

releases and expected environmental concentrations of nitrobenzene based on additional data that have become available since the proposal have led the Agency to conclude that the current data do not support the findings necessary to require testing under TSCA section 4(a).

FOR FURTHER INFORMATION CONTACT:

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(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed test rule package (chloromethane and chlorinated benzenes, published July 18, 1980; 45 FR 48510) and to the second package (dichloromethane, nitrobenzene, and 1,1,1-trichloroethane, published June 5, 1981; 46 FR 30300) for in-depth discussions of the general issues applicable to this action.

II. ITC Recommendations

Section 4(e) of TSCA established the Interagency Testing Committee (ITC) to recommend to EPA chemicals to be considered for priority testing under TSCA. Nitrobenzene was designated by the ITC in its Initial Report to the EPA Administrator on October 12, 1977 (42 FR 55026). The ITC recommended that nitrobenzene be tested for carcinogenicity, mutagenicity, and environmental effects. The ITC estimated the annual release of nitrobenzene to the environment to be twenty million pounds and was

SUPPLEMENTARY INFORMATION:

I. Introduction.

This notice is part of the overall implementation of section 4 of the Toxic Substances Control Act (TSCA), (Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) which contains authority for EPA to require development of adequate data with respect to the effects of chemical substances and mixtures on health and the environment in appropriate circumstances.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health and environmental data if the Agency finds that:

40 CFR Part 773

[OPTS-47004E TSH-FRL 2571-3]

Nitrobenzene; Decision To Withdraw a Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; withdrawal.

SUMMARY: In the Federal Register of June 5, 1981 (46 FR 30300), EPA proposed the testing of dichloromethane, nitrobenzene, and 1,1,1-trichloroethane under section 4(a) of the Toxic Substances Control Act for certain health and environmental effects. A notice on dichlorobenzene appears elsewhere in this issue of the Federal Register; 1,1,1-trichloroethane will be addressed at a later time in another Federal Register document. The Agency has decided not to proceed with rulemaking for nitrobenzene. This withdrawal results from the Agency's evaluation of additional Agency and industry data and also from EPA's knowledge that the manufacturers of nitrobenzene are conducting health and environmental tests that, in conjunction with ongoing government testing programs, are expected to meet all testing data needs currently identified by the Agency. The ongoing tests, along with existing information, are expected to provide sufficient data and experience to reasonably determine or predict the effects that manufacture, processing, distribution, use and disposal of nitrobenzene will have on human health, or in the case of mutagenic effects, to provide a clear basis for determining if there is any need for further testing. With respect to environmental effects, EPA's reevaluation of the environmental

concerned that general population exposure could arise from environmental release and from various dispersive uses:

III. Background

This notice discusses the major issues and comments arising from the publication of the proposed test rule on dichloromethane, nitrobenzene, and 1,1,1-trichloroethane on June 5, 1981 (46 FR 30300), and presents the Agency's rationale for now terminating rulemaking on nitrobenzene. Dichloromethane is addressed elsewhere in this issue of the Federal Register; 1,1,1-trichloroethane will be addressed in a future Federal Register document.

The June 5, 1981, proposed rule requested that interested parties submit written comments on or before August 30, 1981. Because EPA had included certain environmental tests in the proposed rule, on August 13, 1981, (46 FR 40898), the Agency extended the deadline of the original comment period

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to November 30, 1981, to allow for proposal of the relevant environmental test standards and comment on their application to nitrobenzene. These standards were intended to provide industry with the requirements for conducting each of the environmental effects tests listed in the nitrobenzene proposed rule. On November 30, 1981 (46 FR 58108), the comment period was extended a second time, to February 1, 1982. EPA was in the process of changing its approach to adopting test standards for test rules and procedures for the development of test rules, and on March 26, 1982 (47 FR 13012), the Agency announced this change in policy. In a companion notice that same day, the Agency announced it was implementing the changes in policy and procedure for the nitrobenzene proposed test rule (March 26, 1982, 47 FR 13012).

