

**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-NEW EPA No. 2475.01

1(b) Short Characterization/Abstract

This information collection request documents a one-time Paperwork Reduction Act (PRA) burden for proposed rule related changes to labeling requirements for certain minimum risk pesticide products exempt from EPA registration under 40 CFR 152.25(f). These proposed changes are contained in the proposed rule entitled: Pesticides; Revisions to Minimum Risk Exemption.

Under current regulations in 40 CFR 152.25(f) EPA has exempted from the requirement of 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, leads to confusion as to which ingredients are exempt under 152.25(f), and how they should be labeled on products.

The proposed rule reorganizes the ingredients lists and adds specific chemical identifiers to make it clearer to manufacturers; the public; and Federal, state, and tribal inspectors the specific ingredients that are permitted in minimum risk pesticide products. EPA also modifies 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 proposal 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 standardize the labeling requirements.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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

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, Mar. 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. These tests must 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 normally 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 Federal regulation 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 regulation 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 access whether or not the product meets the exemption requirement. 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

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 would not require submission of information to EPA. The rule standardizes 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 will serve as the public notice for this ICR.

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 will solicit consultation feedback from potential ICR respondents and data users with respect to this rule related ICR.

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.

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 regulation, 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 micro-organisms that pose a threat to human health, and they must not include any false and misleading labeling statements.

EPA's proposed rule seeks to modify the label requirements for the minimum risk exemption to:

- 1) Require that common chemical names be used for active and inert ingredients listed on minimum risk product labels. This would require a one-time labeling change for manufacturers to modify how they refer to the chemicals contained in their products, which would 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 would be required 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 effort in the proposed rule would 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 would need to modify their labels to include the

common chemical name of ingredients and provide company contact information as would be required by the proposed changes to the minimum risk exemption.

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

Respondent Paperwork Activity	Description
1. Read instructions	Read germane FIFRA legislation, 40 CFR regulations, applicable guidance and correspondence, and germane labeling PR and FR notices;
2. Plan activities	Decide whether pesticide product is a minimum risk product
3. Create information	Determine how to modify labels to list ingredients as required under proposed changes, 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 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 2 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 annual 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 1158 responses at 5.5 hours per response.

6(b) Estimating Respondent Costs

There are currently an estimated 757 minimum risk pesticide products for sale in the U.S. This estimate is 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 1158 products that would have to be relabeled.

The annual cost for the rule related relabeling activities are estimated to cost \$596,434 per year, for a one-time burden increase.

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 renewal are listed in **Attachment D**.

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. This renewal uses 2006 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 43% 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 43% 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 annual burden and cost estimates:

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

Collection Activities	Burden Hours			Total	
	Mgmt. \$103.62/hr	Tech. \$67.05/hr	Cler. \$33.85/hr	Hours	Costs \$
Read Instructions	3.5	0.0	0.0	3.5	362.67
Plan activities	0.5	0.0	0.0	0.5	51.81
Gather/create information	0.0	1.5	0.0	1.5	100.58
TOTAL	4.0	1.5	0.0	5.5	515.06

Annual Costs: 5.5 hours x 1158 responses per year = 6,369 hours

(a) Management:	4.0 hours x \$103.62 x 1158 Responses =	\$ 479,967.84
(b) Technical:	1.5 hours x \$67.05 x 1158 Responses =	\$ 116,465.85
(c) Clerical:	0 hours x \$33.85 x 1158 Responses =	<u>0</u>
	Total =	\$ 596,433.69

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

	ANNUAL TOTAL		
	Responses	Hours	Costs
Annual Relabeling Activities	1158	6,369	\$596,433.69
Total Annual Response Burden	1158	6,369	\$596,433.69
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 burden of 6,369 hours as the result of a program change: proposed changes to the exemption for minimum risk pesticide products that, if they become final as proposed, would require manufacturers of these products to modify their labels to refer to ingredients using common chemical names and to provide company contact information on the label. This would result in a one-time burden increase for manufacturers of these products. Though the Agency proposes that manufacturers have a period of two years for changing their labels and selling products with older labels, this ICR assumes that all known manufacturers of these products will incur the burden of understanding and beginning a label change in the same year. EPA feels that conducting the calculations in this way may be a likely an overestimate of the burden on these manufacturers, but provides the most comprehensive assessment of this re-labeling burden.

6(f) Burden Statement

The estimated annual respondent burden for this rule-related collection is estimated to be 5.5 hours. 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 rule and this rule related ICR under Docket ID No. EPA-HQ-OPP-2010-0305, which is available for online viewing at <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: Work Sheets used to Calculate Pesticide Registrant Industry Labor Costs
This information follows in this document.

Attachment D

PESTICIDE REGISTRANT INDUSTRY LABOR COSTS

Labor Category	Formula	Managerial	Technical	Clerical
Unloaded Hourly Rate ¹	= W	\$48.31	\$31.26	\$15.78
Benefits Percentage ²	Lb = B/W	43%	43%	43%
Benefits per hour	B = W*Lb	\$20.77	\$13.44	\$6.79
Loaded Hourly Rate	Wb = W + B = W(1+Lb)	\$69.08	\$44.70	\$22.57
Overhead Percentage ³	Lo = OH/Wb	50%	50%	50%
Overhead per hour	OH = Wb*Lo	\$34.54	\$22.35	\$11.28
Fully Loaded Hourly Rate	Wf = Wb + OH = W + B + OH	\$103.62	\$67.05	\$33.85

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.