Air Products

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INTEROFFICE MEMORANDUM

Date December 6, 1977

Subject Meeting Agenda - TSCA Compliance Comm.
December 12, 1977

To TSCA Compliance Committee

From C. E. Blades — Piscataway
(Location, Organization, or Department)

Distribution: W. M. Smith, L. B. Tepper, R. H. Schenck, A. J. Diglio, J. C. Novak, W. Ent, R. Collins, G. Handley, J. Egan, T. Collins, J. Body, H. Parke, E. Handwerk, B. Dalton

The next meeting of the TSCA Compliance Committee is scheduled for 1:30 P.M., December 12, 1977 in Room 113G, Main Office Building, Trexlertown.

The agenda will be as follows:

1. Approval of Minutes -- November 14, 1977 meeting.

2. Old Business:

   a) Significant Adverse Reactions

      (i) Acceptance of the Definitions and Procedure circulated earlier — C. E. Blades

      (ii) G. Handley report on methodology to assure complete collection from GEG.

      (iii) A. J. Diglio report on resolution of questions raised.

   b) Raw Materials Inventory

      Preparations to clarify that all raw materials purchased will be on the Inventory List. — C. Blades/T. Collin

   c) Report on Product File Requirements per MID, Oct. 10, 1977 proposal. — C.Blades/T.Collins

   d) Substantial Risk Notice to Employees

      Consideration of draft notices prepared for executive approval and action. — Blades/Smith/Schenck

continued.....

(320)

(ACTIVITIES)

Date 21 November 1977

INTEROFFICE MEMORANDUM

Subject Significant Adverse Reactions

To TSCA Compliance Committee
(Location, Organization, or Department)

From C. E. Blades
(Location, Organization, or Department)

Committee: A. J. Diglio
W. L. Ent
G. G. Handley
J. C. Novak
R. H. Schenck
W. M. Smith
L. B. Tepper, M.D.

cc: J. H. Body

This letter dealing with significant adverse reactions is now issued with the benefit of comments from the TSCA Compliance Committee.

The Problem

allowed to have been

TSCA requires that manufacturers maintain records of Significant Adverse Reactions to health or the environment caused by the company's chemical products. There are three sources for such records and responsibility for each one is given in the chart below:

Source	Generated By	Maintenance By	Time Retained (yrs)
Customer/Consumer Complaints	Profit Center	TSCA Chairman	5
Environmental Harm	Environmental	TSCA Chairman	5
Employee Health	Safety/Medical	Medical Dir.	30

Insofar as, there is a developing uncertainty concerning the types of incidents to be reported, a directive is required. It shall be the purpose of this memorandum to define the types of information required from reporting units in the corporation.

Proposal

The Act requires manufacturers to maintain records of significant adverse reactions in the health of humans or in the environment caused by the company's chemical products. These records are background documentation for such adverse reactions and the Act has identified the sources for such records as follows:

(320)

(1) Employee Health Records

These are routine medical examination records designed to identify employee health problems and have them organized in such a fashion that repetition of grouped effects may be correlated with a common cause--especially if it should be work related. Adverse health problems which repeat in the medical records of several employees can be readily recalled from the computerized record on demand. Such problems will come to the attention of the medical director in a variety of ways. Once suspect, it is possible to ask the system if these are repeated actions.

(2) Customer/Consumer Complaints

Customers/consumers of company chemical products which observe or think they observe adverse health or environmental reactions attributable to the company's products will issue a complaint. Such complaints do not need to be sought. But the profit center or discreet business entity is required to set up a collection device for customer/consumer complaints and to segregate those involving, or alleging to involve, harm to health or the environment and then report those cases to the TSCA Chairman (APCI) for retention in files for a five-year period. A periodic view of the records by the TSCA Chairman will constitute a report. The Committee recommends an EPMS type computerized monitor be set up.

(3) Environmental Harm

Environmental harm ~~arising~~ from the operations and involving company products or by-products within the company or during transportation to a customer or other location are to be recorded with details of the event and the remedial and/or clean-up action taken. The definition of "environmental harm" has not been given. Thus it would be prudent to be conservative in adoption of criteria for environmental harm until such definition is provided by the EPA. Thus we should report all transportation accidents resulting in releases or spills, all releases in effluents to the waterways and to the atmosphere from our plants which exceed established guidelines. It is proposed that reporting be mandatory on releases which result in a fish kill, destruction of vegetation, contamination of ground waters, any materials of low biodegradability liable to persist in the environment and eventually enter the food chain. It is further proposed that the reporting unit place on file documentation of the adverse reaction reported.

At the 12 December TSCA Compliance Committee Meeting we will review again these guidelines. If approved, it is proposed that reporting units be informed by an appropriate directive. Attached hereto are reporting forms currently in use. An EPMS type system will also be considered.

