

cc: W. M. Smith R. Collins
L. Tepper W. Ent
R. H. Schenck G. Handley
J. C. Novak E. Handwerk
A. J. Diglio J. Starr
R. Fleming

DATE: Sept. 8, 1977

TO: TSCA COMPLIANCE COMMITTEE

FROM: C. E. BLADES

6-352

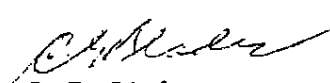
TSCA BULLETIN NO. 19

COMMENTS BY W. MUIR, CHAIRMAN OF THE TSCA INTERAGENCY
TESTING COMMITTEE ON THE PRELIMINARY LIST
OF PRIORITY CHEMICALS FOR TESTING

APCI comments were submitted on specific items included on the list. There appears to be an intention to give us a second chance at commenting on a "LIST OF 90".

CEB:sk

Encl: Chem. Reg. Reporter
pg. 791, 8/19/77


C. E. Blades

AP00049164



Current Report

Pesticides

EPA REQUESTS AUDIT OF 'DEFICIENT' TESTS USED TO SUPPORT PRODUCT APPROVAL, SALE

The Environmental Protection Agency requested 31 pesticide manufacturers July 27 to audit the toxicology studies prepared for them by an Illinois laboratory after finding "significant deficiencies" in the manner in which the studies were conducted.

The studies, done by Industrial Biotest Laboratory (IBT), Northbrook, Ill., a subsidiary of Nalco Chemical Company, were used by EPA in support of approval for sale of pesticide products and approval of residues on food crops. Deficiencies in the studies "may have undermined the scientific integrity of several of these studies to the extent that they can no longer support decisions on the safety of these products," according to Edwin L. Johnson, EPA deputy assistant administrator for pesticide programs.

In a letter to 31 pesticide manufacturers, the Food and Drug Administration and the Department of Agriculture, Johnson said that on-spot inspections and a check of IBT's records showed "significant deficiencies in the manner in which animal toxicology studies were conducted as well as discrepancies between the data."

The letter and a list of recipients appear in the Full Text section of this week's report.

An EPA spokesman told Chemical Regulation Reporter that deficiencies included a feeding study, which IBT said lasted 24 months but which actually was terminated after 18 months, and reporting the use of live test animals after they had previously been reported killed in an earlier experiment.

The spokesman said EPA is not sure at this point whether the deficiencies were deliberate or just the result of poor work. He said EPA is not alleging that the deficiencies were deliberate, but if this is proven to be the case, EPA has the option of taking enforcement action against the laboratory.

IBT performed health-effects testing for many pesticide manufacturers. In the case of the 33 listed companies and agencies, IBT tests support EPA approval of 123 pesticide ingredients and 160 tolerances, also listed in the Full Text section of this report. Another 100 manufacturers who use IBT test data also may be requested to audit their information, EPA said.

EPA Administrator Douglas M. Costle said in a press release that if the audit reveals irregularities that indicate serious human health or environmental hazards from certain pesticides, several regulatory choices are available, including revoking or modifying the pesticides' registrations or tolerances and referring information on the faulty tests to the Justice Department for appropriate action.

The EPA spokesman said the work of IBT was singled out because EPA had "concrete evidence of faulty testing" performed by the laboratory. This evidence was uncovered in the course of Food and Drug Administration routine inspections of animal testing facilities.

Under a joint FDA-EPA program, FDA investigators audit the quality and authenticity of data developed by labs that test the safety of chemical compounds. The results are shared with EPA if irregularities are found.

Diana Reisa, manager of the EPA audit, said that an audit of five long-term studies performed by IBT were found

to have such "serious deficiencies" as to cause them to be invalidated. These were "backbone" studies, she said — the kind that EPA bases its regulations on. Reasons for the deficiencies were that IBT "did not tool up, cut corners," and performed "sloppy work," she said.

Approximately two months ago, she said, FDA informed EPA that it was not going to accept any more data from IBT unless it is certified. It was at this point that EPA took the initiative to examine IBT data because EPA has better computer and data storage capability than FDA, she said.

