

(2) Communications (letters, contact reports of telephone conversations, and 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(4) Published and unpublished data.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 and comments received in response thereto.

This 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 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. 2061)]

Dated: December 23, 1982.

John W. Hernandez,  
Acting Administrator.

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[OPTS-47003B; FRL 2262-2]

**Acrylamide; Response to the Interagency Testing Committee**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice is EPA's response to the Interagency Testing Committee's (ITC's) recommendation that EPA consider requiring environmental effects testing of acrylamide under section 4(a) of the Toxic Substances Control Act (TSCA). On November 2, 1982, the American manufacturers of acrylamide notified the Agency that they had initiated a program to test acrylamide for its acute toxic effects on a representative group of aquatic vertebrates and invertebrates and for its chronic effects on an aquatic invertebrate. EPA believes that the ongoing industry testing program is likely to provide adequate data to reasonably determine or predict the environmental effects of acrylamide. Alternatively, the program's results may raise concerns which might indicate a need for additional testing to characterize acrylamide's chronic effects on aquatic organisms. In either case, the Agency has concluded that it does not have a basis at this time to initiate rulemaking under section 4(a) to require environmental effects testing of acrylamide.

**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: (800-424-8065). 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 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 designated acrylamide for environmental and health effects testing in its Second Report, submitted to the Agency on April 10, 1978, as published in the Federal Register of April 19, 1978, (43 FR 16684).

EPA's response regarding the testing of acrylamide for health effects was published in the Federal Register of July 18, 1980 (45 FR 48510). Consideration of the environmental effects of acrylamide was deferred at that time pending the development of environmental effects test standards.

The reasons for the ITC's recommendation for environmental effects testing were: (1) The high production volume of acrylamide, (2) the uses of both acrylamide and polyacrylamide which bring acrylamide into direct contact with the environment, and (3) the knowledge that acrylamide is highly toxic to the nervous systems of mammals coupled with very little knowledge of its environmental release and ecological effects. The ITC expressed particular concern for acrylamide's effects on plant and animal life in the aquatic environment and its ability to be leached from polyacrylamide.

**II. Acrylamide's Release to the Environment—Environmental Fate and Effects**

Acrylamide is produced in the United States by three manufacturers at four locations (Ref. 21). It is also imported, mainly from Japan (Ref. 23). The 1979 production and importation figures for acrylamide were 66 million and 1.3 million pounds, respectively (Refs. 14 and 26). Eighty-eight percent of the

acrylamide produced goes into the manufacture of polyacrylamide, with the remaining acrylamide used for soil grouting, as an intermediate in the synthesis of N-substituted monomers, in gel chromatography, and in electrophoresis (Ref. 26). Polyacrylamide is used primarily as a flocculant in the treatment of wastewater and drinking water. Another major market for polyacrylamide is the pulp and paper industry, where it is used, among other things, as a dry-strength additive, especially in the manufacture of high quality white paper (Refs. 14 and 24). From these uses, contamination of water by residual acrylamide monomer is possible; environmental contamination is also possible through its use as a chemical grout. Chemical grouts are used in a variety of applications including repair of sewer lines; waterproofing mines, tunnels, and foundations; and stabilizing rock and soil in mines, roadbeds, and dams (Refs. 14 and 24). Dow Chemical Company has estimated that sources of acrylamide exposure (e.g. acrylamide manufacture, storage and transport, polyacrylamide manufacture and use, and acrylamide grouting operations) could provide up to 210,000 pounds of acrylamide monomer for release into the environment annually (Ref. 9). A draft contractor report prepared for EPA estimated a higher figure of 550,000 pounds of acrylamide monomer released annually into the environment (Ref. 14).

Acrylamide is a highly water-soluble compound (216 g/100 ml at 30°C) with a very low vapor pressure (0.007 mm Hg at 25°C) (Ref. 17). Based on its chemical-physical properties and experimental evidence, acrylamide does not adsorb to soils or sediments or bioaccumulate in organisms (Refs. 3, 6, and 15). Acrylamide's chemical-physical properties further indicate that this compound, whatever its release site, will tend to partition into and remain in the aquatic environment until it is degraded (Ref. 25). Acrylamide, under aerobic conditions, has been shown to be readily degraded in freshwater by bacteria with a reported half-life of 55 to 70 hours after acclimation of the bacteria to the compound for 33 to 50 hours (Ref. 4). Half-lives of acrylamide under estuarine or saltwater conditions were slightly longer. Anaerobic degradation, as would occur in sediments, is reported to be very slow, but, as acrylamide binds very poorly to sediments, accumulation in this compartment is unlikely (Refs. 3 and 16).

