SUMMARY: American Cyanamid Company has amended a pesticide petition proposing the establishment of tolerances for residues of the insecticide flucythrinate in or on certain commodities.

ADDRESS: By mail submit written comments to: Program Management and Support Division (TS-757C), Attn: Product Manager (PM) 17, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, deliver comments to: Rm. 229, CM#2, Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Written comments must be identified by the document control number (PF-352) and the petition number 2F2806. All written comments filed in response to this notice will be available for public inspection in the Program Management and Support Division office at the address above from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Timothy A. Gardner, PM-17, CM#2, Rm. 207, 703-557-2690.

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the Federal Register of February 9, 1983 (48 FR 6018) which announced that the American Cyanamid Company, P.O. Box 400, Princeton, NJ 08540 had submitted pesticide petition 2F2806 proposing to amend 40 CFR 180.400 by establishing tolerances for residues of the insecticide flucythrinate ((≥)-cyano(3-phenoxyphenyl)methyl(+)-4-(difluoromethoxy)-alpha-(1-methylethyl) benzeneacetate) in or on certain raw agricultural commodities. American Cyanamid has amended the petition by decreasing the tolerance levels for whole milk from 0.3 part per million (ppm) to 0.1 ppm and milk fat from 6.0 to 2.0 ppm; and proposing tolerances for meat and meat byproducts of goats, hogs, horses, and sheep at 0.10 ppm and fat of goats, hogs, horses, and sheep at 1.0 ppm.

The proposed analytical method for determining residues is gas chromatography.

(Sec. 408(d)(2), 68 Stat. 512, (21 U.S.C. 346a(d)(2))

Dated: November 3, 1983.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 83-30540 Filed 11-10-83; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-42041; PSH-FRL 2446-4]

1,3-dioxolane; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Eleventh Report of the Interagency Testing Committee (ITC) designated 1,3-dioxolane for health effects testing consideration. Following the ITC designation, Ferro Corporation and PPG Industries submitted to EPA a proposed testing program for health effects. The Agency has tentatively concluded that this program is sufficient to evaluate the potential health effects of 1,3-dioxolane which were of concern to the ITC. Consequently, EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require further health effects testing of 1,3-dioxolane at this time. This notice constitutes the Agency's response to the ITC's designation of 1,3-dioxolane, as required by section 4(e) of TSCA. EPA seeks comments on the Agency's conclusions and on the adequacy of the proposed testing program.

Interested persons are invited to comment on the adequacy of the industry program and on EPA's proposed acceptance of it in lieu of initiating a rulemaking procedure.

DATE: All comments must be submitted by December 29, 1983.

ADDRESS: Written comments should bear the document control number (OPTS-42041) and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M St., SW., Washington, D.C. 20460.

The administrative record supporting this action is available for public inspection in Room E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M St., SW., Washington, D.C. 20460; toll free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. The data developed as a result of such testing will be used by EPA to evaluate the risks that these chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of test rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any one time for priority consideration by EPA. EPA is required to respond within 12 months of the date of a priority designation, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so.

1,3-Dioxolane was designated for priority testing in the Eleventh Report of the ITC, submitted to the EPA Administrator on November 3, 1982, and published in the Federal Register on December 3, 1982 (47 FR 54626) (Ref. 19). The ITC recommended that a battery of short-term mutagenicity tests, chemical disposition and metabolism studies, and a 90-day inhalation toxicity study with histopathology be considered. The ITC based its recommendations for health effects testing on the concern that potential exists for widespread human exposure through the manufacture and processing of 1,3-dioxolane and the use of products containing 1,3-dioxolane.

Subsequent to the ITC report, Ferro Corporation (Ferro), the sole U.S. manufacturer of 1,3-dioxolane, and PPG Industries (PPG), the principal processor, contacted EPA to discuss the designation of 1,3-dioxolane for priority consideration and the possibility of an industry-sponsored testing program in lieu of the Agency initiating rulemaking. On July 5, 1983, Ferro and PPG formally submitted a proposed industry-sponsored testing program designed to address the health effects concerns of the ITC (Refs. 5,6). This notice fulfills EPA's statutory obligations under section 4(e) and informs the public that EPA is proposing to accept the industry program and is not initiating rulemaking at this time. EPA is requesting comments on the Ferro and PPG proposed testing program and the Agency's tentative decision to accept it in lieu of section 4(a) rulemaking.

