

ATTACHMENT 2

Copy of Public Comments on ICR Renewal and EPA's Response

July 17, 2009

MEMORANDUM

FROM: Oscar Hernandez, Director /s/
Risk Assessment Division (7403M)
Office of Pollution Prevention and Toxics

TO: Angela Hofmann, Director
Regulatory Coordination Staff (7101M)
Office of Prevention, pesticides, and Toxic Substances

SUBJECT: Public Comments on TSCA 8(e) ICR Renewal (#0794.12);
OMB Control No. 2070-0046

EPA received one public response on the proposed TSCA 8(e) 2009 Information Collection Request renewal published in the Federal Register on February 13, 2009. RAD has reviewed these comments, which are from Steven J. Goldberg of the BASF Corporation.

BASF recommends that information collected should be limited to commercialized substances on the Inventory or notified to the Agency (e.g., through LVE or polymer exemption), and that submissions be delayed until the study is complete. Also, BASF states that the current guidance to submit any information within the 30 calendar days results in submission of preliminary information with additional submission containing clarifications. They stated that the consequence is greater numbers of submissions of limited information rather than fewer submissions with complete information. Therefore, BASF recommends that submission should be delayed until all the biological endpoints of a particular study can be evaluated rather than after identification of every toxicological change.

EPA stands by its decision for reporting requirements. Information that is reported on chemicals varies from one submitter to another. The guidance states that full reports or summarized results may be submitted to the Agency and that limited studies, preliminary results, and draft reports may constitute sufficient evidence for Section 8(e) reporting. For consistency, EPA finds it necessary to enforce the current requirements used in the guidance that will allow for a proper evaluation of the risk and/or hazard of a substance based upon full and current disclosure by all involved parties. The Agency collects and will continue to collect early documentation of potential problems for early warning of the potential hazard of a chemical.

BASF believes that the Agency has underestimated the clerical time to prepare and submit confidential information. They stated that the clerical time could be reduced through electronic submission. Also, BASF points out that electronic submission can greatly decrease the burden of submission and reduce the amount of paper that the Agency needs to handle. Encryption technology is available that would allow secure transmission, and other forms of electronic submission such as password-protected CD's could be used. Furthermore, BASF states that it is also unclear what the retention policy of the Agency is regarding paper submission, but if documents are retained for 10 years, there is a need to reduce the paper that the Agency needs to manage.

EPA is currently looking to move to electronic reporting. However, we will continue to use the process that is in place at this time.

Attached are copies of the ACC comments and the revised TSCA 8(e) ICR Part 6.

Attachments