

**SUPPORTING STATEMENT
FOR AN INFORMATION COLLECTION REQUEST (ICR)**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Proposed Rule ICR Amendment for the Proposed Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies Rulemaking (RIN 2070-AK54)

OMB Control No.: 2070-[tbd]

EPA ICR No.: 2619.01

Docket ID No.: EPA-HQ-OPP-2019-0508 (<http://www.regulations.gov>)

1(b) Short Characterization/Abstract

This information collection request (ICR) addresses the information collection activities in the proposed rule entitled “Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies; Proposed Rule” (RIN 2070-AK54). The Environmental Protection Agency (EPA) is proposing an exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) for certain PIPs that are created in plants using biotechnology, as long as their pesticidal substances are found in plants that are sexually compatible with the recipient plant and meet the proposed exemption criteria, ensuring their safety. The current exemption for PIPs is limited to PIPs moved through conventional breeding. EPA's proposed rule would allow certain PIPs created through biotechnology to also be exempt under existing regulations, in cases where those PIPs 1) pose no greater risk than PIPs that meet EPA safety requirements, and 2) could have otherwise been created through conventional breeding. The proposed rule also includes a process through which developers of PIPs based on sexually compatible plants created through biotechnology submit either a self-determination letter or request for EPA confirmation that their PIP meets the criteria for exemption. For increased flexibility in bringing PIPs to market, a developer can also submit both. EPA anticipates several benefits that may result from exempting these PIPs. These include lower costs from reduced regulatory burden, increased research, development, and commercialization of pest control options for farmers, particularly in minor crops, and reduced use of conventional pesticides which could provide environmental benefits.

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. The existing ICR addresses the information collection activities associated with the registration of a pesticide product under FIFRA section 3 and related tolerance determinations under FFDCA section 408. FIFRA provides EPA with the authority to regulate the distribution, sale and use of pesticides in the United States and 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." FFDCA provides EPA with the authority to establish tolerances (maximum residue limits) or exemptions for pesticide chemical residues that meet the safety standard.

The proposed exemption and related notification process will provide individuals and entities with an alternative to the activities covered by the existing ICR that are associated with submitting a registration application and a petition for a tolerance or an exemption from the requirement for a tolerance. As such, once these activities are finalized the estimated burden and costs in this ICR amendment will represent an off-set of the existing burden and costs. At the final rule stage, the exemption related activities and associated burden will be incorporated into the existing ICR.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

The proposed exemption and related notification requirements are authorized by FIFRA section 3 (7 USC 136a)¹ and FFDCFA section 408 (21 USC 346a)². Governing regulations and guidelines are contained in 40 CFR parts 152, 156 and 158, with regulations specific to PIPs are found in 40 CFR part 174.³

2(b) Practical Utility/Users of the Data

EPA will review the proposed exemption notifications, which will provide information on the identity and composition of the product and its history of safe exposure to humans and the environment. Based on the submitted information, EPA will determine if a product qualifies for being exempt from the requirements of registration under FIFRA and the requirement for a tolerance or tolerance exemption under FFDCFA.

The proposed notification requirements will ensure that the modification does not result in a novel substance and that the expression profile of the PIP is indistinguishable from what is found within naturally interbreeding plants.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER PRA REQUIREMENTS

3(a) Non-duplication

Duplication will not occur in this program, as EPA has the sole authority to regulate pesticides and establish tolerances or tolerance exemptions in the United States. In addition, each applicant must submit information unique to the particular product.

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

Pursuant to 5 CFR 1320.11(b), the proposed rule will announce the availability of this ICR and provide a 60-day public comment opportunity. Comments received on this ICR will be addressed in the response to comment document that will accompany the final rule.

3(c) Consultations

¹ EPA provides a summary of this law, along with a link to the U.S. Code, on our website: <https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. You can also find more information about pesticide registration service fees here: <https://www.epa.gov/pria-fees>.

² EPA provides a summary of this law, along with a link to the U.S. Code, on our website: <https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>.

³ An electronic version the CFR is maintained by the Government Printing Office here: <https://www.ecfr.gov/>

Under 5 CFR 1320.8(d)(1), agencies are required to consult with respondents about the information collection activities and related estimates before submitting an ICR request to OMB for approval under the PRA. In the proposed rule, EPA specifically seeks stakeholder feedback on the burden estimates presented in this ICR and on the clarity of the information collection activities.

3(d) Effects of Less Frequent Collection

Once per product is the least frequent possible.

3(e) General Guidelines

The proposed rule involves a submission (i.e., the notification) and recordkeeping. The following discussion is a summary of a more detailed discussion of applicable PRA guidelines that is contained in the existing ICR.

(i) Recordkeeping.

The recordkeeping activities applicable to pesticide registrants exceed OMB's guideline that agencies should not require records to be retained for more than three years (5 CFR 1320.5(d)(2) (iv)). As authorized under FIFRA section 8, 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. However, 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).

