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PART IV

ENVIRONMENTAL PROTECTION AGENCY

TOXIC SUBSTANCES CONTROL ACT

Third Report of the Interagency Testing Committee; Receipt of Report and Request for Comments

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[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 995-1]

THIRD REPORT OF THE INTERAGENCY TESTING COMMITTEE

Receipt of the Report and Request for Comments

AGENCY: Environmental Protection Agency.

ACTION: This Notice requests comments on recent additions to the Interagency Testing Committee's Priority List of chemical substances recommended for testing under the Toxic Substances Control Act.

SUMMARY: The Interagency Testing Committee established under section 4(e) of the Toxic Substances Control Act (TSCA) has transmitted its Third Report to the Administrator of the Environmental Protection Agency (EPA). This Report revises and updates the Committee's Priority List of chemicals. The Report identifies those additional chemical substances the Committee is recommending to EPA for priority consideration for promulgation of test rules under section 4 of the act.

The Third Report is being published with this Notice. The Agency invites interested persons to submit comments on the Report.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Section 4 of TSCA authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances in order to develop data relevant to determining the risks that such chemical substances may present to health and the environment.

Section 4(e) of TSCA establishes an Interagency Testing Committee to make recommendations of chemical substances to the Administrator of EPA to be given priority consideration for test rules under section 4. The Committee's recommendations are set forth in the form of a Priority List. Up to 50 of the chemical substances on the Priority List may be designated by the Committee for which EPA must within 12 months of designation initiate rulemaking to require testing or publish in the FEDERAL REGISTER its reasons for not doing so.

The Committee's initial recommendations to the Priority List, of four substances and six categories of substances, were published in the FEDERAL REGISTER on October 12, 1977 (42 FR 55026). Revisions to that list appeared in the Committee's Second Report and were published in the FEDERAL REGISTER on April 19, 1978 (43 FR 16684). Those revisions were the addition of four substances and four categories of substances to the Priority List.

In its Third Report, the Committee is recommending the addition of one chemical substance and two categories of chemical substances to the Priority List.

These three additions have also been designated by the Committee for EPA to initiate rulemaking within 12 months or publish its reasons for not doing so.

AVAILABILITY

The Committee's Third Report appears in the FEDERAL REGISTER following this notice.

The information dossiers used by the Committee in developing the recommendations presented in the Third Report will be transmitted by the Committee to EPA in the next few weeks.

Copies of the Third Report and/or dossiers are available from: John B. Ritch, Jr., Director, Industry Assistance Office, Office of Toxic Substances (TS-799), EPA, 401 M Street SW., Washington, D.C. 20460. Call toll free 800-424-9065; in Washington, D.C., call 554-1404.

REQUEST FOR COMMENTS

EPA invites interested persons to submit comments on the Committee's new recommendations. In view of the October 1979 statutory deadline for initiating rulemaking (or publishing reasons for not doing so), the Agency requests that comments be submitted no later than March 30, 1979.

Comments should bear the identifying notation OTS-040005 and should be submitted to Joyce Barbour, Document Control Officer, Chemical Information Division, Office of Toxic Substances (TS-793), Room 711-A, EPA, 401 M Street SW., Washington, D.C. 20460. All written comments will be available for public inspection in Room 711, East Tower, at the same address, between 8:30 a.m. and 4:30 p.m., weekdays.

Dated: October 23, 1978.

STEVEN D. JELLINEK,
Assistant Administrator for Toxic Substances.

THIRD REPORT OF THE TSCA INTERAGENCY TESTING COMMITTEE TO THE ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

OCTOBER 1978:

CONTENTS

TSCA INTERAGENCY TESTING COMMITTEE

STATUTORY MEMBER AGENCIES

Council on Environmental Quality: Carroll Leslie Bastian; Nathan J. Karch, Alternate.

Department of Commerce: Orville E. Paynter; Bernard Greifer, Alternate.

Environmental Protection Agency: Warren R. Muir; Joseph J. Merenda, Alternate.

National Cancer Institute: James M. Sontag.

National Institute of Environmental Health Sciences: Hans L. Falk; Warren T. Piver, Alternate.

