

123670400

**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: Final Rule-related ICR Amendment for Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests

EPA ICR No.: 0277.23

OMB Control No.: 2070-0060

Docket ID No.: EPA-HQ-OPP-2020-0124

Abstract:

This information collection request (ICR) represents an amendment to an existing ICR entitled “*Application for New and Amended Pesticide Registration*,” identified as EPA ICR No. 0277.22 and approved under OMB Control No.: 2070-0060. The amendment focuses on the information collection activities in the final rule entitled “Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests” (RIN 2070-AJ49). In this rule, EPA codifies certain activities related to product performance data requirements to support registration of pesticidal products claiming efficacy against three categories of invertebrate pests. Those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian long_horned beetle). The two latter categories are non-agricultural pests considered to be of significant economic or ecological importance. Product performance data (efficacy studies) document how well the pesticide performs the intended function (such as killing or repelling) against an invertebrate pest.

Product performance data is only a fraction of the information collection activities associated with the registration of a pesticide product under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3. This amendment recalculates the burden by decreasing the hourly burden for a small portion of the product performance data, generally efficacy data, that may be submitted to the Agency as part of the registration of pesticidal products package.

The Product Performance Rule ICR references the Section 3 ICR. The publication of the final rule will reduce burden to registrants, and will have no significant impact on Agency burden. The Rule will reduce the number of incomplete submissions of data (IC #2) to the Agency by 12 per year, each of which has an estimated burden of 14 hours. Currently, EPA estimates in the Section 3 ICR that 7,273 similar submissions are sent to the EPA annually, at a cost of 102,000 hours. A reduction of 12 submissions would reduce the number of submissions to 7,261 and reduce the hour burden by 168 hours annually. Further, the Rule will clarify data requirements and will result in reduced data generation costs (IC #4) equivalent to 4,515 hours annually. EPA estimates that the total average annual burden hours from data generation for new and amended products is 482,500 hours, so the Rule will reduce burden due to data generation to under 479,000 hours. In total, EPA estimates that the Product Performance Rule will reduce burden hours annually by 4,683 hours (4515+168). IC #1, IC #3, and Agency burden will not be impacted by this rule.

The total respondent burden calculated in the Application for New and Amended Pesticide Registration ICR is \$108.7 million annually. If the proposed rule is finalized, that burden will be lowered to \$108.4 million annually. This is primarily existing burden not attributable to this proposed rule and covered under EPA ICR No. 0277 and approved under OMB Control No.: 2070-0060.

Subsequent to the publication of the Notice of Proposed Rule Making, the ICR entitled "Application for New and Amended Pesticide Registration," (OMB Control No.: 2070-0060) was renewed and the total approved burden was increased from 1,524,893 to 1,562,517 hours. When adjusted to account for this the burden change, which is unrelated to this final rule, this final rule reduces the burden by 4683 hours from 1,562,517 to 1,557,834.

Table 1: IC Summary Table: Annual Burden and Cost over the Three-Year ICR Period			
IC Category	Responses	Burden	Burden Reduction
Respondents			
IC #2: "Type B" application for registration of a new or amended product that contains a currently registered active ingredient	7261	101659	168
IC #4: Data Generation (for New AIs & New Products)	695	478016	4515
Annual Total	7956	579,675	4683
Agency			
IC #2: "Type B" application for registration of a new or amended product that contains a currently registered active ingredient	N/A	N/A	N/A
IC #4: Data Generation (for New AIs & New Products)	N/A	N/A	N/A
Annual Total	N/A	N/A	N/A

Supporting Statement

1. Explain the circumstances that make the collection of information necessary.

The ICR entitled “*Application for New and Amended Pesticide Registration*,” EPA ICR No. 0277.22 and approved under OMB Control No.: 2070-0060, is designed to provide the EPA with the necessary information to evaluate an application for the registration of a pesticide product, as required under Section 3 of the FIFRA, and the relevant regulations at 40 CFR 158 and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (see **Attachment A**, **Attachment B**, and **Attachment C**). Under FIFRA, EPA must evaluate pesticides comprehensively before they can be marketed and used in the United States to ensure that they will not pose unreasonable adverse effects to human health and the environment. This registration evaluation includes determining whether the composition of the pesticide warrants the proposed claims for it, the pesticide’s labeling complies with all applicable requirements (e.g., is not false or misleading), and the pesticide will perform its intended function without unreasonable adverse effects on human health and the environment. See FIFRA Section 3(c) (5). Pesticides that meet this test are granted a license or “registration” which permits their distribution, sale and use according to requirements set by EPA to protect human health and the environment.

