

**ENVIRONMENTAL PROTECTION AGENCY**

[OPPTS-41056; FRL-6786-7]

**Forty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments**

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

**ACTION:** Notice.

**SUMMARY:** The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its Forty-Eighth Report to the Administrator of the EPA on May 15, 2001. In the 48<sup>th</sup> ITC Report, which is included with this notice, the ITC adds 5 "chlorinated trihalomethyl pyridines," 2 "trihaloethylidene bisbenzenes," 3-chlorotrifluralin, and 4 "trichlorophenylidihydropyrazols" to its *Priority Testing List* and solicits voluntary information for these chemicals under the ITC's Voluntary Information Submissions Policy (VISP). This action is part of the ITC's ongoing effort to evaluate chemicals with potential to persist and bioconcentrate, and with suspicions of toxicity and few data. In this Report, the ITC also removes 22 alkylphenols and ethoxylates, methylal, and ethyl silicate from its *Priority Testing List* and requests that EPA promulgate TSCA section 8(d) health and safety data reporting rules for 3-amino-5-mercapto-1,2,4-triazole and glycoluril.

**DATES:** Comments, identified by docket control number OPPTS-41056, must be received on or before November 5, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-41056 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone numbers: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: John D. Walker, ITC Executive Director (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone

number: (202) 564-7527; fax: (202) 564-7528; e-mail address: walker.johnd@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This notice is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process TSCA-covered chemicals and you may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this notice is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

You may also access additional information about the ITC and the TSCA testing program through the web site for the Office of Prevention, Pesticides and Toxic Substances (OPPTS) at <http://www.epa.gov/opptsfrs/home/opptsim.htm/>, or go directly to the ITC home page at <http://www.epa.gov/opptintr/itc/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-41056. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of

the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260-7099.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-41056 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260-7093.

3. *Electronically.* You may submit your comments electronically by e-mail to: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov), or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS-41056. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI Information that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

We invite you to provide your views and comments on the ITC's 48<sup>th</sup> Report. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. Provide specific examples to illustrate your concerns.
5. Offer alternatives for improvement.
6. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. Background**

TSCA (15 U.S.C. 2601 *et seq.*) authorizes the Administrator of the EPA to promulgate regulations under section 4(a) of TSCA requiring testing of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the ITC to recommend chemicals and chemical groups to the Administrator of the EPA for priority testing consideration. Section 4(e) of TSCA directs the ITC to revise the TSCA section 4(e) *Priority Testing List* at least every 6 months.

*A. The 48<sup>th</sup> ITC Report*

The 48<sup>th</sup> ITC Report was transmitted to the EPA's Administrator on May 15, 2001, and is included in this notice.

In the 48<sup>th</sup> ITC Report, the ITC:

1. Adds 5 "chlorinated trihalomethyl pyridines," 2 "trihaloethylidene bisbenzenes," 3-chlorotrifluralin, and 4 "trichlorophenyldihydropyrazols" to its *Priority Testing List* and solicits voluntary information for these chemicals under the ITC's VISP. This action is part of the ITC's ongoing effort to evaluate chemicals with potential to persist and bioconcentrate, and with suspicions of toxicity and few data.

2. Removes 22 alkylphenols and ethoxylates, methylal, and ethyl silicate from its *Priority Testing List*.

3. Requests that EPA promulgate TSCA section 8(d) health and safety data reporting rules for 3-amino-5-mercapto-1,2,4-triazole and glycoluril.

*B. Status of the Priority Testing List*

The current TSCA 4(e) *Priority Testing List* as of May 2001 can be found in Table 1 of the 48<sup>th</sup> ITC's Report which is included in this notice.

**List of Subjects**

Environmental protection, Chemicals, Hazardous substances.

Dated: September 26, 2001.

**Charles M. Auer,**

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

**Forty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency**

*Table of Contents*

Summary

- I. Background
- II. TSCA Section 8 Reporting
  - A. TSCA Section 8 Reporting Rules
  - B. ITC's Use of TSCA Section 8 and Other Information
  - C. Promoting More Efficient Use of Information Submission Resources
  - D. Coordinating Information Requests
  - E. Requests to Promulgate TSCA Section 8(a) PAIR and Section 8(d) HaSD Reporting Rules
- III. ITC's Activities During this Reporting Period (November 2000 to April 2001)

IV. Revisions to the TSCA Section 4(e)

*Priority Testing List*

A. Chemicals Added to the *Priority Testing List*

1. Chlorinated trihalomethyl pyridines
2. Trihaloethylidene bisbenzenes
3. 3-Chlorotrifluralin
4. Trichlorophenyldihydropyrazols

