

may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

VI. References

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3. U.S. EPA. Letter from Charles M. Auer to Peter E. Voytek with attachment entitled: "Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Ethylene Dichloride, June, 1997." (June 26, 1997).
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List of Subjects

Environmental protection, Hazardous chemicals.

Dated: May 13, 2003.

Stephen Johnson,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 03-13721 Filed 6-2-03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0067; FRL-7287-4]

TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is hereby finalizing revisions to certain parts of EPA's "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (policy statement) issued March 16, 1978, concerning the reporting of "substantial risk" information pursuant to section 8(e) of the Toxic Substances Control Act (TSCA). EPA is making these revisions

after having considered public comments that were solicited in 1993 and 1995. Specifically, the revisions address the reporting of information on the release of chemical substances to, and the detection of chemical substances in, environmental media, the reporting deadline for written "substantial risk" information, and the circumstances under which certain information need not be reported to EPA under section 8(e) of TSCA. EPA is republishing the policy statement in its entirety in this document, including both those portions of the policy statement that are revised and those portions that are not affected by any revisions. Since the policy statement was published in 1978, this republication is intended to ensure that a single reference source for the TSCA section 8(e) policy and guidance is easily available to the regulated community and other interested parties.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Richard Hefter, Chief, High Production Volume Chemicals Branch, Risk Assessment Division, Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7649; e-mail address: hefter.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, import, or distribute in commerce chemical substances and mixtures. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers, processors, and distributors (NAICS 325)
- Petroleum refiners and distributors (NAICS 324)
- Manufacturers of plastic parts and components (NAICS 325211)
- Paints and coatings and adhesive manufacturing (NAICS 3255)
- Cleaning compounds and similar products manufacturing (NAICS 3256)
- Electronics manufacturing (NAICS 334 and 335)
- Automobiles manufacturing (NAICS 3361)

- Aircraft manufacturing (NAICS 336411)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit VIII., Part II., of this document. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2002-0067. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. Information about the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and OPPTS-related programs is available from <http://www.epa.gov/opptsmnt/>.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents

of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

II. Background

A. What Action is the Agency Taking?

The Agency is revising and clarifying certain provisions of the TSCA section 8(e) policy statement issued in 1978. Specifically the Agency is changing the interpretation that section 8(e) notices should be submitted within 15 working days by lengthening the reporting period to 30 calendar days. The Agency is revising and clarifying the guidance regarding the release and detection of chemical substances in environmental media, which includes previously unsuspected chemical contamination such as in soil and ground water, and emergency incidents of environmental contamination such as spills to water and releases to the atmosphere. Also, the Agency is expanding the types of information that it believes need not be reported under section 8(e) and changing the reporting periods to provide additional time for industry compliance with TSCA section 8(e). In addition, EPA is updating certain reporting contact phone numbers and the address for reporting section 8(e) notices.

While the Agency is only revising portions of the 1978 guidance it has issued in earlier documents, EPA is including in this **Federal Register** document, along with the revised guidance, those portions of earlier guidance documents that are not being changed. In that way, members of the regulated community will be able to find all current EPA guidance on compliance with section 8(e) in this **Federal Register** document, without having to consult older documents as well.

The Agency is including in this guidance document its preferences for how and where section 8(e) notices should be submitted. Although these preferences could be codified in procedural rules under the Administrative Procedures Act (APA), 5 U.S.C. 551 *et seq.*, EPA is not at this time adopting them as rules. While submitters of section 8(e) notices are not therefore obligated to comply with the preferences articulated in this document, EPA encourages submitters to consider and follow them when

preparing and submitting TSCA section 8(e) notices.

Finally, the bulk of this document contains EPA’s guidance on certain types of information it currently believes generally meet the statutory standard of “information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.” Some of this guidance is new, and reflects public comment following the Agency’s requests for comments in 1993 and 1995. As noted earlier, this document also contains earlier guidance issued on section 8(e) that has not been changed and that is being reprinted here for the convenience of all interested persons.

During the Compliance Audit Program (CAP) (see Unit II.C.), EPA reviewed the provisions in the reporting guidance for incidents involving chemical contamination of the environment. The changes set out in this document were developed as a result of that review. In 1993, EPA issued a **Federal Register** notice (58 FR 37735, July 13, 1993) that proposed changes to the reporting guidance. In 1995, after consideration of comments received on the 1993 proposal, EPA sought additional public comment on proposed changes to the reporting guidance (60 FR 14756, March 20, 1995) (FRL-4937-6). Unit III. describes the changes EPA proposed, the comments received on the proposed changes, and the Agency’s resolution of the issues raised by the comments.

B. What is the Agency’s Authority for Taking this Action?

TSCA section 8(e) states, “Any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C. 2607(e).

EPA hopes and expects that this guidance will be useful to manufacturers, including importers, processors, and distributors of chemical substances in fulfilling their responsibilities under section 8(e). This guidance is not, however, a substitute for rulemaking and it does not impose any binding requirements upon either the regulated community or the Agency. In any particular set of circumstances, any person who has a question about

the applicability of section 8(e) to certain information is welcome to contact EPA. In responding to such person, the Agency will consider the guidance contained in this document, but the guidance will not be determinative. It is also important to point out that the guidance provided will not be unalterable, and that the Agency may revise this guidance without notice or an opportunity to comment. EPA has sought public comment on this guidance so that it can ensure the utility of the guidance for the intended audience. If it becomes necessary, the Agency will revise this guidance.

