RECORDING ALLEGATIONS OF SIGNIFICANT ADVERSE REACTIONS UNDER TSCA - U.S.

Monsanto procedure for handling the Recordkeeping Requirements of Final U.S. Environmental Protection Agency Rule Under Section 8(c) of the Toxic Substances Control Act (TSCA).

1. ***Abstract of Rule*** - Manufacturers and certain processors of chemical substances and mixtures must maintain records of significant adverse reactions to health or the environment alleged to have been caused by a substance, mixture, article, process, effluent or emission. These records are subject to EPA inspection.

   Rule Reference - 40 CFR Part 717 (48 FR 38178 - August 22, 1983)

   Note: The Rule does not apply to pesticides, food, food additives, drugs or cosmetics when manufactured, processed or distributed for these uses.

2. ***Key Definitions*** - (See Section 717.3 of the Rule for complete listing of definitions.)

   a. "Allegation" means a statement made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

   b. "Known human effect" means a commonly recognized human health effect of a particular substance or mixture described either in:

      i. Scientific articles or publications abstracted in standard reference sources.
      ii. The firms product labeling or material safety data sheets (MSDS).

   However, an effect is not a "known human effect" if it:

      i. Was a significantly more severe toxic effect than previously described.
      ii. Was a manifestation of a toxic effect after a significantly shorter exposure level than described.
      iii. Was a manifestation of a toxic effect by an exposure route different from that described.

   c. "Significant adverse reactions" are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

3. ***Exemptions from the Rule that relate to Monsanto***

   a. Activities involving solely mining or other solely extractive functions.

   b. Significant adverse reactions that are known human effects.

   c. Significant adverse reactions to the environment directly attributable to incidents of environmental contamination that have been reported to the federal government under any applicable authority.

4. ***Who can receive an allegation?***

   Allegations can come from a variety of sources including employees, contractors, customers and neighbors.

   As a result, Monsanto's receiving network must be broad Initial receptors include: plant, laboratory and other Monsanto location supervision; plant and other Monsanto location managers, the Monsanto medical community at all locations, the offices of the Operating Company Directors of Environmental Operations, sales and marketing contacts, switchboard operators at all locations and environmental network contacts.

5. ***Procedure for Handling Health or Environmental Allegations***

   The Monsanto Toxic Substances Control Act (TSCA) Section 8(c) procedure consists of a four-step review and decision process. (Note: A separate procedure for litigation claims will be used see Appendix 3.1.
   A determination than an allegation is not recordable under the Rule can be made at any step in the process. The procedure is shown schematically on Appendix 3.2).

5. ***Procedure for Handling Health or Environmental Allegations*** **(continued)**

   a. ***Step One*** - Each plant or other Monsanto-designated locations or laboratory will have at least one identified and trained TSCA Section 8(c) key contact. The Director of Environmental Operations (DEO) or designate from the appro-priate operating companies, representatives of the WHSA (World Headquarters Site Administration), and Director, Regulatory Management (DRM), Toxic Substances will serve as the key contacts for the General Offices. The DEO's have responsibility under this procedure for free-standing divisions and subsidiaries of which Monsanto owns 50 percent or more of the voting stock or other equity rights, or for which Monsanto has the power to control the management and policies of that firm. At Step One, all initial receptors will automatically transfer persons making oral allegations to the key contact at their locations. Initial receptors will also transfer written allegation to the key contact at their location. (There are two exceptions with respect to oral allegations: If the initial receptors are either members of the Department of Medicine and Health Sciences Occupational Medicine (DMHS-OM) group (physicians) or the DEO's office, then these individuals can judge at Step One if an oral allegation is excluded.) Decision Criteria for Step One: pesticides, food, food additives, drugs, or cosmetics are excluded. If a decision is made that the allegation is excluded, the allegation, if written, will be discarded and, if oral, will not be acted on under the Rule.

