UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 16, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Danielle Jones
Desk Officer
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)
725 17th Street, N.W.
Washington, DC 2050

RE: Request to Use Emergency Process under the Paperwork Reduction Act to Amend an Existing Approval to Include Additional Respondent Guidance (OMB Control No. 2070-0033; EPA ICR No. 1139.24)

Dear Ms. Jones:

Pursuant to Section 3507(j) of the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), as implemented in OMB regulations at 5 CFR § 1320.13, the Agency hereby requests emergency processing to make a substantive change to the existing approval under OMB Control No. 2070-0033 (EPA ICR No. 1139.24) to include the burden associated with pre-issuance outreach and the use of the attached **User Guide for submitting TSCA Section 4 Test Order Information** and a **Questions and Answers** document.

The currently approved information collection request (ICR) covers the collection of information necessary for the timely and efficient implementation of Section 4 of the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. In accordance with the terms of clearance for that ICR, EPA developed the attached documents to provide more detailed guidance and instructions for recipients of the TSCA Test Orders, and plans to provide opportunities for such entities to engage with EPA prior to the issuance of a given Test Order, as well as increase overall stakeholder outreach to keep the regulated community informed of considerations related to the development of Test Orders. The additional guidance and engagement are intended to increase efficiencies and reduce burdens for all participants.

Background
Under the PRA, an agency may ask OMB to authorize a collection of information if the Agency has determined that the collection is needed prior to the expiration of time periods established under the PRA if the agency determines that the agency cannot reasonably comply with the normal clearance procedures under the PRA because public harm is reasonably likely to result if normal clearance procedures are followed, an unanticipated event has occurred, or the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.

In submitting an emergency processing request pursuant to PRA Section 3507(j), the Agency must submit a request that includes a "written determination." describing the collection activity (5 CFR § 1320.1 J(a)), identifying the time period within which OMB should act on the request (5 CFR § 1320.1

3(c)), and specifying that the Agency has taken all practicable steps to consult with affected parties in order to minimize burden related to the emergency collection (5 CFR § 1320. 13(d)).

This document provides the required "written determination" to request emergency processing and approval of the requested addition of the guidance and instructions for respondents to the approval under OMB Control No. 2070-0033.

What is the Requested Time Period for OMB Action?
EPA requests that OMB take action on this request by September 30, 2021, with an approval period of at least 180 days.

As discussed, EPA will then immediately initiate a revision/renewal of the revised ICR that includes the attached guidance and follow the usual PRA process with the standard 60-day and 30-day notice and comment opportunities.

What Information Collection Activities are Involved in this Emergency Request?
This request involves the incorporation of burden associated with the use of the attached guidance documents and Test Order specific pre-issuance outreach.

The existing ICR covers the activities associated with the issuance of Test Orders generally. The information required under TSCA Section 4 may be used to provide EPA with the necessary information on, among other categories of information, health effects, ecological effects, environmental fate, and exposure to predict the effects of chemicals on human health or the environment. EPA's statutory authority under TSCA Sections 4(a)(1) or 4(a)(2) may be used to ensure the safety of existing chemicals in the marketplace by applying a statutory and regulatory approach that includes prioritizing, evaluating, and managing risks of chemicals under TSCA Section 6. EPA may also need to develop information under TSCA Section 4 pursuant to other authorities provided under TSCA Section 4(a)(2), including pursuant to TSCA Section 5. Also, EPA may be required to develop a testing action under TSCA Section 4 in response to a recommendation received from the TSCA Interagency Testing Committee (ITC).

EPA developed the attached User Guide and Questions and Answers document to assist stakeholders with Section 4 Test Order requirements and the submission process. The documents discuss both information already required under the existing ICR, and information that the Agency would recommend as a voluntary matter in specified situations, which in the past has been submitted on a case-by-case basis, EPA believes these documents will help submitters meet the requirements of TSCA Section 4, and better understand the utility of submitting complete and accurate information. The documents will also clarify the testing requirements and notification process questions for individuals subject to TSCA Section 4 Test Orders