Environmental monitoring at sites of acrylamide and polyacrylamide

manufacture and use in the United States and Great Britain indicates that levels of acrylamide reaching surface waters from industrial effluents would generally be non-detectable (below 0.08 ppb) to up to 3.4 ppb (Refs. 2, 7, 11, and 12). However, an extreme value of 1,500 ppb was recorded by Going (1978) in a small stream receiving effluent directly downstream from a polyacrylamide producer in Virginia, and local concentrations of acrylamide in similarly high ranges have been found in the vicinity of local grouting operations (Refs. 11, 13, and 19). In the Going (1978) study acrylamide was not detected in water, soil, sediments or air during the course of monitoring other sampling locations either at that site or at sampling locations near four other industrial sites located in the Eastern, Southern and Midwestern United States. The limits of detection for acrylamide in that study were 0.1 to 3.4 ppb, 0.8 ppb and 80 ppb, for air, water, and soil and sediments, respectively.

Acrylamide is considered to be a potent neurotoxicant to mammals; a chronic no-effect level to mammals has been indicated to be an ingested dose of 0.3 to 1.0 mg/kg/day, based on a long term toxicity study on the domestic cat (Ref. 18). Limited information on birds indicates that birds are similarly affected by the chemical (Ref. 10). The Agency has only limited data concerning the effects of acrylamide on aquatic vertebrate species; the data indicate that fish are sensitive to the acute lethal effects of acrylamide in the 100 ppm range (Refs. 8, 10, and 22). The Agency has recently received one study indicating that acrylamide may be extremely toxic to aquatic invertebrates. Establishment of a concentration of approximately 50 ppb of acrylamide in a natural stream in England caused a reduced species diversity to occur among the invertebrate population within six hours after exposure (Ref. 5). Data on the toxicity of acrylamide to plants do not suggest a concern greater than that posed by the compound to animal species (Refs. 1 and 20).

Under present conditions of use and release of acrylamide, no unreasonable risk to the terrestrial or atmospheric environments is expected because exposure to these environmental compartments is expected to be insignificant. However, based on the foregoing information, EPA believes that acrylamide is of potential concern to the aquatic environment (especially the freshwater environment) given its chemical-physical properties and its present use and release pattern. Although the Agency also believes that

the exposure of the aquatic environment to acrylamide will be on a local, short-term basis or at very low levels, as demonstrated by available monitoring data, the Agency is concerned that acrylamide may be especially toxic to aquatic invertebrates. The Agency is concerned that acrylamide is a neurotoxicant not only to mammals but also to aquatic organisms. Therefore, testing to evaluate the effects of acrylamide on aquatic organisms should be performed.

### III. Testing Program Proposed by Representatives of the Acrylamide Industry

In the spring of 1982, the EPA began discussions with American Cyanamid, Dow Chemical Company, NALCO Chemical Company and the Standard Oil Company of Ohio (herein collectively referred to as Industry) regarding the need for testing of acrylamide to characterize its environmental effects. As a result of EPA's conclusion that aquatic testing was necessary, Industry has initiated a testing program which consists of acute, 96-hour, flow-through toxicity tests on three freshwater vertebrates (the bluegill, fathead minnow and rainbow trout), two freshwater invertebrates (the midge and waterflea) and one saltwater invertebrate (the mysid shrimp). Observations on swimming behavior will be made on the organisms during the testing. In addition, Industry is in the process of contracting to perform a chronic toxicity test on the mysid shrimp. The mysid was considered the best species to use in this case as it requires an intact behavioral response for reproductive success, unlike the midge and waterflea species which are parthenogenic; the protocols for these studies have been reviewed by EPA's scientists and found to be acceptable. They are available for examination in the public record of this proceeding.

