U.S. Environmental Protection Agency

TOXIC SUBSTANCES CONTROL ACT

Notification of Substantial Risk Under Section 8(e)

Policy Clarification and Reporting Guidance

Source: 68 FR 33129-33140 (June 3, 2003); 70 FR 2162-2164 (Jan 12, 2005)

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: (i) The effects outlined below should not be reported if the respondent has actual knowledge that the Administrator is already informed of them. (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. Nature and Sources of Information Which "Reasonably Supports Conclusion" of Substantial Risk.

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, 1977, including not only written reports, memoranda and other documents examined after January 1, 1977, but also information referred to in discussions and conferences in which the person participated after January 1, 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 CPR 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/tsca8e/doc/cbi.htmXI.

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).