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. 1204.10

b) Abstract

This Information Collection Request (ICR) is a proposed renewal of an existing ICR that is currently approved by OMB and is due to expire May 31, 2007. Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency which may be relevant to the balancing of the risks and benefits of a pesticide product (see Attachment A).

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).

As expected, implementation of the 1998 final regulations initially resulted in an increase in the number of incident reports submitted annually. That was assumed to be the result of increased awareness and understanding on the part of pesticide registrants of their reporting responsibilities under FIFRA section 6(a)(2). After the first year under the regulations, incident reporting leveled off and has remained generally consistent. Study submissions, on the other hand, have gradually decreased as the pesticide reregistration program data call-in activities wound down. For the purposes of this analysis, the estimate for study and incident submissions is the average for the past three fiscal years (2003-2005).

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.

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)

b) Practical Utility/Users of the Data

The Office of Pesticide Programs (OPP) is the primary user of the information that registrants would submit to the Agency under FIFRA section 6(a)(2). The information submitted is an essential component of the Agency's pesticide registration and reregistration programs, and will be an essential component of the registration review program. These programs 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 is found in section 3(c)(2)(B) of FIFRA, and is covered by other ICRs that are also approved by OMB. 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 justified 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 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) Public Notice Required Prior to ICR submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA published in the Federal Register (71 FR 62429, October 25, 2006) a notice soliciting comments on this information collection activity and the Agency's intent to renew the OMB approval of this ICR. No comments were received in response to this notice.

The proposed renewal ICR, the FR notices, and the revised renewal ICR which includes the consultations are located in the docket for this action, which can be accessed at http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2006-0616.

c) Consultations

As part of preparation of this ICR renewal, EPA contacted representatives of a cross-section or 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:

- Mason Chemical Co., (Elizabeth Tannehill; 800-362-1855)
- Spartan Chemical Co., (Ronald T. Cook; 800-537-8990)
- Chase Products Co., (Aludia B. Hernandez; 708-865-1000)
- Clorox Services Co., (Dana Clark; 925-425-6629)
- PBI Gordon, (Gene Sturner; 816-460-6289)
- Osmose, Inc., (Teri Muchow; 716-319-3255)
- Bayer CropScience, (Janet Dykes; 919-549-2000)
- Syngenta Crop Protection, (Dennis Hackett; 336-632-2535)

All provided comments except for Spartan Chemical Company. Their responses are in Attachment G. What follows is a summary of their comments.

Regarding the availability of this information from another source, six of the seven respondents agreed that there was no other source. One respondent suggested that poison control centers may have pesticide related incident reports, but not in a format useful to the Agency.

Regarding frequency of reporting, there was a mixed response. Some felt that those incidents required to be reported on a monthly basis could be as effectively reported quarterly. PBI Gordon noted that quarterly reporting tends to be seasonal, so it is useful in revealing trends in adverse effects. The Agency believes that the reporting periods in the regulations strike the balance between timely receipt of information by EPA and sufficient time for the registrant to accumulate and vet information to be reported.

Most respondents indicated that the instructions for reporting adverse effects information are clear and the Voluntary Reporting Forms (Attachment J) are useful. Two respondents suggested the Agency put more guidance on the Web in the form of Frequently Asked Questions (FAQ). One registrant would like to see regular training sessions conducted by the Agency because of heavy staff turnover. It should be noted that the Agency is preparing a plain language version of the regulations and plans to publish it on the 6(a)(2) Web page during 2007.

The response to questions regarding e-submission of adverse effects information was decidedly mixed. Several respondents indicated interest in increased use of electronic submission. Among those representatives, some believed magnetic media submissions could save some time and costs. On the other hand, one specified "direct entry into self-correcting on-line form" as a way to improve efficiency. Another expressed concern about electronic signature standards. Yet another wanted a guarantee of FIFRA CBI protection if e-submission were employed. Finally, two respondents said continuing with paper submission was fine.

