SUPPORTING STATEMENT
FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting

OMB No.: 2070-0142 EPA ICR No.: 1693.05

1(b) Short Characterization/Abstract

The Environmental Protection Agency (EPA) is responsible for the regulation of pesticides as authorized by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Prior to EPA granting a registration, the manufacturer of the pesticide must demonstrate to the Agency that the use of the pesticide product will not result in any unreasonable adverse effects to humans or the environment. EPA is also responsible under the Federal Food, Drug, and Cosmetic Act (FFDCA) for establishing a tolerance or exemption from the requirement of a tolerance for pesticide residues on food or feed.

The Agency promulgated a final rule, codified at 40 CFR part 174, that addresses the regulatory status of pesticidal substances that are produced by plants (plant-incorporated protectants). A plant-incorporated protectant (PIP) is defined in the final rule as "the pesticidal substance that is intended to be produced and used in a living plant and the genetic material necessary for the production of such a substance." The rule (Attachment A) exempts a wide range of PIPs from registration requirements under FIFRA, and it imposes two new requirements on manufacturers of some PIPs.

This Information Collection Request (ICR) covers the two information collection related provisions contained in the rule, i.e., the provision that requires registrants that make Confidential Business Information (CBI) claims to substantiate such claims when they are made, and the provision that requires manufacturers of PIPs exempted from requirements of registration under the final rule to report adverse effects to the Agency. The current CBI regulations at 40 CFR part 2 require that claimants substantiate their CBI claims for their own records when the claim is made, and subsequently provide the substantiation to EPA only if requested. The substantiation, however, is not required to be included with the submission to EPA in which the CBI claims are made. The burden associated with the existing requirement is already approved by OMB.

Although 40 CFR 174 requires the claimant to include the CBI substantiation in the PIP-related submissions to EPA, it is difficult to identify any additional burden that such a requirement might actually impose. Nevertheless, the Agency has chosen the conservative approach of including potential burden and costs for preparing and submitting the CBI substantiation at the time of submission of the information containing the CBI claim as required by the rule.

The provisions of 40 CFR 174 that are related to information collection activities which are part of registration activities, e.g., data requirements for pesticide registrations, are already approved by OMB under the PRA, and that approval is not impacted by the clarification provided in the final rule. Information collection activities related to pesticide registration are approved under OMB Control Nos. 2070-0060 (Application for New or Amended Pesticide Registration), 2070-0024 (Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients), and 2070-0040 (Application for Experimental Use Permit (EUP) to Ship and Use a Pesticide for Experimental Purposes Only). This ICR, therefore, discusses the paperwork burdens associated with the requirement for registrants to substantiate CBI claims when they are made, and the requirement for manufacturers of PIPs exempted from registration requirements under the final rule to report adverse effects to the Agency within 30 days.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Although FIFRA requires the registration of most pesticides, it also authorizes the Agency's regulation of unregistered pesticides. FIFRA section 3(a) provides that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may limit the distribution, sale, or use of any pesticide that is not registered under section 3 of FIFRA, or subject to an experimental use permit under section 5 of FIFRA, or subject to an emergency exemption under section 18 of FIFRA. Pesticides that are "not registered" include pesticides that are exempt from FIFRA requirements under section 25(b) (Attachment B).

FIFRA section 2(bb) defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act" (7 U.S.C. 136(bb)).

Section 25(b)(2) of FIFRA allows EPA to exempt, by regulation, any pesticide from some or all of the requirements of FIFRA, if the pesticide is of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of that Act (7 U.S.C. 136w(b)(2)). EPA interprets FIFRA section 25(b)(2) to authorize EPA to exempt a pesticide or category of pesticides that EPA determines poses a low probability of risk to the environment, and that is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA.

To determine whether a pesticide qualifies for an exemption under section 25(b)(2), EPA evaluates both the potential risks and benefits of the use of the pesticide. In evaluating a pesticide under the first exemption criterion, whether use of the pesticide poses a low probability of risk to the environment, EPA considers the extent of the potential risks caused by use of the pesticide to the environment, including humans and other animals, plants, water, air and land. Potential risks to humans include dietary risks as well as non-dietary risks such as those resulting from

occupational or residential exposure to the pesticide. EPA uses the FFDCA section 408 standard in evaluating dietary risks. EPA will not exempt pesticides under section 25(b)(2) that fail the low probability of risk criterion.

