



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

June 7, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Danielle Jones
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)
725 17th Street, N.W.
Washington, DC 20503

RE: Emergency Processing Request for TSCA New Chemicals "Points to Consider" Information Document

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 is hereby requesting emergency processing of the collection of information necessary for the timely and efficient implementation of section 5 of the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. More specifically, the Agency seeks to issue a new information document entitled "*Points to Consider When Preparing TSCA New Chemical Notifications*" (hereinafter, "*PtC*") which is not currently covered under an approved information collection request (ICR). The vast majority of information collections associated with TSCA section 5 activities are covered under an existing EPA ICR No. 0574.16, OMB Control No. 2070-0012, and EPA is actively working to both renew that ICR and expand its scope to cover the new PtC document. EPA created the PtC document to assist submitters of new chemical notices, to speed Agency review, and to reduce time consuming interactions among stakeholders of submissions.

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 section 3507(j), the Agency must submit a request that includes a "written determination" describing the collection activity (5 CFR §1320.13(a)), identifying the time period within which OMB should act on the request (5 CFR §1320.13(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, along with the accompanying ROCIS forms, provides the required "written determination" to request emergency processing and approval of the collection activity described.

Requested Time Period for OMB Action

EPA requests that OMB take action by June 11, 2018.

What Information Collection Activities are Involved in this Emergency Request?

Pursuant to TSCA section 5, any person seeking to manufacture a new chemical substance or a chemical substance for a significant new use must provide notice to EPA at least 90 days prior to commencing manufacture of that chemical. EPA reviews these notices, makes an affirmative determination on the chemical, and, if appropriate, regulates the chemical to address any unreasonable risks identified before the chemical is allowed to proceed to the marketplace. The 2016 amendments to TSCA imposed a number of new responsibilities related to new chemical reviews. Specifically, TSCA requires that EPA now assess a new chemical under the “conditions of use” - the circumstances under which the chemical is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of. TSCA also now requires that EPA make one of five affirmative determinations on the new chemical within the statutory review period, or refund any user fee that was collected to defray the costs of the review.

EPA reviews the information provided in the notice and other relevant information to evaluate the health and environmental effects of the new chemical substance and make the required determination.

Submitters are already required to provide certain information when they complete and file notifications with the Agency (see, e.g., 40 CFR parts 720 and 723). If the required information is not submitted as part of the notification, EPA may declare the notification to be incomplete. However, if sufficiently specific information is lacking, EPA typically makes conservative assumptions, which oftentimes lead to the practice of iterative reviews and frequent suspensions of the notice review period while submitters work with the Agency to provide and/or develop additional information. Notifications that lack detail typically result in follow-up or additional interaction with submitters, which in turn, adds time to the new chemical review process. If the submitter later provides additional information, EPA will generally conduct additional analyses and/or re-evaluate the notification in light of the additional information.

EPA developed the PtC document to assist the Agency in meeting its new responsibility to make affirmative determinations on new chemical notices, to speed review times, within the statutory period under TSCA, and to reduce the frequency of time consuming interactions with submitters in cases where EPA has questions about the submission. This document discusses 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 this document will help submitters meet the requirements of TSCA Section 5 and applicable regulations, and better understand the utility of submitting complete and accurate information with their original submission. The document will also facilitate more efficient EPA reviews and increase the likelihood that the Agency will be able to complete those reviews within the statutory time period without the need for suspensions of the notice review period.

Is the Information Collection Essential and Necessary for the Proper Performance of the Agency Functions?

Yes. TSCA section 5 requires EPA to make an affirmative determination on a new chemical substance under the conditions of use within a 90-day statutory review period. EPA receives approximately 1000 new chemical notices each year. The issuance of the PtC is a critical step towards meeting our statutory responsibilities to review these notices in a timely and efficient manner.

Rationale for the Emergency Request

EPA has determined that OMB's approval of this collection of information is needed prior to the expiration of the time periods established under the PRA. The issuance of this document and 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. The new requirements in TSCA related to new chemicals were effective immediately, and EPA continues to receive and review notices now. 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 preventing companies from accessing applicable and helpful EPA guidance with respect to PMNs and SNUNs submitted prior to OMB approval of the ICR and cause harm due to the ensuing delays in marketing new chemical substances because companies do not have access to the guidance. This would prolong the issues that submitters and EPA have experienced.

Why can't the Agency reasonably comply with the normal clearance procedures?

The normal clearance procedures under the PRA require agencies to provide a 60-day public comment opportunity before submitting an ICR to OMB for review and approval. The OMB review and approval process involves another mandated 30 days for additional public comment. Combined with the necessary internal EPA development and clearance time frames, the normal clearance procedures under the PRA typically take at least 6 months to complete.

The new requirements in TSCA related to new chemical reviews were effective immediately upon signature of the amendments on June 22, 2016, and EPA has been working diligently to implement them. However, the imposition of new responsibilities on EPA coupled with the continued receipt of new chemical notices resulted in a backlog of submissions. The PtC document is urgently needed for EPA to move towards a more timely and efficient new chemical review process. Complying with the normal clearance procedures for collection of information under the PtC could prolong the backlog issues EPA has experienced.

Has the Agency taken practicable steps to consult with affected parties in order to minimize burden?

Yes. EPA has been engaged in a continuing series of joint EPA/industry/public interest group meetings to facilitate the identification and exchange of critical information related to the TSCA New Chemicals Program. These include numerous "pre-submission" or "pre-notice" meetings with individual companies, presentations and delivery of training courses at professional meetings, and public meetings held on August 9, 2016, December 14, 2016 and December 7, 2017. Additionally, EPA's PtC document was released in draft form at the December 6, 2017 – Public Meeting on Progress Implementing the New Chemicals Review Program Under Amended TSCA (see <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/public-meeting-progress-implementing-changes-new>). EPA solicited and received public comment on the draft PtC document and has incorporated those comments into the updated version associated with this request. As a general matter, chemical manufacturers supported the PtC document and the additional clarity it provides into EPA's new chemical review process.

What are the Estimated Burden and Costs for This Information Collection Activity?

EPA estimates that it will take submitters 1.4 managerial and technical hours per notice to read through and familiarize themselves with the document. This burden applies to PMN, SNUN, TME, and LVE/LoREX notices. Another document was published previously for biotechnology new chemical notices. The annual burden for the currently approved ICR No. 0574.16, OMB Control No. 2070-0012, is 117,176 hours. The total estimated increase in burden due to these documents would be 1,379 hours, or around 1.17%

Requested Approval Period

EPA asks that OMB approve this collection for 180 days, i.e., through December 8, 2018. This will allow sufficient time for EPA to proceed with an ICR to be processed and approved under the regular process. EPA intends to include the estimated burdens associated with the PtC document in a forthcoming ICR renewal package related to TSCA Section 5 activities.

Thank you for your assistance in processing this request. Should any questions arise, please contact me on 202-564-0258.

Sincerely,

Angela F. Hofmann
Director of Regulatory Coordination

Attachment

cc: Nancy Beck (EPA/OCSP)
Charlotte Bertrand (EPA/OCSP)
Peter J. Smith (EPA/OCSP)
Jeff Morris (EPA/OCSP/OPPT)
Tala Henry (EPA/OCSP/OPPT)
Courtney Kerwin (EPA/OEI)
Eric Schultz (EPA/OEI)
Jim Laity (OMB/OIRA)
Jim Kim (OMB/OIRA)