Section 8(e) Requirement to Report Substantial Risks to Health or the Environment

Summary of the Requirement. 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, must inform the EPA of the information unless the person knows that the EPA has already been adequately informed. Such information is commonly referred to as "substantial risk information."[1]

Who is Subject to the Requirement? All manufacturers, importers, processors and distributors in commerce of chemical substances, as well as certain company officers and employees, are subject to this requirement.[2] A business organization can relieve its individual officers and employees of responsibility for reporting directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for internal submission and corporate processing of pertinent information. Those procedures must at a minimum (1) specify the information that officers and employees must internally submit; (2) indicate how the 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 the officer or employee in writing of the company's disposition of the report, including whether or not the report was submitted to EPA.

Any employee of a company that has established and internally publicized such procedures, and who has submitted information in accordance with them, has discharged his Section 8(e) reporting obligations. Notwithstanding the establishment of such procedures, all officials responsible and having authority for the organization's execution of its TSCA §8(e) obligations retain personal liability for ensuring that the appropriate "substantial risk" information is reported to EPA (68 FR 33137, June 3, 2003). Individuals retain their right, protected under TSCA Section 23, to report directly to EPA irrespective of their company's decision whether or not to report.[3]

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1. On March 16, 1978, the EPA published a "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (the "1978 Statement") concerning the Section 8(e) requirement (43 FR 11110-16). The language in the 1978 Statement was revised on June 3, 2003 when the USEPA replaced the 1978 Statement with new reporting guidance titled "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance" ("2003 Guidance" or "Guidance"). The 2003 Guidance provides guidance for compliance purposes and is reprinted on the following pages. The 2003 Guidance is interpretive guidance and a statement of Agency policy, and is, according to the Agency, thus exempt from the notice-and-comment provisions of the Administrative Procedure Act (5 U.S.C. §553). The EPA's 2003 Guidance is, therefore, not a rule or regulation, and is not found in the Code of Federal Regulations.

2. Company officers and employees who are individually responsible for ensuring reporting under the TSCA Section 8(e) requirement include the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its Section 8(e) obligations. Also, any other officer or employee who is capable of appreciating the significance of pertinent information is subject to the Section 8(e) reporting requirements (68 FR 33137, June 3, 2003).

3. TSCA Section 23 provides in part that

> No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has-
>
> 1. commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;
>
> 2. testified or is about to testify in any such proceeding; or
>
> 3. assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

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What information Must be Reported? Section 8(e) requires the reporting of information that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. EPA defines a "substantial risk of injury to health or the environment" as a risk which is of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. These two criteria should be weighed differently depending upon the seriousness of the effect and the extent of the exposure, i.e., the more serious the effect, the less heavily one should weigh the actual or potential exposure, and vice versa.[4] Any economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether the risk is "substantial" (68 FR 33138, June 3, 2003). Several examples of substantial risk information in the areas of human health effects, environmental effects, and emergency incidents of environmental contamination are discussed in parts V and VI of the 2003 Guidance. The Guidance's part VII discusses information that is exempt from Section 8(e) reporting.

When Must the Report be Submitted? All non-exempt substantial risk information must be received by EPA not later than the 30th calendar day after the date the person obtains the information, [5] with the exception of

1) information on emergency incidents of environmental contamination (which must be reported by telephone as soon as a person has knowledge of the incident), and
2) certain specified types of information, including information that will be reported to the USEPA or to certain other authorities within specified time periods.[6]

Special Notes. EPA considers effects for which substantial risk information must be reported to include **1) human health effects, 2) non-emergency situations involving environmental contamination,** and **3) emergency incidents of environmental contamination.** Part V of EPA's 2003 Guidance for Section 8(e), which is printed immediately following this explanation, contains guidance as to effects which must be reported:

1) Human Health Effects include: a) 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; and b) 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.

As noted above, a "substantial risk of injury to health or the environment" is a risk of considerable concern because of 1) the seriousness of the effect and 2) the fact or probability of its occurrence. The Agency states in Part V of its Guidance that the human health effects listed above are so serious that relatively little weight is given to exposure—the mere fact that the implicated chemical is in commerce constitutes sufficient evidence of exposure (68 FR 33138, June 3, 2003). The Agency has stated that:

> "In some cases, e.g., the observance of certain types of serious toxicologic effects in animals or humans, exposure to the chemical substance(s) or mixtures is presupposed and will constitute suffi-

4. 56 FR 4128 (February 1, 1991); 68 FR 33138 (June 3, 2003).
5. See Part IV of EPA's 2003 Guidance. 68 FR 33138 (June 3, 2003).
6. See Part VII(c) through (h) of the 2003 Guidance.