C. What is the Agency's Current Policy on and Interpretation of the TSCA Section 8(e) Reporting Requirements?

The section 8(e) reporting requirements became effective on January 1, 1977, the effective date of TSCA. The statutory language of section 8(e) requires the exercise of a certain degree of judgment in determining what information must be reported. Although section 8(e) is self-implementing, EPA issued a proposed policy statement in the **Federal Register** of September 9, 1977 (42 FR 45362), and sought public comment with regard to the Agency's interpretation and implementation of section 8(e). Following receipt and consideration of public comments, on March 16, 1978 (43 FR 11110) (FRL-849-2), EPA issued a final TSCA section 8(e) policy statement hereinafter cited as the "1978 Policy Statement." The 1978 Policy Statement described the types of information that EPA considers reportable under section 8(e) and described the procedures for reporting such information to EPA.

In the **Federal Register** of February 1, 1991 (56 FR 4128), the Agency announced a one-time voluntary TSCA section 8(e) CAP. The CAP was designed primarily to: (1) Obtain any section 8(e) information that was required to have been submitted to EPA before the CAP, and (2) encourage companies to voluntarily search ("audit") their files for data reportable under section 8(e). The TSCA section 8(e) CAP established a schedule of monetary penalties for failure to submit section 8(e) data before the CAP, and also established a ceiling on penalties that would be collected from any single company.

D. The Reason for Issuing Revised Guidance

Companies considering whether to participate in the CAP had raised questions about Parts V.(b)(1) and V.(c) of the 1978 Policy Statement. Those

sections outlined the reportability of data on "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination," respectively. In order to answer the questions raised by the companies, the Agency reviewed existing section 8(e) guidance and determined that Parts V.(b)(1) and V.(c) of the 1978 Policy Statement needed clarification and refinement. Therefore, in the **Federal Register** of June 20, 1991 (56 FR 28458), EPA announced that the Agency was suspending application of Parts V.(b)(1) and V.(c) of the 1978 Policy Statement.

That **Federal Register** document also stated that EPA was going to provide more specific guidance about the types of information on environmental releases and detection of environmental contamination that should be submitted under section 8(e). Phase 2 of the CAP, which was to deal with data on environmental contamination, would be triggered by publication of that revised guidance (phase 1 of the CAP had dealt with studies of "effects" of toxic substances on health or the environment.). On July 13, 1993, EPA issued a **Federal Register** document (58 FR 37735) that proposed changes to the 1978 Policy Statement, clarifying the types of environmental contamination data that EPA believes are subject to section 8(e) reporting.

Comments received on the proposed changes took issue with a number of the revisions proposed by the Agency as well as with the original guidance. Based on the comments received, it became apparent that any final guidance would likely be significantly different from previous guidance and should therefore be applied prospectively. Since the CAP was essentially a retrospective exercise, the decision to make substantial revisions in the guidance for reporting on environmental contamination called into question the utility of carrying out phase 2. Consequently, the Agency, in consultation with CAP participants, decided to conclude the CAP after phase 1 "effects" reporting. Letters were sent to CAP participants announcing the change in the program, and the CAP was terminated on May 15, 1996. EPA reached final settlements with CAP participants, announced those settlements on October 15, 1996, and collected payment for stipulated penalties.

III. Section 8(e) Policy Clarifications and Revisions

EPA's interpretation of section 8(e) is that it requires the reporting of certain

"substantial risk" information concerning the release of chemical substances to, and the detection of chemical substances in, any environmental medium. In order to enhance implementation of TSCA section 8(e), EPA is, in this **Federal Register** document, publishing a complete version of the policy statement which reflects comments received on proposed refinements to the policy statement published on July 13, 1993 (58 FR 37735), and March 20, 1995 (60 FR 14756). EPA has also decided to reinstate application of Part V.(c) relating to "emergency incidents of environmental contamination," which was suspended on June 20, 1991 (56 FR 28458).

A. What Changes were Proposed in 1993?

In a notice published in the **Federal Register** on July 13, 1993 (58 FR 37735), EPA proposed the following changes to the 1978 Policy Statement:

1. Revise the 1978 reporting guidance as to when the discovery of "widespread and previously unsuspected [chemical] distribution in environmental media" would trigger a substantial risk notice under section 8(e). EPA indicated that the key elements to consider would be the known hazard potential of the contaminant, how "widespread" the substance is in the environment, and the potential for actual human or environmental exposure. EPA further stated that the weight to be given exposure considerations would be judged in light of hazard potential, i.e., the more hazardous the chemical the less one would weigh exposure considerations.

2. Expand the categories of information cited in the 1978 reporting guidance that EPA believed no longer need to be reported to under section 8(e). The major change proposed was intended to reduce the potential for TSCA section 8(e) submissions to be duplicative of reporting under other mandates, by allowing an exemption for information reported under other EPA reporting requirements (including those delegated to the states). Also, a clarification of what would constitute "corroborative" data not subject to reporting was proposed.

3. Change the interpretation that section 8(e) notices for information other than "emergency incidents of environmental contamination" should be submitted within 15 working days by lengthening the reporting period to 30 calendar days.

4. Eliminate the need to follow up an emergency release notification under Part V.(c) with a written report.

5. Clarify standards for claiming CBI in section 8(e) notices.

6. Correct the address under Part IX. of the 1978 Policy Statement.

B. Summary of Public Comments on the 1993 and 1995 Proposed Revisions and EPA's Responses

In addition to the brief summaries of public comments and Agency responses presented in this **Federal Register** document, EPA has prepared a "response to comments" document that addresses in greater detail the significant comments it received on the proposed changes. The public version of the "response to comments" document, which does not contain any CBI information, is publicly available in the docket described in Unit I.B.1 of this document.

