

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of November 19 Through November 26, 1982]

Date	Name and location of applicant	Case No.	Type of submission
November 19, 1982.	Exxon Company, U.S.A., Washington, D.C.	HED-0091, HEJ-0027	Motion for Discovery/Request for Protective Order. If granted: Discovery would be granted to Exxon Company, U.S.A. in connection with its Statement of Objections in response to the Proposed Decision & Order (Case No. HYX-0008 and HYX-0014) issued to Little America Refining Company, Exxon Company, U.S.A. would enter into a Protective Order with Little America Refining Company regarding the release of proprietary information to Exxon Company, U.S.A. in connection with Little America Refining Company's year end entitlements review proceeding (Case Nos. HYX-0008 and HYX-0014).
November 22, 1982.	Bill Forney, Inc., Washington, D.C.	HEG-0025, HRS-0020	Petition for Special Redress and Request for Stay. If granted: The Office of Hearings and Appeals would review the policy of operator liability and determine if it should apply in the Proposed Remedial Order issued Bill Forney, Inc. (Case No. BRO-1450). Bill Forney, Inc. would receive a stay of the Proposed Remedial Order proceeding (Case No. BRO-1450) pending the disposition of the Petition for Special Redress.
November 22, 1982.	Robert K. Wilcox, Coconut Grove, Florida	HFA-0101	Appeal of an Information Request Denial. If granted: The November 9, 1982 Information Request Denial issued by the Director of the DOE Office of Executive Secretariat would be rescinded, and Mr. Robert K. Wilcox would receive access to information regarding a uranium plant in North Korea.
November 24, 1982.	Appalachian Observers, Clinton, Tennessee	HFA-0102	Appeal of an Information Request Denial. If granted: The November 10, 1982 Information Request Denial issued by Oak Ridge Operations would be rescinded and the Appalachian Observer would receive access to documents relating to subsidies of the Oak Ridger newspaper by the Atomic Energy Commission.

[FR Doc. 82-34089 Filed 12-15-82; 8:45 am]
BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY - Toluene

[OPTS-42024; FRL 2224-3]

Toxic Substances; Toluene; Response to the Interagency Testing Committee

Agency: Environmental Protection Agency (EPA).
Action: Notice.

SUMMARY: The Interagency Testing Committee (ITC) established under Section 4(e) of the Toxic Substances Control Act, designated toluene for health effects testing as published in the Federal Register of October 12, 1977 (42 FR 55059). EPA has decided not to develop a test rule under Section 4(a) for toluene at this time because results from completed testing and planned testing programs will supply sufficient information to characterize or reasonably predict the health effects recommended for consideration by the ITC.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-511, 401 M St., SW., Washington, D.C. 20460, toll free: (800-544-1404), in Washington, D.C.: (202-554-1404), outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) authorizes the Administrator of EPA to promulgate

regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining 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 one time for priority consideration by EPA.

In October, 1977, the Interagency Testing Committee (ITC) designated toluene for priority consideration and recommended that it be tested for carcinogenicity, teratogenicity, other chronic effects, and epidemiology (42 FR 55059). The ITC did not recommend any environmental effects testing for toluene. The primary basis for the ITC testing recommendations was the belief that these effects could not be adequately characterized from the information available at that time. According to the ITC the carcinogenicity studies were limited in design, while other chronic effects were difficult to identify at lower dose levels. In addition, the ITC felt that there was not enough information to characterize adequately the potential teratogenic effects of toluene nor was there sufficient epidemiologic information. The ITC recognized that there were substantial negative mutagenicity data and did not recommend any further mutagenicity testing for toluene.

Additional reasons for the ITC recommendations were the large production volume and exposures associated with toluene. Toluene is produced primarily from petroleum with an annual production rate in excess of

five billion pounds. Toluene is used primarily as a solvent, a component of gasoline, and as a chemical intermediate in the manufacture of a variety of different products. Because toluene is used in a large number of consumer products, a large number of consumers are exposed to toluene. In addition to consumer exposure, more than four million workers are occupationally exposed to toluene.

This notice provides EPA's response to the ITC's designation of toluene for health effects testing consideration.

II. Decision Not To Initiate Rulemaking

EPA has decided that testing under section 4 is not warranted because the ongoing and planned health effects testing is expected to provide information from which the effects recommended for consideration by the ITC can reasonably be determined or predicted. The health effects tests by the American Petroleum Institute, National Cancer Institute, the National Toxicology Program, and the National Institute for Occupational Safety and Health will address the ITC's testing recommendations.

