Information-Reporting Procedures under the Toxic Substances Control Act (TSCA), Subsection 8(e)†

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A corporate-wide procedure is described which has been established to capture the necessary information under Subsection 8(e) of the Toxic Substances Control Act (TSCA) in a standard fashion and to assure that it is evaluated and processed within the designated limited time frame.

INTRODUCTION

The Toxic Substances Control Act (TSCA) which became effective on Jan 1, 1977, charges the Environmental Protection Agency (EPA) with the responsibility for regulating chemical substances "whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment"[1] and, if necessary, to take appropriate regulatory action to minimize any risks arising from these substances. The law encompasses the more than 50 000 chemical substances manufactured or imported for commercial purposes as well as the thousands of substances now in the various stages of research and development. Under TSCA, manufacturers, processors, exporters, and importers are required to have current and accurate information on every chemical substance handled at a specific location. The archives for these data are the responsibility of the individual corporation, though the government must be made aware that the corporation indeed has this repository of information and that it is promptly available when needed. Section 8 of the Act addresses this critical and still controversial area dealing with the reporting and retention of information.

The purpose in implementing the regulatory and nonregulatory provisions of TSCA is twofold: (1) to control toxic substances directly, (2) to support other government and nongovernmental programs in controlling toxic substances. Congress felt that industry has the responsibility of both collecting the data as well as assessing the information necessary to determine possible risks. The burden has been put squarely on the industry which manufactures or processes chemicals to conduct the required tests and to submit to the EPA data on the effects and behavior of chemicals. When necessary, the EPA is authorized to take steps to limit manufacturing, processing, use, or disposal of a chemical substance which may present an unreasonable risk.

Two important sections of the Act are designed to aid in assessing possible risks: Section 8(c), the recording and possible reporting of alleged significant adverse reaction, and Section 8(e), the reporting of any information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.[2]

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of the seriousness of the effect coupled with the fact or probability of its occurrence and the nature and extent of exposure to the risk. These criteria are differently weighed for different types of effects. For example, a single incidence of human cancer, birth defect, mutagenicity, death, or serious or prolonged incapacitation must be reported if one (or a few) chemical(s) is (are) strongly implicated as the causative agent. These human health effects are considered so serious that relatively little weight is given to exposure; the mere fact that the implicated chemical is in commerce is sufficient. In contrast, adverse environmental effects must be serious, and there must be a potential for widespread exposure. Environmental effects include such information as significant changes in the ecology related to chemical exposure, pronounced accumulation of a chemical in animals, birds, fish, or other marine life, or previously unknown, widespread presence of a chemical in the environment.

There is an obvious direct relationship between Section 8(c) allegation and 8(e) information on substantial risk. An allegation does not need supporting information—formal proof of evidence—while the report of substantial risk under Section 8(e) must be accompanied by information which "reasonably supports the seriousness of the effect or the probability of the recurrence".[2]

If additional supporting information is generated during the evaluation of an allegation, then that information should be reevaluated under Section 8(e) guidelines. The converse of complying under Section 8(c) requirements does not relieve the manufacturer or importer of responsibility for a possible Section 8(e) submission.

SECTION 8(E)

Substantial information is information, rather than suspicion, which reasonably supports a conclusion that a chemical substance presents a substantial risk of injury to health or the environment. Though consideration of corroborative evidence may be necessary, the information need not be conclusive that the risk exists. Obviously, some substantial risk information need not be reported. An example in this category is information which is well-known to the public and has been documented in the scientific literature and referenced in English by the accepted abstract services. Another example is data that have already been submitted to EPA in writing in compliance with any of the acts administered by the Agency.

Fortunately, the EPA has asserted that an individual in a company may discharge the Section 8(e) obligations, with its possible civil and criminal penalties, by notifying a company official of the pertinent information, provided that the company has established procedures for employee submission and corporate processing of submitted information. Such a program has been implemented at BASF Wyandotte Corporation. Special reporting forms have been designed as a further aid in assuring that all the necessary information is collected and processed promptly.