1. Comments on the 1993 proposed changes. EPA received comments from 49 companies and industry associations in response to the 1993 **Federal Register** document. Commenters suggested that EPA's proposed plan for environmental reporting lacked criteria that were sufficiently clear to enable companies to separate "routine" releases, which need not be reported, from the "extraordinary" releases, which were to be reported under section 8(e). Commenters stated that EPA should provide clearer criteria for determining when a situation presents a "substantial risk," and should provide as many "bright lines" as possible to indicate what would and would not be reportable under section 8(e). Specifically, commenters:

- Questioned EPA's interpretation of when contamination would be "widespread."

- Stated that only a contaminant's "known" toxicity should be considered.

- Stated that for contamination to be reportable, it must be "previously unsuspected" contamination.

- Stated that the contamination must result in actual or high probability of significant exposure to humans or non-human organisms.

- Stated that any contamination to be reported under section 8(e) must "present" a substantial risk rather than only a speculative "may present."

- Proposed that EPA establish a decision tree that companies could follow to determine whether to report incidents involving environmental contamination under section 8(e). Commenters stated that if companies had sequential criteria, they would be in a much better position to comply with

the reporting requirements of section 8(e).

- Supported the change to the section 8(e) notice reporting period from 15 working days to 30 calendar days.

The bulk of the remaining comments concerned circumstances under which companies need not report information to EPA. EPA had proposed to exempt from reporting under TSCA section 8(e) information companies were required to report under other EPA authorities (including those delegated to the States). However, the exemption would only apply if the information was submitted under the other authorities within 30 days of obtaining the information. Commenters believed that this would offer little relief because many of the other authorities have reporting periods longer than 30 days. The companies would either have to accelerate their reporting under authorities other than TSCA section 8(e) or submit two reports, one within 30 days under section 8(e) and another within the time frame of the other requirement. The commenters suggested allowing a longer time frame, i.e., 90 days or longer, for that information submitted under authorities other than TSCA section 8(e).

Commenters also suggested expanding the "other authorities" exemption to include reporting under all Federal environmental statutes as well as State laws and regulations, especially when a site is undergoing remediation for contamination with hazardous waste and any environmental or health threats associated with those contaminants are being addressed in the course of the remediation.

Finally, EPA received comments on the relationship of the revised guidance to phase 2 of the CAP. The sentiment expressed by all those who commented on this issue was that, given the limited guidance in the 1978 Policy Statement, EPA's suspension of the guidance section on environmental contamination, and the likelihood that EPA's final guidance would be essentially "new," the final guidance should only be enforced prospectively. Consequently, companies should not be subject to any liability for past failures to report under the criteria of the "new" guidance.

2. EPA's response to comments on the 1993 proposed changes; the 1995 proposed draft guidance. In response to the comments received on the 1993 proposed changes to the 1978 guidance, on March 20, 1995, EPA issued revised proposed guidance to address the commenters' concerns.

First, in the 1995 notice, EPA proposed clarifications to the situations

involving environmental contamination which EPA believes would need to be reported. Language suggested in comments to the 1993 notice was adopted, specifying that the contamination must be "previously unsuspected," that "exposure" has occurred or there is a substantial likelihood that it will occur, and that the chemical(s) in question is "known" to cause serious adverse effects. EPA stated that information on those effects could be obtained from several sources:

- Databases available to the public (online or in paper versions), such as the National Library of Medicine (NLM) databases (Toxline, Medline, Hazardous Substances Data Bank, etc.), National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), EPA's Aquatic Toxicity Information Retrieval database (AQUIRE) (Now the Ecotoxicology (ECOTOX) database www.epa.gov/ecotox/).

- Reports to EPA or other government agencies.

- Unpublished data known to the person or entity subject to reporting.

As regards the issue of what is meant by "known" to cause serious adverse effects, EPA did not mean that the effects must be conclusively shown and did not intend a higher standard of certainty than for the "effects" reporting part of the 1978 Policy Statement. In that notice, EPA stated that all that is needed for an effect to be "known" is that the information reasonably supports that the chemical can cause the effect(s) of concern. This issue is addressed in the 1978 Policy Statement in EPA's response to comments that questioned the use of "may suggest" language regarding information obtained and the reporting of substantial risk information (see Supplementary Information paragraph (3) of the 1978 Policy Statement).

In addition, EPA agreed to allow the use of "benchmark levels" to help determine if the information should be reported. EPA has established benchmark levels for various substances. Benchmark levels are concentrations that either trigger a regulatory response, or concentrations above which a substance is presumed to present a risk to health and/or the environment. For instance, the Agency has developed Reference Doses (RfD's) for numerous substances under its Integrated Risk Information System (IRIS). Reference doses establish a level of exposure where no adverse effects would be expected to be manifested. Thus, if a person found groundwater contaminated with a chemical at a level that did not exceed the RfD for that

substance, the person could assume that a substantial risk does not exist. It should be noted that benchmark levels are often medium-specific, so their use should be limited accordingly.

Examples of certain benchmark levels can be found at the following EPA Web sites: <http://www.epa.gov/iris/> and <http://www.epa.gov/ost/drinking/standards/dwstandards.pdf>.

Second, EPA increased the number of types of information that it believed need not be reported under TSCA section 8(e). The types of information proposed to be exempted included:

- Draft and final reports made available to the public by other Federal agencies.
- Data obtained from scientific journals and databases, including, but not limited to, those to which EPA subscribes.
- Information obtained from news publications and radio/television broadcasts.

• Information obtained at scientific meetings or conferences where EPA is the sponsor, where the information is presented by an EPA employee or contractor acting on behalf of EPA, and at other similar meetings, provided that such information is cited or abstracted in a scientific journal or database within 90 days of a person subject to reporting under section 8(e) obtaining such information.

