

Status and Future Directions of the

High Production Volume Challenge Program





Office of Pollution Prevention and Toxics



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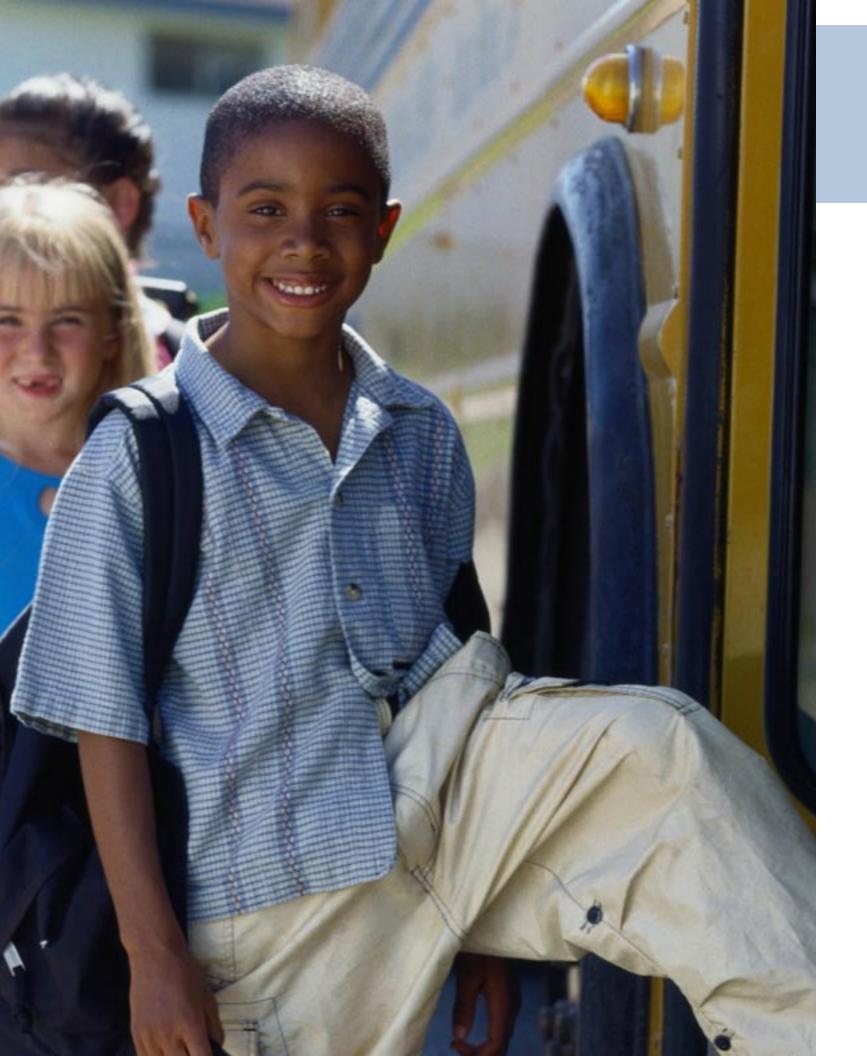


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The HPV Challenge Program

Since the Program's inception in 1998, industry chemical manufacturers and importers have participated in the Challenge by sponsoring over 2,200 chemicals.

he U.S. EPA's High Production Volume (HPV) Challenge Program is ensuring that basic health and environmental effects data on approximately 2,800 HPV chemicals is made available to the public. Since the Program's inception in 1998, industry chemical manufacturers and importers have participated in the Challenge by sponsoring over 2,200 chemicals. More than 400 companies and 100 consortia have sponsored 1,371 chemicals directly in the Program and an additional 851 chemicals have been sponsored indirectly in an international counterpart to the HPV Challenge Program, the International Council of Chemical Associations (ICCA) HPV Initiative. Three hundred fifty-three test plans have been submitted as of July 2004 for 1,266 of the 1,371 chemicals sponsored directly in the HPV Challenge Program (or 92%). EPA expects that the end of 2004 will be a critical time as sponsors work to fulfill their commitments by submitting test plans and data summaries for the remaining 8% of the sponsored chemicals, and also to submit completed data packages where additional testing was needed.

Overall, the HPV Challenge Program has continued to strive to meet its outlined goals. Extensive voluntary participation has been achieved as companies, individually or as part of consortia, have agreed to sponsor chemicals. Additionally, the public has been an important participant in the Program

by providing feedback to sponsors on their test plans and data summaries. A key EPA goal in managing the HPV Challenge Program has been to provide clear guidance for assisting participating sponsors. Guidance has been made available on a wide variety of subjects, including category formation, developing robust data summaries, and assessing the adequacy of existing data. Because of the HPV Challenge Program, significant amounts of data have been made public for the first time (59% of the data submitted was not publicly available at the start of the Program).

The Agency is also stepping up its efforts to provide the public with available data. EPA is developing the HPV Information System (HPVIS), which will provide the public with an efficient way to comprehensively search and retrieve data included in the sponsor-submitted data summaries. EPA is also working collaboratively with the European Union to develop a Global HPV Portal. The Agency is designing the Portal to provide a central location for domestic and international users to access consolidated international HPV chemical data repositories. In addition to the database development efforts, the Agency is working on implementing a strategy to address orphan (unsponsored) HPV chemicals in an effort to secure data related to those chemicals. The orphan strategy is outlined in Appendix 5 of this report.

In summary, the HPV Challenge Program has made outstanding progress toward meeting its goals and commitments, and on preparing for future work on HPV chemicals.

After briefly summarizing the background of the HPV Challenge Program, the following topics are described in this report:

- How the Program Works,
- Overall HPV Challenge Program Achievements,
- EPA's Work With Sponsors To Address Overdue Test Plans,
- Orphan Chemicals, and
- Future Directions and Developing Issues.

History of the Program

The HPV Challenge Program, officially launched in late 1998, was created to ensure that a baseline set of data on approximately 2,800 high production volume chemicals would be made available to the public. The American Chemistry Council (ACC)¹, Environmental Defense (ED)², and the American Petroleum Institute (API) participated in the launch of the Program. HPV chemicals are manufactured or imported in amounts equal to or greater than one million pounds per year and were identified for this program through data reported under the Toxic Substances Control Act

(TSCA) Inventory Update Rule (IUR) during 1990. HPV chemicals that are not sponsored in the Program may be subject to regulations ("test rules") under Section 4 TSCA because these chemicals require needed testing.

A basic premise of the Program is that the public has a right to know about the hazards associated with chemicals in their environment. Everyone – including industry, environmental protection groups, animal welfare organizations, government groups, and the general public, among others – can use the HPV chemical data provided through the HPV Challenge Program to make informed decisions related to the human and environmental hazards of chemicals that they encounter in their daily lives.

The HPV Challenge Program was established in response to several studies that showed that there were relatively few U.S. HPV chemicals for which an internationally agreed upon set of data for hazard screening was available to the public. This data set addresses areas, also known as "endpoints," that illustrate a chemical's properties and effects.

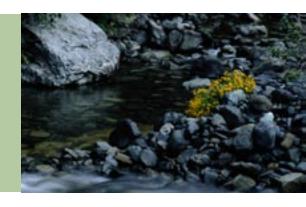
One of the studies providing motivation for the Challenge was EPA's *Chemical Hazard Data Availability Study*³ (1998). This study (see the figure on the following page) showed that 43% of

¹ACC = formerly known as the Chemical Manufacturers Association.

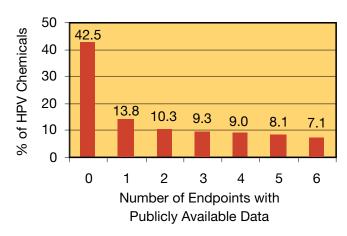
²ED = formerly known as Environmental Defense Fund.

³Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? (1998). Washington, DC: U.S. Environmental Protection Agency. (Website: http://www.epa.gov/oppt/chemrtk/hazchem.pdf).





Lack of Publicly Available Screening Data



high production volume chemicals had no publicly available data on basic toxicity and only 7% had a full set of basic data for six endpoints⁴. Subsequently, the Agency challenged U.S. manufacturers and importers of HPV chemicals to voluntarily sponsor chemicals in the Program. Sponsorship entails making screening-level health and environmental data available to the public. Public availability of these data is a fundamental principle of the Program. The data set sought by the HPV Challenge Program is known as the Screening Information Data Set (SIDS) that was developed by the Organization for Economic Cooperation and Development (OECD). The SIDS provides an internationally agreed upon set of test data

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for screening high production volume chemicals for human and environmental hazards, and helps to make an informed, preliminary judgment about the hazards of HPV chemicals.

For a more detailed History of the Program, see Appendix 1.

How the Program Works

Commitments to sponsor chemicals in the HPV
Challenge Program have come from companies
and consortia both inside and outside the United
States. The chemical industry has demonstrated
this commitment to product stewardship by making
publicly available screening-level hazard data that
will allow EPA, industry, and other stakeholders to
effectively gauge potential hazards of HPV chemicals.

As part of their commitment to the HPV Challenge Program, sponsors submit data summaries of existing information along with a test plan that proposes a strategy to fill data gaps. These documents are then posted to the HPV Challenge Program website. The following timeline graphic shows how the majority of sponsors' materials were submitted to the Agency between 2001-2003.

Sponsors submit test plans for either individual chemicals or for a category of chemicals. A chemical category comprises a group of substances, usually similar in chemical structure, with a regular pattern of properties and effects. Data for chemicals in the category can be used to estimate the chemical properties and effects of other category members.

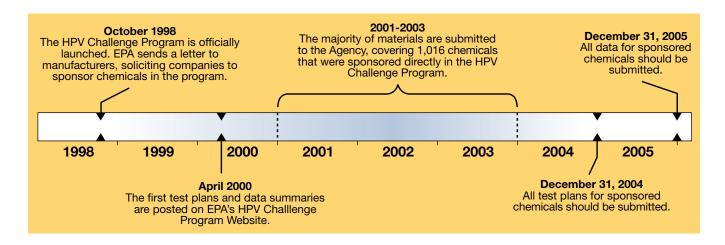
A 120-day comment period begins when test plans and data summaries submitted directly to the HPV Challenge Program are posted to the Program website. It is at this time when all stakeholders – industry, environmental protection groups, animal welfare

groups, private citizens, etc. – can comment on the data summary and test plan submissions, and EPA comments on all of the submissions.

Sponsors can also indirectly submit data through the International Council of Chemical Associations (ICCA) HPV Initiative, which is a complementary program aimed at HPV chemicals from around the world.

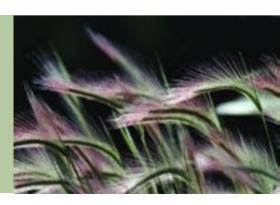
For more information regarding How the Program Works, see Appendix 2.

HPV Challenge Program Timeline



⁴The six endpoints: acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate.





Overall HPV Challenge Program Achievements

The HPV Challenge Program has resulted in many achievements. The accomplishments include: chemical manufacturers work individually or through consortia to sponsor chemicals, test plans and data summaries for the chemicals that have been submitted, the public has commented on materials posted to the website, and EPA has provided detailed guidance documents to assist stakeholders in participating in the Program.

Extensive Voluntary Participation

Participation in the HPV Challenge Program has created attention by exceeding all expectations. A total of 2,222 chemicals have been sponsored, with 1,371 chemicals sponsored directly in the Program by 401 companies and 103 consortia and an additional 851 chemicals sponsored indirectly in the ICCA HPV Initiative.

For chemicals sponsored directly in the HPV Challenge Program, 353 test plans have been submitted for 1,266 of the 1,371 sponsored chemicals (or 92%). Of these 353 test plans, 114 are for categories of chemicals and the remaining 239 are for individual chemicals. EPA expects that the end of 2004 will be a critical time as sponsors work to fulfill their commitments by submitting test plans and data summaries for the remaining 8% of the sponsored chemicals, and also work to submit completed data packages where additional testing was needed.

Public Comments

The HPV Challenge Program provides a unique opportunity for all stakeholders, including the public, to comment on test plan and data summary submissions. Comments are important because sponsors consider this feedback when revising their test plans and data summaries. All comments are posted to the website for public availability.

Environmental Defense has submitted comments on 89% of all posted test plans. Two animal welfare groups – People for the Ethical Treatment of Animals (PETA) and Physicians Committee for Responsible Medicine (PCRM) – submitted comments on 62% of all test plans, and private individuals and other groups submitted comments on fewer than 3% of all test plans. Comments from Environmental Defense often refer to whether they are in agreement with the sponsor's category hypothesis, use of supporting chemicals, estimations or Structure-Activity

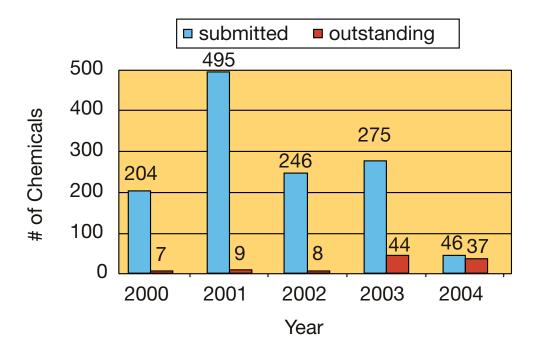
Relationships (SARs, which are techniques to show how data for one chemical can be used to cover data needs for a similar chemical), proposed testing, and adequacy of submitted data. Comments from PETA and PCRM generally indicate whether they agree with the proposed test plan or not, and specifically with regard to whether animals will be used for testing purposes. These animal welfare organizations often state reasons for why testing should not be performed.

Guidance Documents

A key EPA goal in managing the HPV Challenge Program has been to provide clear guidance to assist stakeholders in participating in the Program. EPA's "Guidance Documents" webpage can be found on the EPA website at http://www.epa.gov/chemrtk/guidocs. htm. Guidance is provided for subjects such as category formation, developing robust data summaries, and assessing adequacy of existing data, to name a few. A number of EPA's guidance documents have achieved international acceptance through their incorporation in OECD guidance documents.

The guidance document on development of chemical categories provides guidance on approaches and issues encountered in category formation and application under the HPV Challenge Program. The document offers advice on how companies could group chemicals with similar characteristics into

Chemicals Sponsored Directly in the HPV Challenge Program







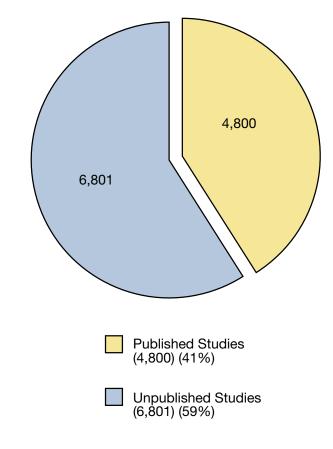
categories, and then evaluate existing data and conduct testing to characterize the category – all without having to perform every test on every individual chemical. EPA's "Guidance on Developing Robust Summaries" document presents guidance on what technical information, on an endpoint-by-endpoint basis, is necessary to adequately describe a particular study. The term "robust summary" is used to describe this technical content. Robust study summaries are intended to provide sufficient information to allow a technically qualified person to make an independent assessment of a given study report without having to go back to the full study report, and to also allow evaluation of the proposed test plan. A robust study summary therefore concisely reflects the objectives, methods, results, and conclusions of the full study report.

Test Plan and Data Submissions Are Now Available

EPA analyzed submitted test plans to determine how the health and environmental effects endpoints were addressed. Sponsors proposed to meet data needs through the use of existing scientifically adequate data, estimation techniques such as Structure-Activity Relationships (SARs), or proposed new testing. An examination of submitted data revealed that a significant amount of unpublished data have now been made public by the sponsors. This indicates that

many sponsors made significant efforts in evaluating the hazards of their chemicals prior to the launch of the HPV Challenge Program, but often did not make the data available to the public. In fact, 59% of the existing data reported under the HPV Challenge Program, which represents over 6,800 studies, was not publicly available before the launch of the Program. This represents a major success of the HPV Challenge Program.

Sources of Existing Data

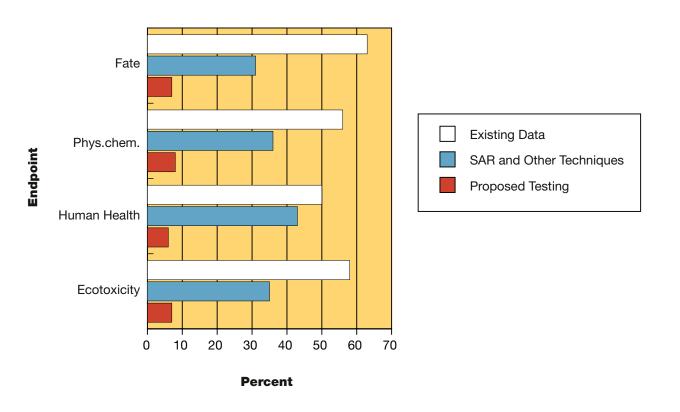


The submission of existing, unpublished data to EPA under the HPV Challenge Program has also significantly minimized the amount of new testing that sponsors have proposed. Sponsors have made maximum use of Program guidance concerning the use of SAR and category proposals, which also reduced the need for new testing. New testing has been proposed for fewer than 10% of the chemicals' endpoints.

The Category Approach

One of the most significant results of the HPV
Challenge Program has been the use of the category
approach to address the SIDS endpoints. In fact,
81% of all chemicals addressed in test plans have
been included in a category. Categories require a

Endpoint Data Sources







supporting hypothesis of how the category chemicals relate to each other, as well as a description of how data for one chemical can be used to predict the toxicological responses of similar chemicals in the category. EPA and other stakeholders then comment on the reasonableness of the hypothesis, the adequacy of supporting data, and any proposed testing. Once the sponsor submits its final category analysis, EPA will either agree that the category "held," or will notify the sponsor that the sponsor may need to consider additional testing or restructure the category.

The ICCA HPV Initiative

Test plans and data summary submissions for chemicals sponsored indirectly through the ICCA HPV Initiative are not provided to EPA to post on the HPV Challenge Program website. Therefore, EPA determines progress in the ICCA HPV Initiative by tracking how many chemicals sponsored in the Initiative go to an OECD SIDS Initial Assessment Meeting (SIAM), which is a meeting where OECD member countries agree on initial hazard assessment for HPV SIDS chemicals.

Chemicals Sponsored Indirectly through the ICCA HPV Initiative

Start Year or Test Plan Receipt Year	Total Expected Chemical Submissions	SIAM Chemicals Sponsored by ICCA
1999	38	14
2000	149	54
2001	487	98
2002	133	19
2003	127	17
2004	40	27
Total	974	229

Of the 974 chemicals sponsored in the ICCA HPV Initiative, 229 chemicals had been through the OECD SIDS process by July 2004. This number accounts for 24% of the total ICCA commitments. It is important to point out that 123 chemicals are dually sponsored both directly in the HPV Challenge Program as well as indirectly in the ICCA HPV Initiative. Earlier in this report, it was noted that 851 chemicals are sponsored in the ICCA HPV Initiative; however, when the 123 dually sponsored chemicals are considered, total ICCA HPV Initiative sponsorship increases to 974 chemicals.

For more information regarding Overall HPV

Challenge Program Achievements, see Appendix 3.

EPA's Work With Sponsors To Address Overdue Test Plans

Although EPA has received a large number of test plans, a few commitments to supply information in 2003 or earlier have not been met. In order to evaluate which sponsors were responsible for overdue test plans, the Agency reviewed commitment information submitted by companies and consortia, and then sent a letter to sponsors of chemicals with overdue test plans in April 2004. EPA received responses from many of these sponsors updating the status of their commitments. As of July 2004, test plan and data summary submissions were overdue from 24 sponsors for 47 chemicals.

The Agency expects that sponsors will uphold their commitments and submit test plans and data summaries for these chemicals by the end of 2004.

For more information regarding Overdue Test Plans, see Appendix 4.

Orphan Chemicals

While the success of the HPV Challenge Program has been significant, 330 chemicals that were eligible for sponsorship in the Program continue to remain unsponsored. These chemicals are also known as "orphans." The Agency is taking steps to ensure that screening-level data are made available to the public for the 330 orphan chemicals through a last chance at voluntary sponsorship, as well as through future TSCA information gathering and test rules.

For more information regarding Orphan Chemicals, including a detailed outline of EPA's Draft Orphans Strategy, see Appendix 5.

Future Directions and Developing Issues

Public access to hazard data is integral to the HPV Challenge Program. Test plan and data summary submissions, sponsor commitment information,





chemical lists, guidance documents, and other materials can be found at the HPV Challenge Program Website (http://www.epa.gov/chemrtk). EPA has recently provided enhanced search capability on its existing "Robust Summaries and Test Plans" webpage (http://www.epa.gov/chemrtk/hpvrstp.htm) that allows the public to more efficiently search for test plan and data summary submissions. Production of the HPV Information System (HPVIS), a much more comprehensive, data-searchable application, is the ultimate goal. This system will allow users to thoroughly search across all test plan and data summary-related materials – including the data presented within and among data summaries. The first release of HPVIS is scheduled for late 2004 / early 2005.

As the HPV Challenge Program enters its final year and as EPA prepares to provide the industry-submitted data to the public in a searchable database format, the Agency has made great strides to press forward with developing and planning for the delivery of a Global HPV Portal. The Portal is a system that will provide a central location for domestic and international users to access consolidated international HPV chemical data repositories. EPA is working collaboratively with the European Commission (EC), in consultation with the Organization for Economic Cooperation and Development (OECD), and with the additional participation of Canada and Japan to develop this system. The aim of the Global HPV Portal is to

provide seamless information sharing between the European Union's (E.U.) International Uniform Chemical Information Database (IUCLID) and EPA's HPVIS. The two leads – EC and EPA – have worked diligently on the Portal requirements in an effort to share information and make data more readily available to stakeholders from around the world.

Additionally, now that the majority of the test plans and data summaries that were committed to under the HPV Challenge Program have been submitted, the Agency is focusing on using the data for identifying chemicals of concern. The Agency is working with the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) and NPPTAC's HPV Work Group to develop a screening approach for identifying and prioritizing chemicals for further work. Once EPA has implemented a plan for prioritizing chemicals, the next steps include employing mechanisms to obtain additional hazard data (beyond the basic screening-level of the SIDS) or exposure data through voluntary or regulatory approaches for priority chemicals as needed. Developing approaches to obtain data on newly emerging HPV chemicals that were reported in recent IUR cycles is also viewed as an important follow-on step for the Challenge.

For more information regarding Future Directions and Developing Issues, see Appendix 6.

HPV Challenge Program Conclusions

In conclusion, EPA is very pleased with the overwhelming response from companies and consortia to the HPV Challenge Program. The extraordinary response to the Program has resulted in a tremendous amount of sponsor-submitted test plan / summary data being made publicly available. More than 400 companies and 100 consortia have sponsored over 2200 chemicals in the Program. In addition to the 851 chemicals sponsored indirectly through the ICCA HPV Initiative, 353 test plans have been submitted for 1,266 (92%) of the 1,371 chemicals sponsored directly in the HPV Challenge Program.

The majority of the test information that addresses the SIDS endpoints was comprised of unpublished, existing data, which because of the HPV Challenge Program has now been made publicly available. In addition, category approaches and SAR techniques have been applied to extend the available data to other related chemicals, thereby reducing the need for new testing. The Agency has developed a strategy to address those from the original list of approximately 2800 chemicals that have either not been sponsored or have been sponsored but submission of test plans / data summaries are currently overdue. This strategy, plus efforts to develop the HPVIS while working with other governments in developing the Global HPV

Portal, will help ensure that more data are accessible in the U.S. and internationally.

The Agency is working with the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) and NPPTAC's HPV Work Group to develop a screening approach for identifying and prioritizing chemicals for further work. In addition to chemicals identified from the 1990 IUR, EPA is in the process of considering options for addressing HPV chemicals that were reported in the most recent IUR reporting. EPA's Office of Pollution Prevention and Toxics will continue to inform the public about the HPV Challenge Program and the potential uses of the collected data. Continued cooperation by sponsors and other participating stakeholders in the Program will ultimately result in public accessibility to a large amount of useful HPV chemical data that were largely not available to the public at the Program's start in 1998. EPA recognizes the contributions by industry and other stakeholders in the HPV Challenge Program's accomplishments.