In evaluating a pesticide under the second exemption criterion, whether the use of the pesticide is likely to cause unreasonable adverse effects on the environment even in the absence of regulatory oversight under FIFRA, EPA balances all the potential risks to human health, including any dietary risks, and risks to the remainder of the environment from use of the pesticide against the potential benefits associated with its use. In balancing risks and benefits, EPA considers the economic, social, and environmental costs and benefits of the use of the pesticide. If the pesticide meets both exemption criteria, EPA may exempt the pesticide from regulation under FIFRA section 25(b)(2).

Under FFDCA section 408(a) (Attachment C), a pesticide chemical residue in or on food is not safe unless EPA has issued either: a tolerance for the residue and the residue is within the tolerance limits, or an exemption from the requirement of a tolerance for the residue (21 U.S.C. 346a(a)(1)). FFDCA section 408 authorizes EPA to determine a residue is safe and exempt from the requirement of a tolerance if the Administrator ". . . has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information" (21 U.S.C. 346a(c)(2)(A)). Section 408 of the FFDCA also directs EPA to specifically consider harm that may result to infants and children as a result of pesticide chemical residues.

A determination that a pesticide chemical meets the safety standard of section 408(a) of the FFDCA may also be relevant to whether a pesticide qualifies for a FIFRA section 25(b)(2) exemption with respect to human health risks arising from other routes of exposure. However, FIFRA does not provide for exemption of a pesticide in food based solely upon consistency with the FFDCA section 408 exemption standard. At a minimum, EPA also must evaluate risks arising from occupational exposure to humans and determine that such risks meet both exemption criteria. In addition, EPA must evaluate the risks to the environment from the pesticide and determine both that the pesticide poses only a low probability of environmental risks, and that use of the pesticide is not likely to cause any unreasonable adverse effects on the remainder of the environment in the absence of regulation under FIFRA.

2(b) Practical Utility/Users of the Data

EPA believes that requiring the substantiation of CBI claims for PIPs at the time of submission to the Agency will help ensure a timely EPA response to submissions for PIPs, protect the public's right to access information consistent with FIFRA, and ensure that information qualifying as CBI is properly protected from unauthorized disclosures. Since registrants are already required to ensure that CBI claims are proper prior to asserting the CBI protection for information submitted to EPA, this requirement simply affects the time at which the substantiation is submitted to the Agency, i.e., it requires the inclusion of this substantiation with the submission.

The Agency's analysis of the potential risks and benefits of PIPs has led it to conclude that the categories of PIPs described in 40 CFR part 174, subpart B warrant exemption. However, it is possible that there may be unforeseeable adverse effects to human health or the environment from the testing and use of otherwise exempted PIPs, as the exemptions at subpart B are broad and cover literally thousands of potential substances, some of which under certain use conditions have the potential to be toxic. The Agency therefore included, as a condition of exemption, a requirement to report to EPA within 30 days any factual adverse effects associated with these otherwise exempt PIPs. These reporting requirements are similar to reporting requirements imposed on registrants under FIFRA section 6(a)(2) for registered pesticides. However, since the 6(a)(2) reporting requirement applies to registered pesticides and many PIPs are exempted from registration requirements, the separate reporting requirement is necessary in order to obtain any information on unforeseen adverse effects from the exempted PIPs.

The information supplied to substantiate claims of confidentiality will be used by the Agency to determine whether CBI claims comply with the confidentiality provisions of FIFRA. Early substantiation of CBI claims will enable the Agency to promptly release information supporting PIPs registration decisions, without delaying registrations in order to obtain CBI substantiation once a decision has been made to register a PIP, while still protecting legitimate CBI.

The adverse effects reports on exempted PIPs will be utilized by the Agency to evaluate adverse effects to determine if any additional regulatory actions are warranted. These reports will also enable the Agency to report to appropriate oversight bodies and the public its evaluation of such adverse effects and will help support any additional decision on regulatory oversight.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non duplication

In fulfilling its mission as the Federal agency primarily responsible for the regulation of pesticides, EPA works closely with the U.S. Department of Agriculture (USDA) which has responsibilities under the Federal Plant Protection Act (FPPA), and the U.S. Food and Drug Administration (FDA) which has responsibilities under the FFDCA. EPA, USDA and FDA consult and exchange information when such consultation is helpful in resolving safety questions. The three agencies also strive for consistency between programs, adopting consistent approaches, to the extent permitted by the respective statutory authorities. A consistent approach between agencies is easier for the regulated community to understand. It is also more likely to conserve resources, as submitters would more likely be able to use data developed for one agency to meet requirements posed by another agency for the same or similar products.