National Institute for Occupational Safety and Health: Jean G. French, Vice Chairperson; Vera W. Hudson, Alternate.

National Science Foundation: Marvin E. Stephenson, Chairperson; Carter Schuth, Alternate.

Occupational Safety and Health Administration: Joseph K. Wagoner; Fred W. Clayton, Alternate.

LIAISON AGENCIES

Consumer Product Safety Commission: Joseph McLaughlin.

Department of Defense: Seymour L. Friess.

Department of the Interior: Charles R. Walker.

Food and Drug Administration: Allen H. Heim; Winston deMonsabert.

COMMITTEE STAFF

Executive Secretary: Carol A. Mapes.
Secretary: Madye B. Cole.

ACKNOWLEDGMENTS

The Committee members acknowledge the support and invaluable contributions of the many individuals and groups who have significantly aided us in our work. These include:

The Federal agencies who have cooperated by providing support through the liaison members;

Clement Associates, Inc., technical support contractor;

The U.S. Environmental Protection Agency (EPA) for funding the technical support contract and the National Institute for Occupational Safety and Health, the Council on Environmental Quality, and the National Cancer Institute for assisting in the funding;

Former liaison member Robert Hehir, Consumer Product Safety Commission;

Former EPA staff member Donald G. Barnes, Office of Toxic Substances;

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EPA staff members who assisted the Committee in a variety of activities, in particular: John W. Lyon, Office of the General Counsel; Ralph C. Northrop, Jr., Office of Toxic Substances; and Amy Rispin, Office of Toxic Substances;

The numerous experts who prepared presentations and material for the Committee;

The industries that responded to the Contractor's request for information on specific chemical substances and categories; and

The many individuals and organizations who responded to the Committee's previous reports.

SUMMARY

A major section (Sec. 4) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469) provides for the testing of chemicals in commerce which may pose an unreasonable risk to human health or the environment. This section of the Act also provides for establishment of a Committee, composed of representatives from eight designated Federal agencies, to recommend chemical substances or mixtures to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules. The Committee makes such revisions in the Section 4(e) Priority List as it determines to be necessary and transmits them to the Administrator, at least every 6 months.

As a result of its deliberations during the past six months, the Committee is revising the TSCA Section 4(e) Priority List by the addition of one individual substance and two categories of substances. Each of these new recommendations is being designated by the Committee for action by EPA within 12 months. The Committee considers these additions to be of the same priority as the previous entries. The chemical substance and categories being added to the Priority List are presented alphabetically, together with the types of studies recommended, as follows:

Substance or category	Recommended studies
Chlorinated Benzenes, Tri-, Tetra- and Penta-	Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, environmental effects, and epidemiology.
1,2-Dichloropropane.	Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, environmental effects, and epidemiology.
Glycidol and its derivatives.	Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, and epidemiology.

Information dossiers on these new entries will be forwarded to the EPA Administrator at the earliest practicable date.

THIRD REPORT OF THE TSCA INTERAGENCY TESTING COMMITTEE TO THE ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

OCTOBER 1978.

CHAPTER 1. INTRODUCTION

1.1 Background

The Interagency Testing Committee (Committee) was established under Section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469). The specific mandate of the Committee is to identify and recommend to the Administrator of the U.S. Environmental Protection Agency (EPA) chemical substances or mixtures in commerce which should be tested to determine their potential hazard to human health and/or the environment. The Act specifies that the Committee's recommendations to the Administrator will be in the form of a list (sec. 4(e) Priority List) to be published in the FEDERAL REGISTER. The Committee also is directed to make such revisions in the list as it determines to be necessary and transmit them to the Administrator, at least every 6 months after submission of its initial list.

The Committee has eight statutory members appointed by the Federal agencies identified for membership in Section 4(e)(2)(A) of the Act as well as a number of alternate members as permitted by Section 4(e)(2)(B)(i). In addition, the Committee has invited several other Federal agencies with programs related to the control of toxic substances to designate liaison representatives to participate in its meetings. The current Committee members, alternates, and liaison representatives are identified in the front of this report.