A E Bladosiewicz

CEB:sjd
Attachment - Report Forms

_____ GROUP

ENVIRONMENTAL HARM REPORT

FOR PERIOD _____ 19___ TO _____ 19___

REPORTED BY _____

1. List here reference memoranda describing event which caused the environmental harm.

2. Summarize here the action taken in each case and assess the extent of damage or environmental impact.

The foregoing is an accurate and complete report of all environmental harm events for the indicated period and group within the company.

(Signed) _____

Date _____ 19___

TSCA 8-1(APD)(5/15/77)

PROFIT CENTER_____

CUSTOMER COMPLAINT REPORT

FOR PERIOD_____19___ TO_____19____

REPORTED BY_____

1. List here the names of complainants (company name). (Attach copy)

2. Summary of action taken (or attach memorandum and give reference here).

The foregoing is an accurate and complete report of all customer complaints and their disposition for the above indicated period and Profit Center.

(Signature)_____

Date_____19___

SCA 8-2(APD) (3/15/77)

November 29, 1977

DIRECTIVE ON

SUBSTANTIAL RISK NOTIFICATION

The Toxic Substances Control Act, signed by President Ford in October 1976, became effective January 1, 1977. One of the features of the act which became effective on January 1, 1977 is contained in Section 8(e) known as "Substantial Risk Notification". As passed by the Congress, any person engaged in the manufacture, processing, or distribution of chemical substances, who obtains information which ~~leads to~~ the conclusion that substantial risk to human health or the environment exists is required to notify the Environmental Protection Agency of such risk.

Referring to APCI's standard practice (p. 5) and to directions given at the training sessions on TSCA compliance, the company procedure for dealing with matters of potential "substantial risk" is given. It is reproduced here.

> "The Company is required to inform the EPA immediately if it obtains any information which reasonably supports the conclusion that one of its chemical products presents a substantial risk of injury to health or the environment. Any one in the Company obtaining such information shall immediately forward it through the appropriate line management to the Group/Division Manager with environmental responsibility and to the TSCA Chairman who, along with the committee and appropriate management shall evaluate the degree of risk presented."

On September 9, 1977, the EPA published in the Federal Register a "proposed guidance" for Substantial Risk Notification. It is important to recognize that such is a "proposed" guidance. It, therefore, represents the thinking of a particular group of people within the EPA. Comments were invited and the TSCA Committee of APCI has submitted such to the agency. There is reason to expect that specifics of the proposed guidance will be altered as a result of APCI's and others' comments.

continued.....

The key concerns to employees are:

(1) All employees capable of appreciating pertinent information relative to substantial risk are required to submit pertinent information to corporate processing.

(2) The time period required to notify the EPA following receipt of pertinent information is short. (EPA has suggested 15-60 days in different options.)

(3) An employee's responsibility under the Act is completed when he has advised his supervisor in writing of his concerns. Failure to advise his supervisor could open the way for agency enforcement action.

The purpose of this notice is to advise APCI employees of the company procedures for compliance with TSCA Section 8(e), Substantial Risk Notification. The following procedures are to be followed in all sectors of the company:

(1) All employees capable of appreciating pertinent information relative to substantial risk are required to notify their line supervisor in writing with a copy to the TSCA Compliance Committee Chairman (C. E. Blades). Such written notification requires documentation with attached reports describing the information which leads to a potential conclusion of substantial risk to health or the environment.

(2) Beginning January 1, 1978, all orders for toxicological testing are to be placed through the TSCA Chairman's office. Reports of results, the management of toxicological testing contracts, and the responsibility for evaluation and pertinence of testing will reside with C. E. Blades and the TSCA Compliance Committee.

For your guidance, we summarize below the types of information which could lead to a Substantial Risk Notification.

(a) Demonstrated instances (or a series of events in a pattern which lead to a conclusion of a relationship) in which a product produces cancer, gene mutations, birth defects, death, or serious or prolonged incapacitation in humans.

continued.....

(b) Epidemiological studies, bioassays (in vitro or in vivo) which would reasonably support the conclusion of substantial risk of injury to human health or the environment when levels of exposure and degree of toxic hazard are taken into consideration.

(c) Information which illustrates:

(i) extreme persistance or non-biodegradability.

(ii) pronounced bioaccumulation (e.g., 50,000 x in 30 days for fish) or (10,000 partition coeff.)

(iii) interference with biogeochemical cycles (e.g., kills or inhibits nitrifying bacteria).

(iv) stimulates primary producers in aquatic ecosystems (e.g., phosphates and algae).

