supplement this record periodically with additional relevant information received.

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

Dated: May 28, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-14826 Filed 6-1-84; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-42002A; TSH-FRL 2563-4]

Fluoroalkenes; Proposed Decision To Adopt a Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), in its Seventh Report, designated a group of six fluoroalkenes as a category of chemicals for health effects testing. On October 30, 1981, EPA published an Advance Notice of Proposed Rulemaking (ANPR), indicating that the Agency was initiating rulemaking to require testing of certain fluoroalkenes under section 4(a) of the Toxic Substances Control Act (TSCA) and proposing not to test 3,3,3-trifluoro-1-propene. The Fluoroalkenes Industry Group (FIG), manufacturers of vinyl fluoride, vinylidene fluoride, tetrafluroethene, and hexafluoropropene, responded to the ANPR by submitting unpublished test reports, exposure studies, and plans for further testing. Based on Agency evaluation of these submissions, EPA has tentatively decided to accept industry's proposed testing program and to discontinue the rulemaking initiated in the ANPR. Interested persons are invited to comment on this decision. In addition, in this notice the Agency finalizes its tentative decision not to require testing of 3,3,3-trifluoro-1-propene and announces a decision not to require testing of trifluoroethene.

DATE: Comments must be submitted by August 3, 1984.

ADDRESS: Written comments should bear the document control number [OPTS-42002A] and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M Street 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., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M Street 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: The Interagency Testing Committee designated a group of six fluoroalkenes for health effects testing. Based on the evaluation of comments received in response to the ANPR of October 30, 1981, EPA has tentatively decided to accept industry's proposed testing program and to discontinue the rulemaking initiated in the ANPR.

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.;* 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 test rules under section 4(a) of the Act.

The ITC designated the chemical category "fluoroalkenes" for priority testing consideration in its Seventh Report, as published in the Federal Register of November 25, 1980 (45 FR 78432). The Agency responded to the ITC's designation, as required by section 4(e) of TSCA, by issuing an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register of October 30, 1981 (46 FR 53704). In response to the ANPR, the Fluoroalkenes Industry Group (FIG) submitted a proposed testing program for four of the six designated fluoroalkenes identified by the Agency as meeting the ITC's category definition. Since publication of the ANPR, the Agency has also received data under Sections 8(a) and 8(d) of TSCA on several of the fluoroalkenes. The Agency is (a) proposing to accept the industry program for four of the fluoroalkenes and to discontinue the rulemaking initiated in the ANPR and (b) not requiring testing of the other two chemicals in the category.

II. Fluoroalkenes

A. Chemical Background

1. *Chemical description.* The ITC defined the "fluoroalkenes" that they were designating for priority testing consideration to include those compounds having the general chemical formulas $C_nH_{(2n-x)}F_x$, where n equals 2 or 3 and x equals 1 to 6. Six fluoroalkenes meeting this category definition were identified from the TSCA Chemical Substances Inventory. These six compounds are listed in Table 1 along with their production volumes.

TABLE 1.—PRODUCTION

Chemical	Empirical formula	CAS No	1977 production*	Ref.
Vinyl fluoride (VF).	C_2H_3F	75-02-5	<7	(1)
Vinylidene fluoride (VDF).	$C_2H_2F_2$	75-38-7	10	(2)
Trifluoroethene.	C_2HF_3	359-11-5	0.001-0.1	(3)
3,3,3-Trifluoro-1-propene (TFP).	$C_3H_3F_3$	677-21-4	<< 2	(4)
Tetrafluoroethene (TFE).	C_2F_4	116-14-3	10-50 17.4	(5) (6)
Hexafluoropropene (HFP).	C_3F_6	116-15-4	1-10	(5)

*Million pounds.

