BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0687; FRL-9971-89]

Proposed Information Collection Request (EPA ICR No. 1204.13); Comment Request; Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), "Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2)" (EPA ICR No. 1204.13, OMB Control No. 2070-0039), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through September 30, 2018. 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.

DATES: Comments must be submitted on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2017-0687 online *using www.regulations.gov* (our preferred method), by email to *OPP_Docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public 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.

FOR FURTHER INFORMATION CONTACT: Amaris Johnson, Field and External Affairs Division, Office of Pesticide Programs, (7506P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-9542; email address: *johnson.amaris@epa.gov*.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i.) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii.) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii.) enhance the quality, utility, and clarity of the information to be collected; and (iv.) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another Federal Register notice to announce the

submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency which may be relevant to the balancing of the risks and benefits of a pesticide product. The statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an unreasonable adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, the EPA has limited the scope of factual information that the registrant must submit. The Agency's regulations at 40 CFR part 159 provide a detailed description of the reporting obligations of registrants under FIFRA section 6(a)(2).

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this ICR include anyone who holds or has ever held a registration for a pesticide product issued under FIFRA Section 3 or 24(c). The North American Industrial Classification System (NAICS) is 325300 (Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing).

Respondent's obligation to respond: mandatory (FIFRA 6(a)(2)).

Estimated number of respondents: 1,452 (total).

Frequency of response: On Occasion.

Total estimated burden: 301,118 hours (per year). Burden is defined at 5 CFR 1320.03(b).

T*otal estimated cost:* $19,999,815 (per year).

Changes in Estimates: There is an increase of 71,778 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to the expectation that the number of responses will increase by 16% from 93,000 in the last ICR

approval to approximately 108,000 for this ICR renewal. The increase is due to EPA's revised expectations regarding the number of incident reports that will be submitted to the Agency, which reflects historical information on the number of responses received. The increase in the number of incident reports has also prompted the need for additional information discussed in section 4 of the supporting statement. Since the last ICR was approved, the EPA has found it necessary to request additional data in certain subject areas under 40 CFR 159. First, due to a significant increase in the number of adverse incidents for spot-on domestic animal pet products from several registrants, EPA began requiring more standardized post-market surveillance reporting on adverse effects and submission of sales information, so the Agency can better evaluate incident rates. Second, the Agency requested additional information from the registrant of an herbicide to help explain circumstances for incidents of alleged tree and plant damage. Finally, new concerns about neonicotinoid pesticides and the loss of bee colonies led to EPA's request for more documentation from registrants for these products.

Next Step in the Process for this ICR: EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq*.

Dated: January 11, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018-02547 Filed: 2/7/2018 8:45 am; Publication Date: 2/8/2018]