Data Audit

According to EPA, the IBT laboratory did approximately 4,300 health effects tests for pesticide producers. EPA is requesting from the manufacturers an audit of the raw data and validation of chronic feeding, reproduction, teratogenicity, oncogenicity, nerve damage, and metabolism studies in support of tolerance petitions and all neurotoxicity studies performed by IBT. Audits of studies submitted in support of the registration of products with home uses and in support of other major uses will be conducted later.

This audit is limited to studies performed by IBT, Johnson said, but he asked the pesticide manufacturers to submit a plan for validating all studies submitted to EPA and to inform EPA of any questionable practices by any contract laboratories.

The manufacturers were requested to submit to EPA a time frame during which they intend to perform the audit. No deadline was set on the audit, Reisa said, because the manufacturers are going to have to "flood IBT with requests for new data."

Reisa also said EPA has received some responses from manufacturers. Neither they nor IBT has shown any resistance to the audit, she said, and added that IBT suggested that an audit is the proper way to resolve the problems of deficient test studies.

A. J. Frisque, IBT president, said only that the laboratory is cooperating with EPA in the effort to expedite the program for review of IBT's studies.

Meanwhile, a spokesman for EPA's registration division said the program to reregister pesticides is in a "holding pattern" until the companies conduct tests and certify the studies as being good.

Testing

INTERAGENCY COMMITTEE TO BEGIN SCORING CHEMICALS IN SEPTEMBER

The interagency committee charged with selecting 50 priority chemicals for early address by the Environmental Protection Agency plans to begin scoring chemicals on its preliminary list around the beginning of September, according to the chairman of the committee.

Warren Muir, chairman of the TSCA Interagency Testing Committee, told Chemical Regulation Reporter August 16 that until that meeting in September, the committee probably will meet in executive session to work out contractor and personnel matters, including interviewing and selection of an executive secretary for the committee.

Muir has chaired the interagency group as a representative of the Council on Environmental Quality. Although he recently moved to EPA to assist in the organization of the Office of Toxic Substances, he said he will retain his position as chairman of the committee.

Selection of Chemicals

Muir said the committee probably will discuss the weighting system to be used and begin the actual scoring of the chemicals on September 1 or September 8. In the meantime, he said, the group has prepared an outline for its final report to EPA and has selected a number of chemicals for which dossiers are to be prepared by September 1 by the committee's contractor, Clement Associates, Inc.

Clement will make recommendations to the committee on scoring the preliminary list of chemicals, Muir said, based on the substance's potential for carcinogenic, mutagenic, and teratogenic activity; other human effects; potential ecological hazards; and the need for further testing (Current Report, August 5, p. 731).

The scored chemicals then must be integrated into some sort of index, he said, from which they can be ranked. After the substances are ranked, he said, dossiers will be prepared for the top 90 chemicals and public comments will be reviewed before the selection of the 50 priority chemicals for testing by EPA.

Muir said that only two public comments had been received thus far on selection of the priority list. He added, however, that he expected to receive a great number of comments before the selection process is completed.

Comments were to be submitted in triplicate by August 22 to Phyllis Tucker, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20006. Comments received after that date will not be considered by the committee in developing its list of 50 chemicals, but will be considered in future revisions of the list.

Dibromochloropropane

ADDITIONAL PESTICIDE PLANTS TO BE INCLUDED IN STUDY OF WORKER STERILITY

Major manufacturers of the soil fumigant dibromochloropropane (DBCP) are suspending production of the chemical and additional pesticide plants in California are to be studied by federal and state health officials as an investigation into the cause of sterility among workers at the Occidental Chemical Company is widened.

The California Food and Agriculture Department August 12 suspended the sale of DBCP in the state after sterility in workers at the Lathrop, Calif., Occidental plant was linked to exposure to the chemical (Current Report, August 12, p. 761). The Occupational Safety and Health Administration also took action August 12, warning users or producers of DBCP in a telegram to take "appropriate action" for the protection of potentially exposed employees.

The suspension of DBCP sales, which also prohibits use of supplies of the chemical now in storage, is applicable only in California. However, Dow Chemical Company, a major producer of DBCP under the trade name Fumazone, said August 11 it is halting production because "the chemical may cause sterility in male workers." A spokesman for another major manufacturer of DBCP, Shell Chemical Company, which produces the chemical on a seasonal schedule from October through April, said August 15 that the company will decide in September whether to resume production of the chemical.