Members of the category are all gases at room temperature with boiling points ranging from −16°C for trifluoropropene to −82°C for vinylidene fluoride. They are highly volatile and moderately degradable in the atmosphere, reacting with ozone, hydroxyl radicals and atomic oxygen to cleave the double bond or form addition products. All the chemicals are insoluble in water. Vinyl fluoride and vinylidene fluoride are flammable over wide ranges of concentration and are explosive at concentrations of 2.6 to 21.7 percent and 5.5 to 21.3 percent by volume, respectively (Ref. 7). Tetrafluoroethene polymerizes readily, and sometimes violently in the absence of inhibitors, even below room temperature. Uncontrolled polymerization can cause explosive degradation to carbon and carbon tetrafluoride, and therefore it is essential to avoid storing tetrafluoroethene under pressure unless the vessels are adequately shielded (Ref. 8).

Hexafluoropropene is listed as nonflammable (Ref. 9), but it is generally co-polymerized with tetrafluoroethene, so any precautions applied because of tetrafluoroethene's hazardous nature will generally be applied to the processing of hexafluoropropene.

2. *Uses of the chemicals.* The fluoroalkenes in this category are all used exclusively as precursors in the manufacture of polymers and elastomers; there is no other use for these compounds (Ref. 7,10).

3. *Production and processing.* The process by which the monomers are made is carried out in a closed system, and the monomer is transferred to the processing areas in closed systems. Polymerization is carried out in high pressure vessels located behind barricaded closed areas of the factory.

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In the case of vinyl fluoride, vinylidene fluoride, and tetrafluoroethene, if the monomers are not well contained, an explosion hazard arises. Processes are controlled by operators located in control rooms outside of the reaction area. The Fluoroalkenes Industry Group maintains that these monomers are produced and consumed in plants designed to prevent the escape of the chemicals, because of the explosion hazard. In addition, they contend that there are strong economic considerations which dictate that monomer losses must be held to the absolute minimum (Ref. 10).

4. *Release to the atmosphere.* According to the information provided by industry, all manufacturing and processing operations are subject to strict controls to minimize product losses, and product loss is reported as minimal (Ref. 11).

5. *Human exposure.* Table 2 lists estimates provided by the various manufacturers and by NIOSH of the numbers of workers exposed to each chemical. Actual measurements of exposure to the various chemicals were described in the ANPR. Subsequent to the ANPR the FIG reported on human and area monitoring studies conducted for vinyl fluoride, tetrafluoroethene, hexafluoropropene and vinylidene fluoride. All data indicated average human exposure levels are less than 1 ppm. Area monitoring levels were reported as not exceeding 10 ppm. Individual personal monitors did not exceed 5 ppm peak level. As discussed in the ANPR, given the limited uses of the fluoroalkene monomers, human exposure to these chemicals outside of the workplace is not likely to occur.

TABLE 2.—WORKER EXPOSURE

Chemical	Worker exposure estimates			
	Manufacturer	Ref.	NIOSH	Ref.
Vinyl fluoride	100	(1)	1400	(12)
Vinylidene fluoride.	460	(2)	1900	(13)
Trifluoroethene.	¼ man year	(3)	N/A	
3,3,3-Trifluoro-1-propene.	5	(4)	N/A	
Tetrafluoroethene.	<800	(4)	5000	(14)
Hexafluoropropene.	<800	(6)		

B. Regulatory Background

1. *ITC Recommendations.* The ITC recommended that members of the fluoroalkenes category be tested for carcinogenicity, mutagenicity, teratogenicity, reproductive effects, and other toxic effects with particular emphasis on the renal and cardiovascular systems. The basis for these recommendations was a number of animal studies on the health effects of several of the category members and a possible structure-activity relationship between the category chemicals and other chemicals that are known to cause adverse health effects. While the ITC did not specify a structural configuration in their category definition, their discussion of effects of concern is limited to those fluoroalkenes that contain at least one fluorine atom attached to a double bonded or vinyl carbon.

2. *Scoping Workshop.* To facilitate TSCA section 4 activities, the Agency held a scoping workshop for fluoroalkenes and other 7th ITC list chemicals on March 12, 1981. Notice of the workshop was published in the Federal Register on February 13, 1981 (46 FR 12317–12323). Industry representatives, academic experts, labor, environmental groups, and the general public met with EPA staff to discuss the issues which EPA needed to resolve in order to respond to the ITC report.

