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: Consolidated Pesticide Registration Submission Portal (New)

EPA ICR No.: 2624.01

OMB Control No.: 2070-[NEW]

Docket ID Number: EPA-HQ-OPP-2020-0273

Abstract

This new information collection request (ICR) consolidates the collection activities and related burdens contained in the following eight ICRs that are currently approved under the Paperwork Reduction Act (PRA) through July 31, 2023, July 31, 2023, August 31, 2023, August 31, 2023, March 31, 2024, January 31, 2025, May 31, 2025, and July 31, 2025:

- "Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients'' (EPA ICR No. 0597.13, OMB Control No. 2070-0024);
- "Notice of Supplemental Distribution of a Registered Pesticide Product'' (EPA ICR No. 0278.13, OMB Control No. 2070-0044);
- "Experimental Use Permits (EUPs) for Pesticides'' (EPA ICR No. 0276.18, OMB Control No. 2070-0040);
- "Pesticide Program Public Sector Collections (FIFRA § 18/24(c))" (EPA ICR No. 2311.05, OMB Control No. 2070-0182);
- "Application for New and Amended Pesticide Registration'' (EPA ICR No. 0277.24, OMB Control No. 2070-0060);
- ''Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting'' (EPA ICR No. 1693.10, OMB Control No. 2070-0142);
- ''Submission of Unreasonable Adverse Effects Information Under FIFRA 6(a)(2)'' (EPA ICR No. 1204.14, OMB Control No. 2070-0039); and
- ''Compliance Requirement for Child Resistant Packaging'' (EPA ICR No. 0616.13, OMB Control No. 2070-0052).

The OMB Terms of Clearance for several of these ICRs directed EPA to consolidate the ICRs to simplify the burden presentation and calculations for the public due to the shared or anticipated collection method involving submissions via the Pesticide Submission Portal in EPA's Central Data Exchange (CDX). This consolidation is expected to clarify the capabilities of the Pesticide Submission Portal for respondents and will streamline the activities related to tracking the ICR renewal activities for both the public and EPA.

The new ICR covers the EPA pesticide registration collection activities supporting the statutorily mandated pesticide registration program under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including the activities associated with the following:

- Pesticide registration
- Pesticide use
- Pesticide sale and distribution
- Pesticide permitting activities
- Determinations regarding whether a product must be regulated under FIFRA
- Pesticide tolerances.

The collection activities vary and are dependent on the request from the Agency, the respondent, or both to fulfill the associated requirement or voluntary submission. Due to the diverse nature of the collections and affected industries, the term “respondent” will be used to refer to those engaging in any or all of the collections described in this ICR, unless a specific term offers more clarity.

In general, before an individual or entity can sell or distribute pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. EPA grants a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements.

The Agency currently collects data on physical chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, and product performance. The information required is dependent on the use and type of product registration (**OMB Control No. 2070-0060**). This data is also used to determine whether the pesticide product must be sold and distributed in Child-Resistant Packaging (CRP) or if it qualifies for an exemption from CRP requirements by meeting certain criteria regarding toxicity and use (**OMB Control No. 2070-0052**).

A respondent wanting to obtain a registration for a pesticide product must submit an application package consisting of information relating to the identity and composition of the product, proposed labeling, and supporting data (or a statement that they have offered to pay for use of someone else’s data) for the product, as mentioned above and outlined in 40 CFR part 158. Standard pesticide registrations do not require Confidential Business Information (CBI) substantiations to be submitted at the time the CBI claim is made. However, under 40 CFR part 174, respondents claiming CBI for plant-incorporated protectant registrations must submit a substantiation with the CBI claim. Plant-incorporated protectants (PIPs) are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance. EPA regulates both the pesticidal substance in the plant and the necessary genetic material for production of the pesticide -- the plant itself is not regulated (**OMB Control No. 2070-0142**).

If a respondent seeks to register a pesticide product developed for food or feed crops, they must ascertain if the Agency has established a tolerance or a tolerance exemption for the active ingredient in the product on those crops. If not, the respondent may petition the Agency to establish a pesticide tolerance or exemption for the active ingredient on the specific crop or crop groupings. Or the respondent may petition the Agency to establish a blanket tolerance exemption for all food commodities. Under FFDCA, EPA is responsible for regulating pesticides used to protect crops grown for human food and animal feed and for setting limits on the amount of pesticide residues that may remain in or on foods. These limits on pesticide residues left on foods are called "tolerances," or maximum residue limits. A pesticide should have a tolerance or tolerance exemption to be used on food or feed crops. In setting tolerances and tolerance exemptions, EPA must make a finding that the tolerance is "safe," meaning that there is a reasonable certainty of no harmful effects of human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure (**OMB Control No. 2070-0024**).