1.2 Previous reports

In July 1977, the Committee published a Preliminary List of 330 chemical substances and categories which it had identified for further consideration (Reference No. 1). Using previously described techniques (Reference No. 2), the Committee ultimately identified approximately 80 chemical substances and categories for detailed review and requested its technical contractor to prepare dossiers on selected chemicals and categories. The review of these dossiers, combined with the knowledge and professional judgment of the Committee members, formed the basis for the Committee's initial recommendations to the EPA Administrator (Reference No. 2) and subsequent additions to the Section 4(e) Priority List (Reference No. 3).

1.3 Committee activities during this reporting period

During the past six months, the Committee completed a detailed review of all chemicals and categories selected for dossier preparation as well as the review of a number of additional chemicals, with the following exceptions: (a) Those chemical substances and categories for which dossiers are being prepared and will be reviewed prior to the Committee's April, 1979, report; and (b) those chemicals whose further consideration has been deferred pending receipt of additional information.

1.4 Future committee activities

The Committee is currently updating its Master File of chemicals. This effort will be followed by a selection of chemicals and scoring procedures similar to those described in previous Committee reports (Reference Nos. 2 and 3). These procedures will provide one method for identifying additional chemicals for detailed review and, simultaneously, will enable a periodic re-evaluation of those chemicals which have been reviewed, but not selected for inclusion in the section 4(e) Priority List.

CHAPTER 2. AVAILABILITY OF TESTING FACILITIES AND PERSONNEL

The Committee again emphasizes its concerns about the National capability for conducting long-term tests of biological effects, as expressed in its second report to the EPA Administrator (Reference No. 3). As previously stated, the Committee's paramount concern is for the availability of adequately trained personnel. The Committee, therefore, reiterates its belief that the Civil Service Commission could do much to stimulate interest in professions such as toxicology, pathology, epidemiology, and related environmental and occupational health specialties by creating series and registers for these professions.

- The Committee supports current efforts by the Environmental Protection Agency to initiate the establishment of a Civil Service Commission series for toxicologists.
- The Committee again recommends a National survey to assess the future availability of personnel and testing facilities.
- The Committee again recommends that this survey also determine the adequacy of the supply of test organisms for assessing specific health and environmental effects.

To determine whether the number of personnel and facilities are adequate to meet the predicted needs of TSCA/EPA, there also must be some assessment of the TSCA testing requirements in relation to those of other Federal agencies and the private sector.

- The predicted competition for these facilities by users from the Federal and private sectors might be partially alleviated if some short-term, national-testing-priority scheme were developed to enable the most crucial needs to be met as additional personnel and facilities are developed.

CHAPTER 3—RECOMMENDATIONS OF THE COMMITTEE

3.1 Chemical substances and categories recommended for testing

The Interagency Testing Committee is revising the TSCA section 4(e) priority list by the addition of one individual substance and two categories of substances for which testing is recommended. These chemicals were selected after consideration of the factors identified in TSCA section 4(e)(1)(A), other relevant factors identified by the Committee, and the knowledge and professional judgment of Committee members. The recommended studies deemed appropriate for determining the potential hazard(s) of each new entry and the reasons for such recommendations are described in section 3.3 of this report. As in the case of the Committee's previous recommendations, each chemical substance and category is being designated by the Committee for action by EPA within 12 months.

Table 1 presents the complete section 4(e) priority list including the date by which the EPA Administrator must take action on each entry. As in previous Committee reports (Reference Nos. 2 and 3), the entries are listed alphabetically. The Committee considers each of its new entries to the list to be of equal importance. Therefore, each of these new entries should be given the same priority for purposes of initiating action as required under TSCA section 4(e). Unless stated otherwise, the chemical substance recommended for testing is the product to which the population is exposed.

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3.2 Designated substances on which studies are planned or ongoing

The Committee is aware that it has added to the section 4(e) priority list certain chemical substances which are either currently under study or have been selected for study by other groups. Such studies may concern one or more of the effects for which the Committee has recommended testing. Set forth below is the Committee's reasoning for its past and future designation of such substances.