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> cient evidence of exposure for a determination to be made to submit the new-found toxicological data. Such serious effects include, but are not limited to, (1) Birth defects and/or serious developmental effects (including those observed in the presence of maternal toxicity), and (2) cancer (as evidenced by benign and/or malignant tumors).
> "Any decision-making process for determining section 8(e)-reportability should focus primarily on whether new toxicologic or exposure data offer reasonable support for a conclusion of substantial risk and should not focus to any great extent, if at all, on whether the information is conclusive regarding the risk. Therefore, a decision to report pursuant to section 8(e) should not involve (1) Exhaustive health or environmental assessments, or (2) any evaluation of the economic or social benefits of the use(s) of the subject chemical(s)." 56 FR 4128 (February 1, 1991).

The US EPA has stated that if certain serious health effects are discovered, the information should be considered for immediate reporting under section 8(e) without further evaluation:

> "The following are examples of information that should be considered immediately for reporting under section 8(e) of TSCA.
> "1. New information concerning statistically or biologically significant increases in benign and/or malignant tumors in an animal study; a "weight-of-the-evidence" risk assessment should not be used to discount the findings.
> "2. Statistically or biologically significant increases in teratologic or other serious reproductive effects observed in animals; the level of maternal toxicity observed in the study should not be used to discount the findings.
> "3. Serious toxic effects (e.g., cancer, birth defects, and neurotoxicity) observed in tests of chemical substances or mixtures at the research and development stage; such findings should not be discounted because the company believes that there is no exposure to the chemical(s).
> "Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA's section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e)." 56 FR 4128 (February 1, 1991).

In contrast to the human health effects information discussed above, the effects listed below ("non-emergency situations involving environmental contamination," and "emergency incidents of environmental contamination") must involve, or be accompanied by the potential for, significant

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levels of exposure (because of general production levels, persistence, typical uses, common means of disposal, or other pertinent factors).[7]

2) Non-Emergency Situations Involving Environmental Contamination include:
a) 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 to non-human organisms has occurred, or that there is substantial likelihood that such exposure will occur); [8]
b) measurements and indicators of pronounced bioaccumulation[9] not known to the Administrator should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect;
c) any non-trivial adverse effect not known to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media;
d) ecologically significant changes in species' interrelationships;[10] and
e) facile transformation or degradation to a chemical having an unacceptable risk as defined above.

3) Emergency Incidents of Environmental Contamination include 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 a) 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.

Information attributing any of the effects described above (under Human Health Effects, Non-Emergency Situations Involving Environmental Contamination, or Emergency Incidents of Environmental Contamination) to a chemical substance or mixture should be reported if it is from 1) designed, controlled studies, or 2) reports concerning and studies of undesigned, uncontrolled circumstances. These types of information are further explained in Part VI of the Agency's Guidance: "Nature and Sources of Information Which 'Reasonably Supports the Conclusion' of Substantial Risk."

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7. 68 FR 33138 (June 3, 2003).

8. The mere presence of a chemical in an environmental media, absent the additional information noted in this paragraph "a)", would not trigger reporting under section 8(e). Also, 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 Section 8(e). 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 (AWQC) 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. 63 FR 33138 (June 3, 2003).

9. Such measurements and indicators include 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. 63 FR 33138 (June 3, 2002).

10. Ecologically significant changes in species' interrelationships include changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth or survival. Examples include: 1) excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems; 2) interference with critical biogeochemical cycles, such as the nitrogen cycle. 63 FR 33138 (June 3, 2003).

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Information Which Need Not Be Reported. "Substantial risk" information need not be reported under TSCA Section 8(e) if:

(a) It is obtained in its entirety from one of the following sources:
1. A USEPA study or report;
2. An official draft or final publication or report published or made available to the general public by another Federal agency;
3. Information developed by another Federal agency as a result of a toxicological testing/study program in which the USEPA is collaborating with respect to design, review, or evaluation of testing/sampling plans or resultant data;
4. Scientific publications, including bibliographic databases, available electronically or in hard copy;
5. Scientific databases, for example, Agricola, Biological Abstracts, Chemical Abstracts, Dissertation Abstracts, Index Medicus, etc.;
6. A news publication, for example, a newspaper, news magazine or trade press with circulation in the United States; or a radio or television news report broadcast in the United States;[11]
7. A public scientific conference or meeting held within the United States, provided, however, that:

a) the information is captured accurately by means of a meeting transcript, abstract or other similar record; and

b) the information has been cited in a database, publication or report of the type described in Paragraphs 1., 2., 3., 4., or 5. above within 90 days of the subject person obtaining the information;
8. A conference where the subject information is presented by a USEPA employee or by a contractor acting on behalf of the USEPA; or
9. A public scientific conference sponsored or co-sponsored by the USEPA.

(b) It corroborates (i.e., substantially duplicates or confirms) a well recognized/well established serious adverse effect in terms of, for example, 1. routes of exposure; 2. dose; 3. species; 4. strain; 5. sex; 6. time-to-onset of effect; and 7. nature and severity of effect, for the chemical(s) under consideration. However, this exemption from reporting does not apply if the information concerns effects observed in association with "emergency incidents of environmental contamination."