(ii) Electronic submissions.

As discussed in the proposed rule, EPA intends to consider offering the use of the Pesticide Submission Portal (PSP), a fully electronic system used for submitting registration forms to EPA, as an option for submitting the proposed PIPs notification and/or the request for EPA confirmation. The PSP leverages the Agency's existing Central Data Exchange (CDX) to provide a method for submitting information to EPA within a secure online environment. CDX requires initial user registration for which the paperwork burden estimate is already covered and approved under OMB Control No. 2025-0003 (*Cross-Media Electronic Reporting Rule ICR*). Extensive guidance regarding available electronic submission options is available via the Office of Pesticide Program's (OPP) website at <http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

3(f) Confidentiality

Although EPA urges the submitter to minimize the amount of information claimed as Confidential Business Information (CBI), 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 proposed exemptions that is claimed as CBI or that is otherwise restricted from public disclosure by law as trade secret, commercial, or financial information.

3(g) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this collection activity. In addition, 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 proposed 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 proposed rule, which is also available in the docket for the proposed rule. In general, EPA believes that potential respondents can be identified by the following North American Industrial Classification System (NAICS) codes:

Category	NAICS codes	Examples of potentially affected entities
Pesticide and other agricultural chemical manufacturing	32532	Individuals or entities engaged in activities related to the registration of a pesticide product.
Crop Production	111	Seed companies.
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of PIPs.
Research and Development in the Physical, Engineering, and Life Sciences (except Nanobiotechnology)	541714	Biotechnology research and development laboratories or services.

4(b) Information Collection Activities

Currently, the producer of a PIP derived from sexually compatible plant created through biotechnology is required to apply for an experimental use permit (EUP), provide data or information on product characterization, toxicology, nontarget organism effects, environmental fate, and resistance management and field-testing and then register the PIP as they would any other pesticide. In addition, 40 CFR 174.71 requires that any subsequently discovered adverse effect be reported to the Agency. These activities and associated burdens are already approved under OMB Control No. 2070-0060 (EPA ICR No. 0277). As detailed in the existing ICR, the estimated annual burden per respondent ranges from 14 to 646 hours for registration application activities, and from 527 to 46,000 hours for data generation related to registration of a new active ingredient, with the variation related to the type of registration involved.

As proposed, the developer of a PIP based on sexually compatible plants created through biotechnology would instead submit either a self-determination letter or request for EPA confirmation that their PIP meets the criteria for the exemption. This ICR addresses the information collection activities and related burden and cost estimates associated with the proposed exemption, which are described in more detail in the proposed rule itself.

(i) Data items.

Under the proposed exemption, **a developer who elects to self-determine eligibility** for the exemption of a plant-incorporated protectant listed under proposed § 174.21(d) must submit a letter of self-determination for an exemption to EPA prior to engaging in activities subject to FIFRA. Under proposed § 174.91, the letter of self-determination must:

- (1) Provide the name and contact information for the submitter (including phone and email address), company name, or other affiliation.
- (2) Identify the exemption for which eligibility is self-determined (i.e., cite the paragraph under proposed §§ 174.26 or 174.541 that is applicable to the PIP (i.e., (a)(1), (a)(2)(i), (a)(2)(ii), (a)(2)(iii), or (a)(2)(iv)).
- (3) Include the following statement of certification, filling in the information described in italics:

"I, *[name of submitter]*, on behalf of *[name of company]* am submitting this Plant-Incorporated Protectant Exemption Self-Determination consistent with the provisions of 40 CFR part 174. I hereby confirm that the plant-incorporated protectant known as *[name of the plant-incorporated protectant]* is eligible under 40 CFR 174.21 to be exempt from the requirements of FIFRA, other than the requirements of 40 CFR 174.71 and 174.73. I understand that it is a violation of 18 U.S.C. 1001 to willfully make any false statement to EPA. I further understand that if this self-determination is not consistent with the provisions of 40 CFR part 174, this plant-incorporated protectant product may not be exempt from the requirements of FIFRA, and *[name of company]* may be subject to enforcement actions and penalties under FIFRA sections 12, 13, and 14, 7 U.S.C. 136j, 136k, and 136l. Moreover, I also understand that if this self-determination is not consistent with 40 CFR part 174, the residues of this plant-incorporated protectant may not be exempt from the requirement of a tolerance under the FFDCA, and *[name of company]*, as well as foods containing such residues, may be subject to enforcement actions and penalties under Chapter III of the FFDCA, 21 U.S.C. 331 *et seq.*"

- (4) The statement must be dated and signed by an authorized representative of the developer of the plant-incorporated protectant.

