

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) below 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) below, 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) below 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.

The Agency considers effects for which substantial-risk information must 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) *Environmental effects*—(1) Widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).

(2) Pronounced bioaccumulation. 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) 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.

(4) 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.

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.

(5) Facile transformation or degradation to a chemical having an unacceptable risk as defined above.

(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.

NOTICES - Federal Register

Vol. 43, No. 52

Thurs., March 16, 1978

Pages 11111-11112

IX. REPORTING REQUIREMENTS

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

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 distributing establishment with which he is associated.

(d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number).

(e) Summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and

(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 shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (b) through (f) above as possible. A written report, in accordance with instructions (a) through (f) above, is to be submitted within 15 days. Twenty-four hour emergency telephone numbers are:

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), 215-597-9898.

Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.

Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.

Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.

Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.

Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.

Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6254.

Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

NOTICES - Federal Register
Vol. 43, No. 52
Thurs., March 16, 1975
Page 11113