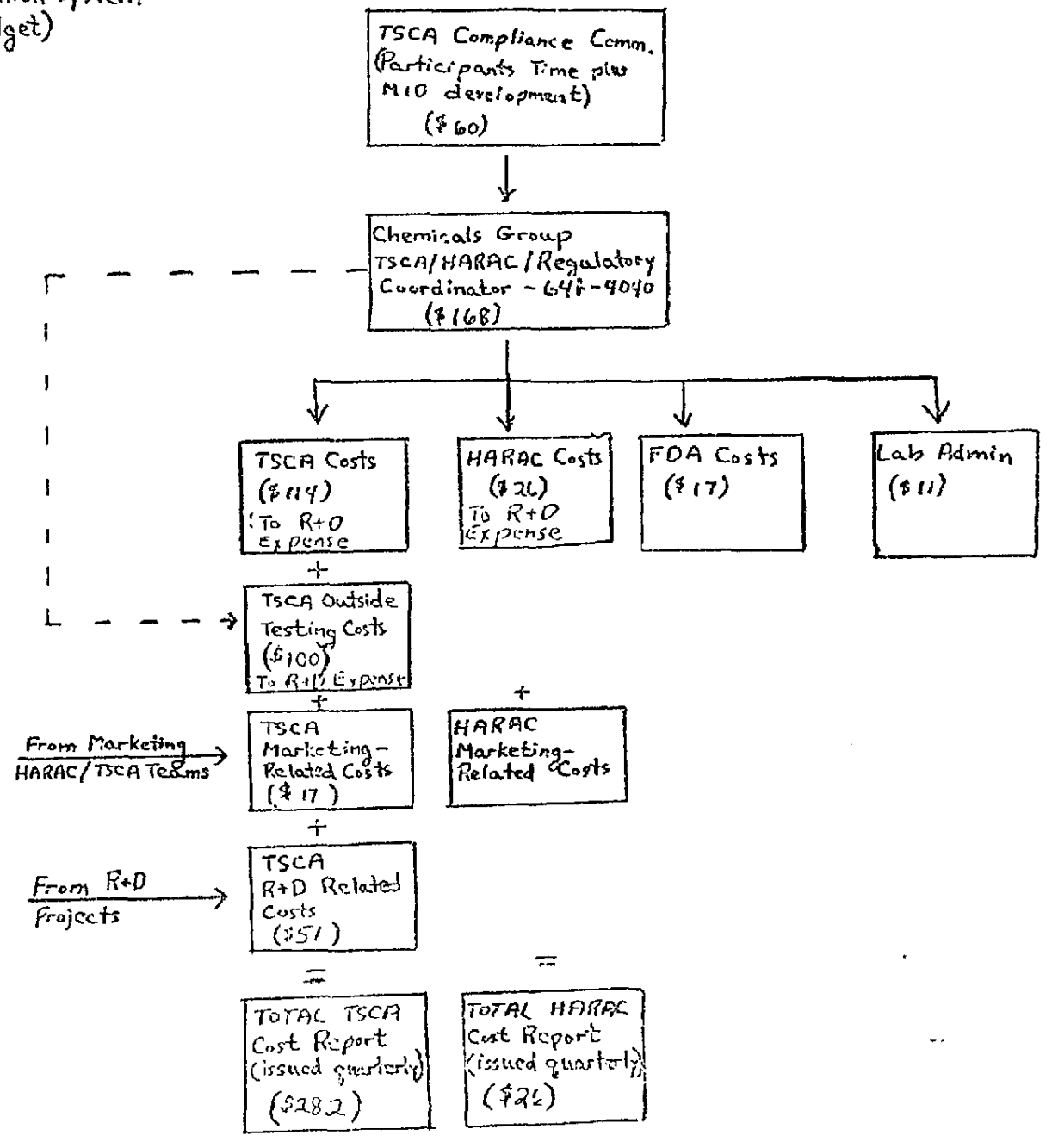
(d) Emergency incidents, especially spills which endanger human health or the environment as in (a), (b), (c).

CEB:sk

C. E. Blades

Exhibit 1

TSCA Cost Collection System
($000 FY 78 Budget)



HP 11/8/77

EXHIBIT II

TSCA Costs By Profit Center
Budget FY 1978

($000)

To Profit Centers	From Coordinator's Office	From Outside Testing	From Profit Center Marketing	From Profit Center R&D	Total
Processes & Catalysts	$ 11	$ -	$ -	$ -	$ 11
Chemical Additives	23	67	-	26	116
Acetylenics	17	-	-	-	17
Polymers	2	33	-	25	60
Industrial Chemicals	29	-	9	-	38
Ammonia	6	-	-	-	6
Plastics	2	-	1	-	3
Fabricated Plastics	1	-	-	-	1
Specialty Gas	23	-	7	-	30
TOTAL	$114	$100	$17	$51	$282

HWP/dls
11/10/77