A. Health Effects Findings

In the proposed rule, EPA based its health effects testing requirements for nitrobenzene on the authority of section 4(a)(1)(A) of TSCA. In proposing the finding, the Agency stated that the manufacture, processing, distribution in commerce, use, and disposal of nitrobenzene may present an unreasonable risk of injury to human health due to reproductive and teratogenic activity because: (1) There were existing data and experience that indicate a potential human health hazard from nitrobenzene with respect to these effects; (2) EPA believed that persons were exposed to nitrobenzene in the workplace, as consumers, and as a result of release of nitrobenzene into the environment. Although testing for structural teratogenic effects and reproductive effects was not recommended by the ITC, EPA believed that these areas were of concern and should be evaluated.

In its review of nitrobenzene exposure and toxicity conducted for the proposed rule, the Agency determined that two health effects cited by the ITC, oncogenicity and mutagenicity, may present an unreasonable risk of injury to human health; however, testing was not proposed for these effects. Oncogenicity testing was not proposed because a two-year bioassay was being performed by the National Toxicology Program (NTP), which assumed responsibility for managing the National Cancer Institute's bioassay studies. EPA believed that the NTP study should be sufficient for the Agency's needs for oncogenicity, subchronic effects, and chronic effects testing; therefore, it concluded that no additional testing for these effects should be required.

Independent of the NTP effort, the Chemical Industry Institute of Toxicology initiated a separate nitrobenzene two-year bioassay and completed a prerequisite 90-day subchronic inhalation study. The NTP, having completed the subchronic phase of its nitrobenzene bioassay, decided on November 3, 1983 not to proceed with chronic testing of nitrobenzene because the CIIT was to commence its chronic testing of the chemical on November 28, 1983. The CIIT is to have its final report on the chronic study available for Agency review on December 1, 1986.

In the proposed nitrobenzene rule, the Agency stated that although mutagenicity testing according to a testing sequence was necessary, EPA would perform the initial testing because criteria for progressing from initial mutagenicity tests to higher tier mutagenicity tests were not available at that time and because EPA had not yet developed test standards for certain mutagenicity tests. This was to be an exception to the general policy prescribed in section 2 of TSCA that industry should develop necessary test data. The Agency reasoned that (1) EPA's sponsorship of those tests would contribute to the Agency's development of test standards in those areas; (2) information on the effects would be important to the risk assessment of nitrobenzene, and testing should not be delayed; and (3) the cost of the testing would be relatively low.

The proposal noted that when the Agency had completed the lower tier mutagenicity testing, EPA would assess the need for additional higher tier mutagenicity testing. If, based on the analysis of lower tier results, the Agency determined the need for higher tier testing, this would be announced in a subsequent proposed rule, including an appropriate comment period.

EPA has continued its evaluation of mutagenicity test sequencing for chemicals presenting mutagenic concerns. The Agency has also continued its review of the available nitrobenzene mutagenicity data. Recently the National Toxicology Program has reported that nitrobenzene had been tested for the ability to induce gene mutations in bacteria (*Salmonella typhimurium*) and for its ability to induce chromosomal aberrations and sister chromatid exchanges in mammalian cells *in vitro*. Nitrobenzene was negative in all three tests. The Agency is proceeding with further testing which will include a determination of nitrobenzene's ability to induce sex-linked recessive lethal (SLRL) mutations in *Drosophila melanogaster* and dominant lethal

effects in rats. The results of these tests will be available in summer, 1984. Further testing will depend on the outcome of these studies.

B. Environmental Effects Findings

The ITC recommended environmental effects testing for nitrobenzene. The Agency determined that environmental effects testing was needed to determine the effects resulting from the manufacture, processing, distribution in commerce, use or disposal of nitrobenzene. In the proposed rule, EPA based its environmental effects testing requirements on the authority of section 4(a)(1)(B) of TSCA. In proposing the finding, the Agency stated its belief that: (1) Nitrobenzene was produced in substantial quantities (575 million pounds in 1978), and (2) there was substantial release to the environment. Of the nitrobenzene produced in the U.S., EPA estimated that approximately 12.75 million pounds would be expected to reach the atmosphere (1978), and rainout would carry a substantial quantity of this emission to soil and to the aquatic environment. The Agency also stated that a substantial quantity of nitrobenzene might be released from manufacturing activities to surrounding aquatic areas.