Regarding burden hours and costs, three respondents felt the rates were reasonable. One could not comment because it has little adverse effects information to report. PBI Gordon, Bayer, and Syngenta felt the burden hours were low. It should be noted, however, that these are large companies which tend to have higher expenditures for 6(a)(2) work given the increase in number of registrations. EPA's estimates are averages for both very small and 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.

In addition to these consultation activities, dialogue between industry and the Agency on adverse effects information reporting requirements, content, definitions, format, and timing is frequent and on-going. In addition to phone conversations, e-mails, and letters, Agency staff participate in meetings with individual registrants as well as gatherings of large groups of registrants from time to time. These communications permit an exchange of issues, problems, and solutions on many issues.

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

This information collection is well within the guidelines provided under the PRA and the implementing regulations issued by OMB. It should be noted, however, that even though the 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 average 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, or re-registration under FIFRA section 3 or section 4, respectively, 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. 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 final rule, 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, registration review under section 3 (g), re-registration under section 4 (which are approved by OMB under separate ICR approvals. 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 final rule, 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 final rule allows flexibility in the method or format for the required submission. In essence, the final rule 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 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 standards 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, but conversion has not yet been scheduled. This too would be 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.

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 1,720 registrants with active registrations in November 2005, 736 hold only one product registration and 741 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 2005 were used.

As of November 2005, for purposes of this analysis, the Agency assumes 1,720 registrants with active registrations. The number of registrations held by each registrant ranges from 1 to 707 and the median is two. Seven hundred and thirty-six registrants hold only one product registration and 1,477 hold ten or fewer registrations. Thirty-two registrants hold 51 - 100 product registrations. Only 38 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 1,720 registrants assumed for this analysis.

The Agency received an average of 240 study-related submissions annually from FY2003 through FY2005. For purposes of this analysis, the Agency assumes 240 study-related submissions will be received each year in the future.

From FY2003 through FY 2005, the Agency received an average of 967 submissions per year from registrants containing an average of 53,960 incidents/year. Of these, 6,512 incidents were individually reported and 47,448 were reported as aggregate statistics on the yearly average. A small number of incidents – an average of 157 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 E), 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.

The number of registrants represented by the incident report submissions from FY2003 through FY2005 is 210. 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 54,000 (53,960 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 17,200 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.

The ICR that accompanied the final regulations estimated substantial burden associated with the first year of implementation of the regulatory program. Since the one-time effort to learn about the regulations and establish or modify internal processes and systems has been accomplished, this ICR estimates burden hours and costs associated with a mature, on-going 6(a)(2) program.

b) Estimating Respondent Costs

i) Estimating Labor Costs

The following tables illustrate the estimated respondent burden and costs. While the spreadsheets that underlie the tables calculated in dollars and cents, the results are rounded to the nearest dollar. Please note that the burden/costs are calculated differently for 6(a)(2) studies and incidents and for training as an additional activity.

For a period of some years, when estimating labor rates for most OPP program ICR renewals, the Agency adjusted the ICR renewal labor rates by using a method such as the NASA Gross Domestic Product (GDP) Deflator Inflation Calculator to index the labor cost for a particular year. However, in July 2006, Agency economists completely re-estimated wages, benefits, and overhead for all labor categories for the pesticide industry, state government and Agency employees. The Agency analysis uses currently available information on labor rates and other benefits from publicly available websites. A copy of the methodology used to re-estimate the labor rates and formulas used to derive the fully loaded rates and overhead costs are listed in attachment F.

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 $100.86, $64.80, and $33.05 per hour, respectively. These labor rates are fully loaded and include benefits and overhead costs.

