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:	Labeling Requirements for Certain Minimum Risk Pesticides Under FIFRA Section 25(b)
EPA ICR No.:	2475.04
OMB Control No.:	2070-0187
Docket ID No.:	EPA-HQ-OPP-2021-0346

Abstract

This information collection request documents the Paperwork Reduction Act (PRA) burden for the labeling requirements for certain minimum risk pesticide products exempt from Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration under 40 CFR 152.25(f). These requirements were updated in the final rule entitled: Pesticides; Revisions to Minimum Risk Exemption (80 FR 80653; December 28, 2015).

Under 40 CFR 152.25(f), EPA has exempted from the requirement of FIFRA registration certain pesticide products if they are composed of specified ingredients and labeled accordingly. EPA created the exemption for minimum risk pesticides to eliminate the need for industry or business to expend significant resources to apply for and maintain regulated products that are deemed to be of minimum risk to human health and the environment. In addition, exempting such products freed Agency resources to focus on evaluating formulations whose toxicity was less well characterized, or was of higher toxicity.

The 2015 Final Rule reorganized the ingredients lists and added specific chemical identifiers to clarify to manufacturers, the public, and Federal, state, and tribal inspectors the specific chemical substances that are permitted in minimum risk pesticide products. EPA also modified the label requirements to require the use of specific label display names of ingredients and to require producer contact information on the label. The primary goal of this rulemaking was to clarify the conditions of exemption for minimum risk pesticides by clarifying the specific ingredients that are permitted in minimum risk pesticide products and to provide company contact information on the label. The previous version of this ICR covered the paperwork burdens associated with existing products updating their labels to comply with the new requirements during the 2015 Final Rule's compliance period. EPA anticipates that those burdens have been

realized and is now accounting for the potential burden for new products coming into the market.

Table 1: Summary Total Burden and Costs

	TOTAL		
	Responses	Hours	Costs
Annual Labeling Activities	87	478.5	$61,018.45
Total Response Burden	260	1,435.5	$183,055.35
Agency Burden Estimate		00.00	00.00

SUPPORTING STATEMENT

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

Authorizing legislation is contained in Sections 3 and 25 of FIFRA, as amended. Requirements for labels of minimum risk pesticide products are described in 40 CFR 152.25(f) (See attachments A, B, and C).

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.

Under FIFRA 25(b)(2), EPA may exempt from the requirements of FIFRA any pesticide that is “of a character unnecessary to be subject to [FIFRA].” Pursuant to this authority, in March 1996, EPA promulgated 40 CFR 152.25(g), which exempted from FIFRA any pesticide products consisting solely of specified ingredients that EPA judged to pose minimum risk to humans and the environment (61 FR 8876, March 6, 1996). This provision was later redesignated as 152.25(f) (66 FR 64759, December 14, 2001). Unlike producers of registered pesticides, producers of products exempted under 152.25(f) do not register their products with EPA, pay registration fees, or report production to EPA.

This exemption is in contrast to a typical FIFRA section 3 registration of a pesticide. A section 3 registration is a scientific, legal, and administrative process through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product.

The producer of the pesticide must provide data to EPA, using tests done according to either EPA guidelines or other methods determined acceptable by EPA on a case-by-case basis. The data from these tests are used to determine whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or groundwater from leaching, run-off and spray drift. Potential human risks include short-term toxicity and long-term effects such as cancer and reproductive system disorders. EPA also must approve the language that appears on each pesticide label. A pesticide product can only be used according to the directions on the label or labeling accompanying it at the time of sale, through its use and disposal. The labeling is the primary enforcement mechanism for Federal, state, and tribal authorities.

Since minimum risk pesticide products are not registered by EPA, the product information associated with the pesticide registration process under Section 3 of FIFRA are never submitted to EPA. However, approximately 39 states and the District of Columbia require products that are exempt from FIFRA requirements under 152.25(f) to obtain a state-registration. Generally, state registration of a federally-registered pesticide relies heavily on the previous Federal review of the product's toxicity, use patterns, and label. In contrast, given that minimum risk pesticides are exempt from Federal registration under FIFRA, the numerous states that do regulate these products use review criteria that vary from state to state. In some states, manufacturers of minimum risk products are only required to pay a registration fee; in others, there is a label review, which can include a review of the ingredients used in the product; and a few require Material Safety Data Sheets and data on product efficacy.