Generally, respondents are not required to submit applications or any other related data or information regarding testing to any other federal agency or to any other EPA program office. However, there may be requirements under the FPPA for plants that produce PIPs. Under the FPPA, the USDA's Animal and Plant Health Inspection Service (APHIS) regulates field testing

of genetically altered plants, while EPA will have regulatory oversight of the pesticide substances produced by those plants. In instances where review under the FPPA may be triggered, the respondent will need to contact APHIS for a determination of whether the plant containing a PIP is a plant pest that will need a permit. In addition, registrants may be required to obtain an experimental use permit (EUP) for PIPs-related field trials. In such cases, registrants would be expected to comply with the applicable EUP requirements. As described in section 1(b) of this supporting statement, the paperwork activities associated with EUPs are addressed in a separate ICR. In any case, there is no known duplication related to the requirements covered in this ICR, i.e., the up-front CBI substantiation or the submission of adverse effects reports for exempted PIPs. Each respondent must submit information unique to his/her product application, or allegation received, and will do so only once on occasion.

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

In preparing to renew this ICR, EPA published a notice in the Federal Register which provided a 60-day public notice and comment period on the draft ICR (see 72 FR 11862; March 14, 2007). EPA did not receive comment in response to this notice.

3(c) Consultations

In developing its approach to PIPs, EPA requested advice from two scientific advisory groups at three meetings. In 1992, a subpanel of the FIFRA Scientific Advisory Panel (SAP) reviewed a draft proposed policy statement and answered a series of scientific questions concerned primarily with EPA's proposed exemptions under FIFRA. The following year, a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) met to address a series of scientific questions concerned primarily with EPA's proposed exemptions under the FFDCA. In 1994, a joint meeting of these two groups met to address a series of scientific questions on approaches to PIPs under both FIFRA and FFDCA. Advice from these scientific advisory groups was considered in developing the provisions codified at 40 CFR 174.

In addition to the public consultation described above, consultation and/or dialogue between industry and managers in the Biopesticides and Pollution Prevention Division (BPPD) of the Office of Pesticide Programs (OPP) occurs on an informal, on-going, as-needed basis, during the submission and review of an application for EUP or registration. Experience has shown that if any sort of problem arises, be it technical, administrative, or otherwise, or, if there are suggestions for improvements in the program, the applicants will not hesitate to inform BPPD. Any questions or consultations connected with a particular submission are addressed in a meeting or telephone conversation with the applicant, and do not necessarily occur at specified intervals.

During the preparation of this ICR renewal, EPA staff contacted the following representatives of pesticide registrants by e-mail and asked them for their responses to questions concerning the information collection and assessment of the burden estimates in the ICR (see Attachment D):

- Myrna Q. Sevilla, BHN Research, email: mqs@BHNseed.com

- Penny Hunst, Dow Agrosciences, email: felusrg@dow.com

- Russell Schneider, Monsanto Co., 202-383-2866, e-mail: russell.p.schneider@monsanto.com

No reports concerning adverse effects related to exempted PIPs have been submitted to EPA, so the registrants were asked only about up-front substantiation of confidential business information claims. The three respondents consulted generally agreed that the information EPA asks for is not available from another source, and that the instructions for submission are clear, although one suggested a standard form for substantiation of CBI claims. They also expressed interest in electronic reporting, "but only if EPA can guarantee absolute secure transmission and data storage," as one respondent put it. All three stated that the burden estimates used by EPA in this ICR renewal request are realistic.

3(d) Effects of Less Frequent Collection

Not applicable. The information is submitted either in conjunction with the application or when an adverse effect occurs for an exempted PIP. This activity is conducted only once per "event," and therefore, there are no available means by which the Agency can reduce the frequency.

3(e) General Guidelines

The collection activities covered by this ICR comply with the guidelines provided under the PRA and the implementing regulations issued by OMB..

