

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