The National Cancer Institute/National Toxicology Program Carcinogenesis Testing Program is beginning chronic studies to determine the carcinogenic potential of toluene in Fischer 344 rats and B6C3F1 mice (Ref. 8). The chronic studies are designed to investigate the carcinogenicity and other chronic effects of toluene using inhalation as the route of exposure. Subchronic inhalation studies have been completed in which Fischer-344 rats and B6C3F1 mice were exposed to toluene by inhalation at concentrations of 0, 100, 625, 1250, 2500, and 3,000 ppm for 6 hrs/

day, 5 days/wk for 15 weeks. Clinical observations in the mice, which were shown to be more sensitive to toluene toxicity, indicated reduced body weights, a dose-related dragging of the abdomen (low carriage), dyspnea, ataxia and tremors at the two highest dose levels. No gross lesions could be detected and no definitive chemical-related microscopic lesions were noted. Also, the National Toxicology Program completed a subchronic oral study with toluene on October 26, 1981 (Ref. 6). The adverse health effects observed in male and female mice receiving 2,500 and 5,000 mg/kg/day (the two highest doses administered) for 13 weeks, 5 days per week included subconvulsive jerking, prostration, impaired grasping reflex, bradypnea, hypothermia, ataxia, hypoactivity, and a decreased body weight. No clinical pathological changes were detected in this study. The chronic inhalation studies for toluene are scheduled to begin on September 29, 1982. In light of these studies, EPA believes that further carcinogenic or chronic studies are not necessary at this time.

In 1978, subsequent to the ITC's recommendation, the American Petroleum Institute submitted to EPA a teratology study on toluene (Ref. 1). There have been several other studies which characterize the teratologic potential of toluene (Refs. 3, 4, and 7). Toluene exposure produced a dose-related decrease in fetal weight and increases in incidence of fetal death. EPA believes that these studies are adequate to reasonably predict the teratologic potential of toluene. Therefore, no further teratologic studies are necessary at this time.

The National Institute for Occupational Safety and Health (NIOSH) is conducting a retrospective cohort mortality study of workers exposed to toluene employed in the shoe manufacturing industry (Ref. 5). Because this study is being performed by NIOSH, an additional epidemiologic study would be unnecessary. EPA is, therefore, not requiring any further epidemiologic studies be done on toluene.

In addition to the studies noted above, the American Petroleum Institute (API) intends to perform a two-generation reproductive test on toluene in order to characterize any potential reproductive hazards that might be associated with toluene (Ref. 2). This two-generation reproduction study on toluene will be part of API's 1982-1983 research program.

III. References

- (1) American Petroleum Institute—8(d) Submission—Toluene—Teratology Study, August 30, 1978.
- (2) Correspondence from William F. O'Keefe, American Petroleum Institute, to Steven D. Newburg-Rinn, EPA, June 29, 1982 on an API Two Generation Reproductive Study.
- (3) Hudak A, Rodics K, Stuber I, et al. 1977. The effects of toluene inhalation on pregnant CFY rats and their offspring. *Munkavedelem*, 23:25-30.
- (4) Hudak A, Ungvary G., 1978. Embryotoxic effects of benzene and its methyl derivatives: toluene and xylene. *Toxicology*, 11:55-63.
- (5) National Institute for Occupational Safety and Health. Mortality and industrial hygiene study of workers exposed to toluene. September, 1981.
- (6) International Research and Development Corporation. 1981. Subchronic oral toxicity test with toluene in mice; Subchronic inhalation toxicity test with toluene in rats and mice. Bethesda, Maryland: National Toxicology Program, U.S. Department of Health and Human Services. Report numbers 5701-103 and 5701-113B.
- (7) Nawrot PS, Staples RE. 1979. Embryofetal toxicity and teratogenicity of benzene and toluene in the mouse. *Teratology*, 19/241A.
- (8) National Toxicology Program. 1982. Outline of the protocol for the NCI carcinogenesis bioassay of toluene.

IV. Public Record

EPA has established a public record for this testing decision (docket number OPTS-42024). The record includes:

- (1) Federal Register notice containing the designation of toluene to Priority List.
- (2) Letters.
- (3) Contact reports of telephone conversations and meeting summaries.
- (4) Published and unpublished data.

The records, which include basic information considered by the Agency in developing this decision, are available for inspection in the OTS Reading Room from 8:00 am. to 4:00 pm. on working days in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement the record with additional relevant information as it is received.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2601))

Dated: December 8, 1982.

Anne M. Gorsuch,
Administrator.

[FR Doc. 82-34155 Filed 12-15-82; 8:45 am]
BILLING CODE 6560-50-48

[OPTS-42025; FRL 2224-4]

Toxic Substances; Xylenes; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice constitutes EPA's response to the Interagency Testing Committee's designation of xylenes for priority consideration for mutagenicity and teratogenicity testing and for an epidemiological study under section 4(a) of the Toxic Substances Control Act. With respect to mutagenicity and teratogenicity, EPA does not plan to initiate rulemaking under section 4(a) to require health effects testing of xylenes at this time because the Agency finds that there are sufficient data now available to reasonably predict any potential effects of this nature from xylenes. Although epidemiological data are highly desirable, a study is not now being required because the mixed exposure pattern associated with these chemicals makes conducting such a study infeasible.

FOR FURTHER INFORMATION CONTACT: Douglas C. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, toll free: (800-554-1404), 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) authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining 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.

In October, 1977, the ITC designated xylenes for mutagenic and teratogenic effects testing and an epidemiological study (42 FR 55028). Xylenes are a category consisting of the three isomers of dimethyl benzene: *ortho*-xylene, *meta*-xylene and *para*-xylene. The composition of commercial "mixed xylenes" varies depending on feedstock source and refinery conditions. However, the main components are