

TO: See Distribution

Please note particularly
Page 3 of the attachment
dated 12/15/78 covering
emergency incidents and the
text of Parts V and IX of
the EPA Policy Statement.

W.R.C.

4-2017)

LOYEES RE
TANTIAL RISK
N 8(e) -
NTROL ACT

M. C. Throdahl
P. S. Park
G. Roush, Jr.

D1D
E2NE
A2SA

MAP

IRC

Res. Labs

MCI

MPR

CH

Please see that all personnel in your Operating Company
or your Organizational Unit in Grade Level 34 and above
receive a copy of the attached packet of procedures
and guidelines for compliance with the legal requirements
of Section 8(e) of TSCA.

This packet consolidates all information that has been
communicated to our employees and includes the original
Internal Procedures and Supplements thereto. It gives
each employee ready reference to his obligations and
rights, together with Company policy with respect to the
handling of substantial risk information.

I know you recognize the need for maintaining a high
degree of awareness amongst our employees on Section 8(e)
and I very much appreciate your cooperation in helping
me achieve this end.

Will you please confirm to me when this requested distri-
bution has been completed.

WRC
W. R. Corey
Director, TOSCA

WRC:ms

Attachments

NOTIFICATION OF EMPLOYEES RE
TRANSMITTAL OF SUBSTANTIAL RISK INFORMATION

SECTION 8(e)

TOXIC SUBSTANCES CONTROL ACT

SECTION 8(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS

"Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such a substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

INTERNAL PROCEDURES FOR TRANSMITTAL
OF SUBSTANTIAL RISK INFORMATION
TO THE DIRECTOR OF DMEH
MONSANTO COMPANY

The Toxic Substances Control Act obligates the Company to report immediately to the U. S. Environmental Protection Agency any information it obtains which reasonably supports the conclusion that a chemical substance or mixture manufactured, processed or distributed in commerce by the Company presents a substantial risk of injury to health or the environment. (Information need not be reported if it is known that the U. S. EPA already has it.)

In order to fulfill this obligation, it is necessary to establish a communications network within the operating companies and other specified organizational units to facilitate the transmission of pertinent information. Each specified organizational unit shall have a designated individual to whom such information should be communicated. They are as follows:

C. F. Callis	-	MIC
W. D. Carpenter	-	MAP
R. K. Flitcraft	-	MRC
P. H. Hobson	-	MTC
D. E. Morris	-	Corp. Research Labs
J. B. Duncan	-	MCP
W. B. Papageorge	-	MCI
R. H. Schlattman	-	MPR
A. W. Andrews	-	CED
P. O. DeGarmo	-	DMEH

The procedure described below shall be followed in order to provide for a rapid and orderly flow of such information.

Anyone obtaining information of the type described above should immediately submit such information to his supervisor. The supervisor shall immediately relay the information to the location or department manager, whichever is applicable, who in turn transmits it to the proper designated individual in his organizational unit. The information is then transmitted directly to the Director of the Department of Medicine and Environmental Health.

It is imperative that the flow of information through this transmittal chain be rapid. In the event of non-availability of a member of the communication's network at the time information is first obtained, such member should be by-passed in the interest of speed.

All individuals involved in submission of substantial risk information to the Director of DMEH should keep a record of date of receipt and pertinent identifying details.

With respect to all information received by the Director of DMEH under Section 8(e), a Committee comprised of the Director of DMEH, Environmental Counsel and the appropriate Operating Company Director, Environmental Operations will determine on behalf of the Company whether a reporting obligation exists and will act accordingly. Personnel through whom the information was submitted shall be informed of the decision concerning reporting and the reasons for the action taken.

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SUPPLEMENT TO INTERNAL PROCEDURES FOR TRANSMITTAL OF

SUBSTANTIAL RISK INFORMATION TO THE DIRECTOR OF DMEH, MONSANTO COMPANY

On March 16, 1978, the EPA published in the Federal Register its "Statement of Interpretation and Enforcement Policy" which describes the Agency's interpretation of Section 8(e) of the Toxic Substances Control Act. The Statement asserts that the reporting obligation on substantial risk information applies to individual officers and employees of a company who are capable of appreciating the significance of pertinent information as well as the company itself. However, the Statement continues by saying that the individual reporting obligation can be fully discharged by notifying a designated company official of the pertinent information in accordance with procedures established by the Company.