Appendix 1: History of the Program

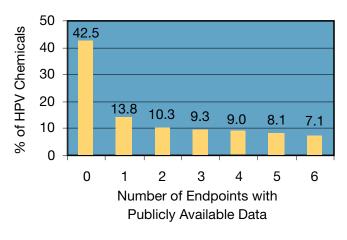


he HPV Challenge Program was established in 1998 in response to several studies that revealed how little health and environmental effects data were publicly available for HPV chemicals. Environmental Defense's *Toxic Ignorance*⁵ study in 1997 showed that, for a sample of 100 HPV chemicals, there were relatively few U.S. HPV chemicals with health hazard screening data. In 1998, EPA's Chemical Hazard Data Availability Study⁶ addressed all HPV chemicals and resulted in similar findings; specifically, 43% of high production volume chemicals had no publicly available data on basic toxicity and only 7% had a full set of basic data (see the figure below). These results were subsequently supported by the American Chemistry Council's Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals⁷ study in 1998. This lack of data

inhibits the public's ability to evaluate whether the chemicals that may be found in their environment, homes, workplaces, and the products that they buy are of concern. Prior to the HPV Challenge Program, such data were generally not available to the public.

EPA responded to this lack of data by inviting U.S. manufacturers and importers of HPV chemicals to voluntarily sponsor chemicals in the HPV Challenge Program. Sponsorship entails the identification and initial assessment of the adequacy of existing data, the conduct of new testing only if the sponsor determines that adequate data do not exist, and making the new and existing data available to the public. Public availability of data is the fundamental principle of this program. Any new testing on the HPV chemicals in the HPV Challenge Program is to be completed by the end of 2004 with all data to be made available to the public by the end of 2005.

Lack of Publicly Available Hazard and Fate Data



HPV Challenge Program Design

Sponsors can participate in the HPV Challenge Program either directly through the Program or indirectly through the International Council of Chemical Associations (ICCA) HPV Initiative and/ or the Organization for Economic Cooperation and Development's (OECD) HPV Screening Information Data Set (SIDS) Program. The ICCA HPV Initiative

Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States (1997). New York, NY: Environmental Defense Fund. (Website: http://www.environmentaldefense.org/documents/243_toxicignorance.pdf).

Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? (1998). Washington, DC: U.S. Environmental Protection Agency. (Website: http://www.epa.gov/oppt/chemrtk/hazchem.pdf). Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (1998). Arlington, VA: Chemical Manufacturers Association.

and OECD HPV SIDS Program are aimed at HPV chemicals from around the world. The information sought by the HPV Challenge Program is based on the OECD HPV SIDS Program, which includes an internationally agreed upon set of endpoints for screening high production volume chemicals for human and environmental hazards. The SIDS is regarded as the minimum data set needed to make an informed, preliminary judgment about the hazards of a given HPV chemical.

For chemicals sponsored directly through the HPV Challenge Program, each sponsor submits a test plan to identify SIDS data needs along with a strategy to fill data gaps. Each sponsor also submits a detailed summary of existing data (robust summaries) for an individual chemical or a group of chemicals with similar structures and/or functionalities (category). The sponsor's test plan is posted for public comment to EPA's "Robust Summaries and Test Plans" webpage at http://www.epa.gov/chemrtk/hpvrstp.htm. The test plan is subject to a 120-day public comment period to allow EPA and other stakeholders to review and comment on the test plan and robust summaries and to submit additional data that may be used to reduce the need for new testing. Sponsors subsequently develop new data, if necessary, and submit appropriate robust summaries. As described below, voluntary participation in the HPV Challenge Program provides the flexibility to propose chemical categories and more flexible schedules for conducting necessary testing.

Chemicals sponsored indirectly through the ICCA HPV Initiative are tied in directly with the OECD HPV SIDS Program (http://www.icca-chem.org).

The basic ICCA HPV Initiative process consists of first obtaining company or consortium sponsorship for the ICCA-listed HPV chemicals. Then, the ICCA HPV Initiative solicits national sponsorship from an OECD member country. Once the member country sponsorship is achieved, the company or consortium works with the sponsor country to develop the necessary materials. Completed materials will be submitted to OECD by countries so that a screening-level hazard assessment can be completed.

Chemicals not otherwise sponsored will be considered for inclusion in a test rule under TSCA Section 4. The purpose of the test rule is to serve as a regulatory backstop to the voluntary HPV Challenge Program and the ICCA HPV Initiative; and thereby ensure that basic data are available for all HPV chemicals. The first HPV test rule was proposed on December 26, 2000 (65 FR 81658). On that same date, another Federal Register notice (65 FR 81686) was also issued, and described the HPV Challenge Program (http://www.epa.gov/chemrtk/ts42213.pdf).

1990 HPV Challenge Program Chemical List

The 1990 HPV Challenge Program Chemical List consists of all HPV chemicals reported in the 1990 Inventory Update Rule. Inorganic chemicals and polymers, except in special circumstances, were not subject to the IUR reporting requirements. The 1990 HPV Challenge Program Chemical List contained 2,782 chemicals. A second list, the 1994 List of HPV Additions, contained approximately 500 HPV chemicals that were newly reported as HPV in the 1994 IUR. The 1994 List of HPV Additions is not

a part of the HPV Challenge Program at this time, but was provided for use by companies who desired to propose categories of chemicals and wished to include chemicals from the 1994 list in their category definitions. Additionally, in some cases, companies or consortia have sponsored chemicals that are not on either the 1990 HPV Challenge Program Chemical List or the 1994 List of HPV Additions. For the purposes of this report, these chemicals are included in the number of sponsored chemicals, and no distinction is made between these chemicals and those chemicals on the 1990 HPV Challenge Program Chemical List once they are sponsored.



Appendix 2: How the Program Works



S. manufacturers and importers of HPV chemicals were invited to voluntarily sponsor chemicals in the HPV Challenge Program. To become a sponsor of one or more HPV chemicals a company or consortium sends a letter to EPA announcing its commitment to participate in the HPV Challenge Program and its willingness to adhere to the Program's procedures. The commitment letter includes chemical names and Chemical Abstract Services (CAS) registry numbers to be sponsored, the year of the Program in which the sponsor will submit test plans and supporting robust summaries, and the name and contact data for the technical person within the company to contact for additional information. Sponsorship can be undertaken by individual companies or through a consortium of companies. Many companies collaborate with other companies or trade associations that manufactured the same or similar chemicals by forming consortia. Consortia help avoid duplication of effort and reduce individual companies' expenditures needed for data collection or testing. As a first step toward fulfilling a commitment, the sponsor submits robust summaries of existing data and a test plan showing how it plans to fill data gaps. Chemicals can be submitted individually or as categories of chemicals. Categories of chemicals

are proposed when test plan and robust summaries are submitted, and are not identified in the initial sponsorship commitment letter.

EPA has received numerous commitments to sponsor chemicals since the beginning of the Program in late 1998. The Agency extended the initial timeframe for commitments to be received from March 1999 to December 26, 2000. This date was chosen because it was the date on which a proposed TSCA Section 4 test rule containing 37 unsponsored chemicals from the 1990 HPV Challenge Program Chemical List was published. Commitments received after December 26, 2000, were deemed "viable commitments." In addition to adhering to the standard components of the HPV Challenge Program, companies agreeing to sponsor chemicals via viable commitments also provide full copies of new and existing studies. Companies and consortia that committed to sponsor chemicals prior to issuance of the proposed test rule were not expected to submit full studies; instead, they were to submit robust summaries of the studies. When defining the number of sponsored chemicals within the HPV Challenge Program, the Agency does not consider viable commitments a separate sponsorship classification.

Companies and Consortia Sponsoring Chemicals

Participation in the HPV Challenge Program has been remarkable and has exceeded all expectations.

As of July 2004, a total of 401 companies and 103 consortia were sponsoring chemicals directly through the HPV Challenge Program. These numbers include companies and consortia that sponsor chemicals

through the HPV Challenge Program and those that sponsor chemicals in both the HPV Challenge Program and through the ICCA HPV Initiative. The following table contains a list of the participating companies and consortia, along with their trade association affiliation, if applicable, and the number of chemicals that they are sponsoring.

Participating Companies and Consortia in the HPV Challenge Program

{Company and consortium names are presented according to how they were submitted to the Agency. Participating companies in the ICCA HPV Initiative or OECD HPV SIDS Program are not included if they are not also participating directly in the HPV Challenge Program. Trade association affiliation is noted for members of the following three trade associations: American Chemistry Council (ACC), American Petroleum Institute (API), and Synthetic Organic Chemical Manufacturers Association (SOCMA). Lists of ACC and SOCMA member companies were found on their web sites. A member company list for API is not available on its website; however, a list of links to API member companies is available at http://api-ec.api.org/links/index.cfm, and was used in this analysis to identify known API member companies -- it is not a complete list.}

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
<u>Companies</u>		
3М	ACC	4
A.E. Staley Manufacturing Company		14
Abitibi Consolidated (Formerly Donohue, Inc.)		1
Aceto Corp	SOCMA	3
Agri-Energy, LLC		1
Air Liquide America	ACC	1
Air Products and Chemicals, Inc.	ACC	9
Akzo Nobel	ACC	1
Akzo Nobel - Eka Chemicals Incorporated	ACC	36
Akzo Nobel - Polymer Chemicals Business Group	ACC	1
Akzo Nobel - Polymer Chemicals Metal Alkyls	ACC	21
Akzo Nobel - Resins	ACC	36
Akzo Nobel Chemicals Inc.	ACC	91
Akzo Nobel Functional Chemicals LLC	ACC	3
Akzo Nobel Functional Chemicals LLC - Phosphorus Chemicals	ACC	9
Al-Corn Clean Fuel Cooperative		1
Albemarle Corporation	ACC, API, SOCMA	32
Albina Fuel Co. dba Albina Asphalt		36
Alchem, Ltd.		1
ALCO Chemical		34
Alliance Forest Products		1
Alliant Techsystems Inc.		1
Amerada Hess Corporation		392
Ameribrom Inc.	SOCMA	6
Angus Chemical Company		2
Aqua-Clor		3
Arch Chemicals, Inc.	ACC	3
Archer Daniels Midland Company (ADM)		14
Arizona Chemical Company		129

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Asahi Glass Co., Ltd.		1
Ashland Inc.	ACC, API	2
Asphalt Materials, Inc.		36
Atlantic Richfield Company (ARCO)		392
Atofina Chemicals, Inc.	ACC	38
Atofina Oil and Chemical Company	ACC	392
Atofina Petrochemical Inc.	ACC	3
Ausimont S.p.A.		1
Ausimont USA, Inc.		2
Baerlocher USA		19
Baker Petrolite Corporation	API, SOCMA	35
BASF Corporation	ACC, SOCMA	149
BASF Performance Copolymers, LLC	ACC, SOCMA	1
Baule USA		1
Bayer AG Corporation	ACC, SOCMA	3
Bayer Corporation	ACC	70
Bedoukian Research, Inc.	SOCMA	45
Big West Oil LLC/Flying J Inc.		392
Bimasco, Inc.		5
BioLab, Inc.		4
Blacklidge		5
Blackman Uhler Chemical Company (Division of Synalloy Corp.)	SOCMA	1
Blue Ridge Paper Products		1
Boise Cascade Corporation		82
Borden Chemical, Inc.	SOCMA	1
Borden Chemicals and Plastics (BCP) Limited Operating Partnership	SOCMA	2
Borregaard Italy	SOCMA	4
Bowater Incorporated		1
ВР	ACC, API	480
Broin Enterprises, Inc.		1
Buckeye		1
Buffalo Color Corporation		14
Bush Boake Allen Inc.		32
The C.P. Hall Company	ACC	49
Cabot Corporation		1
Calcasieu Refining Company		392
Capital Resin Corporation	SOCMA	2
Cardolite Corporation	SOCMA	1
Cargill, Inc. North American Corn Milling Division		1

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Cargill, Incorporated		13
Caribbean Methanol Company Limited		1
CBC (America) Corp.	SOCMA	1
Celanese Ltd.	ACC	22
Cenex Harvest States Cooperatives		392
Champion International Corporation		45
Chevron Oronite Company LLC	ACC, SOCMA	75
Chevron Phillips Chemical Company, LP	ACC, SOCMA	91
Chevron Products Company	ACC, SOCMA	394
Chief Ethanol Fuels, Inc.		1
Chippewa Valley Ethanol Company (CVEC)		1
Ciba Specialty Chemicals Corporation	ACC, API	49
Ciba Specialty Chemicals Corporation - Water Treatments	ACC, API	3
Ciba Specialty Chemicals Corporation, Plastic Additives Segment	ACC, API	14
Citgo Asphalt Refining Corporation (CARCO)		392
Citgo Petroleum Corporation		392
Citrus and Allied Essences, Ltd.		45
Clariant Corporation	SOCMA	37
Clearon Corporation		3
Cleveland Asphalt Products, Inc.		36
The Clorox Company		65
Cobitco, Inc.		36
Cognis Corporation	ACC, SOCMA	134
Colas, Inc.		36
Color Intermediates, Inc.		25
Colorcon, Inc.		5
Condea Servo LLC		19
ConocoPhillips Company	API	392
Copperhead Chemical Company Inc.	SOCMA	1
Corn Plus		1
Corsicana Technologies, Inc.	SOCMA	29
Countrymark Cooperative, Inc.		392
Crompton & Knowles Colors Incorporated	ACC	1
Crompton Corporation	ACC	447
Cross Oil Refining & Marketing, Inc.		392
Crown Central Petroleum Corporation		392
CVC Specialty Chemicals, Inc.		2
Cytec Industries Inc.	ACC	67
Daikin America, Inc.	ACC	1

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Dakota Gasification Company	ACC	395
DanChem Technologies, Inc.	ACC, SOCMA	1
Day-Glo Color Corp.		1
Degussa AG	ACC, SOCMA	3
Deltech Corporation	SOCMA	3
Denco, LLC		1
Derivados Electroquimicos Levante SA (DELSA)		3
Dixie Chemical Company, Inc.	ACC, SOCMA	6
Dover Chemical Corporation	ACC	5
Dow AgroSciences	ACC, API, SOCMA	1
The Dow Chemical Company	ACC, API, SOCMA	124
DRAGOCO, Inc.		45
DSM Chemicals North America, Inc.	ACC, SOCMA	2
DSM Fine Chemicals, Inc.	ACC, SOCMA	1
DynaChem, Inc.		2
Dynegy Midstream Services LP		392
Dyno Nobel Inc.		1
DyStar LP		1
E. A. Mariani Asphalt Company		36
E.I. du Pont de Nemours and Company	ACC	167
Eastern Paper, Inc.		1
Eastman Chemical Company	ACC, SOCMA	204
Eastman Kodak Company	ACC	13
Ecofuel		1
Ecolab Inc		5
Edginton Oil Company		392
Eighty-Eight Oil Company		392
Eliokem, LLC	ACC	34
Elkhorn Operating Company		392
Emulsion Products of Alaska, Inc.		5
Enron Methanol Company		1
Enterprise Products Company		392
Equilon Enterprises, LLC and Motiva Enterprises, LLC		392
Equistar Chemicals, LP		77
Equitable Oil Purchasing Company		392
Equiva Services LLC		392
Ergon - West Virginia, Inc.		392
Ergon Asphalt & Emulsions, Inc.		36
Ergon Ref Inc		392

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
ESCO Company Limited Partnership	SOCMA	5
Ethanol2002		1
EXOL		1
Exxon Company, USA	ACC, API	392
ExxonMobil Chemical Company	ACC, API	263
Farmland Industries Inc.		392
Ferro Corporation	ACC, SOCMA	86
Fertilizers & Chemicals, Ltd.		3
Fina Oil and Chemical Company, Inc.		455
Finch, Pruyn & Company, Incorporated		1
FINETEX, Inc.		3
Firmenich, Incorporated		17
First Chemical Corporation		5
Flexsys America L.P.	SOCMA	34
Flint Hills Resources LP		392
FMC Corporation	ACC, API, SOCMA	10
Formosa Hydrocarbons Company, Inc.		392
Formosa Plastics Corporation, USA		74
Fragrance Resources		45
Gaylord Chemical Corporation		2
GE Plastics	API	1
General Electric (GE)	API	15
GEO Specialty Chemicals		1
Georgia Gulf Corporation	ACC	4
Georgia-Pacific Corporation		2
Georgia-Pacific Resins, Inc.		38
Giant Industries, Inc.		392
Givaudan Fragrances Corporation		60
Global Octanes Corporation		392
Golden Bear Oil Specialties		392
The Goodyear Tire & Rubber Company		475
Great Lakes Chemical Corporation	ACC	13
Greif Bros. Corporation		1
Groupe SNPE		59
Gulf States Asphalt Co., LLP		5
Gulf States Paper Corporation		1
Haarmann & Reimer (H&R)		13
Hampshire Chemical Corp.		5
Harcros Chemicals Inc.		6

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Hatco Corporation	SOCMA	47
Heartland Corn Products		1
Heartland Grain Fuels, LP		1
Hercules Incorporated		130
High Plains Corporation		1
Hills Materials Company		5
Holly Corporation		392
Honeywell International Inc.	ACC, SOCMA	395
Hovensa LLC		392
Hunt Refining Company	API	392
Huntsman Advanced Materials Americas Inc.	SOCMA	3
Huntsman Corporation	SOCMA	83
Huntway Refining Company		392
ICI	ACC	1
ICI Americas, Inc.	ACC	156
Ihara Chemical Industry Co., Ltd.		1
INDSPEC Chemical Corporation		1
INEOS N.V.		1
Infineum USA L.P.	ACC, API	73
Inland Paperboard and Packaging, Inc.		37
Inland Refining, Inc.		392
Inolex Chemical Company		72
International Flavors & Fragrances, Inc. (IFF-US)		48
International Paper		37
International Specialty Products (ISP)	ACC, SOCMA	4
ISOCHEM INC (formerly Vandemark Inc.)	SOCMA	2
J. Manheimer Inc.		46
Kao Corporation	ACC	1
Kao Specialties Americas LLC (formerly High Point Chemical Corporation)	ACC	58
Kemin Industries, Inc.		19
Kern Oil & Ref Co		392
King Industries, Inc.		4
Koch Industries, Inc.		470
Koei Chemical Co., Ltd.		9
Korea Hyeop Hwa Chemical Industry Company, Ltd.		1
KoSa		13
Kuraray Co., Ltd.	SOCMA	46
La Gloria Oil and Gas Company		392
Lindau Chemicals, Inc.		6

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Lion Oil Company		392
Loctite Corporation		1
Longview Fibre Company		1
Lonza Inc.	SOCMA	38
Louis Marsch, Inc.		5
Louisiana-Pacific Corporation		1
The Lubrizol Corporation	ACC, API, SOCMA	103
Lyondell Chemical Company		22
Lyondell Methanol Co.		1
Lyondell-Citgo Refining Company Ltd.		392
Mallinckrodt Inc.		32
Marathon Ashland Petroleum LLC	API	409
Mason Chemical Company		5
McAsphalt Industries Limited		36
McIntyre Group, Ltd.		3
MeadWestvaco	ACC	112
Merichem Chemicals & Refinery Services LLC	ACC, API	392
Merisol USA LLC	ACC, API	405
Metachem Products, LLC		4
Methanex Methanol Company	ACC	1
The Methanol Sector Group, a Sector Group of CEFIC		1
MFG Chemical, Inc.	SOCMA	3
Midwest Grain Products		1
Millennium Chemicals Inc.	ACC	60
Milliken Chemical	ACC	6
Minnesota Corn Processors, Inc. (MCP)		1
Mitsubishi Gas Chemical Company, Inc.	ACC	2
MLPC International		1
Mobil Oil Corporation		392
Monsanto Company	ACC	2
Morflex, Inc.	SOCMA	1
Motiva Enterprises, LLC		392
Murphy Oil USA, Inc.	API	392
Nalco Chemical Company	ACC	10
Nan Ya Plastics Corporation, America		3
National Cooperative Refinery Association		392
National Starch (ICI Americas)	ACC	2
Navajo Refining Company		392
Nepera, Inc.	ACC	7

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Neville Chemical Company		392
New Energy Corp.		1
New England Emulsions Corp.		36
NIPA Inc.		1
Nippon Petrochemicals Co., Ltd.		1
Nissan Chemical America Corporation		3
Nissan Chemical Industries, Ltd.		1
Nisso America, Inc.		3
NOVA Chemicals Inc.	ACC	78
Noveon, Inc.	SOCMA	132
Occidental Chemical Corporation (OxyChem)	ACC, API	4
OMG Americas, Inc.	ACC	32
OmniSpecialty Corporation		2
Omnova Solutions Inc.	SOCMA	1
Ondeo Nalco Energy Services (ONES)		29
P. H. Glatfelter Company		1
Packaging Corporation of America (PCA)		37
Pariallel Products		1
PDV Midwest Refining, L.L.C.		409
Pelron Corporation	SOCMA	19
Pennzoil-Quaker State Company		392
Phillips Petroleum Company		386
Pilot Chemical Company	SOCMA	5
Placid Refining Company LLC		392
Plasmine Technology, Inc.		36
PMC Specialties Group, Inc.	SOCMA	9
Polarome International Incorporated		45
Port Townsend Paper Corporation		1
Potlatch Corporation		1
PPG Industries, Inc.	ACC, SOCMA	9
Praxair Inc	ACC, API	1
Premcor Refining & Marketing INC		392
Prime Materials & Supply Corp.		5
Pro-Corn, LLC		1
The Procter & Gamble Company	ACC	89
Proviron Fine Chemicals NV	SOCMA	1
PURAC America, Inc.		1
Quaker Chemical Corporation		47
Quest International		45

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
R. T. Vanderbilt Company, Inc.	ACC	37
Raisio Chemicals		36
Rayonier		37
Reichhold Inc.		2
Reilly Industries, Inc.	ACC	10
Resolution Performance Products LLC		32
Reynolds Metals Company		392
Rhein Chemie Corporation		59
Rhodia Inc.	ACC, SOCMA	216
Rhodia Organique Fine Limited	ACC, SOCMA	1
Riverwood International Corporation		37
Rohm and Haas Company	ACC	73
Rubicon Inc.		1
Rutgers Organics Corporation	SOCMA	2
Rutherford Chemicals LLC dba Nepera	ACC	9
Sabic Americas Inc.	ACC	1
Safety-Kleen Oil Recovery		392
Sand Creek Chemical Limited Partnership		1
Sartomer Company, Inc.	ACC	2
Sasol North America Inc.	ACC	499
Saturn Methanol Company, LLC		1
Schenectady International (SII)	ACC	18
Seaco, Inc.		5
Sensient Colors Inc.		5
Sensient Flavors Inc		45
Shell Chemical Company	ACC, API	74
Shell Chemicals Limited	ACC, API	1
Shell Oil Company	ACC, API	392
Shepherd Chemical Company	ACC	32
Shikoku Chemicals Corporation		3
ShinWon Corporation		1
Sid Richardson Gasoline Co		392
Silver Eagle Refining, Inc.		392
Sinclair Oil Corporation		392
Smurfit Stone Container Corp.		37
SNF Holding Company	ACC	3
Solutia	ACC	55
Solvay Advanced Polymers, Inc. (SAPI)	ACC, SOCMA	1
South Hampton Refining Co.		392

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Southern Chemical Corporation		1
SpecialtyChem Products Corporation		4
Specified Fuels & Chemicals, LLC		392
St. Laurent Paperboard Inc.		1
St. Marks Powder, Inc.		1
Star Enterprise		392
Stepan Company	ACC	95
Sterling Chemicals, Inc.		18
Stockhausen GmbH & Co. KG		2
Stora Enso North America (Formerly Consolidated Papers, Inc.)		1
Suit-Kote Corporation		5
Sumitomo Chemical America, Inc.	ACC, SOCMA	1
Sun Chemical Corporation	SOCMA	26
Sunoco, Inc. (R&M)	ACC	526
Sybron Chemicals Inc.		1
Symrise		45
Syngenta Crop Protection AG	SOCMA	1
Takasago International Corporation (USA)		1
Tecnal Corporation		45
Tejas Energy, LLC		392
Teknor Apex Company		22
Terra Industries		1
Tesoro Petroleum Companies, Inc.		392
Texaco Inc.	API	392
Texas Petrochemicals Corporation (TPC)		74
Thompson-McCully Oil Co.		36
Ticona LLC		2
Tomah3	ACC	46
Toray Fine Chemicals Co., Ltd.		1
Tosco Corporation		392
Trinidad and Tobago Methanol Company Limited (TTMC)		1
Troy Chemical Company	ACC	3
Troy Corporation	ACC	19
True Oil Company		392
U.S. Oil & Refining Co.		392
Ultramar Diamond Shamrock Corporation		392
Unilever Home & Personal Care - USA		48
Unique Paving Materials Corporation		36
Unitex Chemical Corporation	SOCMA	1