II. Assessment of Exposure and Health Effects

A. Production, Use, and Exposure

1,3-Dioxolane ($C_3H_6O_2$) (CAS No. 646-06-0) is a flammable, colorless, volatile

liquid that is miscible in water and soluble in organic solvents. Like most acetals, it is stable in neutral or slightly basic solution, but it can be hydrolyzed in strong acid (Ref. 3).

Ferro is the sole U.S. producer of 1,3-dioxolane. The 1977 TSCA Chemical Substance Inventory estimated that the annual production level is between 1 and 10 million pounds (Ref. 18). Ferro has advised EPA that it produces fewer than 3 million pounds per year, all of which is produced at its Grant Chemical Division in Louisiana (Ref. 8).

The major use of 1,3-dioxolane is as a stabilizer in the production and distribution of 1,1,1-trichloroethane (TCEA) (Refs. 8, 16). Over 95 percent of the domestically manufactured 1,3-dioxolane is purchased by PPG for use as a stabilizer in TCEA at concentrations ranging from 0.5 percent to 1.0 percent. Additional minor uses of the remaining production include use in pharmaceuticals, dialysis membranes for kidney machines, as a component in electrolytes and as a research chemical (Ref. 8). None of these minor uses is expected to result in substantial human exposure. Furthermore, the use of 1,3-dioxolane in pharmaceuticals and dialysis membranes is regulated by the Federal Food, Drug, and Cosmetic Act, and not by TSCA.

The ITC was concerned that there was potential for widespread exposure to 1,3-dioxolane. The National Occupational Hazard Survey (NOHS), which is based on exposure during the manufacture, processing and the ultimate use of a chemical, estimated that 10,602 workers are potentially exposed to 1,3-dioxolane in eleven industrial worker categories (Ref. 13). Ferro states that the production of the chemical takes place in a closed system and estimates that fewer than twenty workers are exposed to 1,3-dioxolane during production and that exposure levels are less than 10 ppm (Ref. 9). PPG has stated that four individuals are potentially exposed to a 40 percent solution of 1,3-dioxolane at their TCEA manufacturing facility. PPG further states that its TCEA transfer, solvent mixing, and storage functions are all considered closed systems (Ref. 16).

Neither the American Conference of Governmental Industrial Hygienists (Ref. 1) nor the Occupational Safety and Health Administration (OSHA) (Ref. 15) has set threshold limit values or standards for 1,3-dioxolane. However, a standard of 350 ppm has been adopted by OSHA for an 8-hour time-weighted average (TWA) exposure to TCEA (Ref. 15). Therefore, assuming 350 ppm 8-hour TWA to be a worst case or maximum worker exposure to TCEA, the resulting exposure to 1,3-dioxolane, at a concentration from 0.5 percent to 1.0 percent by weight of TCEA, would be approximately 2 ppm dioxolane. Actual area monitoring data in 1982 from PPG's Lake Charles, LA, TCEA manufacturing facility, indicated 8-hour TCEA levels ranging from 0.1 ppm to a maximum of 12.7 ppm in the work area. A maximum of 18 ppm for 15 minute samples was recorded in the solvent loading area. Assuming equal volatilities for 1,3-dioxolane and TCEA, PPG calculated that the air concentrations for 1,3-dioxolane would range from less than 0.001 ppm to 0.1 ppm (Ref. 16).

However, there is wide potential for human exposure, both occupational and general population, through the use of products containing TCEA stabilized with 1,3-dioxolane. The primary use of TCEA is as an industrial solvent for vapor degreasing of metals or plastics. TCEA is also a component of many consumer products including drain cleaners, adhesives, water repellant sprays, spot removers, and furniture polishes. There is no estimate for the number of people potentially exposed through these, and other consumer uses. However, NIOSH estimated that the number of workers exposed to TCEA through its manufacture, processing, and use is 2.6 million (Ref. 12).

It is estimated that U.S. production of TCEA was 645 million pounds in 1978 (Ref. 2). The percentage of that production which is stabilized with 1,3-dioxolane is unknown. However, as 95 percent of the estimated 3 million pounds of 1,3-dioxolane produced annually is used as a stabilizer in TCEA at concentrations of 0.5 percent to 1.0 percent by weight, it can estimated that 285 to 570 million pounds of TCEA stabilized with 1,3-dioxolane is produced annually. Therefore, there is substantial potential for extensive human exposure through the use of TCEA stabilized with 1,3-dioxolane, albeit at low concentration levels. Exposure routes could be by inhalation of vapor from, or dermal contact with, products containing the compound.

