October 4, 2018

SUPPORTING STATEMENT
FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

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

EPA ICR No. **2475.03**

OMB Control No. **2070-0187**

Docket ID No. EPA-HQ-OPP-2018-0139

1(b) Short Characterization/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.

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

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 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 label display name and the percentage (by weight) of active ingredients and list all inert ingredients by their 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. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-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.

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

Pursuant to 5 CFR 1320.8(d), EPA published a Notice in the Federal Register (83 FR 24797; May 30, 2018) announcing the proposal to renew this information collection activity and providing a 60-day public comment period through http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2018-0139. EPA receive one comment during the public comment period; however, the comment submitted to the docket did not pertain to this ICR.

3(c) Consultations

In addition to using the Federal Register to seek public comment, the Agency sent consultation requests, as required under 5 CFR 1320.8(d)(1), to three representatives from producers of minimum risk pesticide products that would be subjected to the labeling requirements under 40 CFR 152.25(f). EPA staff sought feedback on the burden estimates in the ICR, the clarity of instructions provided, and other questions pertaining to the requirements of the minimum risk exemption.

One representative responded to the Agency's request, providing feedback on information that they thought would be helpful to their company's compliance with the exemption. EPA has been and continues to work on these particular issues (i.e., clarification of commonly consumed food commodities as inert ingredients and consideration of example

product labels), and periodically updates its website (https://www.epa.gov/minimum-risk-pesticides) to improve the clarity of the information about the requirements of the minimum risk pesticide exemption.

In addition to general feedback about clarification and guidance, the representative also suggested that EPA take into account the costs for a company who produces the labels for the minimum risk pesticide manufacturer, as these companies impose a charge for labeling changes. In their example, the representative stated that if the ingredient statement is changed, there will be a charge of up to $5,000 dollar in printing plate changes if the product is packaged in a polyethylene bag, and that these figures can vary depending on the type of label and the label changes. The representative suggested that these change charges can cost significantly more than the labor hours.

While EPA understands that there are costs associated with printing plate changes for labeling revisions, EPA does not believe that these costs are directly related to the paperwork activities associated with this ICR. Rather, EPA believes that the production of labels and its associated costs falls under the definition of usual and customary activities (5 CFR 1320.3(b)(2)) since minimum risk producers would not sell the product without a label or branding material. As such, the costs associated with printing labeling should be excluded from the burden and costs estimates presented in this ICR.

A list of the companies contacted, the questions sent to the representatives, and the responses to those questions are available in the public docket (Attachment D).

3(d) Effects of Less Frequent Collection

The frequency of the collection 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.-

3(e) General Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.5(d)(2). This is a one-time collection with no record keeping requirements. This collection does contain third-party disclosure in the form a product label that must be in compliance with the requirements under 40 CFR 152.25(f).

3(f) Confidentiality

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

3(g) Sensitive Questions

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 label display name and percentage (by weight) for each active ingredient and the label display 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 2015 Final Rule modified 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.

2) Require that manufacturer contact information (name of company, address, and phone number) be included on the minimum risk pesticide product label.

The labeling required to comply with the minimum risk exemption will result in a one-time burden for manufacturers with products entering the minimum risk pesticide market. Products in the market prior to the compliance date for the 2015 Final Rule (February 26, 2019) are assumed to have relabeled their products in order to meet the new labeling requirements and are therefore no longer considered in the burden estimates. Any product not complying with the new requirements by February 26, 2019, will be considered an unregistered pesticide product, and may be subject to enforcement actions or may be required to register their product with EPA.

Though this ICR is now only accounting for new minimum risk products, the EPA believes that the respondent activities and paperwork burdens remain the same.

(ii) Respondent Activities for Minimum Risk Pesticide Products

Respondent Paperwork Activity	Description
1. Read instructions	Read relevant 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 label ingredients using a label display name; determine how to include company contact information on the label; Ensure that the labels do not bear claims to control or mitigate microorganisms that pose a threat to human health, and that they do not include any false and misleading labeling statements.

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

5(a) Agency Activities

Minimum risk pesticide products do not typically require any action on the part of the Agency. However, to help companies comply with the labeling requirements, EPA provides and periodically updates web guidance applicable to minimum risk products.

