Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title:	Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies Rulemaking (Final Rule; RIN 2070-AK54)
EPA ICR No.:	2619.02
OMB Control No.:	2070-0214
Docket ID No.:	EPA-HQ-OPP-2019-0508

Abstract

This ICR is designed to serve as an amendment to the existing ICR entitled "Application for New and Amended Pesticide Registration," identified as EPA ICR No. 0277 and approved under OMB Control No. 2070-0060. This action is necessitated by new rulemaking to exempt certain plant-incorporated protectants (PIPs) from the requirement of a registration and its associated information collection requirements for PIPs exempted by that rulemaking. The existing ICR currently addresses the information collection activities associated with the registration of a pesticide product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3 and related tolerance determinations under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408. FIFRA provides EPA with the authority to regulate the distribution, sale and use of pesticides in the United States to ensure that pesticides will not pose unreasonable adverse effects to human health and the environment. Pesticides that meet this test receive a license or "registration." The FFDCA provides EPA with the authority to establish tolerances (maximum residue limits) or exemptions for pesticide chemical residues that meet the safety standard. Further, FIFRA allows EPA to promulgate regulations to exempt from the requirements of FIFRA any pesticide which the Administrator determines is "of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]."

The final rule entitled "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies; Final Rule" (RIN 2070-AK54) provides an exemption for certain PIPs that have been created using biotechnology from certain registration requirements under FIFRA, and from the requirements to establish a tolerance or tolerance exemption for residues of these substances on food and feed under the FFDCA. Specifically, EPA is exempting two types of PIPs with this rulemaking, "PIPs created through genetic engineering from a sexually compatible plant" and "loss-of-function PIPs," and establishes associated recordkeeping

requirements for both types. EPA also establishes a mandatory eligibility determination process for these exempted PIPs; an Agency determination is required for "PIPs created through genetic engineering from a sexually compatible plant" whereas developers of "loss-of-function PIPs" also have the option to "self-determine" that their PIP meets the exemption criteria. The self-determination option requires a strongly reduced set of information on the PIP to be reported to the Agency. Furthermore, akin to all registered and otherwise exempted PIPs, all PIPs exempted by this rulemaking remain subject to the adverse effects reporting requirements.

The net result of this rulemaking can be considered a reduction in the existing burden and costs that would otherwise be associated with the registration and tolerance activities for those PIPs exempted by this rulemaking. A summary of the burden from this rulemaking is provided in Table 1.

Table 1. Summary Total Annual Burden and Costs

	Number of Exemptions	Annual Number of Exemptions	Response per Developer	Annual Burden Hours	Cost
Total Developer Burden per Exemption	1	1	1	85	$12,580
Grand Total Developer Burden for 10 Exemptions	10*	10	1*	850	$125,800
Total Agency Burden per Exemption	1	1	1	5	$457
Grand Total Agency Burden	10	10	1	50	$4,567

*Assumes ten different entities would submit for one exemption each. However, the same entity may submit for multiple exemptions. Given that these are new exemptions, the number of exemptions requested annually is unknown, but EPA has estimated the initial submission number to range from 1 – 10 per year.

The average annual reporting and recordkeeping burdens for developers seeking exemption for a PIP under this rulemaking is estimated to be 850 hours (assuming 10 submissions annually), with an associated cost of $125,800 (there are no maintenance costs). The term "burden" is used as defined at 5 CFR 1320.3(b). This estimate includes the following activities as required by the rulemaking: time for reviewing instructions, gathering and maintaining the data and information, reviewing and submitting information, time to disclose any confidential business information (if applicable), and maintaining records for five years.

The average annual reporting burden for the Agency is estimated to be 50 hours (assuming 10 submissions annually) with an associated cost of $4,567. This entails staff time spent reviewing PIP exemptions submitted for Agency confirmation, time notifying any EPA website manager to update the public-facing website with a new list of exempted PIPs, and time for any website manager to update the Agency website.

