

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

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b)

OMB No. 2070-0187 EPA No. 2475.01

1(b) Short Characterization/Abstract

This information collection request documents a one-time Paperwork Reduction Act (PRA) burden for the final rule related changes to 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 changes are contained in the final rule entitled: Pesticides; Revisions to Minimum Risk Exemption.

Under current regulations in 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 to expend significant resources to regulate products that were 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 existing regulatory structure, however, led to confusion as to which ingredients are exempt under 152.25(f), and how they should be labeled on products.

The final rule reorganizes the ingredients lists and adds 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 is also modifying the label requirements to require the use of specific common chemical names of ingredients and to require producer contact information on the label. The primary goal of this rulemaking is 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.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Authorizing legislation is contained in section 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(b) Practical Utility/Users of the Data

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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, runoff 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 37 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 or not the product meets the exemption requirements. While EPA does not review these products, and therefore a Federal label review is not conducted, to maintain exempt 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 percentage (by weight) of active ingredients and list all inert ingredients. The label information documented in this rule-related ICR accounts for the burden for a one time label update which provides important regulatory information for the Federal, state, and tribal authorities that regulate minimum risk products.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-duplication

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Duplication will not occur in this program, as the required label changes are unique to each applicant since each applicant must submit information to the public unique to the particular product. The rule also will not require submission of information to EPA. The rule standardizes some of the information on product labels, which will reduce the burden on industry by creating labels for the same product registered for use in different states.

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

The Notice of Proposed Rulemaking, published in the Federal Register on December 31, 2012 (77 FR 76979), served as the public notice for this ICR pursuant to 5 CFR 1320.8(d). The Agency did not receive any comments on this ICR during the comment period.

3(c) Consultations

In addition to the public notice and comment period, OMB regulations, 5 CFR 1320.8(d)(1), require agencies to consult with potential ICR respondents and data users about specific aspects of an ICR before the Agency submits the ICR to OMB for review and approval. In accordance with this regulation, EPA solicited feedback from potential ICR respondents and data users with respect to this rule related ICR as part of a Small Business Advocacy Review (SBAR) Panel held for a proposed rulemaking titled “Insect Repellents: Reconsideration of Exemption (Docket ID EPA-HQ-OPP-2010-0227)” under the Small Business Regulatory Enforcement Fairness Act (SBREFA). As part of this SBAR Panel, EPA solicited feedback on a number of issues (Attachment D and E), including:

- An estimate of the number of small entities to which the proposed rules would apply,
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rules, including an estimate of the classes of small entities which would be subject to the requirements and the type of professional skills necessary for preparation of the report or record,
- Identification, to the extent practical, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rules,
- An estimate of costs for different timeframes for implementing label changes.

Feedback from the participants in the SBAR Panel indicated that minimum of 2 years would be needed to re-label their products to avoid significant costs and burden on minimum risk pesticide producers (Attachment F). Since EPA is finalizing a 3-year implementation period, the costs to industry will be less than the projected costs provided by the participants.

3(d) Effects of Less Frequent Collection

Not applicable. This information collection activity is a one-time collection for those existing minimum risk products currently in the market that must change their labels to comply with the new rule.

3(e) General Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.6. This is a one-time collection with no third party reporting or record keeping requirements.

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3(f) Confidentiality

EPA is not requesting any information be submitted to the Agency.

3(g) Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in conjunction with this collection activity. In addition, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents - NAICS Codes

Respondents affected by the collection activities under this ICR are individuals or entities engaged in activities related to the registration of pesticide products. The North American Industrial Classification System (NAICS) assigned to the parties responding to this information are as follows:

- Manufacturers of these products, which includes pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (311119), cosmetics (325620), and soap and detergents (325611).
- Manufacturers who may also be distributors of these products, which includes farm supplies merchant wholesalers (424910), drug and druggists' merchant wholesalers (424210), and motor vehicle supplies and new parts merchant wholesalers (423120).
- Retailers of minimum risk pesticide products (some of which may also be manufacturers), which includes nursery, garden center, and farm supply stores (444220); outdoor power equipment stores (444210); and supermarkets (445110).
- Users of minimum risk pesticides, including the public in general, as well as exterminating and pest control services (561710), landscaping services (561730), sports and recreation institutions (611620), and child day care services (624410). Many of these companies also manufacture minimum risk pesticide products.

4(b) Information Requested

(i) Data items for minimum risk pesticide products (not registered)

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. For instance, each minimum risk pesticide product label must identify the name and percentage (by weight) for each active ingredient and the name of each inert ingredient. The exemption for minimum risk pesticide products also includes restrictions on claims that may be made: The products must not bear claims to control or mitigate microorganisms that pose a threat to human health, and they must not include any false and misleading labeling statements.

