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(CONOCO)

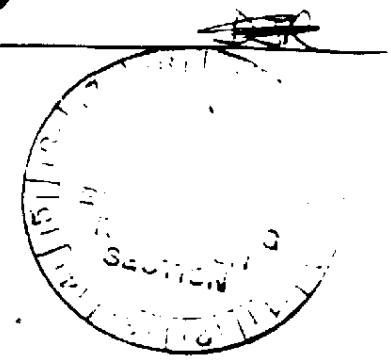
Interoffice Communication

To R&D Supervisors

From R. M. Tillman

Date November 21, 1983

Subject Section 8(c) - Toxic Substances Control Act



A recently promulgated section of the Toxic Substances Control Act becomes effective this date. This 8(c) Section requires that any person who manufactures, processes or distributes in commerce any chemical substance or mixture must keep records of significant adverse reactions to health or the environment alleged to have been caused by the substance or mixture. R&D is covered by this section.

Attached you will find a summary of Section 8(c), a number of questions and answers on the implementation procedure and a form to record any allegations. The form, "Report of a Possible Adverse Effect to Health or the Environment," is much simplified over the form that actually will go on file. Should you have an allegation, send the completed form to your Division Manager. The Division Manager will forward the form to me and I will see that the matter is brought before a review panel and that the proper form is completed and put on file.

It is our intent that all employees be made aware of this new regulation. You should feel free to discuss it with your personnel. We hope to have new posters ready within a week to display on all bulletin boards. The new posters will combine information on both Sections 8(c) and 8(e) of TSCA and will replace the present 8(e) posters.

R. M. Tillman

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SUMMARY OF
SECTION 8(C) OF TSCA

Section 8(c) of the Toxic Substances Control Act requires manufacturers, processors, and distributors of chemical substances and mixtures to:

- keep records of significant adverse reactions to health or the environment alleged to have been caused by the substance or mixture; and

- permit inspection and submit copies of such records upon request of any designated representatives of the EPA.

A final rule, published in Federal Register 48:163, August 22, 1983, implements Section 8(c). It describes the records to be kept and describes the conditions under which certain firms must submit or make the records available to the EPA.

The purposes of the recordkeeping and reporting are to:

- Create a historical record of significnt adverse reactions alleged to have been caused by substance or mixture. EPA can examine such records whenever a chemical is discovered to present possible risks to human health or the environment.

- Provide a means to identify previously unknown chemical hazards and to reveal patterns of adverse effects that might otherwise either not be noticed or go undetected for long periods of time.

The key provisions of Section 8(c) are as follows:

1. "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.

2. "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. Allegations are those submitted in writing or submitted orally. If oral, the firm must transcribe the allegation into written form or request the alleger to submit such an allegation to the firm in writing.

4. Allegations may implicate a substance that caused the stated significant adverse reaction by one of the following:

    - Name of the specific substance.

    - Name of the mixture that contains a specific substance..

- Name of an article that contains a specific substance.
- Name of a company process or operation in which substances are involved.
- Identification of an effluent, emission, or other discharge from a site.

5. Allegations may be made to a firm by any person, such as an employee, individual consumer, neighbor of the plant, another firm on behalf of its employees, or an organization on behalf of its members.

6. Significant human health adverse reactions include, but are not limited to:

   - Long-lasting or irreversible damage, such as cancer or birth defects.
   - Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders, or blood disorders.
   - An impairment of normal activities experienced by all or most of the persons exposed at one time.
   - An impairment of normal activities which is experienced each time an individual is exposed.

7. Known human effects are not required to be recorded, e.g., published in scientific articles or publications in standard reference sources, MSDS, or product labeling.

8. Significant adverse reactions to the environment include, but are not limited to:

   - Gradual or sudden changes in the composition of animal life or plant life, including fungal microbial organisms in an area.
   - Abnormal number of deaths of organisms (e.g., fish kills).
   - Reduction of the reproductive success or the vigor of a species.
   - Reduction in agricultural productivity, whether crops or livestock.
   - Long-lasting or irreversible contamination of components of the physical environment, especially in the case of groundwater and surface water and soil resources that have limited self-cleansing capability.
   - Alterations in the behavior or distribution of a species.

Effects attributable to accidental spill or accidental discharge or other incidents of environmental contamination that have been reported to the Federal government under any applicable authority are not required to be recorded, e.g., NPDES permit violation.

9. Firms subject to the rule include manufacturers of chemical substances, and such manufacturers are also responsible for collecting allegations relating to their processing activities and distribution in commerce activities.

10. Processors, that are not also manufacturers, are subject to the rule if they are engaged in activities described in SIC Codes 2911 (Petroleum Refinery) and 28 (Chemicals and Allied Products).