Due to the Paperwork Reduction Act (PRA) burden changes precipitated by the final rule, this amendment recalculates by decreasing some of the hourly burden activity associated with information collections categorized as Type B actions. The Agency reviews an average of 7,273 Type B actions annually. Product performance data is categorized by the Agency as a Type B action. A subset of product performance data, specifically, product efficacy reviews, account for about 60 reviews, on average, every year, or less than one percent of the total product performance data that may be submitted to the Agency as part of a registration review package.

Product performance data (efficacy studies) document how well the product performs the intended function (such as killing or repelling) against an invertebrate pest. This rule changes the regulatory mechanism by which this information would be collected, but for the most part, the data requirements that EPA is codifying are consistent with EPA's current practices in data supporting applications for registration of a pesticide product that bears a pesticidal claim against one or more of these pests. Additionally, the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) requires EPA to finalize product performance data requirements by September 30, 2021 (see **Attachment F**). Specifically, the Act states that, "The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance specified in clauses (i) through (iv) of subparagraph (B) [bed bugs; premise (including crawling insects, flying insects, and baits), pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips), and fire ants]."

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.

This action is issued under the authority of sections 3, 5, 10, 12, and 25 of FIFRA (7 U.S.C. 136–136y), as amended. Under FIFRA section 3(c)(2)(A), EPA is required to specify "the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time." EPA's codification of these data requirements is in 40 CFR part 158. This information collection is used by EPA to review submittal of the product performance information, the efficacy studies and other information to make registration determinations under FIFRA.

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.

Applications for pesticide registration can be submitted electronically, including forms, studies, and draft product labeling. EPA also offers the use of the Pesticide Submission Portal (PSP), a fully electronic alternative as an option for submitting registration forms electronically. 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.

EPA will continue to accept paper applications but encourages applicants to take advantage of the more efficient PSP option and forego physical transmission costs to submit information to EPA. For electronic submissions, applicants do not need to submit multiple copies of any pieces of their application, the requirement for multiple copies of data and five copies of draft labeling only applies to paper submissions. Extensive guidance regarding available several electronic submission options is available to registrants via the Office of Pesticide Program’s (OPP) website at <http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

4. Describe efforts to identify duplication.

Duplication should not occur in this program, as EPA has the sole authority to regulate pesticides in the United States and establish efficacy data requirements under 40 CFR part 158. Therefore, this information is not requested by other agencies.

EPA supports data sharing (subject to data compensation as directed by FIFRA) to reduce the potential for duplicative studies being submitted to EPA.

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

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

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 burden assumes a minimum of one submittal per product registration which is the least possible collection that allows the Agency to conduct the statutorily required review.

This information collection is only conducted as a registration application is received for consideration. There is no set schedule for submission of this information to EPA.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

The only guideline established under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. The recordkeeping activities applicable to pesticide registrants exceeds OMB's guideline that agencies do not require records 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 registrants to 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*).

8. If applicable, provide a copy and identify the date and page number of publications 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. 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.

Pursuant to 5 CFR 1320.11(b), the proposed rule (86 FR 15362) 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.

The EPA implements procedures to protect any confidential, trade secret or proprietary information from disclosure that provide strict instructions regarding access to and contact with documents 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 brought to the Agency in conjunction with this information collection that may be claimed as confidential, trade secret, commercial, or financial information.

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.

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, "Responsibility for the Maintenance of Records about Individuals by Federal Agencies."

12. Provide estimates of the hour burden of the collection of information.

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

The paperwork burden associated with the rule is based on the information and activities identified in existing ICR and is considered to off-set or serve as an alternative burden for that estimated in the existing ICR. The methodology and approach is consistent with that used for 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 (see **Attachment E**). The full population of respondents for that ICR was 1,751. There are two main categories of applicants for registration: those requiring submission of a full complement of supporting data (e.g., new active ingredients); and those requiring submission of less data (e.g., amendments, for currently registered chemicals). These have been described as Type A and B, respectively. For the reasons described below, EPA considers requests for label claims against pests of significant public health importance, wood-destroying, and invasive species pests to be Type B actions. Table 2 presents the estimated burden and cost estimate per submission for Type B actions.