B. Chemicals Removed From the *Priority Testing List*

1. Alkylphenols and alkylphenol ethoxylates
2. Methylal
3. Ethyl silicate

V. References

VI. TSCA Interagency Testing Committee

**SUMMARY**

This is the 48<sup>th</sup> Report of the TSCA Interagency Testing Committee (ITC) to the Administrator of the U.S. Environmental Protection Agency (USEPA). In this Report, the ITC is adding 5 chlorinated trihalomethyl pyridines, 2 trihaloethylidene bisbenzenes, 3-chlorotrifluralin, and 4 trichlorophenyldihydropyrazols to its *Priority Testing List* and soliciting voluntary information for these chemicals under the ITC's Voluntary Information Submissions Policy (VISP). This action is part of the ITC's ongoing effort to evaluate chemicals with suspicions of toxicity and few data and potential to persist and bioconcentrate. In this Report, the ITC is removing 22 alkylphenols and ethoxylates and methylal and ethyl silicate from its *Priority Testing List*. The ITC is removing 22 alkylphenols and ethoxylates from its *Priority Testing List* because domestic production or importation volumes were not reported to the USEPA in response to 1986, 1990, 1994, and 1998 TSCA section 8(a) Information Update Rules (IURs) and in response to the TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) rule published in the **Federal Register** of July 5, 2000 (65 FR 41371) (FRL-6589-1). The ITC is removing methylal and ethyl silicate from its *Priority Testing List* because data are being developed under the USEPA's High Production Volume (HPV) Challenge Program. The revised TSCA section 4(e) *Priority Testing List* follows as Table 1.

TABLE 1.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST (MAY 2001)

Report	Date	Chemical/group	Action
28 .....	May 1991 .....	Chemicals with Low Confidence Reference Dose (RfD) .....	Designated
		Acetone Thiophenol	
30 .....	May 1992 .....	5 Siloxanes .....	Recommended
31 .....	January 1993 .....	13 Chemicals with insufficient dermal absorption rate data .....	Designated

TABLE 1.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST (MAY 2001)—Continued

Report	Date	Chemical/group	Action
32	May 1993	16 Chemicals with insufficient dermal absorption rate data	Designated
35	November 1994	4 Chemicals with insufficient dermal absorption rate data	Designated
37	November 1995	12 Alkylphenols and alkylphenol ethoxylates	Recommended
39	November 1996	8 Nonylphenol ethoxylates	Recommended
41	November 1997	7 Alkylphenols and alkylphenol ethoxylates	Recommended
42	May 1998	3-Amino-5-mercapto-1,2,4-triazole	Recommended
42	May 1998	Glycoluril	Recommended
46	May 2000	8 Nonylphenol polyethoxylate degradation products	Recommended
47	November 2000	37 Indium chemicals	Recommended
47	November 2000	Pentachlorothiophenol	Recommended
47	November 2000	Tetrachloropyrocatechol	Recommended
47	November 2000	p-Toluidine, 5-chloro-.alpha.,.alpha.,.alpha.-trifluoro-2-nitro-N-phenyl	Recommended
47	November 2000	Benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-ethoxy-1-methyl-2-oxoethyl ester.	Recommended
47	November 2000	3 Chloroalkenes	Recommended
48	May 2001	5 Chlorinated trihalomethyl pyridines	Recommended
48	May 2001	2 Trihaloethylidene bisbenzenes	Recommended
48	May 2001	3-Chlorotrifluralin	Recommended
48	May 2001	4 Trichlorophenylidihydropyrazols	Recommended

## I. Background

The ITC was established by section 4(e) of the Toxic Substances Control Act (TSCA) “to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule for testing under section 4(a).... At least every six months..., the Committee shall make such revisions to the *Priority Testing List* as it determines to be necessary and transmit them to the Administrator together with the Committee’s reasons for the revisions” (Public Law 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*). Since its creation in 1976, the ITC has submitted 47 semi-annual (May and November) Reports to the EPA Administrator transmitting the *Priority Testing List* and its revisions. ITC Reports are available from the ITC’s web site (<http://www.epa.gov/opptintr/itc>) within a few days of submission to the Administrator and from <http://www.epa.gov/fedrgstr> after publication in the **Federal Register**. The ITC meets monthly and produces its revisions to the *Priority Testing List* with administrative and technical support from the ITC Staff, ITC Members, and their U.S. Government organizations and contract support provided by EPA. ITC Members and Staff are listed at the end of this Report.

## II. TSCA Section 8 Reporting

### A. TSCA Section 8 Reporting Rules

Following receipt of the ITC’s Report (and the revised *Priority Testing List*) by the USEPA Administrator, the USEPA’s Office of Pollution Prevention and Toxics (OPPT) promulgates TSCA

section 8(a) PAIR and TSCA section 8(d) Health and Safety Data (HaSD) reporting rules for chemicals added to the *Priority Testing List*. The PAIR rule requires producers and importers of CAS-numbered chemicals added to the *Priority Testing List* to submit production and exposure reports under TSCA section 8(a). The HaSD reporting rule requires producers, importers, and processors of all chemicals (including those with no CAS numbers) added to the *Priority Testing List* to submit unpublished health and safety studies under TSCA section 8(d) that must be in compliance with the revised HaSD reporting rule published in the **Federal Register** of April 1, 1998 (63 FR 15765) (FRL–5750–4). All submissions must be received by the USEPA within 90 days of the reporting rules’ **Federal Register** publication date. The reporting rules are automatically promulgated by OPPT unless otherwise requested by the ITC. It is an ITC policy, for most chemicals that are added to the *Priority Testing List*, to delay automatic promulgation of HaSD reporting rules to allow voluntary submission of studies of specific interest (see Unit II.C. of this Report for further details).

