

Facing the Challenge



A STATUS REPORT ON THE U.S. HPV CHALLENGE PROGRAM

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ENVIRONMENTAL DEFENSE

finding the ways that work

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AUTHORS

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ENVIRONMENTAL DEFENSE

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Environmental Defense is dedicated to protecting the environmental rights of all people, including the right to clean air, clean water, healthy food and flourishing ecosystems. Guided by science, we work to create practical solutions that win lasting political, economic and social support because they are nonpartisan, cost-effective and fair.

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Authorship and acknowledgments

This report was written primarily by Environmental Defense Senior Scientist Richard A. Denison, Ph.D., who was also the principal data analyst. Environmental Defense Senior Attorney Karen Florini co-authored the text.

Several other members of Environmental Defense's staff also made valuable contributions. Allison Gordon unflinchingly executed the tedious initial task of entering much of the raw data underpinning the report, admirably assisted by intern Devon Douglas. As the project neared completion, intern Rebecca French made quick work of equally tedious data analyses. Allison Cobb edited the near-final text, and Stephanie Mickelson smoothly coordinated numerous meetings as well as the final production process, including proofreading. Steve Cochran, Director of Strategic Communications, and Dr. John Balbus, Director of the Environmental Health Program, both contributed key insights.

Expert oversight and review were provided by Dr. George Lucier, Director Emeritus of the Environmental Toxicology Program for the National Institute for Environmental Health Sciences; Dr. Lynn Goldman and Dr. Ellen Silbergeld, both Professors at Johns Hopkins University's Bloomberg School of Public Health; and David Roe, formerly a Senior Attorney with Environmental Defense, who played a key role in the development of the program that is the subject of this report.

Dr. Lucier and Dr. Hazel "Skip" Matthews, toxicology consultant and former Head of the Chemistry Section and Chair of the Nomination Faculty for the National Toxicology Program, were the principal authors of the comments on test plans and robust submitted by Environmental Defense.

Several HPV Challenge Program staff at the U.S. Environmental Protection Agency were kind enough to provide data and respond to numerous questions: Karen Hoffman, Karen Boswell, Rich Hefter, and especially Barbara Leczynski.

Steve Russell of the American Chemistry Council helped us navigate through the complexities of the HPV Challenge Program and its international counterparts.

None of the above individuals bear any responsibility for errors or omissions in this report, which are solely the responsibility of the authors.

Environmental Defense gratefully acknowledges the financial support of the Clarence E. Heller Charitable Foundation, without which we could not have undertaken this work.

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Executive summary

HPV Challenge Program overview

In the mid-1980s, the National Academy of Sciences sounded an alarm: Even the most basic data characterizing human and environmental hazard were not available for nearly 80% of the industrial chemicals used in U.S. commerce in the largest amounts. Over a decade later, that situation had not changed: A 1997 study by Environmental Defense, *Toxic Ignorance*—confirmed soon thereafter by more comprehensive studies undertaken by the U.S. government and the chemical industry—found that the great majority of the most heavily used industrial chemicals lacked sufficient data on toxicity and environmental fate to conduct even a basic hazard assessment, at least as far as could be determined in the public record. As *Toxic Ignorance* noted, “The public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not—much less how serious the risks might be, or whether those chemicals are actually under control.”

Prompted by these findings, Environmental Defense, the U.S. Environmental Protection Agency and the Chemical Manufacturers Association (now the American Chemistry Council) jointly developed a framework for a landmark right-to-know program called the U.S. High Production Volume (HPV) Challenge Program. Under this program, launched in late 1998, chemical producers voluntarily committed to fill gaps in basic screening-level hazard data for HPV chemicals—those produced in the U.S. in amounts of one million pounds or more annually—and to make the data publicly available by no later than 2005.

As the HPV Challenge Program passes its halfway mark, this status report examines the significant progress to date, and also identifies several trends that are cause for concern. The report also evaluates how well individual companies, consortia of companies and major trade associations are doing in honoring their commitments under the program. Our aim is to provide an honest reckoning of what is working and what needs improvement, so as to bolster the chances for the program’s successful and timely completion.

In evaluating the progress of the HPV Challenge Program, it is important to note that the program does *not* aim to provide the comprehensive data needed to fully evaluate a chemical’s hazards. The more modest goal of the program is to generate a complete Screening Information Data Set (SIDS) for each HPV chemical; SIDS is a specific set of about 20 data elements, defined through an international consensus process, that provides information sufficient to conduct a preliminary, screening-level evaluation of chemical hazards. This evaluation can serve as the basis for selecting and prioritizing chemicals for further scrutiny.

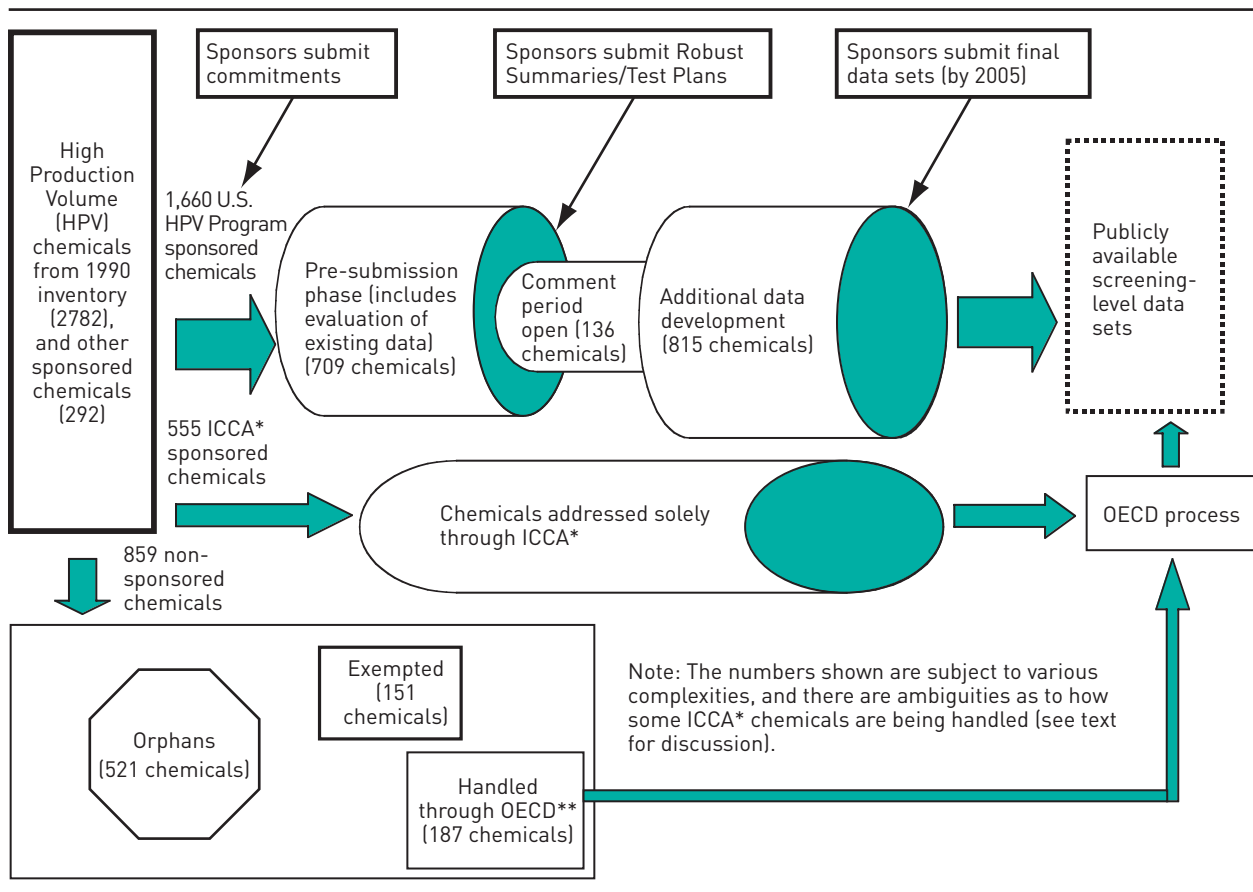
Evaluating an HPV chemical under the program is a multi-stage process (see Figure ES-1). First, the sponsor—a company or consortium of companies that produces a given chemical and has made a commitment for it under the HPV Challenge Program—assesses the extent to which SIDS-relevant hazard data already exist; these data are assembled in a “Robust Summary.” The sponsor identifies any remaining gaps in SIDS data, and develops a “Test Plan” to fill them. Despite this terminology, filling the data gaps does not necessarily require actual testing. For example, where scientifically justified, the HPV Challenge Program

allows and encourages handling structurally or functionally related chemicals as a category, rather than as individual chemicals; in such cases, data gaps may be filled using methods that estimate hazard by interpolation between and among the category members. Use of categories, where scientifically justified, is desirable because it allows data development and testing to be completed for more chemicals faster, at lower cost and with the sacrifice of fewer laboratory animals.

Once a sponsor has developed and submitted a proposed test plan and a set of robust summaries for a chemical or category, these documents are made available for public comment. After review, any needed testing is carried out, and the sponsor prepares and submits a revised, now-complete Robust Summary. At the end of the process, the data—now sufficient to satisfy the SIDS data requirements—are made publicly available.

Because this process can take many months for a given chemical, as of this writing few chemicals have yet completed the process. For this reason, the focus of this report is the initial stages in the process. As a more complete picture of the program emerges through submittal of final data sets, we expect to issue additional status reports and to evaluate the hazard information generated by the program.

FIGURE ES-1
U.S. HPV Challenge Program pipeline as of 12/31/02



*ICCA = International Council of Chemical Associations

**OECD = Organization for Economic Cooperation and Development

Key findings on HPV Challenge Program implementation

The U.S. HPV Challenge Program is a right-to-know program, a major component of EPA's Chemical Right-to-Know Initiative launched in 1998 to improve public access to information about the health and environmental hazards posed by chemicals. Four years into the program's six-year scheduled life, it is poised to dramatically increase public access to basic hazard data on the chemicals used in the largest amounts in U.S. commerce:

- Commitments to develop data for about 2,200 high production volume (HPV) chemicals have been made by more than 400 chemical companies.
- Screening-level hazard data are being developed at a rate that significantly exceeds that of other analogous past and present efforts, both domestic and international.
- EPA has developed, with input from industry and the public, an extensive set of detailed guidance documents on the technical and practical aspects of the program, and a standardized format for collecting and reporting the hazard data being amassed by the program.
- As of the end of 2002, 194 summaries of existing data and plans to develop data to fill the gaps identified have been filed, covering 951 of the 2,200 sponsored HPV chemicals. (Figure ES-1 provides a snapshot of approximately how many chemicals are currently at each stage of the HPV Challenge Program.)
- More than 90% of these plans and summaries have come in during or before the year the sponsor indicated they would.
- Many sponsors appear to have made significant efforts to minimize the use of new tests on laboratory animals to fill data gaps. For the first 142 test plans filed, sponsors have proposed to rely on new testing on animals (specifically rats and mice) to provide only 3.5% of the health-related data, and new testing on animals (specifically fish) to provide only 6.7% of the ecological data; they have proposed using existing data and estimation methods to provide the remainder.¹

This is all good news. But there are also some disturbing trends that need to be addressed or reversed if the program is to fulfill its promise of delivering data to the public on HPV chemicals by the end of 2005. Consider the following:

SPONSORSHIP COMMITMENTS

- More than 500 chemicals within the scope of the HPV Challenge Program are "orphans", i.e., they have not been sponsored, and there is no immediate prospect for developing hazard data for the great majority of them. While it appears likely that some of these chemicals are no longer annually produced in amounts of one million pounds or more (the level defining a high-production-volume chemical), the latest available data indicate that roughly half still are HPV chemicals; see "Searching for homes: the HPV Challenge Program orphans," page 15.

- More than 200 companies have reported that they produce or import at least one of the orphan chemicals, but have not volunteered to sponsor them (see Table 2 and Appendix A). Listed below are the 10 companies that reported producing the most orphans, along with the number of orphans they reported producing.²

Company name	# of orphans	Company name	# of orphans
1. BASF	21 (3)	6. Lonza, Inc.	11
2. Henkel Corporation	15	7. Allied-Signal, Inc.	10
3. Koppers Ind., Inc.	14	8. Creanova, Inc.	10
4. Aceto Corporation	13	9. Exxon Corporation	10
5. Dupont	12 (1)	10. Nipa Hardwicke, Inc.	9

Values in parentheses indicate the number of orphans for which the company has indicated to EPA that it no longer produces the chemical or that it believes it is no longer produced at an HPV level.

- Despite having authority under the Toxic Substances Control Act (TSCA) to issue “test rules” that require testing of these orphan chemicals, to date EPA has proposed only a single test rule covering a scant 5% of these orphans, and has yet to finalize that rule.
- Nearly 400 of the U.S. HPV Challenge Program’s designated HPV chemicals are no longer sponsored under the U.S. program at all; rather, they are now being handled *exclusively* under the HPV Initiative of the International Council of Chemical Associations (ICCA) through the Organization for Economic Cooperation and Development’s (OECD) Screening Information Data Set (SIDS) Program. The number of such chemicals has been growing rapidly, with more than 230 sponsors having shifted their sponsorship from the U.S. program to the ICCA Initiative in the last year alone. While full sets of screening-level hazard data on these chemicals are ultimately expected to be made public, the OECD SIDS process does not require sponsors to submit test plans for review, nor is there an opportunity for public involvement in the review process. Moreover, the pace of the OECD program appears to be much slower than that of the U.S. program, and many of the shifted chemicals are at an early stage in the OECD process. Sponsors’ willingness or ability to develop data on the schedule they originally agreed to under the U.S. program is uncertain at best. This trend thus puts at risk both timely program completion and the transparency and public accountability of the overall process.
- Hundreds of sponsors have decided to delay initiation of data development for their chemicals, thereby “back-loading” the program’s schedule and jeopardizing timely completion of the program.

TIMELINESS IN SUBMITTING TEST PLANS AND ROBUST SUMMARIES

- As of the end of 2002, test plans and robust summaries are late for nearly 400 chemicals; submissions for more than 100 of these are more than a year overdue.
- Four years into the program, with only one year remaining in which to submit test plans and robust summaries, those submitted through the end of 2002

cover only 57% of the core list of chemicals with commitments under the HPV Challenge Program.³ In the year remaining, test plans and robust summaries for the remaining 43% of the committed core list chemicals, plus those remaining for other committed chemicals beyond the core list, will need to be developed and submitted. Thus, the initial objective of having a relatively even spacing of program work over the allotted years has not been achieved.

- The performance of individual companies, consortia of companies and major trade associations in submitting test plans and doing so on time varies widely, from exemplary to poor (see Tables 4 and 5 and Appendices B and C).

Listed below are the companies (of those with at least 10 commitments to the U.S. program) with the 10 best and the 10 worst records in meeting their commitments on time, as measured by the percentage of their commitments for which submissions are more than a year overdue; see Table 4 for a complete list.

Company name	# of commitments	# > 1 yr overdue	% > 1 yr overdue
10 Best			
Albemarle Corporation	12	0	0%
OMG Americas, Inc.	17	0	0%
BASF	35	0	0%
MeadWestvaco	18	0	0%
Cytec Industries, Inc.	17	0	0%
Georgia-Pacific	12	0	0%
Schenectady International	17	0	0%
The Lubrizol Corporation	11	0	0%
Bush Boake Allen, Inc.	19	0	0%
Arizona Chemical Company	42	0	0%
10 Worst			
Aztec Peroxides, Inc.	10	10	100%
Vulcan Chemicals	14	9	64%
Degussa	22	10	45%
PPG Industries, Inc.	13	5	38%
Honeywell International, Inc.	15	5	33%
General Electric (GE)	23	6	26%
Hercules Incorporated	27	7	26%
Ciba Specialty Chemicals Corp.	18	2	11%
ICI Americas, Inc.	110	11	10%
Velsicol Chemical Corporation	10	1	10%

QUALITY OF TEST PLANS AND ROBUST SUMMARIES

- The quality of test plans and robust summaries submitted to date is decidedly mixed, ranging from excellent to unacceptable.
- The performance of individual companies, consortia of companies and major trade associations with respect to the quality of their submissions also varies widely. As one means of ranking sponsors by the quality of their submissions, Environmental Defense assigned grades to the 111 industry submissions it has reviewed, and calculated a “grade point average” (GPA) for each sponsor.⁴ Table ES-1 lists the sponsors earning the highest and lowest

GPA, along with the number of submissions for each sponsor and the total number of chemicals they cover. (See Table 6 for a complete list.)

- For a majority of test plans reviewed to date, comments submitted by EPA and Environmental Defense indicate a likely need for the sponsor to conduct additional data development or testing beyond that initially proposed.

TABLE ES-1

Highest and lowest GPAs for sponsors of chemicals under the U.S. HPV Challenge Program

(based on grades assigned by Environmental Defense to each submission it reviewed)

Sponsor name	# of submissions	# of HPV chemicals	GPA (A=4.0)
TRADE ASSOCIATION/CONSORTIUM SPONSORS			
11 Best			
Aluminum Alkyls Consortium	1	20	4.0
American Methanol Institute Testing Group	1	1	4.0
Benzotriazoles Coalition	1	3	4.0
Chlorobenzene Producers Association	1	4	4.0
Dioxolane Manufacturers Consortium	1	1	4.0
Du Pont & Akzo-Nobel Chemicals	1	1	4.0
Ethanol HPV Challenge Consortium	1	1	4.0
Great Lakes Chemical Corp. & PPG Industries	1	1	4.0
NMA/NBMA Association	1	2	4.0
Phenolic Benzotriazoles Association	1	4	4.0
Propylene Carbonate/T-Butyl Alcohol HPV Cmte.	2	2	4.0
5 Worst			
USOC/ETAD Disperse Blue 79:1 Consortium	1	1	0.0
American Forest & Paper Association (AF&PA)	1	1	2.0
Color Pigments Manufacturers Association, Inc.	1	1	2.0
Mercaptans/Thiols Council	1	2	2.0
Silicones EH&S Council of North America	1	2	2.0
INDIVIDUAL COMPANY SPONSORS			
10 Best			
Air Products and Chemicals, Inc.	1	1	4.0
BASF Corporation	1	9	4.0
Bayer Corporation	1	1	4.0
Cardolite Corporation	1	1	4.0
Ciba Specialty Chemicals Corp. - Additives	1	1	4.0
E.I. du Pont de Nemours and Company	7	10	4.0
Ferro Corporation	1	1	4.0
Merisol USA LLC	2	9	4.0
The Procter & Gamble Company	1	1	4.0
Velsicol Chemical Corporation	4	4	3.8
6 Worst			
The Dow Chemical Company	2	2	0.0
Huntsman Corporation	1	1	0.0
Eastman Chemical Company	5	5	1.2
Deltech Corporation	3	3	1.3
3M	1	2	2.0
Schenectady International (SII)	1	17	2.0

- In the case of test plans for proposed categories, EPA and public comments indicate deficiencies in the definition of or justification for the proposed category in nearly half of the category test plans. Guidance on and criteria for category formation are incomplete and have been interpreted differently by different sponsors. These findings are of particular cause for concern because nearly 90% of the 951 chemicals covered by the test plans submitted through the end of 2002 are in proposed categories.
- Many comments were submitted well after the close of the formal comment period, contributing to delays in initiating development of data to fill identified data gaps.

PUBLIC ACCESS TO INFORMATION RELATED TO PROGRAM STATUS AND PROGRESS

- Despite the fact that the U.S. HPV Challenge Program is a right-to-know program, access to information about the program's implementation and the status and pace of work is seriously limited, restricting the public's ability to understand its progress and prospects for timely completion. This situation compromises the program's transparency.
- EPA has yet to release even a beta version of the repository database for final sets of HPV chemical hazard data, which is intended to serve as the vehicle for making these data publicly available.

Major recommendations

Clearly, efforts will need to be redoubled if the program's objective of having all data on HPV chemicals publicly available in 2005 is to be met. Here is what we believe most urgently needs to happen:

- Producers of orphan chemicals should immediately step up and sponsor them voluntarily, and EPA should act expeditiously to issue test rules for them if that does not occur.
- Sponsorships now under the U.S. program should remain there, and sponsors who have shifted their commitments to the ICCA initiative under the OECD SIDS Program should commit to providing test plans and robust summaries for public review, either through the U.S. HPV Challenge Program or through ICCA or its U.S. affiliates. Initiation of data development, submission of test plans and robust summaries and submission of final data sets should take place on the schedule sponsors originally committed to, even if that precedes formal initiation of the OECD program's consideration of a chemical.
- Industry sponsors need to ensure that their test plans and robust summaries are of high quality by closely adhering to available guidance documents. Deficiencies identified through EPA and public comments should be addressed and, while not specifically mandated under the program, revised documents should be made publicly available.

