SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR) [ADDENDUM]

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

TITLE: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting (Proposed Rule Related Addendum)

OMB No.: 2070-0142 EPA ICR No.: 1693.04

1(b) Short Characterization/Abstract

This information collection request (ICR) addendum covers exemptions from FIFRA that EPA is proposing for certain plant-incorporated protectants (PIPs) based on plant viral coat protein genes (PVCP-PIPs). EPA is proposing to define a PVCP-PIP as "a plant-incorporated protectant derived from one or more genes that encode a coat protein of a virus that naturally infects plants. This includes plant-incorporated protectants derived from one or more plant viral coat protein genes that produce only RNA and no virus-related protein." PVCP-PIPs introduced into plants with the intention of preventing or mitigating viral disease meet the FIFRA section 2(u) definition of "pesticide" because they are introduced into plants with the intention of "preventing, destroying, repelling, or mitigating any pest…" (7 U.S.C. 136(u)) and plant viruses meet the FIFRA section 2 definition of "pest" (7 U.S.C. 136(t)). EPA is proposing this exemption because the Agency believes that the PVCP-PIPs covered by this exemption would be of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act.

A PIP can be exempt from the requirements of FIFRA, other than the adverse effects reporting requirements of 40 CFR 174.71, if it meets all three of the requirements listed in 40 CFR 174.21. Section 174.21(a) requires that the PIP meet the criteria listed in at least one of the sections in §§ 174.25 through 174.50. Section 174.21(b) requires that when the PIP is intended to be produced and used in a crop used as food, the residues of the PIP are either exempted from the requirement of a tolerance under FFDCA or no tolerance would otherwise be required for the PIP. Section 174.21(c) requires that any inert ingredient that is part of the PIP is on the list codified at §§ 174.485 through 174.490.

The proposed rule would establish 40 CFR 174.27, which would contain three criteria that when met would allow PVCP-PIPs to meet the general requirement for exemption for all PIPs listed at 40 CFR 174.21(a). In order to be exempt from the requirements of FIFRA, a PVCP-PIP must satisfy the criteria for proposed 40 CFR 174.21(a) and comply with sections 174.21(b) and (c).

The three criteria that EPA is proposing to be inserted at 40 CFR 174.27 are intended to address three issues that may be associated with a PVCP-PIP: (1) the potential for increased weediness or invasiveness of the crop plant containing the PVCP-PIP or any wild or weedy relatives that could acquire the PVCP-PIP through gene flow thereby causing negative effects on

either the agro-ecosystem or natural environments (addressed in proposed § 174.27(a)), (2) the potential for viruses with novel properties to develop through novel viral interactions (addressed in proposed § 174.27(b)), and (3) human or nontarget organism exposure to proteins that have not previously existed in nature and thus should be examined to determine whether they have potentially toxic or allergenic properties (addressed in proposed § 174.27(c)).

In order to satisfy 40 CFR 174.21(a), a PVCP-PIP would have to satisfy proposed §§ 174.27(a), (b), and (c). The requirements at § 174.27(d) would also have to be met to qualify for exemption. Proposed §§ 174.27(a), (b), and (c) each can be met in one of two ways: a product developer may self-determine that paragraph (1) of the criterion applies (i.e., § 174.27(a)(1), (b)(1), or (c)(1)) or the Agency may determine that paragraph (2) of the criterion applies (i.e., § 174.27(a)(2), (b)(2), or (c)(2), respectively). Paragraph (1) of each proposed criterion (i.e., § 174.27(a)(1), (b)(1), and (c)(1)) describes an objective, well-defined characteristic. Therefore, the developer may determine whether the PVCP-PIP meets the requirement. Paragraph (2) of each proposed criterion (i.e., § 174.27(a)(2), (b)(2), and (c)(2)) is conditioned on an Agency determination because it may involve analysis of several types of information. Each criterion may be satisfied either by self determination under paragraph (1) or Agency determination under paragraph (2) irrespective of how the other two criteria are satisfied; there is no requirement that all three criteria must be satisfied under either paragraph (1) or paragraph (2) in order to qualify for the exemption.

