cost burden estimate was considerably low. The burden information Bayer submitted as part of the company's burden analysis included, "scientific review of studies; contract services to handle and report incidents on a timely basis; computerized reporting systems; trending and analysis infrastructure and efforts; costs associated with investigation of alleged field incidents; sample and tissue analysis of affected plants and animals; legal fees and guidance; archiving costs and systems, and employee time and efforts (as a percentage of average salary and benefits)." Since Bayer is a very large global company, EPA believes Bayer probably has higher per hour costs for 6(a)(2) reporting than most of the other 1,732 registrants currently subject to 6(a)(2) reporting requirements. However, some of the burden activities Bayer has submitted to EPA are not Paperwork Reduction Act (PRA) burdens. The non-PRA burden activities include cost associated with investigation of alleged field incidents, trending and analysis infrastructure and efforts, and sample and tissue analysis of affected plants and animals. These activities are not required by the regulation. EPA also suspects that some of the other burden categories Bayer described such as legal fees and guidance and contract services of quality to handle and report incidents on a timely basis might also contain an aggregation of 6(a)(2) PRA and non-PRA burden activities. Bayer did not provide enough of a detailed breakdown of these burden

activities for EPA to determine which activities were solely PRA burden related. Bayer also submitted a case for the inclusion of "opportunity costs generated from delays in conducting business and productivity costs associated with the time allocated for compliance with 6a2." These are not PRA activity costs. EPA calculates PRA activity burdens as the minimum activities required by section 6(a)(2) of FIFRA (40 CFR 159). When the non-PRA burdens are deleted from the Bayer burden activities, the Agency expects Bayer's cost to be closer to the industry sector averages for Pesticide, Fertilizer, and Other Chemical Manufacturing (NAICS 325300) as calculated by the U.S. Bureau of Labor Statistics (BLS) and used in the ICR.

Bayer also felt they had a capital investment due to the expenses of their computerized reporting systems. For small to midsize companies the capital costs of data system investments to support 6(a)(2) activities is aggregated within the cost of tracking a number of business activities. EPA assumes these companies do not have data servers or departments dedicated solely to 6(a)(2) reporting. EPA calculations include overhead costs which accounts for a percentage of the capital investment that uses a portion of the computerized infrastructure to address 6(a)(2) reporting. However, global companies, like Bayer, have dedicated staff to track 6(a)(2), animal studies, and pharmaceutical and other compliance tracking. EPA understands global companies have developed software and data systems to help fulfill their compliance reporting requirements, but also notes these dedicated department costs probably do not disaggregate the PRA and non-PRA 6(a)(2) reporting burdens. 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 does not have sufficient information to change the estimated per hour industry wage rates in the ICR.

Canberra also notes the costs of communicating to and training distributors is an extra cost that can be substantial but did not submit any data to allow the EPA to reconsider calculations.

EPA provides frequent consultation to assist in the understanding of the 6(a)(2) regulations. These activities have included dialogue between industry and the Agency on adverse effects information reporting requirements, content, definitions, format, and timing. In addition to phone conversations and preparing e-mails and letters, Agency staff members have participated in meetings with individual registrants as well as gatherings of large groups such as the Pesticide Program Dialogue Committee. These communications permit an exchange of issues, problems and solutions on many issues.

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

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) Notice on February 24, 2010 (75 FR 8336) announcing the proposed renewal of this information collection activity and provided a 60-day public comment period. No public comments were received.

### 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 Section 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 three 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

No questions of a sensitive or private nature are included in this information collection. If information of a sensitive nature is submitted, 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 325320 (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, 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;
(2) epidemiological or exposure studies of human population groups indicating greater exposure than previously reported;
(3) studies or incidents tending to show lack of efficacy of certain pesticide products with public-health related uses;
(4) incidents involving toxic or adverse effects to human or other non-target organisms;
(5) information on excess residues on food or feed, or residues in surface water, ground water or drinking water;
(6) information on metabolites, degradates, contaminants or impurities which may be of toxicological concern;
(7) information showing that certain health-related products fail to perform as claimed or that pests have developed resistance to a product; and
(8) other information which may be relevant to risk/benefit determinations of any type.