### B. ITC’s Use of TSCA Section 8 and Other Information

The ITC reviews the TSCA section 8(a) PAIR reports, TSCA section 8(d) HaSD reporting studies and “other information” that becomes available after the ITC adds chemicals to the *Priority Testing List*. “Other information” includes TSCA section 4(a) and 4(d) studies, TSCA section 8(c) submissions, TSCA section 8(e) “substantial risk” notices, “For Your Information” (FYI) submissions, ITC

voluntary submissions, unpublished data submitted to and from U.S. Government organizations represented on the ITC, published papers, as well as use, exposure, effects, and persistence data that are voluntarily submitted to the ITC by manufacturers, importers, processors, and users of chemicals recommended by the ITC. The ITC reviews this information and determines if data needs should be revised, if chemicals should be removed from the *Priority Testing List*, or if recommendations should be changed to designations.

### C. Promoting More Efficient Use of Information Submission Resources

To promote more efficient use of information submission resources, the ITC developed VISIP. VISIP provides examples of data needed by ITC Member U.S. Government organizations, examples of studies that should not be submitted, the milestones for submitting information, guidelines for using the TSCA Electronic HaSD Reporting Form, and instructions for electronically submitting full studies. The TSCA Electronic HaSD Reporting Form can be used to provide information electronically on ITC voluntary submissions, TSCA section 8(d) studies, FYI submissions, and TSCA section 8(e) studies. VISIP is described in the ITC’s 41<sup>st</sup> Report published in the **Federal Register** of April 9, 1998 (63 FR 17658) (FRL–5773–5) and is accessible through the world wide web (<http://www.epa.gov/opptintr/itc/visip.htm>). To facilitate the implementation of VISIP, the ITC developed the Voluntary Information Submissions Innovative Online Network (VISION). VISION is described in the ITC’s 42<sup>nd</sup> Report

published in the **Federal Register** of August 7, 1998 (63 FR 42554) (FRL-5797-8) and is accessible through the world wide web (<http://www.epa.gov/opptintr/itc/vision.htm>). VISION includes the VISP and links to the TSCA Electronic HaSD Reporting Form (<http://www.epa.gov/opptintr/.er/hasd.htm>) including revised section 3.2 of the TSCA Electronic HaSD Reporting Form to provide more use and exposure information (see the ITC's 46<sup>th</sup> Report published in the **Federal Register** of December 1, 2000 (65 FR 75552) (FRL-6594-7) for details).

The ITC requests that chemical producers, importers, processors, and users provide information electronically via VISION on chemicals for which the ITC is soliciting voluntary information. To enhance visibility, the ITC will be adding all chemicals to the *Priority Testing List* for which it is soliciting voluntary information. If the ITC does not receive voluntary information submissions to meet its data needs according to the procedures in VISP, the ITC may then request that EPA promulgate the appropriate TSCA sections 8(a) and 8(d) reporting rules to determine if there are unpublished data to meet those needs. The ITC requests that those companies responding to a TSCA section 8(d) HaSD reporting rule provide data by using the TSCA Electronic HaSD Reporting Form.

#### D. Coordinating Information Requests

To avoid duplicate reporting, the ITC carefully coordinates its information solicitations and reporting requirements with other national and international testing programs, e.g., the National Toxicology Program, the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program, and the USEPA's HPV Challenge Program. The ITC is currently focusing its efforts on persistent non-HPV chemicals that have exposure potential, but few, if any, publicly available ecological or health effects data. The ITC is working with the USEPA's workgroups, such as the Persistent Bioaccumulative Toxics (PBT), Endocrine Disruption, and perfluorocetyl sulfonate chemicals workgroups to develop data that will complement the objectives of those programs.

#### E. Requests to Promulgate TSCA Section 8(a) PAIR and Section 8(d) HaSD Reporting Rules

The ITC has not received any submissions on the chloroalkenes, chlorinated trihalomethyl pyridines, trihaloethylidene bisbenzenes,

trifluralins and trichlorophenyldihydropyrazols in response to its solicitation for use and exposure information in the ITC's 45<sup>th</sup> Report. Therefore, the ITC is asking the EPA to promulgate a TSCA section 8(a) PAIR rule for the 3 chloroalkenes added to the *Priority Testing List* in the ITC's 47<sup>th</sup> Report published in the **Federal Register** of April 3, 2001 (66 FR 17768) (FRL-6763-6) and 5 chlorinated trihalomethyl pyridines, 2 trihaloethylidene bisbenzenes, 3-chlorotrifluralin, and 4 trichlorophenyldihydropyrazols added to the *Priority Testing List* in this 48<sup>th</sup> ITC Report. The PAIR data will provide production and exposure information and aid in the selection of chemicals for potential TSCA section 8(d) HaSD reporting rules.