11. A retailer is exempt from this rule unless it is also a manufacturer or a processor subject to this rule. A firm whose sole activity is the distribution of chemical substances (i.e., a distributor that is not also a manufacturer or a processor) is exempt.

12. Also exempt are manufacturers or manufacturing sites whose only activity involves mining or other extractive industry functions, i.e., extraction of petroleum or natural gas, to mine or extract coal, quarry non-metallic minerals -- including extraction of salts from brines.

13. Records of allegations received at any plant will be maintained at the company's headquarters or at a location central to its operations. Human health allegations for employees are to be maintained for 30 years, and for nonemployees and environmental effects, 5 years.

14. No automatic reporting provision is included in the rule. The EPA can request copies of records by notice in the Federal Register or letter-reporting not less than 45 days from date of notification.

15. There is no employee notification provision; only the supervisory personnel are expected to be educated in how to handle employee allegations.

16. No formal alleger feedback is required, although the EPA encourages firms to inform allegers regarding the ultimate disposition of their allegations.

17. Follow-up investigations to an allegation are not required; however, the results of any self-initiated investigation must be maintained on file as part of the record.

QUESTIONS & ANSWERS REGARDING TSCA 8(c) IMPLEMENTATION

The purpose of the questions and answers is to clarify various aspects of the new rule as well as to assist the departmental and facility TSCA coordinators in answering questions that may be raised by the employees.

(1) **Q: What is the primary purpose of the 8(c) program?**

A: It establishes a record keeping program to assist in the identification of any unknown chemical hazards.

(2) **Q: When is the effective date of 8(c)?**

A: Conoco must maintain records on allegations made on or after November 21, 1983.

(3) **Q: What is an "allegation"?**

A: An "allegation" is a statement made without formal proof or regard for evidence.

(4) **Q: What is a significant adverse reaction?**

A: A significant adverse reaction is one that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

(5) **Q: What are significant adverse reactions to human health?**

A: **Allegations of significant adverse reaction to human health include:**

- **Long-lasting or irreversible damage, such as cancer or birth defects.**
- **Partial or complete impairment of bodily functions, such as reproductive, neurological or blood disorders.**
- **An impairment of normal activities which is experienced each time an individual is exposed.**
- **An impairment of normal activities experienced by all or most of the persons exposed at one time.**

(6) **Q: What are significant adverse reactions to the environment?**

A: Allegations of significant adverse environmental reactions that must be recorded (even if restricted to the environs of a plant or disposal site) include:

- o Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms in an area.
- o Abnormal number of deaths of organisms (e.g., fish kills).
- o Reduction of the reproductive success or vigor of a species.
- o Reduction in agricultural productivity, whether crops or livestock.
- o Alterations in the behavior or distribution of a species.
- o Long-lasting or irreversible contamination of components of the physical environment, especially in the case of ground water, and surface water and soil resources that have limited self-cleansing capability.

(7) **Q: How does this "8(c)" procedure differ from our present "8(e)" procedure?**

A: The new 8(c) procedure sets up a recording system for allegations that chemicals have caused: (1) previously unknown significant adverse reactions to humans, or (2) significant adverse reactions to the environment not already reported to the federal government. It does not require reporting to the government. The 8(e) system deals with substantial risks to health or environment. It requires a higher degree of relationship between cause and effect, frequently deals with more serious effects, and requires notification to EPA in the event of a reportable incident.

(8) **Q: How will Conoco's 8(c) program be carried out in relation to the 8(e) program, i.e., separate, combined, or a limited combination?**

A: Conoco departmental TSCA coordinators prefer utilization of a limited combination of the two programs, with employees being notified of the 8(c) requirements via a combined 8(c and 8(e) poster that will be posted on strategic bulletin boards, replacing the existing 8(e) poster. Applicable supervisory staff and operating department 8(c) coord.-

nators will be educated as to the 8(c) requirements and how to handle the allegations. The existing 8(e) pamphlet and training will remain as currently used, and new combined 8(c) and 8(e) reporting forms will be used, replacing the existing 8(e) reporting form.

(9) **Q: Can an allegation recorded under 8(c) lead to an 8(e)?**

A: Yes. Several similar alleged adverse effects filed under Section 8(c) could contribute to the development of a notification of substantial risk as required by Section 8(e). The EPA indicates that previous Section 8(e) notices have been submitted as the result of allegations from workers or customers that indicated a potential problem.

(10) **Q: Does the allegation under 8(c) have to be in writing or can it be made orally?**

A: All employee and nonemployee allegations must be submitted in writing on the Conoco form. An employee may develop his allegation via consultation with his supervisor. Nonemployees should consult with their point of contact (or designee).

(11) **Q: To whom should an allegation be made?**

A: The employee's supervisor, or the point-of-contact or designee for a nonemployee.