- EPA's guidance governing categories should be enhanced in light of experience to date. The guidance needs to better address how a category is defined and the criteria that must be met to justify inclusion of specific chemicals within the category. In addition, the guidance should address other major unresolved issues, including the process to be followed for revisiting proposed category definitions and justifications once a test plan for a proposed category has been carried out, and how specific hazard values are to be assigned to individual members of a category that have not been directly tested.
- All relevant parties—EPA, Environmental Defense and especially industry—need to honor their commitments to make comprehensive data available in a manner that allows the public to understand and gauge the status and progress of the program.
- The backlog of overdue test plans and robust summaries needs to be erased quickly and not be allowed to build up again. Industry sponsors need to honor their original start dates for submitting test plans and robust summaries, barring truly exceptional circumstances.
- All commenters need to abide by the 120-day comment period.
- EPA should promptly complete construction of its repository database for HPV chemical hazard data and make it available for receiving final data sets as they are submitted. Establishment of this database is critical in the near future lest it become a rate-limiting factor in the program.

Although implementation of the U.S. HPV Challenge Program has by no means been flawless, it nonetheless constitutes a remarkable achievement that is charting new territory. Both the amount of hazard data being developed and made available, and the pace at which this is occurring, are unprecedented—and, remarkably, are being achieved through a voluntary program in which hundreds of companies are participating and to which a federal agency has devoted substantial resources and shown considerable creativity and determination. Many of the shortcomings and challenges we identify are perhaps to be expected in a program of this magnitude and aspiration; some causes of delay could not reasonably have been anticipated at the outset, or result from improvements made to the original program framework. At the same time, we believe these shortcomings and challenges must be overcome if the program is to succeed. What is needed now is a recommitment on the part of all participants to see the program through to completion.

Introduction

More than 25 years ago, in the Toxic Substances Control Act (TSCA) of 1976, Congress declared that it is the policy of the United States that “adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [defined to include import] and those who process such chemical substances and mixtures.”⁵ TSCA contained omnibus authority to require the development of data sufficient to characterize the hazards posed by chemicals used in commerce.

That authority has been exercised only sporadically, despite the longstanding concern that many or even most of the tens of thousands of chemicals used in commerce have not been tested, or at least that data characterizing their hazard are not publicly available. The National Academy of Sciences was first to formalize and analyze in detail this concern, finding in 1984 that basic toxicity testing data were not available for nearly 80% of chemicals used in U.S. commerce in the largest amounts.⁶ Soon thereafter, toxicity testing began to receive international attention when the Organization for Economic Cooperation and Development (OECD) in 1990 launched its Screening Information Data Set (SIDS) program to develop and collect a defined set of screening-level hazard data on high-volume chemicals.

In the late 1990s, Environmental Defense undertook to determine whether the situation had materially changed in the intervening years. Our 1997 *Toxic Ignorance* report⁷ concluded that it had not, based on an examination of publicly available data for a representative sample of so-called high-production-volume (HPV) chemicals—those industrial chemicals that are manufactured in or imported into the U.S. in amounts of one million pounds or more annually.⁸ Our conclusions were confirmed in more comprehensive studies released in 1998 by the U.S. government and the chemical industry.⁹ Subsequently, Environmental Defense, the U.S. Environmental Protection Agency and the Chemical Manufacturers Association (now the American Chemistry Council) jointly developed a framework for a landmark program called the U.S. High Production Volume Challenge Program. Under the HPV Challenge Program, producers of about 2,200 of the highest-volume chemicals in U.S. commerce have voluntarily committed to identify and fill gaps in basic screening-level hazard data for these chemicals, and to make these data publicly available.

As the HPV Challenge Program reaches its halfway mark, this status report examines the significant progress to date, and also identifies several trends that are cause for concern. It also ranks the relative performance of individual companies, consortia of companies and major trade associations participating in the program with respect to how well they have honored their commitments. Our aim is to provide an honest reckoning of what is working and what needs improvement, so as to bolster the chances for a successful and timely completion of the program.

Origin of the HPV Challenge Program

The genesis of the U.S. HPV Challenge Program dates back to 1997, when Environmental Defense published *Toxic Ignorance*, which suggested that more than 70% of the highest-volume industrial chemicals in U.S. commerce lacked sufficient data on toxicity and environmental fate to conduct even a basic hazard assessment, at least as far as could be determined in the public record.¹⁰ As *Toxic Ignorance* noted, “The public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not—much less how serious the risks might be, or whether those chemicals are actually under control.”

Simultaneous with the release of *Toxic Ignorance*, Environmental Defense challenged the CEOs of the 100 largest U.S. chemical companies to fill the data gaps voluntarily for the chemicals that they manufactured.¹¹ While some companies agreed to do so, others refused.¹²

The disturbing findings reported in *Toxic Ignorance* led both government (the U.S. Environmental Protection Agency) and the chemical industry (the Chemical Manufacturers Association, since renamed the American Chemistry Council) to conduct their own, more extensive studies.¹³ Both found that the problem was even worse than Environmental Defense had indicated: More than 90% of the high-production-volume (HPV) industrial chemicals in U.S. commerce lacked sufficient hazard-screening data available in the public record.¹⁴ (Unlike Environmental Defense’s pilot study that examined 100 regulated HPV chemicals for health-related data elements only, the EPA and CMA studies examined virtually all HPV chemicals (nearly 3000) for both human health and ecological data elements.)

The close congruence of findings in studies performed by industry, government, and environmentalists gave those findings especially high credibility. These developments set the stage for then-Vice President Gore’s exhortation to industry in April 1998 to commit to a voluntary program to fill gaps in basic hazard data—and a directive to EPA to mandate that chemical producers fill gaps that were not filled voluntarily.¹⁵ Soon thereafter, the HPV Challenge Program was launched through a joint announcement of a framework for the program by Environmental Defense, EPA and CMA on October 9, 1998.¹⁶

How the program works

As stated in the joint announcement, the basic elements of the program were:

- **A defined timetable and list of chemicals:** Work was to begin in 1999 and be completed by the end of 2004 (i.e., a little more than six years from launch), with interim milestones to ensure steady progress in each of the intervening years. Data were to be submitted to EPA and made public within two years after work commenced on a particular chemical, with data on the last group of chemicals to be made public no later than mid-2005.
- **Voluntary emphasis with mandatory backing:** Companies that manufacture or import HPV chemicals were invited to voluntarily sponsor their chemicals. Sponsorship entails assessing the adequacy of existing data (including previously unpublished data), conducting new testing where needed, and making the results publicly available. After the sign-up period closed, the U.S. Environmental Protection Agency was to have issued regulations to mandate testing for non-sponsored (so-called “orphan”) chemicals.¹⁷ Participation in the voluntary program was intended to let manufacturers share efficiencies that would not be available under a regulatory mandate. In either event, data development costs were to be borne entirely by manufacturers or importers of the chemicals, not by taxpayers.
- **Continuous public access to data development status and results:** The American Chemistry Council (ACC, formerly the Chemical Manufacturers Association) committed to create an Internet-accessible database to enable the public to follow the status of each chemical in the program at all times, including the names of specific manufacturers or importers who sponsored the chemicals. EPA and Environmental Defense also committed to help keep the public informed about progress in the program, with an emphasis on whether the promised data development activity was taking place and was doing so on time. The U.S. EPA took lead responsibility for making program documents (and ultimately program results) available by means useful to diverse public stakeholders.
- **International sharing of testing responsibility:** In order to meet the aggressive time frame of developing data on all chemicals by the end of 2004, a significant increase in the pace of data development by manufacturers in other countries needed to be achieved. The signatories agreed to work with other nations and international groups to assure commensurate increases in their rate of data development. (Though not expressly stated, it was assumed that the international activities would occur under the aegis of the OECD.)
- **Information sources:** Data were to be developed and made available in a manner that did not necessarily require new animal testing. Sponsors were first to determine whether scientifically adequate data existed (including previously unpublished data). They were also encouraged to use non-animal (*in vitro*) methods where available, as well as to apply techniques that allow extrapolation from existing data on one set of chemicals to estimate values for structurally or functionally related chemicals. Only where these sources

did not yield acceptable data was new testing to be conducted. (See the “How are data developed?” section that follows for more on the program’s extent of reliance on these various data sources.)

Program stages

SPONSORSHIP COMMITMENTS

As initially planned, manufacturers and importers were to have committed to sponsor HPV chemicals by December 1, 1999, with each commitment specifying a “start year” between 1999 and 2003 for initiating any needed testing. EPA indicated its intent to subject those HPV chemicals not sponsored in the program by that date to a test rule under Section 4 of TSCA. Companies could still sponsor chemicals after that date, but they would have to provide full copies of all studies, rather than the detailed summaries of studies required for chemicals sponsored prior to the deadline.

Because of various delays in getting the program underway, several of these dates slipped. EPA decided to designate any sponsorship commitment received prior to December 26, 2000, a “full” commitment. This new date (more than a year after the original deadline) coincided with the publication date of the Agency’s first proposed TSCA test rule, which covered 37 HPV chemicals that at the time were unsponsored.¹⁸ EPA has continued to allow commitments (termed “viable”) after that date, subject to the above-mentioned restrictions.

While a few sponsors designated a 1999 start year, none actually met that commitment, in part because of delays in the issuance of guidance documents covering important aspects of the program. Since then, many sponsors have informed EPA that they have shifted the start year they initially designated to a later year. Nearly 40 chemicals now have a start year of 2004 (see Table 3 for a list of these chemicals and their sponsors)—even though the program framework established 2003 as the last allowable start year.

Despite these initial delays, the basic objective of having all testing completed by the end of 2004 and all data publicly available in 2005 remains unchanged.

SUBMISSION OF ROBUST SUMMARIES AND TEST PLANS

After committing to provide data for a chemical, sponsors are to submit “robust summaries” of existing hazard and environmental fate information available for the sponsored chemical, along with a test plan detailing which additional tests, if any, are proposed to fill the remaining data gaps. If a category of chemicals is being sponsored, the sponsor’s submission is to: (i) identify each chemical comprising the category, (ii) provide a clear definition of the category and justification for addressing the chemicals as a category, and (iii) describe existing data for each category member and indicate how these and any newly generated data will be used to provide a value for each SIDS data element for each category member. (EPA has issued detailed guidance on the content and format of robust summaries and test plans; for categories, draft guidance addresses category definition and justification.¹⁹) EPA then posts the documents on its web site and opens a 120-day public comment period.²⁰

COMMENT PROCESS

One of the most significant enhancements to the program since its launch was establishment of a formal 120-day comment period for test plans and robust

summaries, during which EPA as well as any member of the public can access and review the documents.²¹ Comments submitted by EPA and other interested parties are posted on the Agency's web site. Although not specifically required under the program, sponsors are encouraged to respond to the comments, and many have submitted revised summaries and test plans, which are posted along with the original documents.²²

SUBMITTAL OF FINAL RESULTS

A full data set for each chemical—whether drawn from existing data or the results of new testing—is due within 24 months of the close of the comment period. These data are to be submitted in a prescribed database format to allow for ready electronic access. EPA is developing an Internet-accessible database to provide public access to the data.

What chemicals are covered under the HPV Challenge Program?

HPV chemicals in the U.S. are defined as industrial chemicals manufactured and/or imported in the amount of one million pounds or more annually.²³ Volume data for industrial chemicals in U.S. commerce are required to be reported every four years by manufacturers and importers, and are compiled by EPA, under authority of the TSCA Inventory Update Rule (IUR). In developing the HPV Challenge Program, the 1990 Inventory list of chemicals manufactured or imported in amounts of one million pounds or more was used as the initial “core list” of HPV chemicals.²⁴ That list contains 2,782 substances (see “Getting with the program: Who's who among the HPV Challenge Program chemicals,” page 6).

Over time, chemicals have been removed from this list for a variety of reasons (see “Getting with the program,” page 6). In addition, some companies have committed to sponsor additional chemicals that were identified as HPV after 1990, as well as non-HPV chemicals. Currently, 1,910 chemicals from the original 1990 list are sponsored either directly in the HPV Challenge Program or indirectly through the OECD SIDS Program, while an additional 292 chemicals beyond that list also have sponsorship commitments. “Getting with the program,” page 6, provides more detail on the relationship between all HPV chemicals, those within the scope of the HPV Challenge Program, and those being handled through the OECD.

Who develops the data?

A key feature of the HPV Challenge Program is that producers of HPV chemicals, rather than taxpayers, bear the costs of developing the required data for their chemicals, including the costs of any new testing. Because there are often multiple manufacturers or importers of the same chemical, in many cases these companies have formed consortia for developing the data, often under the auspices of various trade associations such as the American Chemistry Council and the American Petroleum Institute. More than 400 companies, either independently or through participation in one of more than 100 consortia, have committed to sponsor chemicals. Companies can participate in either of two ways: directly through the Challenge Program or indirectly through the International Council of Chemical Associations (ICCA) HPV Initiative under the OECD HPV SIDS Program.²⁵

Getting with the program: Who's who among the HPV Challenge Program chemicals

See Figure 1

HPV CHEMICALS

There are 3,277 unique HPV chemicals.²⁶

- 2,782 are from the 1990 Inventory Update Rule (IUR) List, which constituted the initial HPV Challenge Program Chemical List.
- 495 are additional chemicals reported as HPV on the 1994 Inventory List.²⁷

HPV CHALLENGE PROGRAM CHEMICALS

1,777 chemicals from the 1990 Inventory List are still within the scope of the HPV Challenge Program. The other 1,005 from the 1990 list were removed for one or more of the following reasons (see Figure 1B):

- 847 are being handled under the OECD SIDS Program (see below for more detail).
- 158 were determined by EPA not to be within the scope of the HPV Challenge Program (although they still may be sponsored under the program, as seven currently are), for the following reasons:
 - 56 are polymers or inorganic compounds that should not have been reported in the 1990 Inventory (such classes of compounds are exempt from reporting requirements).
 - 56 are no longer HPV, i.e., were produced in amounts less than one million pounds annually after 1990.²⁸
 - For 46 others, EPA found either that they already had sufficient publicly available data to characterize their hazard, or that their hazard characterization would not be enhanced by further testing.

73 HPV chemicals from the 1994 Inventory List, while not formally subject to the Challenge Program, are being sponsored voluntarily under it.

51 chemicals not on the 1990 or 1994 Inventory HPV lists are being sponsored voluntarily directly under the HPV Challenge Program; most of these are non-HPV chemicals that are members of proposed categories comprised primarily of HPV chemicals, and are included to enhance the justification for considering the group of chemicals to be a viable category.

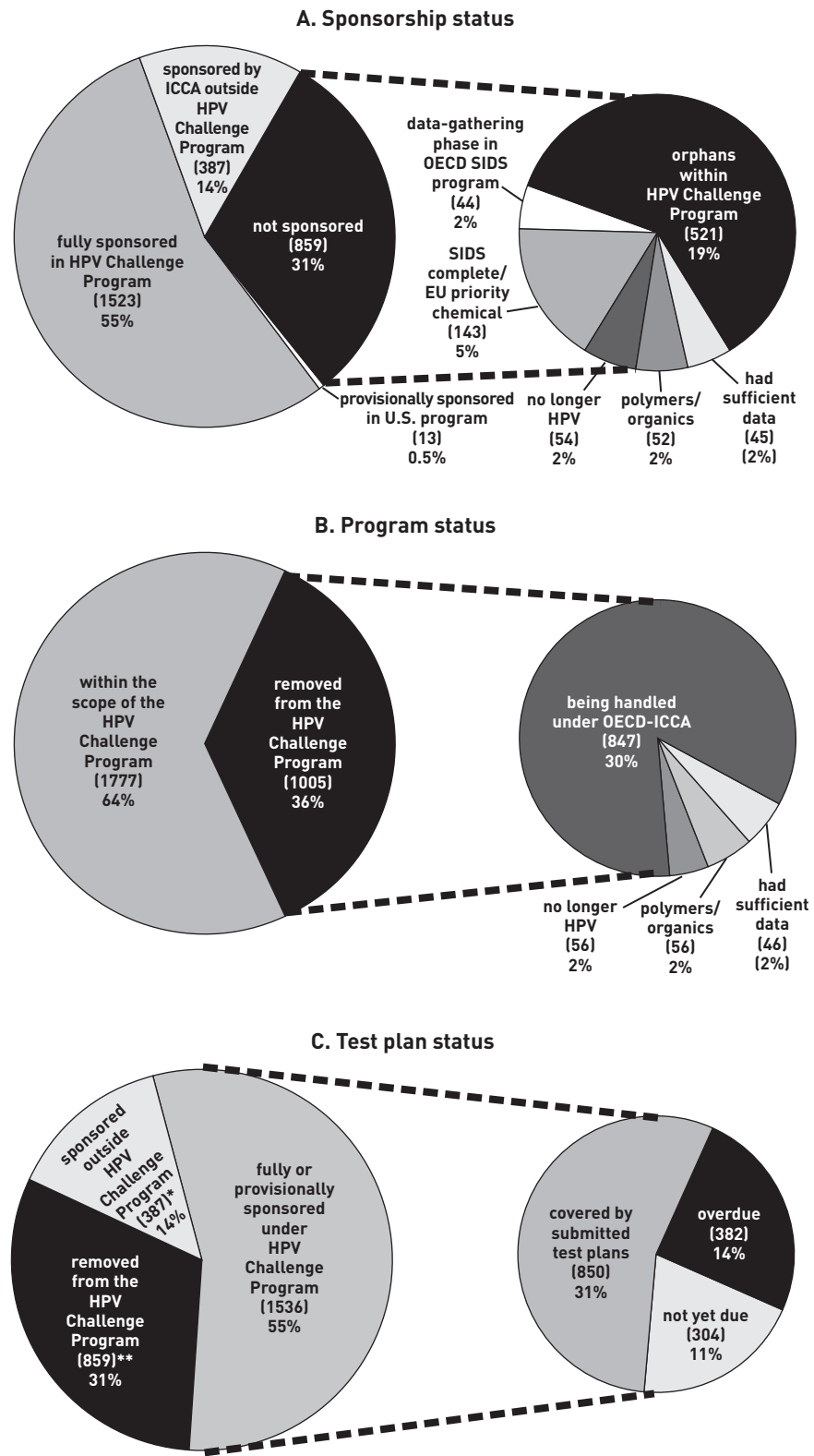
OECD SIDS CHEMICALS FROM THE 1990 INVENTORY LIST

847 chemicals from the 1990 Inventory List are being handled under the OECD SIDS Program.²⁹

- 33 are also independently sponsored under the HPV Challenge Program.
- 240 are sponsored under both the HPV Challenge Program and the HPV Initiative of the International Council of Chemical Associations (ICCA).
- 387 are sponsored under the ICCA HPV Initiative only.
- 187 are currently not sponsored either directly or indirectly under the U.S. program, for one of the following reasons:
 - 143 are already in or through the final stage of the OECD SIDS Program or are being assessed independently because they are on a Priority List of the European Union's Existing Chemicals Program;
 - 44 are in the information gathering phase of the OECD SIDS Program, but do not yet have an OECD member country sponsor, which is required to proceed through the program.

Sources for the statistics cited: Environmental Defense analysis of: [1] EPA's latest available HPV Company/Chemical lists (current as of 11-22-02) contained in database files dated 12-5-02, downloaded from EPA's ChemRTK web site (www.epa.gov/chemrtk/hpvchmlt.htm); [2] EPA's latest master summary table of program commitments, dated 11-22-02, downloaded from EPA's ChemRTK web site (www.epa.gov/chemrtk/sumresp.htm); [3] ICCA's latest list of commitments for all chemicals, generated as a report on January 3, 2003 using its HPV Chemical Tracking System (www.iccahpv.com/reports/ChemicalSearch.cfm); [4] ICCA's latest HPV working list, dated January 7, 2003, downloaded from ICCA's web site for its Global Initiative on High Production Volume (HPV) Chemicals (www.cefic.org/activities/hse/mgt/hpv/hpvinit.htm); [5] the most recent OECD HPV Chemicals List compiled in 2000 (www.oecd.org/pdf/M00017000/M00017224.pdf); and [6] a list of OECD SIDS chemicals and their status, generated as a report on January 2, 2003 using the OECD Integrated HPV Database (cs3-hq.oecd.org/scripts/hpv/).