(c) It is information that will be reported to the USEPA:
1. Within 90 calendar days of obtaining the information (for non-emergency situations involving environmental contamination, with respect to "widespread and previously unsuspected distribution in environmental media"); or
2. Immediately (for "emergency incidents of environmental contamination"); or
3. Within 30 calendar days of obtaining the information (for all other types of §8(e) reportable information)

pursuant to a mandatory reporting requirement of any statutory authority that is administered by the USEPA (including but not limited to mandatory reporting requirements in: TSCA; FIFRA; the

11. The rationale for these exemptions from section 8(e) reporting is 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. 68 FR 33133 (June 3, 2003).

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Clean Water Act; the Clean Air Act; the Safe Drinking Water Act; the Marine Protection, Research and Sanctuaries Act; CERCLA ("Superfund"); RCRA; the Pollution Prevention Act; and EPCRA).

(d) It is information that will be reported to a State:
1. Within 90 calendar days of obtaining the information (for non-emergency *site-specific* contamination information, with respect to "widespread and previously unsuspected distribution in environmental media"), or
2. Immediately (for "emergency incidents of environmental contamination") or
3. Within 30 calendar days of obtaining the information (for all other types of §8(e)-reportable information)

pursuant to a mandatory reporting requirement under any Federal statute administered by the USEPA for which implementation has been delegated to that State (for example, NPDES permit requirements), or pursuant to a mandatory reporting provision of an EPA-authorized State program established under a Federal statute that is administered by the USEPA, for example State RCRA programs.

(e) It is information that will be reported to the Federal government:
1. Within 90 calendar days of obtaining the information (for non-emergency *site-specific* contamination information, with respect to "widespread and previously-unsuspected distribution in environmental media"); or
2. Immediately (for "emergency incidents of environmental contamination")

pursuant to a mandatory reporting requirement under any Federal statute.

(f) It is information regarding:
1. non-emergency incidents of environmental contamination with respect to "widespread and previously-unsuspected distribution in environmental media"; or
2. "emergency incidents of environmental contamination"

that is submitted to the Federal government or to a State that is developed in connection with an authorized (i.e., authorized by the relevant Federal or State authority) site remediation program.

(g) It is information regarding:
1. non-emergency incidents of environmental contamination with respect to "widespread and previously-unsuspected distribution in environmental media"; or
2. "emergency incidents of environmental contamination"

concerning a site under the control of another person who is subject to the TSCA §8(e) reporting requirement.

(h) It is information regarding:
1. non-emergency incidents of environmental contamination with respect to "widespread and previously-unsuspected distribution in environmental media"; or
2. "emergency incidents of environmental contamination"

concerning a non-United States site, provided that 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) to occur in an area of the United States.

Making Claims of Confidentiality of Information. In Section X ("Confidentiality Claims") of its 2003 Guidance the USEPA states that: "EPA may release to the public health and safety data claimed confidential, including information submitted in a notice of substantial risk under

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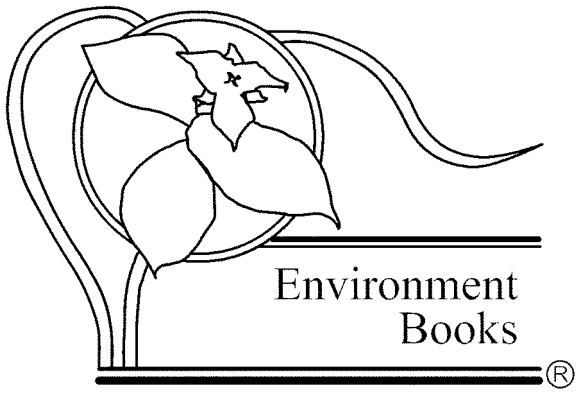
Section 8(e) of TSCA. EPA will disclose any information claimed confidential only to the extent, and by means of the procedures, set forth in 40 CFR part 2." Companies should follow the procedures specified in Sections X(c), (d) and (e) of the Guidance when claiming that submitted information is confidential. By following those procedures, companies will help ensure that confidential information is not made part of the file available to the general public. The procedures involve creating and submitting two copies of the TSCA Section 8(e) notice as described in Sections X(c) and (d), and substantiating all claims of confidentiality at the time of first submittal of the Section 8(e) information to EPA as described in Section X(e).

TSCA Section 8(e) Compliance Audit Program (CAP). In February, 1991, the US EPA announced a "one-time voluntary compliance program designed to strongly encourage companies to voluntarily audit their files for studies reportable under section 8(e)." This Compliance Audit Program (the TSCA CAP) provided a limited time frame within which participating companies could report previously-unreported studies, with stipulated penalties and a limit on total liability of $1 million per company. This voluntary program was designed to provide the Agency with a potentially substantial amount of information while insulating companies from significant penalties for late reporting. [12] Over 100 companies participated in the CAP. The CAP is now ended.



12. Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56 FR 4128 (February 1, 1991); 56 FR 19514 (April 26, 1991); 56 FR 23458 (June 20, 1991); 56 FR 49478 (September 30, 1991).

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