SUPPORTING STATEMENT

1. **Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

   The Agency finds the approach to require information collection for an eligibility determination for PIPs exempted by this rule necessary as EPA finds that doing so will provide additional clarity to developers of PIP products under certain circumstances and increase transparency and public trust in products containing these PIPs. The exemption and related notification requirements are authorized by FIFRA section 3 (7 USC 136a) and FFDCA section 408 (21 USC 346a). Governing regulations and guidelines are contained in 40 CFR parts 152, 156 and 158, with regulations specific to PIPs, including the final rule found in 40 CFR part 174. See attachments A, B, and C respectively.

2. **Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.**

   Because the exemption for certain PIPs is a new rulemaking, this ICR describes a new collection. For PIPs for which developers seek an EPA determination of eligibility, EPA will review the documentation provided in support of the exemption. This includes information such as a description of the pesticidal trait that results from the genetic modification, how the trait was engineered into the plant, and the identity of the recipient plant. EPA will then determine if a product meets the exemption criteria outlined in the rulemaking and thus whether it qualifies for exemption from the requirements of registration under FIFRA and the requirement for a tolerance or tolerance exemption under FFDCA. Again, the Agency eligibility determination is mandatory only for “PIPs created through genetic engineering from a sexually compatible plant.” “Loss-of-function PIPs” have the option to submit a self-determination to the Agency, which includes basic PIP identification information (e.g., recipient plant species, modified gene ID), and a self-certification that the PIP qualifies for exemption (Attachment D).

   Information required to be maintained by the developer (but not necessarily submitted to the Agency) of an exempt PIP under the new recordkeeping requirements, which apply to both “PIPs created through genetic engineering from a

sexually compatible plant" and "loss-of-function PIPs," will aid in maintaining compliance assessment capabilities.

EPA also intends to publish a public list on its website that will provide basic information on PIPs exempted by the rule. This list is to be updated periodically and serves to increase transparency for PIPs derived through these newer technologies.

3. **Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.**

   Submissions for a request for EPA confirmation or a letter of self-determination must be made electronically, which means that they may not be made by mailing the information in physical form to the Agency (e.g., sending hard copies or data storage devices such as DVD). Specifically, electronic submissions are required to be made through EPA's established electronic submission portal which receives legally acceptable data in a secure manner. That system is used, amongst other things, for submission of pesticide registration applications, and will now additionally accommodate the eligibility determination processes associated with the PIPs identified in the final rule. The same electronic system has been used by developers exclusively for all pesticide registration applications submitted to EPA in the past two years, as physical submissions were not allowed during the COVID-19 pandemic. The electronic submission process will accommodate submissions when the final rule is effective 60 days after date of publication in the Federal Register.

   The Agency finds that electronic form of collection provides the fastest and most efficient means of communication between a developer and the Agency and that it can reduce burden on both parties. For example, an electronic submission process means that EPA can send an automated response to a submitter of a self-determination letter confirming receipt of the submission, which serves as the effective start of the exemption. This automated response reduces the burden on the Agency to first prepare and then send a physical letter and drastically reduces the time a PIP exemption can go into effect. Further, the electronic submission process also allows the Agency to provide direct guidance in the submission portal on how to complete the submission successfully, potentially reducing the need for re-submissions and therefore delays getting potential products to the market.

4. **Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

   This is a new collection, one that has not been required before to obtain the new exemption benefit established by the final rule. EPA has the sole authority to

regulate pesticides and establish tolerances or tolerance exemptions in the United State, thus no other agency or program seeks this information.

5. **If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.**

   EPA's cost analysis found that the rulemaking does not disproportionally impact small businesses. Further, EPA offers assistance to all developers seeking an exemption for a PIP under the new rule, facilitating their compliance with the requirements for obtaining an exemption. For example, for PIPs exempted under this rulemaking, EPA is using its established electronic submission portal for registrations that all developers of pesticide products have already been required to use exclusively during the COVID-19 pandemic and that they are familiar with. In developing the exemption-specific electronic submission process, EPA put special emphasis on maximizing ease of submission with the goal to create an intuitive process. For example, submitters can navigate back-and-forth through the various steps of submission and help buttons are strategically placed to link submitters to relevant pages within the submission portal.

