ENVIRONMENTAL PROTECTION AGENCY

[OPTS-42011A; TSH-FRL-2100-6]

2-Chlorotoluene; Response to the Interagency Testing Committee

March 29, 1982.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Eighth Report of the Interagency Testing Committee (ITC), transmitted to the Administrator of the EPA on April 24, 1981, the Committee designated the chemical 2-chlorotoluene for testing considerations. Following publication of the ITC report and a public meeting on June 16, 1981, the sole American manufacturer of 2-chlorotoluene, Hooker Chemicals and Plastics Corporation, presented to the EPA plans for testing its health and environmental effects. The Agency has discussed the planned testing with Hooker and, after an opportunity for public review and comment, decided to accept the program. Consequently the EPA is not, at this time, proposing a section 4(a) rule to require health or environmental effects testing of 2-chlorotoluene.

FOR FURTHER INFORMATION CONTACT: Douglas G. 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: (800-424-9065), 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) authorizes the 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 the TSCA [90 Stat. 2010; (15 U.S.C. 2601 et seq.)] established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

The IRC placed 2-chlorotoluene on its priority testing list in April 1981, requiring the EPA to respond to such listing within 12 months of the date it was made, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so. The ITC recommended testing of 2-chlorotoluene for carcinogenicity, mutagenicity, chronic effects, reproductive effects, teratogenicity, chemical fate, bioconcentration, and chronic toxicity to fish and aquatic invertebrates.

II. Proposed Testing

Hooker Chemicals and Plastics Corporation is the sole American manufacturer of 2-chlorotoluene. At a public meeting held by the EPA on July 16, 1981, Hooker announced that it was planning additional testing of 2-chlorotoluene. After discussions with Agency staff, a detailed testing scheme and schedule was submitted for EPA review and comment. A revised version was made available to the public for comment in January 1982 (47 FR 3596, January 26, 1982).

Hooker's proposal for health effects testing is a tiered system, with lower tier tests acting as triggers to additional testing or as stop points following review of the data with EPA personnel. The complete health effects tier can be seen in Figure 1, along with decision points and estimated schedules. A more detailed portrayal of the mutagenicity test program is seen in Figure 2.

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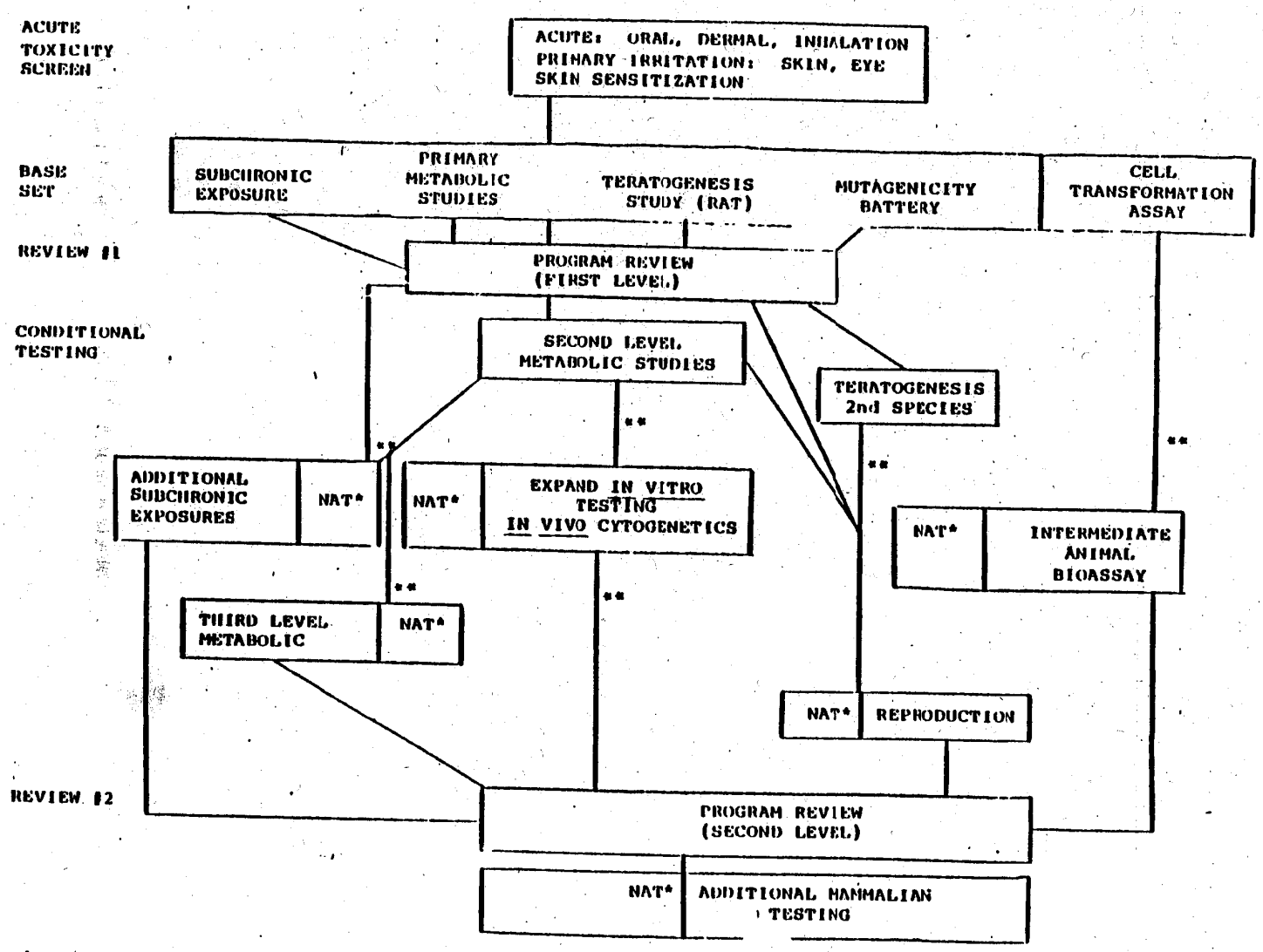
Figure 1