The Committee generally does not regard knowledge that studies are planned or ongoing as a sufficient basis to defer consideration of a substance for designation for the effect under investigation or for any other effect. The Committee's judgment as to whether a substance has been adequately tested for health and environmental effects must rest with the data that are presently available. Such data do not exist for planned studies and may be in various stages of generation for ongoing studies. In addition, the Committee is unable to predict if an ongoing study would be successfully concluded (i.e., disease, toxicity, or other unforeseen events may cause a study to be aborted). Whenever they have been identified, planned and ongoing studies are noted in the dossiers on designated substances.

TABLE 1—THE TSCA SECTION 4(e) PRIORITY LIST, ARRANGED ALPHABETICALLY

Chemical substance or category	Designated for action by
Acrylamide	April 1979.
Alkyl epoxides	October 1978.
Alkyl phthalates	October 1978.
Aryl phosphates	April 1979.
Chlorinated benzenes, mono- and di-	October 1978.
Chlorinated benzenes, tri-, tetra- and penta-	October 1979.
Chlorinated naphthalenes	April 1979.
Chlorinated paraffins	October 1978.
Chloromethane	October 1978.
Cresols	October 1978.
Dichloromethane	April 1979.
1,2-Dichloropropane	October 1979.
Glycidol and its derivatives	October 1979.
Halogenated alkyl epoxides	April 1979.
Hexachloro-1,3-butadiene	October 1978.
Nitrobenzene	October 1978.
Polychlorinated terphenyls	April 1979.
Pyridine	April 1979.
Toluene	October 1978.
1,1,1-Trichloroethane	April 1979.
Xylenes	October 1978.

The above statement does not mean that the Committee's consideration of substances will never include planned or ongoing studies. If the details of a study are know and its conclusions imminent, the Committee may delay considering the substance until the results become available. When the Committee considers that a chemical substance is under sufficient assessment by other groups, it may defer consideration of the substance. Because the Committee recognizes that each case must be judged individually, it has not establish formal criteria regarding the impact that planned or ongoing studies may have on its recommendations.

3.3 Reasons for Recommending Testing of the Additional Substances and Categories

Table 2 summarizes the studies recommended for each additional entry on the section 4(e) priority list. As directed by TSCA section 4(e)(1)(B) the Committee also is presenting its reasons for recommending specific types of studies. In addition to the rationales presented herein, supporting dossiers of information are being finalized and will be transmitted to the Administrator, EPA, at the earliest practicable date.

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Table 2. Summary of Recommended Studies

Substance or Category	Carcino-genicity	Muta-genicity	Terato-genicity	Other* Toxic Effects	Environ-mental Effects	Epidemiology
1. Chlorinated Benzenes, Tri-, Tetra- and Penta-	X	X	X	X[a]	X	X
2. 1,2-Dichloropropane	X	X	X	X[b]	X	X
3. Glycidol and Its Derivatives	X	X	X	X[c]		X

*The systems of particular concern are as follows: a) neurological and hematopoietic; b) reproductive and neurological; and c) reproductive.

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3.3.A Chlorinated benzenes, tri-, tetra- and penta-

Recommended studies: Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, environmental effects, and epidemiology.

Category identification: This category consists of: 1,2,3-trichlorobenzene (CAS No. 87-61-6); 1,2,4-trichlorobenzene (CAS No. 120-82-1); 1,3,5-trichlorobenzene (CAS No. 108-70-3); 1,2,3,4-tetrachlorobenzene (CAS No. 634-66-2); 1,2,3,5-tetrachlorobenzene (CAS No. 634-90-2); 1,2,4,5-tetrachlorobenzene (CAS No. 95-94-3); and pentachlorobenzene (CAS No. 608-93-5).