If a PVCP-PIP satisfies all three criteria under paragraph (1) by developer self determination (i.e., it meets proposed §§ 174.27(a)(1), (b)(1), and (c)(1)) and it satisfies §§ 174.21(b) and (c), EPA is proposing that the developer submit a notification to the Agency of that determination and certify that the PVCP-PIP qualifies for exemption under FIFRA, i.e., that the PVCP-PIP meets §§ 174.21(a), (b), and (c). In addition, EPA is proposing that the developer maintain information adequate to support the determination. Such records must be made available for EPA inspection and copying or be otherwise submitted to the Agency for review upon request for the duration of time that the PVCP-PIP is sold or distributed. EPA is proposing that these records be kept so that EPA could review a particular exemption determination if needed at a future date.

EPA is proposing to require that the notifications contain:

- The name of the crop (including genus and species) containing the PVCP-PIP.
- The name of the virus from which the coat protein gene was derived.
- The name of the virus(es) to which resistance is conferred.
- When available, a unique identifier.

EPA is proposing this notification requirement because it provides a mechanism that allows the Agency to keep a record of all PVCP-PIPs that may be sold or distributed. EPA expects that such a list would be useful to developers whose products are moving in international trade because it would enable EPA to post information on the United States Regulatory Agencies Unified Biotechnology Website (found at *http://usbiotechreg.nbii.gov/database_pub.asp*) indicating that the developer has determined that the product satisfies the Agency's safety requirements. Such information can facilitate acceptance by importing countries. Absent such a

posting, the field for EPA information would be blank, and importers might question the regulatory status of the product in the United States. In addition, EPA considers that such a list may be useful to the Agency for ensuring enforcement and compliance with FIFRA regulations because it will enable compliance personnel to ascertain the exemption status of products encountered in distribution and trade channels.

If a PVCP-PIP does not satisfy a particular criterion under paragraph (1) (i.e., § 174.27(a)(1), (b)(1), or (c)(1)), EPA proposes that as an alternative route to exemption, the product developer would submit data or other information to the Agency to demonstrate that a particular PVCP-PIP meets paragraph (2) of that criterion (i.e., it meets § 174.27(a)(2), (b)(2), or (c)(2), respectively). In addition, as part of this submission, a developer would also include a certification as to any determination that the product meets § 174.27(a)(1), (b)(1), and/or (c)(1), as appropriate. During its review under § 174.27(a)(2), (b)(2), and/or (c)(2), EPA would not review the developer's determination that the product met any criterion under § 174.27(a)(1), (b)(1), or (c)(1).

In addition, EPA is proposing that information supporting the submission be maintained as records that will be available for EPA inspection as necessary for the duration of time that the PVCP-PIP is sold or distributed.

This ICR addendum, therefore, discusses the paperwork burdens associated with the recordkeeping and reporting to support registration exemptions claims by developers of PVCP-PIPs, whether through self-determined or agency-determined criteria.

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(c) 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

Records maintained to support exemptions claimed for PVCP-PIPs will be used to verify that determinations were made correctly by developers regarding their products. Submissions of information to enable the EPA to determine whether criteria are met will be used by the Agency to allow such exemptions. The alternative to meeting these requirements is more burdensome registration.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non duplication

There is no known duplication of the requirements to substantiate an exemption for PVCP-PIPs according to the criteria specified in this collection request. The need for an exemption to a FIFRA requirement is unique to this rule and would not duplicate any other paperwork collection activity.

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

The proposed rule serves as the public notice for this ICR addendum. Interested parties should submit comments as directed at the end of this document. Responses will be considered in developing the final rulemaking.