6. **Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

   The Agency finds the approach to require information collection for an eligibility determination for PIPs exempted by this rule justified as EPA finds that doing so will provide additional clarity to developers of PIP products under certain circumstances and increase transparency and public trust in products containing these PIPs. Further, the recordkeeping requirements will aid in compliance assessment. Because EPA is requiring that information be collected for each newly exempt PIP, once per newly exempted PIP is the least frequent possible collection.

7. **Explain any special circumstances that require the collection to be conducted in a manner:**

   a) **requiring respondents to report information to the agency more often than quarterly;**

   b) **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

   c) **requiring respondents to submit more than an original and two copies of any document;**

   d) **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**

e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or_____

h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Questions 7 a, b, c, e, f, and g are not applicable.

Question 7d: The recordkeeping activities applicable to pesticide registrants exceed OMB's guideline that (a) agencies should not require records to be retained for more than three years (5 CFR 1320.5(d)(2)(iv)). The general recordkeeping requirements for this final rule ICR, implementing the requirements of § 174.73, require that for 5 years, starting with the effective date of a PIP exemption the respondent must maintain documentation of either the letter of self-determination or the request for EPA confirmation (or both, if applicable) along with all supporting documentation for the specific exemption (if applicable) listed in subpart E and make the documentation of exemption eligibility available to EPA upon request.

EPA regulations under 40 CFR 169.2(k) require that registrants retain records containing research data relating to a registered pesticide, including all data submitted to EPA in support of a registration, for as long as the registration is valid, and the producer is in business. The burden related to the recordkeeping requirements is covered under another ICR (see OMB Control No. 2070-0028, Recordkeeping Requirements for Producers of Pesticides under Section 8 of FIFRA). When this rule is finalized, ICR 2070-0028 will be amended per this ICR to include the 5-year recordkeeping requirement for exempted PIPs.

Question 7h: In the interest of public transparency, EPA urges the submitter to minimize the amount of information claimed as Confidential Business Information (CBI). However, if the submitter chooses to submit CBI information, EPA will protect from disclosure all data and/or information submitted to the Agency in accordance with FIFRA Section 10 and 40 CFR Part 2, Subpart B.

8. **If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.**

   a) Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

   b) Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

   This information collection request was initially published for public comment as part of the Notice of Proposed Rule Making (NPRM) and the proposed rule docket entitled "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies; Proposed Rule" (RIN 2070-AK54). The proposed ICR is part of docket EPA-HQ-OPP-2019-0508, published on October 9, 2020 (85FR197). Pursuant to 5 CFR 1320.11(b), the proposed rule announced the availability of this ICR and provided a 60-day public comment opportunity. Comments received on the proposed rule are addressed in the final rule. EPA did not receive any public comment on the draft ICR amendment.

9. **Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

   This question is not applicable to this ICR.

10. **Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.**

    In accordance with FIFRA Section 10 and 40 CFR Part 2, Subpart B, EPA will protect from disclosure all data and/or information submitted to the Agency in conjunction with the exemptions claimed as CBI or that is otherwise restricted from public disclosure by law as trade secret, commercial, or financial information. No SORN or PIA information is required under this collection.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No information of a sensitive or private nature is requested in conjunction with these information collection activities, and these information collection activities comply with the provisions of the Privacy Act of 1974 and OMB Circular A-108, as amended, "Responsibilities for the Maintenance of Records about Individuals by Federal Agencies."

12. Provide estimates of the hour burden of the collection of information. The statement should:

a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.

c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.

Affected Entities

The final rulemaking requirements addressed in this ICR affects individuals or entities engaged in activities related to the development of PIP products and are described in more detail in the cost analysis prepared for the final rule. In general, EPA believes that potential respondents can be identified by the following North American Industrial Classification System (NAICS) codes:

- 32532 - Pesticide and other agricultural chemical manufacturing.