The timeframes for the tolerances actions are established by the Pesticide Registration Improvement Act (PRIA) as amended in 2018. The vast majority of actions to establish tolerances or tolerance exemptions are taken in response to petitions from registrants for the establishment of new tolerances for an existing pesticide ingredient. The Agency may also initiate tolerance actions.

Pesticide tolerances are also needed to support the interstate movement of pesticide-treated foods in commerce. The Food and Drug Administration (FDA) is responsible for tolerance enforcement. Food commodities found to contain pesticide residues in excess of established tolerances are considered adulterated, and are subject to seizure by FDA, and may result in civil penalties.

After a registration is approved, under FIFRA §6(a)(2), registrants are still required to submit any factual information they acquire regarding adverse effects associated with their pesticidal products. It is up to the Agency to determine whether or not that factual information constitutes an *unreasonable* adverse effect to human health and the environment. In addition, manufacturers of PIPs exempted from registration requirements are also required to report adverse effects to the Agency (**OMB Control No. 2070-0039**).

At any time, a pesticide registrant may sell or distribute registered pesticides under an Agency-approved alternate brand name in addition to the registered primary brand name, or under a different entity's name and address. Sale and distribution is called "supplemental distribution," and the product is called a "distributor product." EPA requires pesticide registrants who enter into supplemental distribution agreements with other companies to submit EPA Form 8570-5, *Notice of Supplemental Distribution of a Registered Pesticide Product*. Supplemental registrations are only an extension of a currently federally registered pesticide product (**OMB Control No. 2070-0044**)**.**

Registrants may seek, at their discretion, to amend a registration by submitting data and/or proposed, revised label to EPA. Also, EPA often issues regulatory decisions or guidance that applies to some registered pesticide products and requires labeling revisions to be implemented by the registrant. The revised label is submitted to the Agency as an amendment along with a cover letter, EPA Form 8570-1, and other forms, and necessary data as needed (**OMB Control No. 2070-0060)**.

In the context of its registration activities for conventional pesticides, EPA operates a reduced risk program. This program offers an incentive through a shortened regulatory review schedule for proposed uses that might be beneficial to the public and the environment owing to their risk profile, compared to alternatives for pest control (**OMB Control No. 2070-0060**). The reduced risk program is described in an EPA policy notice known as the Reduced-Risk Initiative (PR Notice 97-3, “Guidelines for Expedited Review of Conventional Pesticides under Reduced-Risk Initiative and for Biological Pesticides”).

Summary Total Burden and Costs

Information Collection (IC)	Total Number of Respondents	Total number of Responses	Response per Respondents	Annual Burden (hours)	Total Cost ($)
Application for an EUP -- Chemical Pesticides	25	8	0.32	273	$22,479
Application for an EUP -- Plant-Incorporated Protectants (PIPs)	6	2	0.33	294	$24,352
Plant-Incorporated Protectants - Substantiation of Confidential Business Information Claims	24	24	1.00	516	$50,036
Plant-Incorporated Protectants -- Adverse Effects Reporting	1	1	1.00	2	$216
Application for emergency exemption for pesticides FIFRA §18	60	143	2.28	14,157	$1,018,355
Notice of pesticide registration by states to meet a Special Local Need under FIFRA §24(c)	60	223	3.72	11,596	$1,110,833
"Type A" application for registration of a new active ingredient or a new us e for a currently registered active ingredient	1,808	213	0.118	41,322	$3,624,358
"Type B" application for registration of a new or amended product that contains a currently registered active ingredient	1,808	7,209	4.00	101,926	$11,712,612
"Type C" application for registration of new conventional active ingredients or uses that may qualify as "reduced risk" chemicals and/or OP replacements	1,808	5	0.003	3,230	$292,122