      If the allegation is oral and not excluded, the key contact will inform the alleger that such allegation may be recordable under the Rule and request that the alleger submit a written and signed allegation to the key contact. Monsanto Form 8(c)A, shown on Appendix 2, is available to be used for all employee related oral health allegations and can be used at the discretion of the DEO for external oral health allegations. All key contacts must note on a written allegation the date of its receipt.

   b. ***Step Two*** - The key contact at a Monsanto location or the appropriate DEO for the General Offices will provide Monsanto employees with Form 8(c)A for oral allegations of health effects. Written allegations will then be reviewed by the key contact, who will then make a Step Two decision. The key contact will determine if the written allegation is exempted from the Rule using the criteria in paragraph 3 above. If a decision is made that an allegation is exempt from the Rule, the allega-tion will be discarded. Otherwise, the allegation will be sent to the appropriate DEO for review.

   c. ***Step Three*** - The appropriate DEO will serve as the coordinator for Step Three and Step Four activities. Allegations received from the location (plant, etc.) key contacts will be reviewed by the DEO and a Step Three decision made. A Step Three decision also will be made by the DEO or other General Offices key contact regarding allegations made to the General Offices receptors. If the Step Three decision is that the allegation is not recordable under the Rule, the allegation will be discarded. Otherwise the allegation will proceed to Step Four.

   d. ***Step Four*** - The DEO will form a committee to make decisions with respect to allegations that must be recorded under the Rule. The committee will be chaired by the DEO and consist of appropriate members of DMHS-OM for human effects, appro-priate members of Environmental Sciences for environmental effects, Environmental Law and the DRM, Toxic Substances. If the decision is that the alle-gation is not recordable under the Rule, the allegation will be discarded. The DEO will provide feedback to the location key contact. If the Step Four decision is that the allegation is recordable under the Rule, then the DRM-Toxic Substances, will place the allegation and documents mandated by the Rule in the TSCA Section 8(c) file. The DEO will provide feedback to the location key contact.

6. ***Record keeping***

   The TSCA Section 8(c) file will be kept in the Office of the DRM Toxic Substances. The file structure will confirm to requirements of Section 717.15 of the Rule. Files pertaining to adverse reactions to health of employees will be retained for 30 years. Files pertaining to other adverse reactions will be maintained for 5 years.

7. ***Communications***

   a. Disposition of written allegations will be communi-cated back to the individual making the allegation. The key contact will facilitate the communication.

   b. A summary of the TSCA Section 8(c) procedure will be periodically communicated to all affected employees and updated, as appropriate.

(Reviewed and Approved: Environmental Safety and Health Committee, October 20, 1987.)