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 regulation 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 account for these activities are approved by OMB under separate ICRs. Registrants also 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 regulationspecifies 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 a Master Record Identifier Number as are all other pesticide studies. Adverse effects incident reports are entered into a computerized data base which can track incidents by chemical, submitter, type of incident, 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). A 6(a)(2) study could be submitted electronically just as easily as a non-6(a)(2) study. Regarding incidents, electronic submission is possible, but would require a number of activities to be completed as prerequisites. First, OPP would work with registrants to develop a standard form for submitting incident reports. The resulting form would have to be approved by OMB. This standard form would be an essential precursor to electronic submission of incident data. The submission technique would comply with the Agency's electronic submission standards. Finally, OPP has been working on conversion of many of its existing databases to a single integrated system. The current incident data base is expected to become part of an integrated system and this is an essential precursor to electronic submission of incident data.

It should be noted that at the time the final regulations went into effect 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. The Agency does not mandate a specific format for the required submission, but, as noted above, has worked with industry to provide one to facilitate submissions. It is interesting to note that of the 1733 registrants with active registrations in November 2008, 718 hold only one product registration

and 762 hold from two to ten registrations. The median number of registrations per company is two.

The requirements of FIFRA section 6(a)(2) related to studies fall largely on basic producers, i.e., a producer who produces 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.

To further simplify compliance, EPA has issued detailed guidance, see Attachments C and D. Because at the present time there is no standard reporting format prescribed in the regulations, the submitters can use a format of their choosing.

### 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 used current statistics on the number of registrants of active products. For burden estimates related to study and incident data submissions, actual statistics for FY 2006-2008 were used.

As of November 2008, for purposes of this analysis, the Agency assumes 1,733 registrants with active registrations. The number of registrations held by each registrant ranges from 1 to 705 and the median is two. Seven hundred and eighteen (718) registrants hold only one product registration and 1,480 hold ten or fewer registrations. Thirty-three (33) registrants hold 51 - 100 product registrations. Only 37 companies hold more than 100 registrations.

Former registrants have an obligation to report adverse effects information for one 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 1,733 registrants assumed for this analysis.

The Agency received an average of 183 study-related submissions annually from FY2006 through FY2008. For purposes of this analysis, the Agency assumes 183 study-related submissions will be received each year in the future.

From FY2006 through FY 2008, the Agency received an average of 956 submissions per year from registrants containing an average of 70,622 incidents per year. Of these, 5,866 incidents were individually reported and 64,756 were reported as aggregate statistics on the yearly average. A small number of incidents, an average of 455 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.

The level of registrant reporting could have been 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 '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.

From FY2006 through FY2008 a total of 187 registrants submitted incident reports.

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 Acetochlor Registration Partnership may report for their member registrants for specific types of incidents.

For purposes of this ICR renewal, the Agency estimates that it will continue to receive 71,000 (rounded-up to two significant digits) incident reports from the regulated community each year. It is the estimated number of incidents - not the total number of registrants or number of registrants represented by current incident reporting - that drives the burden estimates in this analysis.

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 17,330 individuals requiring training each year. Please note that this estimate is strictly 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 data on 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) at http://www.bls.gov/oes/current/oes_nat.htm.

Sectors: The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of

collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm ).

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: We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs. Attachments F and F.1 contain worksheets providing the breakout of these costs. Costs are indexed to 2008 data.

To derive the labor rates for this ICR, Agency economists estimated the wages for the management, technical, and clerical labor categories using the methodology cited above. The respondent costs for this renewal for managerial, technical and clerical rates are estimated at $109.82, $60.39 and $35.89 per hour, respectively. These labor rates are fully loaded and include benefits and overhead costs.

Tables 1 - 6 summarize the annual burden hours and costs to registrants for compliance with the section 6(a)(2) requirements, including the PRA calculations for employee 6(a)(2) training.