B. Health Effects Information

Information available on the health effects of 1,3-dioxolane is limited. Two Russian reports provided the bulk of the information (Refs. 11,17). While these studies provided some acute and chronic toxicity data, the validity of the findings was difficult to assess due to the lack of details on methodology. However, acute toxicity data entered in the Registry of Toxic Effects of Chemical Substances (Ref. 14) from a Union Carbide Data Sheet, give for 1,3-dioxolane an oral LD_{50} (rat) of 7,640 mg/kg; a dermal LD_{50} (rabbit) of 8,480 mg/kg; and an inhalation LC_{LO} (rat) of 32,000 ppm for 4 hours (LC_{LO} is the lowest concentration at which deaths were observed).

Several *Salmonella typhimurium/* Mammalian Microsomal Assays (Ames Assay) have been completed for 1,3-dioxolane, all having negative results (Refs. 4,7,8,10,). No other valid health effects studies have been reported in the literature.

III. Planned Testing

Ferro and PPG have jointly proposed to sponsor testing which is designed to accommodate the health effects concerns and tests recommended by the ITC for 1,3-dioxolane.

In order to respond to the ITC's recommendation for a battery of short-term mutagenicity tests, the industry has proposed to perform a cell transformation test, an *in vitro* cytogenetics test and a test for gene mutations in mammalian cells in culture. The proposed mutagenicity tests would complement the existing *Salmonella typhimurium/* Mammalian Microsomal Assays.

Further, the industry will conduct a comprehensive independent review of a 2-year drinking water chronic toxicity study on albino rats with 1,3-dioxolane, which was begun for PPG prior to the designation of 1,3-dioxolane by the ITC. While this chronic toxicity study has not been completed, the experimental portion of the study has been done and tissues have been taken at terminal sacrifice, but no histopathological examinations have been performed. The uncut tissues will be examined microscopically, and a final report on the results completed. EPA has been provided with preliminary data from the study.

This proposed review, validation, and completion of the study, to be performed by an independent pathology laboratory, will serve to respond to the ITC's concerns regarding the subchronic toxicity potential of 1,3-dioxolane. The validation will yield information on the quality, soundness and the scope of the usefulness of the results of this 2-year study to assist in the assessment of the health effects of 1,3-dioxolane. EPA is aware that the oral route of exposure used in the existing chronic toxicity study is not the route which was recommended by the ITC. However, EPA believes that this study should not be overlooked because, if the study is sufficiently validated, the toxicity information which can be obtained from it will be greater than that which could be obtained from a 90-day subchronic

study. In addition, proceeding with the nearly completed study will accelerate the gathering of that information.

PPG and Ferro have agreed to perform the testing according to a prescribed schedule. The cell tranformation, cytogenicity, and gene mutations tests will be commenced within 60 days following publication of EPA's final notice of acceptance of the testing program and completed within four months after commencement. The validation and completion of the chronic toxicity study shall commence within 60 days after publication of the final notice. The final report from the chronic toxicity study will the provided to the Agency within twelve months following publication of the final notice. If industry does not make a good faith effort to adhere to be proposed schedule, the Agency will consider initiating the rulemaking process.

Upon completion of the validation of the chronic study and the first-tier mutagenicity tests, PPG and Ferro have agreed to meet with EPA scientists to discuss the interpretation of the test results and, if necessary, to develop additional testing plans for the future. Depending upon the results of the testing and validation discussed above, future testing could include repeating the chronic study, a 90-day subchronic study, metabolism and pharmacokinetics studies and/or additional mutagenicity studies.

The Agency has tentatively concluded that the proposed testing plan is sufficient to provide the initial information necessary to enable EPA to assess the potential health hazards of 1,3-dioxolane which the ITC identified in their report. Further, because testing will be initiated sooner than through rulemaking, the industry-sponsored program will permit EPA to judge the need for any additional testing more readily than if the Agency initiated a rulemaking process.

Ferro and PPG have agreed to furnish EPA with the names and addresses of laboratories conducting the tests described above as soon as they are available. The specific tests being performed by each laboratory shall be indicated.

The two companies have also agreed to adhere to the Good Laboratory Practice Standards issued by the U.S. Food and Drug Administration as published in the Federal Register of December 22, 1978 (FR 59986). Ferro and PPG have agreed to permit laboratory inspections and study audits in accordance with the provisions outlined in TSCA section 11 at the request of authorized representatives of the EPA for the purpose of determining compliance with this agreement. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practice provisions.