3(f) Confidentiality

Although the EPA urges submitters to minimize the amount of information that is claimed as CBI, any data and/or information submitted to the Agency may be claimed as trade secret, or commercial or financial information and will be protected from disclosure by the EPA under FIFRA section 10 and the associated regulations as contained in 40 CFR Part 2, Subpart B. When information that is claimed as trade secret or CBI is provided to the Agency, such information is subject to the protections and procedures set forth in FIFRA Section 10. Nothing in this rule affects those protections.

Even if a registrant fails to include the required substantiation for any CBI claims made in the PIP application when that application is submitted to EPA, the Agency intends to still handle such claims in accordance with the FIFRA Confidential Business Information Security Manual. This manual contains instructions relative to all contact with confidential documents, including responsibility of EPA employees, physical security measures, CBI materials within EPA, CBI typing procedures (documents typed internally or by contract), and interdivisional routing procedures. The manual dictates all CBI must be marked or flagged as such, that it must be kept in secure, i.e., double-locked areas, and that all CBI to be destroyed must be cleared by a document control officer and placed in EPA's paper shredder.

3(g) Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in conjunction with this collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The respondents for the information collection activities contained in this ICR include producers and importers of PIPs. These entities may be classified under the following North American Industrial Classification System (NAICS) codes:

32532	Pesticides and Other Agricultural Chemical Manufacturing
54171	Research and Development in the Physical, Engineering, and Life Sciences
325414	Biological Products (except Diagnostic) Manufacturing
611310	Colleges, Universities, and Professional Schools
422910	Farm Supplies Wholesalers
422930	Flower, Nursery Stock, and Florists' Supplies (Wholesalers)

4(b) Information Requested

(i) Data items, including record keeping requirements

Registrants must continue to review the regulations regarding CBI, review the materials in their submission for which claims are being made; and ensure that CBI claims are properly made. Pursuant to 40 CFR 174, registrants must submit a substantiation for any CBI claim made for information for PIPs submitted to EPA. The Agency is not imposing any new requirements regarding the basis for making a CBI claim, or the points that must be addressed to substantiate any CBI claim that is made. These requirements already exist in 40 CFR part 2. In addition, EPA is not imposing any specific form or format for these substantiations. (See 40 CFR 174.9)

Manufacturers of PIPs exempted from registration requirements must submit to EPA any information they subsequently obtain regarding adverse effects on human health or the environment alleged to have been caused by the exempted PIP. The Agency anticipates that the entities will obtain adverse effects information during the normal course of business, and then will make a report to the Agency with adequate background information for the Agency to be able to make a decision to either ask for additional information or to act on the information presented. The Agency does not foresee any extra data collection effort to find adverse effects beyond the normal course of business but rather envisions these effects being discovered from ongoing studies of various PIPs or customer complaints. Although EPA specifies the content of

any adverse effects report submitted to EPA, EPA is not imposing any specific form or format for these reports. (See 40 CFR 174.71)

In addition, entities may also be asked to respond to Agency questions that arise based on the submission, whether it be the CBI substantiation, or the adverse effects report. Such follow-up activities are assumed as part of the initial burden estimates. Should further information be necessary, e.g., should the adverse effect information reported to EPA indicate the need for a study or other additional information, any additional Agency requirement would come in the form of a data call-in covered under the existing regulations and ICR (Data Call-Ins: Special Review and Registration Review; OMB Control No. 2070-0057; EPA ICR No. 922). This ICR is not intended to address such activities.

(ii) Respondent Activities

The requirements for up-front CBI substantiation and adverse effects reporting are separate requirements that only occur on occasion. The CBI substantiation occurs when an entity is submitting PIP related information to EPA that contains CBI claims pursuant to 40 CFR part 2. The adverse effects reporting occurs when an entity obtains information regarding adverse effects on human health or the environment alleged to have been caused by the exempted PIP.

Although each activity is distinct, a typical respondent for each activity is expected to engage in the following activities:

Read Regulations	The respondent needs to become familiar with the regulations governing CBI substantiation or adverse effects reporting as they pertain to PIPs.
Plan Activities	The respondent must develop/amend and implement a plan to ensure compliance with these requirements. The registrant is also encouraged to consult with the Agency.
Gather Information	The information necessary to provide the required substantiation or any information obtained on adverse effects must be assembled.
Review Information	The respondent must check the CBI substantiation for accuracy and completeness, or verify that the adverse effects report accurately reflects the information they have obtained.
Complete Paperwork	The information must be compiled into a document(s) or report(s) and prepared for submission to EPA.
Submit Information	The respondent must submit the information to the Office of Pesticide Programs as required.
Store, Maintain, and File Information	The final rule does not contain any new recordkeeping requirements. Please note however that FIFRA section 8, and the related regulations in 40 CFR part 169, require registrants to store and maintain certain information related to their pesticide products. Since no new recordkeeping requirements were imposed by this rule, EPA did not include any related burden in this ICR.