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. Products coming into the minimum risk market must comply with the requirements in order to be exempt from EPA registration and FIFRA requirements.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

No new reporting or recordkeeping burdens are associated with this renewal ICR. The total burden for all respondents completing the minimum risk labeling activities for new products entering the market is estimated to be 1,435.5 hours, based on a one-time response for roughly 260 responses at 5.5 hours per response. Burdens for products existing prior to February 26, 2019, were accounted for in the previous version of this ICR and are assumed to be in compliance with the updated requirements.

6(b) Estimating Respondent Costs

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, for a one-time burden. The annual burden is estimated to cost $52,202 per year. Cost rates have been

indexed to September 2016 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.**

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 2016 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 1: Est. Burden/Cost per Label (Minimum Risk Exemption - New Product Labeling; No Registration)

Collection Activities	Burden Hours			Total	
	Mgmt. $/hr	Tech. $/hr	Cler. $/hr	Hours	Costs $
	$124.81	$67.19	$43.74		
Read Instructions	3.5	0.0	0.0	3.5	436.84
Plan activities	0.5	0.0	0.0	0.5	62.41
Gather/create information	0.0	1.5	0.0	1.5	100.79
TOTAL	4.0	1.5	0.0	5.5	600.03

Annual Burden & Costs: 5.5 hours x 87 responses/year = 478.5 hours/year
(a) Management: 4.0 hours x $124.81 x 87 Responses = $ 43,433.88
(b) Technical: 1.5 hours x $67.19 x 87 Responses = $ 8,768.30
(c) Clerical: 0 hours x $43.74 x 87 Responses = $ 0
Total = $ 52,202.18

Total Burden & Costs: 5.5 hours x (87 responses/year x 3 years) = 1,435.5 hours
(a) Management: 4.0 hours x $124.81 x (87 responses/year x 3 years) = $ 130,301.64
(b) Technical: 1.5 hours x $67.19 x (87 responses/year x 3 years) = $ 26,304.89
(c) Clerical: 0 hours x $43.74 x (87 responses/year x 3 years) = $ 0
Total = $ 156,606.53

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 Labeling Activities	87	478.5	$52,202.18
Total Response Burden	260	1,435.5	$156,606.53
Agency Burden Estimate		00.00	00.00

6(e) Reasons for Changes in Burden

There is a decrease of 4,933.5 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease reflects EPA's updating of burden estimates for this collection based upon the assumption that products existing prior to the 2015 Final Rule's compliance date of February 26, 2019, have met the requirements of the rule update. This ICR now accounts for those products that are considered new to the market after the 2015 Final Rule compliance date. Based on these assumptions, the number of labeling responses per

year has decreased from 386 to 87, with a corresponding decrease in the associated burden. This change is an adjustment.

The total burden hours per response (5.5 hours) has not changed for this ICR renewal. However, because of the decrease in the number of labeling activities per year, the total response burden estimate has decreased from 6,369 hours to 1,435.5 hours, with a resultant decrease in the total labor costs from $701,914 to $156,606.53.

6(f) Burden Statement

The respondent burden for this information collection is estimated to average 5.5 hours per product. Burden is defined in 5 CFR 1320.3(b). 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 numbers are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9. The OMB control number for this collection of information is 2070-0187.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2018-0139, which is available for online viewing at http://www.regulations.gov. 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-2018-0139 and OMB control number 2070-0187, to both EPA and OMB as follows:

• To EPA online using http://www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

• To OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

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.

7. 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-2018-0139. 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**. Available online at https://www.gpo.gov/fdsys/pkg/USCODE-2011-title7/pdf/USCODE-2011-title7-chap6-subchapII-sec136a.pdf

Attachment B: **7 U.S.C. 136w – Section 25 of FIFRA**. 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.** Available online at https://www.ecfr.gov/cgi-bin/text-idx?SID=1c52b6e865d2945433708daaca89d5ff&mc=true&node=se40.26.152_125&rgn=div8

Attachment D: **Consultations Summary for the Renewal ICR, entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b) Information Collection Request"**

Attachment E: **Work Sheets used to Calculate Pesticide Industry Labor Costs.**