FIGURE 1
Disposition of the 2782 chemicals on the 1990 core list



*includes 22 chemicals covered by test plans
**includes one chemical covered by a test plan

What types of hazard data are being developed on HPV chemicals?

The HPV Challenge Program seeks to develop basic screening-level hazard data on HPV chemicals. The program adopted the OECD's "Screening Information Data Set" (SIDS) as its set of required data elements. Developed in the early 1990s through consultations among government officials from OECD member countries and industry and environmental community representatives, SIDS constitutes an agreed-upon minimum set of data elements needed to conduct a basic hazard assessment of a chemical for screening purposes. Under the U.S. program as well as the OECD and ICCA initiatives, data are being developed on each of the following SIDS data elements for each HPV chemical:

Physical-chemical data

Melting point
Boiling point
Vapor pressure
Water solubility
Partition coefficient

Ecotoxicological data*

Acute toxicity to fish
Acute toxicity to aquatic invertebrates
Toxicity to aquatic plants

* For chemicals with low water solubility or certain other properties, chronic ecotoxicity testing may be required as well or instead.

Environmental fate and pathway data

Photodegradation
Stability in water
Transport/distribution between compartments (fugacity)
Biodegradation

Mammalian toxicological data

Acute toxicity
Repeated dose toxicity
Reproductive toxicity
Developmental toxicity
Genetic toxicity *in vitro* (gene mutation)
Genetic toxicity *in vitro* or *in vivo* (chromosomal aberration)

How are data developed?

As previously mentioned, the HPV Challenge Program does *not* mandate new testing in order to provide data on each data element for each chemical. Rather, sponsors can propose to meet the minimum data requirements for each SIDS data element in several ways: (1) by providing published, scientifically adequate data; (2) by providing previously unpublished, scientifically adequate data; (3) through the application of an estimation technique (e.g., structure-activity relationship (SAR) models, or "read-across" methods within a chemical category, as more fully discussed in the next section); (4) by providing a rationale for not testing;³⁰ or (5) by proposing new testing (using approved non-animal methods where available). Existing data can only be used if they meet specific quality criteria specified in EPA guidance.³¹ Likewise, sponsors applying estimation techniques in assessing chemical categories are expected to adhere to EPA guidance governing their use.³²

EPA has tracked sponsors' proposed approaches through a periodic review of test plans and robust summaries. The table below presents EPA's estimates of the percentage of all health and environmental data elements³³ that sponsors have proposed to meet through: (a) use of existing scientifically adequate data, (b) use of an estimation technique or providing a rationale for not testing, or (c) new testing. The percentages in the first and third columns are those for chemicals covered in the first 46 test plans and robust summaries submitted under the program, while those in the second and fourth column cover an additional 96 industry submissions (a total of 142).³⁴

Data source	Health data elements		Environmental data elements	
	<i>First 46 submissions</i>	<i>First 142 submissions</i>	<i>First 46 submissions</i>	<i>First 142 submissions</i>
Adequate existing studies	25%	64%	17%	51%
Estimation methods or rationale for not testing	69%	32%	78%	42%
New proposed testing	6.2%	3.5%	5.4%	6.7%

These data indicate that, to date, sponsors have proposed to fill data gaps using only minimal new testing, relying far more heavily on data gleaned from existing studies and estimation techniques.

Use of chemical categories

Where scientifically justified, the HPV Challenge Program encourages sponsors to develop data for structurally or functionally related chemicals as a category, rather than as individual chemicals. A chemical category is a group of chemicals that possess physical, chemical and toxicological properties that either are similar, or follow a predictable pattern, due to their structural similarity. Chemicals may be considered structurally similar if they:

- possess one or more functional groups in common (e.g., aldehyde, epoxide, ester, etc.);
- are derived from the same or similar precursors or are expected to break down in the environment or organisms into degradation products that are structurally similar;
- exhibit an incremental and constant change across the category (e.g., a group of chemicals differing only in carbon chain length).

Each chemical in a category need not necessarily be tested for each SIDS data element, as long as the final data set provides data sufficient to conduct a screening-level hazard assessment of all category members. According to EPA's draft guidance on developing categories, "[T]he final data set must allow one to estimate the hazard for the untested endpoints, ideally by interpolation between and among the category members. In certain cases, such as where toxicity is low and no upward trend is expected, extrapolation to the higher category members may be acceptable."³⁵

Much of the data for chemicals in categories was anticipated to be provided through application of estimation techniques based on structural similarities or relationships among category members, rather than through new testing. Use of categories was encouraged because it allows data development and testing to be completed for more chemicals faster, at lower cost, and with the sacrifice of fewer laboratory animals. It was also anticipated, however, that identifying appropriate categories and developing their associated hazard data would not necessarily be straightforward tasks, and that they would require considerable review.

For this reason, EPA requested that test plans for categories of chemicals be submitted by the end of 2001;³⁶ if a proposed category did not behave as predicted,

TABLE 1

85 categories proposed through 2002 under the U.S. HPV Challenge Program

Category name	# of chemicals*	Category name	# of chemicals*
Acetic Acid & Salts	13	Isodecyl/Phenyl Phosphites	4
Aliphatic Esters	46	Linear and Branched Alkylbenzene	6
Alkaryl Sulfonate	12	Sulfonic Acids and Derivatives	
Alkenyl Succinic Anhydrides	3	Low 1,3-Butadiene C4	8
Alkyl Acetate C6-C13	6	Low Benzene Naphthas	11
Alkyl Alcohols C6-C13	6	Metal Carboxylates	20
Alkyl Diphenyl Oxide Sulfonates (ADPODS)	5	Methyl Mercaptans Analogs	2
Alkyl Sulfides	5	Mixed Xylenols	6
Alkylphenols	17	Monocyclic Aromatic Amines (MAA)	4
Aluminum Alkyls	20	Mononitriles	3
Aminosilanes	2	Monoterpene Hydrocarbons	12
AMPS®	3	N-(methyl)-Acrylamides	2
Anethole	2	N,N-Dimethylalkanamides	2
Aromatic Terpene Hydrocarbons	1	Neoacids C5-C28	6
Arylpolyolefins	2	Olefin Hydroformylation Products	17
Benzothiazole-Based Thiazoles	4	Perfluoro-Compounds, C5-C18	2
Benzotriazoles	3	Petroleum Coke	2
Benzyl Derivatives	8	Petroleum Gas	153
Bicyclic Terpene Hydrocarbons	9	Petroleum Oxidates and Derivatives Thereof	8
C5 Noncyclics	16	Phenolic Benzotriazoles	4
C6-C10 Aliphatic Aldehydes and Carboxylic Acids	4	Phosphoric Acid Derivatives	2
Chlorobenzenes	4	Phthalate Esters	18
Cinnamyl Derivatives	4	Polybutylene Succinic Anhydrides	2
Crude Butadiene C4	12	Propylene Streams	2
Cyclic Anhydrides	6	Resin Oils and Cyclodiene Concentrates	10
Dibasic Esters	3	Rosin Adducts and Adducts Salts	6
Dicamba and Acifluorfen Intermediates	9	Rosin Esters	7
Dicarboxylic Acids	3	Rosins and Rosin Salts	6
Diethylbenzene-Rich Streams	2	Substituted Diphenylamines	8
Diisopropylbenzenes	3	Substituted p-Phenylenediamines	5
Dinitriles	2	Succinimide Dispersants	2
Dithiophosphate Alkyl Esters	9	Sulfenamide Accelerators	2
Ethylphenols	3	Sulfosuccinates	3
Fatty Acid Dimers and Trimer	4	Tall Oil and Related Substances	7
Fatty Nitrogen Derived Amides	29	Tall Oil Fatty Acids and Related Substances	6
Fatty Nitrogen Derived Amines	29	Terpenoid Primary Alcohols and Related Esters	4
Fatty Nitrogen Derived Cationics	13	Terpenoid Tertiary Alcohols and Related Esters	11
Formates	4	Thiobis, Propanoic Acid Derivatives	3
Fuel Oils	12	Thiurams	2
Gasoline	85	Trimellitates	4
High Benzene Naphthas	19	Waxes and Related Materials	8
Higher Olefins	25	Zinc Dialkyldithiophosphates	9
Hindered Phenols	8		
Ionone Derivatives	2		

*Number of chemicals indicates number of unique CAS registry numbers within a category. See footnote 37.

sufficient time would remain to conduct additional testing on individual category members within the program's timeframe. It was expected that, in some cases, an iterative process would play out: proposal of a category and its test plan, provisional acceptance for data development purposes, revision of the category and test plan (possibly including abandonment of the category approach) based on initial results, and completion of any needed testing to provide adequate data for all category members.

Nearly half (43%) of all test plans submitted through the end of 2002 are for proposed categories ranging in size from 2 to as many as 153 HPV chemicals.³⁷ Moreover, nearly 90% of all chemicals covered by these test plans are in proposed categories. These trends are to be expected, based on the request that category test plans be submitted before the end of 2001. It should be noted, however, that 24 of the 85 category test plans received to date were submitted in 2002. Table 1 lists the categories proposed in test plans submitted through the end of 2002 and the number of chemicals included in each proposed category.

Mid-course review: Progress of the HPV Challenge Program

This section of the report reviews the current status of the following key initial stages of the HPV Challenge Program:

- Sponsorship commitments
- Test plan and robust summary submittals
- Test plan and robust summary review and revision
- Public access to status information, industry submissions and results

For each area, we delineate what from our perspective were the original expectations, and based on these, what is working well and what isn't. Because few chemicals have completed the entire process, the focus in this report is on the initial stages. As a more complete picture emerges through submittal of final data sets, we will issue additional status reports that assess the extent of progress made in the later stages of the program and the implications of the hazard data being generated.

Sponsorship commitments³⁸

EXPECTATIONS

- Sponsorship of most, ideally all, U.S. HPV chemicals.³⁹
- Issuance by EPA of test rules requiring testing of “orphan” HPV program chemicals (i.e., those not voluntarily sponsored).
- Commitments to initiate data development for all sponsored program chemicals no later than 2003, so that work would be completed by the end of 2004 and the last of the data would be publicly available by 2005.
- A steady rate of progress in each year of the program to avoid overload.
- A clear, defined schedule for initiation and completion of data development and making the results public.

WHAT'S WORKED

- ☑ A total of 2,202 chemicals have full sponsorship commitments.⁴⁰ This figure includes 292 chemicals beyond those on the core HPV Challenge Program list.
- ☑ EPA has developed, with input from industry and the public, a set of standardized formats which are being used to compile the screening-level hazard data being generated by the program, facilitating data reporting as well as evaluation and dissemination.

WHAT HASN'T WORKED

- ☑ A total of 521 chemicals from the core list remain “orphans,” i.e., have not been sponsored (Figure 1A). Between July and November 2002, 14 new orphans arose under the U.S. program because sponsors withdrew their commitments, while 17 prior orphans are now sponsored.⁴¹ Table 2 and Appendix A

identify the companies that produce orphan chemicals, based on data from the 1998 Inventory, the most recent publicly available.⁴² For 236 of the orphans, the Inventory did not disclose the identity of the companies that reported producing them, either because the companies requested that their identity be withheld as confidential business information, or because the chemicals are no longer being produced at levels requiring reporting. Of the remaining 285 orphans, 202 companies publicly reported producing at least one orphan in 1998 (see Appendix A), and 21 companies publicly reported producing or importing at least five orphans (see Table 2).⁴³ “Searching for homes,” page 15, discusses the limited prospects for these chemicals to be assessed outside of the U.S. HPV Challenge Program, and illustrates that

TABLE 2
Companies reporting that they produced or imported five or more “orphan” chemicals in 1998

Company name	# of orphans*
BASF	21 {3}
Henkel Corporation	15
Koppers Ind., Inc.	14
Aceto Corporation	13
E.I. du Pont de Nemours & Co., Inc.	12 {1}
Lonza, Inc.	11
Allied-Signal, Inc.	10
Creanova Inc.	10
Exxon Corporation	10
Nipa Hardwicke, Inc.	9
Dow Chemical Company	8 {1}
Eastman Chemical Company	8 {2}
FMC Corporation	8 {3}
Sloss Industries Corporation	7
Zeneca, Inc.	7
Ciba Specialty Chemicals Corporation	6
Huntsman Petrochemical Corporation	6
Mitsui Chemicals	6
Union Carbide Corporation	6
3M	5

This table lists those companies that publicly reported producing or importing at least five of the orphan chemicals in the latest Inventory Use Rule (IUR) reporting cycle, conducted in 1998. See Appendix A for a more comprehensive list of all companies that publicly reported producing or importing one or more orphan chemicals in 1998. **Neither list can be regarded as complete because they exclude any company that claimed its identity and association with production or import of these chemicals as confidential business information (CBI).**

IUR data for 1998 are the most recent publicly available data on production and import of industrial chemicals (which are collected quadrennially). EPA is in the process of compiling data collected in 2002, but they are not yet publicly available.

*Numbers in parentheses indicate the number of chemicals for which the company has indicated in a letter to EPA that it no longer produces the chemical in question. Numbers in brackets indicate the number of chemicals for which the company has indicated in a letter to EPA that it believes the chemical is no longer an HPV chemical. Such changes in production status, if accurate, would clearly not have been reflected in the 1998 IUR data. These letters are posted in the section on withdrawn commitments in EPA’s master summary table of program commitments, available at www.epa.gov/chemrtk/sumresp.htm.

Sources: We used non-confidential 1998 IUR data contained in two databases obtained from EPA: (1) The 1998 List of Companies Reporting 1990 HPV chemicals, downloaded from the HPV Challenge Program website (www.epa.gov/chemrtk/hpvcost.htm); (2) A database of non-confidential data reported under the 1998 IUR Rule obtained from the EPA Office of Pollution Prevention and Toxics in November 2002.

All companies listed as reporting production or import of orphan chemicals in either database were compiled, and then the number of orphans reported by each company was calculated.

the majority of orphans continue to be produced in or imported into the U.S. in very large volumes, often well in excess of the threshold that defines an HPV chemical.

- ❑ EPA has proposed—but not yet finalized—a test rule covering only 25 of the 521 orphan chemicals. (Although EPA’s December 2000 proposed test rule covered 37 HPV chemicals,⁴⁴ 12 of those subsequently received sponsorship commitments.)
- ❑ Since the inception of the HPV Challenge Program, a large—but untracked and hence unknown—number of sponsors have shifted the start years they originally designated to a later year, hence delaying submission of test plans and robust summaries for the affected chemicals. See “Moving target: The shift in start years for HPV Challenge Program chemicals,” page 18.
- ❑ In part as a result of these shifts, work on more chemicals is to begin later than originally anticipated. Nearly 40 chemicals now have a start year of 2004, even though the last start year allowed under the program is 2003 (see Table 3 for a list of these chemicals and their sponsors). These shifts increase the risks that the HPV Challenge Program will not be completed by 2005 as planned.
- ❑ A total of 387 chemicals from the HPV Challenge Program 1990 Inventory core list⁴⁵ are now being handled *exclusively* under the ICCA HPV Initiative through the OECD SIDS Program. The number of such chemicals has been growing rapidly: Between December 2001 and November 2002 alone, sponsors of 234 core list chemicals shifted their sponsorship from the U.S. program to the ICCA Initiative under the OECD SIDS Program (Figure 2). While hazard data on these chemicals are ultimately expected to be made public, the OECD SIDS process does not provide an opportunity for public review of test plans and robust summaries. Moreover, because it is not required under the OECD SIDS Program, sponsors of these chemicals are unlikely to make their test plans publicly available for review under the U.S. program; only 10 such chemicals are included in the test plans submitted through the end of 2002. Finally, it is not known whether sponsors are or will be starting data development in the year they initially proposed. Hence, their status with respect to timeliness of test plan submittal and commencement of data development is uncertain and is no longer being tracked under the U.S. program. We have analyzed the current status of these chemicals under the OECD SIDS Program, and found the following:
 - 10 of these chemicals (3%) are included in test plans submitted to the U.S. program.
 - 59 (15%) are already in or through the final stage of the OECD SIDS Program or are being assessed independently because they are on a Priority List of the European Union’s Existing Chemicals Program.
 - For 209 (54%), their sponsors have secured a country sponsor and are now in the initial information gathering phase of the OECD SIDS Program;

Searching for homes: The HPV Challenge Program orphans

As of the end of 2002, 521 chemicals—representing 29%, or nearly one-third, of the chemicals on the 1990 Inventory core list that are still within the scope of the U.S. program—are unsponsored.⁴⁶ This large number of orphan chemicals prompts a number of questions.

ARE THESE CHEMICALS STILL HIGH-PRODUCTION-VOLUME CHEMICALS?

For a chemical to be deemed no longer HPV for purposes of the Challenge Program, EPA requires that all companies that reported producing the chemical on the 1990 Inventory provide support for the claim it is no longer HPV and is not likely to become HPV again. In addition, all companies that reported producing the chemical on the 1994 and 1998 Inventories but not the 1990 Inventory must verify the chemical is no longer HPV and is not likely to become HPV again.⁴⁷ (Inventory data for 1998 are the most recent publicly available data on production and import of industrial chemicals; the inventory is updated quadrennially, and 2002 data are not yet available). Publicly reported Inventory data exclude any data designated by reporting companies as confidential business information.)

Data from the 1994 and 1998 Inventories reveal the following:

- For 389 (75%) of the 521 orphans, production volumes exceeding 1 million pounds were reported in one or both of the 1994 and 1998 Inventory reporting cycles. A total of 342 chemicals exceeded 1 million pounds in 1994, while 274 exceeded this amount in 1998.
- In order to assess the range in production volumes *most recently* reported for the orphan chemicals, we examined the 274 orphan chemicals from 1998 for which production volume data were reported by EPA to exceed 1 million pounds. This analysis revealed the following:
 - For 3 orphans, production exceeded 1 billion pounds.
 - For 4 orphans, production was between 500 million and 1 billion pounds.
 - For 15 orphans, production was between 100 and 500 million pounds.
 - For 15 orphans, production was between 50 and 100 million pounds.
 - For 61 orphans, production was between 10 and 50 million pounds.
 - For 176 orphans, production was between 1 and 10 million pounds.
- For the other 132 (25%) of the orphans, 1998 data suggest they may no longer be HPV chemicals.
 - For 33 (6%) of the orphans, production volumes below 1 million pounds were reported in both of the 1994 and 1998 Inventory reporting cycles.⁴⁸
 - For 99 (19%) of the orphans, no production was reported in one or both reporting cycles.

The exclusion of confidential business information from the publicly available database used for this analysis clearly precluded us from generating a full picture. Nevertheless, this analysis of the most recent publicly available data shows that production volumes for the majority of HPV Challenge Program orphans are high, often well in excess of the threshold defining an HPV chemical, and that they have ranked as HPV chemicals through multiple reporting cycles.

HOW LIKELY ARE THEY TO BE ASSESSED THROUGH OTHER CHANNELS?

- As noted above, 37 HPV chemicals that were orphans at the time were covered by a proposed test rule issued by EPA in December 2000; it has not yet been finalized. Of these, 12 subsequently received sponsorship commitments, nine under the U.S. program, two under the ICCA Initiative and one under both programs. When the test rule is finalized, data will be developed on a mandatory basis for the remaining 25 orphans. Barring further voluntary sponsorships, EPA will have to issue additional test rules covering the other orphans if they are to be assessed.
- While all 521 of the orphans are considered high production volume chemicals under the OECD, none are currently being handled under the OECD program.

WHAT IS THE CHEMICAL NATURE OF THE ORPHANS?

It might be thought that many of the orphan chemicals have gone unsponsored because of some peculiarity in their chemical structures. EPA guidance for the HPV Challenge Program does distinguish between so-called Class 1 and Class 2 substances. Class 1 substances are defined as those that are “single compounds composed of molecules with particular atoms arranged in a definite known structure.” Class 2 substances are defined as “chemical substances which may have variable compositions or be composed of a complex combination of different molecules.”⁴⁹ While the U.S. HPV Program makes no allowance for not testing Class 2 substances—and many are found among the sponsored HPV chemicals—our examination of the orphan chemicals found that the majority in fact have simple chemical structures: at least 55% of the orphans are Class 1 substances.