The ITC is asking the USEPA not to promulgate TSCA section 8(d) HaSD reporting rules for the alkylphenols and alkylphenol ethoxylates that were added to the *Priority Testing List* in the ITC's 39<sup>th</sup> Report published in the **Federal Register** of February 25, 1997 (62 FR 8578) (FRL-5580-9) and in the ITC's 41<sup>st</sup> Report because of a need to further review the data. The TSCA section 8(d) HaSD reporting rule for methylal that was added to the *Priority Testing List* in the ITC's 42<sup>nd</sup> Report is no longer needed since this chemical is being removed from the *Priority Testing List* in this Report (see Unit IV.B.2. of this Report).

At this time, the ITC is requesting that EPA not promulgate TSCA section 8(d) HaSD reporting rules for the 5 chlorinated trihalomethyl pyridines, 2 trihaloethylidene bisbenzenes, 3-chlorotrifluralin, and 4 trichlorophenyldihydropyrazols added to the *Priority Testing List* in this ITC Report, to allow producers, importers, processors, and users an opportunity to voluntarily provide the requested information (see Unit IV. of this Report).

After review of the information provided in the TSCA section 8(a) PAIR rule published in the **Federal Register** of July 24, 2000 (65 FR 45535) (FRL-6589-1), the ITC is requesting that the USEPA promulgate TSCA section 8(d) HaSD reporting rules for 3-amino-5-mercapto-1,2,4-triazole (CAS No. 16691-43-3) and glycoluril (CAS No. 496-46-8). These TSCA section 8(d) HaSD reporting rules will require the submission of pharmacokinetics, subchronic toxicity, immunotoxicity, genotoxicity, carcinogenicity, reproductive and developmental effects, and ecological effects studies. The chemical purity of 3-amino-5-mercapto-1,2,4-triazole and glycoluril in these studies should exceed 90%.

### III. ITC's Activities During this Reporting Period (November 2000 to April 2001)

In its 45<sup>th</sup> and 46<sup>th</sup> ITC Reports, the ITC discussed its strategies to screen and evaluate chemicals for persistence and bioconcentration potential. These strategies are referred to as Degradation Effects Bioconcentration Information Testing Strategies (DEBITS). DEBITS provides a means to prioritize chemicals based on degradation, ecological or human health effects, and bioconcentration information. In its 45<sup>th</sup> ITC Report, the ITC added several chemicals to its web site to solicit measured bioconcentration data and use and exposure information. To avoid duplicate reporting requirements, the ITC is removing the USEPA's HPV Challenge Program chemicals (<http://www.epa.gov/opptintr/chemrtk/hpvchmlt.htm>) and European Union's HPVCs (<http://ecb.ei.jrc.it/existing-chemicals/>) from its web site. In its 46<sup>th</sup> ITC Report, the ITC initiated efforts to implement DEBITS by focusing its efforts on structural classes of chemicals from a subset of 42 moderate production volume (MPV) chemicals (production/importation volumes between 100,000 and 1,000,000 pounds) with estimated or measured bioconcentration factors (BCFs) > 250 and about 70 structurally related non-MPV chemicals (also with BCFs > 250). In its 47<sup>th</sup> ITC Report, the ITC added more of these chemicals from its DEBITS prioritization to its *Priority Testing List*. Other chemical groups such as nitro musks, polycyclic musks, and tertiary butyl peroxy chemicals were reviewed but not added to the *Priority Testing List*.

During this reporting period, the ITC continued to focus its efforts on structural classes of MPV chemicals by adding 5 chlorinated trihalomethyl pyridines, 2 trihaloethylidene bisbenzenes, 4 trichlorophenyldihydropyrazols, and 3-chlorotrifluralin to its *Priority Testing List* and soliciting voluntary health and ecological effects information for these chemicals under the ITC's VISP. The ITC evaluated several chlorinated pyridines, and azo bis (alpha nitriles) and decided not to add them to the *Priority Testing List* at this time.

### IV. Revisions to the TSCA Section 4(e) Priority Testing List

#### A. Chemicals Added to the Priority Testing List

1. *Chlorinated trihalomethyl pyridines*—i. *Recommendation*. Five non-HPV chlorinated trihalomethyl pyridines are being added to the *Priority Testing List* to obtain information on

uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects as well as the percent by weight of any of the 5 unreacted chlorinated trihalomethyl

pyridines in formulated products. The 5 non-HPV chlorinated trihalomethyl pyridines are 3,5-dichloro-2-(trichloromethyl)pyridine (CAS No. 1128-16-1), 2,3,4,5-tetrachloro-6-(trichloromethyl)pyridine (CAS No. 1134-04-9), 3,4,5-trichloro-2-

(trichloromethyl)pyridine (CAS No. 1201-30-5), 2,6-dichloro-3-(trichloromethyl)pyridine (CAS No. 55366-30-8), and 2,3-dichloro-5-(trichloromethyl)pyridine (CAS No. 69045-84-7). See Table 2 below.