Ferro and PPG have further agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of the acceptance of any protocols by EPA and made available during an inspection or submitted to EPA if requested by EPA or its designated representative. In addition, correspondence and other documents relating to interpretation and evaluation of data shall also be retained.

Ferro and PPG understand that TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Further, they understand that the Agency plans to publish in the Federal Register a notice of the receipt of any test data submitted under this agreement. Subject to TSCA section 14, the notice shall provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, such data shall be made available by the Administrator for examination by any person.

Finally, Ferro and PPG understand that failure to conduct the testing according to the specified protocols and failure to follow Good Laboratory Practices may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

EPA is soliciting comments on the Ferro and PPG proposed testing program and the Agency's decision to accept it in lieu of section 4(a) rulemaking at this time. After considering these comments, EPA will either publish in the Federal Register a final notice of acceptance of a negotiated test program or will initiate rulemaking under section 4(a) of TSCA.

IV. Decision Not To Initiate Rulemaking

EPA believes that the testing program and validation of an existing study, proposed by Ferro Corporation and PPG Industries, will provide sufficient data to reasonably predict the potential mutagenic and subchronic health effects of 1,3-dioxolane which were of concern to the ITC. Therefore, EPA has tentatively decided not to initiate rulemaking under section 4(a) of TSCA to require the testing of 1,3-dioxolane for those effects at this time.

The ITC also recommended chemical disposition and metabolism studies. However, at this juncture EPA believes that there is not sufficient evidence to indicate that metabolism and pharmacokinetics studies would aid in the hazard assessment for this chemical. The primary value of such studies would be in the interpretation and extrapolation of data indicating chronic organ-specific toxicity of 1,3-dioxolane. Until the proposed review and validation of the previous 2-year chronic study is completed, the necessity of metabolism studies has not been established (Ref. 20). Therefore, EPA is not requiring chemical disposition and metabolism studies at this time.

V. References

(1) ACGIH. 1982. American Conference of Governmental Industrial Hygienists. TLVs. Threshold limit values for chemical substances in work air adopted by ACGIH for 1982.

(2) Battelle Columbus Laboratories. 1980 (Aug.). Final report on risk assessment of 1,1,1-trichloroethane. Washington, DC: Office of Toxic Substances, U.S. Environmental Protection Agency. Contract No. 68-01-0543.

(3) CSG. 1983. Final Technical Support Document: 1,3-Dioxolane. Capital Systems Group, Inc., EPA Contract 68-01-6530. Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency.

(4) Celanese. 1982. Letter from G.S. Kirshenbaum, Celanese Corporation, to USEPA, January 18, 1982. Submission of 8(d) information. Mutagenicity Evaluation of (1,3-dioxolane) in the Ames *Salmonella*/Microsome Plate Test-Final Report. Litton Bionetics, February 1980.

(5) Cerar. 1983A. Letter from Jeffrey O. Cerar to Richard Treast (EPA) on behalf of Ferro Corporation and PPG Industries. July 5, 1983.

(6) Cerar. 1983B. Letter from Jeffrey O. Cerar to Richard Troast (EPA). Supplement to Letter of July 5, 1983. July 19, 1983.

(7) Dow. 1983. Letter from Robert L. Hagerman, Dow Chemical Company, to USEPA, February 21, 1983. Submission of 8(d) information. Mutagenic Evaluation of (1,3-Dioxolane)—LBI Project #2506. Litton Bionetics, January 20, 1975.

(8) Ferro. 1983A. Letter from Lowell E. Snodgrass, Ferro Corporation to Office of Pesticides and Toxic Substances, USEPA, January 12, 1983. Comments on the 11th ITC Report.

(9) Ferro. 1983B. Letter from Lowell E. Snodgrass, Ferro Corporation to Office of Toxic Substances, USEPA, February 3, 1983. Supplement to comments on the 11th ITC Report.

(10) Goodyear. 1983. Letter from W.D. Davis, Goodyear Tire and Rubber Company, to USEPA, January 31, 1983. Submission of 8(d) information. Laboratory Report No. 79-55: Mutagenicity Evaluation of 1,3-Dioxolane. November 20, 1979.