Source for the statistics cited in this sidebar: A database file provided to Environmental Defense by EPA in November 2002. The database includes non-confidential aggregated production/import volume data as reported to EPA by chemical manufacturers and importers in each of the last 4 reporting cycles (1986, 1990, 1994 and 1998) under the Inventory Update Rule (IUR). The list of chemicals with production or import volumes exceeding one million pounds reported under the 1990 Inventory served as the core list for the U.S. HPV Challenge Program. Data from the latest (2002) reporting cycle are not yet available.

TABLE 3

Sponsors with chemicals for which 2004 is listed as the start year

Company or consortium name	Consortium members	Chemical name	CAS #
<i>Full or viable commitments under the HPV Challenge Program</i>			
American Chemistry Council (ACC) Health, Environmental, and Research Task Group (HERTG)	BP plc; Castrol Industrial North America, Inc.; Chevron Oronite Company LLC; Crompton Corporation; Ethyl Corporation; ExxonMobil Chemical Company; Ferro Corporation; Infineum USA LP; Rhein Chemie Corporation; Rhodia, Inc.; The Lubrizol Corporation	Plumbane, tetraethyl-	78002
		Methylcyclopentadienyl manganese tricarbonyl	12108133
		2,5-Pyrrolidinedione, 1-[2-[[2-[[2-(2-aminoethyl) amino] ethyl] amino] ethyl] amino] ethyl]-, monopolyisobutenyl derivs.	67762725
Synthetic Organic Chemical Manufacturers Association (SOCMA) Isatoic Anhydride Coalition	PMC Specialties Group, Inc.	Isatoic anhydride	118489
The DCB Coalition	Clariant Corporation; Korea Hyeop Hwa Chemical Industry Company, Ltd.; OmniSpecialty Corporation	3,3'-Dichlorobenzidine dihydrochloride	612839
Arizona Chemical Company		Rosin, fumarated, decyl ester	71243680
Chevron Oronite Company LLC		Plumbane, tetraethyl-	78002
		Methylcyclopentadienyl manganese tricarbonyl	12108133
Clariant Corporation		Benzedine, 3,3'-dichloro-, dihydrochloride	612839
DegussaAG		Disilazane, 1,1,1,3,3,3-hexamethyl-	999973
		2,5,7,10-Tetraoxa-6-silaundecane, 6-ethenyl-6-(2-methoxyethoxy)-	1067534
		Silane, (3-chloropropyl) trimethoxy-	2530872
Inspec USA, Inc.		Benzaldehyde, 4-methoxy-	104938
Phillips Petroleum Company		Asphalt, sulfonated, sodium salt	68201321
PMC Specialties Group, Inc.		Anthranilic Acid, Methyl Ester or Methylyl Anthranilate	134203
R.T. Vanderbilt Company, Inc.		Antimony, tris(dipentylthio-carbamato)-	15890252
Solutia		Phosphoric acid, dibutyl phenyl ester	2528361
Union Carbide Corporation		4-Vinylcyclohexene	100403
<i>Provisional commitments under the HPV Challenge Program</i>			
Color Pigments Manufacturers Association, Inc. (CPMA)	Clariant Corporation; Eastman Chemical Company; Lonza, Inc.	Acetoacet-O-toluidide	93685
		Acetoacetanilide	102012
		Methyl acetoacetate	105453
		N,N-Dimethylacetamide	127195

TABLE 3 (CONTINUED)

Sponsors with chemicals for which 2004 is listed as the start year

Company or consortium name	Consortium members	Chemical name	CAS #
		Acetoacetic acid, ethyl ester	141979
		Copper, [phthalocyaninato(2-)]- (CI Pigment Blue 15)	147148
		Diketene	674828
		Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-	1047161
		CI Pigment Red 49, barium salt (2:1)	1103384
		CI Pigment Green 7	1328536
		Toluene sulfonamide	1333079
		N,N-Dimethylacetoacetamide	2044646
		CI Pigment Red 53, barium salt (2:1)	5160021
		CI Pigment Red 57, calcium salt (1:1)	5281049
		Benzidine Yellow OT (CI Pigment Yellow 14)	5468757
		Acetoacetanilide, 2,2''-[[3,3'- dichloro-4,4'-biphenylene]bis (azo)]bis [4' chloro-2',5'- dimethoxy-	5567157
		Quino[2,3-b]acridine-7,14-dione, 5,6,12,13-tetrahydro-	5862384
		1,4-Cyclohexanedicarboxylic acid, 2,5-dioxo-, dimethyl ester	6289469
		CI Pigment Yellow 12	6358856
		CI Pigment Red 48, calcium salt (1:1)	7023612
		CI Pigment Red 48, barium salt (1:1)	7585413
Full or tentative commitments through the International Council of Chemical Associations (ICCA)			
Hampshire Chemical Corp.		Propionic acid, 3-mercapto-	107960
Dow Corning Corporation		Disilazane, 1,1,1,3,3,3- hexamethyl-	999973
		Silane, (3-chloropropyl) trimethoxy-	2530872
Thioesters Association	ATOFINA Chemicals, Inc.; Bruno Bock Chemische Fabrik GmbH & Co. KG; Crompton Corpora- tion; Cytec Industries, Inc.; Hampshire Chemical Corp.; Rohm and Haas Company	Propionic acid, 3-mercapto-	107960
Union Carbide Corporation		Isophorone	78591
The Dow Chemical Company		Methoxydihydropyran	4454051

Source: EPA's latest master summary table of program commitments, dated 11-22-02, downloaded from EPA's ChemRTK website (www.epa.gov/chemrtk/sumresp.htm).

Moving target: The shift in start years for HPV Challenge Program chemicals

Over time, many sponsors of HPV Challenge Program chemicals have informed EPA that they are changing the start year for their sponsorship commitments. EPA staff have indicated that in late 2001 alone they received more than 100 letters from sponsors requesting that their initial proposed start years be moved to a later year. EPA responded to these letters by changing the start year indicated in its master summary table to the new one requested by the sponsors. EPA has not, however, tracked the extent of these changes in start years over time, nor has it maintained a listing of the start years for the original commitments.

Our analysis suggests that this shifting of start years has continued unabated during 2002. In addition, more recently, EPA has itself—without prompting by sponsors—altered the start years reported in its master summary table to match those actually met; start years have been shifted forward or back in time to correspond to the year in which test plans were actually received.⁵⁰

To gauge the extent of such changes, we compared the start years listed in the 7-12-02 version of the EPA master summary table to those in the latest version of the table, dated 11-22-02. We found that in these five months alone, EPA recorded start year shifts for commitments covering a total of 382 chemicals. As shown in the table below, of these 382 commitments, 61 shifted to an earlier start year, 321 to a later start year; most shifts were by one year, although some were by two or even three years.

Commitments moved earlier	61	Commitments moved later	321
1 year earlier	39	1 year later	307
2 years earlier	20	2 years later	12
3 years earlier	2	3 years later	2

The majority of these shifts in start years involved commitments to CAS numbers for which test plans have already been submitted. The table below shows how these shifts break down:

Commitments moved earlier	61	Commitments moved later	321
Test plans not yet submitted	4	Test plans not yet submitted	49
Test plans already submitted	57	Test plans already submitted	272
Submitted before new SY	1	Submitted before new SY	195
Submitted during new SY	53	Submitted during new SY	77
Submitted after new SY	3	Submitted after new SY	0

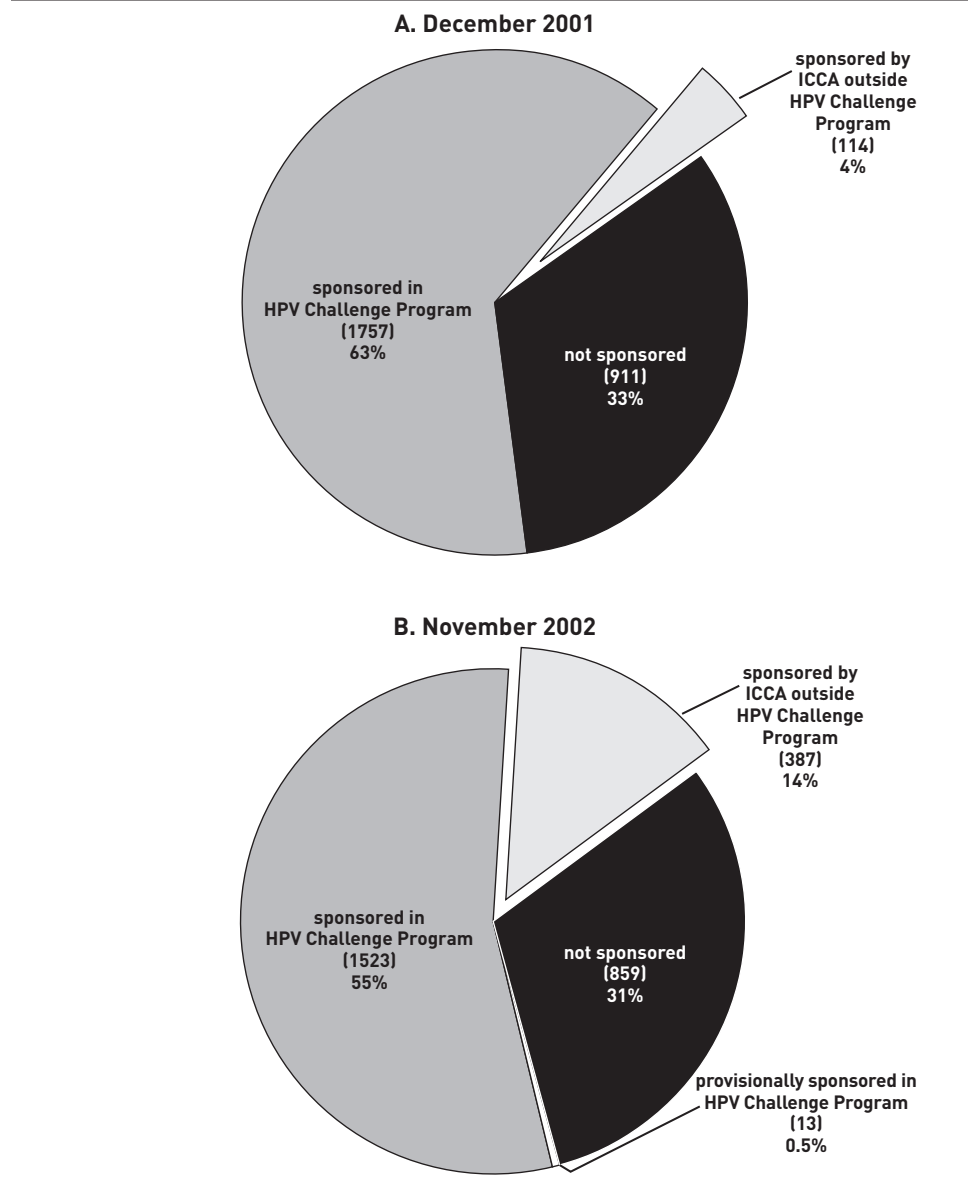
For those shifts involving commitments to CAS numbers for which test plans have already been submitted, almost all of these shifts—whether to an earlier or later start year—were to years preceding or corresponding to the year in which the test plan was submitted. Most or all of these shifts likely reflect the above-mentioned alteration by EPA of the start years reported in its master summary table to match those actually met.

Only four of the shifts to an earlier start year involved commitments to CAS numbers for which test plans have already been submitted. However, 49 such commitments were moved later, presumably to reflect an anticipated or actual delay in initiation of work on a chemical.

The shift to later start years carries two serious consequences for the HPV Challenge Program. First, the shifts put at risk the program's objective of distributing commitments, and therefore data-development work, on a fairly even basis over the years 2000–2003. More significantly, they imperil the prospect of meeting the deadline of making all data public by 2005. (Indeed, as mentioned previously, nearly 40 chemicals now have start years of 2004 even though the last start year permitted under the program is 2003; see Table 3 for a list of these chemicals and their sponsors.)

Second, because EPA has not tracked the extent of start year changes over time, nor maintained a listing of the start years for the original commitments, it is difficult or impossible to know how many test plans have been or will be submitted after the start year originally designated by the sponsor—and hence to gauge whether the program is keeping pace with its original schedule. Given this situation, we have chosen to establish the start years provided in EPA's master summary table dated 7-12-02 as the baseline. In the next section we compare the actual test plan and robust summary submittal dates to these baseline start years to determine whether the test plans and robust summaries were submitted early, on time or late, or are overdue.

FIGURE 2
Change in 1990 core list sponsorship status



the timing of completion of data development for these chemicals is highly uncertain, as many such chemicals have remained in this program phase for years.

- For 109 of these chemicals (28%), their industry sponsors have not yet been able to identify a country sponsor, hence their fate is even more uncertain.
- Of the subset of these chemicals that shifted sponsorship from the U.S. program to the ICCA Initiative in just the last year, an even higher fraction—more than 90%—are either only in the information-gathering phase or have yet to find country sponsors.

Shifting gears: How shifts in sponsorship to the ICCA Initiative risk timely program completion

As already noted, a large number of sponsors have shifted their sponsorship from the U.S. HPV Challenge Program exclusively to the ICCA Initiative under the OECD SIDS Program, including sponsors of more than 200 core list chemicals that did so between December 2001 and November 2002 alone. For the chemicals directly affected by these shifts, the timeline for data development becomes both less certain and is not being systematically tracked, and there is little or no opportunity for public involvement in the review process.

Equally disturbing, however, is the potential for these shifts in sponsorship to affect the pace of data development even for chemicals that remain in the U.S. program. Eastman Chemical Company's recent submission for C4 Aldehydes Self Condensation Products (also known as Solvent C) illustrates this concern.⁵¹ Solvent C is a mixture of 10 major chemical components. In its submission, Eastman does not propose to develop data directly for Solvent C; rather, Eastman asserts that its obligation to the U.S. HPV Challenge Program has been met by providing a test plan and set of robust summaries that heavily rely on yet-to-be-generated hazard data for several of the individual components of the mixture. Data development for these component chemicals is being handled under the ICCA Initiative and the OECD SIDS Program; assessments of three of the chemicals are not complete and the timing of their completion is uncertain. As EPA states in its comments on Eastman's submission, Eastman has not met its commitment under the U.S. program "because not only does the test plan fail to explain how it will use the combined data [from the individual chemicals], but once all testing and program reviews are completed the submitter needs to follow through with a final analysis of the available data and how they characterize the properties of the mixture."⁵²

Eastman's revised document clarifies that the chemicals being assessed under the OECD SIDS Program are now scheduled for formal review within the next year. Assuming the reviews do not raise issues requiring further discussion or work and hence deferral of final approval of these assessments (a not-uncommon occurrence), this schedule increases the likelihood that the needed data will be available in a time-frame compatible with that of the U.S. program. However, Eastman insists on maintaining that its obligations under the U.S. Program have already been met, which in our view is clearly not the case.

In any case, this example vividly illustrates how the shifting of chemicals out of the U.S. program can jeopardize timely completion of data development—not only for the shifted chemicals but even for chemicals that remain sponsored under the U.S. program.

CONCLUSIONS

- A large number of HPV chemicals (1,910) from the 1990 Inventory core list, and nearly 300 chemicals beyond this list, have been sponsored. However, another 521 HPV chemicals—representing 29%, or nearly one-third, of the core list of chemicals that are still within the scope of the U.S. program—remain unsponsored.⁵³ See Table 2 and "Searching for homes," page 15.
- EPA has proposed—but has yet to finalize—a test rule covering only 25, a scant 5%, of these orphans.
- Hundreds of sponsors have decided to change their designated start years, potentially delaying initiation of data development for their chemicals and resulting in a greater "back-loading" of the work, risking a timely program completion. See "Moving target," page 18.

- A large number of sponsors have shifted their sponsorship from the U.S. HPV Challenge Program exclusively to the ICCA Initiative, with sponsors of more than 200 core list chemicals having done so between December 2001 and November 2002 alone. The ICCA Initiative operates through the OECD SIDS Program, under which the timeline for completing data development is both less certain and not being systematically tracked under the U.S. program, and in which there is little or no opportunity for public involvement in the review process. The pace of the OECD program is also much slower than that of the U.S. program, and many of the shifted chemicals are at an early stage in the OECD process. For a substantial majority of the nearly 400 core list chemicals that now have exclusive sponsorship outside the U.S. program, their nascent status in the OECD SIDS Program seriously diminishes the prospect that their sponsors will succeed in developing data for them by 2005. This trend puts at risk both the timely program completion and the transparency and public accountability of the process. “Shifting gears: How shifts in sponsorship to the ICAA Initiative risk timely program completion,” page 20, cites one recent example in which a sponsor asserts that its obligation to the U.S. HPV Challenge Program has been met by providing a test plan and set of robust summaries that heavily rely on hazard data for chemicals that are now being handled under the ICCA Initiative and the OECD SIDS Program—even though the data for some of these chemicals have yet to be developed, and there is no firm schedule for doing so. This example illustrates how the shifting of chemicals out of the U.S. program can jeopardize timely completion of data development—not only for the shifted chemicals but even for those that remain sponsored under the U.S. program.

Test plan and robust summary submittals through 2002⁵⁴

(See Figures 3 and 4)

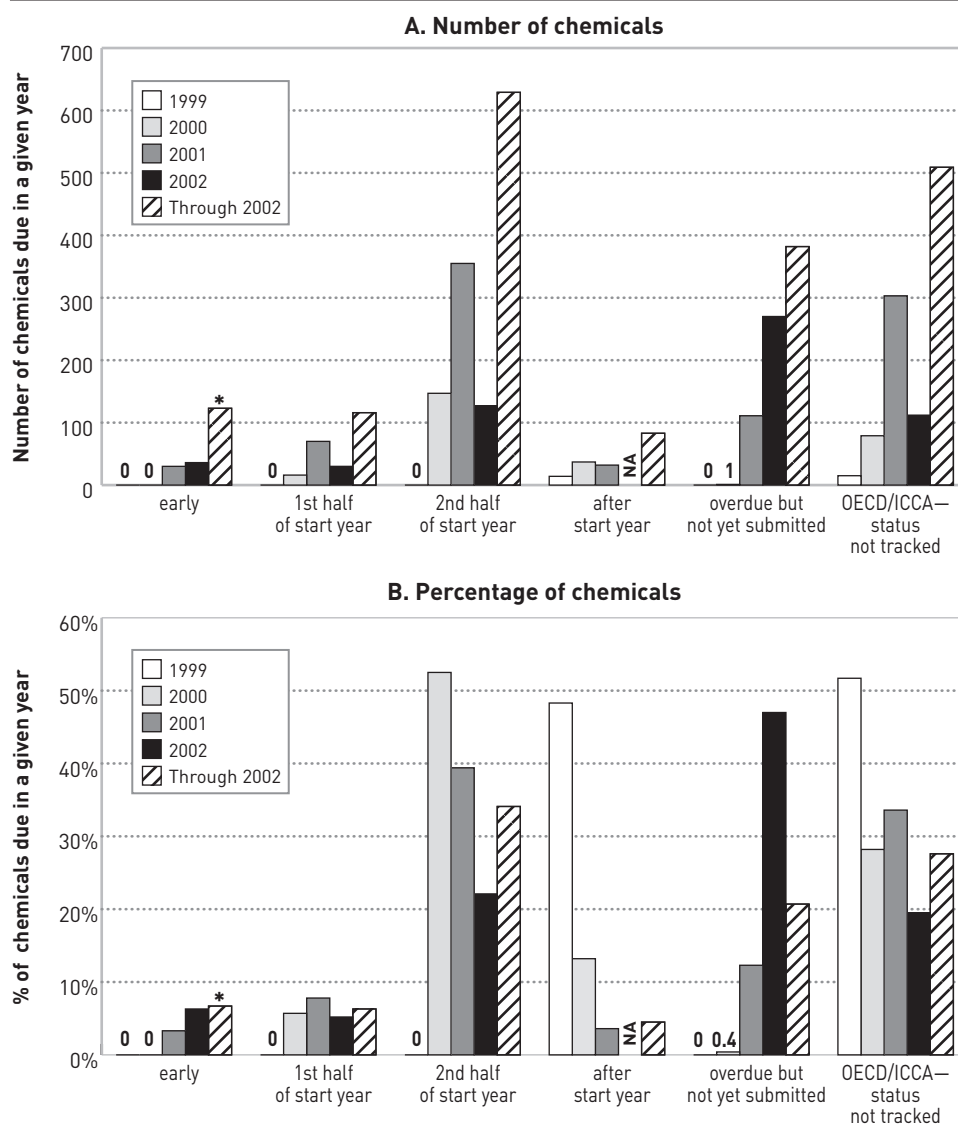
EXPECTATIONS

- Data development on a small number of chemicals would begin in 1999.⁵⁵
- The start years for the remaining chemicals would be relatively evenly distributed among the four main start years (2000—2003) so as to even out the workload for all parties.
- Sponsors would submit their test plans and robust summaries during the start years they initially designated.⁵⁶