Any individual in the corporation may initiate an Evidence of Substantial Risk Report by submitting the necessary information, forms being available from the department manager's office (Figure 1). The new information must be de-

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Evidence Of Substantial Risk Report | BASF Wyandotte Corporation

REPORT NO.

TOXIC SUBSTANCES CONTROL ACT – SECTION 8 (e)

HEALTH RELATED ☐ ENVIRONMENTALLY RELATED ☐

Name of Chemical Substance or Mixture

Nature of evidence of risk *(illness, environmental effect, etc.)*

Summary of new information *(if applicable, attach copies of reports, tests, results, etc.)*

Is this substantial risk information public knowledge? ☐ *Yes* ☐ *No* ☐ *Not Sure*

Is the EPA aware of this information? ☐ *Yes* ☐ *No* ☐ *Not Sure*

Identify other BWC personnel who may have pertinent information:

EMPLOYEE'S NAME	EMPLOYEE NO.	DEPARTMENT
EMPLOYEE'S SIGNATURE	DATE	LOCATION
DEPARTMENT MANAGER SIGNATURE	DATE	TELEPHONE

DISTRIBUTION
WHITE – RISK ASSESSMENT COORDINATOR
YELLOW – EMPLOYEE
PINK – DEPARTMENT MANAGER

Figure 1. Evidence of substantial risk report.