3(c) Consultations

In developing its approach to PVCP-PIPS, EPA sponsored or cosponsored with other Federal agencies, six conferences relevant to development of this proposed rule. In addition, EPA has requested the advice of two scientific advisory bodies at five meetings while developing its approach to plant-incorporated protectants. Information from these conferences and advice from all six meetings was incorporated as appropriate in the development of this proposed rule. More information regarding these consultations can be found in the preamble to the proposed rule.

3(d) Effects of Less Frequent Collection

Not applicable. The frequency of collection cannot be reduced because the information would be collected only once per exempted PVCP-PIP.

3(e) General Guidelines

The collection activities covered by this ICR comply with the PRA guidelines established 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 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 plant-incorporated protection 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 plant-incorporated protectants. These entities may be classified under the following North American Industrial Classification System (NAICS) codes:

- 111 - Crop Production
- 32532 - Pesticides and Other Agricultural Chemical Manufacturing
- 54171 - Research and Development in the Physical, Engineering, and Life Sciences
- 611310 - Colleges, Universities, and Professional Schools

These respondent/NAICS codes represent an amendment to the existing ICR and are a technical correction intended to more accurately reflect the respondent universe. Three categories were deleted, and one was added. The deleted respondent categories, Biological Products Manufacturing (325414), Farm Supplies Wholesalers (422910), and Flower, Nursery Stock, and Florist Supplies (422930) do not represent entities actively engaged in the development of PIPs. The added category, Crop Production (111) includes seed production, which does cover aspects of development and production of PIPs.

4(b) Information Requested

(i) Data items, including record keeping requirements

Developers of PVCP-PIPs who are claiming self-determined exemptions from the need to register their products will be required to gather and maintain information that supports their determination. This information must be maintained for the duration of time that the developer claims the exemption. Developers pursuing this option must also submit a certification to EPA that they are claiming the exemption for their product according to the criteria set forth in the regulation.

Developers of PVCP-PIPs who rely on Agency determinations will be required to gather and make submissions of certain information to EPA.

(ii) Respondent Activities

The requirements for both developer- and Agency-determined exemptions are one-time events for each product.

A typical respondent for each event is expected to engage in the following activities:

Read regulations	The respondent needs to become familiar with the regulations governing exemptions as they pertain to PVCP-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 EPA.
Gather Information	The information necessary to provide the required substantiation of an exemption must be assembled.
Review Information	The respondent must check the substantiation for accuracy and completeness.
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	Persons claiming exemption must maintain records substantiating their claim for the duration of time that they maintain their claim of exemption.

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

5(a) Agency Activities

The Agency must evaluate exemption requests for Agency-determined exemptions when submitted. The Agency is expected to engage in the following activities:

Consult with the developer	EPA will respond to any questions either in writing or verbally during 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 plant-incorporated protectant, or a request for Agency review for exemption, the submission is recorded or logged in by the Agency to document its receipt. The Agency will enter the necessary information into the computer for routing and tracking purposes.
Review submissions	EPA will review the incoming materials for exemption requests for completeness and appropriateness.
Store the information	EPA will maintain the information contained in the submitted application package.

5(b) Collection Methodology and Management

For requests for Agency review to determine whether a PVCP-PIP qualifies for an exemption, a file will be created, and the report will be forwarded to the appropriate product manager within BPPD. The manager ensures that the initial 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.

5(c) Small Entity Flexibility

The Agency has taken steps to ensure that the burden on developers of PVCP-PIPs for determining and verifying exemptions is minimized. The need for submissions to the Agency has been reduced to the minimum amount possible consistent with needs to reduce risk. The one-time nature of determinations places this collection at the lowest burden possible while still maintaining necessary oversight.

5(d) Collection Schedule

The activities associated with exempting PVCP-PIPS are conducted once per product.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

Burdens for this analysis consist primarily of the tasks associated with compiling and submitting information supporting exemption from the need for registration under either self-determination criteria or Agency-determination criteria.