WHAT’S WORKED

- ☑ 194 test plans and sets of robust summaries covering 951 chemicals have been submitted. Of these 951 chemicals, 873 are from the 1990 Inventory core list.
- ☑ 91% of these test plans were submitted during (78%) or prior to (13%) their start years.⁵⁷

FIGURE 3
Pace of test plan submittals



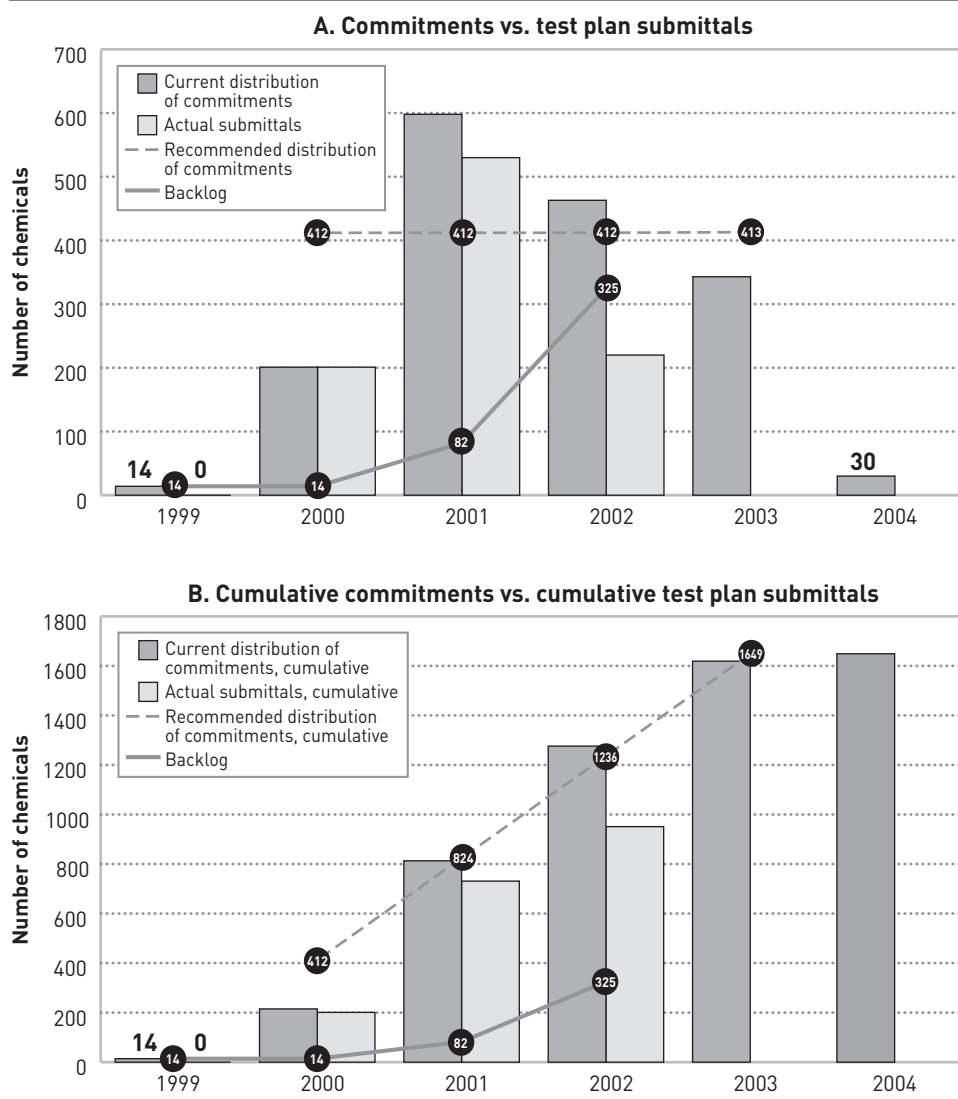
*includes chemicals not due until 2003 and 2004

WHAT HASN'T WORKED

- ❑ No test plans or robust summaries were submitted in 1999 due to delays in issuance of guidance.
- ❑ Test plans and robust summaries covering 382 chemicals are overdue. These include one due in 2000, 111 due in 2001, and 270 due in 2002 (see Figure 1C and Figure 3).⁵⁸
- ❑ For test plans and robust summaries that have been submitted during their start year, a large fraction have come in during the last few weeks of the year, impeding an evenly distributed workload (see Figure 3).

Tables 4 and 5 and Appendices B and C rate the performance of individual

FIGURE 4
Pace of test plan commitments vs. submittals



companies, trade associations and consortia of companies with respect to how well they have met their commitments to develop test plans and submit those test plans on time.⁵⁹ There is wide variation in the extent to which these sponsors are honoring their commitments on a timely basis.

CONCLUSIONS

- Currently, test plans and robust summaries are overdue for 382 chemicals⁶⁰ (see Figure 4). This does *not* count hundreds of chemicals for which the initial start years have been shifted to a later year (see “Moving target,” page 18). Nor does it count the hundreds of chemicals now being handled through the ICCA Initiative under the OECD SIDS Program, for which initiation and completion dates for data development are unclear and untracked under the U.S. program (see Figure 3).

TABLE 4

Performance through 2002 of chemical companies in meeting commitments under the U.S. HPV Challenge Program (companies with 10 or more total commitments)

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002						DUE AFTER 2002			
		Submitted early/on time	Submitted late	Not submitted <1 year overdue	Not submitted >1 year overdue	number	% of total	number	% of total	number	% of total
All companies	2308**	1347	58%	123	5%	311	13%	172	7%	355	15%
Aztec Peroxides, Inc.	10	0	0%	0	0%	0	0%	10	100%	0	0%
Vulcan Chemicals	14	4	29%	0	0%	1	7%	9	64%	0	0%
Degussa	22	3	14%	1	5%	1	5%	10	45%	7	32%
PPG Industries, Inc.	13	1	8%	5	38%	1	8%	5	38%	1	8%
Honeywell International, Inc.	15	0	0%	4	27%	5	33%	5	33%	1	7%
General Electric (GE)	23	3	13%	3	13%	6	26%	6	26%	5	22%
Hercules Incorporated	27	11	41%	1	4%	8	30%	7	26%	0	0%
Ciba Specialty Chemicals Corp.	18	8	44%	3	17%	1	6%	2	11%	4	22%
ICI Americas, Inc.	110	45	41%	3	3%	50	45%	11	10%	1	1%
Velsicol Chemical Corporation	10	2	20%	4	40%	0	0%	1	10%	3	30%
Equistar Chemicals, LP	32	29	91%	0	0%	0	0%	3	9%	0	0%
Solutia	33	12	36%	0	0%	5	15%	3	9%	13	39%
Rhodia, Inc.	33	17	52%	1	3%	1	3%	3	9%	11	33%
The Dow Chemical Company	45	22	49%	0	0%	3	7%	4	9%	16	36%
Koch Industries, Inc.	83	53	64%	1	1%	10	12%	7	8%	12	14%
E.I. du Pont de Nemours and Co.	49	15	31%	8	16%	11	22%	4	8%	11	22%
Chevron Products Company	127	71	56%	2	2%	23	18%	10	8%	21	17%
Sunoco, Inc. [R&M]	115	61	53%	3	3%	23	20%	9	8%	19	17%
Eastman Chemical Company	39	28	72%	0	0%	1	3%	3	8%	7	18%
The C.P. Hall Company	13	12	92%	0	0%	0	0%	1	8%	0	0%
Flexsys America LP	18	13	72%	0	0%	2	11%	1	6%	2	11%
Huntsman Corporation	20	18	90%	0	0%	0	0%	1	5%	1	5%
BP	183	122	67%	3	2%	26	14%	9	5%	23	13%
Ferro Corporation	23	15	65%	0	0%	5	22%	1	4%	2	9%
Noveon, Inc.	28	21	75%	0	0%	0	0%	1	4%	6	21%
Bayer Corporation	30	14	47%	1	3%	5	17%	1	3%	9	30%
Millennium Chemicals, Inc.	35	30	86%	3	9%	1	3%	1	3%	0	0%
Chevron Phillips Chemical Co., LP	41	24	59%	0	0%	8	20%	1	2%	8	20%
Chevron Oronite Company LLC	61	31	51%	11	18%	0	0%	1	2%	18	30%

Crompton Corporation	126	60	48%	4	3%	27	21%	2	2%	33	26%
ExxonMobil	67	49	73%	12	18%	0	0%	1	1%	5	7%
Clariant Corporation	11	1	9%	1	9%	8	73%	0	0%	1	9%
ATOFINA Chemicals, Inc.	21	6	29%	0	0%	12	57%	0	0%	3	14%
Troy	10	7	70%	0	0%	3	30%	0	0%	0	0%
Phillips Petroleum Company	68	40	59%	0	0%	16	24%	0	0%	12	18%
Kao Specialties Americas LLC	31	26	84%	0	0%	5	16%	0	0%	0	0%
The Goodyear Tire & Rubber Co.	10	9	90%	0	0%	1	10%	0	0%	0	0%
Shepherd Chemical Company	13	12	92%	0	0%	1	8%	0	0%	0	0%
Akzo Nobel	40	29	73%	3	8%	3	8%	0	0%	5	13%
Sasol North America, Inc.	26	22	85%	1	4%	1	4%	0	0%	2	8%
Arizona Chemical Company	42	32	76%	8	19%	1	2%	0	0%	1	2%
Bush Boake Allen, Inc.	19	12	63%	7	37%	0	0%	0	0%	0	0%
The Lubrizol Corporation	11	8	73%	3	27%	0	0%	0	0%	0	0%
Schenectady International (SII)	17	14	82%	3	18%	0	0%	0	0%	0	0%
Georgia-Pacific	12	10	83%	2	17%	0	0%	0	0%	0	0%
Cytec Industries, Inc.	17	12	71%	1	6%	0	0%	0	0%	4	24%
MeadWestvaco	18	17	94%	1	6%	0	0%	0	0%	0	0%
BASF	35	26	74%	0	0%	0	0%	0	0%	9	26%
OMG Americas, Inc.	17	17	100%	0	0%	0	0%	0	0%	0	0%
Albemarle Corporation	12	10	83%	0	0%	0	0%	0	0%	2	17%

See Appendix B for a ranked list of all companies with at least one commitment.

* Primary ranking based on values in shaded column. Companies with the same percentage of commitments >1 year overdue are ranked by the percentage of commitments <1 year overdue, then by percentage of commitments that were submitted late.

** Total number of commitments across all companies is higher than total number of chemicals with commitments because many chemicals have more than one sponsoring company.

TABLE 5

Performance through 2002 of major trade associations and consortia in meeting commitments under the U.S. HPV Challenge Program (trade associations and company consortia with five or more total commitments)

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002				DUE AFTER 2002	
		Submitted early/on time number	Submitted late number	Not submitted <1 year overdue number	Not submitted >1 year overdue number	number	% of total
All consortia	1214**	729	63	202	144	12%	
Society of the Plastics Industry	11	1	1	1	8	73%	
American Petroleum Institute	406	249	7	53	37	9%	
American Chemistry Council	418	319	16	7	26	6%	
Synthetic Organic Chemical Manufacturers Association	30	27	0	0	1	3%	
The Flavor and Fragrance High Production Volume Consortia	59	39	15	4	1	2%	
ETAD North America Stilbene Fluorescent Brighteners	7	0	0	7	0	0%	
Consumer Speciality Products Assn./ADBAC Steering Cmte.	5	0	0	5	0	0%	
The Soap and Detergent Association	112	7	0	105	0	0%	
Mercaptans/Thiols Council	10	2	0	8	0	0%	
Alkyl Diphenyl Oxide Sulphonates	5	0	5	0	0	0%	
Pine Chemicals Association	36	25	11	0	0	0%	
Aluminum Alkyls Consortium	20	20	0	0	0	0%	
Color Pigments Manufacturers Association	16	1	0	0	0	0%	
IHF Committees	7	7	0	0	0	0%	
International Association of Color Manufacturers	5	0	0	0	0	0%	
Thioesters Association	5	3	0	0	0	0%	
Asphalt Emulsion Manufacturers Association	5	5	0	0	0	0%	
McConaughay Technologies, Inc. and 10 other companies	5	5	0	0	0	0%	

See Appendix C for a ranked list of all company consortia.

* Primary ranking based on values in shaded column. Consortia with the same percentage of commitments >1 year overdue are ranked by the percentage of commitments <1 year overdue, then by percentage of commitments that were submitted late.

** Total number of commitments across all consortia is higher than total number of chemicals with commitments because some chemicals have more than one sponsoring consortium.

- Through the end of 2002—four years into the program, with only one year remaining in which to submit test plans and robust summaries—those that have been submitted cover 951 chemicals, including 873 core list chemicals. These 873 chemicals constitute 57% of the 1990 core list of chemicals with commitments under the U.S. program.⁶¹
- Hence, in the year remaining, test plans and robust summaries for the remaining 43% of the committed core list chemicals within the scope of the U.S. Program, plus those for other committed chemicals beyond the core list, will need to be developed and submitted. The initial objective of having a relatively even spacing of program work over the allotted years has not been achieved. Sustained efforts will be needed if all data are to be made publicly available in 2005, as originally committed.

Test plan/robust summary review and revision⁶²

(See Figures 5 and 6)

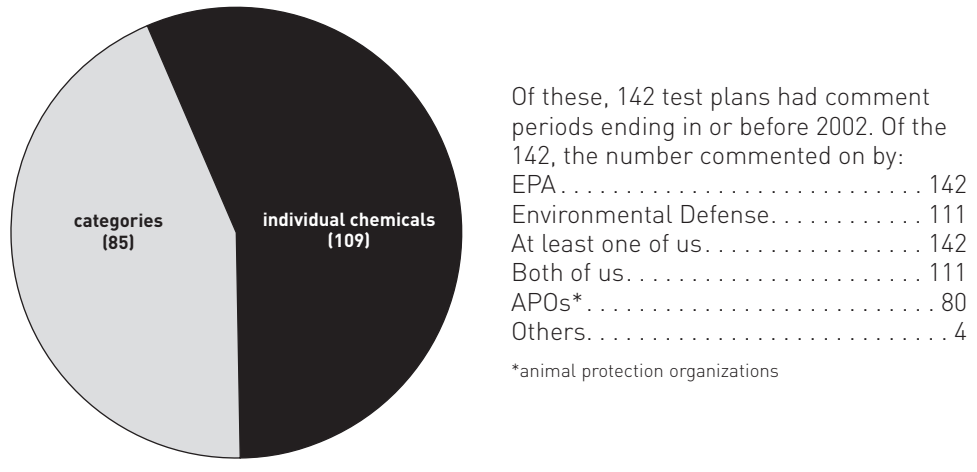
EXPECTATIONS⁶³

- EPA and Environmental Defense would comment on most or all test plans and robust summaries.
- Other members of the public would have an opportunity to comment as well.
- Sponsors would consider these comments before proceeding to develop data, revising test plans and robust summaries as needed.

WHAT'S WORKED

- ☑ Of the 142 submitted test plans and sets of robust summaries for which comments were due through the end of 2002, EPA filed comments on all 142.
- ☑ Environmental Defense filed comments on 111 (78%) of these test plans and robust summaries (see Figure 5).
- ☑ Comments were received from animal protection organizations on 80 of the 142 test plans and sets of robust summaries, and from other parties on four of these submissions.
- ☑ Industry sponsors have submitted and EPA has posted responses to comments and revisions to 40 test plans and/or sets of robust summaries. (Although it would be desirable for revised plans to be routinely submitted and posted, such a step is not required under the program framework.)
- ☑ The great majority of these responses have effectively addressed the comments received from EPA. Our review of these responses found 26 of them to be fully responsive, 12 to be partially responsive and one to be non-responsive. While only a few direct responses to Environmental Defense's comments have been submitted, revised test plans have frequently included changes reflecting our comments.

FIGURE 5
Statistics on 194 test plans submitted as of 12/31/02

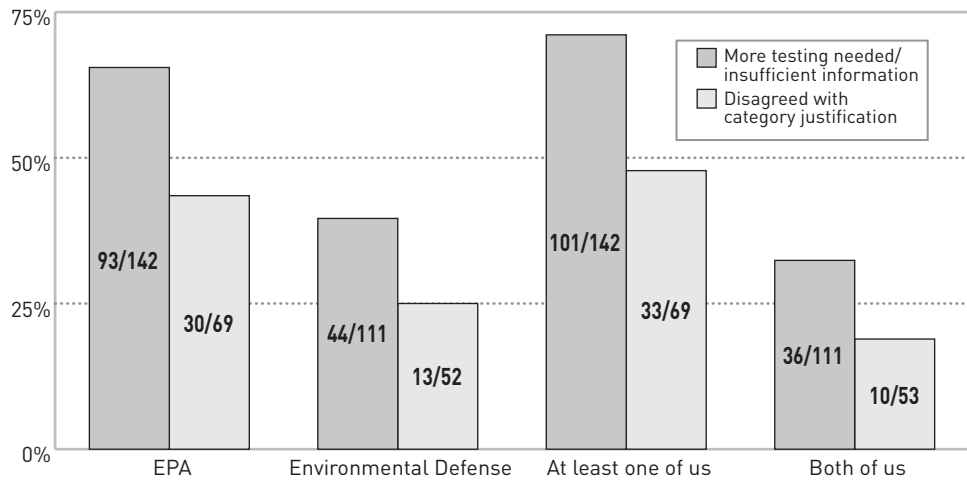


☑ While not required, some sponsors have submitted helpful information characterizing use of and/or exposure to the chemicals.⁶⁴

WHAT HASN'T WORKED—YET OR AS WELL

☒ Of the 142 test plans and robust summaries EPA or Environmental Defense or both has reviewed, for 101 of them (71%) at least one of us thought more data development or testing was needed, or we reserved judgment pending sponsor clarification (see Figure 6). On the other hand, in numerous instances, one or both of us argued that proposed tests were not necessary and hence should not be conducted in light of animal welfare concerns; see “Less testing is sometimes better,” page 29.

FIGURE 6
Summary of test plan comments



Values shown are: test plans receiving a given comment/total test plans reviewed.

- ❑ Of the 69 test plans and robust summaries for chemical categories that one or both of us has reviewed, at least one of us disagreed with the category definition or justification for 33 of them (48%).
- ❑ While not required under the program's framework, responses to comments and revisions have been submitted and posted for public review for only a minority of the test plans and robust summaries receiving comments.
- ❑ Most of the EPA and public comments on test plans and robust summaries submitted through the end of 2002 have not been provided within the formal

Less testing is sometimes better

Under the U.S. HPV Challenge Program, animal welfare concerns dictate that new testing involving laboratory animals be conducted only when data are not already available or cannot be developed using scientifically valid estimation methods.⁶⁵ As noted previously, new testing has been proposed by sponsors to fill only a small fraction of existing data gaps. Even so, in a number of cases sponsors have proposed animal testing that EPA and/or Environmental Defense, in their comments on those test plans, have argued is unnecessary and should not be conducted. Some representative examples follow:⁶⁶

p-Cumylphenol: EPA argued against conducting more acute toxicity studies, noting that the sponsor had submitted an adequate acute oral toxicity study. EPA also argued that a combined repeat dose/reproductive/developmental toxicity screening test was sufficient and obviated the need to conduct the separate pre-natal developmental toxicity test proposed by the sponsor.

2,3-Dihydro-2,2-dimethyl-7-benzofuranol: Environmental Defense opposed the sponsor's proposal to conduct acute dermal tests, arguing that they are not part of the Screening Information Data Set (SIDS) and would add little useful information to the assessment of human health risks. Environmental Defense also agreed with the proposal to combine repeated dose and reproductive/developmental toxicity studies into a single study because the combined approach minimizes the number of animals required.