EPA proposed testing for: Aquatic vertebrates (acute toxicity, chronic toxicity); aquatic invertebrates (chronic toxicity); birds (acute toxicity, chronic toxicity); terrestrial plants (root elongation/seed germination, early seedling growth); bioconcentration (plant uptake/translocation); and chemical fate (soil adsorption). In the proposed rule, the Agency also indicated that EPA would perform several chemical fate and environmental effects tests: freshwater and saltwater vascular aquatic plants; terrestrial invertebrates; full life cycle tests on terrestrial plants; chemical persistence, and acute and chronic testing of coldwater, saltwater vertebrates. The Agency stated that it would perform these tests because TSCA section 4 test standards were not available for directing such studies at that time.

However, as a result of the Agency's review of additional environmental release and waste treatment data, EPA now believes that the releases of nitrobenzene to the environment are not substantial. Furthermore, the Agency does not believe that the current data on nitrobenzene environmental effects justify testing for environmental fate or effects under section 4(a)(1)(A). Therefore, EPA is terminating its rulemaking to require environmental fate and effects testing and the Agency will not conduct the chemical fate and

environmental effects testing that was indicated in the proposed rule.

IV. Major Comments

The comments received in response to the proposed rule were exclusively from industry sources, with most being submitted by the Nitrobenzene Association, a consortium of nitrobenzene producers formed in May of 1981. Most of the comments regarding worker exposure and environmental release were supplied by the Nitrobenzene Association and were based on a survey (Ref. 2) of nitrobenzene manufacturers and customers conducted by the Synthetic Organic Chemical Manufacturers Association (SOCMA). According to SOCMA, the survey was designed to gather worker exposure and environmental release data from manufacturers and information concerning customers' use of nitrobenzene as a chemical intermediate, a solvent, and as an additive to consumer products.

The major issues identified during the comment period are detailed below. The scientific analyses upon which the section 4 findings were based in the proposed rule were presented in the Nitrobenzene Support Document, which is available from the Office of Toxic Substances' TSCA Assistance Office.

A. Worker Exposure

The Nitrobenzene Association challenged the Agency's estimate that 13,547 workers were exposed to nitrobenzene yearly. Relying on the survey by SOCMA, they reported the number of exposed workers to be 832. The Association indicated that this included workers exposed to nitrobenzene during its manufacture, during the manufacture of aniline, while using the chemical in other industrial processes, and nitrobenzene usage by customers in other manufacturing processes.

Based on the National Occupational Hazard Survey (NOHS) compiled by the National Institute for Occupational Safety and Health (NIOSH), the Agency continues to believe that the number of workplace exposures to nitrobenzene are or may be significantly higher than reported in the Association's survey. The NOHS survey, reanalyzed by NIOSH in April of 1982, reported 13,641 worker exposures (NIOSH, 1982). Of this total, 40 percent were workers actually observed working around nitrobenzene while another 43 percent were workers exposed to trade name products later identified as containing nitrobenzene.

B. Release to Air

In the proposed rule, EPA estimated that 275,000 pounds of nitrobenzene were released to the atmosphere through production and use in aniline manufacture and 12.75 million pounds through the solvent uses (Anderson et al. 1980) of nitrobenzene in petroleum refinery operations and in cellulose ether manufacture. The Agency based this latter figure on a trade publication's citation of solvent uses of nitrobenzene (for cellulose ethers and in the petroleum industry) and a survey or chemical release quantities (Ref. 1) that estimated that the total quantity of nitrobenzene employed in solvent applications was eventually lost to the atmosphere. The Agency believed that much of this material would be carried back into aqueous environments or to soil by rainout.

Subsequent to the proposal of the nitrobenzene rule, the Nitrobenzene Association informed the Agency that their survey of producers and users revealed no use of nitrobenzene in either cellulose ether or refinery operations. In investigating this inconsistency, the Agency found that neither the trade citation (Ref. 4) nor the basis for the release estimate could be confirmed.

The Nitrobenzene Association reported the total nitrobenzene release to air, as reported by customers, to be 18,700 pounds and also reported that only 28,200 pound of nitrobenzene were released to the air by manufacturers during production and use.

EPA has also received relevant data through the Preliminary Assessment Information Rule, issued under section 8(a) of TSCA (47 FR 26992). This rule required manufacturers of subject chemicals resulting from manufacturing and other activities. EPA has reviewed the nitrobenzene data (reported here as an aggregate range to protect individual corporate confidential business information) and reports the total loss to air and water collectively to be 66,000-110,000 pounds annually. Under the 8(a) rule, losses are reported as total losses to the environment, not as separate losses to air and to water. EPA finds these figures to be reasonably close to those reported by the Nitrobenzene Association and has conducted the rest of its analysis based upon the somewhat more detailed figures reported by the Nitrobenzene Association.