Table 2: Estimated Average Burden and Cost per Type B Submission

Collection Activities, Type B	Burden Hours			Total	
	Mgmt.	Technical	Clerical	Hours	Costs
	\$132.14/ hr	\$87.24/hr	\$48.83/hr		
Read Instructions	7	0	0	7	\$852
Plan activities	0.5	0	0	0.5	\$61
Gather/create information	0	1.5	0	1.5	\$108
Compile and review	0.5	0.5	0	1	\$97
Complete paperwork	0	0	3	3	\$123
Submit information					
Store/maintain data	0	0	1	1	\$41
Third party disclosure					
TOTAL	8	2	4	14	\$1,282

*Numbers may not sum due to rounding.

EPA notes that "Type B" activities involve a registrant or applicant assembling and submitting an application for registration of a new or amended product that contains a currently registered active ingredient. Because this rulemaking is about publishing the standards for label claims, the impacted activities would generally be "Type B" activities. "Type A" actions include applications for new active ingredients. Submission of applications for new active ingredients may also include product labeling, and so in some cases Type A actions may be influenced by the rule. However, EPA did not observe any cases of this in our 60-product sample of submissions. Further, Type B actions are more than 20 times as common as Type A actions, so the majority of the burden reduction from this rule will be from Type B actions. Type C actions are applications for a new active ingredient or a new use of a currently registered

active ingredient but also include a “reduced risk” rationale document addressing risk reduction parameters. The Type C reduced risk rationale is not impacted by the rule. EPA did not observe any cases of this in our 60-product sample of submissions. Type B actions are almost 1,000 times as common as Type C actions, and so will account for the majority of the burden reduction from this rule.

EPA does not expect the final rule to significantly change the estimates of the paperwork burden from the submission process. As documented in the September 24, 2020, Application for New and Amended Pesticide Registration ICR, the Agency reviews 7,273 Type B actions annually.

Product efficacy reviews account for about 60 reviews, on average, every year, or less than one percent of the total product performance data (Type B actions); thus, the burden of these particular actions has little measurable effect on the overall average. EPA has not estimated the burden associated with applications for efficacy reviews specifically, but it is probably greater than the average Type B action. In particular, the burden associated with the first two steps Reading Instructions and Planning Activities, may be high because requirements have not been codified and it may be difficult for applicants to ascertain what information should be submitted. Codifying the requirements would make it easier for applicants to obtain the information they need, reducing the burden of seeking that information and identifying the appropriate studies.

EPA estimates the total average annual cost of paperwork burden from data generation for new and amended products is \$33.7 million. This rule will save \$315,000 annually, or 1% of the total paperwork burden from data generation. EPA estimates that the total average annual burden hours from data generation for new and amended products is 483,000 hours. The rule will reduce the burden by 4,515 hours, or 1% of the estimated total hourly burden from data generation.

EPA estimates that annually 12 data packages are submitted to the EPA that lack the appropriate efficacy data to support the requested label claims. EPA expects the rule to eliminate this category of waste because applicants would know what data are required. A reduction of 12 applications per year with an estimated paperwork burden of \$1,282 implies a cost savings of approximately \$15,000 annually resulting from the rule. Each action is estimated to take 14 hours – a reduction of 12 applications per year implies a reduction in burden hours of 168 annually. When the rule is finalized, assuming the annual baseline for data packages remains as projected, EPA expects the number of Type B actions to decline from 7,273 to 7,261 per year over the next three years.

In the long run, EPA expects the rule to lead to increased clarity among registrants about EPA data requirements, and the reduction in uncertainty resulting from the rule may lead registrants to submit more data packages. If registrants increased the number of data packages submitted to the Agency by more than 12 annually, this would result in increased total submissions, and associated total burden, but with fewer incomplete data packages. The Agency does not have information on whether the clarity resulting from the implementing the rule will result in an increase or decrease in the number of total submissions to the Agency relative to prior to the publication of the rule.