Notice of supplemental distribution of a registered pesticide product	1,885	1,885	1	603	$63,692
Compliance requirement for child-resistant packaging	31	12	0.387	3,535	$298,652
IR-4 Tolerance petitions for pesticides on food/feed crops and new inert ingredients	26	26	1	45,214	$4,618,671
Tolerance petitions for pesticides on food/feed crops and new inert ingredients	139	139	1	239,914	$29,289,563
FIFRA §6(a)(2) Incident submissions	1,452	107,798	74.2	255,473	$21,076,096
FIFRA §6(a)(2) Study submissions	1,452	237	0.16	770	$61,332
FIFRA §6(a)(2) Training	1,452	17,424	12	44,867	$3,914,632
Data generation for new AIs and new products	1,808	789	0.44	1,412,356	$105,979,209
Total Respondent	**5,435**	**136,138**		**2,175,048**	**$183,157,210**
Total Agency				**454,345**	**$44,999,485**

SUPPORTING STATEMENT

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

The Environmental Protection Agency (EPA) regulates the manufacture and use of all pesticides (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and establishes maximum levels for pesticide residues in food under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition to the implementation of the mandates in FIFRA and FFDCA section 408, EPA implements the Pesticide Registration Improvement Extension Act (PRIA) and key parts of the Food Quality Protection Act (FQPA), and the Endangered Species Act. More information about the statutory mandates and EPA's pesticide registration program can be found on EPA's website at https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp. _

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.

The collection activities addressed in this ICR are necessary for EPA to fulfill its statutory mandates under FIFRA and FFDCA. The information collected supports regulatory decisions that ensure pesticide products in the marketplace do not cause any unreasonable risk to humans or the environment, taking into account their economic, social, and environmental costs and benefits of their use. They also ensure that pesticide residues on food pose no aggregate dietary risk and are consistent with the rigorous standards set under FFDCA §408. The process of registering a pesticide is a scientific, legal, and administrative procedure through which the Agency examines the

ingredients of the pesticide; the particular site or crop where it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. The Agency also evaluates and approves the language that appears on each pesticide label to ensure the directions for use and safety measures are appropriate to any potential risk. Following label directions is required by law and is necessary to ensure safe use.

This ICR covers several of the collection activities associated with the pesticide registration program that involve the submission of information to EPA through an electronic submission portal. Several examples, among others, of how EPA uses the collections to regulate registered and exempt pesticide products include the following:

- Make pre-application determinations of whether products need regulation under FIFRA.
- Ensure the efficacy of registered antimicrobial pesticide products targeting public health pests that are available in the marketplace.
- Protect children and adults from serious illness or injury resulting from accidental ingestion or contact with a pesticide product by ensuring proper product packaging.
- Protect the public's right to access information consistent with FIFRA and ensure that information qualifying as CBI is properly protected from unauthorized disclosures.
- Determine whether a request for an EUP is justified to allow for pesticide research.
- Ascertain the cause/effect relationship when a pesticide is registered and later found to have adverse effects and allow the Agency to review new data which may contain important health data.

The adverse effects information submitted under FIFRA §6(a)(2) after the registration process is considered by EPA in conjunction with other information to determine whether the terms and conditions of pesticide products containing a specific active ingredient should change during the registration review process or at other times. Registrants have indicated that the type of information collected under FIFRA §6(a)(2) is valuable to them as well. Registrants may actively seek unanticipated and/or adverse effects information as part of product stewardship, which improves customer relations, minimizes liability, or protects or expands market share.

The requirement of respondents to report adverse effects associated with exempt PIPs products within 30 days is necessary in order to obtain any information on unforeseen adverse effects from the exempted PIPs. These reporting requirements are similar to, but separate from, reporting requirements imposed on registrants under FIFRA §6(a)(2) for registered pesticides. The FIFRA §6(a)(2) reporting requirement applies to registrants and many PIPs are exempted from registration requirements.

These collections also allow the Agency to acquire the necessary data to make statutory determinations to grant or deny a FIFRA §18 request. Unexpected changes in climatic conditions, natural disasters, pandemics, development of pest resistance,

and/or importation of invasive pests are some of the unpredictable situations that could necessitate a FIFRA §18 emergency exemption request. In these situations, there is an urgent need for the use of a pesticide, a use that may be unregistered and for which there is insufficient time to obtain a FIFRA §3 registration.

Similarly, to address existing or imminent pest problems, states may register a new pesticide product for any use, or an additional use of a federally registered pesticide under FIFRA §24(c) if it's determined that currently registered pesticide products are not available or effective against the target pest/use site scenario.