**Table 1: Annual Respondent Burden/Cost Estimates per Submission - STUDIES**

| | BURDEN HOURS (PER STUDY) | | | TOTAL | |
|---|---|---|---|---|---|
| COLLECTION ACTIVITIES | Management $109.82/hr | Technical $60.39/hr | Clerical $35.89/hr | Hours | Costs ($) |
| Read Instructions | 0.10 | 0.20 | 0.00 | 0.30 | 23.06 |
| Create Information | 0.00 | 1.00 | 0.00 | 1.00 | 60.39 |
| Compile and Review | 0.10 | 0.50 | 0.00 | 0.60 | 41.18 |
| Complete Paperwork | 0.00 | 0.10 | 0.50 | 0.60 | 23.98 |
| Store and Maintain Data | 0.00 | 0.20 | 0.50 | 0.70 | 30.02 |
| TOTAL | 0.20 | 2.00 | 1.00 | 3.20 | 178.63 |

ANNUAL BURDEN: 3.2 Total Hours x 183 Studies =586 Hours

ANNUAL COSTS: (a) Management: 0.20 hours/study x $109.82/hour x 183 Studies = $ 4,019
(b) Technical: 2.00 hours/study x $60.39/hour x 183 Studies = $ 22,103
(c) Clerical: 1.00 hour/study x $35.89/hour x 183 Studies = $ 6,568
TOTAL = $ 32,690

**Table 2: Annual Respondent Burden/Cost Estimates per Submission - INCIDENTS**

| | BURDEN HOURS (PER YEAR) | | | TOTAL | |
|---|---|---|---|---|---|
| COLLECTION ACTIVITIES | Management $109.82/hr | Technical $60.39/hr | Clerical $35.89/hr | Hours | Costs ($) |
| Read Instructions | 0.00 | 0.10 | 0.00 | 0.10 | 6.04 |
| Create Information | 0.00 | 0.50 | 0.00 | 0.50 | 30.20 |
| Compile and Review | 0.20 | 0.50 | 0.00 | 0.70 | 52.16 |
| Complete Paperwork | 0.00 | 0.00 | 0.50 | 0.50 | 17.95 |
| Store and Maintain Data | 0.00 | 0.10 | 0.20 | 0.30 | 13.22 |
| TOTAL | 0.20 | 1.20 | 0.70 | 2.10 | 119.57 |

ANNUAL BURDEN: 2.10 Total Hours x 71,000 Incidents = 149,100 Hours

ANNUAL COSTS: (a) Management: 0.20 hours x $109.82 x 71,000 Incidents = $ 1,559,444

| | | | | |
|---|---|---|---|---|
| (b) Technical: | 1.20 hours x | $60.39 x 71,000 Incidents | = | $ 5,145,228 |
| (c) Clerical: | 0.70 hours x | $35.89 x 71,000 Incidents | = | $ 1,783,733 |
| | | TOTAL | = | $ 8,488,405 |

**Table 3: Total Annual Respondent Burden/Cost for Required Submissions**

| | Per Submission Estimates | | Total Submissions Expected each Year | Totals | |
|---|---|---|---|---|---|
| | Burden Hours | Costs ($) | | Burden Hours | Costs ($) |
| Studies | 3.2 | 178.63 | 183 | 586* | 32,690* |
| Incident | 2.1 | 119.56 | 71,000 | 149,100** | 8,488,405** |
| TOTAL | 5.3 | 298.19 | 71,183 | 149,686 | 8,521,095 |

*taken from Table 1 calculations
**taken from Table 2 calculations

**Table 4: Registrant Burden/Cost Estimates for Additional Activities - TRAINING**

| Activities/registrants | Burden Hour per Respondent | | | Totals | |
|---|---|---|---|---|---|
| | Management $109.82/hr | Technical $60.39/hr | Clerical $35.89/hr | Hours | Costs ($) |
| Plan training | 0.50 | 0.10 | 0.00 | 0.60 | 60.95 |
| Conduct employee training | 0.50 | 1.50 | 1.00 | 3.00 | 181.39 |
| Follow-up, tracking | 0.00 | 0.10 | 0.20 | 0.30 | 13.22 |
| Total | 1.00 | 1.70 | 1.20 | 3.90 | 255.55 |