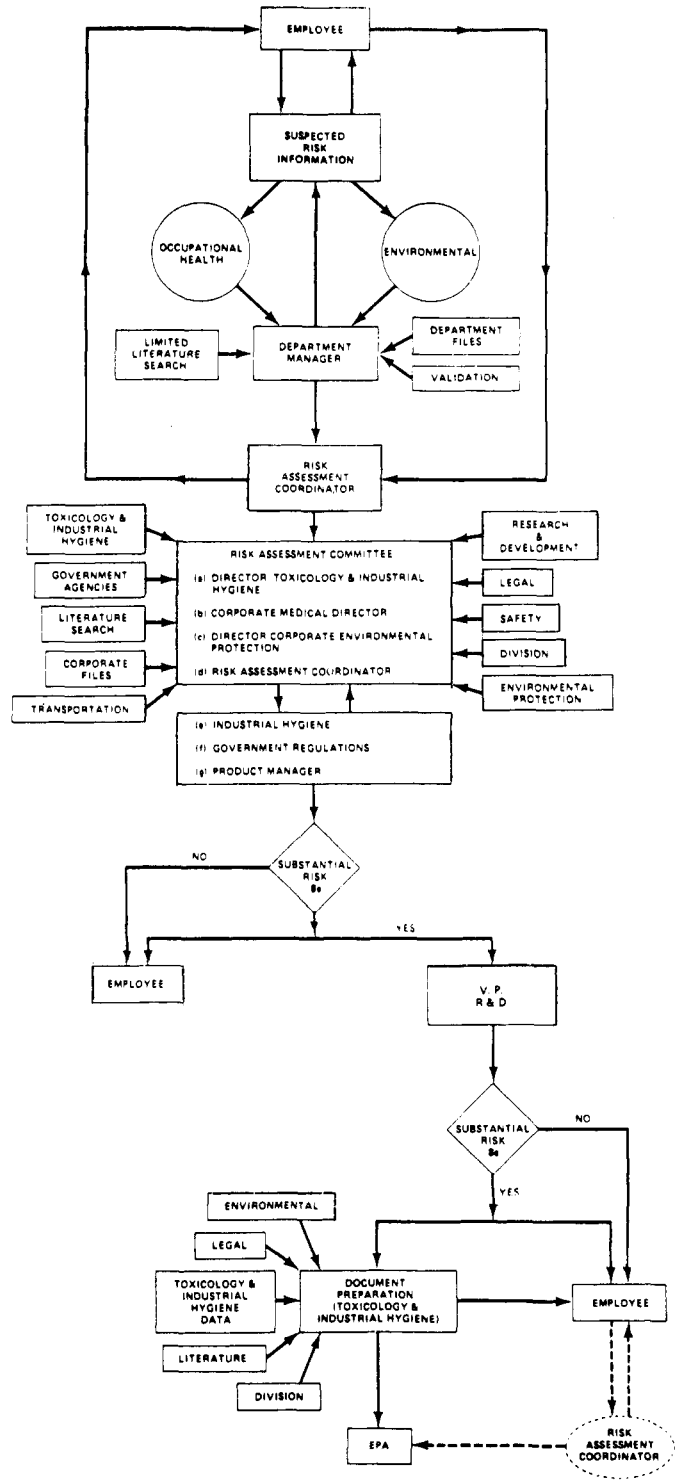

Figure 2. Information flow for suspected substantial risk reports.

scribed concisely, including medical description of symptoms (if health) or scientific description of environmental hazard. Applicable dates, nature and location of occurrence, concentrations, circumstances, and ambient conditions are recorded and any supporting documentation is attached. All pertinent information must be immediately submitted to the Risk Assessment Coordinator, whose responsibility is to coordinate the evaluation and processing of the submission (Figure 2). The Risk Assessment Coordinator logs the time the information is received and sends the employee an acknowledgment indicating that the information has been received. Since a knowledgeable person in the corporation is now aware of the information and is capable of appreciating its significance, the critical 15-working-day evaluation period is initiated. The information and any supporting information are immediately forwarded to the Risk Assessment Team which has been established to conduct the internal review.

The team is chartered to gather information from all individuals within the corporation who have particular expertise on the chemical and risk in question and, based on their evaluation, determine, according to guidelines issued by EPA, whether or not a reportable substantial risk exists. The Risk Assessment Team is chaired by the Director of Toxicology and Industrial Hygiene and has two additional permanent members—the Corporate Medical Director and the Director of Corporate Environmental Protection. Assistance may be requested from other individuals in the corporation such as the division product manager, division TSCA coordinator, legal director, director of safety and loss prevention, and research personnel to help in the evaluation.

An opinion must be reached by the Risk Assessment Team within 8 working days after the Coordinator has obtained the information if evidence of substantial risk exists. If evidence of substantial risk according to Section 8(e) guidelines exists, then the recommendation, along with comments and supporting data, is forwarded to the Vice President of Research and Development, who reevaluates the data within 5 working days to determine if the report qualifies for transmittal to the EPA. Regardless of the evaluation results, the employee is kept informed of the progress and is promptly notified in writing of the final action (Figure 3).

Should the individual disagree with the decision and feel that the chemical substance or mixture does comprise evidence of substantial risk, he has the option of reporting directly to the EPA (Figure 4). However, it is suggested that he contact the Risk Assessment Coordinator to discuss the findings and evaluation of the report before taking any further formal

Evidence Of Substantial Risk Report

BASF Wyandotte Corporation

REPORT NO. _____

TOXIC SUBSTANCES CONTROL ACT – SECTION 8 (e)

DISPOSITION STATEMENT

To: _____ (ORIGINATOR OF REPORT) _____ (DEPARTMENT)

From: _____ _____ (TITLE)

This is to inform you of action taken by 3WC in response to your Substantial Risk Report No. _____,

with regard to _____ (NAME OF CHEMICAL SUBSTANCE OR MIXTURE), submitted on _____ (SUBMISSION DATE)

☐ Your report was submitted to the Federal Environmental Protection Agency on _____ as evidence of substantial risk. You will be kept informed of any response from EPA.

☐ The Risk Assessment Team concluded that the information presented did not meet EPA criteria for "evidence of substantial risk" as outlined in the EPA Policy Statement, dated March 16, 1978.

Your reporting obligation under TSCA Section 8(e) was fully discharged by the Evidence of Suspected Risk Report No. _____ which you submitted on _____

Summary of Information: _____

If you disagree with the conclusion that your report does not comprise "evidence of substantial risk," you may wish to contact the Risk Assessment Coordinator to discuss the findings and evaluation as well as report the information directly to:

Document Control Officer
Chemical Information Division, OTS (WH-557)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Section 23 of TSCA 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 purpose of the Act.

