E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2021-0315; FRL-8735-01-OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on an Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB). The ICR, entitled: "Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects" and identified by EPA ICR No. 2195.06 and OMB Control No. 2070-0169, represents the renewal of an existing ICR that is scheduled to expire on April 30, 2022. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2021-0315, using *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Mission Support Division (7101M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 34-0159; email address: *siu.carolyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. 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.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. 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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects.

ICR number: EPA ICR No. 2195.06.

OMB control number: OMB Control No. 2070-0169.

ICR status: This ICR is currently scheduled to expire on April 30, 2022. 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 for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the *Federal Register* when approved, are listed in 40 CFR part 9, 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.

Abstract: The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). The EPA regulations at 40 CFR Part 26 protect subjects of "third-party" human research (i.e., research that is not conducted or supported by the EPA). In addition to other protections, the regulations require affected entities to submit information to EPA and an institutional review board (IRB) prior to initiating, and to the EPA upon the completion of, certain studies that involve human research participants. The information collection activity consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional exposure of human subjects, these individuals (respondents) are required to submit study protocols to the EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to the EPA. This renewal ICR estimates the third-party response burden from complying with the requirements in 40 CFR Part 26.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 10,242 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are any entities that submits protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA.

Respondent's obligation to respond: Mandatory under 40 CFR part 26.

Estimated total number of potential respondents: 5 annually for research involving intentional exposure of human subjects and 5 annually for all other submitted research with human subjects.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 10,242 hours.

Estimated total annual costs: $ 1,051,0896. This includes an estimated burden cost of $ 0 for capital investment or maintenance and operational costs.

III. Are There Changes in the Estimates from the Last Approval?

The estimated respondent burden remains 10,242 hours, which is the same as that approved by OMB for the existing ICR. The anticipated number of responses per year is based on the submissions to the Agency in the recent past and recognition that some of the studies underway will be submitted prior to the start of the renewal period. The annual burden per activity is estimated to be 1,446 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other research with human subjects.

In addition, OMB has requested that EPA move towards using the 18-question format for

ICR Supporting Statements used by other federal agencies and departments and that is based on the submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. The Agency does not expect this change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

IV. What is the 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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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