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Unocal Corporation	API	392
Valero Energy Corporation		392
Vance Brothers, Inc		36
VanDeMark Chemical Company Inc.		1
Velsicol Chemical Corporation		53
Vestal Asphalt, Inc.		36
Vulcan Chemicals	ACC	45
Vulcan Construction Materials, LP	ACC	5
W.R. Grace & Co.	ACC	13
Wacker Biochem Corporation	ACC, SOCMA	2
Wacker Silicones Corporation	ACC, SOCMA	1
Westlake Chemical Corporation		75
Weyerhaeuser Company		37
Whitaker Roads Corporation		36
Willamette Industries, Inc.		1
Williams Energy Services		393
Williams Ethanol Services, Inc. (and its affiliate Nebraska Energy LLC)		1
Williams Olefins, LLC (formerly Union Texas Petrochemicals Corporation)		74
Williams Refining, LLC		392
Wynnewood Refining Company		392
Zeneca Ag Products, Inc.		3
<u>Consortia</u>		
Akzo Nobel - Polymer Chemicals Business Group / PPG Industries, Inc.	ACC, SOCMA	1
Akzo Nobel - Polymer Chemicals Metal Alkyls / E.I. Du Pont de Nemours and Company	ACC	1
Albemarle Corporation / Ciba Specialty Chemicals Corporation - Additives	ACC, API, SOCMA	1
Alkyl Diphenyl Oxide Sulphonates (ADPOS)		5
Aluminum Alkyls Consortium		20
Ameribrom Inc. / Great Lakes Chemical Corporation	ACC, SOCMA	1
American Chemistry Council (ACC)		
Acetic Acid and Salts Panel	ACC	13
Acetylene HPV Consortium	ACC	1
Aliphatic Esters Panel	ACC	47
Benzoates Panel	ACC	1
Brominated Biocides Panel Dimethylhydantoin (DMH) Task Force	ACC	1
Brominated Flame Retardant Industry Panel (BFRIP)	ACC	3
Brominated Phthalates Panel	ACC	1
Diisocyanates (DIC) Panel	ACC	1

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Ethylbenzene Panel HPV Test Group	ACC	3
Fatty Nitrogen Derived (FND) Amides Panel	ACC	29
Fatty Nitrogen Derived (FND) Amines Panel	ACC	29
Fatty Nitrogen Derived (FND) Cationics Panel	ACC	13
Fatty Nitrogen Derived (FND) Nitriles Panel	ACC	17
Health, Environmental, and Research Task Group (HERTG)	ACC	59
Higher Olefins Panel	ACC	24
Hydroquinone Precursors & Derivatives Panel	ACC	4
Monocyclic Aromatic Amines and Nitro Aromatics (MAANA) Panel	ACC	5
Olefins Panel HPV Work Group	ACC	74
Oxo Process Panel	ACC	1
Phosgene Panel	ACC	1
Phthalate Esters (PE) Panel HPV Testing Group	ACC	21
Pyridine and Pyridine Derivatives HPV Work Group	ACC	9
Rubber and Plastics Additives (RAPA) Panel	ACC	34
Specialty Acrylates and Methacrylates (SAM) HPV Work Group	ACC	2
American Forest & Paper Association (AF&PA)		1
American Methanol Institute Testing Group (AMITG)		1
American Petroleum Institute (API) Petroleum HPV Testing Group	API	392
APAG		1
Aromatic Sulfonic Acids Association (ASAA)		2
Asphalt Emulsion Manufacturers Association (AEMA)		36
ATOFINA Chemicals, Inc. / Celanese Ltd.	ACC	1
ATOFINA Chemicals, Inc. / Chevron Phillips Chemicals, LP	ACC, SOCMA	1
Benzotriazoles Coalition		3
BPD/BPA Coalition		2
Cabot Corporation / Degussa AG / Wacker Silicones Corporation	ACC, SOCMA	1
Chlorobenzene Producers Association		4
Ciba Specialty Chemicals Corporation - Additives / Cytec Industries Inc.	ACC, API	1
Color Pigments Manufacturers Association, Inc. (CPMA)		25
Committee on HPV Challenge for Cyclohexanol		1
Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture		5
DADMAC HPV Committee		1
The DCB Coalition		1
Diethyl Ether Producers Association, Inc. (DEPA)		1
Dimethyl Sulfoxide (DMSO) Producers Association		1
Dioxolane Manufacturers Consortium		1
DMMP Consortium		1

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
The Dow Chemical Company / Solutia	ACC, API, SOCMA	1
E.I. du Pont de Nemours and Company / ExxonMobil Chemical Company / The Dow Chemical Company	ACC, API, SOCMA	1
E.I. du Pont de Nemours and Company / Solutia	ACC	6
Eastman Chemical Company / Solutia	ACC, SOCMA	3
Eastman Chemical Company / The Dow Chemical Company	ACC, API, SOCMA	1
ETAD North America Disperse Blue 79:1 Consortium		1
ETAD North America Stilbene Fluorescent Brighteners		8
Ethanol HPV Challenge Consortium		1
European Fluorocarbon Technical Committee		1
ExxonMobil Chemical Company / Resolution Performance Products LLC	ACC, API	1
Ferro Corporation / Ticona LLC	ACC, SOCMA	1
The Flavor and Fragrance High Production Volume Consortia (FFHPVC)		
Alicyclic Primary Alcohol/Aldehyde/Carboxylic Acid Consortium		1
Aromatic Consortium		13
Cyclohexyl Derivatives Consortium		1
Linear Aliphatic C7-C9 Alcohol/Aldehyde/Carboxylic Acid Consortium		3
Terpene Consortium		45
Great Lakes Chemical Corporation / Albemarle Corporation	ACC, API, SOCMA	2
Hexamethoxymethylmelamine (HMMM) Coalition		1
Huntsman-Nissan-TGIC Consortium		1
IHF Committee on HPV Challenge for Cyclic Acid Anhydrides		6
IHF Committee on Nylon 6 and Its Precursors		1
INDSPEC Chemical Corporation / Sumitomo Chemical America, Inc.	ACC, SOCMA	1
International Association of Color Manufacturers		5
Isocyanurate Industry Ad Hoc Committee (IIAHC)		3
LAB Sulfonic Acids Coalition		3
Lesser Ketones Manufacturing Association		1
The MBOCA Consortium		1
McConnaughay Technologies, Inc.		36
Metal Carboxylates Coalition		19
NMA/NBMA Association		2
Phenolic Benzotriazoles Association		4
Phosphite Producers HPV Consortium		4
Pine Chemicals Association (PCA) HPV Task Force		36
Propylene Carbonate / T-Butyl Alcohol HPV Committee		2
Quat HPV Challenge Task Force		2
The Soap and Detergent Association (SDA)		

Sponsoring Organization Name	Trade Association(s)	Number of Chemicals Sponsored
Linear Alkylbenzene Sulfonate/Alkyl Benzene Sulfonate (LAS/ABS) Consortium		6
Triclocarban (TCC) Consortium		1
Society of the Plastics Industry Inc. (SPI)		
Epoxy Resin Systems Task Group		2
Synthetic Organic Chemical Manufacturers Association (SOCMA)		
Biphenyl Work Group (BWG)	SOCMA	1
Dibasic Esters (DBE) Group	SOCMA	3
Isatoic Anhydride Coalition	SOCMA	1
Sulfosuccinates Group	SOCMA	3
Urea Resins Group	SOCMA	1
Thioesters Association		4
Toluenesulfonamide Testing Group		1
Trioxane Manufacturers Consortium		1
U.S. Nitroglycerin Producers Consortium (USNPC)		1

Companies and consortia sponsoring chemicals exclusively through the ICCA HPV Initiative are not included in these numbers. The record of ICCA commitments is supplied to the Agency by the American Chemistry Council.

Sponsored Chemicals

Throughout the course of the Program, the chemical lists have been annotated to reflect changes in the status of chemicals; for instance, whether the chemical has been determined to fall outside of the scope of the Program or if the chemical is sponsored through the ICCA HPV Initiative. Chemical lists are posted on EPA's website at http://www.epa.gov/chemrtk/volchall.htm.

Chemicals considered outside the scope of the Program include those: that were not HPV according to 1990 IUR information; for which it was determined that testing would not further our understanding of the chemicals' properties; chemicals sponsored under the OECD HPV SIDS Program; that are polymers or inorganics; or that are no longer considered high production volume. However, sponsorship of chemicals that fall outside the scope of the Program was permitted. In fact, 50 such chemicals have been sponsored. Many of these 50 chemicals were sponsored as a member of a category and many were already sponsored in the OECD HPV SIDS Program. Sponsorship of categories was encouraged under the HPV Challenge Program. Benefits of category sponsorships include:

- Economic savings, because less testing may be needed for category chemicals,
- Fewer animals are needed to test a category of chemicals as opposed to doing each test on each individual chemical, and
- Screening-level data on a larger number of chemicals may be provided to the public (by including chemicals beyond the scope of the Program).

Status of Chemical Sponsorship

At the HPV Challenge Program's start, 368 chemicals that would otherwise have been included in the Program fell outside the scope of the Program for the reasons described in the previous section. Removing chemicals from the scope of the Program left 2,414 chemicals available for sponsorship from the 1990 HPV Challenge Program Chemical List. Over the course of the Program, due to factors such as sponsorship of some of the 368 chemicals over time, the number of chemicals that fell outside the scope of the Program decreased to 352 chemicals.

The overall number of sponsored chemicals as of July 2004 as compared to the October 1998 launch of the

Program is remarkable. As of July 2004, EPA received commitments for 1,859 of the 2,782 chemicals on the 1990 HPV Challenge Program Chemical List. An additional 363 chemicals that were not on the List have also been sponsored, bringing the total number of sponsored chemicals to 2,222.

By July 2004, of the 2,782 chemicals on the 1990 HPV Challenge Program Chemical List, there were 571 chemicals left unsponsored. The Agency has further analyzed the high production volume status of the 571 chemicals, and, based upon the results, the number of chemicals still available for sponsorship decreased to 330. The Unsponsored Chemicals analysis presented later in this report provides a complete description of this analysis. In addition to the 1,859 sponsored

Detailed Status of 1990 HPV Challenge Program Chemical List

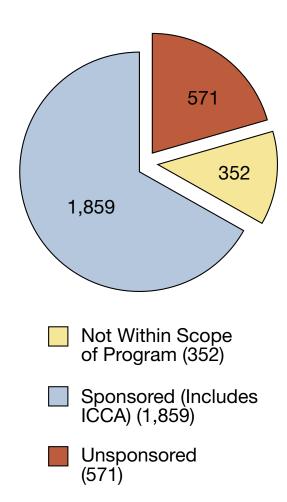
Chemicals on 1990 HPV Challenge Program Chemical List	# of Chemicals
Chemicals Removed from Scope of Program*:	
Testing Would Not Further Our Understanding	39
Sponsored under OECD HPV SIDS Program (and Not ICCA HPV Initiative)	190
Polymer or Inorganic	62
"No Longer HPV"	61
Total Removed*	352
Sponsored (includes chemicals sponsored under the ICCA HPV Initiative)	1,859
Unsponsored	571
Total	2782

^{*} Note that chemicals removed from the scope of the Program may fall into more than one classification. Additionally, chemicals sponsored that are not considered within the scope of the Program are included in the 1,859 count, often as members of a category; they are not removed.

chemicals and 571 orphan chemicals, 352 chemicals that would otherwise have been included in the Program are not considered within the scope of the HPV Challenge Program. The following table provides a detailed description of these chemicals that are considered outside the scope of the Program for the reasons described in the previous section.

The figure below illustrates the progress of chemical sponsorship in the Program.

Sponsorship Status of the 2,782 Chemicals on the 1990 HPV Challenge Program Chemical List (as of July 2004)

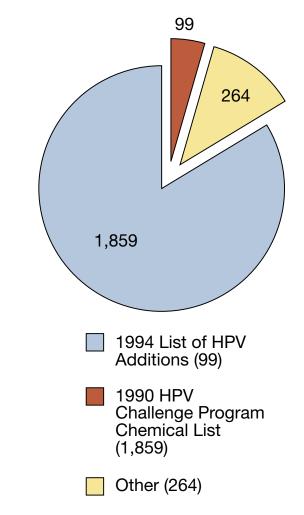


In addition to the 1,859 chemicals sponsored from the 1990 HPV Challenge Program Chemical List, an additional:

- 99 have been sponsored from the 1994 List of HPV Additions, and
- 264 have been sponsored that are not on either the 1990 HPV Challenge Program Chemical List or the 1994 List of HPV Additions.

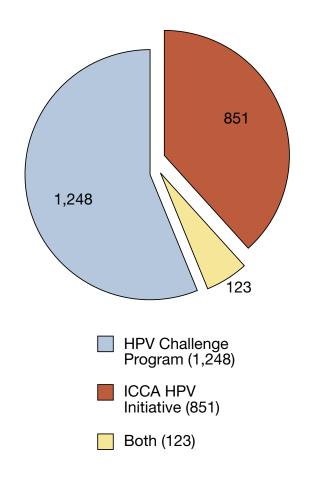
The Agency considers all of these 2,222 chemicals to be sponsored under the HPV Challenge Program. The figure below illustrates this distribution.

2,222 Chemicals Sponsored Within the HPV Challenge Program



Of these 2,222 chemicals for which commitments have been made, some are sponsored through the HPV Challenge Program and some are sponsored through the ICCA HPV Initiative. Note that 123 chemicals are sponsored both in the HPV Challenge Program and through the ICCA HPV Initiative (see the figure below).

Sponsorship Distribution Between HPV Challenge Program, ICCA HPV Initiative, and Both Programs



The sponsor of a chemical may or may not be the same in both programs. Additionally, a sponsor may have chosen to work through only one program, but has not officially informed EPA that the dual sponsorship status has changed. Until EPA is notified in writing by the sponsor stating that sponsorship has changed from one program to another, records will continue to show the chemical as sponsored under both programs.



Appendix 3: Overall HPV Challenge Program Achievements

t the onset of the HPV Challenge Program, EPA provided guidance documents to assist stakeholders in participating in the Program. As of July 2004, sponsors had submitted 353 test plans, covering 1,266 chemicals. Environmental protection and animal welfare groups have submitted the majority of public comments on these test plans.

As part of their commitment to the HPV Challenge Program, sponsors submit a test plan and robust summaries in a start year that they chose at the initial time of sponsorship. Sponsors submit test plans for either individual chemicals or for a category of chemicals. A chemical category is a group of related chemicals that lend themselves to evaluation and testing as a group. The chemicals can be grouped based on similarities in chemical structure or functionality. If testing is strategically planned, fewer than the full number of tests for each individual chemical will be necessary – thereby reducing testing costs, as well as often reducing the number of animals needed. Each chemical or category of chemicals will have a test plan that describes how the sponsor intends to fill data gaps. Test plans are submitted along with robust summaries of existing data. Testing will only be conducted when there are inadequate existing data or when other approaches (e.g. SAR) are not adequate to meet the need. EPA reviews the categories and makes suggestions as to how to improve them.

Guidance Documents

HPV Challenge Program guidance documents can be found on EPA's "Guidance Documents" webpage at http://www.epa.gov/chemrtk/guidocs.htm. Guidance is provided for subjects such as category formulation, developing robust summaries, and assessing data adequacy, to name a few. A number of EPA's guidance documents have achieved international acceptance through their incorporation in OECD guidance documents.

The following documents help stakeholders participate in the Program:

- 1. Revision of Two Toxicity Test Guidelines
- 2. Submissions of Exposure Information
- 3. Supplemental Acute Toxicity Protocol
- 4. Guidance on Developing Robust Summaries
- 5. Letters to Manufacturers/Importers Regarding
 Animal Welfare
- 6. The Use of Structure-Activity Relationships (SAR) in the HPV Challenge Program
- 7. Guidance on Searching for Chemical Information and Data
- Guidance on Confidentiality Claims Related to Company-Chemical Associations under the HPV Challenge Program

- 9. HPV Chemical Human Health Testing: Animal Welfare Issues and Approaches
- 10. Guidance for Assessing Adequacy of Existing
 Data
- 11. Guidance for Development of Chemical Categories in the HPV Challenge Program
- 12. Manual for Investigation of HPV Chemicals
- 13. Guidance for Testing Closed System
 Intermediates for the HPV Challenge Program
- 14. Procedures for Removing Chemicals that are No Longer HPV and are not Likely to Become HPV Again from the HPV List
- 15. Guidance for "What to Test " for the HPV Challenge Program
- 16. OECD SIDS Manual (this OECD guidance document links from the EPA website to the OECD website)

The guidance document on development of chemical categories provides guidance on approaches and issues encountered in category formation and application made to the HPV Challenge Program. The document offers advice on how companies could group chemicals with similar characteristics into categories, and then evaluate existing data and conduct testing to characterize the category – all without having to perform every test on every individual chemical. EPA's "Guidance on Developing Robust Summaries" document presents guidance on what technical information, on an endpoint-by-endpoint basis, is necessary to adequately describe a particular study. The term "robust summary" is used to describe this technical content. Robust study summaries are intended to provide sufficient information to allow a technically qualified person to make an independent

assessment of a given study report without having to go back to the full study report, and to also allow evaluation of the proposed test plan. A robust study summary therefore concisely reflects the objectives, methods, results, and conclusions of the full study report.

Submitted Test Plans

There were 353 total test plans submitted to the HPV Challenge Program as of July 2004. Of these 353 test plans, 114 were for categories of chemicals, and the remaining 239 were for individual chemicals. There were 1,266 submitted test plan chemicals, along with 621 submitted supporting chemicals that were used to augment the chemical analyses. The 114 category test plans average 9 chemicals per category.

Test Plan Comments

After test plans and robust summaries are submitted and then posted to the website, a 120-day comment period begins. It is at this time that all stakeholders — industry, environmental protection groups, animal welfare groups, private citizens, etc. — have the opportunity to make comments on the test plan and robust summary submissions. Comments are important because sponsors consider this feedback when revising their test plans and robust summaries. EPA comments on all test plans. All of the comments are posted to the website for public availability. As of July 2004, there were 350 test plans posted to the website. Of these 350 test plans:

11 test plans had not yet reached the end of the 120-day comment period.

- EPA commented on 290 test plans.
- Environmental Defense commented on 302 test plans.
- Animal welfare organizations People for the Ethical Treatment of Animals (PETA) and Physicians Committee for Responsible Medicine (PCRM) – commented on 210 test plans.
- Private individuals and other groups commented on 10 test plans.

Environmental Defense submitted comments on the majority (89%) of all posted test plans that had reached the end of the 120-day comment period. PETA and PCRM submitted comments on 62% of all test plans that had reached the end of the 120-day comment period. Note that these two animal welfare organizations are grouped together because they often jointly submit comments, as well as submit comments on behalf of other animal welfare organizations.

Comments from Environmental Defense often refer to whether they are in agreement with the sponsor's category hypothesis, use of supporting chemicals, estimations or Structure-Activity Relationships, proposed testing, and adequacy of submitted data. Comments from PETA and PCRM generally indicate whether they agree with the proposed test plan, and specifically in regard to whether animals will be used for testing purposes. These animal welfare organizations often state reasons for why testing should not be performed.

Test Plan and Data Submissions

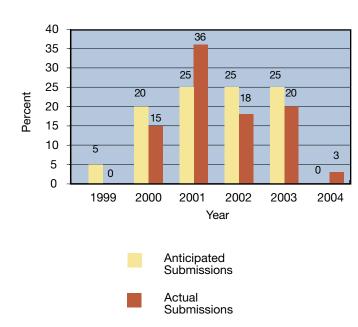
There are 1,371 chemicals that are sponsored in either the HPV Challenge Program alone (1,248) or together in both the HPV Challenge Program and the ICCA HPV Initiative (123). In order to evaluate the progress of the HPV Challenge Program, EPA analyzed the number of chemical sponsorships expected and received under the Program. For this section of the report, the Agency did not consider commitments made exclusively through the ICCA HPV Initiative (851) because the Agency does not expect to receive test plan and robust summary submissions for these submissions. Commitment goals are met for the ICCA HPV Initiative through the Organization for Economic Cooperation and Development's (OECD) HPV Screening Information Data Set (SIDS) Program.

Start Years

Sponsors establish chemical commitments by stating the "start year" in which they will begin participation in the HPV Challenge Program by submitting a test plan showing how it plans to fill data gaps and robust summaries of existing data. Complete submissions – of test plans and robust summaries, revisions, and results from new studies – are expected for all sponsored chemicals by the end of 2005. At the beginning of the Program, EPA envisioned that the receipt of test plans would spread out through the

years 1999 and 2003, with an anticipated breakdown of 5% of those test plans in 1999, 20% in 2000, and 25% through each of the years 2001-2003. The figure below illustrates the anticipated and actual test plan submissions.

Anticipated Test Plan Submission Year Versus Actual Test Plan Submission Year

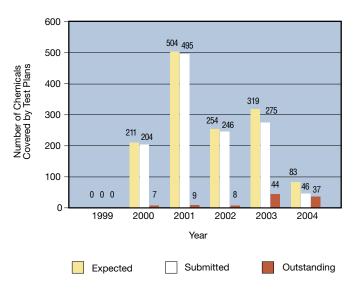


As shown above, 92% of all chemical commitments were actually met by July 2004. The remaining 8% of the commitments are expected to be met by the end of 2004.

Sponsors have notified EPA of changes in their start years. These changes in start year appear to result primarily from sponsors who experience problems in analysis, while many others experience coordination problems with fellow consortium members. While some sponsors submit their materials in an earlier year (thereby moving up their start year), most changes in

start year commitment occur when sponsors request a later start year. Hence, some of the chemical commitments expected prior to 2004 will be fulfilled in that year.

Number of HPV Sponsored Chemicals Included In Test Plans (as of July 2004)



The figure above displays when test plans have been submitted for sponsored chemicals, and the number of chemicals with outstanding test plans:

- Expected: 1,371 chemicals
- Submitted: 1,266 chemicals
- Outstanding: 105 chemicals

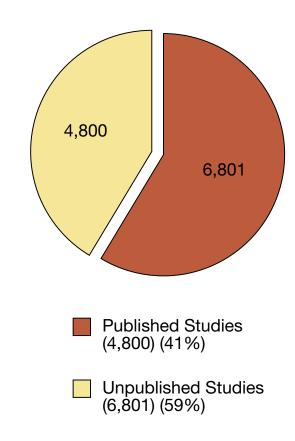
For recordkeeping purposes, if a sponsor submitted a test plan in a year that is later than their original start year, then their start year was changed to the year in which they actually submitted their materials. For example, EPA expected test plans covering 211 chemicals in 2000 and received 204 chemical analyses from those expected, leaving 7 outstanding chemicals that have not yet been submitted in subsequent years

- the start year for these chemicals will be changed to reflect the year in which actual submissions occur. As the chart reflects, the largest number of chemicals expected and received occurred in 2001, with 504 chemicals expected and 495 chemicals received. Since there are a total of 105 outstanding chemicals, it is anticipated that many of the sponsors of these chemicals will submit materials by the end of 2004. Sponsors of late chemicals have been notified that test plans and robust summaries for these chemicals have passed the start year to which the sponsor had committed.

Data Submitted to the HPV Challenge Program in Test Plans

As discussed earlier, the primary impetus for the HPV Challenge Program was the consistent results of reports from Environmental Defense, the American Chemistry Council, and EPA that publicly available hazard data were lacking on a majority of the 2,782 1990 HPV chemicals. Following EPA's guidance, sponsors identify existing data on HPV chemicals and submit these data in the form of robust summaries and test plans. To determine the source of existing data included in test plan submissions (that is, published and publicly available at some level, or unpublished data), each test plan posted on the HPV website, for which comments were due through June 2004, was examined – accounting for 344 test plans. This examination revealed that an extremely large amount of previously unavailable data has been submitted in test plans and robust summaries and is now publicly available. The figure to the right illustrates the number of studies that were published and unpublished.

Sources of Existing Data Submitted in Test Plans (as of June 2004)



The table on the following page shows the numbers of published and unpublished studies broken down by ecological and human health endpoints, and selected physicochemical and environmental fate endpoints; some endpoints are routinely determined with estimation techniques. The numbers of published and unpublished studies documented in the robust summaries prepared for each SIDS endpoint are listed.