DISTRIBUTION
WHITE – RISK ASSESSMENT COORDINATOR
YELLOW – EMPLOYEE
PINK – DEPARTMENT MANAGER

F 3040

Figure 3. Disposition statement.

action. The Risk Assessment Coordinator must be notified if an employee chooses to submit evidence of substantial risk directly to the EPA and a copy of the report sent to his attention.

Emergency incidents relating to environmental effects are to be reported by telephone to the EPA by appropriate personnel within 24 h, followed by a written report within 15 days.

SUMMARY

A corporate-wide procedure has been developed and implemented which permits the processing of TSCA Section 8(e) substantial risk information in a rapid but orderly fashion. The severe time restraints imposed by the regulations can be met and still allow for a complete, thorough, and knowledgeable evaluation of the submission.

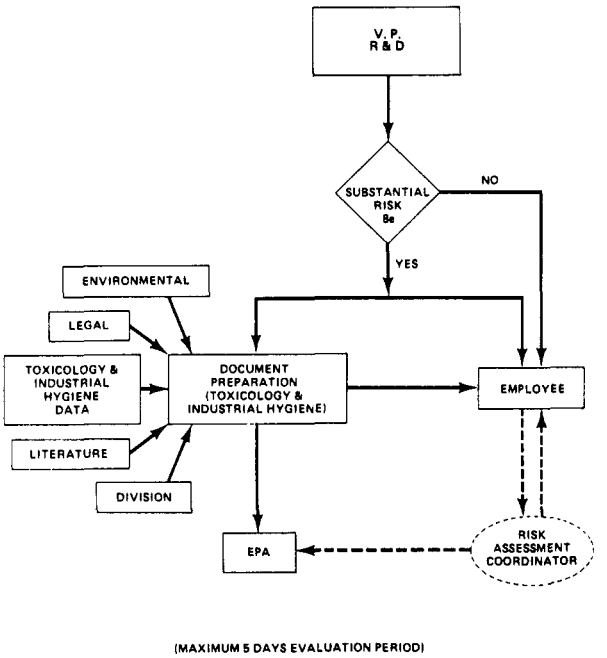

Figure 4. Confirmation of suspected substantial risk report.

ACKNOWLEDGMENT

We thank the staff of the Toxicology and Industrial Hygiene Department who aided materially in the design of the reporting procedures.

REFERENCES AND NOTES

(1) U.S. Congress Senate: *Toxic Substances Control Act*, Public Law 94-469, 94th Congress, 2nd Session, S. 3140, pp 2003–2051.
(2) (a) *Fed. Regist.* **1977**, *42* (175), 45362–45366. (b) Ibid. **1978**, *43* (52), 11110–11116.

LETTERS TO THE EDITOR

BIBLIOMETRICS AND DRUGS

Dear Sir:

In the August 1980 issue you published a letter[1] by M. Osinga which posed some questions about an article of mine[2] that appeared last November.

The interrogation is rather puzzling. I have been challenged to "prove that bibliometric traits cause the clinical success of a drug". Bibliometric traits no more cause the clinical fate of a drug than footprints in the snow cause the appearance of their maker. It baffles me why cause-and-effect would be invoked at all. Not only is it irrelevant—it is counterproductive.

Nevertheless, perhaps a very simple explanation will clarify the situation. Just as rabbits leave rabbit tracks and squirrels leave squirrel tracks—successful drugs leave different bibliometric tracks than do unsuccessful drugs. Sometimes these track records can be used to make predictions. That's all there's to it!

(1) M. Osinga, "Bibliometrics and the Clinical Fate of Drugs", *J. Chem. Inf. Comput. Sci.*, **20**, 192 (1980).
(2) D. A. Windsor, "Using Bibliometric Analyses of Patent Literature for Predicting the Clinical Fates of Developing Drugs", *J. Chem. Inf. Comput. Sci.*, **19**, 218–221 (1979).

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