TABLE 2.—CHLORINATED TRIHALOMETHYL PYRIDINES IDENTIFIED BY DEBITS

CAS No.	Chlorinated trihalomethyl pyridine	HPV	BCF	Fish LC <sub>50</sub>
001128-16-1	3,5-Dichloro-2-(trichloromethyl)pyridine	No	238	3.5
001134-04-9	2,3,4,5-Tetrachloro-6-(trichloromethyl)pyridine	No	2343	0.1
001201-30-5	3,4,5-Trichloro-2-(trichloromethyl)pyridine	No	747	2.7
001817-13-6	3,6-Dichloro-2-(trichloromethyl)pyridine	Yes	238	3.5
001929-82-4	2-Chloro-6-(trichloromethyl)pyridine	Yes	84	9.3
055366-30-8	2,6-Dichloro-3-(trichloromethyl)pyridine	No	238	3.1
069045-78-9	2-Chloro-5-(trichloromethyl)pyridine	Yes	76	7.6
069045-83-6	2,3-Dichloro-5-(trichloromethyl)pyridine	Yes	238	3.2
069045-84-7	2,3-Dichloro-5-(trifluoromethyl)pyridine	No	45	12.2

ii. *Rationale for recommendation.* The 5 non-HPV chlorinated trihalomethyl pyridines are predicted to persist in the environment. They present suspicions of toxicity based on fish LC<sub>50</sub> values and mutagenicity based on data from structurally related compounds. Several of these non-HPV chlorinated trihalomethyl pyridines are produced/imported in substantial amounts (>100,000 pounds) and have potential to bioconcentrate.

iii. *Supporting information.* The ITC used DEBITS to identify 9 chlorinated trihalomethyl pyridines (Table 2 of this unit). Four of these chlorinated trihalomethyl pyridines are in the USEPA's HPV Challenge Program, including the registered pesticide, nitrapyrin (CAS No. 1929-82-4). The ITC is not soliciting information on the HPV chemicals but did review the available toxicity and ecological effects information on these compounds to better evaluate the data needs for the non-HPV chlorinated trihalomethyl pyridines.

The trichloro- and tetrachloro trichloromethyl pyridines have estimated bioconcentration factors (BCFs) > 250 while 2 of 3 dichloro trichloromethyl pyridines have estimated BCFs very close to this threshold (i.e., BCFs of 238). All five chloro trihalomethyl pyridines have fish LC<sub>50</sub> values about 10 milligram/Liter (mg/L) or less, indicating that they have potential to cause acute effects in fish. The fish LC<sub>50</sub> values are based on measured or estimated values for fathead minnows. The predicted mode of toxic action (based on fathead minnow models described by Russom et al., 1997) for 4 of 5 chlorinated trihalomethyl pyridines is narcosis. The tetrachloro trichloromethyl pyridine

(CAS No. 1134-04-9) with the lowest fish LC<sub>50</sub> value and highest BCF is predicted to have a mode of toxic action based on uncoupling of oxidative phosphorylation.

There were no health effects data available for the 5 chlorinated trihalomethyl pyridines being added to the *Priority Testing List*. However, there were some available health effects data for the two HPV monochloro substituted trichloromethyl pyridines (CAS Nos. 1929-82-4 and 69045-78-9) and a HPV dichloro trichloromethyl pyridine (CAS No. 69045-83-6).

Subchronic and mutagenicity data were available for 2-chloro-5-(trichloromethyl)pyridine (CAS No. 69045-78-9). Mice exposed to 10 parts per million (ppm) of 2-chloro-5-(trichloromethyl)pyridine died after 4 days. Histologic examination of these animals revealed hepatic necrosis and vacuolization. No treatment related effects were observed at 0, 0.1, or 1.0 ppm exposure levels (Dow Chemical Co., 1991). In a dermal irritation study with rats, a dose of 500 mg/(kilogram) kg/day [for 21 days (18 hours per day)] 2-chloro-5-(trichloromethyl)pyridine produced a well-defined systemic toxic response characterized by hepatic necrosis and a disturbance of lipid metabolism. As a result of topical irritation among the rats in the 100 mg/kg/day group, the no-observed-adverse-effect-level (NOAEL) was 20 mg/kg/day (Hazelton Laboratories, 1992). In a number of mutagenicity test systems, 2-chloro-5-(trichloromethyl)pyridine was found to be mutagenic (Confidential, 1984a; Confidential 1984b; and Confidential 1984c).

Subchronic data were available for 2,3-dichloro-5-(trichloromethyl)pyridine (CAS No. 69045-83-6). Degenerative

lesions occurred in the nasal turbinates of rats and mice exposed to 0.5 ppm 2,3-dichloro-5-(trichloromethyl)pyridine for 2 weeks (Confidential, 1986).