For purposes of this ICR addendum, EPA is assuming that approximately six PVCP-PIP exemptions will be claimed over the three-year approval period for this ICR. The Agency is

basing this estimate on examination of the number of PVCP-PIPs that are currently in pre-application stages of development. The actual number that reach this stage of product development may be lower. The Agency is assuming that roughly half of the exemptions would qualify for full developer-determination, while half would require at least some Agency review. For simplification, the Agency is assuming that those requiring some Agency review would require complete Agency review.

The burden associated with different individual submissions may vary depending upon the nature of the criteria evaluated and whether field or laboratory testing is required. The Agency examined several likely scenarios with different levels of burden depending on the nature of the PVCP-PIP and what information would be needed to ensure that each qualified for exemption. A burden estimate of each scenario was determined. The scenario burdens resulting from fully developer- and fully Agency-determined exemptions were separately calculated. The results are presented in Tables 1 and 2, for developer- and Agency-determinations, respectively.

Table 1: Average Burden and Cost Estimates for Exemption for PVCP-PIPs (Developer Determined)

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($137/hr)**	**Tech. ($93/hr)**	**Clerical ($42/hr)**	**Burden (hrs)**	**Costs ($)**
Read Regulations	0.5 ($69)	1 ($93)	0	1.5	$162
Plan Activities	0.5 ($69)	0.5 ($47)	0	1	$116
Create Information	0	3.5 ($325)	0	3.5	$325
Gather Information	0	2 ($186)	1 ($42)	3	$228
Compile and Review Information	0.5 ($69)	0.5 ($47)	1 ($42)	2	$158
Complete Paperwork	0	1 ($93)	2 ($84)	3	$177
Submit Information	0.5 ($69)	0.5 ($47)	2 ($84)	3	$200
Maintain and File Information	0	0.5 ($47)	4 ($168)	4.5	$215
Totals	2 ($274)	9.5 ($884)	10 ($420)	21.5	$1578

*Columns may not add due to rounding.

Table 2: Average Burden and Cost Estimates for Exemption for PVCP-PIPs (Agency Determined)

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($137/hr)**	**Tech. ($93/hr)**	**Clerical ($42/hr)**	**Burden (hrs)**	**Costs ($)**
Read Regulations	0.5 ($69)	1 ($93)	0	1.5	$162
Plan Activities	1 ($137)	0.5 ($47)	0	1.5	$184
Create Information	0	4 ($372)	0	4	$372
Gather Information	0	2 ($186)	1 ($42)	3	$228
Compile and Review Information	0.5 ($69)	1 ($93)	1 ($42)	2.5	$204
Complete Paperwork	0	1.5 ($140)	2 ($84)	3.5	$224
Submit Information	0.5 ($69)	0.5 ($47)	2 ($84)	3	$200
Maintain and File Information	0	0.5 ($47)	4 ($168)	4.5	$215
Totals	2.5 ($344)	11 ($1023)	10 ($420)	23.5	$1787

*Columns may not add due to rounding.

6(b) Estimating Respondent Costs

Respondent costs are based on managerial, technical and clerical burden hours estimated at $137, $93, and $42 per hour, respectively. These are the estimated labor rates for respondents for the ICR that this ICR addendum amends, adjusted using an inflation cost index of 1.052 obtained from the Bureau of Labor Statistics to adjust for the two years (2004 to 2006) since the estimates in the latest ICR were made. These labor rates are fully loaded and include benefits and overhead costs.

6(c) Estimating Agency Burden and Costs

The Agency will incur burden and costs while performing the various activities necessary to receive and review certifications from respondents making developer-determined exemption claims and submissions from respondents requesting that EPA make an Agency-determined exemption decision. These activities are described in Section 4 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 annual burden and cost estimates for the Agency's activities for the three-year period covered by this ICR addendum. Agency labor rates are based on the values used in the ICR that this Addendum amends, adjusted for inflation using a two-year adjustment factor of 1.052. The resulting hourly rates are $101, $74, and $35 per hour for management, technical, and clerical staff, respectively. The rates were adjusted to account for benefits and overhead then rounded off for ease of calculation.