The rationale for these proposed changes was to relieve persons who are potentially subject to reporting under section 8(e) from the burden of considering information from secondary sources when the secondary source does not provide sufficient information for a person to judge whether the information should be reported. For instance, a manufacturer of a chemical might obtain a news article about research done by another company. A person reading the article would need the underlying study to evaluate the true significance of the results of the research and, based on that evaluation, make a judgment as to whether there is a substantial risk of injury to human health or the environment. In such a case, the potential reporting obligation falls on the company that generated the research discussed in the news article.

Third, EPA retained the interpretation proposed in the 1993 **Federal Register** notice that section 8(e) notices for information other than "emergency incidents of environmental contamination," should be submitted within 30 calendar days. EPA continues to believe that the change from 15 working days to 30 calendar days would significantly relieve the burden on persons subject to section 8(e) reporting

without substantially affecting EPA's ability to appropriately evaluate and respond in a timely manner to the reported information.

Fourth, EPA identified the group of statutes for which exemptions would be granted from reporting of non-emergency information under TSCA section 8(e), specifying the other statutes administered by EPA and those for which implementation was delegated to the States. The maximum allowable reporting period, in lieu of reporting under section 8(e), under those other authorities was increased from 30 to 90 days from the date reportable non-emergency situations of chemical contamination was obtained by a person subject to section 8(e), i.e., persons reporting to the other authorities within the 90-day time frame would be exempt from reporting the information under section 8(e). EPA believed that extending the time for reporting non-emergency situations of chemical contamination would allow for those instances where assembling several types of information in order to determine whether section 8(e) applies could take more than 30 days and was consistent with the majority of the reporting periods under the other statutes.

Fifth, if the Federal government or a State requires that information be submitted on a site remediation program carried out under Federal or State regulations, that information would not have to be separately submitted under section 8(e) beyond an initial section 8(e) notification. The Agency believed that once the chemical contamination situation has been identified, such as by a notice under section 8(e), and the site is undergoing remediation, little if any additional benefit is gained by subsequent section 8(e) reporting concerning that chemical contamination situation at the same site.

Sixth, usually only the person who operates or owns a site at which environmental contamination has occurred would have the responsibility to report under section 8(e). It is unlikely that a person not associated with a site as an owner or operator would have access to a sufficiently wide range of information about an environmental contamination situation to determine whether data on the contamination meet the test for section 8(e) reporting. This is unlike the acquisition of effects test data, because data on effects are not site-specific and have general applicability for production and use of the chemical of interest in the United States. Similarly, persons subject to section 8(e) would not have to report information obtained

about a site outside the United States unless there is potential for contamination from that site to enter the United States.

Seventh, because of the number of changes made to the proposed guidance in the 1995 **Federal Register** notice and the fact that it represented a significant change from the original guidance suspended on June 20, 1991, the Agency concluded that the revised guidance when issued should be applied prospectively. This eliminates the need for companies to review files currently in their possession for information that may be subject to section 8(e) reporting in accordance with the revised guidance. However, data in such files could be subject to section 8(e) reporting if data obtained by a company after issuance of the revised guidance triggered a review of such preexisting data and in doing so the combination of preexisting and new data met the section 8(e) reporting criteria.

Eighth, the Agency stated that it would develop, in cooperation with interested parties, a "question and answer" (Q. and A.) document that would provide further detail and "real world" examples to further assist persons in fulfilling their section 8(e) reporting responsibilities as regards the revised guidance. The Agency stated that it intends to work with interested parties to prepare such a Q. and A. document, which EPA expects to have available several months from the issuance of the final reporting guidance. At that time, the Agency intends to post the Q. and A. document on the TSCA section 8(e) homepage (<http://www.epa.gov/oppt/tsc8e>). A copy may also be obtained from the contacts listed under **FOR FURTHER INFORMATION CONTACT**. As additional examples, or questions and answers are identified as being of potential value to share broadly, the Agency will refine this Q. and A. document.

Finally, some commenters requested an additional opportunity to review the revised draft guidance developed in response to the extensive comments of the proposed revisions in the July 13, 1993 **Federal Register** notice. On March 20, 1995 (58 FR 37735), the Agency published a notice of availability in the **Federal Register** of the revised draft guidance and allowed 45 days for comment. The 1995 draft guidance substantially responded to the comments received on the 1993 proposed revisions.

3. Comments on the 1995 proposed changes and EPA's response. In response to the Agency's request for comment on the revised draft guidance published in 1995, EPA received

comments from 22 companies and trade associations. The commenters generally agreed that the changes made by EPA addressed most of their major comments on the 1993 proposed guidance, and that the 1995 revised guidance was a significant improvement. For example, the Monsanto Company stated: "The repropose guidance, as summarized in the draft policy text for public comment dated March 9, 1995, is a significant improvement over the guidance published July 13, 1993. The repropose guidance significantly minimizes the duplicative over-reporting burden that characterized the earlier guidance document. We support the repropose guidance document and believe it is generally consistent with the Congressional intent of the original drafters of TSCA, as well as current Agency and Congressional efforts to reform government reporting requirements to minimize duplicative and unneeded over-reporting. The repropose guidance document on environmental release/contamination is a significant move in the direction of clarifying the Agency's need for information that reasonably supports a conclusion of substantial risk." (Ref. 1).

In addition to their statements of support for the proposed changes, the commenters requested a number of clarifications/definitions of terms, editorial rewordings, and other less substantive changes that are addressed in a "response-to-comments" document that can be found in the docket as described in Unit I.B.1. Commenters expressed strong support for making the new guidance prospective, ending the CAP at phase 1, and developing a Q. and A. document. As previously discussed, EPA is in agreement with those comments.