At the scoping workshop industry representatives presented information on their plant's production volumes as well as exposure and release estimates and made new test data available to EPA. In addition they volunteered to submit additional testing protocols for Agency review. EPA heard evaluations from academic experts on the need for additional testing. Following the workshop, the manufacturers of four of the chemicals in the fluoroalkenes category (vinyl fluoride, vinylidene fluoride, tetrafluoroethene, and hexafluoropropene) formed a consortium known as the Fluoroalkene Industry Group (FIG), which subsequently furnished EPA with exposure reports on these four compounds and test protocols for testing planned or in progress on vinylidene fluoride and tetrafluoroethene.

3. *Response of EPA to the ITC Report.* EPA reviewed all available data, recommendations, and submissions in determining its response to recommendations of the ITC. EPA had previously indicated that although it would generally initiate testing action through publication of a proposed rule, it would initiate action on chemical categories and certain complex chemicals through publication of an Advance Notice of Proposed Rulemaking (ANPR). The reasons the Agency had for utilizing an ANPR for the fluoroalkenes were applicable to categories in general and specific to the fluoroalkenes.

In general, development of rulemaking for a category of chemicals involves issues both more numerous and complex than for a single chemical. In this particular case, the rationale behind the findings for testing of the fluoroalkenes category included a complex integration of structure-activity relationships (SAR) among fluoroalkenes and other chemicals having demonstrated adverse health effects. This time-consuming effort coupled with the other required actions of a TSCA section 4 finding led the Agency to choose the ANPR approach for this category.

As an aid in choosing which chemicals to test within the fluoroalkenes category, EPA proposed in the ANPR to subcategorize the chemicals. The members of each subcategory were expected to share structure-activity relationships based on the number and location of the fluorines substituted for hydrogen on the carbon atoms of the molecules. This type of subcategorization was suggested by industry participants at the scoping workshop. The ITC's SAR analysis was based on the number of fluorines in the molecule. The subcategories proposed in the ANPR were:

Subcategory A—Vinyl fluoride and vinylidene fluoride

Subcategory B—Trifluoroethene, tetrafluoroethene and hexafluoropropene

Subcategory C—3,3,3-Trifluoro-1-propene.

The structural relationships of members of the subcategories can be described chemically as follows: Subcategory A contains compounds with one or two fluorines substituted on one of the double-bonded (vinyl) carbons while subcategory B contains compounds with three or more fluorines substituted for the hydrogens on the double-bonded (vinyl) carbons as well as on the adjacent (alpha) carbon. Subcategory C contains only 3,3,3-trifluoro-1-propene which has none of its fluorines attached to a double-bonded carbon. EPA expected to propose testing of one chemical from each of the first two subcategories. Such testing would establish the toxic effects for a compound with few fluorines and for one with many fluorines. The third subcategory was not proposed for testing because 3,3,3-trifluoro-1-propene does not share the structure on which the ITC's testing recommendations were made: its fluorines are linked chemically to an allylic carbon rather than a vinylic carbon. It is reported that the chemical activity of these two kinds of structures is totally different (Ref. 15).

4. *Comments received on the ANPR.* The Natural Resources Defense Council

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(NRDC) submitted comments which questioned whether the issuance of an ANPR for the fluoroalkenes satisfies the statutory requirement under TSCA section 4(e) to either initiate a rulemaking proceeding or provide reasons for not doing so within twelve months of an ITC designation. The Agency believes that the issuance of an ANPR does indeed initiate rulemaking under TSCA section 4(a) and has presented the bases for this position to a federal district court in the case of *NRDC et al.* v. *EPA*, 83 Civ. 8844 (S.D.N.Y. 1983).

NRDC also questioned the appropriateness of the subcategorization scheme set forth in the ANPR and suggested that all of the category members should be tested. The Agency agrees, in part, that the subcategorization scheme presented in the ANPR may not have merit. However, the Agency presently believes that the mutagenicity testing on VF, VDF, TFE, and HFP and the chronic studies being conducted on VDF and TFE will provide sufficient data to enable EPA to reasonably predict the health effects of the fluroralkenes. (See Unit IV.B.)