Although the information collection burdens for developer- and Agency-determined exemptions were roughly equal, the Agency burdens for reviewing submissions associated with these two different types of exemptions differ. When a developer-determined exemption certification is submitted, EPA will normally only receive the certification and maintain a record of it with minimal consultation and review. When the Agency is called upon to make a determination, it will have to review information submitted, review cited literature, determine if the submission is appropriate, and consult with the developer. Consequently, the Agency burden will be higher in the case of an Agency-determined exemption. As with respondent burden calculations, in preparing Tables 3 and 4, EPA assumed for simplification that developer-determined exemptions would be entirely developer-determined and Agency-determinations would be entirely Agency-determined.

Table 3: Average Agency Burden and Cost Estimates for Developer-Determined Exemption for PVCP-PIPs

	Burden and Cost Estimates			Totals	
Activities	**Mgmt. ($101/hr)**	**Tech. ($74/hr)**	**Clerical ($35/hr)**	**Burden (hrs)**	**Costs ($)**
Consult with Developer	0.5 ($51)	2 ($148)	0	2.5	$199
Record Submissions	0	1 ($74)	1 ($35)	2	$109
Review Submissions	2 ($202)	8 ($608)	0	10	$810
Store the Information	0	0.5 ($37)	1 ($35)	1.5	$72
Totals	2.5 ($253)	11.5 ($867)	2 ($70)	16	$1,190

*Columns may not add due to rounding.

Table 4: Average EPA Burden and Cost Estimates for Agency-determined Exemption for PVCP-PIPs					
	Burden and Cost Estimates			Totals	
Activities	Mgmt. ($101/hr)	Tech. ($74/hr)	Clerical ($35/hr)	Burden (hrs)	Costs ($)
Consult with Developer	1 ($101)	4 ($296)	0	5	$397
Record Submissions	0	2 ($148)	2 ($70)	4	$218
Review Submissions	2 ($202)	80 ($6,080)	0	82	$6,282
Store the Information	0	2 ($148)	2 ($70)	4	$218
Totals	3 ($303)	88 ($6,672)	4 ($140)	95	$7,115

*Columns may not add due to rounding.

Assuming that one claim each of developer- and Agency-determined exemption is submitted each year, the total annual Agency costs for are the costs presented in Table 3 plus the costs in Table 4, or $1,190 + $7,115 = $8,305.

In addition, the Agency may determine that additional follow-up action is necessary for either type of submission.

6(d) Bottom Line Burden and Cost Tables

The following table presents the total estimated annual burden and costs resulting from the change in regulation:

Table 5: Total Average Burden and Cost Estimates Resulting from Changing Regulation						
	Respondent		Agency		Totals	
Activities	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)
Developer-Determined Exemption	21.5	$1,578	16	$1,190	32	$2,768
Agency-Determined Exemption	23.5	$1,787	95	$7,115	111	$8,902
Totals	45	$3,365	111	$8,305	143	$11,670

*Columns may not add due to rounding.

The following table presents the total estimated annual burden and costs resulting covered in the currently approved ICR for Adverse Effects Reporting and CBI Substantiation activities:

Table 6: Total Average Burden and Cost Estimates Currently Approved						
	Respondent		Agency		Totals	
Activities	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)
CBI Substantiations	301	$27,370	147	$9,723	448	$37,093
Adverse Effects Reports	2.3	$202	2.17	$140	4.47	$342
Totals	303	$27,572	149.17	$9,863	452.57	$37,435

*Columns may not add due to rounding.

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

Table 7: Total Average Burden and Cost Estimates						
	Respondent		Agency		Totals	
Activities	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)	Burden (hrs)	Costs ($)
Developer-Determined Exemption	21.5	$1,578	16	$1,190	32	$2,768
Agency-Determined Exemption	23.5	$1,787	95	$7,115	111	$8,902
CBI Substantiations	301	$27,370	147	$9,723	448	$37,093
Adverse Effects Reports	2.3	$202	2.17	$140	4.47	$342
Totals	348	$30,937	260	$18,168	596	$49,105

*Columns may not add due to rounding.

