EPA ICR No. 0574.15; OMB Control No. 2070-0012

Attachment J

Copy of Consultations Message Sent by EPA to Potential Respondents

From: Loraine Passe/DC/USEPA/US

To: [Addressees]

Date: 08/05/2011 07:54 AM

Subject: Information Collection Request (ICR) Consultation

The Office of Management and Budget (OMB) regulations that implement the Paperwork Reduction Act require federal agencies developing any new (non-rule) information collection request (ICR), or proposing to renew an ICR, to announce the ICR activity in the Federal Register and to provide the public with 60 days to comment on the proposed collection activity. In addition to the notice and comment requirement, agencies are also required under 5 CFR 1320.8(d)(1) to consult with potential respondents and data users about specific aspects of an ICR before submitting it to OMB for review and approval, regardless of whether changes have or have not been made to the collection activity.

As part of this required consultation, I am contacting you to solicit your comments on the renewal ICR for Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (OMB Control No. 2070-0012). The meaningful and timely comments the Agency receives from you will help us during the development of this renewal ICR. The notice for the ICR renewal and solicitation of comments was published in the Federal Register on August 3, 2011 (76 FR 46794).

Please note that, if you take this opportunity to provide input, your name, affiliation, and phone number and any information you provide (e.g., copies of emails) will be incorporated and attached to the ICR supporting statement which will be a public document. In addition, you may be contacted by the OMB Desk Examiner for the ICR to verify the accuracy of any comments as reported in the ICR by EPA.

Your timely response to the questions below will be greatly appreciated. We hope to get your responses back by September 30, 2011 so we can consider those responses, as well as any public comments resulting from the Federal Register notice, at the same time. Thank you for your assistance.

Regards,
Loraine Passe
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New Chemicals Management Branch
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OVERVIEW

The information collection request addresses the TSCA section 5 reporting and recordkeeping requirements associated with the new chemicals review and regulatory program, as briefly outlined below.

The Environmental Protection Agency (EPA) administers the New Chemicals Program under section 5 of the Toxic Substances Control Act (TSCA). TSCA section 5 requires that any person who proposes to manufacture or import a "new chemical," (i.e., a chemical not listed on the TSCA section 8(b) Inventory), must provide a premanufacture notice (PMN) or an exemption application to EPA at least 90 days prior to commencing manufacture or import of that chemical. Similarly, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture, import or process a chemical for a use that is determined to be a "significant new use." EPA considers certain genetically engineered microorganisms to be chemical substances for purposes of the notification requirements found in TSCA section 5; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Furthermore, TSCA section 5 authorizes EPA to regulate the manufacture, processing, distribution in commerce, use or disposal of new chemical substances. Using the notice information submitted to the Agency, EPA evaluates the health and environmental effects of new chemical substances. On the basis of its review, EPA may take regulatory action with respect to the manufacture or importation of a new chemical substance or with respect to a substances proposed new use. If EPA takes no action within the 90-day review period for PMNs (30 or 45 days for PMN exemption applications), the submitter is free to manufacture or import the new substance, or to manufacture, import or process the substance for a new use. EPA requires that the submitter inform EPA when non-exempt commercial manufacture, processing or importation of the substance in question actually begins by submitting a Notice of Commencement.

The Government Paperwork Elimination Act (GPEA, Pub. L. 105-277) requires that, when practicable, federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (October 13, 2005; 70 FR 59848; FRL-7977-1) provides that any requirement in Title 40 of the Code of Federal Regulations to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a notice that electronic document submission is available for that requirement.
In light of GPEA and CROMERR, EPA published a final rule entitled, "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (RIN 2070-AJ41)(75 FR 773) to amend the Toxic Substances Control Act (TSCA) section 5 Notification regulations and related provisions to phase-out paper-based submissions and facilitate the introduction and use of a new electronic reporting mechanism. This action enables, and eventually will require, manufacturers, importers, and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit TSCA section 5 notices to the Agency. These include Premanufacture Notices (PMNs) (40 CFR 720, Attachment 3), Significant New Use Notices (SNUNs) (40 CFR 721, Attachment 4), Test Market Exemption Applications (TMEAs) (40 CFR 720), Low Volume Exemption notices (LVEs) (40 CFR 723.50), Low Exposure/Low Release Exemption (LoRex) notices (40

CFR 723.50) (see Attachment 5), Biotechnology notices for genetically modified microorganisms (40 CFR 725, Attachment 6), Notices of Commencement of Manufacture or Import (NOCs) (40 CFR 720.102) and other support documents (e.g., correspondence, amendments and test data).

The Agency introduced CDX reporting in two phases over a two-year period. From April 6, 2010 (the effective date of the rule) through April 6, 2011, the Agency allowed submissions via CDX, optical disc, and paper. Regardless of the delivery method, EPA required that all submissions be generated with new electronic-PMN "e-PMN" computer software. As of April 6, 2011, Paper submissions are no longer accepted for any new notices and support documents (including NOCs). Disc-based submissions (e.g., CDs and data DVDs) for all new notices and support documents will no longer be accepted beyond the second year after the final rule's effective date, April 6, 2012. After this, all submitters will be required to submit electronically via CDX using the e-PMN software. Note that the final CDX and e-PMN software amendments to the PMN notification requirements in 40 CFR 720 also apply to the SNUN requirements in 40 CFR 721.25(a).

QUESTIONS

1. INFORMATION COLLECTION

Is the information that the Agency seeks under this ICR available from any public source, or already collected by another office at EPA or by another agency? If yes, where can the Agency find the data?

The ICR is intended to require that respondents provide detailed responses and certain data so that the Agency can utilize the information in whatever manner is required. Is it clear to you, based on the instructions, that you are required to provide specifics and submit data? If not, what suggestions do you have for clarifying the instructions? Do you understand that you are required to submit or maintain records of certain data elements? Is the format of the reporting forms clear, logical, and easy to complete?

2. ELECTRONIC REPORTING

What, if any benefits are you experiencing from using the e-PMN software and submitting your notices via CDX (e.g., burden reduction, greater efficiency in compiling the information, etc.)? Are the online instruction manuals and guidance documents for using the software and submitting notices electronically accurate and understandable? Is the remainder of the phase-in period, until April 6, 2012, sufficient time to register with CDX and familiarize yourself with the e-PMN software?

3. BURDEN COST ANALYSIS

Do you agree with EPA's estimated burden and costs? Are the Bureau of Labor Statistics (BLS) labor rates accurate? If you have any reason to consider the BLS labor rates inaccurate or inappropriate as used by EPA, explain your rationale.