EPA received a proposed testing program from the Fluoroalkene Industry Group as their comment on the ANPR. This group addressed only the four chemicals in the category which FIG members manufacture. They did not suggest any changes in either the SAR approach or the use of subcategorization. Testing would include additional mutagenicity studies and human exposure monitoring for all four chemicals, a subchronic study on tetrafluoroethene, and a cancer bioassay chronic study for vinylidene fluoride.

5. *EPA's revised position.* The Agency has made a more extended examination of the fluoroalkenes category in the process of deciding whether to accept industry's proposed testing program in lieu of proceeding with a proposed rule. From this review, new information has been obtained which supports EPA's position that:

a. The biological/chemical activity of certain chlorinated ethene compounds (vinyl chloride and other related chemicals) may be extrapolated to fluorinated analogues.

b. The decision not to test 3,3,3-trifluoro-1-propene is appropriate because this compound is not produced in substantial quantities and human exposure to the chemical is quite low such that the findings under 4(a) cannot be made. Moreover, 3,3,3-trifluoro-1-propene is not in the same chemical class as the other fluoroalkenes.

c. There is insufficient SAR information on the five related fluoroalkenes to divide them into subcategories based on differences in structure. However, this does not eliminate use of SAR to potentially define the entire category. (See Unit IV.B.)

d. There is sufficient information to conclude that no testing of trifluoroethene is required. The Agency's concerns cannot be justified because of the low production volume and low human exposure as shown in Tables 1 and 2. However, this chemical will be considered as a candidate for follow-up rulemaking under section 8(a) or 5(a)(2) of TSCA. (See Tables 1 and 2 and Unit IV.A.)

e. The data derived from the FIG testing program will be sufficient to reasonably predict or determine the health effects of concern for the fluoroalkene category. Moreover, EPA believes that this testing will provide data more expeditiously than proceeding through proposed and final rules. Thus, the Agency has tentatively decided to adopt the testing program submitted by the FIG as a negotiated testing agreement.

III. Testing Proposed By Industry

A consortium of manufacturers of four of the fluoroalkenes in the category, known as the Fluoroalkenes Industry Group (FIG), and including DuPont, Allied Corporation, American Hoechst Company, ICI Americas Inc., and the Pennwalt Corporation, has met with EPA to submit testing data not available to the ITC, and to indicate their plans for further health effects testing. The FIG's proposed testing program is described below (Ref. 35). Of the six fluoroalkenes identified as category members, these manufacturers produce vinyl fluoride (VF), vinylidene fluoride (VDF), tetrafluoroethene (TFE) and hexafluoropropene (HFP) for which they have submitted protocols for tests which they have agreed to perform: Mutagenicity tests on VF, VDF, TFE and HFP. Oncogenicity/chronic effects testing on VDF. Workplace exposure monitoring (in addition to that previously reported) on all four chemicals in all the manufacturing plants.

Trifluoroethene and 3,3,3-trifluoro-1-propene are discussed in Units II.B.3. and II.B.5., respectively.

One week after EPA's acceptance of the test program, contracts for testing will be distributed to the laboratories for execution within three weeks. Mutagenicity testing would begin for two chemicals within the same calendar quarter as acceptance of the program, and the work would be completed on these tests four months later. The other chemicals would be started in sequence, and all work would be completed and reports issued approximately one year after initiation of testing.

A 90-day range-finding subchronic study on VDF is planned, and the lifetime study is scheduled for initiation following evaluation of the 90-day study. These studies will begin in the summer of 1984.

The FIG has submitted draft protocols for collecting new exposure information on VF, VDF, TFE, and HFP. The member companies will supply information on each fluoroalkene used at each site. The data will be combined into a single table for each of the four fluoroalkenes, and the combined tables as well as original tables completed for each site will be submitted to EPA. The protocols have been reviewed by EPA, and the industry is now finalizing the protocols according to EPA's guidance. The Agency believes that these studies will provide sufficient information to evaluate the extent of worker exposure to the fluoroalkene category members and, if appropriate, to suggest further reduction in exposure.