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.

Collection submissions are received either through the Pesticide Submission Portal, email, or mail; printed to produce a paper copy, if applicable; pin-punched by date, screened, and entered into OPP's central data system, the Pesticide Registration Information System (PRISM), to track their progress through their respective registration process. The database continually tracks all registration actions from the registration-pending stage through to full registration approval and until a product is canceled. The database maintains information on both currently registered products and previously registered products, thereby acting as a pesticide registration historical file.

A folder, or "jacket," containing all relevant documents is then created for the submission package and sent to the respective Product Manager (PM) for appropriate action. ITRMD maintains official file jackets, in which copies of the submission, EPA's reviews, registration approvals, correspondence, label, the CSF and other related information are all retained.

4. Describe efforts to identify duplication.

These collections are unique and are administered by EPA pursuant to FIFRA and FFDCA §408 as amended by FQPA. The collections are specific to the needs of the Federal pesticide laws which negate the need for similar data by other federal agencies or EPA offices.

Respondents submit information unique to their pesticide registration. If the product is not unique, existing data may be referenced. On amended applications, the applicant can refer to any previously submitted information that they own, thereby satisfying data requirements without the burden of providing duplicate information or additional data development. EPA's registration program allows for collaboration through data citation and ensuring that original data generators/submitters are compensated when their data are cited in another application.

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

The Agency believes that the burden imposed on small entities by these collections has been reduced to the minimal level at which these programs can effectively function under the requirements specified in FIFRA and FFDCA and the regulations for the enforcement of FIFRA and FFDCA as amended by FQPA. Much of the information needed for the collections is generated simultaneously by the respondent as part of the normal data gathered during research and development to satisfy baseline pesticide registration requirements. In other cases, EPA has taken the following measures to reduce small entity burden when applicable:

- Respondents seeking a pesticide registration under FIFRA §3 can complete EPA Form 8570-27 ("Formulator's Exemption Statement") which reduces the data submission burden on an applicant for registration of a product that uses an EPA-registered pesticide product as the source of its active ingredient. This form exempts the applicant from furnishing the generic data that were already submitted by the company registering the source product.
- The Agency also maintains a pesticide database so that respondents can easily determine whether a particular study has been submitted, and by whom it was submitted, as well as the specific chemical and site(s). As a result, applicants encounter little difficulty in identifying available data needed to support an application for registration.

For EUPs, the Agency has identified the minimum amount of data required to conduct a risk assessment of the proposed research. These data requirements are flexible and may be adjusted as appropriate to the specific product under review. Prior to the initiation of any small-scale field testing involving genetically-altered or non-indigenous microbial pest control agents, the respondent must submit a notification to the Agency so that a determination can be made as to whether an EUP is required. Because the notification requirements have been designed from the outset to minimize the burden on respondents, there are no special measures taken for small businesses since the burden is considered to be at a minimal level.

Regardless of the size of the registrant, FIFRA §6(a)(2) regulations provide simplified reporting and extended reporting timeframes for most incident reports. Currently, there is no standard reporting format prescribed in the regulations, therefore, the submitters can use a format of their choosing to report incidents. While the Agency does not mandate a specific format for the required submission, EPA has worked with industry to develop guidance that both facilitates submissions and simplifies compliance.

At times, small entities seek a tolerance or an exemption from the requirement of a tolerance for pesticide residues resulting from registered uses. Tolerances are PRIA actions with fees established by Congress with the provision of fee waivers and fee exemptions in certain circumstances. EPA's website is a resource for the public on fees

and the process for seeking a waiver or exemption of fees: http://www2.epa.gov/pria-fees/pria-fee-waivers-small-businesses.

Small entities are not impacted by collections under FIFRA §§ 18 and 24(c) which apply directly to states, U.S. Territories, and federal agencies only; it does not apply to other entities. States are not "small entities" as defined by the Regulatory Flexibility Act. No PRIA fees or monetary collection is connected with either section 18 or 24c activities.

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.

Collection activities are initiated by respondents for the pesticide registration actions in this ICR on an "as needed" basis. Respondents' submission of data is voluntary, and for the pursuit of a pesticide registration or determination to sell and distribute their pesticide product under FIFRA and FFDCA as amended by FQPA. There are no set means by which EPA can reduce the frequency except to eliminate the collection altogether. If the information were not submitted, EPA would be unable to fulfill its statutory responsibilities to regulate pesticides and protect human health and the environment.