Although Dow still is in the process of gathering information, preliminary data on workers at the company's Magnolia, Ark., plant show some workers with low sperm counts indicating sterility, according to a Dow spokesman. The Shell spokesman said his company has begun medical examinations of workers at its Mobile, Ala., plant that presently produces DBCP and at a Denver plant that produced the chemical until 1975.

NIOSH: Other Chemicals Suspect

Although DBCP is the "greatest suspect" for causing the employee sterility at the Occidental plant, it is not the only one, according to Channing Meyer, a National Institute for Occupational Safety and Health physician heading an investigating team at the Occidental plant. Meyer told BNA that ethylene dibromide, a nematocide, and carbaryl, an insecticide, also were present in the agricultural chemical section of Occidental and are considered suspect. Like DBCP, ethylene dibromide and carbaryl were shown to be possible causes of sterility in tests on laboratory animals, Meyer said.

All three chemicals are under review by the Environmental Protection Agency as possible candidates for rebuttable presumption against registration.

Meyer reported on the results of medical tests completed as of August 15 on 23 Occidental workers who were directly involved in the formulation of pesticides. The findings were abnormal for 13 men, including nine who had a sperm count of zero, two who had a count of one million, one who had a count of 10 million, and one who had a count of 20 million. Medical opinions of what is considered a normal sperm count range between 50 million and 60 million.

Tests to find adverse effects on liver, kidney, and bone marrow proved negative, Meyer said. Examination of three female workers who may have been exposed to DBCP also showed nothing abnormal, he added.

Additional Tests

Donald Wharton, of the University of California at Berkeley, is to begin testing an additional 50 to 100 Occidental employees, including workers from allied areas of the plant, laboratory technicians who may have entered the pesticide section, repairmen, and clerical staff, according to Meyer.

Wharton also will examine a control group of 25 to 50 employees at Occidental who worked in areas completely separate from the section of the plant where the exposed employees worked, Meyer said.

In the next phase of the investigation, Meyer said, NIOSH and state officials want to look at four or five other pesticide plants in California to compare workers' health and conditions at those plants with Occidental. He said half the plants studied would be chosen because they formulated pesticides similar to those at Occidental and the other half would be companies which produced pesticides unlike Occidental's, such as parathion.

"It wouldn't do us any good just to study all five formulators of DBCP in California," he said.

It still is unknown whether the loss of fertility suffered by the workers is reversible once exposure has been stopped, Meyer said. An additional concern is that the previous study of the effects of DBCP on animals showed that it caused stomach cancer in rats, he said.

EPA: 'Not Jumping In'

Although EPA is examining DBCP as part of its review of pesticides prior to rebuttable presumption against registration, the agency is "not jumping in" at this point to act against the chemical until it has more information, accord-

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DATE: Sept. 8, 1977

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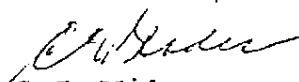
FROM: C. E. BLADES

6-352

TSCA BULLETIN NO. 20

The attached from Pesticide & Toxic Chemical News discusses content of a draft proposal on rules relative to "SUBSTANTIAL RISK". The draft is of interest as a barometer of EPA/OTS thinking on the subject. We can evaluate this in the context of our own concerns with TNBA.

CEB:sk
Encl.


C. E. Blades


AP00049167

"Legal deficiencies" of the plan identified by EPA included: No authority to deny a certification on the grounds of pesticide misuse and falsification of records or to suspend or revoke certification under any circumstances; no specific prohibition against the use of restricted use pesticides by noncertified applicators; no recordkeeping requirements; no reporting requirements; and applicator competency determination method does not meet the Section 4 standards.

Pennsylvania's applicator certification plan has been "fully approved" by EPA.



DRAFT TSCA GUIDANCE ON "SUBSTANTIAL RISK" NOTICES REJECTS EXPERT PANEL SCREENING

"Guidance" for industries submitting "substantial risk" information to the Environmental Protection Agency under Section 8(e) of the Toxic Substances Control Act (TSCA) rejects the notion that industry should not report such information until it assembles a panel of experts to decide whether, in fact, the risk is "substantial."