Numbers of Published and Unpublished Sources of Existing Data, by Endpoint (as of June 2004)

Discipline Area	Specific Endpoint	<u>Published</u>	<u>Unpublished</u>	<u>Total</u>
Health Effects	Acute-Oral	357	864	1221
	Acute-Inhalation	138	346	484
	Acute-Dermal	101	472	573
	Repeat Dose	556	682	1238
	Gene Tox-In-Vitro	901	889	1790
	Gene Tox-In-Vivo	303	275	578
	Repro/Dev	459	431	890
	Subtotal	2815	3959	6774
Environmental Effects	Acute-Fish	223	639	862
	Acute-Daphnid	154	490	644
	Acute-Algae	94	312	406
	Subtotal	471	1441	1912
Environmental Fate	Biodegradation	308	590	898
	Subtotal	308	590	898
Physicochemical	Water Solubility	319	224	543
Properties	Vapor Pressure	278	221	499
	Partition Coefficient	183	189	372
	Boiling Point	426	177	603
	Subtotal	1206	811	2017
Totals		(41%) 4800	(59%) 6801	(100%) 11601

As can be seen from the numbers of studies listed in the above table, a significant amount of unpublished data has now been made public by the sponsors. This indicates that the sponsors, either individually or through the many consortia participating in the Program, have made a concerted effort to bring forth such existing data and represents a major success of the HPV Challenge Program. It also indicates that many sponsors made significant efforts to evaluate the hazards of their chemicals prior to the launch of the HPV Challenge Program, but often did not make those underlying data available to the public.

The submission of existing, unpublished data has had a significant effect on the amount of new testing that

sponsors have proposed (as discussed in the following section). When isolating the statistics for acute endpoints (for both health effects and environmental effects) from the table, it is seen that 75% of acute studies were unpublished. The 75% value greatly contrasts the 50% value for unpublished studies for all other endpoints and can possibly be explained by a previously lower interest in publishing acute studies.

Data Development Strategies Described in Test Plans

The following analysis is directly related to the above discussion and shows how sponsors have proposed to address the SIDS endpoints. EPA analyzed test plans for which comments were due through June 2004 to determine how the health and environmental effects endpoints were addressed. Three methods were available to meet the minimum data needs for each SIDS endpoint. Data needs were met by:

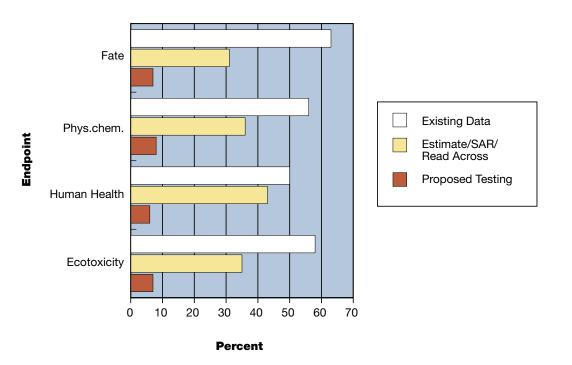
- Using existing scientifically adequate data,
- Using an estimation technique such as Structure Activity Relationship (SAR) or "read-across" categories, or
- Proposing new testing.

For human health effects, five endpoints (acute, repeat dose, reproductive, developmental, and genetic toxicity) were considered. For environmental effects, three acute toxicity endpoints were examined (acute toxicity to fish, daphnia, and algae). The 344 reviewed test plans address 112 categories and 232 single chemicals.

The figure below illustrates that sponsors have made maximum use of EPA's guidance concerning the

use of SAR and category proposals. Additionally, and in combination with the significant amount of unpublished data made available through the robust summaries, only a minimal amount of new testing has been proposed. Overall, for physicochemical and fate endpoints, as well as health and environmental effects, fewer than 10% of the endpoints are proposed to be addressed with new testing. The exact mix and number of new tests may change as sponsors consider EPA and public comments and the remainder of test plans is submitted; however, there is no reason to believe that the overall conclusions will change significantly. Comments could lead to some additional tests being performed, but could also result in fewer tests. Perhaps the most striking conclusion from these statistics and the illustration below is that most of the data existed, but were simply unpublished. Consistent with that conclusion is how relatively little new testing is being contemplated.

Endpoint Data Sources (as of June 2004)



Categories

One of the most significant results of the HPV Challenge Program has been the use of the category approach to address the SIDS endpoints. The category approach has led to the need to conduct far less testing than initially anticipated. As of July 2004, of the 353 submitted test plans, 114 contain category proposals covering 1,027 chemicals. These 1,027 chemicals represent 81% of the chemicals addressed by the test plans. EPA developed guidance on category formulation, and this guidance can be found on EPA's "Development of Chemical Categories in the HPV Challenge Program" webpage at http://www.epa.gov/chemrtk/categuid.htm.

There are three types of category proposals. The first type is referred to as a "traditional" category. A traditional category is a set of chemicals that share a similar functional group or cover a regular increase in chain length over the category. The second type of category is a "complex mixture family." The complex mixture family category contains chemicals from a complex mixture of similar chemical structures; e.g., long-chain fatty acids or tall oils. They are commonly structured around a manufacturing process where different products are created and differ only in the relative proportions of the structurally similar mixture components. The third type of category is a "process stream." A process stream category typically contains petroleum-related groupings, again based on a manufacturing process, except that in this type the mixture is composed of structurally different materials; e.g., paraffins, aromatics, or alicyclics.

Each of the three types of categories that are submitted to the HPV Challenge Program rely on a supporting hypothesis or underlying theory of how the chemicals are related and how data reported for one chemical can be used to predict the toxicological responses of similar chemicals in that category. The supporting category hypothesis varies by the category type. "Traditional" categories are usually premised on predictable increases or decreases in toxicity through the category members or, in the case of ecotoxicity, a change in the toxicity manifested as the physicochemical properties change; e.g., an increasing LogKow where the toxicity is likely to shift from acute to chronic toxicity. (LogKow is the octanol-water partition coefficient for a neutral molecule, and it is generally used as a relative indicator of the tendency of an organic compound to adsorb to soil.) For a "complex mixture family," the hypothesis is based on the assumption that because the complex mixtures are composed of similar components, the toxicity will be similar for the individual products in the category. Finally, for process stream categories, the hypothesis is usually that increasing or decreasing amounts of a particular component will determine the toxicity of the various category members; e.g., removal of the aromatic fraction as the petroleum stream is further processed will ultimately result in decreased toxicity.

While about 30 percent of the categories initially submitted by sponsors needed additional information or restructuring to support the category hypothesis (most have been revised by the sponsors), the significant result has been that a large number of chemicals were able to be characterized with a limited

amount of additional testing and within a time period significantly shorter than if a chemical-by-chemical approach to developing the needed data was used.

EPA's approach to the assessment of categories under the HPV Challenge Program has two principle steps. The first step is a review of the category test plan and supporting robust summaries. In this step, EPA comments on the reasonableness of the category hypothesis and the adequacy of the supporting data and any proposed testing. EPA's comments are sent to the sponsors at the end of the 120-day comment period. Sponsors revise their submissions based upon comments that they receive from the public and EPA.

The second step involves the sponsor's preparation and submission of the "Final Category Analysis" per the category guidance, which follows completion of any needed testing. The sponsor's analysis is used to indicate that the underlying category hypothesis is reasonable and that existing and new test data can be extrapolated to address the untested category chemicals' endpoints. EPA's review at this step would be either to agree with the analysis as presented or to advise the sponsor that EPA does not believe that the category "held." If a category does not hold, then EPA advises the sponsor that additional testing needs to be considered and/or the category needs restructuring, possibly with the need to subdivide the category or treat the category members as individual chemicals.

Accomplishments of the ICCA HPV Initiative

The International Council of Chemical Associations (ICCA) – as identified earlier in this report – has its

own initiative on international HPV chemicals and plays a role in the overall HPV Challenge Program. The ICCA HPV Initiative has evolved from interest regarding the OECD HPV SIDS Program, as well as other general concerns related to chemical testing and assessment on a global scale. The ICCA HPV Initiative calls for providing data on approximately 1,000 international high production volume chemicals by the end of 2004. The assessment work will be tied directly to the OECD HPV SIDS Program. Completed dossiers will be submitted to OECD so that a screening-level hazard assessment can be completed. OECD has been working to restructure its program to accelerate its process and handle the increased volume of data. More detail on OECD's process and program can be found at http://www.oecd. org/topic.

Comparison of the HPV Challenge Program and ICCA HPV Initiative

There is considerable consistency between the HPV Challenge Program and the ICCA HPV Initiative, as well as with the OECD HPV SIDS Program. All three programs:

- Are focused on HPV chemicals (note that HPV thresholds vary from the domestic to international programs);
- Are based on the OECD SIDS battery of testing;
- Include steps of data gathering, test plan development, and conducting SIDS testing as needed to provide a complete set of SIDS endpoints; and
- Allow the use of category approaches to group chemicals and the use of SAR analysis as an alternative to testing, where scientifically acceptable.

The OECD HPV SIDS Program and ICCA HPV Initiative also include the step of preparing the SIDS Initial Assessment Report (SIAR), which provides a screening-level assessment of chemical hazards. The submission of exposure data and the preparation of a SIAR are not elements for participation under the HPV Challenge Program, although EPA encourages industry to include these elements in their submissions under the Challenge. One additional notable difference between the HPV Challenge Program and the ICCA HPV Initiative is that of public accessibility of data. The HPV Challenge Program posts all test plan and robust summary submissions on the HPV Challenge Program website and includes a provision for receiving public comment; the ICCA HPV Initiative and the OECD HPV SIDS Program provide for comment within the country of sponsorship, and each country decides how broadly to share the data during the review stage. When completed, OECD HPV assessments are made available internationally through the United Nations Environment Programme (UNEP).

Companies willing to perform the additional work under these other programs (providing exposure data and preparing a SIAR) are welcome to identify their HPV Challenge Program chemicals as contributions to either or both of the OECD HPV SIDS Program and the ICCA HPV Initiative. Additionally, companies deciding to sponsor chemicals under the HPV Challenge Program were given the opportunity to identify those chemicals as U.S. contributions to the OECD HPV SIDS Program and/or the ICCA HPV Initiative.

Sponsorship Under the ICCA HPV Initiative

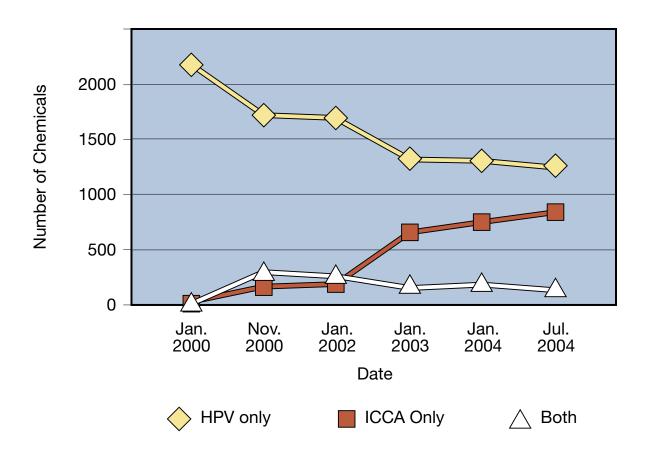
Official notification of ICCA commitments is received through ICCA's contact at the American Chemistry

Council. Some ICCA commitments are currently unconfirmed, and these "tentative" commitments have not been included in this analysis. Although chemicals sponsored through the ICCA HPV Initiative are considered as commitments to the HPV Challenge Program, the Agency did not include ICCA chemicals in its overdue test plan analysis. The Agency encourages ICCA to address those chemicals that are overdue within its own program and to more routinely, and in more detail and precision, update the Agency and the public about the current status of chemicals within the ICCA HPV Initiative.

In February of 2000, the HPV Challenge Program began to recognize commitments made to sponsor chemicals indirectly through the ICCA HPV Initiative. Since then, overall sponsorship under the HPV Challenge Program increased with the addition of chemicals sponsored through the HPV Challenge Program and through the ICCA HPV Initiative. In addition, some sponsors decided to modify how they complete their commitments for sponsorship, usually by moving from the HPV Challenge Program to the ICCA HPV Initiative.

The Agency did not track the specific movements of sponsors or chemicals from one program to another, but rather focused its tracking on overall sponsorship numbers. The figure below illustrates shifts in sponsorship over time among chemicals sponsored through the HPV Challenge Program, through the ICCA HPV Initiative, and those chemicals sponsored in both programs.

Changes in Sponsorship in the HPV Challenge Program, ICCA HPV Initiative, and Both Programs (as of July 2004)



As previously mentioned in this report, chemicals can be sponsored either directly through the HPV Challenge Program or indirectly through the ICCA HPV Initiative. At the beginning of the Program, all sponsorships were in the HPV Challenge Program, with none in the ICCA HPV Initiative. Over time, sponsorship in the ICCA HPV Initiative has increased while sponsorship in the HPV Challenge Program has decreased. It is important to note that the overall

number of sponsored chemicals (when including ICCA sponsorships) has increased. As of July 2004, a total of 1,248 chemicals had been sponsored through the HPV Challenge Program alone, 851 chemicals had been sponsored through the ICCA HPV Initiative alone, and 123 through both the HPV Challenge Program and the ICCA HPV Initiative. The following table details the number of chemicals in each program over time.

Details of Sponsorship in the HPV Challenge Program, ICCA HPV Initiative, and Both Programs (as of July 2004)

	HPV On	ly	ICCA Only		Both (HPV, ICCA)		
Date	Chemicals	% of Total	Chemicals	% of Total	Chemicals	% of Total	Total Chemicals
01/25/2000	2123	100.0	0	0.0	0	0.0	2123
06/16/2000	1815	86.9	70	3.4	204	9.8	2089
11/06/2000	1715	79.6	144	6.7	296	13.7	2155
05/21/2001	1713	79.6	155	7.2	285	13.2	2153
01/15/2002	1643	78.9	178	8.5	262	12.6	2083
07/12/2002	1417	64.1	491	22.2	302	13.7	2210
01/31/2003	1357	63.1	624	29.0	169	7.9	2150
07/18/2003	1321	61.0	664	30.7	179	8.3	2164
01/16/2004	1325	59.2	736	32.9	177	7.9	2238
07/30/2004	1248	56.2	851	38.3	123	5.5	2222

The number of chemicals that have moved from the HPV Challenge Program to ICCA HPV Initiative raises a concern because the data submitted under ICCA are not as readily publicly accessible – OECD makes final reports available through UNEP, but access is limited before this occurs.

Data Submitted Under the ICCA HPV Initiative

As a measure of progress within the ICCA HPV Initiative, the Agency has chosen to consider SIDS Initial Assessment Meeting (SIAM⁸) agendas as equivalent to submitting a test plan and robust summaries under the HPV Challenge Program;

in both cases, a full set of SIDS hazard data is ultimately provided. This was chosen as a measure because participation in the OECD process is part of participating in the ICCA HPV Initiative.

Using the SIAM agendas with ICCA chemicals, the table below illustrates progress of chemicals under the ICCA HPV Initiative. Note that this table reflects the start year given by ICCA and whether or not the chemical has been through a SIAM as of year-end 2003; it does not reflect the year in which the chemical actually went through a SIAM. That year may or may not be the same.

Of the 974 chemicals sponsored in the ICCA HPV Initiative, 229 chemicals had been through the OECD SIDS process by July 2004. This number accounts for 24% of the total ICCA commitments. It is important to point out that 123 chemicals are dually sponsored both directly in the HPV Challenge Program as well

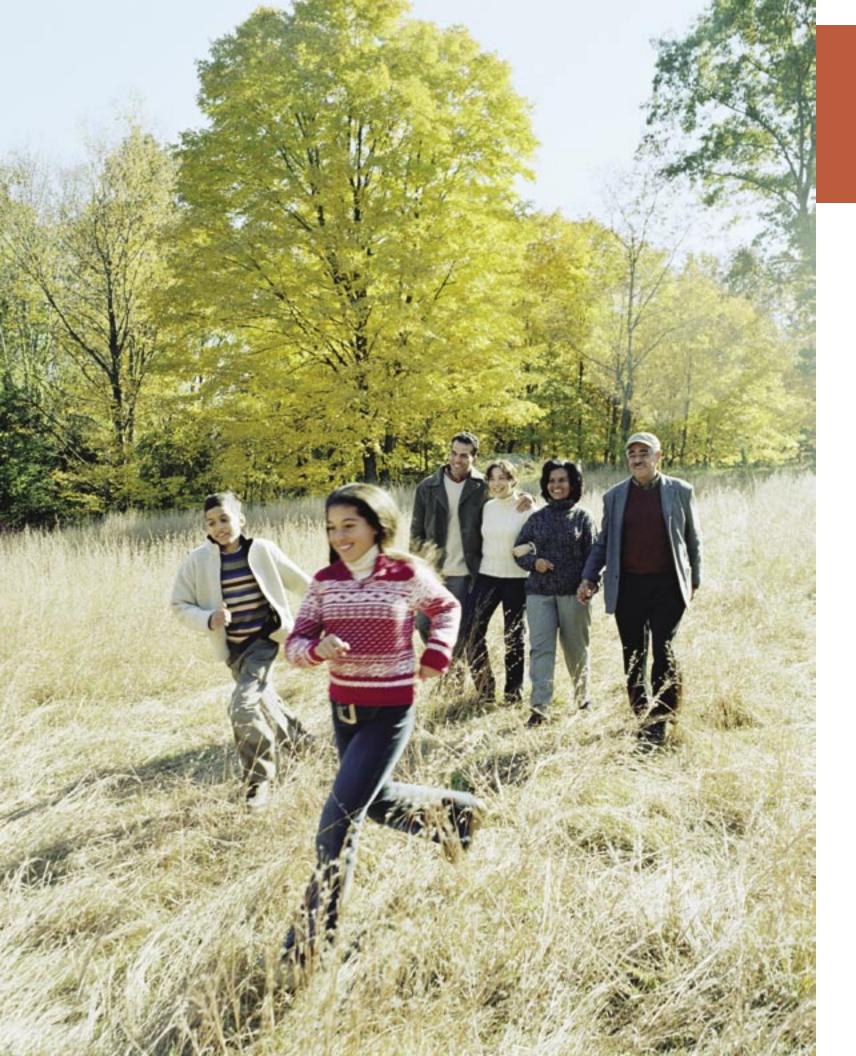
Status and Future Directions

as indirectly in the ICCA HPV Initiative. Earlier in this report, it was noted that 851 are sponsored in the ICCA HPV Initiative; however, when the 123 dually sponsored chemicals are considered, total ICCA HPV Initiative sponsorship increases to 974 chemicals.

Chemicals Sponsored Indirectly through the ICCA HPV Initiative (as of July 2004)

Start Year or Test Plan Receipt Year	Total Expected Chemical Submissions	SIAM Chemicals Sponsored by ICCA*
1999	38	14
2000	149	54
2001	487	98
2002	133	19
2003	127	17
2004	40	27
Total	974	229

^{*} This table does not reflect the year in which the chemical went through a SIAM.



Appendix 4: Overdue Test Plans



responsible for overdue test plans, the Agency reviewed commitment information submitted by companies and consortia. Correspondence concerning commitments is recorded and posted to EPA's "Summary Report" webpage at http://www.epa.gov/chemrtk/sumresp.htm, including correspondence from individual sponsors, consortia, consortium members, and from companies not participating in the Program. The Agency has received much correspondence from companies and consortia committing to sponsor chemicals, changing an aspect of their commitment, or in some cases, withdrawing their commitment.

The Agency developed an approach for determining overdue test plans and their sponsors, taking into

consideration HPV Challenge Program goals and the fact that there are cases of more than one sponsor for a given chemical. If a test plan were received, then the chemical's test plan was not considered overdue, regardless of whether another company or consortium had also sponsored it. If no test plan had been received for a particular chemical, then all consortia (but not their members) and independent sponsors of that chemical were considered to have an overdue test plan for that chemical.

The Agency sent the following letter to sponsors of chemicals with overdue test plans in April 2004.

Letter Sent to Sponsors with Overdue Test Plans in April 2004

April 12, 2004

Technical Contact Organization Name Organization Address City, State, Zip Code

Dear

I want to personally acknowledge and thank you for your commitment to the High Production Volume (HPV) Challenge Program. Participation in the HPV Challenge Program has exceeded EPA's expectations and, although the success of the program has been significant, there are a number of commitments that have not yet been met and are considered late. Preparations are underway for release of the HPV Challenge Program Status Report in May, 2004. The HPV Challenge Program Status Report will identify those sponsors whose commitments are overdue.

Our records indicate that your organization has sponsored the chemical(s) listed in the attached table for a start year of 2003 or earlier but robust summary and test plan information has not been received by the Agency. The commitment start year indicates the year of the Program in which sponsors agreed to begin the evaluation of each chemical by submitting robust summaries of existing data and a test plan showing how the sponsor plans to fill any data gaps. Under the HPV Challenge Program, all test plans and robust summary submissions should be submitted in the year indicated. Any needed new testing on the HPV chemicals in the HPV Challenge Program is to be completed by the end of 2004 with all data to be made available to the public by 2005. So that the Agency may meet its HPV Challenge Program's objectives, we are no longer accepting changes to start years and commitments not yet fulfilled are considered late.

While we are not accepting changes to start years, the Agency does expect sponsors to uphold their commitments and submit test plans and robust summaries as soon as possible. If no test plan/robust summary submission is received before the end of 2004 for these commitments, then the Agency will consider these chemicals as "orphans"—or unsponsored. Chemicals not voluntarily sponsored in the HPV Challenge Program will become candidates for test rules under Section 4 of the Toxic Substances Control Act (TSCA).

The Agency understands that over time, for a variety of reasons, sponsorship plans may change; however, it is incumbent upon sponsors of unmet commitments to update the Agency so that its records may accurately reflect the current commitment status. Information should be sent to:

Administrator
US Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attention: Chemical Right-to-Know Program

or through e-mail at: ncic_oppt@epa.gov and chem.rtk@epa.gov by April 30, 2004. Please note that any correspondence containing Confidential Business Information (CBI) should not be sent to the above address or through e-mail.

If you have any questions or concerns, please contact Karen Lannon of my staff at 202-564-8163. Thank you.

Sincerely,

Charles M. Auer, Director
Office of Pollution Prevention and Toxics

Attachment

EPA received responses from many of these sponsors updating the status of their commitments. Some intend to fulfill their commitments through the ICCA HPV Initiative; others have withdrawn from the Program; some have submitted test plans; and others still intend to fulfill their commitments through providing a test plan at a later date.

As of July 2004, test plan and robust summary submissions were overdue for 47 unique chemicals. Note that this reference to 47 chemicals contrasts the 270 outstanding Program chemicals from earlier in the report, as this 47 figure does not include: chemicals that were due in 2004, chemicals for which test plans

have most recently been submitted, withdrawals from the Program, and chemicals moving to the ICCA HPV Initiative, among other factors. One of the 47 chemicals has two sponsors; therefore, there are a total of 48 overdue sponsorship commitments. There are 24 sponsors (13 companies and 11 consortia) responsible for these 48 commitments. The Agency expects that sponsors will uphold their commitments and submit test plans and robust summaries. If no test plan or robust summary submission is received for overdue chemicals, then the Agency will ultimately consider these chemicals as unsponsored B or orphans. A complete listing of the 48 overdue chemical commitments is shown below.