5. THE INFORMATION COLLECTED – AGENCY ACTIVITIES, COLLECTION METHODOLOGIES, AND INFORMATION MANAGEMENT

5(a) Agency Activities

The Agency must evaluate the CBI substantiations when submitted, and process any adverse effect reports for exempted PIPs when received. Although these activities are distinct and separate, the Agency is expected to engage in the following activities:

Consult with the registrant	The Agency will respond to any questions either in writing, or verbally via meetings or by telephone, and provide any other assistance or guidance requested.
Record submissions	Whether the submission involves an application package for the registration of a PIP, or an adverse effects report for allegations related to an exempted PIP, the submission is recorded or logged in by the Agency to document its receipt. The Agency will create an electronic record of the necessary information for routing and tracking purposes.
Review submissions	The Agency will review the incoming materials with CBI claims to evaluate the CBI substantiations for completeness and appropriateness, and will review the incoming adverse effects reports to determine what, if any, substantive review or action might be necessary as follow-up to the alleged adverse effects.
Store the information	The Agency will maintain the information contained in the submitted application package, including the CBI substantiation that was submitted, and will maintain any adverse effects report(s) submitted.

5(b) Collection Methodology and Management

Respondents to this ICR providing substantiation of CBI claims at the time the claims are made must necessarily submit the information as part of their larger package for registration of a pesticide product, since it is parts of that package that are claimed as CBI. Although EPA is working to allow electronic submission of registration packages, they are currently submitted by mail.

All information received by the Agency pertaining to CBI substantiation or adverse effects for exempted PIPs will be routed to the Biopesticides and Pollution Prevention Division (BPPD) of the Office of Pesticide Programs (OPP). It will be pin-punched by date, screened, and entered into the Office of Pesticide Programs Information Network (OPPIN).

For registration packages involving PIPs, a file will be created and the application package will be forwarded to the appropriate Manager within BPPD. The Manager assures that the initial OPPIN entry is correct, reviews the information, and if necessary, routes the submitted data through scientific and/or administrative review. If the scientific information indicates that the submission is deficient in any manner, the submitter has the option of attempting to correct

the deficiency. If the submission indicates that information claimed as CBI warrants said claim, the applicant is notified and the information is marked as such. The Agency will continue current practice of treating information claimed as CBI as such, until a CBI determination is made. If a determination is made that a CBI claim is not warranted or the claim is not substantiated, the registrant will be notified that the information claimed as CBI, does not qualify as CBI because it does not meet the regulatory requirements. They will be given an opportunity to respond as provided in the existing regulations. The package will then be processed accordingly.

For adverse effects reports related to exempted PIPs, a file will be created and the report will be forwarded to the appropriate product Manager within BPPD. The Manager assures that the initial OPPIN entry is correct, reviews the information, and determines the appropriate review and next steps based on the contents of the report, routing the report through scientific and/or administrative review, as appropriate. If an adverse effect report indicates that additional action is warranted or necessary, the Agency will take appropriate action.

5(c) Small Entity Flexibility

In promulgating the requirements codified at 40 CFR 174, the Agency considered potential small entity impacts, and has taken steps to minimize potential impacts to the extent permitted. EPA believes that the CBI substantiation is fairly easy to provide for information which warrants CBI claims. The entity, regardless of size, is already required to make the CBI determination prior to submitting its registration application to EPA. The rule simply requires that the information be provided with the submission to substantiate the CBI claim. This is reflected in the relatively low cost estimate for CBI substantiation for a PIP submission. This relatively small cost represents a reasonable step to ensure the public has access to all non-confidential information on PIPs once they are registered.

In addition, the Agency has taken steps to ensure that only the person who produces the exempted PIP for sale and distribution is responsible for adverse effects reporting, and only if they obtain the adverse effects information. The Agency has designed such reporting to be minimal and has placed the burden on the Agency to take additional action beyond the entity making the report.

