

public, except as noted below. EPA considers information contained in a notice of substantial risk under TSCA section 8(e) to be health and safety information and, therefore, covered by the term "health and safety study," as defined in section 3(6) of TSCA. TSCA section 3(6) defines a "health and safety study" as "any study of any effect of a chemical substance or mixture on health or the environment or on both, including the underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act."

Under TSCA section 14(b), health and safety information may be disclosed to the public (i.e., may not be protected as confidential). However, the section does not authorize public release of information concerning the manufacturing process of a chemical substance or mixture which is the subject of submitted health and safety information, including data "disclosing the portion of the mixture comprised by any of the chemical substances in the mixture."

In the legislative history of TSCA, the Conference Committee stated that "[i]t is intended that the term (health and safety studies) be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data that bears on the effects of a chemical substance on health or the environment would be included." (Ref. 5). EPA believes that TSCA section 8(e) information, such as information or underlying data from studies carried out to investigate the effects of a chemical (or a mixture of chemicals) on health or the environment, or reports concerning the effects of unintentional or accidental releases or exposures, is information that "bears on the effects of a chemical substance on health or the environment."

Therefore, incident information, exposure studies, and their underlying data should be considered covered under the term "health and safety study." To the extent that information contained in a section 8(e) substantial risk report falls within the meaning of the term "health and safety study" under TSCA, it will not be afforded TSCA "Confidential Business Information" (CBI) protection except as noted in the following paragraph.

EPA considers chemical identity to be part of, the underlying data to, a health

and safety study. See, for example, 40 CFR 716.3 and 40 CFR 720.3(k). Consequently, the confidential identity of a chemical substance will not be protected by EPA unless otherwise provided for under section 14 of TSCA and the interpreting regulations in 40 CFR part 2.

EPA urges persons submitting data under TSCA section 8(e) to observe the limitations imposed on CBI claims by section 14 and the applicable regulations at 40 CFR part 2, subpart B, in order to save both Agency and submitter resources.

## V. References

The following is a listing of the documents that are specifically cited in this guidance document, and which are available as part of the public docket described in Unit I.B.1.:

1. Monsanto Company. Letter from J. Ronald Condray. Comment #12. May 3, 1995.
2. United States Congress. (1976) Report of the Senate Committee on Commerce on S. 3149, No. 94-698: 8.
3. Chemical Manufacturers Association (CMA). Comments of the Chemical Manufacturers Association on TSCA Section 8(e) Notice of Clarification. October 28, 1993.
4. Chemical Manufacturers Association (CMA). Comments of the Chemical Manufacturers Association on TSCA Section 8(e) draft policy statement. Comment #6, p. 24. May 4, 1995.
5. United States Congress. (1976) House of Representatives, 94th Congress, 2d Session. H.R. Report 94-1679 (Conference Report and Debates): 58.

## VI. Statutory and Executive Order Reviews

As discussed in Unit II.B., the guidance document articulates EPA's preferences for how and where TSCA section 8(e) notices should be submitted. The guidance document is not a regulation, and submitters of TSCA section 8(e) notices are not obligated to comply with the preferences. Since this document is not a regulation and does not impose any new binding requirements it is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), or Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect*

*Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). For the same reason, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request as defined by the PRA, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument or form, if applicable.

This document does not contain any new information collection requirements that would require additional OMB review and approval under the PRA. The information collection activities related to the submission of information pursuant to TSCA section 8(e) have been approved by OMB under OMB control number 2070-0046 (EPA ICR No. 0794). The annual respondent burden for this information collection activity is estimated to average 27 hours per initial section 8(e) submission and 5 hours per follow-up/supplemental section 8(e) submission, which includes the average time for processing, compiling and reviewing the requested data, generating the request, follow-up correspondence with EPA, storing, filing, and maintaining the data.

As defined by the PRA and 5 CFR 1320.3(b), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

This document will have a negligible impact on States, local or Tribal governments because they do not generally engage in activities that would subject them to reporting requirements under TSCA section 8(e). Further this guidance document imposes no requirements on any entities, and instead is announcing Agency policies