Chemicals and Sponsors with Overdue Test Plans (as of July 2004)

{Trade association affiliation is noted for members of the following three trade associations: American Chemistry Council (ACC), American Petroleum Institute (API), and Synthetic Organic Chemical Manufacturers Association (SOCMA). The API member list, found at http://api-ec.api.org/links/index.cfm, was not a complete list.}

CAS#	Sponsor Name	Trade Association
110-03-2	Air Products and Chemicals, Inc.	ACC
142-30-3		
1163-19-5	American Chemistry Council (ACC) Brominated Flame Retardant Industry Panel (BFRIP)	ACC
298-07-7	American Chemistry Council (ACC) Health, Environmental, and Research Task Group (HERTG)	ACC
64771-72-8	American Petroleum Institute (API) Petroleum HPV Testing Group	API
68333-23-3		
112-18-5	APAG	
26040-51-7	BTBP Consortium	
100-50-5	The Dow Chemical Company	ACC, API, SOCMA
109-87-5		
630-20-6		
68390-96-5		
68411-72-3		
100-40-3	E.I. du Pont de Nemours and Company	
81-11-8	ETAD North America Stilbene Fluorescent Brighteners	
3709-43-1		
4404-43-7		

CAS#	Sponsor Name	Trade Association
7336-20-1		
13863-31-5		
16470-24-9		
29637-52-3		
67786-25-8		
100-40-3	ExxonMobil Chemical Company	ACC, API
108083-43-8		
98510-89-5	The Flavor and Fragrance High Production Volume Consortia (FFHPVC) Terpene Consortium	
96-49-1	Huntsman Corporation	
929-06-6		
2451-62-9	Huntsman-Nissan-TGIC Consortium	
74-87-3	ICI Americas, Inc.	
105-60-2	IHF Committee on Nylon 6 and Its Precursors	
25322-17-2	King Industries, Inc.	
25619-56-1		
57855-77-3		
63512-64-1		
101-14-4	The MBOCA Consortium	
13560-89-9	Occidental Chemical Corporation (OxyChem)	ACC
1809-19-4	Rhodia Inc.	ACC, SOCMA
143-29-3	Rohm and Haas Company	ACC
27090-63-7	Solutia	ACC
68052-49-3		
111960-92-0		
1333-07-9	Toluenesulfonamide Testing Group	
10605-21-7	Troy Chemical Company	
34375-28-5		
55406-53-6		
553-26-4	Zeneca Ag Products, Inc.	
620-22-4		
626-17-5		



Appendix 5: Orphan Chemicals

Program has been significant, some chemicals eligible for sponsorship in the Program remain unsponsored. As of July 30, 2004, there were 571 chemicals that were on the 1990 IUR HPV list that remained unsponsored in the Program. The Agency recognizes that the 1990 HPV Challenge Program Chemical List is based on IUR reporting from over a decade ago; hence, a number of unsponsored chemicals may no longer be manufactured or imported at high production volumes. In order to determine for which chemicals this may be true, the Agency conducted a comprehensive "No Longer HPV" analysis relying upon existing Program

guidance for determining that a chemical is "No Longer HPV." The "No Longer HPV" guidance may be found at http://www.epa.gov/chemrtk/nolohpv8. htm. Based on results of this analysis, the number of chemicals available for sponsorship decreased from approximately 571 to 330.

Strategies for Obtaining Data on Unsponsored Chemicals

The Agency is considering options to ensure that screening-level data are made available to the public for the 330 unsponsored, or "orphan," chemicals. These orphans are listed below.

330 Orphan Chemicals (as of July 30, 2004)

CAS#	TSCA Chemical Name
56-40-6	Glycine
62-23-7	Benzoic acid, 4-nitro-
62-56-6	Thiourea
74-95-3	Methane, dibromo-
74-97-5	Methane, bromochloro-
75-07-0	Acetaldehyde
75-34-3	Ethane, 1,1-dichloro-
75-36-5	Acetyl chloride
75-46-7	Methane, trifluoro-
75-87-6	Acetaldehyde, trichloro-
77-76-9	Propane, 2,2-dimethoxy-
78-11-5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester)
78-42-2	Phosphoric acid, tris(2-ethylhexyl) ester
81-07-2	1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide
81-16-3	1-Naphthalenesulfonic acid, 2-amino-
81-84-5	1H,3H-Naphtho[1,8-cd]pyran-1,3-dione
83-41-0	Benzene, 1,2-dimethyl-3-nitro-

CAS#	TSCA Chemical Name
84-65-1	9,10-Anthracenedione
84-69-5	1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester
85-40-5	
89-32-7	1H,3H-Benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone
90-43-7	[1,1'-Biphenyl]-2-ol
91-53-2	Quinoline, 6-ethoxy-1,2-dihydro-2,2,4-trimethyl-
91-68-9	Phenol, 3-(diethylamino)-
94-75-7	Acetic acid, (2,4-dichlorophenoxy)-
94-96-2	1,3-Hexanediol, 2-ethyl-
95-94-3	Benzene, 1,2,4,5-tetrachloro-
96-22-0	3-Pentanone
96-23-1	2-Propanol, 1,3-dichloro-
97-00-7	Benzene, 1-chloro-2,4-dinitro-
98-09-9	Benzenesulfonyl chloride
98-16-8	Benzenamine, 3-(trifluoromethyl)-
98-56-6	Benzene, 1-chloro-4-(trifluoromethyl)-
99-51-4	Benzene, 1,2-dimethyl-4-nitro-
100-64-1	Cyclohexanone, oxime
101-34-8	9-Octadecenoic acid, 12-(acetyloxy)-, 1,2,3-propanetriyl ester, (9Z,9'Z,9"Z,12R,12'R,12"R)-
104-15-4	Benzenesulfonic acid, 4-methyl-
104-66-5	Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis-
104-93-8	Benzene, 1-methoxy-4-methyl-
107-39-1	1-Pentene, 2,4,4-trimethyl-
	2-Pentene, 2,4,4-trimethyl-
107-45-9	2-Pentanamine, 2,4,4-trimethyl-
108-19-0	Imidodicarbonic diamide
	Propane, 2,2'-oxybis-
109-86-4	Ethanol, 2-methoxy-
110-18-9	1,2-Ethanediamine, N,N,N',N'-tetramethyl-
110-33-8	Hexanedioic acid, dihexyl ester
110-44-1	2,4-Hexadienoic acid, (2E,4E)-
111-44-4	Ethane, 1,1'-oxybis[2-chloro-
111-85-3	Octane, 1-chloro-
111-91-1	Ethane, 1,1'-[methylenebis(oxy)]bis[2-chloro-
112-52-7	Dodecane, 1-chloro-
118-82-1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)-
118-90-1	Benzoic acid, 2-methyl-
119-33-5	Phenol, 4-methyl-2-nitro-
119-61-9	Methanone, diphenyl-
121-45-9	Phosphorous acid, trimethyl ester
121-69-7	Benzenamine, N,N-dimethyl-

CAS#	TSCA Chemical Name
121-82-4	1,3,5-Triazine, hexahydro-1,3,5-trinitro-
124-18-5	Decane
124-63-0	Methanesulfonyl chloride
127-68-4	Benzenesulfonic acid, 3-nitro-, sodium salt
131-57-7	Methanone, (2-hydroxy-4-methoxyphenyl)phenyl-
137-20-2	Ethanesulfonic acid, 2-[methyl[(9Z)-1-oxo-9-octadecenyl]amino]-, sodium salt
138-25-0	1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester
139-40-2	1,3,5-Triazine-2,4-diamine, 6-chloro-N,N'-bis(1-methylethyl)-
140-08-9	Ethanol, 2-chloro-, phosphite (3:1)
140-93-2	Carbonodithioic acid, O-(1-methylethyl) ester, sodium salt
142-73-4	Glycine, N-(carboxymethyl)-
143-28-2	9-Octadecen-1-ol, (9Z)-
144-62-7	Ethanedioic acid
149-44-0	Methanesulfinic acid, hydroxy-, monosodium salt
150-50-5	Phosphorotrithious acid, tributyl ester
307-35-7	1-Octanesulfonyl fluoride, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-
330-54-1	Urea, N'-(3,4-dichlorophenyl)-N,N-dimethyl-
409-02-9	Heptenone, methyl-
460-00-4	Benzene, 1-bromo-4-fluoro-
506-51-4	1-Tetracosanol
506-52-5	1-Hexacosanol
513-74-6	Carbamodithioic acid, monoammonium salt
515-40-2	Benzene, (2-chloro-1,1-dimethylethyl)-
529-33-9	1-Naphthalenol, 1,2,3,4-tetrahydro-
529-34-0	1(2H)-Naphthalenone, 3,4-dihydro-
542-75-6	1-Propene, 1,3-dichloro-
542-92-7	1,3-Cyclopentadiene
557-61-9	1-Octacosanol
563-72-4	Ethanedioic acid, calcium salt (1:1)
579-66-8	Benzenamine, 2,6-diethyl-
590-19-2	1,2-Butadiene
592-45-0	1,4-Hexadiene
594-42-3	Methanesulfenyl chloride, trichloro-
597-31-9	Propanal, 3-hydroxy-2,2-dimethyl-
598-72-1	Propanoic acid, 2-bromo-
617-94-7	Benzenemethanol, .alpha.,.alphadimethyl-
624-83-9	Methane, isocyanato-
624-92-0	Disulfide, dimethyl
625-55-8	Formic acid, 1-methylethyl ester
628-13-7	Pyridine, hydrochloride
628-96-6	1,2-Ethanediol, dinitrate

CAS#	TSCA Chemical Name
629-59-4	Tetradecane
629-76-5	1-Pentadecanol
645-62-5	2-Hexenal, 2-ethyl-
693-07-2	Ethane, 1-chloro-2-(ethylthio)-
693-95-8	Thiazole, 4-methyl-
756-80-9	Phosphorodithioic acid, O,O-dimethyl ester
870-72-4	Methanesulfonic acid, hydroxy-, monosodium salt
928-72-3	Glycine, N-(carboxymethyl)-, disodium salt
939-97-9	Benzaldehyde, 4-(1,1-dimethylethyl)-
1000-82-4	Urea, (hydroxymethyl)-
1002-69-3	Decane, 1-chloro-
1111-78-0	Carbamic acid, monoammonium salt
1115-20-4	Propanoic acid, 3-hydroxy-2,2-dimethyl-, 3-hydroxy-2,2-dimethylpropyl ester
1323-65-5	Phenol, dinonyl-
1324-76-1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-
1401-55-4	Tannins
1445-45-0	Ethane, 1,1,1-trimethoxy-
1459-93-4	1,3-Benzenedicarboxylic acid, dimethyl ester
1498-51-7	Phosphorodichloridic acid, ethyl ester
1558-33-4	Silane, dichloro(chloromethyl)methyl-
1562-00-1	Ethanesulfonic acid, 2-hydroxy-, monosodium salt
1646-75-9	Propanal, 2-methyl-2-(methylthio)-, oxime
1691-99-2	1-Octanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-N-(2-hydroxyethyl)-
1738-25-6	Propanenitrile, 3-(dimethylamino)-
1912-24-9	1,3,5-Triazine-2,4-diamine, 6-chloro-N-ethyl-N'-(1-methylethyl)-
1918-02-1	2-Pyridinecarboxylic acid, 4-amino-3,5,6-trichloro-
1929-82-4	Pyridine, 2-chloro-6-(trichloromethyl)-
2152-64-9	Benzenamine, N-phenyl-4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]-, monohydrochloride
2210-79-9	Oxirane, [(2-methylphenoxy)methyl]-
2372-45-4	1-Butanol, sodium salt
2409-55-4	Phenol, 2-(1,1-dimethylethyl)-4-methyl-
2425-54-9	Tetradecane, 1-chloro-
2494-89-5	
2524-03-0	Phosphorochloridothioic acid, O,O-dimethyl ester
2524-04-1	Phosphorochloridothioic acid, O,O-diethyl ester
2611-00-9	3-Cyclohexene-1-carboxylic acid, 3-cyclohexen-1-ylmethyl ester
2691-41-0	1,3,5,7-Tetrazocine, octahydro-1,3,5,7-tetranitro-
2702-72-9	Acetic acid, (2,4-dichlorophenoxy)-, sodium salt
2814-20-2	4(1H)-Pyrimidinone, 6-methyl-2-(1-methylethyl)-
2905-62-6	Benzoyl chloride, 3,5-dichloro-

CAS#	TSCA Chemical Name
2915-53-9	2-Butenedioic acid (2Z)-, dioctyl ester
2941-64-2	Carbonochloridothioic acid, S-ethyl ester
3039-83-6	Ethenesulfonic acid, sodium salt
3088-31-1	Ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt
3132-99-8	Benzaldehyde, 3-bromo-
3338-24-7	Phosphorodithioic acid, O,O-diethyl ester, sodium salt
3386-33-2	Octadecane, 1-chloro-
3586-14-9	Benzene, 1-methyl-3-phenoxy-
3710-84-7	Ethanamine, N-ethyl-N-hydroxy-
3724-65-0	2-Butenoic acid
3779-63-3	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(6-isocyanatohexyl)-
3965-55-7	1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt
4035-89-6	Imidodicarbonic diamide, N,N',2-tris(6-isocyanatohexyl)-
4080-31-3	3,5,7-Triaza-1-azoniatricyclo[3.3.1.13,7]decane, 1-(3-chloro-2-propenyl)-, chloride
4170-30-3	2-Butenal
4300-97-4	Propanoyl chloride, 3-chloro-2,2-dimethyl- (This is not the official TSCA Chemical Name, since no official name is available for this CAS number.)
4316-73-8	Glycine, N-methyl-, monosodium salt
4719-04-4	1,3,5-Triazine-1,3,5(2H,4H,6H)-triethanol
4860-03-1	Hexadecane, 1-chloro-
5026-74-4	Oxiranemethanamine, N-[4-(oxiranylmethoxy)phenyl]-N-(oxiranylmethyl)-
5216-25-1	Benzene, 1-chloro-4-(trichloromethyl)-
5460-09-3	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-, monosodium salt
5915-41-3	1,3,5-Triazine-2,4-diamine, 6-chloro-N-(1,1-dimethylethyl)-N'-ethyl-
6381-77-7	D-erythro-Hex-2-enonic acid, .gammalactone, monosodium salt
6473-13-8	2-Naphthalenesulfonic acid, 6-[(2,4-diaminophenyl)azo]-3-[[4-[[7-[(2,4-diaminophenyl)azo]-1-hydroxy-3-sulfo-2-naphthalenyl]azo]phenyl]amino]-3-sulfophenyl]azo]-4-hydroxy-, trisodium salt
6863-58-7	Butane, 2,2'-oxybis-
6865-35-6	Octadecanoic acid, barium salt
7320-37-8	Oxirane, tetradecyl-
7446-81-3	2-Propenoic acid, sodium salt
7795-95-1	1-Octanesulfonyl chloride
8001-58-9	Creosote
8005-02-5	C.I. Solvent Black 7
8007-45-2	Tar, coal
10265-69-7	Glycine, N-phenyl-, monosodium salt
12645-31-7	Phosphoric acid, 2-ethylhexyl ester
13749-94-5	Ethanimidothioic acid, N-hydroxy-, methyl ester
13826-35-2	Benzenemethanol, 3-phenoxy-
14143-60-3	2-Pyridinecarbonitrile, 4-amino-3,5,6-trichloro-
14666-94-5	9-Octadecenoic acid (9Z)-, cobalt salt
16883-83-3	1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl)-3-(2-methyl-1-oxopropoxy)propyl phenylmethyl ester

CAS#	TSCA Chemical Name
17103-31-0	Urea, sulfate (2:1)
17321-47-0	Phosphoramidothioic acid, O,O-dimethyl ester
17976-43-1	2,4,6,8,3,5,7-Benzotetraoxatriplumbacycloundecin-3,5,7-triylidene, 1,9-dihydro-1,9-dioxo-
19438-61-0	1,3-Isobenzofurandione, 5-methyl-
19525-59-8	Glycine, N-phenyl-, monopotassium salt
20068-02-4	2-Butenenitrile, 2-methyl-, (2Z)-
20227-53-6	Phosphorous acid, 2-(1,1-dimethylethyl)-4-[1-[3-(1,1-dimethylethyl)-4-hydroxyphenyl]-1-methylethyl]phenyl bis(4-nonylphenyl) ester
20469-71-0	Hydrazinecarbodithioic acid, compd. with hydrazine (1:1)
21351-39-3	Urea, sulfate (1:1)
22527-63-5	Propanoic acid, 2-methyl-, 3-(benzoyloxy)-2,2,4-trimethylpentyl ester
24448-09-7	1-Octanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-N-(2-hydroxyethyl)-N-methyl-
24615-84-7	2-Propenoic acid, 2-carboxyethyl ester
24634-61-5	2,4-Hexadienoic acid, potassium salt, (2E,4E)-
24794-58-9	Formic acid, compd. with 2,2',2"-nitrilotris[ethanol] (1:1)
25154-38-5	Piperazineethanol
25168-05-2	Benzene, chloromethyl-
25168-06-3	Phenol, (1-methylethyl)-
25321-41-9	Benzenesulfonic acid, dimethyl-
25383-99-7	Octadecanoic acid, 2-(1-carboxyethoxy)-1-methyl-2-oxoethyl ester, sodium salt
25586-42-9	Phosphorous acid, tris(methylphenyl) ester
25646-71-3	Methanesulfonamide, N-[2-[(4-amino-3-methylphenyl)ethylamino]ethyl]-, sulfate (2:3)
26377-29-7	Phosphorodithioic acid, O,O-dimethyl ester, sodium salt
26401-27-4	Phosphorous acid, isooctyl diphenyl ester
26680-54-6	2,5-Furandione, dihydro-3-(octenyl)-
27193-28-8	Phenol, (1,1,3,3-tetramethylbutyl)-
28106-30-1	Benzene, ethenylethyl-
28188-24-1	Octadecanoic acid, 2-(hydroxymethyl)-2-[[(1-oxooctadecyl)oxy]methyl]-1,3-propanediyl ester
28777-98-2	2,5-Furandione, dihydro-3-(octadecenyl)-
28908-00-1	Benzothiazole, 2-[(chloromethyl)thio]-
30574-97-1	2-Butenenitrile, 2-methyl-, (2E)-
31138-65-5	D-gluco-Heptonic acid, monosodium salt, (2.xi.)-
32072-96-1	2,5-Furandione, 3-(hexadecenyl)dihydro-
32210-23-4	Cyclohexanol, 4-(1,1-dimethylethyl)-, acetate
33509-43-2	1,2,4-Triazin-5(2H)-one, 4-amino-6-(1,1-dimethylethyl)-3,4-dihydro-3-thioxo-
34689-46-8	Phenol, methyl-, sodium salt
35203-06-6	Benzenamine, 2-ethyl-6-methyl-N-methylene-
35203-08-8	Benzenamine, 2,6-diethyl-N-methylene-
37439-34-2	2(1H)-Pyridinone, 3,5,6-trichloro-, sodium salt
37734-45-5	Carbonochloridothioic acid, S-(phenylmethyl) ester
37764-25-3	Acetamide, 2,2-dichloro-N,N-di-2-propenyl-

CAS#	TSCA Chemical Name
38185-06-7	Benzenesulfonic acid, 4-chloro-3,5-dinitro-, potassium salt
38321-18-5	Ethanol, 2-(2-butoxyethoxy)-, sodium salt
39515-51-0	Benzaldehyde, 3-phenoxy-
40630-63-5	1-Octanesulfonyl fluoride
40876-98-0	Butanedioic acid, oxo-, diethyl ester, ion(1-), sodium
51632-16-7	Benzene, 1-(bromomethyl)-3-phenoxy-
52184-19-7	Phenol, 2,4-bis(1,1-dimethylpropyl)-6-[(2-nitrophenyl)azo]-
52556-42-0	1-Propanesulfonic acid, 2-hydroxy-3-(2-propenyloxy)-, monosodium salt
52663-57-7	Ethanol, 2-butoxy-, sodium salt
56038-89-2	Benzenamine, N-(1-ethylpropyl)-4,5-dimethyl- (This is not the official TSCA Chemical Name, since no official name is available for this CAS number.)
56803-37-3	Phosphoric acid, (1,1-dimethylethyl)phenyl diphenyl ester
57693-14-8	Chromate(3-), bis[3-(hydroxykappa.O)-4-[[2-(hydroxykappa.O)-1-naphthalenyl]azokappa.N1]-7-nitro-1-naphthalenesulfonato(3-)]-, trisodium
61788-76-9	Alkanes, chloro
61789-32-0	Fatty acids, coco, 2-sulfoethyl esters, sodium salts
61789-65-9	Resin acids and Rosin acids, aluminum salts
61789-85-3	Sulfonic acids, petroleum
63302-49-8	Phosphorochloridous acid, bis(4-nonylphenyl) ester
64742-24-1	Sludges, petroleum, acid
64743-02-8	Alkenes, C>10 .alpha
64743-03-9	Phenols, petroleum
64771-71-7	Paraffins, petroleum, normal C>10
65652-41-7	Phosphoric acid, bis[(1,1-dimethylethyl)phenyl] phenyl ester
65996-78-3	Light oil, coal, coke-oven
65996-79-4	Solvent naphtha, coal
65996-80-7	Ammonia liquor, coal
65996-81-8	Fuel gases, coke-oven
65996-82-9	Tar oils, coal
65996-83-0	Extracts, coal tar oil alk.
65996-86-3	Extract oils, coal, tar base
65996-87-4	Extract residues, coal, tar oil alk.
	Tar, coal, high-temp.
65996-91-0	Distillates, coal tar, upper
65996-92-1	Distillates, coal tar
66071-94-1	Corn, steep liquor
66241-11-0	C.I. Leuco Sulphur Black 1
68081-86-7	Phenol, nonyl derivs.
68082-78-0	Lard, oil, Me esters
68153-60-6	Fatty acids, tall-oil, reaction products with diethylenetriamine, acetates
68187-41-7	Phosphorodithioic acid, O,O-di-C1-14-alkyl esters
68187-57-5	Pitch, coal tar-petroleum

CAS#	TSCA Chemical Name
68187-59-7	Coal, anthracite, calcined
68187-76-8	Castor oil, sulfated, sodium salt
68187-84-8	Castor oil, oxidized
68188-18-1	Paraffin oils, chlorosulfonated, saponified
68308-74-7	Amides, tall-oil fatty, N,N-di-Me
68309-16-0	Fatty acids, tall-oil, 2-(2-hydroxyethoxy)ethyl esters
68309-27-3	Fatty acids, tall-oil, sulfonated, sodium salts
68334-01-0	Disulfides, alkylaryl dialkyl diaryl, petroleum refinery spent caustic oxidn. products
68441-66-7	Decanoic acid, mixed esters with dipentaerythritol, octanoic acid and valeric acid
68442-60-4	Acetaldehyde, reaction products with formaldehyde, by-products from
68442-77-3	2-Butenediamide, (2E)-, N,N'-bis[2-(4,5-dihydro-2-nortall-oil alkyl-1H-imidazol-1-yl)ethyl] derivs.
68476-80-2	Fats and Glyceridic oils, vegetable, deodorizer distillates
68478-20-6	Residues, petroleum, steam-cracked petroleum distillates cyclopentadiene conc., C4-cyclopentadiene-free
68479-98-1	Benzenediamine, ar,ar-diethyl-ar-methyl-
68511-40-0	1-Propanamine, 3-(tridecyloxy)-, branched
68512-63-0	Benzene, ethenyl-, distn. residues
68513-62-2	Disulfides, C5-12-alkyl
68514-41-0	Ketones, C12-branched
68515-89-9	Barium, carbonate nonylphenol complexes
68527-02-6	Alkenes, C12-24, chloro
68553-14-0	Hydrocarbons, C8-11
68584-25-8	Benzenesulfonic acid, C10-16-alkyl derivs., compds. with triethanolamine
68602-81-3	Distillates, hydrocarbon resin prodn. higher boiling
68603-84-9	Carboxylic acids, C5-9
68607-28-3	Quaternary ammonium compounds, (oxydi-2,1-ethanediyl)bis[coco alkyldimethyl, dichlorides
68608-59-3	Ethane, 1,2-dichloro-, manuf. of, by-products from, distn. lights
68609-04-1	Cyclohexane, oxidized, non-acidic by-products, distn. residues
68609-05-2	Cyclohexane, oxidized, non-acidic by-products, distn. lights
68610-90-2	2-Butenedioic acid (2E)-, di-C8-18-alkyl esters
68611-64-3	Urea, reaction products with formaldehyde
68647-60-9	Hydrocarbons, C>4
68649-42-3	Phosphorodithioic acid, O,O-di-C1-14-alkyl esters, zinc salts
68650-36-2	Aromatic hydrocarbons, C8, o-xylene-lean
68782-97-8	Distillates, petroleum, hydrofined lubricating-oil
68815-50-9	Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol
68909-77-3	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues
68915-05-9	Fatty acids, tall-oil, low-boiling, reaction products with ammonia-ethanolamine reaction by-products
68915-39-9	Cyclohexane, oxidized, aq. ext., sodium salt
68918-16-1	Tar, coal, dried and oxidized
68919-17-5	Hydrocarbons, C12-20, catalytic alkylation by-products
68920-64-9	Disulfides, di-C1-2-alkyl

CAS#	TSCA Chemical Name
68937-29-1	1,6-Hexanediol, distn. residues
68937-69-9	Carboxylic acids, C6-18 and C5-15-di-
68937-70-2	Carboxylic acids, C6-18 and C8-15-di-
68937-72-4	Carboxylic acids, di-, C4-11
68953-70-8	Oxirane, reaction products with ammonia, distn. residues
68953-80-0	Benzene, mixed with toluene, dealkylation product
68955-37-3	Acid chlorides, tallow, hydrogenated
68955-76-0	Aromatic hydrocarbons, C9-16, biphenyl derivrich
68955-96-4	Disulfides, dialkyl and di-Ph, naphtha sweetening
68987-41-7	Benzene, ethylenated
68987-66-6	Ethene, hydrated, by-products from
68988-22-7	1,4-Benzenedicarboxylic acid, dimethyl ester, manuf. of, by-products from
68988-99-8	Phenols, sodium salts, mixed with sulfur compounds, gasoline alk. scrubber residues
68990-61-4	Tar, coal, high-temp., high-solids
68990-65-8	Fats and Glyceridic oils, vegetable, reclaimed
69029-75-0	Oils, reclaimed
70024-67-8	Benzenesulfonic acid, C16-24-alkyl derivs.
70084-98-9	Terpenes and Terpenoids, C10-30, distn. residues
70693-50-4	Phenol, 2,4-bis(1-methyl-1-phenylethyl)-6-[(2-nitrophenyl)azo]-
70851-08-0	Amides, coco, N-[3-(dimethylamino)propyl], alkylation products with sodium 3-chloro-2-hydroxypropanesulfonate
71077-05-9	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine product tower residues
72162-28-8	2-Propanone, reaction products with phenol
72854-27-4	Tannins, reaction products with sodium bisulfite, sodium polysulfide and sodium sulfite
73665-18-6	Extract residues, coal, tar oil alk., naphthalene distn. residues
83864-02-2	Nickel, bis[(cyano-C)triphenylborato(1-)-N]bis(hexanedinitrile-N,N')-
84501-86-0	Hexanedioic acid, esters with high-boiling C6-10-alkene hydroformylation products
90640-80-5	Anthracene oil
90640-86-1	Distillates, coal tar, heavy oils
119345-02-7	Benzene, 1,1'-oxybis-, tetrapropylene derivs.
125997-20-8	Phosphoric acid, mixed 3-bromo-2,2-dimethylpropyl and 2-bromoethyl and 2-chloroethyl esters

The following table shows the orphan manufacturers of which EPA is aware and that can be made public without compromising confidential business information.