Numerous health effects data were available for 2-chloro-6-(trichloromethyl)pyridine or nitrapyrin (CAS No. 1929-82-4). Nitrapyrin was well absorbed by dogs when administered using the oral route (Redemann et al., 1966). Oral administration of nitrapyrin at doses of 30 to 50 mg/kg/day and greater in pregnant rats and rabbits caused maternal and fetal toxicity (Berdasco et al., 1988). Nitrapyrin is also reported to be mutagenic in the reverse mutation assay in *Salmonella typhimurium* under most conditions (Zeiger et al., 1988). Hepatotoxicity occurred in rats dermally exposed to 500 mg/kg/day of 2-chloro-5-(trichloromethyl)pyridine for 3 weeks (Hazelton Laboratory, 1992).

iv. *Information needs.* For the 5 non-HPV chlorinated trihalomethyl pyridines in Table 2 of this unit, the ITC needs:

a. Use information, including percentages of production or importation that are associated with different uses;

b. Identification of the chlorinated trihalomethyl pyridines that are intermediates and the final products in which they are contained;

c. Weight percent of chlorinated trihalomethyl pyridines in commercial formulated products; and

d. Pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects data.

2. *Trihaloethylidene bisbenzenes*—i. *Recommendation.* Two non-HPV trihaloethylidene bisbenzenes are being added to the *Priority Testing List* to obtain information on uses, exposures,

environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity,

and ecological effects. The 2 non-HPV trihaloethylidene bisbenzenes are hexafluoroisopropylidenebis (4-hydroxybenzene) and benzene, 1,1'-

(2,2,2-trichloroethylidene)bis-. See Table 3 below.

TABLE 3.—TRIALOETHYLIDENE BISBENZENES IDENTIFIED BY DEBITS

CAS No.	Trihaloethylidene bisbenzene	BCF
000072-43-5 .....	Methoxychlor (2,2-bis( <i>p</i> -methoxyphenyl)-1,1,1-trichloroethane) .....	8128
001478-61-1 .....	Hexafluoroisopropylidenebis (4-hydroxybenzene) .....	556
002971-22-4 .....	Benzene, 1,1'-(2,2,2-trichloroethylidene)bis- .....	1122

ii. *Rationale for recommendation.* The 2 non-HPV trihaloethylidene bisbenzenes have been produced/imported in substantial amounts (>100,000 pounds) and are predicted to persist and bioconcentrate in the environment. Benzene, 1,1'-(2,2,2-trichloroethylidene)bis- (CAS No. 2971-22-4) is structurally related to the insecticide methoxychlor, which has estrogenic activity and has been shown to alter hormone levels, decrease fertility, damage reproductive organs, and retard reproductive development in experimental animals.

iii. *Supporting information.* The ITC used DEBITS to identify 3 trihaloethylidene bisbenzenes (Table 3 of this unit). All are MPV chemicals that have estimated BCFs well over 250 (Table 3 of this unit). One of the trihaloethylidene bisbenzenes is the well studied insecticide, methoxychlor (CAS No. 72-43-5), that is not being added to the *Priority Testing List* but which is currently regulated by a number of international, Federal, and State agencies because of its potential to cause adverse effects in humans. Methoxychlor is included in the USEPA's Toxics Release Inventory (TRI) PBT rule published in the **Federal Register** of November 4, 1999 (64 FR 60194) (FRL-6097-7) and is a candidate for regulatory action under the USEPA's PBT Initiative. The Agency for Toxic Substances and Disease Registry (ATSDR) has recently completed a Toxicological Profile for methoxychlor which summarizes available health effects data (ATSDR, 2000). Among the effects that are relevant to predicting the effects of hexafluoroisopropylidenebis (4-hydroxybenzene) and benzene, 1,1'-(2,2,2-trichloroethylidene)bis- are those related to alteration of hormone levels, including increasing levels of prolactin, follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH) in the pituitary of male rats (Goldman et al. 1986; Gray et al. 1989). In addition to the ATSDR Toxicological Profile that summarizes the health effects of methoxychlor, a Pesticide Information

Profile that summarizes the ecological effects of methoxychlor is available on the web (<http://ace.orst.edu/cgi-bin/mfs/01/pips/methoxyc.htm>). Methoxychlor is slightly toxic to bird species, with reported acute oral LD<sub>50</sub> values of greater than 2,000 mg/kg in the mallard duck, sharp-tailed grouse, and California quail (Hudson et al., 1984). In contrast, methoxychlor is highly toxic to fish; 96-hour LD<sub>50</sub> values for the technical grade 90% pure chemical are less than 20 ug/L for cutthroat trout, atlantic salmon, brook trout, lake trout, northern pike, and large mouth bass (Johnson and Finley, 1980).