According to the guidance, which now is on EPA Administrator Costle's desk for signature, substantial risk information should be submitted to EPA within 15 days after any firm employee or officer capable of appreciating the information's significance obtains the data.

By making the reporting rules applicable to employees as well as to company officers, EPA hopes to force firms to set up internal communications systems which will foster quick transmittal of substantial risk data to EPA.

EPA decided against the panel of experts provision, EPA staff say, because such a procedure would delay transmittal of pertinent data.

As previously reported (See May 4, Page 8), the guidance provides for a two-step notification procedure if all information required on notices cannot be collected within 15 days. Also unchanged is EPA's intent to make Section 8(e) applicable to information obtained before Jan. 1, 1977, which is the effective date of TSCA.

However, the draft which Costle is reviewing says that if a person received risk information prior to Jan. 1, but "has not been aware" of the information since that date, that person would not be required to report. "By limiting the scope of Section 8(e) to risk information of which a person has been aware during 1977, EPA intends to limit the need for searches of historical records and file," the draft says.

EPA staff say that TSCA Section 8(d) can be employed as a means for the Agency to collect specific health and safety studies conducted prior to Jan. 1, 1977, but "at this time," the draft says, "EPA has not yet adopted an approach which establishes requirements for searching and reviewing information obtained before 1977."

TSCA Section 8(e) is the provision under which Occidental Chemical Company notified EPA about infertility among workers exposed to a chemical produced by both Dow and Shell Chemical Company (See separate story).

AP00049168

For Now, Data In Hands of Other Agencies Doesn't Substitute for a Section 8(e) Notice

One change from the earlier drafts is that EPA would not exempt from reporting any data which industry may have submitted to the Food and Drug Administration, the Occupational Safety and Health Administration, the Consumer Product Safety Commission or the National Institute for Occupational Safety and Health. "The recent draft explained that "interagency arrangements for the timely exchange of such information" are not expected to be operational for a year. "In the interim," the draft says, "reports to other agencies do not substitute for reports to EPA under Section 8(e)."

What need not be reported, according to the latest draft, are data which 1) has been published by EPA in reports; 2) has been submitted to EPA under its other authorities 3) has been published in the English language, in scientific literature "widely available" in the U.S.; 4) is "corroborative of well-established adverse effects already documented in the published, English language, scientific literature"; or 5) is contained in notifications of spills under Section 311(b)(5) of the Federal Water Pollution Control Act.

A cover memo distributed with the draft said that exemption 2 should be "subject to conditions designed to ensure that the risk suggested by data (submitted under other authorities) is surfaced for immediate attention."

Also as before (See May 25, Page 2), the guidance is said to apply to "situations" "incidents" which may signal risk, not merely to "intrinsic qualities" of chemicals. When published in the Federal Register, the guidance will provide telephone numbers for immediate notification on situations or incidents which signal substantial risk.

Except for the first requirement, telephone notices should contain all of the information required of written notices, according to the draft. These requirements are as follows: The notice should:

- "(a) be sent by certified mail, or in any other way permitting verification of its receipt by the Agency,
- "(b) state that it is being submitted in accordance with Section 8(e),
- "(c) contain the job title, name, address, telephone number and signature of the person reporting and the name and address of the manufacturing, processing or distributing establishment with which he is associated,
- "(d) identify the chemical substance or mixture,
- "(e) summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and
- "(f) contain the specific source of the information together with a summary and the source of any available supporting technical data.

If (e) and (f) cannot be provided within 15 days, the guidance says, the data submit should describe the potential hazard "insofar as possible," explain the need for the

AP00049169

delay and propose a schedule, not to exceed an additional 15 days, whereby the additional data would be submitted.

Following telephone notices, written reports detailing (a) through (f) would be required.

In its guidance on what information does, in fact, "reasonably support the conclusion of substantial risk," the draft said that "economic or social benefits of use, or costs of restricting use, are not to be considered."

Every "I" Need Not be Dotted Before Reporting Is Required, Draft Declares

Neither human health nor environmental effects need be "conclusively demonstrated" to be caused by the chemical substance or mixture, the draft says, "as long as evidence links the chemical substance or mixture to the effects." Information which ascribes "relatively serious" risk, including but not limited to the following should be reported, the draft states:

"(1) Any instance of cancer, gene mutations, or birth defects. Any instance of toxicity that results in death, or serious or prolonged incapacitation (other than due to gross misuse).