Manufacturers of 1990 HPV Orphan Chemicals Based on 1990, 1998, and 2002 IUR Reporting

{EPA is not permitted to refer to Confidential Business Information (CBI) claims for these chemicals in a public context. Only 296 of the 330 previously identified orphans have a non-CBI manufacturer in 1990; therefore, this table contains 296 -- and not 330 -- CAS numbers. An asterisk in the "1998 Manufacturer" or the "2002 Manufacturer" column indicates that the company in the "1990 Manufacturer" column produced the chemical during that year. Trade association affiliation is noted for members of the following three trade associations: American Chemistry Council (ACC), American Petroleum Institute (API), and Synthetic Organic Chemical Manufacturers Association (SOCMA). Lists of ACC and SOCMA member companies were found on their web sites. A member company list for API is not available on its website; however, a list of links to API member companies is available at http://api-ec.api.org/links/index.cfm, and was used in this analysis to identify known API member companies -- it is not a complete list.}

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
56-40-6	CHATTEM CHEMICALS	*	*	
30-40-0	NAGASE AMERICA CORPORATION			
62-23-7	EI DUPONT DE NEMOURS & CO INC			ACC
	ACETO CHEMICAL COMPANY INC			SOCMA
	HOECHST CELANESE			
	MITSUI & CO (USA) INC			ACC, SOCMA
62-56-6	SAKAI TRADING NEW YORK INC	*	*	
	SKW CHEMICALS INC	*		
	TOMEN AMERICA INC			
	WEGO CHEMICAL & MINERAL CORPORATION			
74-95-3	AMERIBROM INC	*	*	SOCMA
74-33-3	ETHYL CORPORATION - HEALTH SAFETY AND			
74-97-5	AMERIBROM INC	*	*	SOCMA
74-97-5	ETHYL CORPORATION - HEALTH SAFETY AND			
	EI DUPONT DE NEMOURS & CO INC			ACC
75-07-0	HOECHST CELANESE			
	UNION CARBIDE CORPORATION			
	DOW CHEMICAL USA	*	*	ACC, API, SOCMA
75-34-3	GEORGIA-PACIFIC CORPORATION			
	ICI AMERICAS INC			
75-36-5	DELTECH CORPORATION			SOCMA
	ETHYL CORPORATION - HEALTH SAFETY AND			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	HOECHST CELANESE			
75-46-7	EI DUPONT DE NEMOURS & CO INC	*	*	ACC
75-87-6	ENIMONT AMERICA INC			
77-76-9	NOR-AM CHEMICAL COMPANY			
78-11-5	EI DUPONT DE NEMOURS & CO INC			ACC
	ENSIGN-BICKFORD COMPANY		*	
	TROJAN CORPORATION			
78-42-2	ALBRIGHT & WILSON INC			
70 42 2	MOBAY CHEMICAL CORPORATION			
81-07-2	MITSUI & CO (USA) INC	*		ACC, SOCMA
0.0.2	PMC SPECIALTIES GROUP INC			SOCMA
	BASF CORPORATION			ACC, SOCMA
	BIDDLE SAWYER CORPORATION			SOCMA
81-16-3	DIC AMERICAS INC			
0.100	ENIMONT AMERICA INC			
	MOBAY CHEMICAL CORPORATION			
	SUMITOMO CORPORATION OF AMERICA	*	*	
81-84-5	MOBAY CHEMICAL CORPORATION			
	RUETGERS-NEASE			
83-41-0	AMERICAN CYANAMID CO AGRI PRODS RES			
	EI DUPONT DE NEMOURS & CO INC			ACC
	ICI AMERICAS INC	*		
84-65-1	MITSUI & CO (USA) INC			ACC, SOCMA
	MOBAY CHEMICAL CORPORATION			
84-69-5	HULS AMERICA INC			
0.000	UNITEX CHEM CORP	*	*	
85-40-5	ICI AMERICAS INC			
89-32-7	EI DUPONT DE NEMOURS & CO INC	*	*	ACC
00 0 <u>L</u> -1	HULS AMERICA INC			
90-43-7	DOW CHEMICAL USA	*	*	ACC, API, SOCMA

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
91-53-2	MONSANTO COMPANY			ACC
	BASF CORPORATION	*		ACC, SOCMA
91-68-9	HILTON-DAVIS CHEMICAL COMPANY			
	SUMITOMO CORPORATION OF AMERICA	*		
94-75-7	DOW CHEMICAL USA	*	*	ACC, API, SOCMA
	HULS AMERICA INC			
94-96-2	QO CHEMICALS INC			
	UNION CARBIDE CHEMICALS & PLASTICS CO			
95-94-3	STANDARD CHLORINE OF DELAWARE INC	*		
96-22-0	BP CHEMICALS AMERICA INCORPORATED			ACC, API
30 22 0	UNION CARBIDE CHEMICALS & PLASTICS CO	*		
96-23-1	ARSYNCO			
30 20 1	DOW CHEMICAL USA	*		ACC, API, SOCMA
97-00-7	HOECHST CELANESE			
	ICI AMERICAS INC			
98-09-9	MTM HARDWICKE INC			
	SLOSS INDUSTRIES CORPORATION	*		SOCMA
	ELI LILLY AND COMPANY			ACC
98-16-8	HOECHST CELANESE			
	SANDOZ COLORS & CHEMICALS			
98-56-6	OCCIDENTAL CHEMICAL CORPORATION	*		ACC, API
99-51-4	AMERICAN CYANAMID CO AGRI PRODS RES			
3001	EI DUPONT DE NEMOURS & CO INC			ACC
100-64-1	DSM CHEMICALS NORTH AMERICA INC	*	*	
101-34-8	CASCHEM INC	*	*	
104-15-4	ACETO CHEMICAL COMPANY INC	*		SOCMA
	BIDDLE SAWYER CORPORATION			SOCMA
	CI SPECIALITY CHEMICALS INC			SOCMA
	CAPITAL RESIN CORPORATION	*	*	
	CL INDUSTRIES INC			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	INTERNATIONAL FLAVORS AND FRAGRANCES IN			
	RUETGERS-NEASE		*	SOCMA
	SLOSS INDUSTRIES CORPORATION	*		SOCMA
104-66-5	KOCH CHEMICAL COMPANY			
	FRAGRANCE RESOURCES INC			
104-93-8	GIVAUDAN CORPORATION			
	KOCH CHEMICAL COMPANY			
107-39-1	NISSHO IWAI AMERICAN CORPORATION	*		
107-33-1	TEXAS PETROCHEMICALS CORPORATION	*		
107-40-4	TEXAS PETROCHEMICALS CORPORATION	*		
107-45-9	HALTERMANN LTD			
107-43-3	ROHM AND HAAS COMPANY	*	*	ACC
108-19-0	ARCADIAN CORPORATION			
100 10 0	CF INDUSTRIES INC	*	*	
	EXXON CHEMICAL COMPANY	*	*	ACC, API
108-20-3	SHELL OIL COMPANY	*	*	ACC, API
	UNION CARBIDE CORPORATION			
	BASF CORPORATION			ACC, SOCMA
	CAPE INDUSTRIES			
	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*		ACC, API
109-86-4	DOW CHEMICAL USA		*	ACC, API, SOCMA
100 00 4	MONTANA REFINING COMPANY			
	OCCIDENTAL CHEMICAL CORPORATION			ACC, API
	OLIN CORPORATION	*	*	ACC
	UNION CARBIDE CORPORATION			
110-33-8	MONSANTO COMPANY			
	HOECHST CELANESE			
110-44-1	MITSUI & CO (USA) INC	*	*	ACC, SOCMA
	MONSANTO COMPANY			ACC
	TOMEN AMERICA INC	*	*	

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
111-44-4	ET HORN COMPANY	*	*	
111-44-4	OCCIDENTAL CHEMICAL CORPORATION			ACC, API
	HULS AMERICA INC			
111-85-3	LONZA INCORPORATED	*	*	
	NEVILLE CHEMICAL COMPANY			
	HULS AMERICA INC			
112-52-7	LONZA INCORPORATED	*	*	
	NEVILLE CHEMICAL COMPANY			
118-82-1	ETHYL CORPORATION - HEALTH SAFETY AND			
118-90-1	CHUGAI BOYEKI CORP	*		
110-90-1	MOBAY CHEMICAL CORPORATION			
119-33-5	PMC SPECIALTIES GROUP INC	*		SOCMA
	ACETO CHEMICAL COMPANY INC	*		SOCMA
119-61-9	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*	*	ACC, API
119-01-9	HAARMANN & REIMER CORPORATION			
	THE UPJOHN COMPANY			
121-45-9	ALBRIGHT & WILSON INC			
121-45-9	ICI AMERICAS INC			
121-69-7	D&O CHEMICALS INC			
121-82-4	HOLSTON ARMY AMMUNITION PLANT	*		
	ENIMONT AMERICA INC			
	EXXON CHEMICAL COMPANY			ACC, API
124-18-5	HUMPHREY CHEMICAL COMPANY			
124-10-5	SHELL OIL COMPANY			ACC, API
	STERLING DRUG INC	*	*	
	VISTA CHEMICAL CO			
124-63-0	ATOCHEM INC POLYMER DIVISION			
	ACETO CHEMICAL COMPANY INC			SOCMA
127-68-4	BASF CORPORATION	*	*	ACC, SOCMA
	CROWN METRO INC			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	ACETO CHEMICAL COMPANY INC	*		SOCMA
131-57-7	BASF CORPORATION			ACC, SOCMA
	HOECHST CELANESE			
	NEVILLE CHEMICAL COMPANY			
137-20-2	GAF CHEMICALS CORPORATION			
107-20-2	HOECHST CELANESE			
138-25-0	EI DUPONT DE NEMOURS & CO INC	*		ACC
139-40-2	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS			ACC, API
140-08-9	ALBRIGHT & WILSON INC			
140-00-9	OLIN CORPORATION			ACC
140-93-2	AMERICAN CYANAMID CO AGRI PRODS RES			
	CASCHEM INC			
143-28-2	JARCHEM INDUSTRIES INC	*	*	
140-20-2	M MICHEL AND CO INC			
	SHEREX CHEMICAL COMPANY INC			
	ALLOYCHEM INC			
	BROWNING CHEMICAL CORP	*		
	CI SPECIALITY CHEMICALS INC			
	CALABRIAN CORPORATION			
	DOW CHEMICAL USA			ACC, API, SOCMA
144-62-7	EI DUPONT DE NEMOURS & CO INC	*		ACC
144 02 7	MARUBENI AMERICA CORPORATION			
	MITSUBISHI CHEMICAL INDUSTRIES AM INC			
	MITSUI & CO (USA) INC			ACC, SOCMA
	SAKAI TRADING NEW YORK INC			
	VELCO ENTERPRISES LTD			
	WEGO CHEMICAL & MINERAL CORPORATION			
149-44-0	ACETO CHEMICAL COMPANY INC	*		SOCMA
143-44-0	AMERIPOL SYNPOL COMPANY			
307-35-7	3M	*	*	ACC

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
330-54-1	MARUBENI AMERICA CORPORATION			
330-34-1	THOR CHEMICALS INC			
409-02-9	EXXON CHEMICAL COMPANY	*	*	ACC, API
403-02-3	INTERNATIONAL FLAVORS AND FRAGRANCES IN			
	DIAZ CHEMICAL CORPORATION	*	*	
460-00-4	HOECHST CELANESE			
	RHONE POULENC INCORPORATED			
506-51-4	VISTA CHEMICAL CO	*		
506-52-5	VISTA CHEMICAL CO	*		
513-74-6	MERCK AND COMPANY INC			
515-40-2	MTM HARDWICKE INC	*		
529-33-9	RHONE POULENC INCORPORATED			
529-34-0	RHONE POULENC INCORPORATED			
542-75-6	DOW CHEMICAL USA	*	*	ACC, API, SOCMA
342-73-0	SHELL OIL COMPANY	*		ACC, API
542-92-7	NAGASE AMERICA CORPORATION			
342-92-1	VELSICOL CHEMICAL CORPORATION	*	*	
557-61-9	VISTA CHEMICAL CO	*		
563-72-4	EXXON CHEMICAL COMPANY	*		ACC, API
579-66-8	ETHYL CORPORATION - HEALTH SAFETY AND			
590-19-2	EXXON CHEMICAL COMPANY	*	*	ACC, API
390-19-2	VISTA CHEMICAL CO	*		
592-45-0	EI DUPONT DE NEMOURS & CO INC	*		ACC
594-42-3	ICI AMERICAS INC			
617.04.7	HERCULES INCORPORATED	*		
617-94-7	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
624-83-9	RHONE POULENC INCORPORATED			
624-92-0	ATOCHEM INC POLYMER DIVISION			
628-13-7	RHONE POULENC INCORPORATED			
628-96-6	ICI EXPLOSIVES USA INC			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	IRECO INC			
629-59-4	SHELL OIL COMPANY	*		ACC, API
029-39-4	VISTA CHEMICAL CO	*		
629-76-5	SHELL OIL COMPANY		*	ACC, API
645-62-5	UNION CARBIDE CORPORATION	*		
693-95-8	MERCK AND COMPANY INC			
756-80-9	ICI AMERICAS INC			
	AGFA			
	EI DUPONT DE NEMOURS & CO INC			ACC
	EASTMAN KODAK COMPANY	*	*	ACC
	FUJI HUNT PHOTOGRAPHIC CHEMICAL INC			SOCMA
870-72-4	HICKSON & WELCH LIMITED			
	HIGH POINT CHEMICAL CORPORATION			
	HOECHST CELANESE			
	KONICA ROYAL COPIERS	*		
	MOBAY CHEMICAL CORPORATION			
928-72-3	MONSANTO COMPANY	*	*	ACC
	FRAGRANCE RESOURCES INC			
939-97-9	GIVAUDAN CORPORATION			
	INTERNATIONAL FLAVORS AND FRAGRANCES IN			
	AURALUX CORPORATION			
1000-82-4	BASF CORPORATION	*	*	ACC, SOCMA
	DYNO POLYMERS INCORPORATED			
1002-69-3	LONZA INCORPORATED	*	*	
1111-78-0	ARCADIAN CORPORATION			
	CF INDUSTRIES INC	*	*	
1115-20-4	BASF CORPORATION	*	*	ACC, SOCMA
	UNION CARBIDE CHEMICALS & PLASTICS CO			
1323-65-5	MONSANTO COMPANY			ACC
	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
1324-76-1	HOECHST CELANESE			
1324-70-1	PMC SPECIALTIES GROUP INC			SOCMA
	ACETO CHEMICAL COMPANY INC	*		SOCMA
1401-55-4	CROMPTON & KNOWLES COLORS INCORPORATED			
	MALLINCKRODT			
	THE SIEFLOR CORPORATION			
1445-45-0	HULS AMERICA INC			
	HOECHST CELANESE	*		
1459-93-4	MORFLEX CHEMICAL COMPANY INC			
	UNITEX CHEM CORP	*		
1498-51-7	RHONE POULENC INCORPORATED	*		
1558-33-4	EI DUPONT DE NEMOURS & CO INC	*		ACC
	GAF CHEMICALS CORPORATION			
1562-00-1	HENKEL CORPORATION			
	RHONE POULENC INCORPORATED			
1646-75-9	ALLIED-SIGNAL INC	*		
1691-99-2	зм	*	*	ACC
1738-25-6	AIR PRODUCTS AND CHEMICALS INC	*	*	ACC
1700 20 0	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
1912-24-9	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS			ACC, API
1012 24 0	MARUBENI AMERICA CORPORATION			
1929-82-4	DOW CHEMICAL USA	*	*	ACC, API, SOCMA
2152-64-9	PMC SPECIALTIES GROUP INC			SOCMA
	CL INDUSTRIES INC			
2210-79-9	KOCH CHEMICAL COMPANY			
2210-73-3	RHONE POULENC INCORPORATED			
	SHEREX CHEMICAL COMPANY INC			
2372-45-4	FMC COMPANY	*		
2409-55-4	PMC SPECIALTIES GROUP INC	*		SOCMA
2-00-00-4	RHONE POULENC INCORPORATED			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
2425-54-9	LONZA INCORPORATED	*	*	
	ACETO CHEMICAL COMPANY INC	*		SOCMA
	BIDDLE SAWYER CORPORATION			SOCMA
2494-89-5	CROMPTON & KNOWLES COLORS INCORPORATED			
	HOECHST CELANESE	*		
	MITSUI & CO (USA) INC			ACC, SOCMA
2524-03-0	ICI AMERICAS INC			
2524-04-1	ETHYL CORPORATION - HEALTH SAFETY AND			
2024-04-1	ICI AMERICAS INC			
2611-00-9	UNION CARBIDE CORPORATION			
2691-41-0	HOLSTON ARMY AMMUNITION PLANT	*		
2702-72-9	DOW CHEMICAL USA		*	ACC, API, SOCMA
2814-20-2	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*	*	ACC, API
2905-62-6	OCCIDENTAL CHEMICAL CORPORATION	*	*	ACC, API
	ARISTECH CHEMICAL CORPORATION			
2915-53-9	MANUFACTURERS SOAP & CHEMICAL CO INC			
2010 00 0	NATIONAL STARCH AND CHEMICAL CORPORATION			
	TEXTILE RUBBER & CHEMICAL COMPANY			
2941-64-2	ICI AMERICAS INC			
3039-83-6	AIR PRODUCTS AND CHEMICALS INC	*	*	ACC
3088-31-1	LONZA INCORPORATED	*		
3132-99-8	MTM HARDWICKE INC	*		
3386-33-2	LONZA INCORPORATED	*	*	
3586-14-9	MERICHEM COMPANY	*		ACC, API
0000 14 0	MTM HARDWICKE INC	*		
3710-84-7	ATOCHEM INC POLYMER DIVISION			
3779-63-3	BASF CORPORATION			ACC, SOCMA
5.70 00-0	RHONE POULENC INCORPORATED			
3965-55-7	EI DUPONT DE NEMOURS & CO INC	*	*	ACC
4035-89-6	RHONE POULENC INCORPORATED			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
4080-31-3	DOW CHEMICAL USA			ACC, API, SOCMA
4300-97-4	PPG INDUSTRIES INC			ACC, SOCMA
	ECOLAB INC			
4719-04-4	QUAKER CHEMICAL CORPORATION			
	STEPAN CHEMICAL COMPANY			
4860-03-1	LONZA INCORPORATED	*	*	
5026-74-4	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*		ACC, API
5216-25-1	OCCIDENTAL CHEMICAL CORPORATION	*		ACC, API
	ACETO CHEMICAL COMPANY INC	*		SOCMA
	BIDDLE SAWYER CORPORATION			SOCMA
5460-09-3	CROMPTON & KNOWLES COLORS INCORPORATED			
3400-09-3	FABRICOLOR MANUFACTURING CORPORATION			
	ICI AMERICAS INC			
	MOBAY CHEMICAL CORPORATION			
5915-41-3	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS			ACC, API
6381-77-7	PFIZER INC			
0301-77-7	PMP FERMENTATION PRODUCTS INC		*	
	AAKASH CHEMICALS & DYE-STUFFS			
	BIDDLE SAWYER CORPORATION			SOCMA
6473-13-8	BURLINGTON CHEMICAL COMPANY INC			
	CROMPTON & KNOWLES COLORS INCORPORATED			
	FABRICOLOR MANUFACTURING CORPORATION	*		
6863-58-7	EXXON CHEMICAL COMPANY	*	*	ACC, API
0003-30-7	LYONDELL-CITGO REFINING COMPANY LTD			
6865-35-6	ANZON LEAD			
0000-00-0	SYNTHETIC RUBBER PRODUCTS INC			
7320.27.0	ATOCHEM INC POLYMER DIVISION			
7320-37-8	UNION CARBIDE CORPORATION			
7446-81-3	DOW CHEMICAL USA	*	*	ACC, API, SOCMA
7795-95-1	зм	*		ACC

