May 22, 2008

Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
Attention: Desk Officer for EPA,
725 17th Street, NW., Washington, DC 20503

Re: EPA Information Collection Submission To OMB for Review and Approval; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.01, OMB Control No. 2070–New
Docket ID Number EPA-HQ-OPPT-2007-1081

Office of Information and Regulatory Affairs:

We appreciate the opportunity to submit comments to OMB on the *Information Collection Request (ICR) for Tier 1 screening under the Endocrine Disruptor Screening Program (EDSP).*[1] Collectively, our associations represent the leading companies engaged in the business of chemistry. Our members are regulated under a wide range of EPA authorities and have significant interest in the EDSP and in the protection of human health and the environment. It is vitally important the EDSP ICR provides current and accurate estimates of the burden for conducting the EPA required endocrine screening. Companies will rely almost exclusively on the burden estimates provided in the ICR for budgeting purposes and for decision making in responding to test orders.

The chemical industry has actively supported the development and use of accurate cost estimates for the EDSP since the inception of this program. In 1998, industry provided funding to a contractor to develop an initial cost assessment based on the screening assays and tests recommended by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), and this survey was included as Appendix S in EPA's EDSTAC's final report, which EPA submitted to Congress in 1998. In 2003, industry again commissioned a study to update the EDSP Cost Estimate Survey for the Tier 1 screening assays. This 2003 update was necessitated by the numerous changes made by EPA to the original methods proposed by EDSTAC. This updated 2003 Cost Estimate Survey was formally submitted to EPA by ACC in 2003.[2] In 2008, our organizations provided extensive comments to EPA on the Draft EDSP ICR, in which we pointed out

[1] Federal Register / Vol. 74, No. 71 / Wednesday, April 15, 2009 / Notices. Pages 17477 - 17479

[2] Docket IDs: EPA-HQ-OPPT-2002-0066-0457 and EPA-HQ-OPPT-2007-1081.

the serious shortcomings with the accuracy of the draft ICR, including that, based "on actual recent bids and costs for conducting some of the Tier 1 assays....., it would appear that EPA has generally underestimated the costs of Tier 1 by a factor of two or more."

Unfortunately, over the last year, EPA has not addressed many of the serious shortcomings of the draft ICR. We worked with Dr. Richard Belzer to assist us in analyzing the April 15, 2009 EDSP ICR. Dr. Belzer's knowledge of the Paperwork Reduction Act, OMB's Information Collection Rule, and his expertise in evaluating information collection activities of federal agencies proved very insightful. Based on a thorough analysis, it is clear that the April 15, 2009 EDSP ICR contains several serious deficiencies. These shortcomings and deficiencies of the April 2009 EDSP ICR are described in detail in Attachment 1: An Analysis of EPA's Information Collection Request Seeking OMB Approval to Impose Mandatory Tier 1 Assay Testing in Support of the Endocrine Disruptor Screening Program. The major deficiencies are:

- Burden estimates that are technically flawed.
- Deficiencies in complying with the Paperwork Reduction Act.
- Inadequate demonstration by EPA to make a showing of actual practical utility primarily due to the Agency's inability to demonstrate that certain Tier 1 assays can adequately distinguish substances that have endocrine activity from those that do not.

In summary, after a thorough analysis, as described in Attachments 1 through 3, our organizations have concluded that the EPA's April 15, 2009 EDSP ICR is inaccurate and that the actual burdens associated with the EDSP are at least two to three times larger, and could be as high as ten-fold greater, than what EPA has estimated.

It is incumbent upon the Agency to accurately and fully convey the costs of the EDSP, and the short cuts the Agency has taken fall short of meeting this standard. Further, it is necessary for EPA to fully comply with the procedural requirements of the Paperwork Reduction Act and the Agency must demonstrate the practical utility of Tier 1 test data for the Agency's declared statutory purpose. As described in Attachment 1, there are substantial questions regarding the Agency's fulfillment of these standards.

We request that OMB fully and carefully consider these comments and take those steps needed to rectify the ICR in order to assure that the EPA EDSP is implemented in a manner that is fully consistent with administrative requirements.

Sincerely,

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Attachment 1. An Analysis of EPA's Information Collection Request Seeking OMB Approval to Impose Mandatory Tier 1 Assay Testing in Support of the Endocrine Disruptor Screening Program

Attachment 2. Concerns Regarding EDSP and Requirements of TSCA 8(e) and FIFRA 6(a)(2)
Attachment 3. A Summary of Concerns regarding Specific Test Methods Proposed by EPA to be included in the EDSP Tier 1 Battery