(Individuals or entities engaged in activities related to the registration of a pesticide product).

- 111- Crop Production. (To the extent that this category may include some seed companies however seed companies may also be captured in NAICS 32532 and 541714).

- 611310 - Colleges, universities, and professional schools. (Establishments of higher learning which are engaged in development and marketing of PIPs).

- 541714 - Research and Development in the Physical, Engineering, and Life Sciences (except Nanobiotechnology). Biotechnology research and development laboratories or services.

Burden and Cost Estimates for Developers and Agency

Table 2 below presents estimates for burden hours and costs for the submission of a request for EPA confirmation of eligibility. The wage estimates are used for entities captured under NAICS code 541714, because the Agency reviewed wage estimates for all NAICS codes and found the estimates provided for Research and Development in the Physical, Engineering, and Life Sciences to be the most conservative. In the proposed rule, the estimated annual respondent burden for the exemption was 14 burden hours. Although there was no public comment received on the burden estimates, EPA reviewed the estimates provided with the ICR in the proposed rule and found them to be low. While EPA assumes based on best business practices that most developers would have collected the information related to documenting eligibility criteria as part of product development, for this estimate, EPA took a conservative approach in calculating the burden hours. In general, EPA found that it is difficult to estimate exactly how much of the information required by the rule has already been completed by a developer as a part of the development process. For example, some of the specific information required by the Agency may not yet have been documented by the developer, or information that had previously been generated will need to be reformatted to meet the requirements of the rule.

Therefore, EPA estimated burden hours based on the most complex and expensive scenario. Specifically, estimated burden hours assumed that a developer had not collected information related to documenting eligibility criteria as part of product development and that the PIP is a “PIP created through genetic engineering from a sexually compatible plant” that is a known mammalian toxicant and that is derived from a wild relative (i.e., a non-domesticated plant). Developers of PIPs that meet these characteristics are required to provide information that is not required for PIPs that lack these characteristics in addition to information that is to be submitted for all “PIPs created through genetic engineering from sexually compatible plants.”

The wage burden per exemption for this ICR is 85 burden hours and $12,580 per developer. The evaluation of the burden and cost estimates was informed by the

cost analysis of the final rule, which is available in the docket associated with the final rule (EPA-HQ-OPP-2019-0508). Several of the information and data requirements detailed in the cost analysis are related to documenting eligibility criteria.

Burden estimates project that any developer that is submitting a request for EPA confirmation to the agency will likely require two or more professionals to understand exemption eligibility requirements and will have to collaborate to compile the information required for submission. For this reason, similar burden hour estimates are projected to include a person from management and a technical professional. The Agency expects that much of the information requirements have already been collected as a part of the PIP development process and/or standard lab procedure. For this reason, the Agency estimates that documenting the information for the sole purpose of meeting the criteria laid out by the final rule, these costs may be approximately a quarter of the cost of the most complicated case described in the cost analysis with this final rule (the upper bound cost of meeting the requirements for a PIP created through genetic engineering from sexually compatible plant is $46,200).

A description of each Developer or Respondent PRA collection activity is provided in this section.

Table 2: Total Estimated Burden/Cost per Exemption Related Submission per Developer (Respondent)

Collection Activities	**Burden Hours**			**Total**	
	Management	Technical	Clerical		
	$198.76/hr	$104.89/hr	$61.13/hr	Hours	Costs*
Read Instructions	2	2	0	4	$607
Plan activities	5	5	0	10	$1,518
Gather/create information	20	20	0	40	$6,073
Compile and review	10	10	0	20	$3,036
Complete paperwork	0	5	0	5	$524
Submit information	2	2	0	4	$607
Store/maintain data	0.5	0.5	1	2	$213
Third party disclosure	0	0	0	0	$0
TOTAL	**39.5**	**44.5**	**1**	**85**	**$12,580**

*Numbers may not sum due to rounding.