EPA will examine the data from these tests along with other completed studies that the FIG has already submitted to determine whether there is need for additional testing.

The FIG is prepared to discuss and will consider sponsoring further testing of the four named chemicals.

A. Mutagenicity Testing

The FIG has proposed to extend the existing mutagenicity data with the following tests which will be initiated after publication of EPA's final decision following review of comments on this notice. The results of these tests along with other available data will be used to characterize the mutagenic potential of these chemicals.

1. *Salmonella typhimurium* reverse mutation assay (with and without activation) on TFE.

2. Eukaryotic cell gene mutation study using Chinese hamster ovary cells (gene mutation testing in somatic cells in culture) on VF, VDF, TFE, and HFP.

3. *In vitro* cytogenic chromosomal aberration study in Chinese hamster ovary cells (*in vitro*) mammalian cytogenetics tests for chromosomal aberrations) on VF, VDF, TFE, and HFP.

B. Oncogenicity/Chronic Effects Testing on VDF

The FIG notes that VDF is currently scheduled for testing in a two-year animal bioassay funded by industry and carried out under the auspices of the Association of Plastics Manufacturers in Europe. A 90-day range-finding

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subchronic study is to be followed by the main study, according to the final protocols submitted to the Agency.

C. Workplace Exposure Monitoring

The FIG has contended that workplace exposures are lower than those previously cited by the Agency, and that all exposures are much lower than the manufacturers' voluntary control levels for the fluoroalkenes. Therefore, to demonstrate this low level of exposure, the FIG has proposed to conduct an in-depth worker monitoring study at each facility producing a fluoroalkene. This study will utilize a newly developed personal monitoring device which will more accurately measure the four chemicales.

D. Results From Completed Testing

A completed 90-day subchronic inhalation study on TFE conducted by Haskell Laboratories for the Society of the Plastics Industry, Inc. was submitted by the FIG as a part of their proposed testing program (Ref. 16). This study has been reviewed by EPA scientists who reported that the testing seemed to be well conducted with a demonstrated no observed effect level. It is sufficient to reasonably predict the non-oncogenic chronic effects of TFE. The FIG has also submitted results of *S. typhimurium* reverse mutation assays on VF, VDF, and HFP which were reviewed and found to have been conducted using acceptable protocols.

E. Additional Future Testing

The National Toxicology Program (NTP) is considering testing of tetrafluoroethene (TFE) in a two-year chronic bioassay. The prechronic phase of this testing will begin in June 1984.

Subsequent to FIG's proposal to test VDF, NTP decided to perform testing on VDF. NTP has several options at this stage including a decision to follow through with testing of only the mouse since the FIG has agreed to perform testing in the rat. However, NTP's decision will depend on the detailed report of the subchronic study due in late Spring 1984. NTP will follow up this report with their decision on testing in the summer of 1984.

IV. Preliminary Decision To Terminate Rulemaking

A. 3,3,3-Trifluoro-1-Propene and Trifluoroethene

As discussed in Unit II.B.3, 3,3,3-trifluoro-1-propene does not fit the ITC's implied (vinyl) definition of the category. The Agency suggested in its ANPR that this compound be dropped from testing consideration and now formally concludes this act. There are no date indicating that the chemical may present adverse health effects. In addition, the manufacturer reported a very low level of production and worker exposure in written comment to the ANPR. EPA has no data to indicate this information is erroneous. For all of these reasons, the Agency believes that the findings under TSCA section 4(a) cannot be made for 3,3,3-trifluoro-1-propene and thus, is finalizing its decision not to require testing of this chemical.

Trifluoroethene fits the category definition. However because production and worker exposure are at a very low level, which will not support the necessary findings for testing under TSCA section 4, the Agency is discontinuing section 4 rulemaking for this chemical.