One major area where industry commenters requested further changes was the exemption from reporting under section 8(e) for data submitted to EPA or other agencies under other authorities. The commenters were concerned about the extent to which exemptions from reporting under section 8(e) would be granted for reporting under authorities other than EPA statutes administered either by the Agency or, where implementation of an EPA statute has been delegated to the States. EPA had proposed to reduce the potential for duplicative submission under TSCA section 8(e) authorities by allowing an exemption to reporting under section 8(e) for all information which is required to be reported under other EPA statutes including where implementation had been delegated to the States, and where such reporting was required to be submitted within 90

days of being obtained. Industry commenters also questioned the length of the time period for reporting proposed by EPA. Industry commenters requested that the exemption be expanded to: (1) Include any mandatory reporting requirement whether Federal, State, or local, and (2) allow reporting within the time frame provided by the individual reporting authorities.

Regarding expanding the section 8(e) policy statement list of reporting authorities that would fall under a reporting exemption in Part VII. of the policy statement, the July 1993 and March 1995 proposals included an exemption to reporting only if the information was to be submitted under EPA statutes, including statutes such as the Clean Air Act, where implementation has been delegated in large part to the States. Delegation of implementation allowed a clear "nexus" to be shown between a State reporting requirement and EPA, thus following the statutory language of section 8(e) which does not require reporting if a company has "actual knowledge that the Administrator has been adequately informed of such information." The commenters would have EPA expand the reporting exemption by including any Federal, State, or local reporting requirements.

The issue of expanding the reporting authorities is problematic because of the statutory language in section 8(e). However, it is also relevant to look to the purpose of TSCA, and section 8(e) in particular, in light of the legislative history concerning how TSCA should be implemented. TSCA was designed to fill a number of regulatory gaps. Those included review of "new" chemicals, collection of test data on new and existing chemicals, and regulation of chemicals to address risks associated with chemicals' production, use, or disposal. Specifically, regarding the submission of test data, Congress wanted to avoid the potential for industry to withhold "information which would have revealed hazards associated with these chemicals at a much earlier date" (Ref. 2). Thus, the reporting requirement of section 8(e) of TSCA was established so that the Agency would be "adequately informed" to enable it to take corrective action if necessary. While Congress envisioned TSCA as filling a major gap in the regulatory framework protecting human health and the environment, it also directed the Administrator to avoid duplicating existing (and future) regulatory and enforcement authorities.

Given the statutory language of section 8(e), it is hard to make a case that the Administrator is adequately

informed of reporting under State or local authorities, other than those reporting requirements that originate in laws administrated by EPA in which the United States Congress has provided for delegation to the States, and such delegation has occurred. Except where such delegation of EPA authority has occurred, the Agency believes reporting to a state government may not result in EPA getting important information in a timely manner and, therefore, EPA does not believe it is appropriate to exempt from section 8(e), information that is reported to state governments.

However, at least some information reported under other Federal authorities could be viewed differently. While there is not a direct statutory "nexus," often there is a considerable amount of interagency cooperation in dealing with environmental contamination situations, e.g., the National Response Center. To the extent EPA Headquarters and the Regions become involved in joint cleanups, assessments, etc., or act in advisory roles with other Federal agencies, the Administrator could reasonably be considered to be adequately informed. The Agency believes that information reported under other Federal authorities for site-specific contamination within 90 calendar days or immediately pursuant to a mandatory reporting requirement qualifies for exemption from section 8(e) reporting.

While this approach reduces the role of section 8(e) in the reporting of site-specific release/contamination information, Congress' goal in passing TSCA to ensure that important health and environmental related information are reported in a timely fashion will still be met. Further, since there is now a considerable array of Federal health and environmental reporting requirements, including section 8(e), which provide such information and for which there is enhanced public access, Congress's goal is not considered to be compromised by some of the expanded exemptions.

However, product contamination information that could be required to be submitted to the Consumer Product Safety Commission (CPSC) under their regulations is not analogous. CPSC has a more narrow purview (i.e., consumer product safety) and could not adequately assess or address chemical contamination from a product that may also have industrial/commercial applications or may present potential environmental risks during its manufacture and processing. In such instances, reporting to EPA, as well as CPSC would allow EPA, consistent with the intent of TSCA, to address all the potential risks presented, where appropriate. Consequently, EPA has

concluded that section 8(e) reporting will continue to be required for chemical product contamination, because EPA, uniquely among Federal agencies, has the authority to address all potential health and environmental risk aspects of a chemical's life cycle.

Regarding the issue of expanding the reporting exemption in Part VII. of the section 8 policy statement to allow reporting within the time frame provided by the individual reporting authorities, as originally proposed in 1993, companies would not be required to report information under section 8(e) if the information was required to be submitted under other EPA or EPA-delegated authorities, so long as the other statute required reporting within 30 days from the day a person who was required to report obtained information required to be submitted. Commenters noted that only a few of the regulations required reporting within 30 days, so the exemption would be of limited value given that companies would still be required to report the information under section 8(e) as well as under the other regulations. To address this concern, the reporting policy is being changed. Companies would be exempt from reporting information under section 8(e) as long as the company complies with the relevant reporting requirement of another statute, as described in Part VII. of the TSCA section 8(e) policy and guidance, that requires reporting within 90 days from the day a person obtained information required to be submitted. This change was based on information submitted by industry showing that roughly 70 percent of the reporting requirements have reporting periods of 90 days or less (see Ref. 3 at page 29, Table 1). Further, an examination of the cited reporting requirements shows that the 90-day period will capture reports that otherwise would be required under section 8(e), namely newly found environmental contamination from spills, leaking tanks, and other types of releases. By and large, the types of reporting for which the statutory time limits for filing of mandatory reports are longer than 90 days include periodic summary reports, minor operating changes allowed by permits, etc.