Reasons for Recommendations. *Production, release, and exposure*—Although the Committee was not able to obtain accurate production, environmental release, and worker exposure figures, one source suggests that over 1 million workers are exposed to trichlorobenzenes. The Committee also judges that a variety of sources are responsible for the observed contamination of air, water, soil and food chains by chlorinated benzenes. Possible sources of contamination include the use of chlorobenzenes as chemical intermediates and solvents in the manufacture of dyes, lubricants and pesticides as well as other uses such as transformer oils. Recent decreases in the use of polychlorinated biphenyls may result in an increase usage of trichlorobenzenes as transformer oils. Chlorinated benzenes are also present as contaminants in and degradation products of pesticides and occur in chlorinated municipal, agricultural and industrial effluents. The predicted partition coefficients of chlorobenzenes suggest that they may accumulate in biological systems. The high probability for exposure to the human population and environment of these relatively persistent and toxic substances in emphasized in the following recommendations.

Carcinogenicity: No carcinogenicity studies on tri-, tetra- and pentachlorobenzenes were found in the searched literature, although hexachlorobenzene is a demonstrated animal carcinogen. The Committee, therefore, recommends that tests be conducted to assess the carcinogenic potential of these chemicals.

Mutagenicity: Although a single mutagenicity study for 1,2,4-trichlorobenzene was negative, additional testing is needed to assess the mutagenix potential of the chlorobenzenes.

Teratogenicity: Pentachlorobenzene administered to pregnant rats reduced the mean number of live fetuses per litter and increased the incidence of sternal defects and extra ribs. Studies are recommended to assess the teratogenic potential of the chlorobenzenes.

Other toxic effects: Degeneration of liver cells and hepatic porphyria have been observed in rodents exposed to chlorobenzenes. Dose-related increases in liver to body weight ratios in highly porphyric rats were accompanied by the induction of hepatic microsomal enzymes. Monkeys given high doses of 1,2,4-trichlorobenzene showed severe weight loss and fine tremors. Guinea pigs given high doses of chlorobenzenes have been reported to convulse and die. The Committee recommends testing, with emphasis on the neurological and hematopoietic systems, to further assess the toxic effects of the chlorobenzenes.

Environmental effects: There is a paucity of information on the acute and chronic effects of tri-, tetra- and pentachlorobenzenes on wild and domestic birds and mammals, fish, amphibians, reptiles, invertebrates, plants and algae. Since residues have been detected in aquatic situations, particular emphasis should be placed on long-term environmental studies in freshwater and marine environments with concern for the biological significance of residues and effects on reproduction, behavior and survival of fish, fish-eating birds and mammals, and food chain organisms.

Epidemiology: Since the nature of human exposure to chlorobenzenes is extremely broad, the Committee believes that epidemiological studies may be important in assessing the effects of long-term exposure to chlorobenzenes.

3.3.B 1,2-dichloropropane

Recommended studies: Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, environmental effects, and epidemiology.

Substance identification: CAS No. 78-87-5.

Reasons for recommendations. *Production, release, and exposure*—1,2-dichloropropane is produced in large quantities with a production rate in 1976 of 71 million pounds. Because of its widespread use as a solvent, as well as a multiplicity of other uses, 1,2-dichloropropane has a potentially high occupational exposure (over 1 million workers). Its potential use in many consumer products also may lead to wide general exposure. Little is known about the release rate of 1,2-dichloropropane into the environment.

Carcinogenicity: The testing carried out thus far on the carcinogenicity of 1,2-dichloropropane is insufficient to allow an appropriate appraisal of its carcinogenicity. The Committee, therefore, recommends that additional carcinogenicity studies be conducted.

Mutagenicity: Although positive mutagenicity tests have been reported in *Salmonella typhimurium* and in *Aspergillus nedulans* for dichloropropane, the isomer was not specified. The Committee recommends that mutagenicity testing be done specifically on 1,2-dichloropropane.

Teratogenicity: Because no information on the teratogenicity of 1,2-dichloropropane was found in the searched literature, the Committee recommends that teratogenicity tests be conducted.

Other toxic effects: Fatty degeneration of the liver and kidney and necrosis of the adrenals have been observed in experimental animals following acute, high-level exposures to 1,2-dichloropropane. Although one low-level exposure study has been reported, it is considered to be inadequate to assess the chronic effects of 1,2-dichloropropane. Since this compound is structurally similar to 1,2-dibromo-3-chloropropane, the Committee recommends that particular emphasis be placed on the reproductive and neurological effects of this chemical.