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
8001-58-9	ALLIED-SIGNAL INC	*		
0001 00 0	CROWLEY TAR PRODUCTS COMPANY INC	*	*	
	DAICOLOR-POPE INC			
8005-02-5	MORTON INTERNATIONAL INCORPORATED			
	ORIENT CHEMICAL CORPORATION	*	*	
	SHARP ELECTRONICS CORPORATION			
	USR OPTONIX INC	*	*	
	BOSTON COKE CORPORATION	*		
8007-45-2	ERIE COKE CORPORATION	*	*	
0007 40 2	KOPPER COMPANY INCORPORATED			
	TONAWANDA COKE CORP	*	*	
	CHEMTECH_INDUSTRIES INC			
	HIGH POINT CHEMICAL CORPORATION	*		
12645-31-7	HILTON-DAVIS CHEMICAL COMPANY			
12010 01 1	PETROLITE CORPORATION			
	PIEDMONT CHEMICAL INDUSTRIES INC			
	REILLY-WHITEMAN INC			
13749-94-5	EI DUPONT DE NEMOURS & CO INC			ACC
13826-35-2	AMERIBROM INC			SOCMA
10020 00 2	MTM HARDWICKE INC	*		
14666-94-5	EXXON CHEMICAL COMPANY	*	*	ACC, API
16883-83-3	MONSANTO COMPANY			
17103-31-0	UNOCAL SCIENCE & TECHNOLOGY DIVISION	*		
17321-47-0	CHEVRON CHEMICAL CO			ACC, API, SOCMA
17976-43-1	ANZON LEAD			
19438-61-0	AMERICAN CYANAMID CO AGRI PRODS RES			
10 100 01-0	ICI AMERICAS INC			
20068-02-4	EI DUPONT DE NEMOURS & CO INC	*		ACC
21351-39-3	UNOCAL SCIENCE & TECHNOLOGY DIVISION	*		
22527-63-5	HULS AMERICA INC			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
24448-09-7	зм	*		ACC
24615-84-7	HOECHST CELANESE			
24013-04-7	RHONE POULENC INCORPORATED			
	HOECHST CELANESE			
24634-61-5	MITSUI & CO (USA) INC	*	*	ACC, SOCMA
24004 01 0	MONSANTO COMPANY			ACC
	TOMEN AMERICA INC	*	*	
24794-58-9	WR GRACE & CO-CONN	*	*	
25154-38-5	UNION CARBIDE CHEMICALS & PLASTICS CO			
25168-05-2	OCCIDENTAL CHEMICAL CORPORATION	*		ACC, API
25168-06-3	FMC COMPANY	*		
25321-41-9	RUETGERS-NEASE		*	
2002 0	SLOSS INDUSTRIES CORPORATION	*		SOCMA
25586-42-9	EI DUPONT DE NEMOURS & CO INC			ACC
25646-71-3	AGFA	*	*	
200.07.70	OLIN CORPORATION			ACC
26377-29-7	ICI AMERICAS INC			
	DOVER CHEMICAL CORPORATION	*		ACC
26401-27-4	GE SPECIALTY CHEMICALS	*	*	API
	WITCO CHEMICAL CORPORATION			
	DIXIE INTERNATIONAL COMPANY			
26680-54-6	HUMPHREY CHEMICAL COMPANY	*		
	MILLIKEN CHEM	*	*	
	GAF CHEMICALS CORPORATION			
27193-28-8	PMC SPECIALTIES GROUP INC	*		SOCMA
	ROHM AND HAAS COMPANY			ACC
28106-30-1	DELTECH CORPORATION	*		SOCMA
20.00 00-1	DOW CHEMICAL USA		*	ACC, API, SOCMA
28777-98-2	BERCEN INC			
	ETHYL CORPORATION - HEALTH SAFETY AND			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	HUMPHREY CHEMICAL COMPANY	*		
	MILLIKEN CHEM	*	*	
30574-97-1	EI DUPONT DE NEMOURS & CO INC	*	*	ACC
31138-65-5	FARM & IND CHEM CO			
	BERCEN INC			
32072-96-1	DIXIE INTERNATIONAL COMPANY	*	*	
	ETHYL CORPORATION - HEALTH SAFETY AND			
	HULS AMERICA INC			
32210-23-4	INTERNATIONAL FLAVORS AND FRAGRANCES IN	*	*	
	QUEST INTERNATIONAL	*	*	
34689-46-8	MERICHEM COMPANY	*	*	ACC, API
35203-06-6	MONSANTO COMPANY	*	*	ACC
35203-08-8	MONSANTO COMPANY	*	*	ACC
37439-34-2	DOW CHEMICAL USA		*	ACC, API, SOCMA
37734-45-5	ICI AMERICAS INC			
37764-25-3	ICI AMERICAS INC			
38185-06-7	LOMAC INCORPORATED	*		
	FMC COMPANY		*	
39515-51-0	MTM HARDWICKE INC	*		
	NAGASE AMERICA CORPORATION			
40630-63-5	зм	*		ACC
	AMERICAN CYANAMID CO AGRI PRODS RES	*		
40876-98-0	BIDDLE SAWYER CORPORATION			SOCMA
10010 00 0	HEICO CHEMICALS INC			
	NEPERA INC			
51632-16-7	MTM HARDWICKE INC	*		
52184-19-7	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*		ACC, API
52556-42-0	RHONE POULENC INCORPORATED			
52663-57-7	FMC COMPANY	*		
56038-89-2	AMERICAN CYANAMID CO AGRI PRODS RES			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	BASF CORPORATION	*		ACC, SOCMA
57693-14-8	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS		*	ACC, API
	CROMPTON & KNOWLES COLORS INCORPORATED			
	DOVER CHEMICAL CORPORATION	*	*	ACC
61788-76-9	FERRO CORPORATION			ACC, SOCMA
	OCCIDENTAL CHEMICAL CORPORATION	*		ACC, API
	GAF CHEMICALS CORPORATION			
61789-32-0	LEVER BROTHERS CO			
	PPG INDUSTRIES INC			ACC, SOCMA
	GAYLORD CONTAINER CORPORATION	*		
61789-65-9	JAMES RIVER CORPORATION			
	JAMES RIVER GRAPHICS INCORPORATED			
61789-85-3	STEPAN CHEMICAL COMPANY			
	AMOCO CANADA MARKETING CORP			
64742-24-1	DIAMOND SHAMROCK REFINING/MKT			
	SUN REFINING AND MARKETING COMPANY			SOCMA
	CHEVRON CHEMICAL CO			ACC, API, SOCMA
64743-02-8	HALTERMANN LTD			
01110020	MONSANTO COMPANY			ACC
	SHELL OIL COMPANY			ACC, API
	ASHLAND CHEMICAL COMPANY - ENVIRONMENTAL			ACC, API
	COASTAL REFINING & MARKETING INC			ACC, API
64743-03-9	FARMLAND INDUSTRIES INC	*		
	LYONDELL-CITGO REFINING COMPANY LTD			
	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
64771-71-7	MONSANTO COMPANY			ACC
V	SHELL OIL COMPANY			ACC, API
65996-78-3	ACME STEEL COMPANY	*	*	
	ARMCO STEEL COMPANY LP			
	BETHLEHEM STEEL CORPORATION	*		

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	BOSTON COKE CORPORATION	*		
	CITIZENS GAS & COKE UTILITY	*	*	
	EMPIRE COKE COMPANY	*	*	
	GREAT LAKES CHEMICAL CORPORATION - RESEA		*	
	GULF STATES STEEL INC			
	KOPPER COMPANY INCORPORATED	*	*	
	LTV STEEL COMPANY INC	*		
	NATIONAL STEEL CORPORATION	*	*	
	SLOSS INDUSTRIES CORPORATION	*		SOCMA
	TONAWANDA COKE CORP	*	*	
	USS DIVISION OF USX	*	*	
65996-79-4	ARISTECH CHEMICAL CORPORATION			
03930-79-4	KOPPER COMPANY INCORPORATED	*	*	
65996-80-7	EMPIRE COKE COMPANY	*		
03930-00-1	KOPPER COMPANY INCORPORATED	*	*	
	ACME STEEL COMPANY	*	*	
	ARMCO STEEL COMPANY LP			
	EMPIRE COKE COMPANY	*		
65996-81-8	ERIE COKE CORPORATION	*	*	
03930-01-0	KOPPER COMPANY INCORPORATED	*	*	
	SLOSS INDUSTRIES CORPORATION	*		SOCMA
	TONAWANDA COKE CORP	*	*	
	USS DIVISION OF USX	*	*	
	ALLIED-SIGNAL INC	*		
65996-82-9	ARISTECH CHEMICAL CORPORATION			
03330-02-3	KOPPER COMPANY INCORPORATED	*	*	
	REILLY INDUSTRIES INC	*	*	ACC
65996-83-0	ALLIED-SIGNAL INC	*		
03330-03-0	KOPPER COMPANY INCORPORATED	*	*	
65996-86-3	ALLIED-SIGNAL INC			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	KOPPER COMPANY INCORPORATED	*	*	
65996-87-4	ALLIED-SIGNAL INC	*		
03330-07-4	KOPPER COMPANY INCORPORATED	*	*	
	ACME STEEL COMPANY	*	*	
	ALLIED-SIGNAL INC	*		
	ARMCO STEEL COMPANY LP			
	BETHLEHEM STEEL CORPORATION	*	*	
	EMPIRE COKE COMPANY	*	*	
	GREAT LAKES CHEMICAL CORPORATION - RESEA		*	
65996-89-6	GULF STATES STEEL INC			
	KOPPER COMPANY INCORPORATED	*	*	
	LTV STEEL COMPANY INC	*		
	NATIONAL STEEL CORPORATION	*	*	
	REILLY INDUSTRIES INC	*	*	ACC
	SLOSS INDUSTRIES CORPORATION	*		SOCMA
	USS DIVISION OF USX	*	*	
	ALLIED-SIGNAL INC	*		
	ARISTECH CHEMICAL CORPORATION			
65996-91-0	CROWLEY TAR PRODUCTS COMPANY INC			
	KOPPER COMPANY INCORPORATED		*	
	REILLY INDUSTRIES INC	*	*	ACC
	KOPPER COMPANY INCORPORATED	*	*	
65996-92-1	REILLY INDUSTRIES INC			ACC
	WESTERN TAR PRODUCTS CORPORATION	*		
66071-94-1	GRAIN PROCESSING CORPORATION	*	*	
68081-86-7	EXXON CHEMICAL COMPANY	*		ACC, API
68082-78-0	HENKEL CORPORATION			
00002-76-0	REILLY-WHITEMAN INC			
69152 60 6	EXXON CHEMICAL COMPANY			ACC, API
68153-60-6	JETCO CHEMICALS INC			

ASHLAND CHEMICAL COMPANY - ENVIRONMENTAL ACC, API	CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
KOPPER COMPANY INCORPORATED	68187-57-5	ASHLAND CHEMICAL COMPANY - ENVIRONMENTAL			ACC, API
68187-59-7 UCAR CARBON COMPANY INC	00107-37-3	KOPPER COMPANY INCORPORATED	*	*	
UCAR CARBON COMPANY INC	68187-50-7	FMC COMPANY *			
HIGH POINT CHEMICAL CORPORATION NATIONAL STARCH AND CHEMICAL CORPORATION REILLY-WHITEMAN INC CASCHEM INC CASCHEMICAL CORPORATION CASCHEMICAL CORPORATED CARGILL INCORPORATED CARGILL INCORPORATED CARGILL INCORPORATED CARGILL INCORPORATED CARGILL INCORPORATED CASCHEMICAL CORPORATION CASCHEMICAL CORPORATION CASCHEMICAL CORPORATION CASCHEMICAL COMPANY CASCHEMICAL CORPORATION CASCHEMICAL CORPORA	00107-33-7	UCAR CARBON COMPANY INC	*	*	
NATIONAL STARCH AND CHEMICAL CORPORATION REILLY-WHITEMAN INC		CLIMAX PERFORMANCE MATERIALS CORPORATION			
NATIONAL STARCH AND CHEMICAL CORPORATION REILLY-WHITEMAN INC	68187-76-8	HIGH POINT CHEMICAL CORPORATION			
CASCHEM INC CASCHEM INC CASCHEM INC CASC, SOCMA	00107-70-0	NATIONAL STARCH AND CHEMICAL CORPORATION			
BASE CORPORATION		REILLY-WHITEMAN INC			
Base Base Base Corporation	68187-84-8	CASCHEM INC	*	*	
MOBAY CHEMICAL CORPORATION	68188-18-1	BASF CORPORATION	*	*	ACC, SOCMA
68334-01-0 MERICHEM COMPANY	00100-10-1	MOBAY CHEMICAL CORPORATION			
68441-66-7	68309-27-3	CLIMAX PERFORMANCE MATERIALS CORPORATION			
68442-60-4 HERCULES INCORPORATED	68334-01-0	MERICHEM COMPANY	*	*	ACC, API
CARGILL INCORPORATED	68441-66-7	HATCO CHEMICAL CORPORATION	*		
68476-80-2 CARGILL INCORPORATED KARLSHAMNS LIPID SPECIALTIES USA * 68478-20-6 VELSICOL CHEMICAL CORPORATION * 68479-98-1 ETHYL CORPORATION - HEALTH SAFETY AND * 68511-40-0 EXXON CHEMICAL COMPANY ACC, API 5HEREX CHEMICAL COMPANY INC * ACC, API, SOCMA 68513-62-2 EXXON CHEMICAL COMPANY * ACC, API 68514-41-0 EXXON CHEMICAL COMPANY * ACC, API 68515-89-9 SYNTHETIC RUBBER PRODUCTS INC * ACC, API 68527-02-6 DOVER CHEMICAL CORPORATION * ACC COCIDENTAL CHEMICAL CORPORATION * ACC, API	68442-60-4	HERCULES INCORPORATED	*	*	
KARLSHAMNS LIPID SPECIALTIES USA 68478-20-6 VELSICOL CHEMICAL CORPORATION * 68479-98-1 ETHYL CORPORATION - HEALTH SAFETY AND ACC, API 68511-40-0 EXXON CHEMICAL COMPANY ACC, API 68512-63-0 CHEVRON CHEMICAL CO ACC, API, SOCMA 68513-62-2 EXXON CHEMICAL COMPANY * ACC, API 68514-41-0 EXXON CHEMICAL COMPANY * ACC, API 68515-89-9 SYNTHETIC RUBBER PRODUCTS INC * ACC, API 68527-02-6 DOVER CHEMICAL CORPORATION * ACC CCCIDENTAL CHEMICAL CORPORATION * ACC, API	68476-80-2	CARGILL INCORPORATED	*	*	
B8479-98-1 ETHYL CORPORATION - HEALTH SAFETY AND	00470-00-2	KARLSHAMNS LIPID SPECIALTIES USA			
EXXON CHEMICAL COMPANY ACC, API	68478-20-6	VELSICOL CHEMICAL CORPORATION	*		
SHEREX CHEMICAL COMPANY INC SHEREX CHEMICAL CO ACC, API, SOCMA	68479-98-1	ETHYL CORPORATION - HEALTH SAFETY AND			
SHEREX CHEMICAL COMPANY INC ACC, API, SOCMA	68511-40-0	EXXON CHEMICAL COMPANY			ACC, API
EXXON CHEMICAL COMPANY	00311-40-0	SHEREX CHEMICAL COMPANY INC			
68513-62-2 MARATHON OIL COMPANY	68512-63-0	CHEVRON CHEMICAL CO			ACC, API, SOCMA
MARATHON OIL COMPANY 68514-41-0 EXXON CHEMICAL COMPANY * ACC, API SYNTHETIC RUBBER PRODUCTS INC WITCO CHEMICAL CORPORATION DOVER CHEMICAL CORPORATION * ACC OCCIDENTAL CHEMICAL CORPORATION * ACC, API	68513-62-2	EXXON CHEMICAL COMPANY	*	*	ACC, API
68515-89-9 SYNTHETIC RUBBER PRODUCTS INC WITCO CHEMICAL CORPORATION DOVER CHEMICAL CORPORATION * ACC OCCIDENTAL CHEMICAL CORPORATION * ACC, API	00313-02-2	MARATHON OIL COMPANY			API
68515-89-9 WITCO CHEMICAL CORPORATION DOVER CHEMICAL CORPORATION * ACC OCCIDENTAL CHEMICAL CORPORATION * ACC, API	68514-41-0	EXXON CHEMICAL COMPANY	*		ACC, API
WITCO CHEMICAL CORPORATION BOVER CHEMICAL CORPORATION * ACC OCCIDENTAL CHEMICAL CORPORATION * ACC, API	68515-89-9	SYNTHETIC RUBBER PRODUCTS INC			
68527-02-6 OCCIDENTAL CHEMICAL CORPORATION * ACC, API	00313-03-3	WITCO CHEMICAL CORPORATION			
OCCIDENTAL CHEMICAL CORPORATION * ACC, API	68527-02-6	DOVER CHEMICAL CORPORATION		*	ACC
68553-14-0 AMOCO CANADA MARKETING CORP *	00327-02-0	OCCIDENTAL CHEMICAL CORPORATION	*		ACC, API
	68553-14-0	AMOCO CANADA MARKETING CORP	*		

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
	HB FULLER CO			
68584-25-8	HUISH DETERGENTS INC	*	*	
	PILOT CHEMICAL COMPANY	*		SOCMA
68602-81-3	SARTOMER COMPANY INC	*	*	ACC
68603-84-9	HENKEL CORPORATION	*		
68607-28-3	PETROLITE CORPORATION			
68608-59-3	BF GOODRICH COMPANY SPECIALTY CHEMICALS			
00000-33-3	VISTA CHEMICAL CO			
68609-04-1	BASF CORPORATION	*	*	ACC, SOCMA
68609-05-2	BASF CORPORATION	*	*	ACC, SOCMA
68610-90-2	EXXON CHEMICAL COMPANY			ACC, API
	AGRICO CHEMICAL COMPANY			
	AGRICULTURAL MINERALS CORPORATION			
	ARCADIAN CORPORATION			
	CF INDUSTRIES INC	*	*	
68611-64-3	FARMLAND INDUSTRIES INC	*	*	
	SOUTHERN RESIN INC			
	TERRA INTERNATIONAL INC	*	*	
	TRIAD CHEMICAL		*	
	UNOCAL SCIENCE & TECHNOLOGY DIVISION	*		
68647-60-9	CHEVRON CHEMICAL CO			ACC, API, SOCMA
00047-00-3	LYONDELL-CITGO REFINING COMPANY LTD			
68650-36-2	BP OIL COMPANY	*		ACC, API
	AMOCO CANADA MARKETING CORP	*		
68782-97-8	CHEVRON CHEMICAL CO			ACC, API, SOCMA
	LYONDELL-CITGO REFINING COMPANY LTD			
	HENKEL CORPORATION			
68815-50-9	HIGH POINT CHEMICAL CORPORATION	*		
30013-30-3	PIEDMONT CHEMICAL INDUSTRIES INC			
	SEDGEFIELD SPECIALTIES			

CAS#	1990 Manufacturer	1998 Manu.	2002 Manu.	Trade Association
68909-77-3	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
68915-05-9	SHEREX CHEMICAL COMPANY INC			
68915-39-9	BASF CORPORATION	*	*	ACC, SOCMA
68918-16-1	FMC COMPANY	*		
68919-17-5	SHELL OIL COMPANY			ACC, API
00010170	THE GOODYEAR TIRE & RUBBER CO DEPARTMEN	*	*	
68920-64-9	AMOCO CANADA MARKETING CORP	*		
68937-29-1	BASF CORPORATION	*	*	ACC, SOCMA
68937-69-9	HENKEL CORPORATION	*		
68937-70-2	HENKEL CORPORATION	*		
68937-72-4	HENKEL CORPORATION	*		
68953-70-8	DOW CHEMICAL USA	*		ACC, API, SOCMA
00000700	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
68953-80-0	BP OIL COMPANY	*		ACC, API
	SUN REFINING AND MARKETING COMPANY			SOCMA
68955-37-3	HERCULES INCORPORATED	*	*	
68955-76-0	CHEVRON CHEMICAL CO			ACC, API, SOCMA
68955-96-4	BP OIL COMPANY			ACC, API
	LYONDELL-CITGO REFINING COMPANY LTD	*	*	
68987-41-7	EXXON CHEMICAL COMPANY	*		ACC, API
68988-22-7	CAPE INDUSTRIES			
	AMOCO CANADA MARKETING CORP			
68988-99-8	CROWN CENTRAL PETROLEUM CORPORATION	*	*	
	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA
	TOTAL PETROLEUM INC			
68990-61-4	BETHLEHEM STEEL CORPORATION	*	*	
	CITIZENS GAS & COKE UTILITY	*	*	
68990-65-8	KARLSHAMNS LIPID SPECIALTIES USA			
69029-75-0	CHEVRON CHEMICAL CO		*	ACC, API, SOCMA
70024-67-8	PILOT CHEMICAL COMPANY			SOCMA

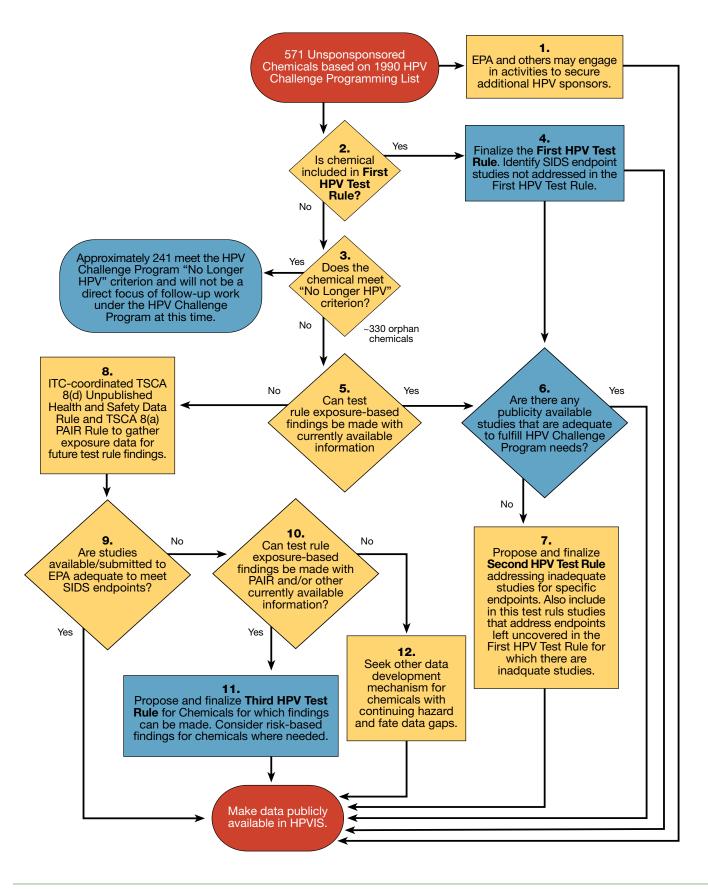
CAS#	1990 Manufacturer 1998 2002 Manu. Manu.			Trade Association	
	STEPAN CHEMICAL COMPANY				
70084-98-9	UNION CAMP CORPORATION				
70693-50-4	CIBA-GEIGY CORPORATION TEXTILE PRODUCTS	*	*	ACC, API	
70851-08-0	RHONE POULENC INCORPORATED				
71077-05-9	TEXACO CHEMICAL COMPANY			ACC, API, SOCMA	
72162-28-8	GE PLASTICS	*	*	API	
73665-18-6	KOPPER COMPANY INCORPORATED	*			
83864-02-2	EI DUPONT DE NEMOURS & CO INC	*		ACC	
84501-86-0	WERNER G SMITH INC	*	*		
90640-80-5	KOPPER COMPANY INCORPORATED	*			
90640-86-1	KOPPER COMPANY INCORPORATED	*	*		
119345-02-7	DOW CHEMICAL USA			ACC, API, SOCMA	
125997-20-8	GREAT LAKES CHEMICAL CORPORATION - RESEA				

The table reveals that for the 330 orphan chemicals, there are: 151 cases where a company member from the ACC trade association could have sponsored a chemical; 83 cases where a company member from the API trade association could have sponsored a chemical; and 91 cases where a company member from the SOCMA trade association could have sponsored a chemical (note that the API company list was not a complete list of members).

The figure below, which is a flowchart on the following page entitled "Preliminary Strategy for Addressing

HPV Challenge Program Unsponsored Chemicals," outlines EPA's initial thinking for obtaining hazard screening-level data for the 330 orphan chemicals and making the data publicly available in the HPV Information System. (HPVIS is a data-searchable application for HPV Challenge Program data that is discussed later in this report.) EPA continues to recognize the HPV Challenge Program as a dynamic and fluid program, and any strategy for addressing orphan chemicals must be flexible to accommodate changing Program circumstances and EPA and stakeholder needs.

Preliminary Strategy for Addressing HPV Challenge Program Unsponsored Chemicals



Flowchart Graphic 1 – EPA and others may engage in activities to secure additional HPV sponsors.

EPA encourages companies and consortia to consider sponsorship of unsponsored chemicals at the present time, before regulatory actions are initiated. EPA plans to work with trade associations and others, and conduct outreach and communications activities targeted at reducing the number of these chemicals. The sustained efforts of stakeholder organizations are essential to making meaningful progress toward reducing the number of unsponsored chemicals.

Flowchart Graphic 2 – Is chemical included in First HPV Test Rule?

EPA proposed a TSCA Section 4 test rule using exposure-based findings (i.e., TSCA section 4(a)(1)(B) – see the description under Flowchart Graphic 5) on December 26, 2000, that would require manufacturers and processors of 37 unsponsored HPV chemicals to conduct specific screening-level testing (65 FR 81658). In this proposed rule, EPA made preliminary determinations that each of the 37 chemical substances is produced (i.e., at the time of the proposed rule) in substantial quantities and that there is substantial human exposure to each of them. The proposed rule was EPA's first action addressing HPV Challenge Program unsponsored chemicals.

Flowchart Graphic 3 – Does the chemical meet "No Longer HPV" criterion?

At the onset of the HPV Challenge Program, the Agency established clear guidance for identifying chemicals as "No Longer HPV" for purposes of the Program. The Program's criterion is that total annual national aggregate production volume must be below one million pounds for both of the two most recent Inventory Update Rule (IUR) reporting periods. The Agency's guidance, entitled "Procedures for Removing HPV Chemicals That Are 'No Longer HPV' and are Not Likely to Become HPV Again From the HPV List" may be found at http://www.epa.gov/chemrtk/ guidocs.htm. To develop the list of orphan chemicals, the Agency considered only chemicals from the 1990 HPV Challenge Program Chemical List. Chemicals on the 1994 List of HPV Additions were not considered, because sponsorship of these chemicals, while accepted, was not officially a part of the HPV Challenge Program.

Of the 2,782 chemicals on the 1990 HPV Challenge Program Chemical List, 571 chemicals remain unsponsored. The Agency applied the "No Longer HPV" criterion using the 1998 and 2002 IUR reporting periods and determined that 241 (42%) met the "No Longer HPV" criterion (i.e., the national aggregate production/importation volumes for these 241 chemicals were less than one million pounds in both the 1998 and 2002 IUR reporting periods). Because the Agency does not consider chemicals currently meeting the "No Longer HPV" criterion to be available for sponsorship under the HPV Challenge Program, the number of unsponsored chemicals is currently 330.