It appears that most or all of the exposure-related or site-specific release/detection information that might be considered reportable under section 8(e) would be required to be reported under other authorities within 90 days of such information being obtained. Therefore, there would be a negligible reduction of the reporting burden if authorities whose reporting time limits exceed 90 days were also exempted from reporting

under section 8(e). Also, such a change seems inconsistent with the statutory language that substantial risk information be "immediately" reported. Given that a 90-day limit appears to resolve most of the problem with potentially duplicative reporting, and that longer limits may not be consistent with the statutory directive for "immediate reporting," EPA has decided to keep the reporting time limit at 90 days as proposed in the 1995 draft guidance.

Additionally, as proposed in the 1993 and repropose 1995 draft guidance, EPA is adopting the interpretation that section 8(e) notices for information other than "emergency incidents of environmental contamination" should be submitted within 30 calendar days. Thus the Agency is changing in this guidance document its interpretation of the term "immediately" in this context. EPA believes the term should be interpreted more flexibly based upon the Agency's experience of processing and use of data reported under section 8(e) and comments received from interested parties. EPA has concluded that, with the exception of reporting related to emergency incidents of environmental contamination, section 8(e) reports should be submitted to EPA within 30 calendar days of obtaining the reportable information, instead of the 15 working days that was articulated in previous guidance. The Agency believes that application of this interpretation for the statutory term "immediately" will not adversely impact section 8(e)'s purpose of assuring that the Agency becomes aware of important risk-related information in a timely manner. In addition, providing 30 calendar days for reporting to the Agency is consistent with the regulations under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, which provides that agencies should not require a written response in fewer than 30 days after receipt without demonstrating that it is necessary to satisfy a statutory requirement or other substantial need (5 CFR 1320.5(d)(2)(ii)). Although TSCA section 8(e) clearly provides the necessary statutory justification to require a shorter response time, the Agency is using the minimum time frame established under the PRA to respond to the commenters who indicated the need for additional time to process a submission.

C. EPA's reinstatement of Part V.(c)

"Emergency incidents of environmental contamination." Part V.(c) of the 1978 Policy Statement, which addresses what constitutes a "substantial risk" in the context of

emergency incidents of environmental contamination, was suspended on June 20, 1991 (56 FR 28458). EPA has decided, for the following reasons, to reinstate Part V.(c):

- EPA is making a number of changes to the reporting guidance that would affect emergency incident reporting. Changes include reporting to the National Response Center, elimination of follow-up written section 8(e) reports, and expansion of the list of authorities persons could report under in lieu of section 8(e).

- Part V.(c) includes the basic elements of the new Part V.(b)(1) guidance: The adverse effect(s) in question have been ascribed to the chemical; human or environmental exposure may occur; exposure (in this case, an emergency release) threatens humans and/or non-human organisms with serious adverse effects.

- EPA believes such reporting under section 8(e) is still necessary. Although many release incidents are covered under other statutes, there may be instances where chemicals that have not yet been reviewed for release reporting under other EPA programs have the requisite hazard characteristics to require a response/notification if there is a release to the environment. In this regard, EPA agrees with a comment from the Chemical Manufacturers Association (CMA—CMA is now the American Chemistry Council) indicating that, if EPA retains the distinction between emergency and non-emergency situations of environmental contamination, "emergency" should be defined. CMA stated: "CMA believes an 'emergency' should be defined as a situation in which a significant threat to human health or the environment is imminent or already present, and where immediate action is necessary to abate the hazard. Such an approach would be consistent with the Agency's previous description of non-emergency situations of environmental contamination as situations which do not require immediate action, but nevertheless reasonably support the conclusion of 'substantial risk.'" (Ref. 4). EPA believes that revised Part V.(b)(1), the reinstated Part V.(c), and the reporting procedures adequately make the distinction described by CMA in that a "substantial risk" in this context is an "emergency incident of environmental contamination" that "seriously threatens" humans or the environment.

IV. Claims of Confidentiality for Data Submitted under TSCA Section 8(e)

In general, health and safety information submitted to EPA—even as confidential—may be released to the

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

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.

IV. Requirement That a Person “Immediately Inform” the Administrator

With the exception of certain information on emergency incidents of environmental contamination (see Part V.(c)) and information submitted under Part VII. (c), (d) and (e), a person has “immediately informed” the Administrator if information is received by EPA not later than the 30th calendar day after the date the subject person obtained such information.

Supplementary information generated after a section 8(e) notification should, if appropriate, be immediately reported (within 30 calendar days of a person obtaining the information). This also applies to submitter responses to EPA requests for additional information related to submitted section 8(e) data. Section 8(e) reporting must be submitted to EPA and should be made as described under Part IX. For emergency incidents of environmental contamination, a person should report by telephone to the appropriate contact as directed in Part IX. as soon as the person has knowledge of the incident. The emergency incident report should contain as much of the information specified in Part IX. as is possible. A follow-up written report is not required.

Note: Preexisting information (i.e., of the kind described under Part V. (b)(1) and (c)) that predates June 3, 2003, is not subject to section 8(e) reporting unless its review is triggered by a person obtaining new information and that in combination with the preexisting information meets the criteria for section 8(e) reporting.

V. What Constitutes Substantial Risks

A “substantial risk of injury to health or the environment” is a risk of considerable concern because of (a) the seriousness of the effect (see subparts (a), (b), and (c) of this part for an illustrative list of effects of concern), and (b) the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is “substantial.”) These two criteria are differentially weighted for different types of effects. The human health effects listed in subpart (a) of this part, for example, are so serious that relatively little weight is given to exposure: The mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure. In contrast, the remaining effects listed in subparts (b) and (c) of this part must involve, or be accompanied by the potential for, significant levels of exposure (because of general production levels, persistence, typical uses,

common means of disposal, or other pertinent factors).