EPA’s final rule is modifying the label requirements for the minimum risk exemption to:

- 1) Require that a designated label display name be used for active and inert ingredients listed on minimum risk product labels. This will require a one-time labeling change for manufacturers to modify how they refer to the chemicals contained in their products, which will result in a one-time burden increase for the manufacturers of these products.
- 2) Require that manufacturer contact information (name of company, address, and phone number) be included on the minimum risk pesticide product label. Though most products already include this information on their labels, it is possible that some companies will need to change their labels to include this information. This could be done simultaneously with any changes to the way product ingredients are listed on the label, and is included in that burden assessment.

The relabeling required by the changes to the minimum risk exemption will result in a one-time burden increase for manufacturers of currently-exempt products. Though it may result in an overestimate of the overall burden, EPA is assuming that all manufacturers will need to modify their labels to include the label display name of ingredients and provide company contact information.

(ii) *Respondent Activities for Minimum Risk Pesticide Products*

Respondent Paperwork Activity	Description
1. Read instructions	Read germane FIFRA legislation, 40 CFR regulations, and applicable guidance and correspondence.
2. Plan activities	Decide whether pesticide product is a minimum risk product.
3. Create information	Determine how to modify labels to list ingredients using a label display name, and to include company information if not already present on the label.

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

5(a) Agency Activities

Minimum risk pesticide products do not typically require any activity on the part of the Agency. However, to help companies transition to the new label requirements, EPA will update the web guidance applicable to minimum risk products and consult with stakeholders to assist with the transition.

5(b) Collection Methodology and Management

None.

5(c) Small Entity Flexibility

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

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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.

5(d) Collection Schedule

This is a one-time collection. Respondents have 3 years to finalize the relabeling activities once the rule becomes effective.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

No new reporting or recordkeeping burdens are associated with this proposed rule related ICR. The total burden for all respondents completing the rule related minimum risk relabeling activities is estimated to be 6,369 hours, based on a one-time burden increase for roughly 1,158 responses at 5.5 hours per response. All relabeling activities associated with this rulemaking will be completed within the 3 years of this ICR.

6(b) Estimating Respondent Costs

There are currently an estimated 216 companies selling approximately 757 minimum risk pesticide products in the U.S. These estimates are derived primarily from products registered in various states; although minimum risk products are exempt from registration by EPA, most states require registration of these pesticide products. Many of these states provide their pesticide registration lists (including for minimum risk pesticides) online, and available to the public. In addition, EPA obtained retail store scanner data (Nielsen, 2008) for personal insect repellent products and conducted on-line searches for products that may not be available in stores.

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 relabeled to comply with the new requirements. EPA has estimated that there are 1.53 SKUs per product, for a total number of 1,158 products that would have to be relabeled. Therefore, approximately 386 products are expected to be relabeled per year over 3 years.

The total cost for the rule-related relabeling activities over 3 years is estimated to cost \$701,914, for a one-time burden increase. Given three years to comply with the rule-related relabeling activities, the annual burden is estimated to cost \$233,971 per year.

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 G**.

Methodology	The methodology uses data on each sector and labor type for an <i>Unloaded wage rate</i> (hourly wage rate), and calculates the <i>Loaded wage rate</i> (unloaded wage rate + benefits), and the <i>Fully loaded wage rate</i> (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs.
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	This ICR uses 2014 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 G). 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 46.3% 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 46.3% 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 change to comply with the information collection activities associated with the rulemaking:

Table 1: Est. Burden/Cost per Label Change (Minimum Risk – No Registration)

Collection Activities	Burden Hours			Total	
	Mgmt. \$/hr	Tech. \$/hr	Cler. \$/hr	Hours	Costs \$
	\$124.02	\$73.37	\$41.70		
Read Instructions	3.5	0.0	0.0	3.5	434.08
Plan activities	0.5	0.0	0.0	0.5	62.01
Gather/create information	0.0	1.5	0.0	1.5	110.05
TOTAL	4.0	1.5	0.0	5.5	606.14

Annual Burden & Costs: 5.5 hours x 386 responses/year = 2,123 hours/year
 (a) Management: 4.0 hours x \$124.02 x 386 Responses = \$ 191,490.91
 (b) Technical: 1.5 hours x \$73.37 x 386 Responses = \$ 42,480.59
 (c) Clerical: 0 hours x \$41.70 x 386 Responses = \$ 0
 Total = \$ 233,971.49

Total Burden & Costs: 5.5 hours x 1,158 responses = 6,369 hours
 (a) Management: 4.0 hours x \$124.02 x 1,158 Responses = \$ 574,472.73
 (b) Technical: 1.5 hours x \$73.37 x 1,158 Responses = \$ 127,441.76

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(c) Clerical: 0 hours x \$41.70 x 1,158 Responses = \$ 0
Total = \$ 701,914.48

6(c) Estimating Agency Burden and Cost

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

6(d) Bottom Line Burden Hours and Cost

	TOTAL		
	Responses	Hours	Costs
Annual Relabeling Activities	386	2,123	\$233,971.49
Total Response Burden	1,158	6,369	\$701,914.48
Agency Burden Estimate		00.00	00.00

6(e) Reasons for Changes in Burden

No change in burden. This is a new rule-related ICR. A new total burden of 6,369 hours as the result of a program change: changes to the exemption for minimum risk pesticide products that will require manufacturers of these products to modify their labels to list the ingredients using common chemical names and to provide company contact information on the label. This will result in a one-time burden increase for manufacturers of these products.