Thus, labeling requirements are the key component of the minimum risk exemption since this is the only information that enforcement authorities have to assess whether the product meets the exemption requirements. While EPA does not review these products, and therefore a Federal label review is not conducted, to maintain exemption status, an exempt product's label must meet certain criteria. The methods for displaying active and inert ingredient information are detailed in the exemption: labels must include the EPA required "label display name" and the percentage (by weight) of active ingredients and list all inert ingredients by their label display name. The label display name for a chemical is name that is codified in the minimum risk regulations at 40 CFR 152.25(f)(1) and (2). Other names for the chemical/substance may exist, but the ingredient statement should only use the EPA label display name. The label information documented in this renewal ICR accounts for the burden of labeling new products entering the market. These labels provide important regulatory information for the Federal, state, and tribal authorities that regulate or enforce minimum risk products.

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.

This question is not applicable to this ICR.

4. Describe efforts to identify duplication.

Duplication will not occur in this program, as the labeling requirements are unique to each minimum risk product. The exemption also does not require submission of information to EPA. The exemption standardizes some of the information on product labels, which reduces the burden on industry by creating labels for the same product registered for use in different states

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

EPA created the exemption for minimum risk pesticides to eliminate the need to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment. Since these minimum risk products do not have to be registered at the Federal level, significant cost savings are available for small business to benefit from this 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 frequency of the collection (3 years) cannot be reduced. This information collection activity is a one-time collection for new minimum risk products entering into the market. This collection provides an accounting of the burden for any new products entering into the market that must comply with the labeling requirements in the minimum risk exemption.

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

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

This question is not applicable to this ICR.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden. 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 of 5 CFR 1320.8(d) and 5 CFR 1320.8(d)(1), EPA published a notice in the Federal Register on September 7, 2021 (86 FR 50114; FRL-8720-01-OCSPP), announcing the planned renewal of this information collection activity, soliciting public comment on specific aspects of the ICR and providing a 60-day public comment period.

The EPA also consulted 7 stakeholders, specifically asking them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR.

EPA consulted with the following entities and received 1 response:

- W. Neudorff GmbH KG
- Bonide Products, Inc.
- Central Pet & Garden
- Rockwell Labs
- S.C. Johnson
- Spectrum Brands
- W.S. Badger Company

In response to the consultation, Rockwell Labs commented that the ICR generally reflected the calculations and actions of the company, except in cases wherein states

asked companies to make label changes before registering or re-registering these products in their states (many states require state registration of minimum risk products even though they are exempt at the federal level). This is not a regulatory burden at the federal level and is therefore not relevant to this ICR.

Rockwell Labs also commented that the requirement that products exempt under FIFRA 25(b) contain no “misleading” claims is burdensome and often subjectively enforced by states. This requirement, which appears in the regulations at 40 CFR 156.10(a)(5), and is referred to in the minimum risk regulations at 40 CFR 152.25(f)(3)(iv), is also applied to pesticide product registered under FIFRA Section 3. While EPA strives to be consistent in its interpretation of the “misleading” claims regulations, the world of misleading claims is constantly being updated based upon the evolving understanding of how consumers view pesticide products, and their claims, in the marketplace. Still, EPA can help provide consistency across states by using existing webpage, such as the Pesticide Labeling Q&A page, to post guidance on problematic claims. In almost all scenarios, a misleading claim on a Section 3 product would also be considered misleading on a minimum risk product exempt from registration under FIFRA 25(b).

See the full consultation response in Attachment D.

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

This question is not applicable to this ICR.

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

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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.

- ***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'.***

Minimum risk pesticide products are exempt from federal registration requirements, and manufacturers of these products do not submit any data, forms, or labels to EPA. They are also not required to conduct annual reporting or recordkeeping. The requirements for minimum risk pesticide products are limited to what active and inert ingredients they may contain, and specific information that must be on product labels. However, to help companies comply with the labeling requirements, EPA provides and periodically updates web guidance applicable to minimum risk products.

There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB. This is based on the assumption that the estimated number of new products entering the market is the same as that used in the previous ICR, that is, 87 per year, with estimated burden hours of 478.5 hours per year. However, in this renewal, burden costs are updated with the 2019 wage rates.

The total burden hours per response (5.5 hours) have not changed for this ICR renewal and the total response burden estimate has remained the same at 1,435.5 hours. With updated wage rates, the total labor costs increased from $156,606.53 to $183,055.35.

Over the next three years, EPA estimates that there will be approximately 49 companies selling approximately 170 new products that meet the requirements of the minimum risk pesticide exemption in the U.S. These estimates are derived primarily from estimates provided by three states (Indiana, Maine, and New Mexico) who register minimum risk pesticides in their states. Although minimum risk products are exempt from registration by EPA, most states require some form of registration for these pesticide products. Additionally, several of these states provide their pesticide registration lists online (including minimum risk pesticides) and are available to the public.