"(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture produces cancer, gene mutations, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation. Consideration should be given to the extent and seriousness of the ailment, and/or whether or not the immediate manifestation may be a precursor of a more serious affliction. Impaired health requiring reporting may include such effects as dermal ailments or nausea if they meet the above criteria."

Environmental effects worthy of reports were listed as follows:

"1. Extreme persistence of a chemical substance not naturally occurring or occurring in greater than natural concentrations as a result of commerce.

"2. Pronounced bioaccumulation, including bioaccumulation in fish beyond 50,000 times water concentration in a 30-day exposure or having a n-octanol/water partition coefficient greater than 10,000.

"3. Interference with critical biogeochemical cycles, such as the nitrogen cycle. Chemical substances which are known to be toxic to key organisms in the cycles (for example, nitrifying bacteria) would present a substantial risk.

"4. Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

"5. Any ecologically significant effects on non-human organisms due to acute or chronic toxicity such as cancer, mutation, birth-defects, or serious or prolonged incapacitation.

"6. Facile transformation or degradation to a chemical having an unacceptable risk as defined above."

AP00049170

Results from epidemiological studies, bioassays, in vivo or in vitro tests or any formal studies on either human health or environmental effects "are not to be withheld until the completion of the studies," the draft says, "but should be reported as soon as they reasonably support the conclusion of substantial risk."

An incident or situation which "critically imperils" a human population or "critically threatens non-human organisms with large-scale and ecologically significant population destruction" should also be reported, the draft says.

Failure to adhere to the guidance could bring civil penalties of up to \$25,000 for each day of violation, as well as criminal penalties. A summary of the guidance notes that EPA would focus enforcement activities on:

"a. employees reasonably capable of appreciating pertinent information who fail to submit or delay submitting such information to supervisors for corporate processing,

"b. supervisors who fail to process substantial-risk information for submission to the Administrator in a timely manner, and

"c. establishments and their chief executive officers that fail to process and notify the Administrator of substantial-risk information in a timely manner."

o

NO DBCP TOLERANCES, EPA SAYS; RPAR DUE IN SEPT.; SOME USES MAY BE CANCELLED

There are no tolerances for residues of dibromochloropropane (DBCP), soil fumigant, on food crops, according to Environmental Protection Agency officials (See Aug. 17, Page 2).

Reasons for this are that when the tolerances were set there was no analytical method for DBCP, and its use as a soil fumigant was not expected to result in residues on crops, the officials said. DBCP is an organic bromide. Tolerances were set on an inorganic bromide basis.

There now is an analytical method and EPA has asked the Food and Drug Administration to check and validate it.

If the method is acceptable, EPA will ask FDA to take regulatory action against food crops containing "illegal" DBCP residues, an EPA official stated.

EPA is expected to issue a DBCP rebuttable presumption against registration (RPAR) notice early next month. The notice will probably be based on oncogenic and reproductive effects, including sterility.

Furthermore, if exposure data warrants it, some uses of DBCP may be cancelled now, another EPA official said.

DBCP soil fumigant substitutes may have the same sterility effects as DBCP, he observed.

There is no present pressure on EPA to cancel or suspend DBCP, one agency official

Another predicted that the agricultural community would not fight hard to keep DBCP on the market because of the sterility effect. "The reaction of the agricultural community to DBCP regulation will probably be different than the reaction to regulation of carcinogens," he asserted.

In a memorandum sent last week to EPA Administrator Costle, EPA's Acting Assistant Administrator for Enforcement, Richard D. Wilson, said the Office of Pesticide Programs (OPP) "Will be responsible for determining what data is needed to suspend, cancel or restrict registration of products containing DBCP."