Source: Burden hours are per Agency estimates (discussed in text above). Wage estimates use the fully loaded hourly rate (includes benefits and overhead) for NAICS 541714, Research and Development in the Physical, Engineering and Life Sciences as of May 2021. Wage estimates are available by the U.S. Bureau of Labor Statistics at https://www.bls.gov/oes/current/naics5_541710.htm.

EPA estimates that the agency may receive up to 10 submissions annually requesting an EPA confirmation of exemption, with 10 representing the upper bound. Consequently, the number of exemptions that that Agency will need to review and

approve annually is similarly estimated to be 10. The total cost burden is detailed by staff "type" in Table 3 below. The total annual hour burden for the developer is projected to be up to 850 hours and the total cost is projected to be up to $125,800.

Table 3: Grand Total Annual Estimated Burden/Cost Across all Developers (Respondents) and all Relevant ICR's

Collection Activities	Burden Hours			Total	
	Management	Technical	Clerical		
	$198.76/hr	$104.89/hr	$61.13/hr	Hours	Costs*
Read Instructions	20	20	0	40	$6,070
Plan activities	50	50	0	100	$15,180
Gather/create information	200	200	0	400	$60,730
Compile and review	100	100	0	200	$30,360
Complete paperwork	0	50	0	50	$5,240
Submit information	20	20	0	40	$6,070
Store/maintain data	5	5	10	20	$2,130
Third party disclosure	0	0	0	0	$0
TOTAL	**395**	**445**	**10**	**850**	**$125,800**

*Numbers may not sum due to rounding.

Source: Burden hours are per Agency estimate (discussed in text above). Wage estimates use the fully loaded hourly rate (includes benefits and overhead) for NAICS 541710 (or 541714) Research and Development in the Physical, Engineering and Life Sciences as of May 2021. Wage estimates are available by the U.S. Bureau of Labor Statistics at https://www.bls.gov/oes/current/naics5_541710.htm.

Many of the burden activities identified in this ICR will be incorporated into existing ICRs after this rule is finalized. The Section 3 ICR (2070-0060) governs activities involved with applying for registrations or exemptions. The PIPs ICR (2070-0142) accounts for adverse effects reporting specifically for PIPs. The Section 8 ICR (2070-0028) estimates the burden for recordkeeping by producers, registrants, and applicants of pesticides. The Tolerance ICR (2070-0024) estimates the burden for applying for a tolerance or an exemption from a tolerance for a pesticide with a food use. These ICR's are listed in Table 4 below. EPA estimated which activities would be associated with each respective ICR. When these ICRs are renewed, they will be amended to include the activities associated with this final rule.

Table 4: Total Annual Estimated Burden/Cost by Relevant ICR

	Section 3 ICR # 2070-0060		PIPs ICR # 2070-0142		Section 8 ICR # 2070-0028		Tolerance ICR # 2070-0024		Total	
	Hours	Cost*	Hours	Cost*	Hours	Cost*	Hours	Cost*	Hours	Cost*
Read Instructions	40	$6,070	0	$0	0	$0	0	$0	40	$6,070

Plan activities	50	$7,590	0	$0	0	$0	50	$7,590	100	$15,180
Gather/ create information	300	$45,550	40	$6,070	0	$0	60	$9,110	400	$60,730
Compile and review	200	$30,360	0	$0	0	$0	0	$0	200	$30,360
Complete paperwork	50	$5,240	0	$0	0	$0	0	$0	50	$5,240
Submit information	40	$6,070	0	$0	0	$0	0	$0	40	$6,070
Store/ maintain data	0	$0	0	$0	20	$2,130	0	$0	20	$2,130
Third party disclosure	0	$0	0	$0	0	$0	0	$0	0	$0
TOTAL	**680**	**$100,890**	**40**	**$6,070**	**20**	**$2,130**	**110**	**$16,700**	**850**	**$125,800**

*Numbers may not sum due to rounding.
Source: Burden hours are per Agency estimate. Wage estimates use the fully loaded hourly rate (includes benefits and overhead) for NAICS 541710 (or 541714) Research and Development in the Physical, Engineering and Life Sciences as of May 2021. Wage estimates are available by the U.S. Bureau of Labor Statistics at https://www.bls.gov/oes/current/naics5_541710.htm.
See attachments D, E, F and G.