B. Fluoroalkenes Testing Program

At the conclusion of each of the key testing programs the Agency will review the need for further testing. EPA believes that the oncogenic/chronic studies on VDF will provide sufficient information to resaonably predict the potential health effects of this chemical. Moreover, data on VDF may allow the Agency to evaluate carcinogenic and other chronic effects of the other chemicals in the category. Health effects data from more than one category member would be beneficial in enabling the Agency to predict the health effects of the others. The oncogenic test results on VDF and TFE, plus mutagenicity tests results on the other category members, should provide the Agency with sufficient data to reasonably predict the oncogenic potential of the group. The Agency will be an active participant in the NTP's decision to perform long-term testing on TFE.

Also, the Agency will evaluate the results of the rodent bioassay tests on VDF and TFE, the existing subchronic testing on TFE, and the mutagenicity results on the four chemicals being tested, to asses overall toxicologic hazard. The monitoring studies will be used to determine whether an unreasonable risk exists for the entire category or for individual members of the category such that additional exposure controls or additional testing should be required.

EPA does not believe that there is sufficient evidence of potential reproductive effects to support a section 4(a)(1)(A) finding to propose testing at this time. This decision will be re-evaluated based on the results of the chronic and subchronic studies on VDF if effects are seen on the reproductive organs or upon organs which, if impaired, can affect reproductive preformance.

The results of teratogenic testing on VDF were negative. Even though the study protocol did not meet EPA standards for testing because there was only one species tested, there was no teratogenic effect found and consequently no finding can be made for potential unreasonable risk due to teratogenic effects.

Consequently, the Agency proposes to accept the FIG's proposed testing program, and not to continue the rulemaking action initiated by the ANPR. Should there be a need for additional clarifying toxicology data, and the FIG does not agree to provide these data, the Agency would expedite the rulemaking process. Additionally the NTP data will be used to assess hazard of not only VDF and TFE, but the applicability of SAR to the group.

V. GLP's and Other Provisions

The FIG has 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 FIG has agreed to adhere to the TSCA Good Laboratory Practice Standards published by the Agency in the Federal Register of November 29, 1983 (48 FR 53922).

The FIG has agreed to permit laboratory audits/inspections at the request of authorized representatives of the EPA in accordance with the authority and procedures outlined in TSCA section 11. This agreement extends to the study on VDF being conducted in Europe. 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 TSCA Good Laboratory Practices.

The FIG has agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of a study will be retained as specified in the TSCA Good Laboratory Practice Standards and made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

The FIG understands that TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA.

The FIG also understands that the Agency plans to publish in the Federal

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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(b). Except as otherwise provided in TSCA section 14, such data will be made available for examination by any person.

Finally, the FIG understands that failure to conduct the testing according to the specified protocol(s) 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.

VI. References

(1) Fluoroalkene Industry Group. Unpublished Report on Potential Exposure to Vinyl Fluoride During Manufacture of Monomer Vinyl Fluoride. Submitted to USEPA June 26, 1981.

(2) Fluoroalkene Industry Group. Unpublished Report on Vinylidene Fluoride (VDF) Exposure. Submitted to USEPA June 26, 1981.

(3) Halocarbon Products Corporation. Letter from L. Ferstandig to A. Keller, June 25, 1982.

(4) Halocarbon Products Corporation. Letter from L. Ferstandig to A. Keller, April 27, 1981.

(5) TSCA Chemical Substances Inventory (EPA 1977).

(6) Fluoroalkene Industry Group. Unpublished Report on Potential Exposure to Tetrafluoroethene During Manufacture of Monomer Tetrafluoroethene. Submitted to USEPA August 13, 1981.

(7) Chemical Hazard Information Profile Vinylidene Fluoride; Vinyl Fluoride. January 30, 1978.

(8) Coffey, S., ed. "Rodd's Chemistry of Carbon Compounds", 2nd Ed. Vol. 1, Part A. Amsterdam: Elsevier. 1964.

(9) Hawley, G.G. "The Condensed Chemical Dictionary", 10th ed. New York: Van Nostrand Reinhold. 1981.