Is the Information Collection Essential and Necessary for the Proper Performance of the Agency Functions?
Yes. EPA has authority under TSCA Section 4 to require manufacturers and processors, among other authorities, to conduct testing and submit data. The purpose of this emergency processing request is to help EPA engage Test Order recipients in the development of the Test Orders, as well as to facilitate the recipient's activities in response of the Test Order. The ICR revisions captured by this request will help EPA consistently and effectively communicate its data needs to potential respondents, especially in terms of ensuring timeliness for EPA's risk evaluations and risk management of existing chemicals under Section 6 of TSCA. To carry out its statutory obligations, EPA needs sufficient and timely information about chemicals undergoing risk evaluation and risk management, including information

related to the chemicals' conditions of use, hazards, exposures, potentially exposed or susceptible subpopulations, health and environmental effects, benefits, reasonably ascertainable economic consequences, alternatives, and other information. The collection of such information is subject to TSCA's strict statutory timeframes (set forth in Section 6).

Rationale for the Emergency Request

The issuance of the guidance documents and reference in any associated collection of information is critical for the Agency to be able to make timely determinations on new chemical notifications as required under TSCA. Data being collected via this authority will be used to inform risk evaluations already underway. The regular process for ICRs under the PRA, which includes two comment periods with 60-day and 30-day timeframes, would disrupt the collection of information by denying access to the guidance documents and preventing companies from accessing applicable and helpful EPA guidance with respect to Test Orders submitted prior to OMB approval of the ICR and cause harm due to the ensuing delays in risk evaluations because companies do not have access to the guidance. This would prolong any issues that submitters and EPA may have experienced that this guidance seeks to help remedy.

Further, under the ICR, EPA would seek to conduct stakeholder outreach prior to issuing a Test Order under Section 4 of TSCA, which will help ensure that affected entities will be kept informed of upcoming Section 4 Test Orders and provide opportunities for such entities to engage with EPA prior to the issuance of a given Test Order.

Why the Agency cannot reasonably comply with the normal clearance procedures?

EPA's timely receipt of the data that would be requested in the next set of Test Orders is critical to ensure that the data is available for consideration in the risk evaluations, which must be completed within specific timeframes established in TSCA. On December 20, 2019, EPA finalized the designation of 20 chemical substances as a high priority for upcoming risk evaluations, and, after a public comment opportunity in April 2020, EPA released the final scope documents for these substances in August 2020.[1] The scope document for each chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in conducting the risk evaluation for that chemical substance. EPA intends to issue Test Orders to obtain data identified as necessary to inform the risk evaluations for these chemicals.

The attached guidance documents will provide more detailed guidance and instructions to the recipients of the Test Orders that are currently under development for the 20 high priority chemicals initiated for risk evaluations. Since the Test Orders may involve the gathering or generation of data for consideration during the risk evaluations that are underway, the availability of the attached guidance is essential before the next set of Test Orders are issued.

Complying with the normal clearance procedures to obtain approval for the use of the attached guidance would have a significant negative impact on potential respondents, perhaps even delaying the issuance of the next set of Test Orders, and thereby preventing the availability of additional data to inform the risk evaluations.

[1] A list of the substances and links to the final scope documents is available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-scope-documents-high-priority-chemicals-undergoing.

Has the Agency taken practicable steps to consult with affected parties in order to minimize burden?
Yes. The User Guide and Questions and Answers documents were developed using questions and requests for guidance raised by affect parties following the issuance of the first set of Test Orders (Section 4 of TSCA) in January 2021. Affected parties have expressed an interest in learning of Test Orders prior to their issuance, and have requested an opportunity to engage with EPA prior to their issuance, which pre-issuance outreach would enable.

What are the Estimated Burden and Costs for This Information Collection Activity?
EPA estimates that it will take submitters 1.45 managerial and technical hours per notice to read through and familiarize themselves with the documents. EPA estimates that it will take submitters 3 managerial and technical hours per notice for pre-issuance outreach. This burden applies to Section 4 Test Orders. The annual burden for the currently approved ICR No. 1139.24, OMB Control No. 2070-0033, is 96,441 hours. The total estimated increase in burden due to the addition of these documents and pre-issuance outreach would be 516 hours, or around 0.54% (per year).

Thank you for your assistance in processing this request. Should any questions arise, please contact Katherine Sleasman of my staff at (703) 347-0409.

Sincerely,

ANGELA HOFMANN

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Date: 2021.09.16 21:27:15 -04'00'

Angela F. Hofmann, Chief
Regulatory Support Branch
Mission Support Division (MSD)
Office of Program Support (OPS)

Attachments