Respondent PRA activities

The following list identifies the expected information collection activities that the developer is likely to engage in when seeking an exemption.

Read instructions

Read and understand the statutory provisions and implementing regulations, guidance and correspondence related to the regulation of PIPs applicable regulations in 40 CFR part 174 associated with the exemption.

Determine eligibility and plan activities

Determine whether the PIP product being developed qualifies under the exemption. If it qualifies, determine next steps and plan activities per 40 CFR part 174.

Gather information

Identify and gather available information needed to determine whether the PIP product being developed qualifies under the exemption.

Compile and Review

Assemble information, evaluate for accuracy, appropriateness, and completeness.

Complete paperwork

Complete self-determination and submit notification to EPA; and/or request an EPA confirmation of eligibility (if applicable). 40 CFR 174.90(b) requires respondents to use the electronic submission portal (a.k.a., Pesticide Submission Portal). The PSP leverages the Agency's existing Central Data Exchange (CDX) to provide a secure method of submitting information within a secure online environment. CDX requires initial user registration for which the paperwork burden estimate is covered under "Cross-Media Electronic Reporting Rule" ICR, OMB No. 2025-0003. See attachment H.

Store/ Maintain Data

The Agency currently has a ICR entitled "*Recordkeeping Requirements for Producers, Registrants and Applicants of Pesticides and Pesticide Devices under Section 8 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA*);" OMB ICR Number 2070-0028. When the rule becomes final, the agency will revise this ICR burden total to reflect the impact of the new rule. For 5 years, starting with the effective date of a plant-incorporated protectant exemption, any person who is required to submit documentation for the determination of eligibility for a plant-incorporated protectant listed under § 174.21(d) must do both of the following:

(a) Maintain documentation of either the request for EPA confirmation or the letter of self-determination (or both, if applicable) along with all supporting documentation for the specific exemption listed in subpart E.

(b) Make the documentation outlined in 40 CFR §174.73(a) available to EPA upon request.

CBI claims

The rule states "any claims of confidentiality for information submitted in the request for EPA confirmation must be made in accordance with the procedures outlined in § 174.9 of subpart A," 40 CFR 174.90c. The Agency currently has a ICR entitled "Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting;" OMB ICR Number 2070-0142. When the rule becomes final, the agency will revise this ICR burden total to reflect the impact of the new rule.

Adverse effects reporting

The rule does not exempt qualifying PIPs from the adverse effects reporting requirements at 40 CFR 174.71. The Agency currently accounts for adverse reporting burden in the ICR entitled, "Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting;" OMB ICR Number 2070-0142. Upon finalization of this rule, the agency will revise this ICR burden total to reflect the impact of the new rule. Because of the criteria for qualifying for an

exemption, EPA does not anticipate adverse effects will occur.

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

a) The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

b) If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There is no capital cost associated with the requirements.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

EPA estimates the average Agency burden per action is 5 hours, with a cost of $457. This time will be used to evaluate the applications to determine that all of the

information required to be eligible for exemption was received and time to update the website to include the newly exempt PIP. This activity will be performed by technical staff. This is a high-end estimate, as some of the actions will not require Agency review. Specifically, developers of loss-of-function PIPs are only required to submit a self-determination letter to the Agency and will thus only require Agency staff to update the website to include the newly exempt PIP. The Agency is projecting up to 10 actions to be received per year. The expected annual Agency burden for this exemption is estimated to be 50 hours, with a cost of $4,570.