Cyclic Neopentetetrayl Diphenyl Phosphite: EPA argued that a combined repeat dose/reproductive/developmental toxicity screening test was sufficient and obviated the need to conduct the separate pre-natal developmental toxicity test proposed by the sponsor. EPA also opposed the sponsor's proposal to assess acute toxicity using both oral and dermal routes of administration, noting that an acute oral toxicity study would satisfy the needs of the U.S. HPV Challenge Program.

Cashew nut shell liquid: Environmental Defense argued against the sponsor's proposal to conduct an acute toxicity study because other proposed studies will provide adequate high-dose toxicity data for screening-level purposes.

1,6-Hexamethylene bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate): Although EPA found the sponsor's acute aquatic toxicity data submitted for fish, invertebrates and algae to be inadequate, EPA argued that no further testing was needed because the uptake of the chemical by aquatic organisms and toxicity to aquatic organisms is unlikely due to the chemical's low water solubility.

Rosin esters: Environmental Defense opposed the sponsor's proposal to conduct acute toxicity testing on one of the category members given the results of pre-existing studies, arguing that "no scientific information of public health value will be obtained from conducting an acute toxicity study, so such a study would be a needless use of animals." Environmental Defense also argued against conducting an *in vivo* genetic toxicity test on another category member, pointing out that according to program guidance, *in vitro* genetic toxicity methods should be used "unless known chemical properties preclude its use," which was not the case in this instance.

Mixed xylenols and ethylphenols: Environmental Defense recommended that *in vitro* cytotoxicity studies be used instead of acute toxicity tests in rodents, arguing that the needed data will be obtained from another proposed test and conducting separate acute toxicity tests in rodents is an unnecessary use of animals.

comment period. EPA submitted 65% of its comments more than two weeks after the close of the comment period, and 31% more than three months late. Environmental Defense submitted 47% of its comments more than two weeks after the close of the comment period, and 5% more than three months late. Most of the comments from other parties were submitted on time.

As a means to gauge the performance of individual companies, consortia and major trade associations with respect to the quality of the test plans and robust summaries submitted, Environmental Defense has assigned an overall grade to each of these it has reviewed.⁶⁷ The grade, while admittedly subjective, reflects our view of the relative adequacy of the proposed scope of data development, clarity and completeness of the information presented, and, in the case of proposed categories, the soundness of the proposed category definition and justification. Table 6 presents our individual grades as well as grade point averages (GPA) for the companies, consortia and major trade associations that sponsored the 111 submissions we have reviewed.

The results indicate a wide disparity in the quality of test plans and robust summaries, with company or consortia GPAs ranging from “A” to “F.” The overall GPA for all 111 submissions we reviewed was 2.9, or a B minus.

CONCLUSIONS

- For a majority of test plans, comments received from EPA or Environmental Defense indicate a likely need for the sponsor to conduct additional data development or testing; in the case of test plans for proposed categories, deficiencies in the definition or justification for the proposed category were identified in nearly half of the test plans.
- The quality of submissions varies widely, as reflected both in the extent of deficiencies identified by commenters and, for those submissions Environmental Defense reviewed, in the overall grades we assigned.
- Because sponsors are not obligated to respond to EPA and public comments on test plans and robust summaries submitted (although some have done so), for most submissions it is not currently possible to tell whether: a) revisions have been made but not submitted; b) revisions will be, but have not yet been, made; or c) revisions will not be made.
- For those test plans and robust summaries that have been revised and resubmitted, the great majority appear to have been responsive to comments received from EPA and Environmental Defense.
- The results indicate that the review stage is proving critically important in flagging and addressing omissions, problems and concerns, and is adding significant value to the overall process.
- While essentially all of the test plans and robust summaries are receiving review and comment, many of the comments are being provided well after the close of the formal comment period. Because EPA has requested that sponsors not initiate data development until they have received EPA’s comments, the lateness of EPA’s comments may have contributed to delays in initiating data development, although the impact of any such delays will be difficult to discern until the final data are submitted.

TABLE 6

“Grade point averages” for sponsors of test plans reviewed by Environmental Defense

<i>A. Trade associations and company consortia</i>							
Sponsor	Overall GPA (A=4.0)	# OF TEST PLANS for proposed categories for individual chemicals Total # of HPV chemicals			Test plan name	# of HPV chemicals in test plan	Test plan grades
For all 111 test plans reviewed	2.9	53	58	663			A=64 B=10 C=20 F=17
Aluminum Alkyls Consortium	4.0	1	0	20	Aluminum Alkyls	20	A
American Chemistry Council	2.8	18	4	173	Acetic Acid & Salts	13	C
					Aliphatic Esters	46	B
					Cyclododecane, 1,2,5,6,9,10-hexabromo	1	A
					Phenol, 4,4-isopropylidene bis[2,6-dibromo-	1	A
					Diethylbenzene-Rich Streams	2	F
					Formates	4	A
					1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated	1	A
					m-Nitrotoluene	1	A
					Monocyclic Aromatic Amines (MAA)	4	C
					Propylene Streams Category	2	A
					Low 1,3-Butadiene C4	8	A
					Fuel Oils	12	C
					High Benzene Naphthas	19	F
					Resin Oils and Cyclodiene Concentrates	10	F
					Phosphoric Acid Derivatives	2	F
					Phthalate Esters	18	A
					Phthalate Esters/Trimellitates	4	A
					Substituted p-Phenylene-diamines	5	A
					Substituted Diphenylamines	8	A
					Thiuram Category	2	A
					Sulfenamide Accelerators	2	B
					Hindered Phenols	8	C
American Forest & Paper Assn.	2.0	0	1	1	Spent Pulping Liquor and Cooking Liquors	1	C
American Methanol Institute Testing Group	4.0	0	1	1	Methanol	1	A

TABLE 6 (CONTINUED)

“Grade point averages” for sponsors of test plans reviewed by Environmental Defense

Sponsor	Overall GPA (A=4.0)	# OF TEST PLANS			Test plan name	# of HPV chemicals in test plan	Test plan grades
		for proposed categories	for individual chemicals	Total # of HPV chemicals			
American Petroleum Institute	3.8	4	0	256	Waxes and Related Materials Gasoline Petroleum Gas Petroleum Coke	8 85 153 2	A A A B
Benzotriazoles Coalition	4.0	1	0	3	Benzotriazoles Category	3	A
Chlorobenzene Producers Assn.	4.0	1	0	4	Chlorobenzenes	4	A
Color Pigments Manufacturers Association, Inc.	2.0	0	1	1	Acetoacet-o-Anisidide	1	C
Dioxolane Manufacturers Consortium	4.0	0	1	1	1,3-Dioxolane	1	A
E.I. du Pont de Nemours & Co. & Akzo Nobel Chemicals, Inc.	4.0	0	1	1	Fatty Butanenitrile, 2,2'-azobis[2-methyl-	1	A
Ethanol HPV Challenge Consortium	4.0	0	1	1	Ethanol	1	A
Great Lakes Chemical Corporation and PPG Industries, Inc.	4.0	0	1	1	Carbonic Acid, Oxydiethylene Diallyl Ester	1	A
IHF Committee on HPV Challenge	3.5	1	1	7	Cyclic Anhydrides Cyclohexanol	6 1	A B
Mercaptans/Thiols Council	2.0	1	0	2	Methyl Mercaptans Analogs	2	C
NMA/NBMA Association	4.0	1	0	2	N-(methyl) Acrylamides	2	A
Phenolic Benzotriazoles Assn.	4.0	1	0	4	Phenolic Benzotriazoles	4	A
Phosphite Producers HPV Consortium	3.0	1	0	4	Isodecyl/Phenyl Phosphite Category	4	B
Pine Chemicals Association (PCA)	3.3	3	0	18	Rosin Esters Fatty Acid Dimers & Trimer Tall Oil and Related Substances	7 4 7	A B B
Propylene Carbonate/T-Butyl Alcohol HPV Committee	4.0	0	2	2	Propylene Carbonate t-Butyl Alcohol	1 1	A A

TABLE 6 (CONTINUED)

“Grade point averages” for sponsors of test plans reviewed by Environmental Defense

Sponsor	Overall GPA (A=4.0)	# OF TEST PLANS			Test plan name	# of HPV chemicals in test plan	Test plan grades
		for proposed categories	for individual chemicals	Total # of HPV chemicals			
Silicones Environmental, Health and Safety Council of North America (SEHSC)	2.0	1	0	2	Aminosilanes	2	C
Society of the Plastics Industry Inc. (SPI)	3.0	0	2	2	n-Butyl Glycidyl Ether	1	A
					Alkyl(C12-C14) Glycidyl Ether	1	C
Synthetic Organic Chemical Manufacturers Association (SOCMA)	2.7	2	1	7	Dibasic Esters Category	3	A
					Sulfosuccinates	3	F
					2-Imidazolidinone, 4,5-dihydroxy-1,3- bis(hydroxymethyl)-, methylated	1	A
The Flavor and Fragrance High Production Volume Consortia (FFHPVC)	3.0	7	1	51	Phenylethyl alcohol	1	C
					Benzyl Derivatives	8	C
					Cinnamyl Derivatives	4	C
					C6-C10 Aliphatic Aldehyde & Carboxylic Acids	4	A
					Monoterpene Hydrocarbons	12	A
					Ionone Derivatives	2	A
					Bicyclic Terpene Hydrocarbons	9	A
					Terpenoid Tertiary Alcohols and Related Esters	11	C
Trioxane Manufacturers Consortium	3.0	0	1	1	1,3,5-Trioxane	1	B
USOC/ETAD Disperse Blue 79:1 Consortium	0.0	0	1	1	C.I. Disperse blue 79:1	1	F
B. Individual companies							
3M	2.0	1	0	2	Perfluoro Compounds	2	C
Air Products and Chemicals, Inc.	4.0	0	1	1	2,4,7,9-Tetramethyl-5-decyne-4,7-diol	1	A
Akzo Nobel Functional Chemicals LLC	2.7	0	3	3	Phosphoryl Chloride, Polymer with Resorcinol Phenyl Ester	1	A
					Trixylenyl phosphate	1	A
					Butylated triphenyl Phosphate	1	F
BASF Corp.	4.0	1	0	9	Dicamba and Acifluorfen Intermediates Category	9	A
Bayer Corp.	4.0	0	1	1	Cyclohexyl Isocyanate	1	A
Cardolite Corp.	4.0	0	1	1	Cashew Nutshell Liquid	1	A

TABLE 6 (CONTINUED)

“Grade point averages” for sponsors of test plans reviewed by Environmental Defense

Sponsor	Overall GPA (A=4.0)	# OF TEST PLANS			Test plan name	# of HPV chemicals in test plan	Test plan grades
		for proposed categories	for individual chemicals	Total # of HPV chemicals			
Ciba Specialty Chemicals Corporation—Additives	4.0	0	1	1	1,6-Hexamethylene bis(3,5-di-tert-butyl-4-hydroxy-hydrocinnamate)	1 1	A A
Cytec Industries Inc.	3.0	0	1	1	2-Amino-2,3-dimethylbutanenitrile	1 1	B B
Deltech Corp.	1.3	0	3	3	p-Methylstyrene Vinyl Toluene p-Ethyltoluene	1 1 1	A F F
E.I. du Pont de Nemours and Company	4.0	2	5	10	Ethane, 2,2-dichloro-1,1,1-trifluoro- 1,5,9-Cyclododecatriene 4,4'-oxydianiline Dicarboxylic Acid Category Dinitrile Category Glycolic Acid Dimethyl Ether	1 1 1 3 2 1 1	A A A A A A A
Eastman Chemical Company	1.2	0	5	5	2-Butanone, 3-methyl- 2,2,4-Trimethylpentane-1,3-diol 1,4-Cyclohexanedimethanol Ethylene glycol diacetate Methyl N-Amyl Ketone	1 1 1 1 1	A C F F F
ExxonMobil Chemical Company	2.7	3	0	18	Alkyl Acetate C6 - C13 Category Alkyl Alcohols C6-C13 Neoacids C5-C28	6 6 6	A C C
Ferro Corporation	4.0	0	1	1	1,2-Dimethoxyethane	1	A
FMC Corporation	2.4	0	5	5	Butyllithium 2,3-Dihydro-2,2-dimethyl-7-benzofuranol Methallyl chloride Cyclopropanecarboxylic Acid Methallyloxyphenol	1 1 1 1 1	A A A F F
Great Lakes Chemical Corp.	2.7	0	3	3	Ethane, 1,2-dibromo Isopropylated Triphenyl Phosphate Phosphoric Acid tris(methylphenyl) ester (Tricresyl Phosphate)	1 1 1	A C C
Huntsman Corp.	0.0	0	1	1	C6-12 Alkyl Derivatives	1	F

TABLE 6 (CONTINUED)

"Grade point averages" for sponsors of test plans reviewed by Environmental Defense

Sponsor	Overall GPA (A=4.0)	# OF TEST PLANS			Test plan name	# of HPV chemicals in test plan	Test plan grades
		for proposed categories	for individual chemicals	Total # of HPV chemicals			
Merisol USA LLC	4.0	2	0	9	Ethylphenols	3	A
					Mixed Xylenols	6	A
Schenectady International (SII)	2.0	1	0	17	Alkylphenols	17	C
The Dow Chemical Company	0.0	0	2	2	Ethyl Monochloroacetate	1	F
					Chloracetyl Chloride	1	F
The Procter & Gamble Company	4.0	0	1	1	Nonanoic acid, sulfophenyl ester, sodium salt	1	A
Velsicol Chemical Corp.	3.8	0	4	4	Chlorendic Anhydride	1	A
					Triethylene Glycol Dibenzoate	1	A
					Dipropylene Glycol Dibenzoate	1	A
					Isodecyl Benzoate	1	B

Public access to status information, industry submissions and results

EXPECTATIONS

- Industry would track commitments by individual companies and consortia, and provide public access to complete and up-to-date status information via the Internet.
- EPA would provide public access via the Internet to documents submitted by industry, as well as comments from EPA and the public.
- EPA would provide public access via the Internet to hazard data on HPV chemicals as the final data sets were submitted.
- Environmental Defense would monitor program progress and report on its status.

WHAT'S WORKED

- ☑ EPA's ChemRTK web site is providing timely access to industry submissions and comments on those submissions.
- ☑ EPA issued a program status report in October 2001, and is also providing in a timely fashion summary tables that compile commitment status information and provide links to relevant documentation.
- ☑ Environmental Defense is issuing this status report, and is planning to make this information available via the Internet in a manner that will allow the status of a given sponsor commitment or chemical to be quickly ascertained.

WHAT HASN'T WORKED

- ❑ While the American Chemistry Council (ACC) and the American Petroleum Institute (API) have each developed web sites for tracking the commitments of its members, no integrated industry database exists. Moreover, neither the ACC nor API database provides complete and up-to-date information even on the status of their own members' commitments. Nor is industry providing access to information on commitments of companies or consortia beyond those associated with ACC and API (except indirectly through submission of information to EPA and EPA's posting of that information on its own web site). Finally, the information on the ACC and API web sites is not provided in database format and is not user-friendly.⁶⁸
- ❑ EPA's web site is not effective at allowing either the status of individual chemicals or the overall program to be readily assessed and tracked. Most of the status information is not provided in database format and is not user-friendly.⁶⁹
- ❑ While the EPA information is updated fairly frequently, and some effort is made to flag changes, it is virtually impossible to discern in a comprehensive manner what information has changed (i.e., has been added, removed or altered) from one posting to the next. This is in large part a result of the decision to use non-database file formats. As a result, quantitative analyses of the sort conducted for this report must start largely from scratch each time data are updated.
- ❑ EPA has not maintained an historical record (other than through links to scanned copies of literally hundreds or thousands of individual commitment letters) of the original start years and changes to them over time. As discussed earlier, this means that true program status vis-à-vis the original commitments is difficult or impossible to ascertain.
- ❑ EPA has yet to release even a beta version of the repository database for HPV chemical hazard data, which is intended to serve as the vehicle for making these data publicly available.
- ❑ While no specific timeframe for Environmental Defense's monitoring activities was established, we would have preferred to have issued this first status report well before now.

CONCLUSIONS

- While considerable information is being made available by EPA that relates to the status of commitments to sponsor chemicals under the U.S. HPV Challenge Program, industry has largely failed to live up to its pledge to track and report such information in a timely and comprehensive manner.
- The information EPA provides on its web site, while timely and comprehensive, is not provided in a manner that allows the overall progress of the program to be gauged, and is provided in a format that complicates the ability of others to analyze the information so as to independently gauge program progress.

- EPA's prompt completion and release of a repository database for HPV chemical hazard data is critical lest it become a rate-limiting factor in the program.⁷⁰
- Environmental Defense's status report has been issued well into the course of the program, lessening the ability of the relevant parties to make needed mid-course corrections.
- These limitations to information all compromise the program's transparency to the public, as well as the ability to demonstrate steady progress toward timely completion.

Some closing thoughts

Although implementation of the U.S. HPV Challenge Program has by no means been flawless, it nonetheless constitutes a remarkable achievement that is charting new territory. Both the amount of hazard data being developed and made available, and the pace at which this is occurring, are unprecedented—and, remarkably, are being achieved through a voluntary program in which hundreds of companies are participating and to which a federal agency has devoted substantial resources and shown considerable creativity and determination. Many of the shortcomings and challenges we identify are perhaps to be expected in a program of this magnitude and aspiration; some causes of delay could not reasonably have been anticipated at the outset, or result from improvements made to the original program framework. At the same time, we believe these shortcomings and challenges must be overcome if the program is to succeed. What is needed now is a recommitment on the part of all participants to see the program through to completion.

Glossary: Key terms and acronyms used in this report

ACC: American Chemistry Council. The primary trade association of the U.S. chemical industry, formerly the Chemical Manufacturers Association, which was a key player in the development of the framework for the HPV Challenge Program. ACC is also the U.S. affiliate to ICCA (see ICCA below).

API: American Petroleum Institute. The major U.S. trade association for the petroleum industry, many of whose members make petroleum-derived chemicals and are sponsors under the HPV Challenge Program.

CAS number: A registry number for a chemical assigned by the Chemical Abstract Service. Because a chemical may have many different valid names, CAS numbers are the most definitive means of identifying specific chemicals. In certain cases, individual CAS numbers are also assigned to mixtures or small classes of chemicals.

EPA: U.S. Environmental Protection Agency, which administers the HPV Challenge Program.

HPV chemical: A high production volume chemical, defined as an industrial chemical produced in or imported into the U.S. at a level of 1 million pounds or more annually. Industrial chemicals are those regulated under the Toxic Substances Control Act (see TSCA below), and exclude pesticides, food additives, drugs and cosmetics. Chemicals reported to be HPV under the 1990 Industrial Update Rule (see IUR below) serve as the initial core list of chemicals subject to the HPV Challenge Program.

ICCA: International Council of Chemical Associations. ICCA consists of representatives of chemical associations from the United States, Canada, Europe, Japan, Australia, Mexico, Brazil, Argentina, and New Zealand. ICCA has its own global initiative on international HPV chemicals, calling for the assessment and testing of about 1,000 “high priority” chemicals by the year 2004. The assessments and testing are directly tied in with the OECD’s HPV SIDS Program.

IUR: Inventory Update Rule, a regulation under the Toxic Substances Control Act (TSCA). Under the IUR, companies that make and use industrial chemicals are required to provide EPA with information every four years on the quantities of chemicals they produce in, or import into, the U.S., if those quantities exceed certain thresholds. EPA makes these data publicly available after removing data claimed by submitters to be confidential business information. Data from the 1990 IUR served to define the initial core list of high production volume chemicals subject to the HPV Challenge Program. Data from the 1998 IUR are the latest publicly available data; data for 2002 have been reported but have not yet been released.

OECD: Organization for Economic Cooperation and Development, an international organization comprised of governmental representatives from the U.S.

and about 30 other countries “sharing a commitment to democratic government and the market economy.” OECD’s Existing Chemicals Program coordinates an international effort to develop data on HPV chemicals, and was the forum under which international consensus was reached on the basic set of hazard data on chemicals needed for a screening level assessment, termed the Screening Information Data Set, or SIDS.

Orphan chemical: A term coined to refer to a chemical within the scope of the HPV Challenge Program that has not been sponsored and has not otherwise been exempted or removed from the program. Because publicly available data on production volume are both incomplete and somewhat dated, there is uncertainty as to whether all such unsponsored HPV chemicals continue to be produced at levels defining an HPV chemical.