Note that information on the effects outlined below should not be reported: (i) If the respondent has actual knowledge that the Administrator is already informed of them, or (ii) information respecting these effects can be obtained either directly by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

The Agency considers effects for which substantial-risk information should be reported to include the following.

(a) *Human health effects.* (1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

(b) *Non-emergency situations involving environmental contamination; environmental effects—(1) Non-emergency situations of chemical contamination involving humans and/or the environment.* Information that pertains to widespread and previously unsuspected distribution in environmental media of a chemical substance or mixture known to cause serious adverse effects, when coupled with information that widespread or significant exposure to humans or non-human organisms has occurred or that there is a substantial likelihood that such exposure will occur, is subject to reporting. The mere presence of a chemical in an environmental media, absent the additional information noted above, would not trigger reporting under section 8(e). Information concerning the detection of chemical substances contained within appropriate disposal facilities such as treatment, storage and disposal facilities permitted under RCRA should not be reported under this part.

Note: From time to time EPA establishes concentrations of various substances in different media that trigger a regulatory response or establish levels that are presumed to present no risk to human health or the environment. For example, EPA establishes Maximum Contaminant Levels (MCLs) in drinking water, Ambient Water Quality Criteria for receiving bodies of water, and Reference Doses (RfDs) or Concentrations (RfCs). For the purposes of section 8(e),

information about contamination found at or below these kinds of benchmarks would not be reportable. Conversely, information about contamination found at or above benchmarks that trigger regulatory requirements, such as Resource Conservation and Recovery Act (RCRA) Toxicity Characteristic Limits, is to be considered for possible reporting, based on potential exposure to humans and/or non-human organisms and other relevant factors.

(2) *Environmental effects.*

Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) *Environmental effects.* Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media, should be reported.

(4) *Environmental effects.*

Ecologically significant changes in species’ interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species’ behavior, growth, or survival, should be reported.

Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

(ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) *Environmental effects.* Facile transformation or degradation to a chemical having an unacceptable risk as defined above should be reported.

(c) *Emergency incidents of environmental contamination.* Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects has been ascribed and which because of the pattern, extent, and amount of contamination (1) seriously threatens humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction, should be reported.

VI. Nature and Sources of Information Which “Reasonably Supports the Conclusion” of Substantial Risk

Information attributing any of the effects described in Part V. of this policy statement to a chemical substance or

mixture should be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII. of this policy statement. A person should not delay reporting until he obtains conclusive information that a substantial-risk exists, but should immediately report any evidence which "reasonably supports" that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Information from the following sources concerning the effects described in Part V. will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.

(1) *Designed controlled studies.* In assessing the quality of information, the respondent should consider whether it contains reliable evidence ascribing the effect to the chemical. Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate. Designed, controlled studies include:

(i) *In vivo* experiments and tests.

(ii) *In vitro* experiments and tests.

Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.

(iii) Epidemiological studies.

(iv) Environmental monitoring studies.

(2) *Reports concerning and studies of undesigned, uncontrolled circumstances.* It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of cancer, birth defects, mutation, death, or serious incapacitation in a human would be reportable if one (or a few) chemicals) was strongly implicated. In addition, it is possible that effects less serious than those described in Part V.(a) may be preliminary manifestations of the more serious effects and, together with another triggering piece of information, constitute reportable information; an example would be a group of exposed workers experiencing dizziness together with preliminary experimental results demonstrating neurological dysfunctions. Reports and studies of undesigned circumstances include:

(i) Medical and health surveys.

(ii) Clinical studies.

(iii) Reports concerning and evidence of effects in consumers, workers, or the environment.

VII. Information Which Need Not Be Reported

"Substantial risk" information need not be reported under section 8(e) if it:

(a) Is obtained in its entirety from one of the following sources:

(1) An EPA study or report.

(2) An official publication or official report (draft or final) published or made available to the general public by another Federal agency and any information developed by another Federal Agency as a result of a toxicological testing/study program, or site evaluation for chemical contamination, in which EPA is collaborating in the design, review, or evaluation of testing/sampling plans or resultant data.

(3) Scientific publications, including bibliographic databases, available electronically or in hard copy (e.g., Science, Nature, New England Journal of Medicine, Medline, Toxline, NIOSH RTECS, International Uniform Chemical Information Database (IUCLID), etc.).

(4) Scientific databases (e.g., Agricola, Biological Abstracts, Chemical Abstracts, Dissertation Abstracts, Index Medicus, etc.).

(5) A news publication (i.e., newspaper, news magazine, trade press with circulation in the United States).

(6) A radio or television news report broadcast in the United States.

(7) A public scientific conference or meeting held within the United States, provided that the information is captured accurately by way of a meeting transcript, abstract, or other such record, and has been cited in a bibliographic/abstract computerized data base, publication, or report of the type cited in paragraphs (a) (1), (2), (3), or (4) of this part within 90 days of a subject person obtaining such information.

(8) A public scientific conference sponsored or co-sponsored by EPA or at a conference where the subject information is presented by an EPA employee or contractor acting on behalf of EPA.

(b) Corroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose, species, strain, sex, time to onset of effect, nature and severity of effect, a well-recognized/well-established serious adverse effect for the chemical(s) under consideration, unless such information concerns effects observed in association with emergency incidents of environmental contamination as described in Part V.(c) and thus should be considered for reporting under section 8(e).