(12) **Q: Will there be feedback on the allegation?**

A: Although not a regulatory requirement, Conoco will endeavor to reply in writing to all allegations. 40 CFR 717.10(d) states that EPA intends that firms should, to the maximum extent practical, provide this feedback.

(13) **Q: What degree of follow-up is required for an 8(c) allegation?**

A: None. However, it is advised that the incident be investigated by the department coordinator under advisement of the Legal Department. Any investigation and responses to allegers must be included in the 8(c) record.

(14) **Q: Is there a required time period to respond to an allegation?**

A: No, but Conoco considers 15 working days to be a reasonable guideline.

(15) **Q: Where can I get reporting forms?**

A: From your supervisor; facility or department environmental coordinator; or any medical or safety personnel.

(16) **Q: Is there a duty to inform employees about the 8(c) program?**

A: No. There is no regulatory requirement for informing employees. (See Item #7.)

(17) **Q: Is there any protection for employees under TSCA?**

A: Section 23 of TSCA states that "no employer may discharge any employee or otherwise discriminate against any employee" because the employee has "commenced a proceeding under this Act".

(18) **Q: Is there an annual training requirement or an annual update requirement?**

A: No. Conoco does not plan an annual update.

(19) **Q: How will records of significant adverse reactions be kept?**

A: A corporate file of <u>all</u> 8(c) allegations will be kept in the Environmental Conservation Department's file similar to our 8(e) file. All human health allegations will also be kept by Medical in the individual's medical records.

(20) **Q: How long are records to be retained?**

A: Employee health-related allegations must be retained for 30 years. Any nonemployee health or any environment-related allegations must be retained for five years [717.15(d)].

(21) **Q: Are accidental spills or discharges subject to 8(c) recording?**

A: No. 717.12(d) provides that if the cause of the significant adverse reaction is directly attributable to a spill or discharge and the incident was reported to the federal government, e.g., NPDES Permit discharge, the incident does not need to be recorded.

(22) Q: **If a state has delegated authority, e.g., under the Clean Water Act, does this satisfy 717.12(d)?**

A: Yes.

(23) Q: **Do the environmental reactions addressed in the 8(c) regulations have to be off-site?**

A: No. The reactions listed in 40 CFR 717.12(c) may be on-site or off-site.

(24)*Q: **Can Conoco exclude from record keeping an allegation of a human effect if the same effect has only been found in animal studies and not previously reported as a human health effect?**

A: No. The allegation should be recorded. However, notifications in the MSDS or product labeling of an adverse effect (e.g., acute effect such as an acid burn) may be sufficient for exclusion from record keeping, even though there is no human experiences with such effects.

(25)*Q: **Can a known adverse environmental effect be excluded from recording?**

A: No. The effect would have to be level of exposure and plant or animal species specific. Chances of this occurring are slim. The only exclusion from record keeping for adverse environmental effects is anticipated to be reporting via other mechanisms, e.g. NPDES DMR.

(26) Q: **What is the expected impact of number of allegations to be filed within Conoco?**

A: There have been 17 8(e)s considered for reporting during the six year history of TSCA. Two were reportable. It is estimated that there will only be a "handful" of 8(c)s considered each year by Conoco.

(27) Q: **Are 8(c) records submitted to EPA?**

A: There is no automatic submission. However, records must be available for inspection by EPA.

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*The indicated answers are based upon language in the preamble to the TSCA 8(c) rule. These are included to indicate EPA's position but are not binding upon Conoco.

(28) **Q: How will Conoco have to report to EPA?**

A: If EPA requires submission of records, it will do so by letter or notice in the Federal Register. Conoco will have at least 45 days from the date of the letter or the effective date of the notice. Report will be sent to the Document Control Officer, Office of Pesticides and Toxic Substances (TS-793) EPA, Washington, D.C. 20460.

(29) **Q: How will EPA enforce compliance with the rule?**

A: EPA will conduct inspections of Section 8(c) records and, on a case-by-case basis, may request the submission of records.

(30) **Q: Are existing records (i.e., allegation or similar complaints on file before effective date of rule) required to be incorporated into Section 8(c) records?**

A: No. Allegations subject to this rule apply only to those received on or after the effective date of this rule. However, the EPA encourages that correlations of allegations subject to this rule be made with existing records for identification of any patterns of adverse reactions.

(31) **Q: Who decides if the allegation is recordable?**

A: The operating department 8(c) coordinator and Conoco's TSCA Advisory Committee. The latter is comprised of Dr. Charles Whetstone, Medical; Michele Malloy, Legal; and Terry Thoem, Environmental Conservation and are available to provide advice to the operating departments.