“Read-across”: A method for estimating values for specific physical-chemical and hazard-related properties of one chemical in a category of chemicals by interpolation between and among, and in some cases extrapolation from, the known values for the same properties other members of the chemical category. Where scientifically appropriate based on the extent of the existing data and the similarity of the chemicals in question, use of read-across methods can provide data sufficient to meet the requirements of the HPV Challenge Program without requiring new testing (see also SAR/QSAR below).

RTK: Right to know. In the context of this report, a term that signifies the right of citizens to have access to information about the hazards posed by chemicals to which they or the environment may be exposed. The HPV Challenge Program is a component of EPA’s Chemical Right-to-Know Initiative.

SAR/QSAR: (Quantitative) structure-activity relationship. The basis for methods used to estimate values for specific physical-chemical and hazard-related properties of a chemical based on the degree of its structural similarity to chemicals with known values for those same properties. Where scientifically appropriate based on the extent of the existing data and the similarity of the chemicals in question, use of SAR/QSAR methods can provide data sufficient to meet the requirements of the HPV Challenge Program without requiring new testing.

SIDS: Screening Information Data Set. A basic set of hazard data on chemicals needed for a screening level assessment, developed through an international consensus process under the Existing Chemicals Program of the OECD. Both in the OECD program and the U.S. HPV Challenge Program, SIDS is regarded as the minimum information needed to complete a preliminary hazard assessment for an HPV chemical.

TSCA: Toxic Substances Control Act. Passed in 1976, the primary federal environmental statute governing industrial chemicals. TSCA provides the statutory authority for EPA’s regulation of industrial chemicals (i.e., chemicals other than pesticides, food additives, drugs and cosmetics), including the authority to require chemical manufacturers to develop data sufficient to characterize the hazards posed by chemicals used in commerce.

Notes

- ¹ Animal protection organizations have filed comments on approximately 80 test plans, generally arguing that no additional animal testing should be conducted at all. EPA and Environmental Defense in their comments have identified a number of specific instances where a sponsor's proposal to conduct animal testing appeared unwarranted. See "Less testing is sometimes better," page 29.
- ² Based on the most recent publicly available data, for production in 1998 as reported under the Toxic Substances Control Act Inventory Update Rule. See "Searching for homes," page 15, for more information. Because of limitations in available data, we could not produce a list of those companies that have no orphans, i.e., all of whose HPV chemicals are sponsored.
- ³ This figure falls to 49% if one considers all of the core list chemicals (including orphans) that remain within the scope of the U.S. program, and it rises to 70% if one considers only those core list chemicals within the scope of the program that have commitments solely through the program (and not the ICCA initiative). See Footnote 61 for derivation of each of these percentages.
- ⁴ The grades were assigned by George Lucier, Ph.D., Director Emeritus of the Environmental Toxicology Program for the National Institute for Environmental Health Sciences, who serves as a consulting adjunct scientist for Environmental Defense and is the principal author of most of our comments on test plans and robust summaries.
- ⁵ Toxic Substances Control Act of 1976, Section 2(b)(1), 15 U.S.C. 2601(b)(1).
- ⁶ National Research Council, *Toxicity Testing*. Washington, D.C.: National Academy Press, 1984. Table 7, p. 84.
- ⁷ Environmental Defense Fund. *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States*. New York, NY: Environmental Defense Fund, 1997. (www.environmentaldefense.org/documents/243_toxicignorance.pdf)
- ⁸ High Production Volume (HPV) chemicals are those subject to the Toxic Substances Control Act (TSCA), which excludes pesticides, food additives and cosmetic and pharmaceutical chemicals. TSCA Section 3(2), 15 U.S.C. 2602(2).
- ⁹ See Footnote 13 below.
- ¹⁰ *Toxic Ignorance* examined the extent of data available for a representative subset of 100 randomly-selected HPV chemicals that were regulated under one or more major environmental laws, and it examined only data available for human health-related data elements.
- ¹¹ Environmental Defense Fund press release, "EDF Requests Top 100 Chemical Makers To Test Their Own Chemicals, July 29, 1997, Washington, D.C.; "Environmental Defense Puts Producers on the Spot Over Untested High-Volume Chemicals," *Chemical Week*, Aug. 6, 1997.
- ¹² Environmental Defense Fund press release, "Eleven Major Chemical Makers Agree to Health Tests; Some Refuse", December 3, 1997, Washington, D.C. (www.environmentaldefense.org/pressrelease.cfm?ContentID=1847) Environmental Defense placed an ad in *USA Today* that same month captioned "Santa isn't the only one making two lists," identifying companies that had agreed to assure the availability of screening data and others that had declined to do so; see www.environmentaldefense.org/pressrelease.cfm?ContentID=1847. See also "Pressure mounts for more thorough chemical testing," *Chemical & Engineering News*, Dec. 16, 1997.
- ¹³ U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals?* Washington, D.C.: U.S. Environmental Protection Agency, April 1998. (www.epa.gov/opptintr/chemtest/hazchem.htm); and *Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals*. Prepared by ICF Kaiser International for the Chemical Manufacturers Association, Arlington, Virginia, 1998.
- ¹⁴ An analogous study conducted in 1999 by the European Union (EU) found that only 14% of high-production-volume chemicals produced in the EU had a full set of publicly-available basic-screening level hazard data. The EU study is available online at ecb.jrc.it/cgi-bin/reframer.pl?A=EX&B=/existing-chemicals/datavail.htm.
- ¹⁵ For press coverage of this challenge, see, for example, Cushman, "Gore Asks Chemical Industry to Test for Any Toxic Effects," *New York Times*, April 22, 1998; Warrick, "Gore Pushes Industry to

- Issue Health Data on Chemicals,” *Washington Post*, April 22, 1998. Also see: Environmental Defense Fund press release, “EDF Applauds Clinton Administration Initiative On Chemical Testing”, April 21, 1998, New York, NY. (www.environmentaldefense.org/pressrelease.cfm?ContentID=1519)
- ¹⁶ See the “Joint Announcement of Cooperative Program for High Production Volume U. S. Industrial Chemicals” and accompanying documents, available online at www.environmentaldefense.org/article.cfm?ContentID=661.
- ¹⁷ EPA was to issue these regulations under the authority of TSCA Section 4, 15 U.S.C. 2603.
- ¹⁸ 65 Federal Register 81658. As stated in this notice: “EPA has made preliminary findings for these [initial 37] chemicals under TSCA section 4(a)(1)(B) that: They are produced in substantial quantities; there is or may be substantial human exposure to them; existing data are insufficient to determine or predict their health and environmental effects; and testing is necessary to develop such data. Testing for additional HPV chemical substances will be proposed at a later date as the Agency learns more about these additional substances with respect to human exposure, release, and sufficiency of the data and experience available on the hazards of the substances.” To date, EPA has yet to finalize the initial proposed test rule, and has not proposed test rules for any additional unsponsored chemicals. Meanwhile, 12 of these chemicals have received sponsorship commitments.
- ¹⁹ Guidance documents for the HPV Challenge Program are available online at www.epa.gov/chemrtk/guidocs.htm.
- ²⁰ Test plans and robust summaries are available online at www.epa.gov/chemrtk/viewsrch.htm.
- ²¹ Shortly after the program was launched (and before any test plans had been submitted), representatives of animal-protection organizations urged inclusion of a comment period. This request, which was widely regarded as meritorious, was promptly implemented and has become a fully integrated component of the program.
- ²² Agency and public comments, as well as sponsors’ responses to comments and revised test plans and robust summaries, can be found online at www.epa.gov/chemrtk/viewsrch.htm.
- ²³ As noted above, HPV chemicals are defined with reference to chemicals that must report under the Toxic Substances Control Act Inventory, which excludes pesticides, food additives, drugs, and cosmetics. See Footnote 8.
- ²⁴ Because of delays in the release of the 1994 IUR report, the 1990 IUR data were the latest available when the HPV program was being developed. Companies are encouraged, however, to sponsor chemicals reported as HPV in 1994 or after, and many have done so; see “Getting with the program, page 6.
- ²⁵ ICCA consists of representatives of chemical associations from the United States, Canada, Europe, Japan, Australia, Mexico, Brazil, Argentina, and New Zealand. ICCA has its own global initiative on international HPV chemicals, calling for the assessment and testing of about 1,000 “high priority” chemicals by the year 2004. The assessments and testing are directly tied in with the OECD’s HPV SIDS Program.
- ²⁶ A given chemical can actually have more than one correct name. For this reason, chemicals are most specifically identified by their CAS (Chemical Abstract Service) registry numbers, which are unique identifiers assigned to individual chemicals or mixtures of chemicals. Sponsorship commitments typically relate to specific CAS numbers. In this report, CAS numbers are used as primary chemical identifiers, and the number of chemicals we cite in a given instance generally represents the number of unique CAS registry numbers. For simplicity, we will generally use the term “chemical” to mean a single CAS number, even though a single CAS number may in fact represent more than one chemical, typically either a mixture of chemicals produced in an industrial process (e.g., fuel oil), or a closely related group of chemicals (e.g., mixed xylenols).
- ²⁷ Although data from the 1998 Inventory List are available, EPA has not identified additional HPV chemicals beyond those already identified from the 1990 and 1994 Inventory lists.
- ²⁸ For a chemical to be deemed no longer HPV, EPA requires that all manufacturers and importers of the chemical that reported to the 1990 Inventory provide support for the claim it is no longer HPV and is not likely to become HPV again. In addition, all manufacturers and importers of the chemical that reported to the 1994 and 1998 Inventories but not the 1990 Inventory must verify the chemical is no longer HPV and is not likely to become HPV again. For more detail, see EPA’s guidance on this topic, available online at www.epa.gov/chemrtk/nolohpv8.htm.
- ²⁹ To proceed through the OECD SIDS program, chemicals must be sponsored by an OECD member

- country. In some cases, data development is done by the member country, but more often (and increasingly) it is undertaken by an industry sponsor working with the country sponsor.
- ³⁰ For example, EPA does not require submission of data on reproductive toxicity for chemicals generated as closed system intermediates which are “strictly confined within a closed process and to which exposure is limited;” see EPA’s guidance on testing of closed system intermediates, available at www.epa.gov/chemrtk/closed9.htm.
- ³¹ See EPA’s guidance on evaluating the adequacy of existing data, available online at www.epa.gov/chemrtk/datadfin.htm.
- ³² See EPA’s guidance on the use of structure-activity relationship models, available online at www.epa.gov/chemrtk/sarfin1.htm.
- ³³ Health-related data elements included in the analysis are acute, repeat dose, reproductive, developmental, and genetic toxicity, and environmental data elements included are acute toxicity to fish, daphnia, and algae.
- ³⁴ Data for the first 46 test plans and robust summaries (those posted on the EPA program web site through October 4, 2001) were published by EPA in its October 2001 program status report (see www.epa.gov/chemrtk/hpvstat.htm); they include test plans for 23 categories and 23 individual chemicals, covering a total of 325 chemicals. Data for the first 142 submissions (those posted through August 22, 2002) were provided to Environmental Defense by Richard Hefter, EPA Office of Pollution Prevention and Toxics, in January 2003; they include test plans for 69 categories and 73 individual chemicals, covering a total of 851 chemicals.
- ³⁵ See EPA’s draft category guidance online at www.epa.gov/chemrtk/categuid.htm.
- ³⁶ See EPA’s draft category guidance online at www.epa.gov/chemrtk/categuid.htm.
- ³⁷ As elsewhere in this report, the term “chemical” typically refers to a single CAS registry number. The number of chemicals in a given category provided in Table 1 and elsewhere in this report corresponds to the number of unique CAS numbers, even though a single CAS number can be assigned to a mixture of more than one chemical. Some categories in the HPV Challenge Program also include non-HPV chemicals, which may provide data that assist in defining the category and allow data for other category members to be estimated. The counts of category members provided in Table 1 include only those that are HPV chemicals.
- ³⁸ *Sources for the statistics cited in this section:* Environmental Defense analysis of: (1) EPA’s latest available HPV Company/Chemical lists (current as of 11-22-02) contained in database files dated 12-5-02, downloaded from EPA’s ChemRTK web site (www.epa.gov/chemrtk/hpvchmlt.htm); (2) EPA’s latest master summary table of program commitments, dated 11-22-02, downloaded from EPA’s ChemRTK web site (www.epa.gov/chemrtk/sumresp.htm); (3) ICCA’s latest list of commitments for all chemicals, generated as a report on January 3, 2003 using its HPV Chemical Tracking System (www.iccahpv.com/reports/ChemicalSearch.cfm); (4) ICCA’s latest HPV working list, dated January 7, 2003, downloaded from ICCA’s web site for its Global Initiative on High Production Volume (HPV) Chemicals (www.cefic.org/activities/hse/mgt/hpv/hpvinit.htm); (5) the most recent OECD HPV Chemicals List compiled in 2000 (www.oecd.org/pdf/M00017000/M00017224.pdf); and (6) a list of OECD SIDS chemicals and their status, generated as a report on January 2, 2003 using the OECD Integrated HPV Database (cs3-hq.oecd.org/scripts/hpv/).
- ³⁹ See the “Joint Announcement of Cooperative Program for High Production Volume U. S. Industrial Chemicals” and accompanying documents, available online at www.environmentaldefense.org/article.cfm?ContentID=661.
- ⁴⁰ An additional 13 chemicals have provisional commitments under the program.
- ⁴¹ Based on a comparison of EPA’s HPV lists for 7-12-02 and 11-22-02. For the new orphans, where sponsors provided an explanation for withdrawing their sponsorship, generally it was that they no longer produce the chemical in question; while this explanation is logical from the perspective of the individual producer, these withdrawals at this point in the program greatly increases the risk either that the chemicals will not be sponsored or that data development will not be completed until after the 2005 target year. Of the 17 newly-sponsored chemicals, 11 are being sponsored directly under the U.S. program, the other six under the ICCA Initiative.
- ⁴² Table 2 lists companies that publicly reported producing or importing at least six of the orphan chemicals in the 1998 Inventory reporting cycle. Appendix A provides a more comprehensive list of all companies that publicly reported producing or importing one or more orphan chemicals in

1998. Neither list can be regarded as complete because they exclude any company that claimed its identity and association with production or import of these chemicals as confidential business information; see text and next footnote.

⁴³ The most recent publicly available data on production and import of industrial chemicals (which are collected quadrennially) are those from the 1998 Inventory reporting cycle. For more information, see www.epa.gov/oppt/iur/iur98/index.htm. EPA is in the process of compiling data collected in 2002, but they are not yet publicly available. For this analysis, we used non-confidential 1998 Inventory data contained in two databases obtained from EPA: (1) The 1998 List of Companies Reporting 1990 HPV chemicals, downloaded from the HPV Challenge Program web site (www.epa.gov/chemrtk/hpvcilst.htm); (2) A database of non-confidential data reported under the 1998 Inventory Rule obtained from the EPA Office of Pollution Prevention and Toxics in November 2002. All companies listed as reporting production or import of orphan chemicals in either database were compiled, and then the number of orphans reported by each company was calculated.

⁴⁴ 65 Federal Register 81658, December 26, 2000.

⁴⁵ Beyond the core list, there are additional chemicals that have been voluntarily sponsored by ICCA; all together, a total of 550 chemicals are exclusively sponsored by ICCA under the OECD SIDS Program and another 249 are sponsored under both the U.S. and OECD programs.

⁴⁶ Of the 1990 Inventory core list of 2782 chemicals, 1,777 are still within the scope of the U.S. HPV Challenge Program (see Figure 1B). Of these, the 521 orphans represent 29%.

⁴⁷ For more detail, see EPA's guidance on this topic: www.epa.gov/chemrtk/nolohpv8.htm.

⁴⁸ For 18 of these orphans, production volumes exceeding 500,000 pounds were reported in one or both of the 1994 and 1998 Inventory reporting cycles. For the other 15 orphans, production volumes between 10,000 and 500,000 pounds were reported in both of the 1994 and 1998 Inventory reporting cycles.

⁴⁹ These definitions are taken from EPA's program guidance on "What to test," available online at www.epa.gov/chemrtk/w2test9.htm.

⁵⁰ Personal communication from B. Leczynski, Chief, Existing Chemicals Branch, U.S. EPA Office of Pollution Prevention and Toxics, January 2003.

⁵¹ Eastman's initial submission for C4 Aldehyde Condensation Products was made on August 30, 2002, and a revised version was submitted on February 5, 2003. These documents are available online at www.epa.gov/chemrtk/c4aldehy/c13949tc.htm.

⁵² See EPA's comments online at www.epa.gov/chemrtk/c4aldehy/c13949ct.htm.

⁵³ See Footnote 46 for derivation of this percentage.

⁵⁴ Statistics in this section include all test plans submitted to EPA through December 31, 2002. *Sources for the statistics in this section:* Environmental Defense analysis of: (1) EPA's latest available HPV Company/Chemical lists (current as of 11-22-02) contained in database files dated 12-5-02, downloaded from EPA's ChemRTK web site (www.epa.gov/chemrtk/hpvchmlt.htm); (2) EPA's latest master summary table of program commitments, dated 11-22-02, downloaded from EPA's ChemRTK web site (www.epa.gov/chemrtk/sumresp.htm); (3) EPA's earlier master summary table of program commitments, dated 7-12-02, downloaded from EPA's ChemRTK web site (www.epa.gov/chemrtk/sumresp.htm); and (4) test plans and robust summaries submitted to EPA through December 31, 2002, and comments on and revisions to test plans and robust summaries posted on EPA's ChemRTK web site through December 31, 2002. (www.epa.gov/chemrtk/viewsrch.htm).

⁵⁵ Initially, data development for a small group (approximately 5%) of chemicals was to have begun in 1999. Delays in the issuance of test plan preparation guidance by EPA and other unforeseen delays pushed back this schedule by approximately six months.

⁵⁶ The initial commitment made under the HPV Challenge Program was to deliver test plans at the beginning of the proposed start year, but as mentioned in the prior footnote, this schedule was pushed back by approximately six months at the outset.

⁵⁷ Our analysis, based on the conservative assumptions described below, shows that 13% of test plans received to date were submitted prior to their proposed start year, 12% within the first six months of their start year, 66% in the last six months of their start year, and 9% after the end of their start year. As mentioned in "Moving target," page 18, the version of EPA's master summary table of HPV Challenge Program commitments, the "HPV Challenge Summary Report," dated 7-12-02 serves as our baseline set of start years. This approach is conservative: Had we had access to the

start years indicated in the original commitments, fewer test plans would have been identified as submitted early or on time, and more would have been identified as submitted late. In addition, EPA's summary table lists the CAS numbers for numerous chemicals more than once, with different start years. For our analysis, we conservatively assumed that the latest of these start years applied; had we used the earlier start years for these chemicals, fewer would have been counted as submitted early and more would have been counted as late. Thus the 91% figure is an overestimation of the number of test plans and robust summaries received during or before their originally designated start year.

⁵⁸ As with our analysis of test plans that have been submitted, where EPA's master table lists a chemical's CAS number more than once with different start years, we conservatively assumed that the latest of these start years applied; had we used the earlier start years for these chemicals, an even greater number would have been counted as overdue. In addition, in counting chemicals representing commitments for which test plans have yet to be submitted, we excluded: (1) any chemical for which a test plan was already submitted even if a separate commitment involving a different sponsor for that chemical has yet to be met; (2) any commitment made solely under an ICCA commitment through the OECD SIDS Program, presuming that test plans will not be submitted to the U.S. HPV Challenge Program for chemicals covered by such commitments, even though test plans for some such chemicals have been submitted; and (3) any chemical which is in or through the final phase of the OECD SIDS Program, even though that same chemical is also listed as fully sponsored under the U.S. program. Again, these are conservative assumptions that reduce the estimated number of chemicals for which test plans were counted as yet to be submitted. Without these assumptions, test plans for several hundred additional commitments would have been counted as yet to be submitted and overdue. Finally, we excluded from our counts all commitments listed in EPA's master table for which a start year was not indicated.

⁵⁹ Tables 4 and 5 rank the performance of U.S. and global chemical companies, and major trade associations and consortia of companies, respectively, that have sponsored multiple chemicals under the U.S. HPV Challenge Program. Appendices B and C provide complete lists of all sponsoring companies and consortia of companies (including trade associations), respectively, ranked by these same performance measures.