Under proposed § 174.93, a **developer who elects to request EPA confirmation of eligibility** for exemption of a plant-incorporated protectant listed under § 174.21(d) must submit to EPA a request for EPA confirmation prior to engaging in activities subject to FIFRA, unless the developer has received confirmation of receipt of a letter of self-determination. The request for EPA confirmation of eligibility for the exemption must contain the same information as required for the self-determination letter (see above), along with the following supporting documentation demonstrating that the plant-incorporated protectant meets the criteria for the exemption (see proposed § 174.95):

- (a) Biology of the plant.
 - (1) The identity of the recipient plant, including genus and species.
 - (2) If the plant-incorporated protectant was derived from another plant species, provide the identity of the source plant including genus and species and information to demonstrate the recipient plant and the source plant are sexually compatible.
- (b) Description of the pesticidal trait and how the trait was engineered into the plant. If the pesticidal substance is a known mammalian toxin or toxicant (e.g., solanine) describe how conventional breeding practices are being used to ensure it does not exceed safe levels in the recipient food plant.
- (c) Molecular characterization of the plant-incorporated protectant.
 - (1) The nucleotide sequence and the amino acid sequence of the plant-incorporated protectant in the recipient plant, including a sequence comparison between the recipient

plant and the relevant comparator (i.e., the source plant if a source plant was used or the unmodified plant if no source plant was used).

(2) For a plant-incorporated protectant where the regulatory region of an existing or inserted native gene has been modified, confirmation that the expression level does not exceed that found in a sexually compatible plant and the plant-incorporated protectant is not expressed in tissues or developmental stages outside of that observed in a plant that is sexually compatible with the recipient plant.

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.

The general recordkeeping requirements in proposed § 174.93, would require that for 5 years, starting with the effective date of a plant-incorporated protectant exemption, any person who produces an exempt plant-incorporated protectant listed under § 174.21(d) must do both of the following:

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

(b) Make the documentation of exemption eligibility available to EPA upon request.

(ii) Respondent PRA activities.

The following table identifies the expected information collection activities that the developer might engage in as a result of the proposed exemption.

Respondent Paperwork Activity	Description
1. Read instructions	A) Read germane statutory provisions and implementing regulations in 40 CFR parts 150-189, guidance and correspondence related to the regulation of PIPs under FIFRA & FFDCA. B) Read applicable regulations in 40 CFR part 174 and related guidance associated with the exemption.
2. Determine eligibility and plan activities	A) Determine whether the PIP product being developed qualifies under the exemption. B) If it qualifies, determine next steps and plan activities per 40 CFR part 174.
3. Gather information	Identify & gather available information needed to determine whether the PIP product being developed qualifies under the exemption.
4. Compile and review	Assemble information, evaluate for accuracy, appropriateness, and completeness
5. Complete paperwork	A) Complete self-determination and submit notification to EPA; or B) Request an EPA confirmation of eligibility.
6. Submit notification or request to EPA	Using preferred option for submission, submit required information to the EPA.
7. Keep records	File and maintain copies of submission and underlying data supporting self-determination and related data submitted to the Agency.

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

5(a) Agency Activities

In general, the degree of Agency activities in the review of data submissions will depend on the complexity of the product being registered, the pre-application determinations being made, and/or whether it is identical or substantially similar to other products already registered. Products containing active ingredients present in currently registered products and proposed for uses currently registered (“me-too” registrations) may require only a minimal review for completeness of the application, the adequacy of the labeling, and the satisfaction of data compensation requirements.

In general, EPA reviews applications for exemptions and, if it is determined that the application qualifies, the product will be exempted from the requirements of registration under FIFRA and/or receive a tolerance or tolerance exemption under FFDCA.

As described in more detail in the existing ICR, EPA activities occur in OPP and generally include the following:

i. EPA receives the self-determination letters and requests for EPA confirmation of eligibility.

The submissions will be received by the Front-End Processing Unit in the Information Technology and Resources Management Division (ITRMD). After screening the notification for administrative completeness, ITRMD will refer the complete letter or request and any accompanying data to the appropriate regulatory division in the Office of Pesticide Programs (OPP). In general, with adjustments in details expected based on adoption of electronic submission and internal management systems, ITRMD is responsible for entering the incoming package into OPP’s central tracking database system, currently that is “OPPIN” and another system is in the pilot stage. If the submission is accompanied by supporting information, ITRMD will forward the data package to a contractor for scanning and data entry into the Agency’s tracking database. After this is complete, the data package is routed to the appropriate regulatory division in OPP for processing.

ii. EPA reviews the request for confirmation of eligibility.

The submission will be reviewed by BPPD to determine whether the exemption criteria are satisfied.

iii. EPA decision.

The Program Manager or Team Leader in BPPD will recommend a decision to the Director of OPP for a final decision on whether to confirm the exemption, and – if the product involves a new food use, a tolerance or exemption is established for an already registered or exempted PIPs. The final decision is made by the BPPD Division Director.

iv. EPA notifies the submitter of EPA’s decision.