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

Apart from data records related to emergency exemptions which are only required to be maintained for two years after their production, all other recordkeeping activities in this ICR exceed OMB's guideline that agencies not require that records be retained for more than three years (5 CFR 1320.5(d)(2)(iv)). As authorized under FIFRA §8, 40 CFR 169.2(k), respondents are required 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 pesticide 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 FIFRA §8.

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 report.

Pursuant to 5 CFR 1320.8(d), in proposing this new ICR, EPA published a **Federal Register Notice** on August 13, 2020, providing a 60-day public comment period (85 FR 49366 (FRL-10010-43)). No comments were received throughout the duration of the 60-day comment period. Under 5 CFR 1320.8(d)(1), Federal Agencies are required to consult with respondents about the information collections before submitting approval requests to OMB. In accordance with this regulation, EPA staff contacted six relevant respondents – two State representatives, and four industry representatives (**Attachment C**). EPA asked for their assessment of the regulatory burden and cost estimates expressed by the Agency in this ICR, the clarity of instructions for respondents, the method and frequency of collection, etc. One respondent submitted comments to the Agency and a copy is displayed in **Attachment B**.

A respondent indicated a cost of maintaining operations of state-level (not federally-mandated) section 3 registrations and federally-mandated section 24(c) Special Local Need pesticide registrations within their developed data system, which is not a cost attributable to paperwork burden. After consideration of comments received, the Agency determined that the cost of maintenance of the respondent's own data system is largely for state-level registration processes, not federal information collection activity requirements (except for a tracking and storing of a relatively small amount of federal section 24(c)s). Additionally, data system maintenance costs do not fall under the burden of information collection activity requirements set upon the respondent and therefore the current burden and cost of the Consolidated ICR collection is accurate as written, with no further adjustments needed

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.

Trade secret or CBI is information submitted to the Agency that is considered proprietary and confidential to the submitter. CBI can include the manufacturing process, product formulation and/or supporting data. When CBI is submitted to the Agency, the information is protected from disclosure under FIFRA §10 and it is handled strictly in accordance with the provisions of the "FIFRA Confidential Business Information Security Manual."

Much of the information submitted pursuant to FIFRA §6(a)(2) constitutes FIFRA §10(d)(1) safety and efficacy information. On September 28, 1999, the Agency issued a class determination that safety and efficacy information submitted under FIFRA §6(a)(2) is not entitled to confidential treatment. The determination enables the Agency to respond more quickly and efficiently to requests for information submitted under FIFRA §6(a)(2).

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.

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

The NAICS codes associated with industries most likely affected by the paperwork requirements are described below. EPA recognizes that while this list may not be comprehensive, it represents a broad spectrum of large and small entities who are engaged in the preregistration of pesticides, pesticide registration process, pesticide post-registration activities and those seeking pesticide tolerances or exemptions.

Table 1: Applicable NAICS Codes

Code	Code Description
325320	Pesticides and Other Agricultural Chemical Manufacturing
541710	Research and Development in the Physical, Engineering, and Life Sciences
325414	Biological Products (except Diagnostic) Manufacturing
611310	Colleges, Universities, and Professional Schools
422910	Farm Supplies Wholesalers
422930	Flower, Nursery Stock, and Florists' Supplies Wholesalers
325300	Pesticide and Other Agricultural Chemical Manufacturing
999200	State Government
424690	Other Chemical and Allied Products Merchant Wholesalers
561710	Exterminating and Pest Control Service
541600	Management, Scientific, and Technical Consulting Services

Table 2: Annual IC Respondent Burden Summary Table

Information Collection (IC)	Total Number of Respondents	Total number of Responses	Response per Respondents	Annual Burden (hours)	Total Cost ($)
Application for an EUP -- Chemical Pesticides	25	8	0.32	273	$22,479
Application for an EUP -- Plant-Incorporated Protectants (PIPs)	6	2	0.33	294	$24,352