There are some health effects data for hexafluoroisopropylidenebis(4-hydroxybenzene) and benzene, 1,1'-(2,2,2-trichloroethylidene)bis-. In an *in vitro* study evaluating endocrine disruption, hexafluoroisopropylidenebis(4-hydroxybenzene) was found to be estrogenic in MCF-7 cells, promoting cell proliferation and increasing protein synthesis (Olea-Serrano, 1998; Perez et al., 1998). Benzene, 1,1'-(2,2,2-trichloroethylidene)bis- had estrogenic activity at doses as low as 1 mg/rat (Bitman and Cecil, 1970). No other health or ecological effect studies were available for these two trihaloethylidene bisbenzenes.

iv. *Information needs.* The ITC needs information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects.

### 3. 3-Chlorotrifluralin—i.

*Recommendation.* 3-Chlorotrifluralin (CAS No. 29091-20-1) is being added to the *Priority Testing List* to obtain information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects.

ii. *Rationale for Recommendation.* 3-Chlorotrifluralin is a non-HPV chemical that has been produced/imported in

substantial amounts (>100,000 pounds) and is predicted to persist and bioconcentrate in the environment. It is a chlorinated analog of the herbicide, trifluralin (CAS No. 1582-09-8). Trifluralin causes adverse effects in experimental animals and is considered to be a possible human carcinogen by the USEPA. 3-Chlorotrifluralin has limited toxicity data even though its potential to persist and bioconcentrate in the environment may be greater than trifluralin.

iii. *Supporting Information.* 3-Chlorotrifluralin meets the DEBITS criteria and has an estimated BCF of 7,700. There are no available subchronic toxicity studies or ecological effects data on this compound. The LD<sub>50</sub> in mice was determined to be 2,744 mg/kg (Industrial Bio-Test Laboratories, 1992). The structurally related trifluralin caused adverse liver and kidney effects in rodents and dogs as a result of subchronic and chronic feeding studies. Trifluralin induced urinary tract tumors (renal pelvis carcinomas and urinary bladder papillomas) and thyroid tumors (adenomas/carcinomas combined) in one animal species (Fisher 344 rats) in one study (USEPA, 2000). Trifluralin is included in the USEPA's TRI PBT rule and is a candidate for regulatory action under the USEPA's PBT Program.

iv. *Information Needs.* The ITC needs information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects.

### 4. Trichlorophenyldihydropyrazols—

i. *Recommendation.* Four trichlorophenyldihydropyrazols are being added to the *Priority Testing List* to obtain information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects (Table 4 of this unit).

TABLE 4.—TRICHLOROPHENYLDIHYDROPYRAZOLS IDENTIFIED BY DEBITS

CAS No.	Trichlorophenyldihydropyrazol	BCF
030707-68-7 .....	3H-Pyrazol-3-one, 5-[(2-chloro-5-nitrophenyl)amino]-2,4-dihydro-2-(2,4,6-trichlorophenyl)- .....	2230
040567-18-8 .....	Benzamide, 3-amino-N-[4,5-dihydro-5-oxo-1-(2,4,6-trichlorophenyl)-1H-pyrazol-3-yl]- .....	92
053411-33-9 .....	3H-Pyrazol-3-one, 5-[(5-amino-2-chlorophenyl)amino]-2,4-dihydro-2-(2,4,6-trichlorophenyl)- .....	44
063134-25-8 .....	Benzamide, N-[4,5-dihydro-5-oxo-1-(2,4,6-trichlorophenyl)-1H-pyrazol-3-yl]-3-nitro- .....	338

ii. *Rationale for recommendation.* The 4 trichlorophenyldihydropyrazols are predicted to persist in the environment. Two of these trichlorophenyldihydropyrazols (CAS Nos. 30707-68-7 and 63134-25-8) are produced/imported in substantial amounts (>100,000 pounds) and have potential to bioconcentrate.

iii. *Supporting information.* Two of the four trichlorophenyldihydropyrazols have estimated BCFs >250 (Table 4 of this unit). The other two chemicals are structurally related but are predicted to have lower bioconcentration potential. There are no available health or ecological effects studies for any of the trichlorophenyldihydropyrazols.

iv. *Information needs.* The ITC needs information on uses, exposures,

environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects.

*B. Chemicals Removed From the Priority Testing List*

1. *Alkylphenols and alkylphenol ethoxylates.* In this Report, the ITC is removing 22 alkylphenols and alkylphenol ethoxylates that were added to the *Priority Testing List* in the ITC's 41<sup>st</sup> Report published in the **Federal Register** of April 9, 1998 (63 FR 17658) (FRL-5773-5). The 22 alkylphenols and alkylphenol ethoxylates are being removed from the *Priority Testing List* because:

i. No domestic production or importation volumes were reported to the USEPA in response to 1986, 1990, 1994, and 1998 IURs (indicating that volumes were less than 10,000 pounds per site in 1985, 1989, 1993, and 1997) and

ii. No domestic production or importation volumes were reported to the USEPA in response to the PAIR rule published in the **Federal Register** of July 5, 2000 (65 FR 41371) (FRL-6589-1) (indicating that volumes were less than 1,000 pounds per site in 1999).

The 22 alkylphenols and alkylphenol ethoxylates being removed from the *Priority Testing List* are listed in Table 5 of this unit.