**Table 5: Total Registrant Burden/Cost Estimates for Additional Activities -TRAINING**

| Activity | Per Registrant - Total | | # Expected | Totals | |
|---|---|---|---|---|---|
| | Hours | Costs ($) | | Hours | Costs ($) |
| Plan training | 0.6* | 60.95 | 1,733 | 1,040 | 105,625 |
| Conduct employee training | 3.0* | 181.39 | 17,330 | 51,990 | 3,143,402 |
| Follow-up, tracking | 0.3* | 13.22 | 1,733 | 520 | 22,905 |
| Total | 3.9* | 255.55 | 20,796 | 53,550 | 3,271,932 |

* taken from Table 4

**Table 6: Total Annual Burden/Cost for Registrants**

| | Per Activity Total Estimates | | Total Activities | Totals | |
|---|---|---|---|---|---|
| | Burden Hours | Costs ($) | | Burden Hours | Costs ($) |
| Studies | 3.2 | 255.60 | 183 | 586* | 32,690* |
| Incidents | 2.1 | 168.60 | 71,000 | 149,100** | 8,488,405** |
| Training | 3.9 | 346.50 | 20,796*** | 53,550*** | 3,271,932*** |
| TOTAL | | | | 203,236 | 11,793,027 |

*taken from Table 1 calculations
**taken from Table 2 calculations
***taken from Table 5

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.

Screening and managing submitted information involves a mixture of technical and clerical skills. Agency economists estimated the labor rates for EPA employees conducting these tasks. The EPA fully loaded employee costs for this renewal for technical and clerical rates are estimated at $71.58 and $41.21 per hour, respectively, a detailed work sheet of these formulas are in Attachment F. These labor rates are fully loaded and include benefits and overhead costs.

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 ICR's. This ICR does include the costs of subject matter experts reviewing incident reporting. The following tables illustrate the estimated Agency burden and costs:

**Table 7: Annual Agency Burden/Cost Estimates per Submission - STUDIES**

| | BURDEN HOURS (per year) | | TOTAL | |
|---|---|---|---|---|
| COLLECTION ACTIVITIES | Technical $71.58/hr | Clerical $41.21/hr | Hours | Costs ($) |
| Screen submitted information | 2.00 | 0.00 | 2.00 | 143.16 |
| Record, file and track submissions | 3.60 | 0.90 | 4.50 | 294.78 |
| TOTAL | 5.60 | 0.90 | 6.50 | 437.94 |

ANNUAL BURDEN: 6.5 Total Hours x 183 studies = 1,190 Hours

ANNUAL COSTS:
(a) Technical: 5.6 hours x $71.58 x 183 studies = $ $73,355
(b) Clerical: 0.9 hours x $41.21 x 183 studies = $ 6,787
TOTAL = $ 80,142

**Table 8: Annual Agency Burden/Cost Estimates per Submission - INCIDENTS**

| | BURDEN HOURS (per year) | | TOTAL | |
|---|---|---|---|---|
| COLLECTION ACTIVITIES | Technical $71.58/hr | Clerical $41.21/hr | Hours | Costs ($) |
| Screen submitted information | 0.132 | 0.00 | 0.132 | 9.43 |
| Record, file and track submissions | 0.0205 | 0.029 | 0.050 | 2.66 |

| | | | | |
|---|---|---|---|---|
| Communications, Guidance | 0.025 | 0.00 | 0.025 | 1.79 |
| TOTAL | 0.177 | 0.029 | 0.207 | 13.88 |

ANNUAL BURDEN: 0.207 Total Hours x 71,000 submissions = 14,697 Hours

ANNUAL COSTS: (a) Technical: 0.177 hours x $71.58 x 71,000 submissions =$ 899,546
(b) Clerical: 0.029 hours x 41.21 x 71,000 submissions = $ 84,845
TOTAL =$ 984,391