(32) **Q: What criteria are used for not recording an allegation?**

A: 40 CFR 717.3(c)(1) indicates that known human effects do not need to be recorded. These include effects described in scientific articles, in a company's material safety data sheets, or on a product label. However, even if an effect is a known human effect, it is recordable if (1) it is significantly more severe, (2) the effect occurs after a significantly shorter exposure period or lower exposure level than previously noted, or (3) the manifestation of a toxic effect is by a different exposure route.

(33) **Q: If an alleged significant adverse reaction is determined not to qualify for record keeping, should documentation be maintained as to how the determination was made?**

A: Such documentation is not required under Section 8(c), but as a protective measure for potential future complaints to the EPA by employees of a lack of response by Conoco, documentation for department and corporate files is advisable.

(34) **Q: How will known human effects be determined?**

A: Medical will provide information on human health effects and operating departments will provide information on Material Safety Data Sheets and product labeling. Environmental Conservation will provide information on environmental effects.

(35) **Q: Does the 8(c) program pertain only to chemical substances and mixtures?**

A: No. Other recordable allegations include an article containing the specific substance; a company process or operation involving the substance; or an effluent, emission, or other discharge from the site.

(36)*Q: **Are manufacturers listed only in SIC 28 and 2911 subject to the regulation?**

A: No, Conoco must review its activities at all sites to determine whether chemical production, manufacture or importation occurs.

(37)*Q: **Why are firms engaged solely in the extractive industry exempt?**

A: EPA believes that the vast majority of substances produced by the extractive industry have been produced for many years and that a substantial amount of information exists regarding the adverse effects on health and the environment. Also, EPA recognizes that other federal agencies...MSHA, OSHA and DOI...adequately oversee this industry. Finally, EPA has other TSCA mechanisms, e.g. 8(a) and 8(e), if adequate concern develops.

(38)*Q: **Why are retailers exempt?**

A: EPA believes that the potential for significant exposure to chemical substances by retail employees is limited.

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(39) **Q: Are research activities exempt?**

A: No. Any activities involving product research and development are included in the manufacture for commercial purpose definition [40 CFR 717.3(e)(1)].

(40) **Q: Which Conoco operating departments are subject to this rule and which are exempt?**

A: It currently appears that only Refining, Chemicals, Concarb, and R&D are definitely required to comply with this rule. It also appears that Consol, Exploration, North American Production, and Natural Gas are exempt by virtue of 40 CFR 717.7(a). However, the possibility exists that other parts of the company may be subject to this rule. The EPA has recently indicated through Q&A's distributed on November 10, 1983, that it broadly interprets the regulations. For example, EPA suggests in the Q&A's that gas processing facilities that remove such substances as butane and propane for separate sell are subject to this rule. Those gas processing operations that only dewater the gas and remove hydrogen sulfide are not subject to the rule. The Q&A's indicate that milling and leaching operations of mining activities are not subject to the rule. However, there is still some question about Conoco's uranium in situ leach operation since processing beyond leaching occurs. The Q&A's also indicate that a corporation's company-owned gasoline stations are subject to the rule.

The above-mentioned interpretations presented in EPA's Q&A's are not regulatory in nature and are not binding. EPA apparently derives the interpretations from paragraph 717.5(a) of the rule, where it is stated that "if manufacture of a chemical substance occurs at any site owned or controlled by a firm, then that firm is subject to this part." Therefore, if EPA's interpretation is upheld as valid, or the regulation is amended, then downstream operations, including all of NGP, CPL, Surface Transportation, and Marketing, could be required to comply with these regulations. In the interim, Conoco plans to continue with its current interpretation of the rule, i.e., Refining, Chemicals, Concarb, R&D, gas processing facilities of NGP that separate such substances as butane and propane for sell, and the uranium in situ leach facility are subject to this rule.

(41) **Q: Does the addition of an additive at a gasoline terminal constitute manufacture?**

A: No. Although this needs further clarification by the EPA, it is assumed that this activity would be considered de minimis processing; hence, the distributor assumption would be maintained.

(42)*Q: **How will Conoco report significant adverse reactions alleged to result from use of other manufacturer's products?**

A: The appropriate operating department will endeavor to notify the supplier.

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REPORT OF A POSSIBLE ADVERSE EFFECT TO HEALTH OR THE ENVIRONMENT

If you think a chemical substance or mixture has caused an adverse human effect, identify that substance and describe how affected. If you think the environment (for example: the air, water, soil, animals, or plants) has been adversely affected by one of the facility's chemical substances or mixtures, identify the substance (if known) and the affected plant and/or animal or contaminated area of the environment.

If you cannot identify the suspected chemical substance or mixture, identify the product, material or item believed to be the cause of the adverse effect, or describe the process or operation, or the effluent, emission or discharge from the facility that you think has caused the adverse effect.

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Signature of Reporter **Date of Report**

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Name of Reporter (Printed) **Date Adverse Effect Occurred**

Send Completed Form To:

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