

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.