2-CHLOROTOLUENE
MAMMALIAN TOXICOLOGY
PROGRAM



TIME SCHEDULE

COMPLETED

IN PROGRESS

AUGUST 1982

AUGUST 1982 TO FEBRUARY 1983

FEBRUARY 1983 TO DECEMBER 1983

DECEMBER 1983 TO DECEMBER 1984

JANUARY 1984

* NA[illegible]o Additional Testing
** Dat[illegible]eview with EPA

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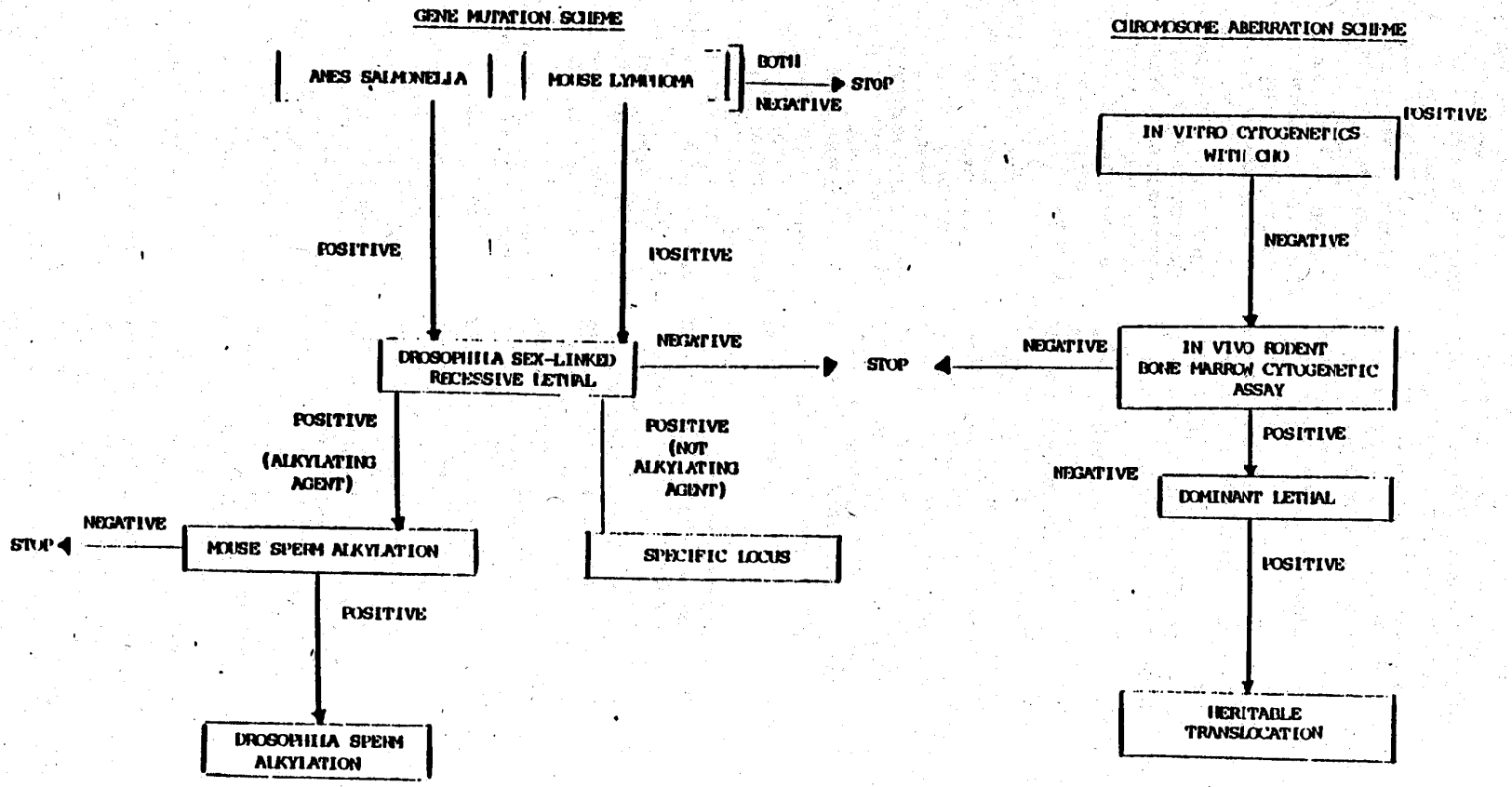
FIGURE 2