5(d) Collection Schedule

The CBI substantiation occurs only upon submission of claims of confidentiality and the adverse effects reporting only occurs on occasion. There is no collection schedule per se associated with these collection activities. These activities are conducted once per submission.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

Burdens for this analysis consist primarily of the administrative burden associated with the drafting and submission of the CBI substantiation and the adverse effects reports. The burden estimates are based on the Agency's experience regarding existing burden estimates related to

CBI substantiation and adverse effects reporting for conventional pesticides, and provide reasonable estimates for the average time necessary to perform each activity for each submission.

For purposes of this ICR, EPA is assuming that no more than 42 PIP-related registration applications with associated CBI substantiations will be submitted over the three-year approval period for this ICR, or 14 per year. The Agency has not received the numbers of submissions projected during the period since this rule was promulgated. This is due to the longer than expected time to develop new PIPs and the continued lack of acceptance in a number of foreign countries. The Agency is continuing to assume 14 applications, and therefore 14 associated CBI substantiations, per year based on the fact that the number of PIPs-related registration applications has been increasing.

Table 1 – Average Respondent Burden and Cost Estimates per Submission for Substantiation of CBI Claims Made in a Plant-Incorporated Protectant Registration Application

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($100.86/hr)**	**Tech. ($64.80/hr)**	**Clerical ($33.05/hr)**	**Burden (hrs)**	**Costs ($)**
Read Regulations	1	2	0	3	$230.46
Plan Activities	2	4	0	6	$460.92
Gather Information	0	4	0	4	$259.20
Review Information	2	1	1	4	$299.57
Complete Paperwork	0	1	2	3	$130.90
Submit Information	0.5	0.5	0.5	1.5	$99.36
Totals	5.5	12.5	3.5	21.5	$1,480.41

Estimated Total Annual Respondent Burden: 14 events x 21.5 hours = 301 hours
Estimated Total Annual Respondent Cost: 14 events x $1,480.41 = $20,725.74

Although the Agency does not anticipate any adverse effect reports to be submitted for exempted PIPs, this ICR includes an estimate of one such report being submitted over the three-year approval period for this ICR. The per-submission estimate is therefore divided by 3 to provide an average annual burden and cost to include in the total annual estimates for this ICR. The total annual average burden and costs for the adverse effects report is calculated as follows:

Table 2 - Average Respondent Burden and Cost Estimates per Submission for Submitting an Adverse Effects Report for an Exempt Plant-Incorporated Protectant

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($100.86/hr)**	**Tech. ($64.80/hr)**	**Clerical ($33.05/hr)**	**Burden (hrs)**	**Costs ($)**
Read Regulations	0.5	1	0	1.5	$115.23
Plan Activities	0.5	0.5	0	1	$82.83
Gather Information	0	1	0	1	$64.80
Review Information	0.5	0.5	0	1	$82.83
Complete Paperwork	0	0.5	1	1.5	$65.45
Submit Information	0	0.5	0.5	1.0	$48.93
Cost for Mailing	0	0	0	0	$0.41
Totals	1.5	4	1.5	7	$460.48

Assuming a single adverse effects report submitted over three year period:

Estimated Total Annual Respondent Burden: (1 event x 7 hours) ÷ 3 = 2.3 hours
Estimated Total Annual Respondent Cost: (1 event x $460.48) ÷ 3 = $153.49

6(b) Estimating Respondent Costs

To derive the labor rates for this ICR, Agency economists estimated the wages for the management, technical, and clerical labor categories using the methodology described in Attachment E. 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.

Since CBI substantiations are simply added to the registration application package and are not submitted separately, there are no additional costs related to the transmittal of this information to the Agency. The costs for submitting the registration application package are already included under the existing ICRs. These respondent burden and cost estimates may also represent an upper bound because the analysis assumes that all PIP-related registration applications will include information that the registrants will claim as CBI which will need to substantiated. It is likely that registrants will recognize, over time, that it is in their interest to make all information on PIPs publicly available to reduce, if not eliminate, the negative impressions of genetically modified foods.

6(c) Estimating Agency Burden and Costs

The Agency will incur burden and costs while performing the various activities necessary to review CBI substantiation submissions and any adverse effects reports submitted for exempted plant-incorporated protectants. These activities are described in Section 5 of this ICR and may include the tracking and review of submissions, requests for additional information, or consultations with applicants. Tables 3 and 4 provide the average EPA burden and cost estimates for performing these activities.