Normally when EPA negotiates such a testing program with Industry, the Agency requests that initiation of testing be deferred until EPA can obtain and consider public comments on the proposed testing. However, in this instance the limited nature of the testing and certain contractual reasons led Industry to initiate testing without awaiting final approval by EPA of the program. The results should be available to the Agency early in 1983.

Industry has furnished EPA with the name and address of the laboratory conducting these tests. Industry has stated that it will adhere to the Good Laboratory Practice Standards (GLP's) issued by the U.S. Food and Drug Administration, as published in the

Federal Register of December 22, 1978 (43 FR 59986). Industry also has offered to permit laboratory audits/inspections in accordance with the authority and procedures outlined in TSCA section 11 at the request of authorized representatives of the EPA. 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 Practices.

Industry has further committed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained as specified in the FDA Good Laboratory Practice Standards, except that all raw data will be retained by the testing laboratory for ten years rather than the two years specified by the FDA GLP's. In addition, the raw data will be made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

The Agency plans to issue in the Federal Register a notice of the receipt of all test data submitted by industry under this test program. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Should Industry fail to conduct the testing according to the specified protocols or fail to follow Good Laboratory Practices, such actions 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.

### IV. Decision Not To Initiate Rulemaking

The Agency has concluded that there are sufficient data on acrylamide's release, fate and effects to indicate that any potential environmental risk presented by acrylamide given its manufacture, use and release pattern, would be limited to the aquatic environment.

EPA believes that the results of testing being undertaken by Industry, combined with existing data, are likely to provide sufficient data to reasonably predict the aquatic toxicity of acrylamide. Furthermore, the Agency believes that any additional testing should not be considered until EPA has had a chance to fully evaluate the testing being performed currently by industry. In view of these ongoing testing activities, EPA

does not believe that it can find that "testing is necessary" as would be a prerequisite for mandating testing under section 4 of TSCA. Therefore, EPA has decided not to initiate a rule to require further environmental testing of acrylamide at this time. It is conceivable that the results of these tests being performed by Industry may raise concerns which might indicate a need to perform additional testing for chronic effects to aquatic organisms (e.g., if the tests show acrylamide to be highly toxic). EPA will evaluate the need for additional testing when these results are available. If these or other new data reveal a need for further testing which Industry is unwilling to conduct, the Agency can require it through a section 4 test rule at that time.

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#### V. Public Record

EPA has established a public record for this decision not to pursue testing under section 4. docket number OPTS-47003E, which is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. This record includes the following information:

1. Federal Register notice containing the designation of acrylamide to the Priority List and any comments on acrylamide in response to that notice.

2. Federal Register notice containing the Agency's response to the ITC recommendation that acrylamide be considered for health effects testing under TSCA section 4(a).

3. Communications: (a) Public and inter-agency communications, including memoranda, comments and proposals.

- (b) Contact reports of telephone conversations.

- (c) Meetings.

4. Industry submitted protocols and testing schedules.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 20001)

Dated: December 27, 1982.

John W. Hernandez,  
Acting Administrator.

[FR Doc. 83-328 Filed 1-3-83; 8:45 am]

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[OPTS-42029; TSH-FRL No. 2246-7]

#### Isophorone; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice is EPA's response to the Interagency Testing Committee's (ITC's) recommendation that isophorone be tested for health effects under section 4(a) of the Toxic Substances Control Act (TSCA). Following publication of the ITC report, the National Toxicology Program initiated a long-term bioassay of isophorone. In addition, the major U.S. manufacturers of isophorone have proposed to carry out mutagenicity and teratogenicity tests of isophorone. EPA believes that, together, these testing programs adequately respond to all of the ITC recommendations other than that for an epidemiology study. The Agency believes that requiring such a study is not warranted at this time. Consequently, the EPA is not, at this time, initiating rulemaking under section 4(a) to require health effects testing of isophorone. EPA seeks comments on its conclusions and on the adequacy of the proposed industry testing program.

**DATE:** Comments should be submitted on or before February 22, 1983.

**ADDRESS:** Written comments should bear the document control number OPTS-42029 and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-106, 401 M St., SW., Washington, D.C., 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 P.M.,