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

	BURDEN HOURS (PER YEAR)			TOTAL	
COLLECTION ACTIVITIES	Management $100.86/hr	Technical $64.80/hr	Clerical $33.05/hr	Hours	Costs ($)
Read Instructions	0.10	0.20	0.00	0.30	23.05
Create Information	0.00	1.00	0.00	1.00	64.80
Compile and Review	0.10	0.50	0.00	0.60	42.49
Complete Paperwork	0.00	0.10	0.50	0.60	23.01
Store and Maintain Data	0.00	0.20	0.50	0.70	29.49
TOTAL	0.20	2.00	1.00	3.20	182.84

ANNUAL BURDEN: 3.2 Total Hours x 240 Studies = 768 Hours

ANNUAL COSTS: (a) Management: 0.20 hours x $100.86 x 240 Studies = $ 4,841
(b) Technical: 2.00 hours x $64.80 x 240 Studies = $ 31,104
(c) Clerical: 1.00 hour x $33.05 x 240 Studies = $ 7,932
TOTAL = $ 43,877

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

	BURDEN HOURS (PER YEAR)			TOTAL	
COLLECTION ACTIVITIES	Management $100.86/hr	Technical $64.80/hr	Clerical $33.05/hr	Hours	Costs ($)
Read Instructions	0.00	0.10	0.00	0.10	6.48
Create Information	0.00	0.50	0.00	0.50	32.40
Compile and Review	0.20	0.50	0.00	0.70	52.57
Complete Paperwork	0.00	0.00	0.50	0.50	16.53
Store and Maintain Data	0.00	0.10	0.20	0.30	13.09
TOTAL	0.20	1.20	0.70	2.10	121.07

ANNUAL BURDEN: 2.10 Total Hours x 54,000 Incidents = 113,400 Hours

ANNUAL COSTS: (a) Management: 0.20 hours x $100.86 x 54,000 Incidents = $ 1,089,288
(b) Technical: 1.20 hours x $64.80 x 54,000 Incidents = $ 4,199,040
(c) Clerical: 0.70 hours x $33.05 x 54,000 Incidents = $ 1,249,290
TOTAL = $ 6,537,618

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	255.60	240	768*	43,877*
Incident	2.1	168.60	54,000	113,400**	6,537,618**
TOTAL	5.3	424.20	54,240	114,168	6,581,495

*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**	
	Managemen t $100.86/hr	Technical $64.80/hr	Clerical $33.05/hr	**Hours**	**Costs ($)**
Plan training	0.50	0.10	0.00	0.60	56.91
Conduct employee training	0.50	1.50	1.00	3.00	180.68
Follow-up, tracking	0.00	0.10	0.20	0.30	13.09
Total	1.00	1.70	1.20	3.90	250.68

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*	56.91*	1,720	1,032	97,885
Conduct employee training	3.0*	180.68*	17,200	51,600	3,107,696
Follow-up, tracking	0.3*	13.09*	1,720	516	22,515
Total	3.9*	250.68*	20,640	53,148	3,228,096

* 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	240	768*	43,877*
Incidents	2.1	168.60	54,000	113,400**	6,537,618**
Training	3.9	346.50	20,640***	53,148***	3,228,096***
TOTAL				167,316	9,809,591

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

***taken from Table 5

i) 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. As part of the newly-developed methodology (Attachment F) Agency economists also estimated labor rates for EPA employees. The EPA employee costs for this renewal for technical and clerical rates are estimated at $66.34, and $47.17 per hour, respectively. These labor rates are fully loaded and include benefits and overhead costs. The Agency contracts out much of the incident data and document management activities. (This is reflected in Table 8 below.) This practice will continue over the life of the ICR.