6(f) Burden Statement

The respondent burden for this rule-related collection is estimated to be 5.5 hours per product. According to the Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. For this collection, the 5.5 hours includes the time needed to:

- Review instructions.
- Develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information.
- Adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources.
- Complete and review the collection of information.
- Transmit or otherwise disclose the information.

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 OMB control number for this information collection will be designated by OMB upon approval. The OMB control numbers for EPA’s regulations in Title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for the proposed and final rule-related ICR under Docket ID No. EPA-HQ-OPP-2010-0305, which is available for online viewing at

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<http://www.regulations.gov>. The docket telephone number is (703) 305-5805. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2010-0305, to (1) EPA online using <http://www.regulations.gov> (our preferred method), or by mail to: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this rule related Information Collection Request (ICR) under the docket identification number EPA-HQ-OPP-2010-0305. These attachments are available for online viewing at <http://www.regulations.gov> or otherwise accessed as described in the sections below.

Attachment A: **7 U.S.C. 136a – Section 3 of FIFRA.** This information is available online at <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title7/pdf/USCODE-2010-title7-chap6-subchapII-sec136a-1.pdf>

Attachment B: **7 U.S.C. 136w – Section 25 of FIFRA.** This information is available online at <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title7/pdf/USCODE-2010-title7-chap6-subchapII-sec136w.pdf>

Attachment C: **40 CFR 152 – Pesticide Registration and Classification Procedures.** Also available online at the National Archives and Records Administration's Electronic Website <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=88d9c3c9f74b07b1127c67fbfa4acde0&rgn=div5&view=text&node=40:23.0.1.1.3&idno=40>

Attachment D: Insect Repellent SER Cover Letter (11/17/2009). Docket ID No. EPA-HQ-OPP-2010-0227. Document ID No. EPA-HQ-OPP-2010-0227-0002.

Attachment E: Questions for Small Entity Representatives (11/17/2009). Docket ID No. EPA-HQ-OPP-2010-0227. Document ID No. EPA-HQ-OPP-2010-0227-0003.

Attachment F: Small Entity Representatives (SER) Comments from 2009 SBREFA Panel, for Minimum Risk Insect Repellents Proposed Rule. Docket ID No. EPA-HQ-OPP-2010-0305. Docket ID No. EPA-HQ-OPP-2010-0305-0016.

Attachment G: **Work Sheets used to Calculate Pesticide Registrant Industry Labor Costs.** This information follows the supporting statement in its electronic file.

Attachment G

PESTICIDE REGISTRANT INDUSTRY LABOR COSTS

Labor Category	Formula	Managerial	Technical	Clerical
Unloaded Hourly Rate ¹	= W	\$56.51	\$33.43	\$19.00
Benefits Percentage ²	Lb = B/W	46.3%	46.3%	46.3%
Benefits per hour	B = W*Lb	\$26.17	\$15.48	\$8.80
Loaded Hourly Rate	Wb = W + B = W(1+Lb)	\$82.68	\$48.91	\$27.80
Overhead Percentage ³	Lo = OH/Wb	50%	50%	50%
Overhead per hour	OH = Wb*Lo	\$41.34	\$24.46	\$13.90
Fully Loaded Hourly Rate	Wf = Wb + OH = W + B + OH	\$124.02	\$73.37	\$41.70

1. Data Source: http://www.bls.gov/oes/current/naics4_325300.htm
 Management: 11-0000, Management Occupations
 Technical: 19-0000, Life, Physical, and Social Science Occupations
 Clerical: 43-0000, Office and Administrative Support Occupations
 May 2014 data

2. Fringe benefits/wage per hour.

1. Data Source: http://www.bls.gov/oes/current/naics4_325300.htm
 Management: 11-0000, Management Occupations
 Technical: 19-0000, Life, Physical, and Social Science Occupations
 Clerical: 43-0000, Office and Administrative Support Occupations
 May 2006 data

2. Fringe benefits/wage per hour.

3. U. S. Environmental Protection Agency, *EPA Air Pollution Control Cost Manual, Sixth Edition*, EPA-452-02-001, January 2002, pg. 2-34. The loading for indirect costs is within the range of 20-70% of the load labor rate (wage + benefits) suggested in EPA guidance.