Environmental effects: In view of its volatility and high specific gravity, the ecological impact of 1,2-dichloropropane may be localized to those environments receiving continuous exposure associated with this chemical's use and disposal. The potential for bioaccumulation suggests the need for further testing to determine the biological significance of exposure to wild and domestic birds, mammals, fish, and invertebrates. Specific areas of environmental concern include: Chronic toxicity to fish and invertebrates; effects on avian and mammalian reproduction and behavior; and effects on soil invertebrates and terrestrial insects.

Epidemiology: There is no information available on chronic effects in humans exposed to 1,2-dichloropropane over an extended period of time. Because of the potentially widespread exposure, epidemiological studies may be particularly important in assessing the human health effects of 1,2-dichloropropane.

3.3.C Glycidol and Its Derivatives

Recommended studies: Carcinogenicity, mutagenicity, teratogenicity, other toxic effects, and epidemiology.

Category identification: This category consists of glycidol (CAS No. 556-52-5) and its derivatives. Example chemicals in this category are glycidyl acrylate (CAS No. 106-90-1), glycidyl methacrylate (CAS No. 106-91-2), allyl glycidyl ether (CAS No. 106-92-3), n-butyl glycidyl ether (CAS No. 2426-08-6), para-cresyl glycidyl ether (CAS No. 2186-24-5), phenyl glycidyl ether (CAS No. 122-60-1), and the diglycidyl ether of bisphenol A (CAS No. 1675-54-3).

Reasons for recommendations.

Production, release, and exposure—Most of these commercially significant chemicals have annual production volumes in excess of 1,000 pounds (1976). Although exposure estimates are not available for all the chemicals in this category, NIOSH estimates that 105,000, 118,000, and 105,000 workers are exposed to glycidol, glycidyl ethers, and glycidyl methacrylate, respectively.

Carcinogenicity: Although glycidol and glycidyl methacrylate have been tested for carcinogenicity, neither meets current testing standards. In view of the potential alkylating properties of glycidol and its derivatives and the demonstrated carcinogenicity of certain members of this category (e.g., diglycidyl resorcinol ether and glycidyl oleate), the Committee recommends carcinogenicity studies.

Mutagenicity: Since glycidol, allyl glycidyl ether, n-butyl glycidyl ether, and phenyl glycidyl ether have been reported to be mutagenic in several assay systems, the mutagenic potential of other category members should be determined.

Teratogenicity: With the exception of negative test results on phenyl glycidyl ether, the teratogenic potentials of these compounds have not been evaluated. The Committee, therefore, recommends studies to evaluate the teratogenic potential of other Compounds in this category.

Other toxic effects: Most of these chemicals are skin and eye irritants, while some induce sensitization and cross-sensitization reactions in exposed workers. A diversity of toxic effects also has been observed in experimental animals following administration of these compounds. The most frequently observed effects are CNS depression, incoordination and ataxia, although some of these compounds reportedly induce testicular atrophy and temporary sterility in rats. Adverse effects on the kidneys, liver, pancreas, and adrenals also have been observed in experimental animals. The Committee, therefore, recommends studies to evaluate the toxicity of these chemicals. The reproductive system is of particular interest.

Epidemiology: Epidemiology studies should be conducted to assess the extent of human health effects.

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REFERENCES

1. *Preliminary List of Chemical Substances for Further Evaluation*, Toxic substances Control Act Interagency Testing Committee, July 1977.

2. *Initial Report to the Administrator, Environmental Protection Agency*, TSCA Interagency Testing Committee, October 1, 1977. Published in the FEDERAL REGISTER, Vol. 42, No. 197, Wednesday, October 12, 1977, pp. 55026-55080. The report and supporting dossiers also were published by the Environmental Protection Agency, EPA 560-10-78/001, January 1978.

3. *Second Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency*, TSCA Interagency Testing Committee, April 1978. Published in the FEDERAL REGISTER, Vol. 43, No. 76, Wednesday, April 19, 1978, pp. 16684-16688. The report and supporting dossiers also were published by the Environmental Protection Agency, EPA 560-10-78/002, July 1978.

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