OPP will send a letter to the applicant that the product is exempt from the requirements of registration under FIFRA and/or a tolerance or tolerance exemption under FFDCA.

v. EPA documentation.

OPP stores, files, and maintains copies of the exemption, from notification and related review to the determination.

5(b) Collection Methodology and Management

All pesticide regulatory determination actions are entered into OPP's central database system (OPPIN, to track progress and final decisions. Once a product has been registered, pertinent status information regarding the product is revised in the tracking database.

5(c) Small Entity Flexibility

EPA offers direct assistance to small entities, facilitating their compliance with the requirements for obtaining an exemption.

5(d) Collection Schedule

Not applicable. The activity is conducted only once at the time that an exemption is sought. There is no set schedule for the submission of this information to EPA.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

The paperwork burden associated with the proposed rule is based on the information and activities identified in the existing ICR and is considered to off-set or serves as an alternative burden for that estimated in the existing ICR. The methodology and approach presented here is consistent with that used for the existing ICR.

6(a) Respondent Burden Hours and Cost

Table 6-1 presents estimates for burden hours and costs for the submission of a self-determination letter, or a request for EPA confirmation of eligibility. The estimates are based on the burden and cost estimates in the existing ICR for a Type A registration action (EPA ICR No. 0277; OMB Control No. 2070-0060).

Table 6-1: Estimated Burden/Cost per Exemption Related Submission

Collection Activities, Exemption Notifications	Burden Hours			Total	
	Mgmt.	Technical	Clerical	Hours	Costs
	\$143.29/hr	\$74.95/hr	\$47.78/hr		
Read Instructions	7	0	0	7	\$1,003
Plan activities	0.5	0	0	0.5	\$72
Gather/create information	0	1.5	0	1.5	\$112
Compile and review	0.5	0.5	0	1	\$109
Complete paperwork	0	0	3	3	\$143
Submit information					
Store/maintain data	0	0	1	1	\$48
Third party disclosure					
TOTAL	8	2	4	14	\$1,487

*Numbers may not sum due to rounding.

6(b) Agency Burden and Cost

The Agency's activities and estimates for the burden and costs associated with processing the proposed exemption related submissions are assumed to be the same as those associated with other exemptions and registration applications as described in the existing ICR (EPA ICR No.

0277; OMB Control No. 2070-0060). In the existing ICR, the overall Agency burden for registration activities is estimated to be 369,127 hours with a total cost of \$33,929,979. Since that estimate represents Agency burden for 8,230 registration actions, the average burden per action is 45 hours, with a cost of \$4,120. At an anticipated one exemption self-determination with a request for EPA confirmation per year, the expected annual Agency burden for this proposed exemption is estimated to be 45 hours, with a cost of \$ 4,120.

6(c) Bottom Line Burden Hours and Cost

Table 6-3 provides the estimates for total annual burden hours and costs associated with the proposed rule for both the respondents and the Agency.

Table 6-2: Estimated Annual Total Burden Hours and Costs

	ANNUAL TOTAL		
	Responses	Hours	Costs
TOTAL RESPONDENT BURDEN	1	14	\$ 1,487
TOTAL AGENCY BURDEN	1	45	\$ 4,120

*Numbers may not sum due to rounding.

6(d) Reasons for Change in Burden

This ICR covers the information collection activities contained in a proposed rule that would create requirements for an exemption from existing registration requirements. As a result, the burden presented in this ICR will serve as an off-set to the existing burden. The net result can be considered a reduction in the existing burden and costs associated with the registration and tolerance activities. At the final rule stage, the Agency will determine the extent to which the existing approved burden hours and costs in OMB's inventory may be reduced. That change will be classified as a program change.

6(e) Burden Statement

The average reporting and recordkeeping burdens for the proposed exemption related submissions is estimated to be 14 hours, with an associated cost of \$1,487 (there are no maintenance and operational costs). Burden is defined in 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a current and 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.

6(f) Docket Information

Since this ICR is accompanying a proposed rule, this supporting statement and related materials are available in the rulemaking docket established under Docket ID No. EPA-HQ-OPP-2019-0508, which is available for online viewing at <http://www.regulations.gov>. Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

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 to both EPA and OMB, referencing the Docket ID No. identified above and RIN 2070-AK54, as follows:

- To EPA online using <http://www.regulations.gov>, and
- To OMB via email to oir_submission@omb.eop.gov. Address comments to *OMB Desk Officer for EPA*.

7. ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the docket identified in Section 6(g) of the Supporting Statement. These attachments are available for online viewing at <http://www.regulations.gov> or otherwise accessed directly as identified in the following index.

Attachment A:	PrePubCopy of the Proposed Rule entitled: Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies (RIN 2070-AK54) (See docket for the version that publishes)
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