(10) Fluoroalkene Industry Group. Comments on Fluoroalkene ANPR (Docket No. 42002) January 26, 1982.

(11) NIOSH. Natl. Inst. Occupational Safety and Health. Criteria for a recommended standard: occupational exposure to vinyl halides. Unpublished. Washington, D.C.: NIOSH, U.S. Dept. Health, Education, and Welfare. 1979.

(12) NIOSH (National Institute for Occupational Safety and Health). Vinyl Fluoride Industrial Hygiene Survey Report. October 1977.

(13) NIOSH/OSHA (National Institute for Occupational Safety and Health/ Occupational Safety and Health Administration). Current Intelligence Bulletin 28. Vinyl Halides Carcinogenicity. September 21, 1978. DHEW (NIOSH) Publication No. 79-102.

(14) NIOSH. SIC/NOSH Survey. Computer printout of survey covering 1972-74. Retrieved by USEPA 1980.

(15) Morrison, R.T. Boyd, R.N. "Organic Chemistry", 2nd Edition. Boston: Allyn and Bacon. 1966.

(16) The Society of the Plastics Industry, Inc. Ninety-Day Inhalation Toxicity Study with Tetrafluoroethylene (TFE) in Rats and Hamsters. Haskell Laboratory Report No. 208-82. July 20, 1982.

(17) Fluoroalkene Industry Group. Proposed Fluoroalkene Testing Program General Study Plan. June 30, 1982.

VII. Public Record

EPA has established a public record for this decision not to initiate testing under section 4 (docket number OPTS-42002A). This record includes:

(1) Federal Register Notice designating the fluoroalkenes to the priority list.

(2) Communications with industry related to the FIG program, consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) FIG program.

(4) Study plans.

(5) Published and unpublished data.

(6) Federal Register ANPR requesting comments on the proposed testing, and comments received.

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

Dated: May 28, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-14828 Filed 6-1-84; 8:45 am]

BILLING CODE 6560-50-M

[[OPTS-42040A]; TSH-FRL 2578-1]

Tris(2-Ethylhexyl) Trimellitate Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Federal Register of November 14, 1983, EPA announced a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of tris(2-ethylhexyl) trimellitate (TOTM) [CAS No. 3319-31-1] pending consideration of public comments on a testing proposal submitted to EPA by the Trimellitate Esters Panel (TEP), a group formed under the sponsorship of the Chemical Manufacturers Association (CMA). No public comments were received and the Agency finds no reason to alter its preliminary decision and is not proposing a section 4(a) rule to require environmental or health effects testing of TOTM.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M Street 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

In the Federal Register of November 14, 1983 (48 FR 51842), the Agency announced a preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of tris(2-ethylhexyl) trimellitate (TOTM). This decision was based on the Agency's evaluation of the existing data on TOTM, the expected exposure pattern for TOTM and the tentative acceptance of a testing proposal submitted by the Trimellitate Esters Panel (TEP), a group formed under the sponsorship of the Chemical Manufacturers Association (CMA).

A draft of TEP's testing proposal was included in the public record (docket number OPTS-42040). The Agency requested comments on both its tentative decision not to require testing of TOTM and on the proposed testing scheme.

II. Summary of Ongoing and Planned Testing Programs

The Trimellitate Esters Panel (TEP) has presented to EPA a proposal for testing TOTM for health effects, environmental effects, and chemical fate. The tests will be modeled after the TSCA testing guidelines. The TEP has provided the Agency with preliminary laboratory selection information and a proposed testing schedule predicated on final program acceptance by the Agency in June 1984. The TEP proposal for TOTM includes the following tests:

1. *Mutagenicity.* To characterize further the genetic activity of TOTM, the TEP will perform an unscheduled DNA synthesis assay in primary rat hepatocytes and a Chinese Hamster Ovary Hypoxanthine Guanine Phosphoribosyl Transferase Forward Mutation assay. These studies are scheduled to begin in July, 1984, and be completed (final report submitted) in January 1985.

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