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. 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 $66.34/hr	Clerical $47.17/hr	Hours	Costs ($)
Screen submitted information	2.00	0.00	2.00	132.68
Record, file and track submissions	3.60	0.90	4.50	281.27
TOTAL	5.60	0.90	6.50	413.95

ANNUAL BURDEN: 6.5 Total Hours x 240 studies = 1,560 Hours

ANNUAL COSTS:
(a) Technical: 5.6 hours x $66.34 x 240 studies = $ 89,161
(b) Clerical: 0.9 hours x $47.17 x 240 studies = $ 10,189
TOTAL = $ 99,350

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

	BURDEN HOURS (per year)	TOTAL

COLLECTION ACTIVITIES	Technical $66.34/hr	Clerical $47.17/hr	Hours	Costs ($)
Screen submitted information	0.052	0.00	0.052	3.45
Record, file and track submissions	0.020	0.006	0.026	1.61
Communications, Guidance	0.017	0.00	0.017	1.13
TOTAL	0.089	0.006	0.095	6.19

ANNUAL BURDEN: 0.095 Total Hours x 54,000 submissions = 5,130 Hours

ANNUAL COSTS: (a) Technical: 0.089 hours x $66.34 x 54,000 submissions = $ 318,830
(b) Clerical: 0.006 hours x 47.17 x 54,000 submissions = $ 15,283
(c) Contractor Costs = $ 80,000
TOTAL =
$ 414,113

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	524.30	240	1,560*	99,350*
Incidents	0.095	8.05	54,000	5,130**	414,113**
TOTAL				6,690	513,463

*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	167,316*	$9,809,591*
Annual Agency Burden/Cost Estimates	6,690**	$513,463**

TOTAL	174,006	$10,323,054

*taken from Table 6
**taken from Table 7

The average per respondent burden is 97.3 hours (167,316 total hours ÷ 1,720 total potential respondents), and the average cost is $5,703 per respondent ($9,809,591 total cost ÷ 1,720 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 registrations held, and the number of incidents that need to be reported.

e) Reasons for Change in Burden

In the previous ICR, OMB approved 155,639 burden hours for submission of information from pesticide registrants under FIFRA 6(a)(2) with a cost of $12,057,947 (in 2003 dollars).

This ICR renewal request reflects an increase of approximately 11,677 burden hours to an annual respondent burden of 167,316 hours at a cost of $9,809,591 (in 2006 dollars). The change in burden reflects a number of adjustments. For this renewal ICR, there are now fewer registrants of active products (1,720 versus 1,877) and therefore fewer employees to be trained (17,200 versus 18,770) than reflected in the existing ICR. The hours used to calculate total burden hours and costs are unchanged from the existing ICR. Total burden hour estimates associated with studies are reduced because the estimated number of study submissions is reduced from 325 studies to 240. Burden estimates associated with the number of incident reports, however, are increased because of the increased volume of incident reporting (17%). Overall, considering both the decrease in studies and the increase in incidents, the total burden hours increased minimally from 155,639 to 167,316.

Labor rates and related burden costs have decreased 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 decreased.

f) Burden Statement

The total annual "respondent" (applicant) burden for the ICR entitled **Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2)**, which is approved by OMB under OMB Control No. 2070-0039, is estimated to be 167,316 hours, with an average potential per respondent burden of 97.3 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-2006-0616. 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-2006-0616 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.

Attachments List

All of the attachments listed below can be found in the docket for this ICR (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-2006-0616 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)

ATTACHMENT B: Final Regulation for FIFRA Section 6(a)(2) reports - Codified as 40 CFR part 159

ATTACHMENT C: PR Notice 98-3 - Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants (w/Attachment)

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

ATTACHMENT E: Class Determination Regarding Confidentiality of 6(a)(2) Information

ATTACHMENT F: Methodology for Estimating OPP ICR Wages Rates for Industry, State, and EPA Labor Costs; Keigwin; July 25, 2006

ATTACHMENT G: List of Consultation Questions and Responses

ATTACHMENT H: Display Related to OMB Control #2070-0039 - *Listings of Related Regulations in 40 CFR 9.1*.

ATTACHMENT I: First Federal Register Notice -71 FR 62429 – *Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2); EPA ICR No. 1204.10, OMB Control No. 2070-0039* (published October 25, 2006).

ATTACHMENT J: Industry's Voluntary 6(a)(2) Incident Reporting Forms & Guidance Documents