AP00049171

Date 31 August 1977

INTEROFFICE
MEMORANDUM

Subject TSCA Compliance Committee Agenda
for September 12, 1977

To Distribution

(Location, Organization, or Department)

From T. B. Collins

Management Information Department

(Location, Organization, or Department)

Distribution

D. F. Baker	S. R. Derbenwick	P. W. C. Mather
C. E. Blades	J. M. Egan	J. C. Novak
J. H. Body	W. L. Ent	R. H. Schneck ✓
P. L. T. Brian	R. Fleming	W. M. Smith
L. C. Claitor	G. G. Handley	L. B. Tepper
R. W. Collins	E. I. Handwerk	J. V. Urenovitch
A. J. Diglio		

A presentation covering the information requirements of the Toxic Substances Control Act will be presented by MID at the next meeting of the TSCA Compliance Committee at 9:00 on 12 September 1977, in conference room 113G. An outline of the presentation is attached.

The presentation will precede the other business of the committee. If you are aware of any other individuals who might have an interest in this presentation, please feel free to invite them.

TB Collins

TBC/dlk

RECEIVED

SEP 6 1977

MANAGEMENT

(320)

AP00049172

INFORMATION REQUIREMENTS OF THE
TOXIC SUBSTANCES CONTROL ACT

NAME, CAS REGISTRY NO., STRUCTURE

BY-PRODUCTS, IMPURITIES, INTERMEDIATES

PRODUCTION VOLUME BY LOCATION

PRODUCT USES

METHODS OF DISPOSAL

EXPOSURE

SIGNIFICANT ADVERSE REACTIONS

HEALTH AND SAFETY STUDIES

AP00049173

Date August 26, 1977

INTEROFFICE
MEMORANDUM

Subject Notice of TSCA Compliance Committee

Meeting - Sept. 12, 1977

To Distribution

(Location, Organization, or Department)

From C. E. Blades

Piscataway

(Location, Organization, or Department)

The regular monthly meeting of TSCA Compliance Committee is scheduled for MONDAY, SEPTEMBER 12, 1977 at 9:00 A.M. in CONFERENCE ROOM 113G, Main Office Building, Trexlertown.

AGENDA

RECEIVED

AUG 29 1977

LABORATORY DEPARTMENT

1. Presentation on Record Keeping & Reporting by Tom Collins of MID.

- a. Discussion

- b. Action Points

2. Proposed Inventory Rules -- Update

- a. Comments by September 16

- b. Report on MCA Activity

3. The Confidentiality Issue -- MCA positions

4. New Developments

5. Experimental Samples -- Company Directive

(Reference: Memo D. G. Holland to E. Galla, 7/27/77)

6. Report on Priority List Commentaries.

7. Business as introduced by committee members.

CEB:sk

Encl.

Distribution: W. M. Smith
L. B. Tepper
J. C. Novak
R. H. Schenck
A. J. Diglio
E. I. Handwerk

W. Ent
G. Handley
Reid Collins
J. Body
Joanne Egan
Tom Collins

C. E. Blades
C. E. Blades

(320)

AP00049174

JUL 28 '77 - CE

INTEROFFICE
MEMORANDUM

Date July 27, 1977

Subject Noryl Foam Stabilizers -
Samples

To E. A. Galla

(Location, Organization, or Department)

From Dr. D. G. Holland

(Location, Organization, or Department)

cc: C. E. Blades
R. A. Blomquist
R. L. Mascioli
W. A. Meeley
M. H. Ziv

[Handwritten initials]

I discussed the shipments of the experimental foam stabilizers for field evaluation with Dr. E. Blades. The materials will be shipped from Linwood in the same fashion in which we ship materials for toxicological testing to Biosearch. The samples will be addressed to a specific individual. The samples will be labeled with our "experimental sample" labels.

It is important that, under separate cover, you address a letter to the particular individual who will receive the samples. This letter will contain a statement that we have the individual's assurance that the testing of these samples will be done under the supervision of technically qualified personnel. The letter should contain a statement which describes the recommended method of use of the material. Additionally, this letter should describe the materials as polymeric solids of low volatility which should be handled with the usual precautions of an experimental material whose toxicology is unknown. The samples therefore should be handled in a manner in which operators avoid inhalation of the solid samples. Adequate ventilation should be employed during high temperature molding of products containing the samples. You may also wish to state that over the past year of experience with the samples we have not observed any toxicological effects in the high temperature milling and compression molding of these materials when utilized in our laboratory under standard laboratory ventilation conditions and that if the materials appear to be commercially viable products we will submit them for detailed toxicological testing.