After considering the inaccuracy of the use estimate figures cited in the proposed rule, the newly received 8(a) data, and because the Agency has no other nitrobenzene air release information that would indicate higher release levels, EPA has concluded that

the release to air is significantly less than it had previously estimated.

EPA does not view the release to the atmosphere of 28,200 pounds and 18,700 pounds of nitrobenzene by manufacturing operations and customer use, respectively, as substantial. In addition, EPA has concluded that organisms in the various environmental compartments are not expected to be exposed to nitrobenzene at any significant levels as a result of these releases and would not be expected to be at risk.

C. Release to Water

In the proposed rule, EPA estimated that approximately 8.3 million pounds of nitrobenzene might be lost to ambient waters yearly. This figure was based on estimates that 8.3 million pounds of nitrobenzene were lost from the production process each year and that the vast majority of this production loss occurred through effluent waste water. The Nitrobenzene Association reported, based on their survey, that release after treatment was only 46,000 pounds annually.

Because of the tremendous disparity between these two release levels, the Agency conducted further analyses in an attempt to confirm or refute the Nitrobenzene Association's release figure. To this end, the EPA Office of Toxic Substances compiled additional data from EPA's Office of Water Regulations and Standards concerning measured industry product/process effluent concentrations, plant flow and stream flow data, stream dilution factors and information concerning waste treatment techniques and efficacy. The Agency has also evaluated and incorporated into this analysis industry survey data concerning treatment methods and efficiency, production levels, and monitoring information and the newly received TSCA section 8(a) data. (Much of this information is TSCA Confidential Business Information (CBI) and will be on file in the CBI portion of the administrative record for this notice). From this analysis, EPA does not now believe there is substantial release of nitrobenzene to the aquatic environment, and the Agency currently estimates that the annual release of nitrobenzene to ambient waters from manufacturing is 54,000 pounds. The concentrations in receiving waters, at release points, probably range from 0.0 to 10.0 ppb (10 µg/l) (Ref. 6). Because these estimated concentrations are significantly below toxic concentrations (48-Hr. LC₅₀ of 27,000 µg/l) reported in tests involving what appears to be the most sensitive aquatic organism (*Daphnia*), (Ref. 5) there is no basis for

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believing that nitrobenzene may present an unreasonable risk to aquatic organisms and therefore no need to require additional aquatic testing.

V. Ongoing Industry Testing Activities

The nitrobenzene industry is conducting a mysid shrimp chronic toxicity test that will provide additional environmental data on a species sensitive to nitrobenzene. The results will provide useful information to compare with the Agency's conclusions concerning anticipated ambient concentrations of nitrobenzene. Any additional requirements for environmental effects testing must await the receipt of and evaluation of this study.

As stated earlier, the Chemical Industry Institute of Toxicology is conducting a two-year chronic study of nitrobenzene and the Agency has reviewed the testing protocol adopted by the CIIT and finds it to be adequate. A final report on this study is to be available to the Agency in December, 1986.

The industry has also initiated the testing of nitrobenzene for reproductive and teratogenic effects. The industry has supplied the Agency with the study plans for these studies and, after reviewing the protocols, EPA believes that the data derived from these studies will provide sufficient information to reasonably determine the potential for nitrobenzene to produce teratogenic or reproductive effects. The industry has indicated that the results of the teratology studies in rabbits and rats will be reported to the Agency in July, 1984 and November, 1984 respectively. The results of the reproductive/fertility study will be reported to the Agency in January, 1985.

EPA has also received assurances from industry that both the health and environmental effects tests will be conducted according to the Food and Drug Administration's Good Laboratory Practices Regulations (December 22, 1978, 43 FR 59986). It is understood by all parties that the studies must be performed according to the quality standards that would apply were this testing to be conducted under final TSCA section 4 rulemaking. Deviation will result in a reexamination of the section 4 testing needs for nitrobenzene. As is required in EPA's TSCA Good Laboratory Practice Standards (48 FR 53922, November 29, 1983), industry has agreed that all raw data and specimens pertaining to the reproductive effects and teratogenic effects and mysid shrimp tests being conducted by industry, will be retained for 10 years from the date of publication of this notice.

