

and interpretations that generally will ease the reporting burdens under section 8(e). This action will not have substantial direct effects on State or tribal governments, on the relationship between the Federal government and States or Indian tribes, or on the distribution of power and responsibilities between the Federal government and States or Indian tribes. As a result, no action is required under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), or under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action requires no special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Specific Revisions to the Policy Statement

For the reasons discussed in Unit III., EPA is making the following specific changes to the 1978 Policy Statement:

1. Part II. Persons Subject to the Requirement is amended by revising the note at the end of Part II.

2. Part IV. Requirement That a Person "Immediately Inform" the Administrator, Part VII. Information Which Need Not Be Reported, and Part IX. Reporting Requirements are revised.

3. Part V. What Constitutes Substantial Risk is amended by revising the heading of paragraph (b) and paragraph (b)(1) and adding the paragraph heading "Environmental effects." to the beginning of paragraphs (b)(2) through (b)(5).

VIII. Republication of TSCA Section 8(e) Policy Statement and Guidance

As discussed previously, the following is a republication of the entire TSCA section 8(e) Policy Statement and Guidance, as amended:

I. Definitions

The definitions set forth in TSCA section 3 apply to this policy statement. In addition, the following definitions are provided for purposes of this policy statement:

The term *manufacture or process for commercial purposes* means to manufacture or process: (1) For distribution in commerce, including for test marketing purposes, (2) for use as a catalyst or an intermediate, (3) for the exclusive use by the manufacturer or processor, or (4) for product research and development.

The term *person* includes any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

The term *substantial-risk information* means information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

II. Persons Subject to the Requirement

Persons subject to section 8(e) requirements include both natural persons and business entities engaged in manufacturing, processing, or distributing in commerce a chemical substance or mixture. In the case of business entities, the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its section 8(e) obligations should ensure that the organization reports substantial risk information to EPA. The business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained. It is therefore incumbent upon business organizations to establish procedures for expeditiously processing pertinent information consistent with the schedule set forth in Part IV.

Those officers and employees of business organizations who are capable of appreciating the significance of pertinent information are also subject to these reporting requirements. An employing organization may relieve its individual officers and employees of any responsibility for reporting substantial-risk information directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for employee submission and corporate processing of

pertinent information. These procedures, at a minimum, should: (1) Specify the information that officers and employees must submit; (2) indicate how such submissions are to be prepared and the company official to whom they are to be submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly advising officers and employees in writing of the company's disposition of the report, including whether or not the report was submitted to EPA (and if not reported, informing employees of their right to report to EPA, as protected by TSCA section 23). An employee of any company that has established and publicized such procedures, who has internally submitted pertinent information in accordance with them, shall have discharged his section 8(e) obligation. Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that the appropriate substantial-risk information is reported to EPA.

Business organizations that do not establish such procedures cannot relieve their individual officers and employees of the responsibility for ensuring that substantial-risk information they obtain is reported to EPA. While officers and employees of such organizations may also elect to submit substantial-risk information to their superiors, for corporate processing and reporting, rather than to EPA directly, they have not discharged their individual section 8(e) obligation until EPA has received the information.

Note: Irrespective of a business organization's decision to establish and publicize procedures described above, the business organization is responsible for becoming cognizant of any "substantial risk" information obtained by its officers, employees, and agents, and for ensuring that such information is properly reported to EPA.

III. When a Person Will Be Regarded as Having Obtained Information

A person obtains substantial-risk information at the time he first comes into possession of or knows of such information.

Note: This includes information of which a prudent person similarly situated could reasonably be expected to possess or have knowledge. An establishment obtains information at the time any officer or employee capable of appreciating the significance of such information obtains it.