

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.

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#### 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,