Plant-Incorporated Protectants - Substantiation of Confidential Business Information Claims	24	24	1.00	516	$50,036
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Application for emergency exemption for pesticides FIFRA §18	60	143	2.28	14,157	$1,018,355
Notice of pesticide registration by states to meet a Special Local Need under FIFRA §24(c)	60	223	3.72	11,596	$1,110,833
"Type A" application for registration of a new active ingredient or a new us e for a currently registered active ingredient	1,808	213	0.118	41,322	$3,624,358
"Type B" application for registration of a new or amended product that contains a currently registered active ingredient	1,808	7,209	4.00	101,926	$11,712,612
"Type C" application for registration of new conventional active ingredients or uses that may qualify as "reduced risk" chemicals and/or OP replacements	1,808	5	0.003	3,230	$292,122
Notice of supplemental distribution of a registered pesticide product	1,885	1,885	1	603	$63,692
Compliance requirement for child-resistant packaging	31	12	0.387	3,535	$298,652
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FIFRA §6(a)(2) Incident submissions	1,452	107,798	74.2	255,473	$21,076,096
FIFRA §6(a)(2) Study submissions	1,452	237	0.16	770	$61,332
FIFRA §6(a)(2) Training	1,452	17,424	12	44,867	$3,914,632
Data generation for new AIs and new products	1,808	789	0.44	1,412,356	$105,979,209
Total Respondent	**5,435**	**136,138**		**2,175,048**	**$183,157,210**

Note: This ICR is consolidating 8 currently approved ICRs with no change in the burden therefore the numbers above reflect no change from the previously approved ICR. All labor and wage calculations are provided in **Attachment F**.

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.

There are **$0** in capital or maintenance and operational costs.

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

Table 3: Annual Agency Burden Estimates for all ICs		
IC Category	**Hours**	**Costs**
IC 1: Application for an EUP -- Chemical Pesticides IC 2: Application for an EUP -- Plant-Incorporated Protectants (PIPs)		
Subtotal:	1,922	$190,727

IC 3: Plant-Incorporated Protectants - Substantiation of Confidential Business Information Claims IC 4: Plant-Incorporated Protectants -- Adverse Effects Reporting		
Subtotal:	254	$24,043
IC 5: "Type A" application for registration of a new active ingredient or a new us e for a currently registered active ingredient IC 6: "Type B" application for registration of a new or amended product that contains a currently registered active ingredient IC 7: "Type C" application for registration of new conventional active ingredients or uses that may qualify as "reduced risk" chemicals and/or OP replacements IC 8: Data generation for new AIs and new products		
Subtotal:	369,127	$36,957,035
IC 9: Notice of pesticide registration by states to meet a Special Local Need under FIFRA §24(c) IC 10: Application for emergency exemption for pesticides FIFRA §18		
Subtotal:	22,880	$2,115,104
IC 11: FIFRA §6(a)(2) Incident submissions IC 12: FIFRA §6(a)(2) Study submissions IC 13: FIFRA §6(a)(2) Training (Not Applicable)		
Subtotal:	24,825	$2,210,380
IC 14: Compliance requirement for child-resistant packaging		
Subtotal:	256	$21,875
IC 15: Notice of supplemental distribution of a registered pesticide product		
Subtotal:	1,260	$130,399
IC 16: Tolerance petitions for pesticides on food/feed crops and new inert ingredients IC 17: IR-4 Tolerance petitions for pesticides on food/feed crops and new inert ingredients		
Subtotal:	33,821	$3,349,922
Grand total:	**454,345**	**$44,999,485**

*Numbers may not sum due to rounding.

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

This information collection combines the burdens from eight previously approved ICRs. The total combined respondent burden hours from those previously approved ICRs by OMB were estimated at 2,175,048 hours, the same amount requested for this ICR.

The total combined cost burden from these eight previously approved ICRs was $170,250,338. The total cost burden requested for this ICR is $183,157,210 – a increase of $12,906,872. The difference between the current cost burden request and

the previously approved requests is due only to adjustments in EPA's estimates of the wage rates and material costs that were revised to reflect 2022 dollars for this ICR.

Table 4. Change in Burden and Cost Estimates

ICR	OMB Control No.	Previous Burden Hours	Previous Cost Estimates	Change in Burden Hours	Change in Cost Estimates
Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients	2070-0024	285,128	$27,475,224	-	$6,434,010
Notice of Supplemental Distribution of a Registered Pesticide Product,	2070-0044	603	$54,463	-	$9,229
Experimental Use Permits (EUPs) for Pesticides	2070-0040	567	$37,497	-	$9,334
Pesticide Program Public Sector Collections (FIFRA § 18/24(c)),	2070-0182	25,753	$1,829,103	-	$300,085
Application for New and Amended Pesticide Registration	2070-0060	1,557,834	$120,563,052	-	$1,405,249
Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting	2070-0142	518	$41,892	-	$8,360
Submission of Unreasonable Adverse Effects Information Under FIFRA 6(a)(2),	2070-0039	301,118	$19,999,815	-	$5,052,245
Compliance	2070-0052	3,535	$249,292	-	$49,360

Requirement for Child Resistant Packaging					
Total		2,175,056	$170,250,338	-	$13,267,872

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

The activities are conducted only as a submission is received for consideration. There is no set schedule for the submission of this information to EPA.