Table 3 - Average Burden and Cost Estimates per Submission for EPA Activities related to - CBI Substantiation

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($93.07/hr)**	**Tech. ($66.34/hr)**	**Clerical ($47.17/hr)**	**Burden (hrs)**	**Costs ($)**
Consult With Registrant	1	3	0.5	4.5	$315.68
Record Submissions	0	0.5	1	1.5	$80.34
Review Submissions	1	2	0	3	$225.75
Store the Information	0	0.5	1	1.5	$80.34
Totals	2	6	2.5	10.5	$702.11

Estimated Total Annual Agency Burden: 14 events x 10.5 hours = 147 hours
Estimated Total Annual Agency Cost: 14 events x $702.11 = $9,829.54

Table 4 - Average Burden and Cost Estimates per Submission for EPA Activities related to an Adverse Effects Report Submitted for an Exempt Plant-Incorporated Protectant					
Activities	**Burden and Cost Estimates**			**Totals**	
	Mgmt. ($93.07/hr)	**Tech. ($66.34/hr)**	**Clerical ($47.17/hr)**	**Burden (hrs)**	**Costs ($)**
Consult With Registrant	0.5	1	0.5	2	$136.46
Record Submissions	0	0.5	1	1.5	$80.34
Review Submissions	1	1	0	2	$159.41
Store the Information	0	0.5	0.5	1	$56.76
Totals	1.5	3	2	6.5	$432.97

Assuming a single adverse effects report might be submitted over the 3 year approval period for the ICR, the total annual average burden and costs for EPA activities related to the adverse effects report is calculated as follows:

Estimated Total Annual Agency Burden: (1 event x 6.5 hours) ÷ 3 = 2.2 hours
Estimated Total Annual Agency Cost: (1 event x $432.97) ÷ 3 = $144.32

In addition, the Agency may determine that additional follow-up action is necessary for either type of submission and will be providing necessary guidance for these requirements.

6(d) Bottom Line Burden and Cost Table

The following table presents the total estimated annual burden and costs for this ICR:

Table 5 – Total Annual Burden and Cost Estimates				
	Respondent		**Agency**	
Activities	**Burden (hrs)**	**Costs ($)**	**Burden (hrs)**	**Costs ($)**
CBI Substantiations	301	20,725.74	147	9,829.54
Adverse Effects Reports	2.3	153.49	2.2	144.32
Totals	303	20,879	149	9,974

Columns and Rows may not add due to rounding

6(e) Reasons for Change in Burden

The Agency does not anticipate a change in the burden. The number of actual submissions is not expected to change and the Agency finds no basis to change the burden estimates per submission. Therefore, the burden hour estimates remain unchanged from the last renewal period.

6(f) Burden Statement

The total annual respondent burden for the collection of information contained in this ICR is estimated to be 303 hours. The annual respondent burden for the collection of information associated with the substantiation at the time of submission for CBI claims related to a PIP registration application is estimated to average 21.5 hours per submission, and the annual

respondent burden for the collection of information associated with the reporting of adverse effects for exempted PIPs is estimated to average 7 hours per submission.

As defined by the PRA and 5 CFR 1320.3(b), "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. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2006-0860, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2006-0860 and OMB Control No. 2070-0142, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Public Information and Records Integrity Branch (PIRIB), Mail Code: 7502P, Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPP-2006-0860. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment A: **40 CFR part 174 - Procedures And Requirements For Plant-Incorporated Protectants**. Also available online at the National Archives and Records Administration's Electronic CFR Webpage

Attachment B **7 USC 136w(b) - FIFRA Section 25(b**). Also available at online at the US House of Representatives' Office of the Law Revision Counsel's US Code website

Attachment C: **7 USC 346a(a) - FFDCA Section 408(a)**. Also available at online at the US House of Representatives' Office of the Law Revision Counsel's US Code website

Attachment D: Record of Consultations Between the U.S. Environmental Protection Agency and Respondents to the Information Collection Request

Attachment E: **Methodology for Estimating OPP ICR Wage Rates for Industry, State and EPA Labor Costs -** Memo From Richard Keigwin, Director Biological and Economic Analysis Division, to Bill Diamond, Arnold Layne, Lois Rossi and Elizabeth Leovey; July 25, 2006

Attachment F: **Display Related to OMB Control #2070-0142** -Listings of Related Regulations in 40 CFR 9.1