Flowchart Graphic 4 – Finalize the First HPV Test Rule. Identify SIDS endpoint studies not addressed in the First HPV Test Rule.

The Agency (as discussed in Flowchart Graphic 2) has already taken some action to obtain data on certain unsponsored HPV chemicals. In this proposed rule, EPA made preliminary findings that each of the 37 chemical substances is produced (i.e., at the time of the proposed rule) in substantial quantities and that the manufacture, processing, distribution in commerce, disposal, and uses of each of the chemicals substances result, or may result in, exposure to a substantial number of workers. The final test rule will not include those chemicals whose national aggregate production volume is less than one million pounds per year as reported to the 2002 IUR or which have been sponsored after the test rule was first proposed on December 26, 2000. Therefore, the 37 chemicals included in the proposed first HPV unsponsored test rule will be reduced in the final rule. Publication of the final rule is expected in 2005.

In developing the testing requirements for chemicals contained in the proposed rule, EPA utilized searchable and electronically available data and sources in EPA's "Chemical Hazard Data Availability Study" (1998) and ACC's "Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals" (1998) to determine whether screening-level data were available. If no data were available through these searches for a SIDS testing endpoint for a given chemical, EPA made the finding

Status and Future Directions

that there are insufficient data to reasonably determine the human health and environmental effects for that chemical's endpoint. If data were available through these searches for a SIDS testing endpoint, EPA did not make determinations about the sufficiency or adequacy of those data for the first proposed rulemaking. Those determinations, as described below, are planned for the coming year. Robust summaries for SIDS endpoints that are determined to be adequate will be made available through the High Production Volume Information System (HPVIS).

Flowchart Graphic 5 - Can test rule exposure-based findings be made with currently available data?

In addition to the First HPV Test Rule described above, the Agency is considering whether it can make the findings needed to promulgate test rules to obtain baseline health and environmental effects data on additional orphan chemicals.

In order to promulgate a TSCA Section 4 test rule, certain findings are required by statute. EPA must first make findings under TSCA section 4(a)(1)(A) (risk-based finding) and/or section 4(a)(1)(B) (exposure-based finding). The test rule proposed on December 26, 2000, was based on exposure-based findings, and additional orphan chemical HPV test rules could also be based on such findings. However, EPA is not precluding the option of issuing test rules based on risk-based findings alone or in addition to exposure-based findings.

The following statutory TSCA section 4(a) findings are required for issuing test rules:

- Risk-Based Finding; or
- Exposure-Based Finding the chemical is or will be produced or imported in substantial quantities and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (II) there is or may be substantial or significant human exposure to the chemical; and
- "Data Adequacy" Finding existing data are insufficient to enable a reasonable determination of the effects of the substance on health or the environment; and
- "Testing is Necessary" Finding testing with respect to such effects is necessary to develop such data.

On May 14, 1993, EPA published the "B" (or exposure-based) Policy that articulates the criteria that EPA uses to determine whether a chemical is or will be "produced in substantial quantities," whether it "enters or may reasonably be anticipated to enter the environment in substantial quantities," and whether there is or may be "significant or substantial human exposure" (58 FR 28736). The general quantitative guidance thresholds for making these determinations are summarized below. However, EPA may also make findings in situations where the quantitative thresholds are not met, if additional factors exist.

- Substantial Production/Importation 1 million lbs/yr; and
- Substantial Release 1 million lbs/yr or 10% of production or import volume/yr; or Substantial Human Exposure 1,000 workers or 10,000 consumers or 100,000 general population; or
- Significant Human Exposure "case-by-case."

Flowchart Graphic 6 – Are there any publicly available studies that are adequate to fulfill HPV Challenge Program needs?

For those orphan chemicals for which the necessary exposure-based production/importation volume, release, and/or findings can be made, EPA will identify and evaluate the existing hazard and fate studies to determine if the studies are adequate to meet the needs of the HPV Challenge Program.

EPA will also conduct an evaluation of the adequacy of the studies for certain endpoints that were not considered in the First HPV Test Rule; specifically, EPA will evaluate the adequacy of studies identified as "available" when the test rule was proposed but for which a data adequacy evaluation was not conducted at that time. If the studies are determined to be adequate, EPA will make the data publicly available on HPVIS.

Flowchart Graphic 7 - Propose and finalize Second HPV Test Rule addressing inadequate studies for specific SIDS endpoints. Also include in this test rule studies that address endpoints left uncovered in the First HPV Test Rule for which there are inadequate studies.

If the existing hazard and fate studies are determined to be inadequate, a second test rule would be proposed to obtain hazard and fate data if statutory findings can be made.

Flowchart Graphic 8 – ITC-coordinated TSCA 8(d) Unpublished Health and Safety Data Rule and TSCA 8(a) PAIR Rule to gather exposure data for future test rule findings.

This step in the proposed strategy will be conducted concurrently with Flowchart Graphics 6 and 7. Regarding those orphan chemicals for which the necessary exposure-based findings cannot readily be made, the Agency will request the Interagency Testing Committee (ITC) to consider adding these chemicals to the TSCA section 4(e) Priority Testing List in the ITC's 55th Report to the EPA Administrator, projected for late 2004. Based on this potential ITC action, EPA may append the chemicals to the TSCA section 8(a) Preliminary Assessment and Information Reporting (PAIR) rule and the TSCA section 8(d) Health and Safety Data Reporting (HaSDR) rule. The PAIR rule would require producers and importers to submit to EPA within the 90-day reporting period (i.e., 90 days from publication of the rule in the Federal Register) one-time reports on production/ importation volumes, end uses, and exposure-related data. The TSCA section 8(d) HaSDR rule would require producers and importers to submit to EPA within the 90-day reporting period (i.e., 90 days from publication of the rule in the Federal Register) copies and lists of certain types of unpublished health and safety studies for the listed chemicals. Submitters could also be requested or may be required to provide robust summaries for studies addressing health and environmental endpoints.

Flowchart Graphic 9 – Are studies available/submitted to EPA adequate to meet SIDS endpoints?

The Agency would review all publicly available studies and studies submitted under the TSCA section 8(d) rule for their adequacy in meeting all SIDS endpoints. To the extent robust summaries are submitted (refer to Flowchart Graphic 8), the Agency would make the robust summaries publicly available through the HPVIS. For those chemicals for which the submitted studies are determined to be adequate, but for which robust summaries were not submitted, EPA would prepare the robust summaries and make the data publicly available in the HPVIS.

Should the submitted or identified studies be found inadequate for certain chemicals, then PAIR data would be evaluated by EPA to determine if a TSCA section 4(a)(1)(B) finding can be made for those chemicals without further research.

Flowchart Graphic 10 – Can test rule exposure-based findings be made with PAIR and/or other currently available information?

The Agency will review the PAIR data to determine if the TSCA section 4(a)(1)(B)(i) finding for a test rule can be made. (See the description of Flowchart Graphic 5 for details.)

Flowchart Graphic 11 – Propose and finalize Third HPV Test Rule for chemicals for which findings can be made. Consider risk-based findings for chemicals as needed.

If the findings can be made, the Agency would propose a third HPV orphan chemical test rule. EPA would consider requesting or requiring robust summaries for studies conducted under this test rule.

Flowchart Graphic 12 – Seek other data development mechanism for chemicals with continuing hazard and fate data gaps.

The Agency solicits input on other data development mechanisms that will help fill hazard and fate data gaps for chemicals that remain as orphan chemicals, if any.

Projected Orphans Data Development Timeline*

Estimated Timeline	First HPV Test Rule	Second HPV Test Rule	Third HPV Test Rule
October 2004		Data Availability/Adequacy Analysis Initiated	8(a)/8(d) Candidates Provided to ITC
December 2004			55 th ITC Report Published
June 2005	Final Rule Published		8(a) and 8(d) Final Rules Published
October 2005		Proposed Test Rule Published	Review of 8(a) and 8(d) submissions initiated
January 2006		Review of Public Comments on Proposed Rule Initiated	
September 2006		Final Test Rule Published	Proposed Test Rule Published
November 2006			Review of Public Comments on Proposed Rule Initiated
August 2007			Final Test Rule Published

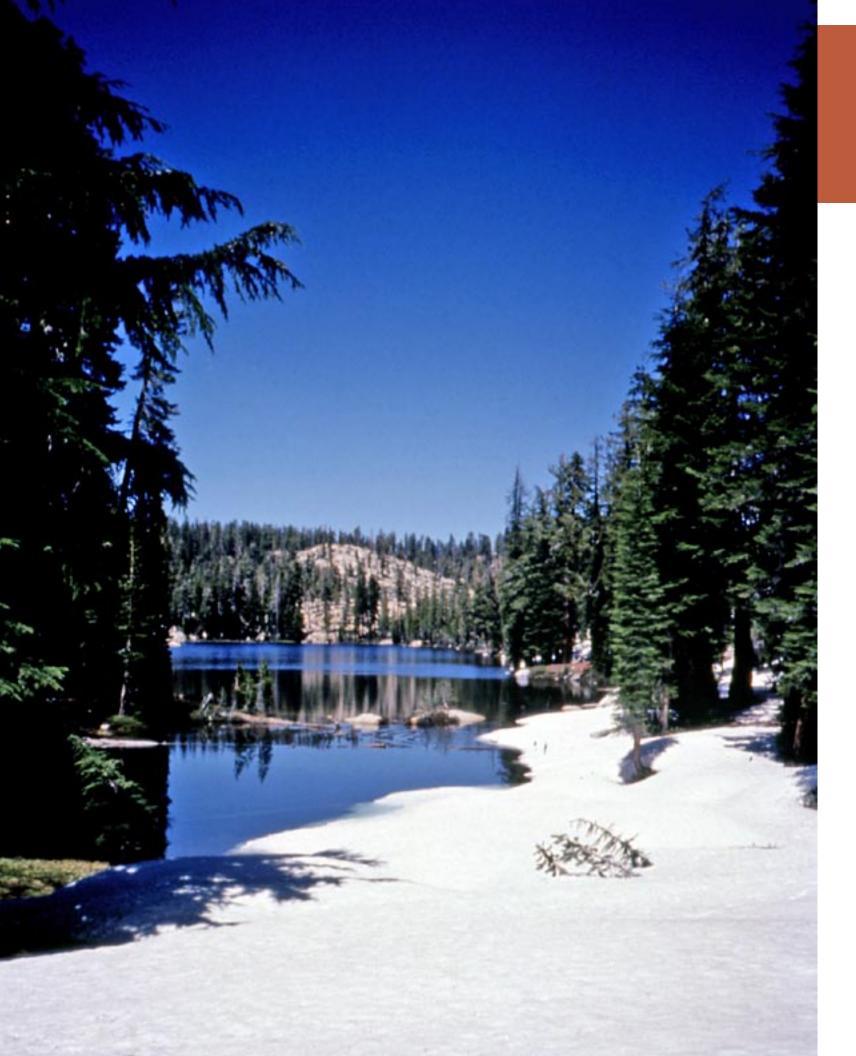
^{*}Timeline assumes that all proposed and final rules will be subject to 90-day OMB review. {This is a projected schedule that the Agency will work to meet in preparing and promulgating test rules as needed. Unanticipated problems or issues could result in delays.}

Beginning in October 2004, EPA would initiate efforts to conduct data availability/adequacy searches for orphan chemicals identified for inclusion in the Second HPV Test Rule. Additionally, the list of orphan chemicals designated as candidates for the HaSDR rule under 8(d) and the PAIR rule under 8(a) would be provided to the ITC.

Subsequently, in 2005, it is anticipated that the First HPV Test Rule containing fewer than the 37 orphan chemicals included on the proposed First HPV Test Rule would be promulgated. In December 2004, it is expected that the ITC would publish its 55th report to the EPA Administrator outlining the Committee's intended priorities and actions.

It is anticipated that the proposed Second HPV Test Rule will be published in October 2005. At the same time, EPA would review data submitted under the HaSDR and PAIR rules for inclusion in the HPVIS or for making the TSCA section 4(a)(1)(B)(i) finding for a Third HPV Test Rule. In January 2006, EPA would begin its review of the public comments submitted on the Second HPV Test Rule.

In September 2006, it is expected that the Second HPV Test Rule would be promulgated and the proposed Third HPV Test Rule would be published, followed by the review of public comments submitted in response to the Third HPV Test Rule in November 2006 and final promulgation in August 2007.



Appendix 6: Future Directions and Developing Issues

PA's "High Production Volume Challenge Program" website is found at http://www. epa.gov/chemrtk/volchall.htm. Test plan and robust summary submissions, sponsor commitment information, chemical lists, guidance documents, and other materials can be found at this site. EPA has recently provided limited search capability on its existing "Robust Summaries and Test Plans" webpage (http://www.epa.gov/chemrtk/hpvrstp.htm) that allows stakeholders to search more efficiently for test plans and robust summaries. The search feature allows users to locate specific test plans by CAS number, chemical name, sponsor (individual company or consortium), or individual/category test plan name. The search then links users to the appropriate submission materials. Various stakeholder volunteers were used to test the newly developed search component of the website, including members of the NPPTAC's (National Pollution Prevention and Toxics Advisory Committee - see "Developing Issues" below) HPV Work Group, a group specifically charged with considering HPV issues, as well as the Forum on State and Tribal Toxics Action (FOSTTA) Chemical Information and Management Project (CIMP) members. Comments were received from the testers, and a production release of this function occurred in April 2004.

A much more comprehensive, data-searchable application with a website front-end is the ultimate goal of the HPV Information System (HPVIS). This system will allow users to thoroughly search across

all test plan and robust summary-related materials – including data presented within and among robust summaries. Among other features, the system will ultimately allow the user to locate specific endpoint data, and it will recognize certain sponsor-provided chemical synonym names in addition to the officially recognized chemical name. The immediate need is to develop enough functionality to populate the HPVIS with data and develop limited querying tools to enable the public to access these data. See the following table for the Projected HPVIS 2004 development timeline.

The development process has begun defining the screen flow and designing system screens. The initial focus involves populating the database with historical submissions that were provided in support of the HPV Challenge Program. EPA will be working with sponsors and trade associations on the process of entering and validating legacy data as well as newly submitted test plan and robust summary data. The initial public release of the database is scheduled toward late 2004 / early 2005.

Availability of screening-level hazard data on HPV chemicals is a global issue. There are many activities addressing this issue worldwide. Coordination and compatibility of various international HPV data systems are essential. EPA is collaboratively working with the European Commission (EC), in consultation with the Organization for Economic Cooperation and Development (OECD), and with the additional

participation of Canada and Japan on a Global HPV Portal. The Portal provides a central information technology location for accessing international HPV chemical data repositories. It focuses on information sharing across geographic, programmatic, and political boundaries. The planning around the Portal is still in the conceptual stages. An articulated vision for the Portal into a more tangible project is expected in the coming months. See the figure below for an illustration of the Portal information sharing concept.

The aim of the Global HPV Portal is to provide seamless information sharing between the European Union's (E.U.) International Uniform Chemical Information Database (IUCLID) and EPA's HPVIS. The two leads – the EC and the Agency – have worked diligently on the Portal requirements over the past year in an effort to share information and make data more readily available to stakeholders from around the world. Some of the benefits resulting from the Portal concept include:

- Information can be shared across IUCLID and EPA's HPVIS without requiring industry to submit data to both systems.
- Government users can seamlessly access a unified picture of non-CBI data contained in both IUCLID and EPA's HPVIS.

- Industry can easily submit and obtain information from both the E.U. and U.S. programs. Industry can also share information with other industry representatives as desired.
- Public users can obtain access to HPV data regardless of whether the data exist in the E.U. program or the U.S. program.
- Public users can access E.U. and U.S. HPV data through a single interface.
- Other programs, such as new chemicals or biocides, can be added to the Portal as desired.
- Databases from other collaborating countries can also be added to the Portal. Countries such as Canada and Japan are working with EC and the Agency.

By the end of 2004, the HPV Portal effort expects to be fully active and engaged with a core team of leaders in place, a System Management Plan drafted, a System Concept document finalized, and requirements defined. The key milestone to be reached by this time is the finalization, formalization, and acceptance of fundamental functions through the completion of the Functional Requirements Specifications document.

Following these achievements, the HPV Portal will continue to implement and update the System

Management Plan, as well as identify and initiate security activities related to the Portal and its development. Likewise, active development efforts will begin with the preparation of a Design Decision Paper, exploration of "buy-or-build" options, and the creation of operational platform and administrative policies. Finally, development of a formal System Design Document will commence.

As the HPV Challenge Program moves toward 2005 and prepares to provide the industry-submitted data to the public in a searchable database format, the Agency has begun to press forward with developing and planning for the delivery of the HPVIS and the Global HPV Portal. This will lead to an international seamless exchange of data. The Office of Pollution Prevention and Toxics (OPPT) plans to continue working directly with sponsors and trade associations on the process of entering and validating legacy data as well as newly submitted test plan and robust summary data. This is a very important step in ensuring that the HPVIS is populated efficiently.

Additionally, now that steadily increasing amounts of the data have been submitted, the Agency, working with the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) and its HPV Work Group, is focusing on approaches for using the data to identify and prioritize chemicals for further work. Once the prioritized chemicals have been identified, the next steps include employing mechanisms to obtain needed hazard (beyond the basic screening-level of the SIDS) or exposure data through voluntary or regulatory approaches.

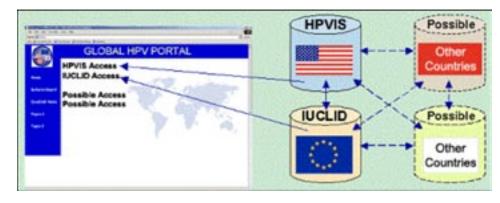
OPPT will continue to inform the public about the HPV Challenge Program and the potential uses of

the data. Preparation of various guidance documents and fact sheets are expected to provide the important background information for helping the general public understand the technical data.

Another priority related to HPV chemicals is how to proceed with obtaining data on the orphans. Additionally, developing and considering options for a program to obtain data on the newly emerging HPV chemicals, which were reported in recent IUR cycles, is viewed as an important next step. A total of 1,118 additional chemicals, that were not HPV on the 1990 IUR, were reported at one million pounds or more under either or both the 1998 or 2002 IURs.

OPPT created the NPPTAC to provide assistance to the office as it begins to address these very important next steps. NPPTAC was specifically established under the Federal Advisory Committee Act (FACA) to provide advice, information, and recommendations on the overall policy and implementation of programs managed by OPPT. OPPT's duties and responsibilities under the Toxics Substances Control Act (TSCA) and the Pollution Prevention Act (PPA) will be addressed, and a work group has been formed to address HPV issues. Specifically, the NPPTAC and its HPV Work Group continue to discuss how OPPT should proceed with using the HPV data to identify and prioritize chemicals of concern, the design and implementation of the HPV Information System (HPVIS), how the Agency should address the emerging HPV chemicals not currently included in the HPV Challenge Program, and how to proceed with obtaining additional data for orphan chemicals. Additional NPPTAC information can be found at http://www.epa.gov/oppt/npptac/.

Global HPV Portal Information Sharing





Key Terms and Acronyms



1990 HPV Challenge Program Chemical List	The list of HPV Chemicals from the 1990 IUR reporting period, from which sponsors may make chemical commitments to supply data.
1994 List of HPV Additions	Approximately 500 organic chemicals that were newly reported as HPV in the 1994 IUR, provided for use by companies in developing categories of chemicals.
ACC	American Chemistry Council.
API	American Petroleum Institute.
CAS Number	Chemical Abstracts Service Number: A unique identification number assigned by the Chemical Abstracts Service (CAS) to each distinct chemical substance recorded in the CAS Chemical Registry System. This number may contain up to 9 digits. For example, the CAS number for Valium is 439-14-5.
Category	A group of substances similar in chemical structure that show a regular pattern of properties and effects. In the HPV Challenge Program, being able to interpolate between and among, or extrapolate from, category members often results in reduced testing, since not all chemicals need to be tested for every SIDS endpoint.
Category Analysis	A submitted plan where a sponsor indicates how their underlying category hypothesis is reasonable, and how existing and new data can be interpolated/extrapolated to address the untested category chemicals' endpoints. EPA reviews the analysis and considers whether it is reasonable or if the category should be considered for restructuring.
Consortium	An organization consisting of two or more companies that agree to sponsor at least one chemical in the HPV Challenge Program.
EC	European Commission: An organization that serves to operate in the best interest of the European Union, specifically through proposing legislation, implementing policies, enforcing law, and negotiating international agreements.
ED	Environmental Defense.
EU	European Union: An organization of democratic European countries that have established common institutions to work toward prosperity.
Endpoint	The chemical or biological effect that is assessed by a test method.
HPV	High Production Volume: Chemicals manufactured or imported in quantities equal to or greater than 1 million pounds per year.
HPVIS	High Production Volume Information System: A publicly accessible website where users will access comprehensive data related to HPV Challenge Program test plan and robust summary submissions.
ICCA	International Council of Chemical Associations: A chemical industry organization that represents chemical manufacturers and producers from around the world, it adds information transfer within the international industry.
IUCLID	International Uniform Chemical Information Database: A system of data collection and evaluation within the EU Risk Assessment Program and accepted by OECD as the data exchange tool within the OECD Existing Chemicals Program.
IUR	Inventory Update Rule: A rule promulgated in 1986 and revised extensively in 2003 by EPA that updates the TSCA Chemical Substances Inventory database every four years. This rule requires manufacturers and importers of certain chemical substances included on the TSCA Chemical Substances Inventory to report current data on the production volume, plant site, and site-limited status of these substances. Reporting in 2006 and beyond will include additional components.

LogKow	The octanol-water partition coefficient for a neutral molecule. It is generally used as a relative indicator of the tendency of an organic compound to adsorb to soil.
NPPTAC	National Pollution Prevention and Toxics Advisory Committee: National advisory body to provide advice, information, and recommendations on the overall policy and operation of programs managed by the Office of Pollution Prevention and Toxics (OPPT).
OECD	Organization for Economic Cooperation and Development: A group of 30 member countries sharing a commitment to democratic government and the market economy, covering economic and social issues such as macroeconomics, trade, education, development, and science and innovation.
OPPT	Office of Pollution Prevention and Toxics. EPA's office wherein the HPV Challenge Program is administered.
Orphan	An unsponsored chemical from the 1990 HPV Challenge Program Chemical List that may be manufactured or imported in quantities equal to or greater than one million pounds in the last two IUR reporting periods.
PCRM	Physicians Committee for Responsible Medicine.
PETA	People for the Ethical Treatment of Animals.
Robust Summary	An abridged reporting of data that includes the study objective, method, results, and conclusions for one endpoint.
SAR	Structure-Activity Relationship: An analysis in which a substance's environmental fate or effects relate to the substance's molecular structure. For the HPV Challenge Program, SAR is often used in category analyses where endpoint data for one chemical can be used to cover endpoint data for another similar chemical.
SIAM	SIDS Initial Assessment Meeting: A gathering of OECD member states to agree on initial hazard assessment for HPV SIDS chemicals.
SIAR	SIDS Initial Assessment Report: OECD member states' evaluations, conclusions, and recommendations for SIDS chemicals that are reviewed and accepted by the OECD at the SIDS Initial Assessment Meeting.
SIDS	Screening Information Data Set: An internationally agreed upon set of screening data developed by the OECD, the SIDS consists of a chemical's (1) general information, (2) physical-chemical data, (3) environmental fate and pathways data, (4) ecotoxicity data, and (5) toxicological data.
SOCMA	Synthetic Organic Chemical Manufacturers Association: The primary trade association serving the specialty-batch and custom chemical industry.
Start Year	The year in which a sponsor commits to submit a chemical's test plan and robust summary.
Test Plan	A summary of available and adequate data, with reference to a summary of data gaps and a rationale for testing, if necessary.
Test Rule	A TSCA Section 4 regulatory mechanism that requires testing of chemical substances and mixtures for which the necessary findings have been made.
TSCA	Toxic Substances Control Act: An Act created by Congress that gives EPA the ability to assess and regulate industrial chemicals in the United States.
UNEP	United Nations Environment Programme: An organization that provides leadership and encourages partnership in caring for the environment. It informs and enables nations to improve their quality of life in global and regional contexts.
Viable Chemical	A chemical for which a commitment was made after December 26, 2000, and therefore involves the submission of full studies in addition to robust summaries of studies.

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EPA's High Production Volume Challenge Program





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