Monsanto established such procedures shortly after passage of the Act and subsequently, in accordance with policy adopted by the Environmental Policy Committee on November 14, 1977, reissued its internal procedural mechanisms and you have received the revised reporting procedure dated December 9, 1977.

The EPA Statement also described certain provisions which should be part of a company's internal procedures governing notifications. In order to fully comply with the EPA recommendations, this supplement to the previous procedure is being distributed.

WHAT CONSTITUTES SUBSTANTIAL RISK

Section 8(e) of TSCA does not define what constitutes substantial risk information. However, a "substantial risk of injury to health or the environment" is a risk of considerable concern because of:

- (a) the seriousness of the effect;
- (b) the fact or probability of its occurrence;
- (c) the nature and extent of exposure to the risk.

These criteria need to be weighted differently for different types of effects, both human and environment. If there is any doubt as to whether information should be reported, it should be submitted in accordance with our procedures to your designated organizational unit individual for review by the committee established for this purpose. It should be noted that information need not be reported if you have knowledge that the EPA has already been informed of it or it has been published in the scientific literature.

EMPLOYEES RIGHTS

Monsanto's policy and its internal substantial risk reporting procedures state that employees who submit information through Company channels will be notified of action taken, together with the reasons for such action. If the employee disagrees with the Company's decision that the information need not be reported, he has the right to report such information directly to the EPA and the Act provides that no employer may discharge or otherwise discriminate against an employee because that employee assisted or participated in an action to carry out the purposes of the Act.

PENALTIES

Section 16 of TSCA contains specific penalties for violation of Section 8(e). These are (1) a civil penalty not to exceed \$25,000 per day, and (2) in the event of knowing or willful violation, criminal penalties consisting of a fine of not more than \$25,000 per day or imprisonment for not more than one year, or both.

If you have any questions concerning this Section 8(e), you should address them to the designated individual for your organizational unit.

NOTIFICATION OF SUBSTANTIAL RISK

EMERGENCY INCIDENTS OF ENVIRONMENTAL CONTAMINATION

Part V of the EPA Statement of Interpretation and Enforcement Policy covering notification of substantial risk under Section 8(e) of the Toxic Substances Control Act deals with the types of information a person obtains which the EPA believes "constitute substantial risk" and thus should be reported. The full text of this Part V of the EPA Statement is reproduced and attached herewith, together with Part IX covering "Reporting Requirements." 

This communication is being issued to draw your particular attention to Subsection (c) of Part V which deals with "Emergency incidents of environmental contamination" and to the last section of Part IX which spells out how such incidents should be reported.

Emphasis on review of these specific subsections is being urged because of the timing of the report to EPA with respect to information concerning an emergency incident of environmental contamination which reasonably supports the conclusion that such contamination presents a substantial risk of injury to health or the environment. EPA has established in its enforcement policy that the incident should be reported by telephone within 24 hours, followed by a written report within 15 days.

Our existing internal procedures for transmitting any type of substantial risk information to the Director of the Department of Medicine and Environmental Health should be followed except that, in the case of emergency incidents, the following paragraph from the December 9, 1977 instructions should be invoked:

"It is imperative that the flow of information through this transmittal chain be rapid. In the event of non-availability of a member of the communications network at the time information is first obtained, such member should be by-passed in the interest of speed".

Immediately upon receipt by the Director of DMEH, of information referred to above, he will determine its reportability to EPA and act accordingly. Persons through whom the information was submitted shall be informed of the decision concerning reporting and the reasons for the action taken.

When an incident is reported to the EPA, a follow-up written report will be prepared and submitted during the prescribed 15 day time-frame.

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: (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) 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.

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IX. REPORTING REQUIREMENTS

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WE-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.

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