Table 5: Grand Total Annual Estimated Burden/Cost to the Agency

Review Activities	**Burden Hours**			**Total**	
	Management	Technical	Clerical		
	$138.47/hr	$91.34/hr	$50.54/hr	Hours	Costs
Confirm eligibility and information requirements & updating website	0	50	0	50	$4,570
TOTAL	**0**	**50**	**0**	**50**	**$4,570**

*Numbers may not sum due to rounding.
Source: Burden hours are per Agency estimate. Wage estimates use the fully loaded hourly rate (includes benefits and overhead) for NAICS 999100 Federal Government as of May 2021. Wage estimates are available by the U.S. Bureau of Labor Statistics at http://www.bls.gov/oes/current/naics4_999100.htm.

15. Explain the reasons for any program changes or adjustments reported in hour or cost burden.

This is an ICR for a new action. The burden estimated here covers the information collection activities contained in the final rule that would create requirements for an exemption from existing registration requirements. As a result, the burden presented in this ICR reduces the existing burden to developers if they were to pursue registration instead of an exemption. Because this action reduces the regulatory requirements for bringing a PIP to market, the net result can be considered a reduction in the existing burden and costs associated with the registration and tolerance activities. The response to number 12 above explains the rationale for updating the burden hours estimates from those included with the proposed rule.

16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

EPA intends to publish a public list of exempt PIPs on an EPA website. Only basic information on the exempted PIPs will be made public and only if these have not been claimed as confidential by the developer. Basic information includes things such as the name of the developer, a description of the trait (e.g., pathogen resistant), and the name of the plant that was engineered to contain the PIP (e.g., corn). The Agency is not planning on publishing any other technical information on the product or EPA's assessment. The information that will be published is directly inputted into the electronic submission portal by the developer as a requirement of the eligibility determination process. A checkbox allows a developer to mark specific information elements at that time. Approximately once a month, the system then creates an automatic list of the information and sends the updated list automatically to EPA's technical staff who will then conduct a quality control check before sending the list to the IT staff (i.e., via email) for publication on EPA's website.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

This question is not applicable to this ICR.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

EPA does not request an exception to the certification of this information collection.

SUPPLEMENTAL INFORMATION

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 the final rule and ICR under Docket ID Number EPA-HQ-OPP-2019-0508, which is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public 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 above.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via http://www.reginfo.gov/public/do/PRAMain. Find

this particular information collection by selecting ‘‘Currently under 30-day Review—Open for Public Comments’’ or by using the search function.

All comments received by EPA will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through http://www.regulations.gov using Docket ID Number: EPA-HQ-OPP-2019-0508.

Attachment	Description
A	FIFRA section 3 (7 USC 136a) https://www.govinfo.gov/content/pkg/USCODE-2018-title7/html/USCODE-2018-title7-chap6-subchapII.htm
B	FFDCA section 408 (21 USC 346a) https://www.govinfo.gov/content/pkg/USCODE-2021-title21/pdf/USCODE-2021-title21-chap9-subchapIV-sec346a.pdf
C	New final rule for 40 CFR part 174 specific regulations for certain Plant-Incorporated Protectants exemptions: See the docket https://www.regulations.gov/search?filter=EPA-HQ-OPP-2019-0508
D	PIP BioTech Exemption Screenshots (EPA Form 9600-053)
E	Application for New and Amended Pesticide Registration, ICR- 2070-0060 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202107-2070-001
F	Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting, ICR, 2070-0142 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202012-2070-004
G	Recordkeeping Requirements for Producers, Registrants, and Applicants of Pesticides and Pesticide Devices under Section 8 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), ICR – 2070-0028 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201808-2070-004
H	Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert

Attachment	Description
	Ingredients, ICR – 2070-0024 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202103-2070-003
I	Cross-Media Electronic Reporting and Recordkeeping Rule, ICR - 2025-0003 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202106-2025-001 See also CDX guidance- https://cdx.epa.gov/about/userguide