**Table 9: Total Annual Burden/Cost for Agency**

| | Per Submission Estimates | | Total Submissions Expected each Year | Totals | |
|---|---|---|---|---|---|
| | Burden Hours | Costs ($) | | Burden Hours | Costs ($) |
| Studies | 6.50 | 437.94 | 183 | 1,190* | 80,142* |
| Incidents | 0.207 | 13.88 | 71,000 | 14,697** | 984,391** |
| TOTAL | | | | 15,887 | 1,064,533 |

*taken from Table 7 calculations
**taken from Table 8 calculations

### d) Bottom Line Hours and Costs Tables

The total burden hours and costs for respondents and the Agency have been calculated and are presented in Table 10:

| Table 10: MASTER TABLE | TOTAL | |
|---|---|---|
| | Hours | Cost |
| Annual Respondent Burden/Cost Estimates | 203,236* | $11,793,027* |
| Annual Agency Burden/Cost Estimates | 15,887** | $1,064,533** |
| TOTAL | 219,123 | $12,857,560 |

*taken from Table 6
**taken from Table 9

The average per respondent burden is 117.27 hours (203,236 total hours ÷ 1,733 total potential respondents), and the average cost is $6,805 per respondent ($11,793,027 total cost ÷ 1,733 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

For the respondent burden, in the previous ICR OMB approved 167,316 burden hours for submission of information from pesticide registrants under FIFRA 6(a)(2) with a cost of $9,809,591. This ICR renewal request reflects an increase of approximately 35,920 burden hours to an annual respondent burden of 203,236 hours at a cost of $11,793,027. This reflects an adjustment in the number of registrants of active products (1,733 versus 1,720) and an increase

in burden to account for additional employees being trained, per commenters suggestion. The change in burden is an adjustment.

The Agency burden has increased, which reflects an increase in the number of incident submissions and more communications relating to incident data. Total burden hour estimates associated with studies are reduced because the estimated number of study submissions is reduced from 240 studies to 183. Burden estimates associated with the number of incident reports, however, are increased because of the increased volume of incident reporting (31%). Overall, considering both the decrease in studies and the increase in incidents, the total respondent burden hours increased from 167,316 to 203,236. The change in burden is an adjustment.

Calculations of labor rates and related burden costs have changed for both EPA and respondents. In previous renewals cycles, the Agency merely adjusted the labor rates to account for inflation. However, for this renewal, Agency economists have completely re-estimated wages, benefits, and overhead for all labor categories for both Agency employees and respondents. Therefore, total burden costs have increased, but may not be directly comparable to the previous ICR.

### f) Burden Statement

The total annual "respondent" (applicant) burden is estimated to be 203,236 hours, with an average potential per respondent burden of 117.27 hours. According to the PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations, after initial display in the final rule, are listed in 40 CFR part 9, and appear on the information collection instrument as applicable, i.e., form or instructions.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPP-2009-0886. An electronic version of the public docket is available at http://www.regulations.gov/which may be used to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the docket ID number identified in this document. The documents are also available for public viewing at the OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington VA. The Docket is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket is (703) 305-5806. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC

20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OPP-2009-0886, the EPA ICR Number 1204.11 and OMB Control Number 2070-0039 in any correspondence, but do not submit 6(a)(2) information to this address. The 6(a)(2) information should be submitted to USEPA, Office of Pesticide Programs as specified in 40 CFR 150.17 and 40 CFR 159.156.

## 7. LIST OF ATTACHMENTS

All of the attachments listed below can be found in the docket for this ICR, or as part of the supporting statement or are available via a link (unless otherwise noted); accessible electronically through **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-2009-0886** 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.

**ATTACHMENT C:**
PR Notice 98-3 - Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants see 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) see 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 Wages Rates for Industry, State, and EPA Labor Costs

**ATTACHMENT G:**
List of Consultation Questions and Responses for 6(a)(2)

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