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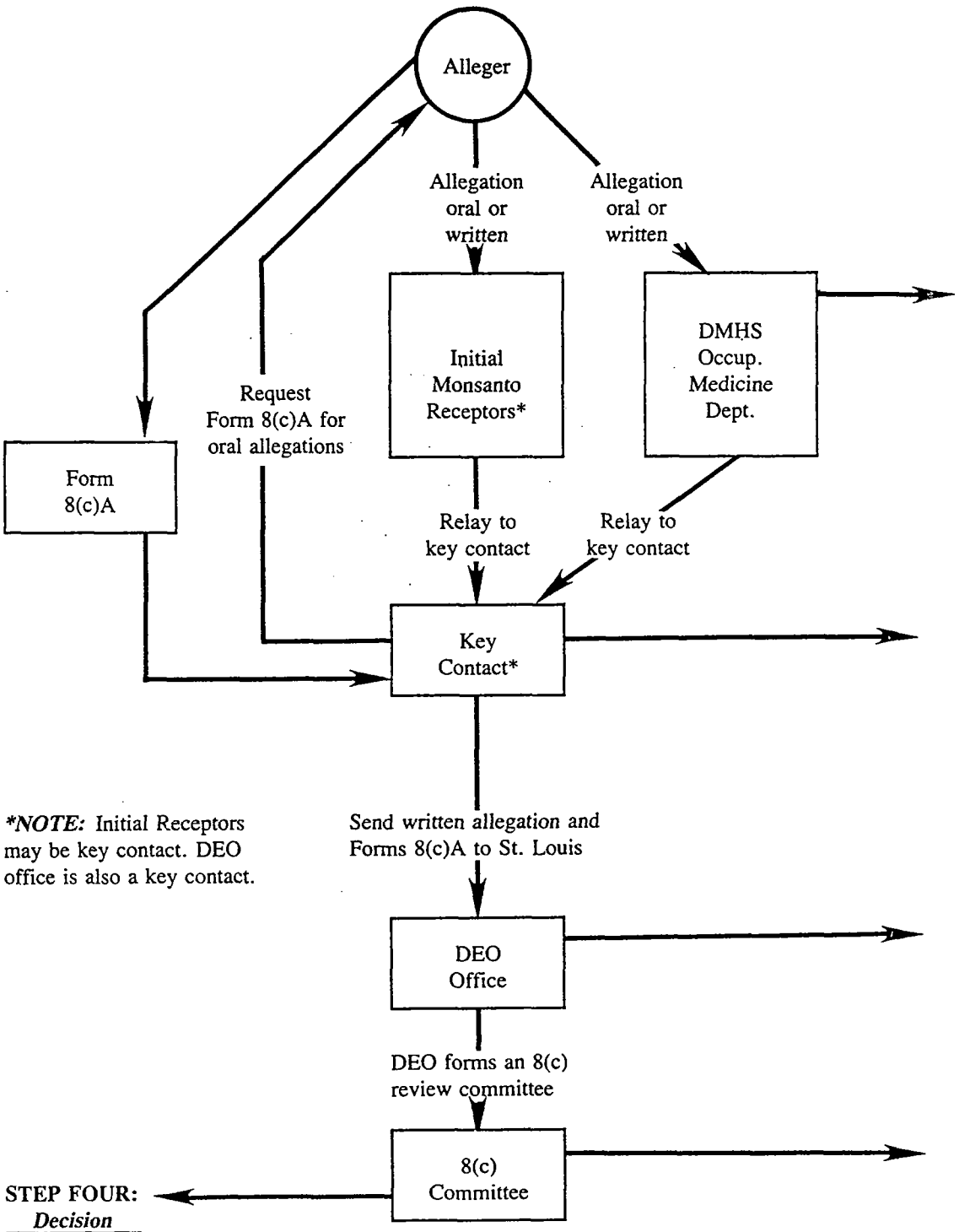
SIMPLIFIED FLOW DIAGRAM OF MONSANTO PROCEDURE FOR HANDLING ALLEGATIONS SUBJECT TO TSCA 8(c)



STEP ONE:
Decision
Not subject to TSCA 8(c) recordkeeping. Drop from process.

STEP TWO:
Decision
Not subject to TSCA 8(c) recordkeeping. Drop from process.

***NOTE:** Initial Receptors may be key contact. DEO office is also a key contact.

STEP THREE:
Decision
Not subject to TSCA 8(c) recordkeeping. Drop from process.

STEP FOUR:
Decision
Not subject to TSCA 8(c) recordkeeping. Drop from process.

STEP FOUR:
Decision
Allegation qualifies for TSCA 8(c) recordkeeping. Put in 8(c) file in St. Louis.

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ESH **PROCEDURE**

TO: SITE KEY CONTACT_____

Form 8(c)A
11/83

REPORTING FORM FOR

ALLEGATIONS OF SIGNIFICANT ADVERSE REACTION TO HEALTH

Toxic Substances Control Act, Section 8(c) 40 CFR Part 717

NAME OF ALLEGER: _____ DATE: ____ / ____ / ____ (MO / DAY / YR)

ADDRESS: *(If not employee)*

_____

_____

_____

SITE LOCATION: _____

SITE ADDRESS: _____

_____

_____

_____

SITE LOC. CODE: _____

(If health effect only): M ☐ F ☐

YR. OF BIRTH: _____

Employer *(if other than Monsanto):* _____

DESCRIPTION OF ALLEGED ADVERSE HEALTH EFFECT:

1. WHAT IS THE HEALTH EFFECT BEING CLAIMED? _____

   _____

2. HOW LONG DID IT LAST? _____

   _____

3. HOW OFTEN HAVE YOU EXPERIENCED EFFECT? _____

   _____

4. IN WHAT WAY DID IT AFFECT YOUR NORMAL ACTIVITIES? _____

   _____

5. HOW WERE YOU EXPOSED? _____

   _____

WHAT SUBSTANCE, MIXTURE, PROCESS OR OPERATION DO YOU THINK CAUSED THE EFFECT YOU DESCRIBED:

_____

_____

_____

_____

Signature

_____

FOR COMPANY USE ONLY:

RECEIVED ON: _____ BY: _____

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