(11) Lomonova GV, Vinogradova VK. 1975. Hygienic normalization of formal glycol in the air of industrial facilities. Gig Tr Prof Zabol 8:45–47. (In Russian; English translation).
(12) NIOSH. 1980. National Institute for Occupational Safety and Health. National Occupational Hazard Survey (NOHS).
(13) NIOSH. 1982A. National Institute for Occupational Safety and Health. Computer printout. National Occupational Hazard Survey (NOHS). Retrieved Nov. 19, 1982.
(14) NIOSH. 1982B. National Institute for Occupational Safety and Health. Computer printout. RTECS (Registry of Toxic Effects of Chemical Substances) data base. Retrieved Dec. 9, 1982.
(15) OSHA. 1981. Occupational Safety and Health Administration. General Industry. OSHA Safety and Health Standards (29 CFR 1910). Washington, DC.
(16) PPG. 1983. Letter from Z. Bell. PPG Industries. to Office of Pesticides and Toxic Substances. USEPA, January 12, 1983. Comments on TSCA 4(a) Priority Chemical—Dioxolane.
(17) Stasenkova KP, Samoilova LM, Dulatova L. 1972. Toxicity of formal glycol (dioxalan-1,3). Sov Rubber Technol (Eng. Transl.) 31 (6): 27–28.
(18) USEPA. 1980. U.S. Environmental Protection Agency. Office of Pesticides and Toxic Substances. Computer printout: producers and importers of chemicals in the non-confidential initial TSCA inventory. Retrieved 1980.
(19) USEPA. 1982. Eleventh Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals. Federal Register, December 3, 1982 (47 FR 54626).
(20) USEPA. 1983. Memorandum. 1,3-Dioxolane Metabolism. DiCarlo FR to Lee CC. Environmental Protection Agency. February 28, 1983.

VI. Public Record

The EPA has established a public record of this testing decision (document control number OPTS–42041). This record includes:

(1) Federal Register Notice designating 1,3-dioxolane to the priority list and comments received in response thereto.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: November 3, 1983.

William D. Ruckelshaus,

Administrator.

[FR Doc. 83–30534 Filed 11–10–83; 8:45 am]

BILLING CODE 6560–50–M

[OPTS–42040; TSH–FRL–2446–3]

Tris(2-Ethylhexyl)Trimellitate; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Eleventh Report of the Interagency Testing Committee (ITC) designated the chemical tris(2-ethylhexyl)-trimellite also known as trioctyltrimellitate (TOTM), for health and environmental effects testing consideration. The ITC suggested that a screening-type approach be utilized for TOTM before additional health effects studies are undertaken. Following the designation, plans for testing the health and environmental effects of TOTM were presented to EPA by the Chemical Manufacturers Association (CMA). The Agency has concluded tentatively that this program, when combined with related data from the CMA Phthalate Esters Program and the National Toxicology Program will supply screening information of the type that the ITC sought and is likely to provide information on which to reasonably predict the toxicity of TOTM. Therefore, at this time, the EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health or environmental effects testing of TOTM. This notice constitutes the Agency's response to the ITC's designation of TOTM, as mandated by section 4(e) of TSCA.

DATE: Comments should be submitted on or before December 29, 1983.

ADDRESS: Written comments should bear the document control number (OPTS–42040) and should be submitted in triplicate to: TSCA Public Information Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E–108, 401 M St., SW., Washingtion, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St., SW., Washington, D.C. 20460; Toll Free: (800–424–9065), In Washington, D.C.: (554–1404), Outside the USA: (Operator 202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2003 *et seq.;* 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA to determine the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so.

The ITC designated TOTM for priority consideration in its Eleventh Report delivered to the Administrator of EPA on November 10, 1982, and published in the Federal Register on December 3, 1982 (47 FR 54624). The ITC recommended that industry first screen TOTM for chemical disposition and metabolism with identification of metabolites. If absorption and/or metabolism were shown to occur, the ITC suggested that reproductive effects and subchronic effects tests should be considered. The ITC also recommended that an evaluation of subchronic effects include assessments of hepatic peroxisomal proliferation and hypolipidemia. In addition, acute and chronic toxicity to fish and aquatic invertebrates were to be considered, as well as toxicity to plants, bioconcentration and chemical fate.

The reasons for the ITC's recommendations for health effects testing were: (1) The presumed structural relationship between TOTM and di(2-ethylhexyl)phthalate (DEHP), (2) the presence of the 2-ethylhexyl moiety in the molecule, and (3) projections of increasing usage of TOTM.

The ITC was concerned about toxicity to aquatic organisms and plants because of its view that: (1) TOTM was expected to be released to the aquatic environment and persist in sediments, (2) TOTM has a potential to bioaccumulate and possibly