(c) Is information that will be reported to EPA within 90 calendar days of

obtaining the information for non-emergency information under Part V.(b)(1), immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information under Part V.(c), or within 30 calendar days of obtaining the information for the other types of information specified under Part V., pursuant to a mandatory reporting requirement of any statutory authority that is administered by EPA (including, but not limited to, the Toxic Substances Control Act; the Federal Water Pollution Control Act; the Clean Air Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Resource Conservation and Recovery Act, the Pollution Prevention Act; the Emergency Planning and Community Right-to-Know Act).

(d) Is information that will be reported to a State within 90 calendar days of obtaining the information for non-emergency information under Part V.(b)(1), immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information under Part V.(c), or within 30 calendar days of obtaining the information for the other types of information specified under Part V., pursuant to a mandatory reporting requirement under any Federal statute administered by EPA for which implementation has been delegated to that State (e.g., National Pollutant Discharge Elimination System (NPDES) permit requirements), or pursuant to a mandatory reporting provision of an EPA-authorized State program established under a Federal statute administered by EPA, e.g., state RCRA programs.

(e) Is information that will be reported to the Federal government within 90 calendar days of obtaining the information for non-emergency site-specific contamination information under Part V.(b)(1) or immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information under Part V.(c), pursuant to a mandatory reporting requirement under any Federal statute.

(f) Is information of the kind under Part V. (b)(1) and (c) submitted to the Federal government or a state that is developed in connection with an authorized (by the relevant Federal or state authority) site remediation program.

(g) Is information of the kind under Part V. (b)(1) and (c) concerning a site under the control of another person who is subject to the section 8(e) reporting authority.

(h) Is information of the kind under Part V.(b)(1) and (c) concerning a non-United States site provided the person who obtains the information does not have reason to believe that there is a substantial likelihood that the contamination will cause environmental contamination, of a nature that would be reportable under Part V. (b)(1) and (c), to occur in an area in the United States.

VIII. Information First Received By a Person Prior to the Effective Date of TSCA

Any substantial risk information possessed by a person prior to January 1, 1977, of which he is aware after that date should be reported within 60 days of publication of this policy statement. The Agency considers that a person is aware of:

(a) Any information reviewed after January 1, 1971, including not only written reports, memoranda and other documents examined after January 1, 1971, but also information referred to in discussions and conferences in which the person participated after January 7, 1977;

(b) Any information the contents of which a person has been alerted to by date received after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects;

(c) Any other information of which the person has actual knowledge.

IX. Reporting Requirements

Notices should be delivered to the Document Processing Center (7407M), (Attn: TSCA Section 8(e) Coordinator), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001

A notice should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency.

(b) State that it is being submitted in accordance with section 8(e).

(c) Contain the job title, name, address, telephone number, and signature of the person reporting and the name and address of the manufacturing, processing, or distribution establishment with which the person is associated.

(d) Identify the chemical substance or mixture (including, if known, the Chemical Abstract Service (CAS) Registry Number).

(e) Summarize the adverse effect(s) or risk(s) being reported, describing the nature and the extent of the effect(s) or risk(s) involved.

(f) Contain the specific source of the information together with a summary and the source of any available supporting technical data.

For emergency incidents of environmental contamination (see Part V.(c)), a person should report the incident to the Administrator or the National Response Center by telephone as soon as he/she has knowledge of the incident. The report should contain as much of the information specified by paragraphs (c) through (f) of this part as possible. If any new substantial risk information concerning the incident and reportable under TSCA section 8(e) is obtained, supplementary reporting by the person is required. A twenty-four hour emergency telephone number is:

The National Response Center, (800) 424-8802 or (202) 267-2675 in the Washington, DC metropolitan area.

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), (617) 223-7265.

Region II (New York, New Jersey, Puerto Rico, Virgin Islands), (201) 548-8730.

Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), (215) 814-3255.

Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), (404) 562-8700.

Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), (312) 353-2318.

Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), (214) 655-6428.

Region VII (Nebraska, Iowa, Missouri, Kansas), (913) 281-0991.

Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), (800) 227-8917.

Region IX (California, Nevada, Arizona, Hawaii, Guam), (415) 972-4400.

Region X (Washington, Oregon, Idaho, Alaska), (206) 553-1263.

X. Confidentiality Claims

(a) EPA may release to the public health and safety data claimed confidential, including information submitted in a notice of substantial risk under section 8 (e) of TSCA. EPA will disclose any information claimed confidential only to the extent, and by means of the procedures, set forth in 40 CFR part 2 (41 FR 36902, September 1, 1976)

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file to be available to the public without further notice to the submitter.

(c) To assert a claim of confidentiality for information contained in a notice,

the submitter must submit two copies of the notice.

(1) The first copy should be complete and unedited, clearly reflecting what specific information is being claimed confidential. This should be done on each page by placing brackets around the specific information in question together with a label such as "confidential," "proprietary," or "trade secret."

(2) The second copy should be identical to the first copy, but with all bracketed information blanked out within the brackets.

(3) Information within the first confidential copy of the notice will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR part 2. The second copy will be placed in an open file to be available to the public

(d) Any person submitting a notice containing information for which they are asserting a confidentiality claim should send the notice in a double envelope.

(1) The outside envelope should bear the same address outlined in Part IX. of this policy statement.

(2) The inside envelope should be clearly marked "To be opened only by the OPPT Document Control Officer."

(e) The submitter should substantiate any CBI claims by answering substantiation questions according to the instructions located in the TSCA section 8(e) website: <http://www.epa.gov/opptintr/tscas8e/doc/cbi.htm>

XI. Failure to Report Information

Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under section 8(e). Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Pursuant to section 17, the Government may seek judicial relief to compel submittal of section 8(e) information and to otherwise restrain any violation of section 8(e).

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 15, 2003.

Stephen L. Johnson,

Assistant Administrator for Prevention, Pesticides, and Toxic Substances.

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