However, many products have more than one size or type of package. Each is referred to as a stock keeping unit (SKU). Each SKU would have to be labeled to comply with the new requirements established in 2015. EPA has estimated that there are 1.53 SKUs per product, for a total number of 260 products that would have to be labeled according the exemption's requirements. Therefore, approximately 87 new products are expected to enter the market per year over the next 3 years.

The total cost for the labeling activities over 3 years is estimated to cost $156,607.00, for a one-time burden. The annual burden is estimated to cost $52,202.00 per year. Cost rates have been indexed to May 2019 dollars.

Agency economists revised the estimated wages, benefits, and overhead for all labor categories for affected industries, state government, and EPA employees based on publicly available data from the US Bureau of Labor Statistics. The formulas used to estimate the labor rates and formulas used to derive the fully loaded rates and overhead costs for this ICR are listed in Attachment E.

Table 2: Wage Rates

Methodology	The methodology uses data on each sector and labor type for an *Unloaded wage rate* (hourly wage rate) and calculates the *Loaded wage rate* (unloaded wage rate + benefits), and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This ICR uses 2019 wage data
Unloaded Wage Rate	Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm.
Sectors	The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table (see Attachment E). Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).
Loaded Wage Rate	Unless stated otherwise, all benefits represent 46.4% of unloaded wage rates, based on benefits for all civilian non-farm workers, from http://www.bls.gov/news.release/ecec.t01.htm. However, if other sectors are listed for which 46.4% is not applicable, the applicable percentage will be stated.
Fully Loaded Wage Rate	We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs.

The following table presents the estimated burden and cost estimates per label to comply with the information collection activities associated with the rulemaking:

Table 3: Estimated Burden/Cost per Label (Minimum Risk Exemption - New Product Labeling; No Registration)

Collection Activities	**Burden Hours**			**Total**	
	Managerial $/hr. $145.34	Technical $/hr. $76.35	Clerical $/hr. $49.61	Hours	Costs $
Read Instructions	3.5	0.0	0.0	3.5	508.67
Plan activities	0.5	0.0	0.0	0.5	72.67
Gather/create information	0.0	1.5	0.0	1.5	114.52
TOTAL	4.0	1.5	0.0	5.5	695.86

Table 4: Annual Respondent Burden & Costs

	Burden Hours	**$/hr.**	**Responses/year**	**Total**	
	5.5		87	Hours/year 478.5	Cost $
Managerial	4.0	$145.34	87		$50,576.67
Technical	1.5	$76.35	87		$9,963.28
Clerical	0	49.61	87		$0
TOTAL				478.5	$61,018.45

Table 5: 3-Year Respondent Burden & Costs

	Burden Hours	**$/hr.**	**Responses/year**	**Years**	**Total**	
	5.5		87	3	Hours/year 1,435.5	Cost $
Managerial	4.0	$145.34	87	3		$151,730.00
Technical	1.5	$76.35	87	3		$29,889.85
Clerical	0	49.61	87	3		$0
TOTAL					1,435.5	$183,055.35

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 operational or maintenance costs associated with this collection.

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

There is no Agency burden related to registration of minimum risk pesticide products since they are exempt from Federal registration.

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

There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB. This is based on the assumption that the estimated number of new products entering the market is the same as that used in the previous ICR, that is, 87 per year, with estimated burden hours of 478.5 hours per year. However, in this renewal, burden costs are updated with the 2019 wage rates.

The total burden hours per response (5.5 hours) have not changed for this ICR renewal and the total response burden estimate has remained the same at 1,435.5 hours. With updated wage rates, the total labor costs increased from $156,606.53 to $183,055.35.

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

This question not applicable to this ICR.

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 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.

SUPPLEMENTAL INFORMATION

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0187). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 152.25(f). 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 5.5 hours per response.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPP-2021-0346, which is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via http://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting ‘‘Currently under 30-day Review—Open for Public Comments’’ or by using the search function.

All comments received by EPA will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats,

information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

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LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through http://www.regulations.gov using Docket ID Number: EPA-HQ-OPP-2021-0346.

Attachment	Title
A	Title 7 Agriculture, §136a. Registration of Pesticides
B	Title 7: Agriculture, §136v Authority of States
C	Title 40: Protection of Environment, PART 152 Pesticide Registration and Classification Procedures, Subpart B—Exemptions, § 152.25:
D	Consultations Summary for the Renewal ICR, entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b) Information Collection Request" – Rockwell Labs
E	Work Sheet Used to Calculate Pesticide Industry Labor Costs