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

- 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.
- 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.
- 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 are no capital investment or maintenance and operational costs for this information collection.

14. Provide estimates of annualized cost to the Federal government.

The incremental burden for the Agency associated with codifying the product performance data requirements is uncertain. The final rule will result in clarity for registrants which may lead to registrants submitting fewer incomplete packages, thus reducing the burden for the Agency. However, given the small number of product performance data submissions relative to the total number of submissions reviewed by the Agency, the burden will not change measurably. Moreover, the increase in clarity may encourage registrants to submit more packages and this may translate to an increased Agency burden. Therefore, the direction and extent of Agency burden in the long term is uncertain but likely to be very small.

The estimated number of Agency FTEs dedicated to the currently approved Section 3 ICR registration and registration support activities is approximately 24 managerial FTEs, 146 technical FTEs, and 7 clerical FTEs. The aggregated Agency estimated FTE dedicated to Section 3 activities is 177 and the burden hours are 369,127. The fully loaded hourly mean wage rate estimate is \$132.14 for managerial occupations, \$87.24 for technical occupations, and \$48.83 for clerical occupations. To calculate the Agency's estimated annual cost of Section 3 activities, the number of FTE's allocated to registration activities is multiplied by these fully loaded labor rates and by 2,080 hours per FTE, which is estimated to be about \$6.68 million for management occupations; \$26.56 million for technical occupations; and \$689 thousand for clerical occupations. The total estimated Agency cost is \$33.93 million.

15. Explain the reasons for any program changes or adjustments reported in Items 13 (or 14) of OMB Form 83-I.

EPA estimates the final rule will result in an average of 12 fewer submissions of incomplete data packages that do not support desired label claims, saving registrants \$15,000 in paperwork costs related to application submission. Further, the Agency estimates the final rule will reduce unnecessary data generation paperwork burden by \$315,000 annually. This is a total annual reduction in paperwork burden of \$330,000 on average, equivalent to an annual reduction in burden hours of 4,683. This is a program change.

The final rule will reduce the cost of registrant paperwork burden from the submission process by 0.15%. The rule will reduce the average cost of paperwork burden from data generation for new and amended products by 1%. Due to the relatively small impact of the rule, the Agency concludes that the rule will not substantively change the burden estimates calculated in the Application for New and Amended Pesticide Registration ICR.

The Agency does not expect an immediate substantial increase in the number of registrations due to the codification of the rule as there is a significant effort of resources and time involved in developing new products. For this reason, EPA expects that the savings presented above

will remain accurate for the period covered by this ICR. However, in the long run, the clarity resulting from the rule may encourage registrants to submit more data packages to the Agency. The Agency does not possess information to indicate whether registrants would submit more packages after the publication of the rule, nor does the Agency possess information to indicate how many more packages registrants would submit.

16. For collections whose results will be published, outline the plans for tabulation and publication.

Not applicable. EPA does not plan to publish the results for this collection.

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 Item 19 of OMB Form 83-I.

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

LIST OF ATTACHMENTS

The attachments for the ICR supporting statement established for the final rule are available in the public docket for the final rule under identification number EPA-HQ-OPP-2020-0124. These attachments are available for online viewing at <http://www.regulations.gov> or otherwise accessed as described in the sections below.

<u>Attachment</u>	<u>Description</u>
A	7 U.S.C. 136a – Section 3 of FIFRA. 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
B	40 CFR part 158 – Current Regulations. An electronic version of part 158, entitled “Data Requirements for Pesticides,” is maintained by the Government Printing Office here: https://www.ecfr.gov/
C	Section 408 of the Federal, Food, Drug and Cosmetic Act, see 21 U.S. Code § 346a - Tolerances and exemptions for pesticide chemical residues at https://www.law.cornell.edu/uscode/text/21/346a

<u>Attachment</u>	<u>Description</u>
D	Proposed Rule –Located in this docket at https://www.regulations.gov/document/EPA-HQ-OPP-2020-0124-0003
E	Currently Approved ICR. Located in the public docket at https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202005-2070-003
F	Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) See https://www.congress.gov/116/plaws/publ8/PLAW-116publ8.pdf