In addition to the above, the sample label should have either your or my name on it so that there is a specific person at Air Products who could be contacted by the user.

[Handwritten signature: Dewey G. Holland]
D. G. Holland

jsv

AP00049175

Date August 15, 1977

INTEROFFICE
MEMORANDUM

Subject Minutes of TSCA Compliance Committee

Meeting - August 15, 1977

To Distribution

(Location, Organization, or Department)

From C. E. Blades

Piscataway

(Location, Organization, or Department)

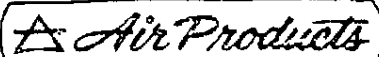
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T. P. Collins
J. Starr
C. E. Blades

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AUG 20 1977

LAKE DEPARTMENT



Date August 15, 1977

INTEROFFICE
MEMORANDUM

Subject Minutes TSCA Compliance Committee

August 15, 1977

To Distribution

(Location, Organization, or Department)

From C. E. Blades

Piscataway

(Location, Organization, or Department)

In Attendance:

Members

W. M. Smith
A. J. Diglio
J. C. Novak
R. W. Collins

C. E. Blades
R. H. Schenck
E. I. Handwerk

Guests

J. Urenovitch (Spec. Gas)
T. B. Collins (MID)
J. Starr (MID)
S. Durbenwick (MID)

1. Priority List

The task of reducing, from 347 to 50, the number of chemicals to be tested under the direction of the EPA is assigned to the Interagency Committee on Priority Chemicals Testing (ICPCT). Emphasis of choice will be on carcinogenic, mutagenic, and teratogenic properties of the chemicals. The ICPCT seeks comments on proposed additions or deletions to the list. Substantiating information must accompany requests to add or delete.

In order to prepare a response to the ICPCT, a list was made of APCI chemicals present among the 347 to be evaluated. Chemicals manufactured or processed by the Industrial Gases Division were discussed. A response to the ICPCT may be offered for acetylene, (arsine), phosphine and lithium hydride. CEB will contact the appropriate business areas in the Chemicals Group to discuss the problem and determine the necessary response.

A responsive action requesting removal of APCI chemicals was suggested due to the possible regulatory action and notoriety attained if a chemical is placed on the top 50 list. Also suggested was the practicality of no action with the intent that if a chemical was listed, then testing costs would be divided among the manufacturers.

continued.....

AP00049177

The TSCA Committee suggests that MMA, MEA, TMA, and TEA be removed on the basis that tertiary amines are not converted to nitrosamines by nitrous acid and primary amines have a low propensity for nitrosamine formation (thermodynamically).

Responses concerning raw materials will not be submitted due to inadequate information.

2. Substantial Risk Notification

Recently obtained acute inhalation data on TNBA is to be reported to the EPA as a point of new information. The data indicate that TNBA is a Class B poison. Although test animals were subjected to TNBA as an aerosol, the risk of similar exposure to plant workers exists. CEB will sign EPA notification letter.

Bill Ent informed the committee that NF₃ production looks very promising for the near future. NF₃ shows positive in the Ames Test (done in-house). Repeat testing is underway on a purified sample.

W. M. Smith reported that at a recent conference with the CIIT, it was felt that a positive Ames test is not sufficient data to elicit "substantial risk" notification. A second in vitro test is required. W. M. Smith suggests a cell transformation test be run on NF₃.

3. Inventory Reporting

The committee was informed of additional proposed requirements for inventory reporting. Of major concern is the issue on confidential treatment of submitted material. Action may be delayed until the finalized regulations are published in October. No recommendation is made by the committee for specific company comments beyond those to be prepared by the MCA, although close monitoring and/or participation is in order.

4. Tenneco Letter

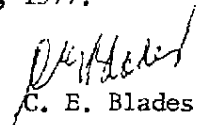
Ray Schenck reported that the law does not require a company to notify customers of "substantial risk" information.

5. MID Involvement

The TSCA Committee will set aside time at the next meeting to hear a report by Tom Collins on MID's possible involvement with TSCA concerning record-keeping and retrieval.

The next meeting is scheduled for SEPTEMBER 12, 1977.

CEB:EH:sk


C. E. Blades

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