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

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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.

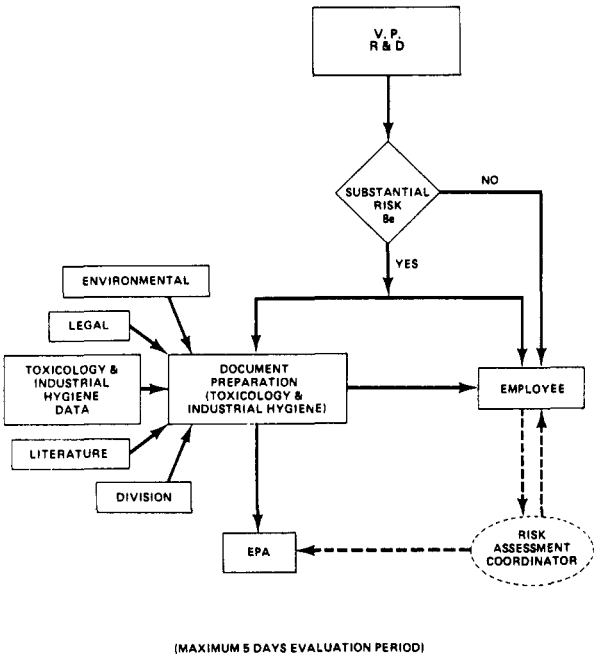

Figure 4. Confirmation of suspected substantial risk report.

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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