TABLE 5.—ALKYLPHENOLS AND ALKYLPHENOL ETHOXYLATES BEING REMOVED FROM THE PRIORITY TESTING LIST

CAS No.	Chemical
000136-81-2 .....	Phenol, 2-pentyl-
002446-69-7 .....	Phenol, 4-hexyl-
002589-78-8 .....	Phenol, 4-hexadecyl-
003279-27-4 .....	Phenol, 2-(1,1-dimethylpropyl)-
009004-87-9 .....	Poly(oxy-1,2-ethanediyl), $\alpha$ -(iso octylphenyl)- $\omega$ -hydroxy-
009063-89-2 .....	Poly(oxy-1,2-ethanediyl), $\alpha$ -(octylphenyl)- $\omega$ -hydroxy-
025401-86-9 .....	Phenol, 2-hexadecyl-
025735-67-5 .....	Phenol, 4-sec-pentyl-
026401-47-8 .....	Poly(oxy-1,2-ethanediyl), $\alpha$ -(4-dodecylphenyl)- $\omega$ -hydroxy-
026401-74-1 .....	Phenol, 2-sec-pentyl-
027157-66-0 .....	Phenol, decyl-
059911-95-4 .....	Poly(oxy-1,2-ethanediyl), $\alpha$ -(4-hexadecylphenyl)- $\omega$ -hydroxy-
061723-87-3 .....	Poly(oxy-1,2-ethanediyl), $\alpha$ -(tridecylphenyl)- $\omega$ -hydroxy-
068081-86-7 .....	Phenol, nonyl derivs.
068784-24-7 .....	Phenol, C18-30-alkyl derivs.
068891-67-8 .....	Phenol, polypropene derivs.
068954-70-1 .....	Phenol, polyethylene derivs.
070682-80-3 .....	Phenol, tetradecyl-
071902-25-5 .....	Phenol, octenylated
084605-25-4 .....	Phenol, 1-methylhexyl derivs.
091672-41-2 .....	Phenol, 2-nonyl-, branched
112375-89-0 .....	Phenol, poly(2,4,4-trimethylpentene) derivs.

2. *Methylal.* Methylal (CAS No. 109-87-5) was added to the *Priority Testing List* in the ITC's 42<sup>nd</sup> Report and recommended for information reporting to meet U.S. Government data needs. In response to that recommendation, the USEPA added methylal to the PAIR rule published in the **Federal Register** of July 24, 2000 (65 FR 45535) (FRL-6589-1). The ITC reviewed the data submitted in response to the PAIR rule. These data indicated that in 1999, 10,000 to

500,000 pounds of methylal were produced under controlled release and enclosed conditions, involving <10 and 10-100 workers, respectively. Methylal's manufacture was associated with industrial products. The ITC is removing methylal from the *Priority Testing List* because it is being sponsored for testing under the USEPA's HPV Challenge Program. Test plans and data developed under the challenge program may be reviewed to

determine if they meet the needs of the U.S. Government.

3. *Ethyl silicate.* Ethyl silicate (CAS No. 78-10-4) was also added to the *Priority Testing List* in the ITC's 42<sup>nd</sup> Report and recommended for information reporting to meet U.S. Government data needs. In response to that recommendation, the USEPA added ethyl silicate to the PAIR rule published in the **Federal Register** of July 24, 2000 (65 FR 45535) (FRL-6589-1) and the

ITC received voluntary use and toxicity data from the Silicones Environmental Health and Safety Council (SEHSC). Data submitted in response to the PAIR rule indicated that in 1999, 10,000 to 500,000 pounds of ethyl silicate were produced under enclosed conditions, that 10–100 workers were involved in the production of ethyl silicate under those conditions and that ethyl silicate's manufacture and customer uses were associated with industrial products. SEHSC's voluntary submissions confirmed that ethyl silicate is used as an industrial, not consumer chemical. Toxicity data voluntarily submitted by SEHSC indicated that:

- i. Ethyl silicate's rat oral LD<sub>50</sub> was 5,920 mg/kg (Smyth et al., 1949);
- ii. No deaths occurred when rats, mice, guinea pigs, and rabbits were exposed to 50 and 88 ppm ethyl silicate for 90 days and the only significant observation was a depression in kidney weights in the mice exposed to 88 ppm ethyl silicate (Pozzani and Carpenter, 1951);
- iii. The mutagenic potential of ethyl silicate was evaluated using the Chinese Hamster Ovary (CHO), Sister Chromatid Exchange (SCE), and Unscheduled DNA Synthesis (UDS) assays; the only significant mutagenic effect was seen in the UDS assay (Slesinski et al., 1981). The ITC is removing ethyl silicate from the *Priority Testing List* because it is being sponsored for testing under the USEPA's HPV Challenge Program. Test plans and data developed under the challenge program may be reviewed to determine if they meet the needs of the U.S. Government.

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## VI. TSCA Interagency Testing Committee

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Council on Environmental Quality  
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