6(e) Reasons for Change in Burden

This Addendum represents a change in program requirements for PVCP-PIPs, as presented in the proposed regulation.

6(f) Burden Statement

The total annual respondent burden for the collection of information contained in this ICR addendum is estimated to be 348 hours. There is a 45 hour increase in burden in comparison to the last approved ICR as a result of the changing regulation. Of the 45 hours, 21.5 hours is associated with claims of developer-determined exemptions, and 23.5 hours is associated with Agency-determined exemptions. Of the 348 hours requested in this ICR, 303 hours cover the adverse effects reporting currently covered by the most recently approved ICR (1693.03) in this series.

Although the exemptions result in an overall decrease for the respondent in terms of registration activities (covered in a different ICR), the requirements for obtaining an exemption result in a minimal burden increase, which is captured by this ICR. Exemptions granted result in an increase in the burden presented in this ICR. The proposed rule which establishes 40 CFR 174.27 will contain criteria which when met would allow PVCP PIPs to meet general requirements for exemption from the requirements of FIFRA for all PIPs listed at 40 CFR 174.21(a). Although there is a burden increase to account for the activities required to obtain an exemption, the exemptions will create a net decrease in the overall burden.

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 codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. The OMB control number for this information collection appears at the beginning of this Supporting Statement. In addition, the OMB control number for the applicable regulation (40 CFR part 174), after initial display in the final rule, are listed in the table at 40 CFR 9.1.

Direct your comments 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, to EPA using the public docket that has been established for this proposed rule at *www.regulations.gov* under Docket ID No. EPA-HQ-OPP-2006-0642. Follow the on-line instructions for submitting comments. You may also go to the ADDRESSES section of the proposed rule to view instructions for mailing your comments to the public docket.

In addition, send a copy of your comments about the ICR to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, Attention: Desk Officer for EPA ICR No. 2070-0142. Since OMB is required to complete its review of the ICR between 30 and 60 days after publication of the proposed rule in the **Federal Register**, please submit your ICR comments for OMB consideration to OMB within 30 days after that publication date.

The Agency will consider and address comments received on the information collection requirements contained in this proposal when it develops the final rule.

ATTACHMENTS TO THIS SUPPORTING STATEMENT

ATTACHMENT A **Supplemental Proposal entitled "Exemption under the Federal Insecticide, Fungicide, and Rodenticide Act for Certain Plant-Incorporated Protectants Derived from Plant Viral Coat Protein Gene(s) (PVCP-PIPs)" This document is available in the docket identified by docket ID number EPA-HQ-OPP-2006-0642.**

ATTACHMENT B **FIFRA Section 25(b)** - available electronically at http://www4.law.cornell.edu/uscode/7/ch6.html

ATTACHMENT C **FFDCA Section 408(a)** - available electronically at http://www4.law.cornell.edu/uscode/21/ch9.html

ATTACHMENT D: **Display Related to OMB Control #2070-0142** - *Listings of Related Regulations in 40 CFR 9.1* - An electronic copy of this attachment follows in the electronic file for this ICR.

ATTACHMENT D

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

As of May 10, 1993, the OMB approval numbers for EPA regulations in Chapter I of Title 40 of the Code of Federal Regulations (CFR) appear in a listing in 40 CFR 9.1 (58 FR 27472). This listing fulfills the display requirements in section 3507(f) of the Paperwork Reduction Act (PRA) for EPA regulations. The listing at 40 CFR 9.1 displays this OMB Control number for the following regulations:

Program Title	40 CFR citation
Procedures and Requirements for Plant-Incorporated Protectants	174.9
Procedures and Requirements for Plant-Incorporated Protectants	174.71

When the final rule is issued, this listing will be revised to include the information collection requirements contained in proposed 40 CFR 174.27.