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The aquatic toxicity testing scheme is a non-tiered set of tests. The following tests will be performed:

Acute fish—trout, fathead minnow
Acute invertebrate—*Daphnia*
Chronic fish (embryo-juvenile test)—fathead minnow
Fish bioconcentration (species to be determined)

Hooker has agreed to permit Good Laboratory Practices/Quality Assurance activities at the request of authorized representatives of the EPA in connection with any and all studies being conducted by and for Hooker. Hooker will supply the EPA with the data from the studies as soon as possible. The Agency will periodically make this information available for public review.

III. Decision not to Require Testing

After a thorough review of the Hooker testing proposal, the EPA has decided not to propose a test rule for 2-chlorotoluene at this time. The EPA believes that the Hooker proposal will meet the testing concerns of the Agency for 2-chlorotoluene. Of the specific recommendations made by the ITC, testing for mutagenicity, teratogenicity, bioconcentration, and chronic fish toxicity are explicitly included in the Hooker proposal. Eli Lilly and Company have submitted an oral 90-day subchronic study to the EPA. Hooker Chemical will be performing metabolic studies which, when evaluated in conjunction with available shorter-term oral, dermal and inhalation studies, will aid the Agency in determining whether additional subchronic tests will be needed. The EPA believes such an approach to be appropriate for the reasons presented in the EPA's Response to the NRDC Comments on the Chlorinated Paraffins (OPTS Docket 42004). For reproductive effects, a decision whether to perform full-scale reproduction studies will be based on results of the 90-day subchronic and the teratogenicity studies. For oncogenicity, the results of cell transformation and short term mutagenicity tests will determine the need for longer term testing. Chemical fate testing is now considered unnecessary because enough data have been submitted by Hooker and by Eli Lilly and Company during the past year to satisfy data needs in that area. Finally, Hooker has proposed to omit chronic toxicity testing of 2-chlorotoluene on aquatic invertebrates, proposing instead to evaluate this effect on the basis of the planned 48-hour *Daphnia* test in conjunction with a comparison of results from the acute and chronic fish studies and bioconcentration studies. From these data, it can be judged whether 2-chlorotoluene is a cumulative toxicant in aquatic species or whether invertebrates appear to be unusually susceptible to the compound. The EPA believes that this is an appropriate approach for testing 2-chlorotoluene.

Because Hooker's proposal covers the concerns of the ITC either directly or indirectly, and Hooker has agreed to include the Agency in all decision-making processes, the acceptance of Hooker's proposal seems a reasonable alternative to a time-consuming and expensive formal TSCA section 4(a) rulemaking. This allows the EPA to focus upon other testing needs not covered by negotiated testing agreements. After considering the Agency's present test rules burden and the range of testing included in this testing proposal, the EPA has determined that the public interest will best be served by Hooker's and the EPA's mutual cooperation in this testing program. Should test results or other information reveal a strong need for additional testing that Hooker is unwilling to perform, the Agency reserves its right to promulgate a test rule.

IV. Public Record

The EPA has established a public record for this testing decision (docket number OPTS-42011) which is available for inspection in the OTS reading room from 8:00 a.m. to 4:00 p.m. Monday through Friday in Rm. E-107, 401 M St., SW., Washington, DC 20460. This record includes basic information considered by the Agency in developing this decision. The Agency will supplement the record periodically with additional relevant information received. The record includes the following information:

(1) Federal Register notice containing the designation of 2-chlorotoluene to the priority list.

(2) Communications before industry testing proposal.

(a) Letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries of Agency-industry and Agency-public meetings.

(3) Testing proposal and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2061))

Dated: April 22, 1982.

Anne M. Gorsuch,

Administrator.

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