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March 24, 2009

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Comments for Docket EPA-HQ-OPPT-2008-0896

Dear Sirs:

BASF Corporation is pleased to provide responses to the questions posed by the EPA in the Federal Register Notice of Friday, Feb 13, 2009 concerning collection of information under TSCA Section 8(e). BASF will limit its responses to the questions posed, but may interject additional comments are they pertain to the reporting criteria and utility of the information. To summarize our responses:

Is the proposed collection of information necessary and will the information have practical utility? In general, BASF feels that the information requested under TSCA Section 8(e) is necessary to the Agency and provides an indication of potential health or environmental issues for chemicals in commerce. Unfortunately, the guidance that the Agency has provided on what substances are subject to reporting and what results are deemed reportable lead to submissions on substances that may never be commercialized or preliminary information of unknown relevance. **Therefore, BASF feels that information 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. These changes could result in a cost savings of over $300,000.00 per year to BASF and hours of Agency time for the review information that has little value.**

How accurate is the Agency's estimate of the burden? BASF agrees with the Agency's statement that the estimated burden per submission is dependent on the nature of the response. However, BASF believes that the Agency has underestimated the clerical time to prepare and submit confidential information. **BASF believes that the clerical time could be reduced through electronic submission.**

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (973) 245-6057
Fax: (973) 245-6706
steven.goldberg@basf.com

CONTAINS NO CBI

318292

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Enhance the quality, utility, and clarity of the information to be collected. BASF feels that the current guidance to submit any information within the 30 calendar days results in submission of preliminary information with additional submission containing clarifications. The consequence is greater numbers of submissions of limited information rather than fewer submissions with complete information. **Therefore, BASF feels 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.**

Minimize the burden of the collection of information through use of electronic submission. BASF feels that electronic submissions 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 could be used. 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. **Therefore, BASF feels that electronic submission should be encouraged.**

BASF has elaborated on each response in the attached document. These comments are provided in the spirit of improving the process and information that the Agency seeks and needs to protect health and the environment.

Sincerely,

Steven J. Goldberg
Vice President and Associate General Counsel
Regulatory Law & Government Affairs

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (973) 245-6057
Fax: (973) 245-6706
steven.goldberg@basf.com

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BASF EXPANDED COMMENTS

Is the proposed collection of information necessary and will the information have practical utility?

In general, BASF feels that the information requested under TSCA Section 8(e) is necessary for the Agency in that it provides an indication of potential health or environmental issues for chemicals in commerce. Unfortunately, the guidance that the Agency has provided on what substances are subject to reporting and what results are deemed reportable lead to submissions of preliminary information that is difficult to put into context. As cited in the Federal Register:

> "Not only should final results from such studies be reported, but also **preliminary results** [emphasis added] from incomplete studies where appropriate[1]."

Furthermore, experimental pesticides are specifically identified as substances for which results of substantial hazards are reportable. As a company that develops crop protection products, BASF tests many experimental pesticides and herbicides only some of which may be commercialized. As stated in the 1991 TSCA 8(e) Reporting Guide:

> "Research and development (R&D) chemicals (including those intended for use as pesticides prior to application for an Experimental Use Permit (EUP) or registration under FIFRA"[2]

This leads to over-reporting of effects on substances which the Agency may never see again. Over the last 3 years, the number of 8(e) submissions by BASF has increased exceeding 100 submissions annually. Ninety percent (90%) of those pertain to pesticidal and herbicidal experimental and research study results (some which may never make it to commercialization) and only 10% pertain to commercial substances. In addition, crop protection products are regulated under FIFRA by the Office of Pesticide Programs for which numerous tests for health and environmental hazards are required. Therefore, the toxicological profile for any crop protection substance will be known to the Agency at the time of registration or experimental use; reporting under Section 8(e) does little to further protect the environment except to notify a different branch of the Agency. This seems duplicative and unnecessary. BASF anticipates that the number of TSCA 8(e) submissions will continue to increase annually based on EPA's current guidance for reporting information under TSCA Section 8(e).

Furthermore, the current guidance on reportable effects and the fines levied against companies for failure to report, create an atmosphere in which even the most minor of effects are submitted to the Agency for fear of under-reporting. Some examples are listed below.

- It has become common practice to submit information of body weight changes observed in repeated-dose studies even though these changes are not associated with any other toxicological effect.