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 Information Collection Request.

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.

PAPERWORK REDUCTION ACTION NOTICE

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-NEW). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR Parts 152-180. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be **2** to **1,790** hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address."

LIST OF REFERENCES & ATTACHMENTS

References

These are specifically cited and are available in the docket and/or via provided links.

1. **Approved ICRs being consolidated**
    a. Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients (OMB Control No. 2070-0024; EPA ICR No. 0597.12)
    b. Submission of Unreasonable Adverse Effects Information Under FIFRA 6(a)(2) (OMB Control No. 2070-0039; EPA ICR No. 1204.13)

c. Experimental Use Permits (EUPs) for Pesticides (OMB Control No. 2070-0040; EPA ICR No. 0276.16)
d. Notice of Supplemental Distribution of a Registered Pesticide Product (OMB Control No. 2070-0044; EPA ICR No. 0278.12)
e. Compliance Requirement for Child Resistant Packaging (OMB Control No. 2070-0052; EPA ICR No. 0616.12)
f. Application for New and Amended Pesticide Registration (OMB Control No. 2070-0060; EPA ICR No. 0277.20)
g. Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting (OMB Control No. 2070-0142; EPA ICR No. 1693.09)
h. Pesticide Program Public Sector Collections (FIFRA 18/24(c)) (OMB Control No. 2070-0182; EPA ICR No. 2311.03)

2. **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**
3. **Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408**
4. ***U.S. Code of Federal Regulations* (CFR); title 40: Protection of Environment; parts 152-180**
5. **Pesticide Registration Notices**
   a. PRN 97-1
   b. PRN 97-3
   c. PRN 97-9
   d. PRN 1998-3
   e. PRN 1998-4
   f. PRN 2011-3
6. **Pesticide Registration Improvement Extension Act of 2018**

Attachments

Attachments to the supporting statement are available in the public docket established for this ICR under the docket identification number **EPA-HQ-OPP-2020-0273**. These attachments are available for online viewing at https://www.regulations.gov or otherwise accessed as described in the sections below.

Attachment	Title
A	**Forms for Pesticide Registration**
A-1	EPA Form 8570-1: Application for Pesticide, Registration/Amendment
A-2	EPA Form No. 8570-4*:* Confidential Statement of Formula
A-3	EPA Form No. 8570-4: Electronic Confidential Statement of Formula (eCSF)
A-4	EPA Form No. 8570-5: Notice of Supplemental Distribution of a Registered Pesticide Product
A-5	EPA Form No. 8570-17: Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only
A-6	EPA Form No. 8570-25: Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need

A-7	EPA Form No. 8570-27: Formulator's Exemption Statement
A-8	EPA Form No. 8570-34: Certification with Respect to Citation of Data
A-9	EPA Form No. 8570-35: Data Matrix
A-10	EPA Form No. 8570-36: Summary of the Physical/Chemical Properties
A-11	EPA Form No. 8570-37: Self-Certification Statement for the Physical/Chemical Properties
B	**Consultation Questionnaire**
C	**Stakeholders Consulted**
D	**Consolidated Respondent Burden Graphs**
E	**Consolidated Agency Burden Graphs**
F	**Labor Wage Rates (2022)**
G	Class Determination Regarding Confidentiality of FIFRA Section 6(a)(2) Information
H	Industry's Voluntary FIFRA Section 6(a)(2) Incident Reporting Forms & Guidance Documents
I	Requirements for Approval of Supplemental Distribution
J	Registration Service Fees Guidance on IR-4
K	Factors for IR-4 Public Interest Finding
L	Setting Tolerances for Pesticide Residues in Food
M	Pesticide Submission Portal (PSP): Screen Shots, Instructions and Related Guidance
N	Annual Reporting and Recordkeeping Burden Hours Per IC