VI. Rationale for Decision To Terminate Rulemaking

This notice documents EPA's decision not to proceed with rulemaking to require testing of nitrobenzene under section 4 of TSCA at this time. With respect to environmental testing, as explained earlier, after reviewing information concerning production/process methods and expected effluents, industry-submitted process and use data, and the limited existing monitoring data, the Agency has determined that the releases of nitrobenzene to air and water appear to be limited. Therefore, the Agency does not believe that there is a sufficient basis to find that the current manufacture, distribution, processing, use, and disposal of nitrobenzene will result in substantial release of nitrobenzene to the environment or that these activities may present an unreasonable risk to the environment. Therefore, EPA has concluded that additional testing of nitrobenzene for environmental effects is not justified under section 4(a) of TSCA at this time.

With regard to human health effects, the Agency still has concerns regarding the toxicological characteristics of nitrobenzene. However, industry and Federal testing efforts are producing data that the agency believes will be sufficient to reasonably determine or predict the potential for nitrobenzene to produce oncogenic, mutagenic, teratogenic or reproductive effects. Thus, the Agency is not issuing a final Section 4 test rule requiring health effects testing of nitrobenzene.

VII. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-47004E) which is available for inspection 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, DC. This record includes the basic information the Agency considered in developing this Notice, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received. This record includes the following information:

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice of proposed rule on nitrobenzene (46 FR 30300, June 5, 1981).

(b) Notice containing the ITC designation of nitrobenzene to the Priority List (42 FR 55026, October 12, 1977).

(c) Notices relating to EPA's health effects test guidelines (44 FR 27337, May 9, 1979; 44 FR 44054, July 26, 1979; 45 FR 77332, November 21, 1980) and EPA Good Laboratory Practice Standards, (44 FR 27334, May 9, 1979; 44 FR 44054, July

26, 1979; 44 FR 77357, November 21, 1983; 48 FR 53922, November 29, 1983). The TSCA guidelines are published by the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161 (703-487-4650), for health effects (PB-82-232984), and environmental effects (PB-82-232992).

(d) Notice of proposed rule on exemption policy and procedures (45 FR 48512, July 18, 1980).

(e) Final Rule on reimbursement policy and procedures (48 FR 31786, July 11, 1983).

(2) Support Documents: consisting of:

(a) Nitrobenzene support document.

(b) Nitrobenzene economic analysis support document.

(3) Communications, consisting of:

(a) Written public and intra-agency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Meeting summaries.

(d) Reports—published and unpublished factual materials.

VIII. References

(1) Anderson GE, et al. 1980. A summary of data on nitrobenzene from Systems Applications Incorporated. Final Report: Human exposure to atmospheric concentrations of selected chemicals. U.S. Environmental Protection Agency (EPA) Contract 68-02-3066, March 5, 1980.

(2) Nitrobenzene Association. 1982. Comments of the Nitrobenzene Association on Proposed Nitrobenzene Test Rule (containing as Appendix A, the Synthetic Organic Chemical Manufacturers Association Survey of Industry Uses and Environmental Releases). January 27, 1982.

(3) NIOSH. 1982. National Institute for Occupational Safety and Health. National Occupational Hazards Survey Data Base (NOHS). Washington, D.C. U.S. Department of Health, Education and Welfare. April, 1982. Computer update of 1976 figures.

(4) SRL. 1981. Aniline and Nitrobenzene. Chemical Economics Handbook, Stanford Research Institute, Menlo Park, CA.

(5) USEPA. 1978. In-depth studies on health and environmental impacts of selected water pollutants. Contract No. 68-01-4846. EG and G Bionomics.

(6) USEPA. 1983. U.S. Environmental Protection Agency. Office of Toxic Substances. Memorandum, January 31, 1983: Nitrobenzene Release to Water from William Burch. Chemical Engineering Branch to Steve Newburg-Rinn. Test Rules Development Branch (not in public docket because of Confidential Business Information contained therein). Washington, D.C.: U.S. Environmental Protection Agency.

The proposal to add 40 CFR 773.3050 to Chapter I of 40 CFR Subpart B.

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published at 48 FR 30300, June 5, 1981, is hereby withdrawn.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2801))

Dated: June 11, 1984.

William D. Ruckelshaus,

Administrator.

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