- Submission of organ weight changes in the absence of pathology.

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[1] Federal Register: June 3, 2003 (Volume 68, Number 106), Page 33139
[2] TSCA 8(e) Reporting Guide, 1991, page 5.

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100 Campus Drive
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steven.goldberg@basf.com

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Submissions such as these are common, but are of little value in assessing the hazards because the effects are too vague. In fact, submission of such information seems contrary to the Agency's own statements on non-specific organ weight changes. From the answers to questions, EPA states:

> Liver or kidney weight changes alone that are less than 10% of total body weight, except in developmental toxicity studies, are rarely in practice considered by EPA to be of biological significance and therefore would not be reportable under TSCA §8(e).[3]

To further complicate the situation, effects do not need to be statistically or biologically relevant to warrant submission. As a result, the Agency is left with incomplete information or information with questionable relevance for health or the environment. **Therefore, BASF feels that information 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.** By limiting submissions to substances on the inventory, substances that are experimental pesticides, isolated intermediates, and non-commercial substances would be excluded **until the manufacturer intends to commercialize the substances.** At that time, all hazard information would be submitted to the Agency, and appropriate warnings would be required on Safety Data Sheets. These changes would likely reduce the overall costs to BASF by nearly $310,000.00, and would reduce the Agency time for review.

How accurate is the Agency's estimate of the burden?

BASF agrees with the Agency's statement that the estimated burden per submission is dependent on the nature of the response. However, BASF believes that EPA's estimate of 2 hours for "general clerical work" is low compared to BASF experience.

> EPA believes that it should take approximately 49 hours[4] per submission to judge and concur on the section 8(e) applicability of obtained information plus two[5] additional hours to prepare/submit the necessary information.[6]

Over the last 3 years, the number of 8(e) submissions by BASF has exceeded 100 submissions annually. BASF anticipates that the number of TSCA 8(e) submissions will continue to increase annually based on EPA's current guidance for reporting information under TSCA Section 8(e). Although the frequency of submissions may vary slightly during certain times of the year, BASF consistently submits on a bi-weekly basis. BASF spends an estimated 5,300 hours annually applicable to TSCA 8(e) submissions: BASF estimates that approximately 4,900 hours is spent annually for the managerial/technical review, data evaluation, decision making and concurrence processes to determine Section 8(e) reportability. This number is derived from EPA's assumption of 49 hours per each submission for this activity, which BASF is in agreement with.
BASF estimates that approximately 400 hours is spent on the administration activity including general/clerical work (typing, copying and sending the Section 8(e) submission). This figure reflects the assumption of 4 hours per each submission for this activity. This figure differs from EPA's

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[3] Answer to Q20, EPA website.
[4] Reflects managerial/technical review, data evaluation, decision-making and concurrence processes to determine the section 8(e) reportability and crafting the usually 1-2 page section 8(e) notification letter.
[5] Reflects general clerical work (typing, copying and sending the section 8(e) submission).
[6] Federal Register February 13, 2009 (Vol. 74, No. 29) pages 7227-7228

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assumption of 2 hours for this activity. **BASF expends approximately $345,000 annually for the reporting of information under TSCA Section 8(e) as outlined above.**

Enhance the quality, utility, and clarity of the information to be collected.
BASF feels that the current guidance to submit any information within the 30 calendar days results in submission of preliminary information with additional submissions containing follow-up clarifications. As stated above, there are several ways in which the Agency can enhance the quality, utility, and clarity of the information submitted. **The submission of preliminary information or information even of non-statistical or non-biologically relevant effects does not provide the Agency with sufficient basis on which to interpret if the risk is substantial.** Although the Agency has clearly stated that risk assessments are not required, and that it prefers that information not be subject to scientific interpretation (e.g., developmental effects concurrent with maternal toxicity), this leaves the submitter with no choice but to flood the Agency with incomplete or toxicologically-irrelevant information. Furthermore, the information provided does little to inform the Public of potential hazards because the information is too preliminary to interpret. The consequence is more submissions of limited information rather than fewer submissions with complete information. **Therefore, BASF feels 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.**

Minimize the burden of the collection of information through use of electronic submission.
BASF feels that electronic submissions 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 could be used. 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. **Therefore, BASF feels that electronic submission should be encouraged.**

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