⁶⁰ Test plans are overdue for a total of 382 chemicals, but test plans covering 57 chemicals due in 2003 or 2004 have already been submitted, yielding a net backlog of 325 chemicals (382-57).

⁶¹ The denominator for this percentage is 1,536 chemicals, which is the number of core list chemicals with full or provisional commitments under the U.S. program, as indicated in Figure 1C (873/1,536 = 57%). Other relevant contexts for considering the 873 core list chemicals and 951 total chemicals covered by submitted test plans include the following:

- Of the 1,777 core list chemicals (indicated in Figure 1B and "Getting with the program," page 6) that encompass all core list HPV chemicals still within the scope of the U.S. program, 873 constitute 49%.
- Of the 1,250 1990 core list chemicals that are still within the scope of the U.S. program and fully sponsored solely under that program, 873 constitute 70%.
- Of the 1,910 1990 Inventory core list chemicals fully or provisionally sponsored (which includes 1990 Inventory chemicals exclusively sponsored through ICCA initiative under the OECD SIDS Program), 873 constitute 46%.
- Of the 2,202 fully sponsored chemicals (which includes 1994 IUR and additional chemicals voluntarily being sponsored, and those being sponsored indirectly as well as directly), 951 constitute 43%.

⁶² Statistics in this section reflect all comments on and revisions to test plans and robust summaries submitted to EPA through December 31, 2002. *Source for the statistics:* Environmental Defense analysis of test plans and robust summaries submitted to EPA through December 31, 2002, and comments on and revisions to test plans and robust summaries posted on EPA's ChemRTK web site through December 31, 2002 (www.epa.gov/chemrtk/viewsrch.htm).

⁶³ As noted above (see Footnote 21), the original framework for the program did not envision a comment period; one was added at the suggestion of animal-protection organizations early in the program's implementation.

⁶⁴ The Alliance for Chemical Awareness, an industry-based organization that has an external advisory board on which Environmental Defense serves, recently issued guidance for developing use and exposure-related information for industrial chemicals, in part for use in the HPV Challenge

Program (available online at www.chemicalawareness.org/exposure/eframework.html). To date, none of the test plans and robust summaries submitted has fully conformed to this guidance.

⁶⁵ The need to avoid unnecessary animal testing has been clearly articulated on numerous occasions. See, for example: (1) EPA's 1999 guidance concerning principles for program participants to follow with respect to animal welfare, available online at www.epa.gov/chemrtk/ceoltr2.htm; (2) EPA's factsheet on animal welfare, available online at www.epa.gov/chemrtk/anfac2.pdf; (3) EPA's 1999 paper, "HPV Chemical Human Health Testing: Animal Welfare Issues and Approaches," which describes approaches which can be used to minimize and optimize animal usage when developing data on HPV chemicals, available online at www.epa.gov/chemrtk/humanml.htm; and (4) Environmental Defense's congressional testimony and other materials addressing animal welfare concerns and promoting the development and use of non-animal testing methods and approaches, available online at www.environmentaldefense.org/documents/646_ACF699.html.

⁶⁶ EPA's and Environmental Defense's comments summarized in this section can be found under the corresponding industry submissions available online at www.epa.gov/chemrtk/viewsrch.htm.

⁶⁷ The grades were assigned by George Lucier, Ph.D., Director Emeritus of the Environmental Toxicology Program for the National Institute for Environmental Health Sciences, who serves as a consulting adjunct scientist for Environmental Defense and is the principal author of most of our comments on test plans and robust summaries.

⁶⁸ Most data on the ACC and API web sites is available solely in the form of PDF or HTML files, which cannot be sorted, counted or parsed in a manner that lends itself to quantitative analysis. Only by painstakingly transforming the data files into database formats would it be possible to analyze the information they contain. Coupled with the fact that the sites are neither comprehensive nor up-to-date, we were not able to employ the information they provide to conduct the analyses provided in this report.

⁶⁹ All of the analyses conducted for this status report were made highly labor-intensive by the fact that (as just discussed with respect to the ACC and API web sites) most data from EPA's web site is available solely in the form of PDF or HTML files, which cannot be sorted, counted or parsed in a manner that lends itself to quantitative analysis. Only by painstakingly transforming the data files into database formats was it possible to analyze the information they contain. One notable exception to this situation is the access provided to the HPV lists themselves, which are provided as downloadable database files.

⁷⁰ Final data sets for the first chemicals to go through the program should shortly be ready for dissemination, given that more than 24 months has already elapsed following the end of the first comment periods in late 2000.

APPENDIX A

Companies reporting that they produced or imported one or more “orphan” chemicals in 1998

Company name (in alphabetical order)	# of orphans*	Company name (in alphabetical order)	# of orphans*
3M	5	Coastal Refining & Marketing, Inc.	1
A.E. Staley Manufacturing Company	1	Colourtex, Inc.	1
Aceto Corporation	13	Condea Vista Company	4
Acme Steel Company	3	Coopers Creek Chemical Corp.	2
Agfa Div. Of Bayer Corp.	2	Creanova, Inc.	10
Air Products And Chemicals, Inc.	1	Crowley Tar Products Company, Inc.	1
AK Steel Corporation	3	Crown Paper Company	1
Akzo Nobel Surface Chemistry, Inc.	2 {1}	Crown Vantage	1
Albemarle Corporation	2	Daicolor-Pope, Inc.	1
Aldrich Chemical Company, Inc.	1	Davos Chemical Corporation	1
Alliant Techsystems, Inc.	1	Deltech Corporation	1
Allied-Signal, Inc.	10	Diaz Chemical Corp.	1
Aluminum Company Of America	1	DIC International (USA), Inc.	1
Ameribrom, Inc.	3	Dixie Chemical Company	5
American Cyanamid Company	1	Dover Chemical Corp.	2
Amoco Corporation	2	Dow Chemical Company	8 {1}
Apollo Colors, Inc.	1	Dow Corning Corporation	1
Arco Chemical Company	2	DSM Chemicals North America, Inc.	1
Ashland Chemical Company	1	Dynachem, Inc.	4
Atotech USA, Inc.	1	Dyno Nobel, Inc.	2
Autoliv Asp., Inc.	1	Dystar LP	2
BASF	21 {3}	E.I. du Pont de Nemours & Co., Inc.	12 {1}
Bethlehem Steel Corporation	3	E.T. Horn Co.	1
Borden Chemical, Inc.	1	Eastman Chemical Company	8 {2}
BP Oil Company	2 {2}	Economy Mud Products Co.	1
Bush Boake Allen, Inc.	1	ELF Atochem North America, Inc.	4
Capital Resin Corp.	1	Empire Coke Co.	4
Cardolite Corp.	1	Erie Coke Corporation	2
Cargill, Incorporated	1	Esprit Chemical Co.	2
Caschem, Incorporated	2	Ethox Chemicals, LLC	1
Castrol Industrial North America	1	Everlight USA, Inc.	1
Cedar Chemical Corp.	1	Exxon Corporation	10
Celanese	3	Fabricolor, Inc.	1
Cerdec Corporation	1 {1}	Farmland Industries, Inc.	1
CF Industries, Inc.	3	First Chemical Corporation	2
Champion Techs., Inc.	1	Flexsys America, LP	1
Charkit Chemical Corp.	4	FMC Corporation	8 {3}
Chattem Chemicals, Inc.	1	Fort James	2
Chem One Corporation	1	Freudenberg-NOK	1
Chemical Products Corp.	1	Gaylord Container Corporation	1
Chevron Chemical Co., LLC	1	General Electric Co.	2
Chugai Boyeki (America) Corp.	1	Givaudan Roure Corporation	1
Ciba Specialty Chemicals Corporation	6	Grain Processing Corporation	1
Cincinnati Specialties, Inc.	3	Great Lakes Chemical Corporation	4 {3}
Citizens Gas & Coke Utility	3	Great Western Chemical Co.	2
Clariant Corporation	2	Hampshire Chemical Corporation	1
Coastal Eagle Point Oil Company	1	Harcros Chemicals, Inc.	1

APPENDIX A (CONTINUED)

Companies reporting that they produced or imported one or more “orphan” chemicals in 1998

Company name (in alphabetical order)	# of orphans*	Company name (in alphabetical order)	# of orphans*
Hatco Corporation	1	Organic Dyestuffs Corp.	1
Heico Chemicals, Inc.	1	Orient Corp. Of America	1
Hempel Coatings (USA), Inc.	1	Ormet Primary Aluminum Corp.	1
Henkel Corporation	15	PBI/Gordon Corp.	1
Hercules, Inc.	3 {1}	PCI Carolina, Inc.	1
High Point Chemical Corporation	1	Phillips Petroleum Company	2
Hitech Inc.	1	PHT International, Inc.	3
Hoechst Celanese	1	PMC, Incorporated	4
Hoechst Corporation	2	Polyal Coatings, Inc.	1
Holston Defense Corporation	2	Praxair, Inc.	1
Huish Detergents, Inc.	1	Reilly Industries, Inc.	4
Humprey Chemical Co.	3	Rheox, Inc.	2
Huntsman Petrochemical Corporation	6	Rhone-Poulenc Ag Co.	1
Hydrite Chemical Co.	1	RIT-Chem Co., Inc.	2
ICI Americas, Inc.	1	Rite Industries, Inc.	1
IMC	2	Rohm & Haas Co.	2
International Business Machines	1	Sakai Trading New York, Inc.	4
International Flavors & Fragrances, Inc.	2	Salsbury Chemicals, Inc.	1
International Specialty Products	1	Sartomer Company, Inc.	1
Itochu Specialty Chemicals	3	Sattva Chemical Company	1
Jarchem Industries, Inc.	1	Schenectady Intl., Inc.	2
Kanematsu USA, Inc.	1	Schweizerhall, Inc.	2
Kimberly-Clark Printing Technologies	1	Shell Oil Co.	3
Koch Petroleum Group, LP	2	SKW Chemicals, Inc.	3
Koppers Ind., Inc.	14	Sloss Industries Corporation	7
Lawter International, Inc.	1	SNPE N. America, LLC	1
Lomac, LLC	1	Solutia, Inc.	3 {1}{1}
Lonza, Inc.	11	Sovereign Chemical Co.	1
LTV Steel Company, Inc.	2	Standard Chlorine Of Delaware	2
M.I. LLC	1	Stepan Company	1 {1}
Merichem-Sasol USA, LLC	3	Struktol Company Of America	3
Milliken Chemical	2	Sumitomo Corporation Of America	3
Mitsubishi	3	Sunbelt Corporation	1
Mitsui Chemicals	6	Sybron Chemicals, Inc.	4
Monsanto Company	2	Syntex Agribusiness, Inc.	1
Morton International, Inc.	2	Tecnal Corp.	1
MRM Toluic Company	1	Teknor Apex Company	3
National Steel Corporation	3	Terra Nitrogen	1
New Boston Coke Corporation	2	Tessengerlo Kerley, Inc.	1
Nipa Hardwicke, Inc.	9	Texas Petrochemicals Corp.	4
Nissho Iwai American Corporation	1	The C.P. Hall Co.	3
Nordic Synthesis, Inc.	1	The Geon Company	2
Novartis Crop Protection, Inc.	3	The Procter & Gamble Company	1
Occidental Chemical Corporation	3 {2}{1}	Tomen America, Inc.	4
OMG Americas	2	Tonawanda Coke Corporation	3
Omnispecialty Corporation	2	Toyo Ink America, Inc.	1

APPENDIX A (CONTINUED)

Companies reporting that they produced or imported one or more “orphan” chemicals in 1998

Company name (in alphabetical order)	# of orphans*	Company name (in alphabetical order)	# of orphans*
U.S. Steel-Unit of USX Corporation	3	Velsicol Chemical Corporation	3
UCAR Carbon Co., Inc.	1	W.R. Grace & Co.-Conn.	1
Union Carbide Corporation	6	Wacker Silicones Corp.	1
Unitex Chemical Corporation	2	Werner G. Smith, Inc.	2
Unocal Agricultural Products	3	Western Tar Products Corporation	1
USR Optonix, Inc.	1	Wheeling-Pittsburgh Steel Corp.	4
Van Waters & Rogers, Inc.	2	Wright Corporation	1
Vanchem, Inc.	1	Zeneca, Inc.	7

This table lists those companies that publicly reported producing or importing at least one of the orphan chemicals in the latest Inventory Use Rule (IUR) reporting cycle, conducted in 1998. **This list cannot be regarded as complete because it excludes any company that claimed its identity and association with production or import of these chemicals as confidential business information (CBI).**

IUR data for 1998 are the most recent publicly available data on production and import of industrial chemicals (which are collected quadrennially). EPA is in the process of compiling data collected in 2002, but they are not yet publicly available.

* Numbers in parentheses indicate the number of chemicals for which the company has indicated in a letter to EPA that it no longer produces the chemical in question. Numbers in brackets indicate the number of chemicals for which the company has indicated in a letter to EPA that it believes the chemical is no longer an HPV chemical. Such changes in production status, if accurate, would clearly not have been reflected in the 1998 IUR data. These letters are posted in the section on withdrawn commitments in EPA's master summary table of program commitments, available at www.epa.gov/chemrtk/sumresp.htm.

Sources: We used non-confidential 1998 IUR data contained in two databases obtained from EPA: (1) The 1998 List of Companies Reporting 1990 HPV chemicals, downloaded from the HPV Challenge Program website (www.epa.gov/chemrtk/hpvc01st.htm); (2) A database of non-confidential data reported under the 1998 IUR Rule obtained from the EPA Office of Pollution Prevention and Toxics in November 2002.

All companies listed as reporting production or import of orphan chemicals in either database were compiled, and then the number of orphans reported by each company was calculated.

APPENDIX B

Performance through 2002 of chemical companies in meeting commitments under the U.S. HPV Challenge Program

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002						DUE AFTER 2002			
		Submitted early/on time number	% of total	Submitted late number	% of total	Not submitted <1 year overdue number	% of total	Not submitted >1 year overdue number	% of total		
All companies	2308**	1347	58%	123	5%	311	13%	172	7%	355	15%
Angus Chemical Company	2	0	0%	0	0%	0	0%	2	100%	0	0%
Aztec Peroxides, Inc.	10	0	0%	0	0%	0	0%	10	100%	0	0%
CBC (America) Corp.	1	0	0%	0	0%	0	0%	1	100%	0	0%
Chattem Chemicals, Inc.	1	0	0%	0	0%	0	0%	1	100%	0	0%
EM Industries, Inc.	1	0	0%	0	0%	0	0%	1	100%	0	0%
Intertrade Holdings, Inc.	1	0	0%	0	0%	0	0%	1	100%	0	0%
Monsanto Company	2	0	0%	0	0%	0	0%	2	100%	0	0%
Philipp Brothers Chemicals, Inc.	1	0	0%	0	0%	0	0%	1	100%	0	0%
UOP LLC	1	0	0%	0	0%	0	0%	1	100%	0	0%
Wacker Chemie GmbH	5	0	0%	0	0%	0	0%	4	80%	1	20%
Nepera, Inc.	6	0	0%	0	0%	0	0%	4	67%	2	33%
Vulcan Chemicals	14	4	29%	0	0%	1	7%	9	64%	0	0%
Ausimont	2	0	0%	0	0%	1	50%	1	50%	0	0%
BioLab, Inc.	2	0	0%	0	0%	1	50%	1	50%	0	0%
Occidental Chemical Corporation (OxyChem)	8	0	0%	0	0%	2	25%	4	50%	2	25%
Omnova Solutions, Inc.	2	1	50%	0	0%	0	0%	1	50%	0	0%
Sartomer Company, Inc.	2	0	0%	0	0%	0	0%	1	50%	1	50%
SpecialtyChem Products Corporation	2	1	50%	0	0%	0	0%	1	50%	0	0%
Degussa	22	3	14%	1	5%	1	5%	10	45%	7	32%
PPG Industries, Inc.	13	1	8%	5	38%	1	8%	5	38%	1	8%
Honeywell International, Inc.	15	0	0%	4	27%	5	33%	5	33%	1	7%
DuPont Dow Elastomers LLC	3	0	0%	0	0%	1	33%	1	33%	1	33%
Nalco/Exxon Energy Chemicals, LP	9	6	67%	0	0%	0	0%	3	33%	0	0%
Sterling Chemicals, Inc.	3	1	33%	0	0%	0	0%	1	33%	1	33%
Air Products and Chemicals, Inc.	7	2	29%	1	14%	0	0%	2	29%	2	29%
General Electric (GE)	23	3	13%	3	13%	6	26%	6	26%	5	22%
Hercules Incorporated	27	11	41%	1	4%	8	30%	7	26%	0	0%

Bruno Bock Chemische Fabrik GMBH & Co. KG	4	0	0%	0	0%	3	75%	1	25%	0	0%
Lyondell Chemical Company	8	1	13%	2	25%	0	0%	2	25%	3	38%
Hampshire Chemical Corp.	5	3	60%	0	0%	0	0%	1	20%	1	20%
Union Carbide Corporation	9	3	33%	0	0%	1	11%	1	11%	4	44%
Ciba Specialty Chemicals Corporation	18	8	44%	3	17%	1	6%	2	11%	4	22%
ICI Americas, Inc.	110	45	41%	3	3%	50	45%	11	10%	1	1%
Velsicol Chemical Corporation	10	2	20%	4	40%	0	0%	1	10%	3	30%
Equistar Chemicals, LP	32	29	91%	0	0%	0	0%	3	9%	0	0%
Solutia	33	12	36%	0	0%	5	15%	3	9%	13	39%
Rhodia, Inc.	33	17	52%	1	3%	1	3%	3	9%	11	33%
The Dow Chemical Company	45	22	49%	0	0%	3	7%	4	9%	16	36%
Koch Industries, Inc.	83	53	64%	1	1%	10	12%	7	8%	12	14%
E.I. du Pont de Nemours and Company	49	15	31%	8	16%	11	22%	4	8%	11	22%
Chevron Products Company	127	71	56%	2	2%	23	18%	10	8%	21	17%
Sunoco, Inc. (R&M)	115	61	53%	3	3%	23	20%	9	8%	19	17%
Eastman Chemical Company	39	28	72%	0	0%	1	3%	3	8%	7	18%
The C.P. Hall Company	13	12	92%	0	0%	0	0%	1	8%	0	0%
Flexsys America LP	18	13	72%	0	0%	2	11%	1	6%	2	11%
Huntsman Corporation	20	18	90%	0	0%	0	0%	1	5%	1	5%
BP	183	122	67%	3	2%	26	14%	9	5%	23	13%
Ferro Corporation	23	15	65%	0	0%	5	22%	1	4%	2	9%
Noveon, Inc.	28	21	75%	0	0%	0	0%	1	4%	6	21%
Bayer Corporation	30	14	47%	1	3%	5	17%	1	3%	9	30%
Millennium Chemicals, Inc.	35	30	86%	3	9%	1	3%	1	3%	0	0%
Chevron Phillips Chemical Company, LP	41	24	59%	0	0%	8	20%	1	2%	8	20%
Chevron Oronite Company LLC	61	31	51%	11	18%	0	0%	1	2%	18	30%
Crompton Corporation	126	60	48%	4	3%	27	21%	2	2%	33	26%
ExxonMobil	67	49	73%	12	18%	0	0%	1	1%	5	7%
Avecia, Inc.	1	0	0%	0	0%	1	100%	0	0%	0	0%
Aventis CropScience USA LP	1	0	0%	0	0%	1	100%	0	0%	0	0%
Clearon Corporation	2	0	0%	0	0%	2	100%	0	0%	0	0%
Derivados Electroquimicos Levante SA (DELSA)	2	0	0%	0	0%	2	100%	0	0%	0	0%

See Table 4 for a ranked list of all companies with at least 10 commitments.

* Primary ranking based on values in shaded column. Companies with the same percentage of commitments >1 year overdue are ranked by the percentage of commitments <1 year overdue, then by percentage of commitments that were submitted late.

** Total number of commitments across all companies is higher than total number of chemicals with commitments because many chemicals have more than one sponsoring company.

APPENDIX B (CONTINUED)

Performance through 2002 of chemical companies in meeting commitments under the U.S. HPV Challenge Program

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002				DUE AFTER 2002					
		Submitted early/on time		Submitted late		Not submitted <1 year overdue		Not submitted >1 year overdue			
		number	% of total	number	% of total	number	% of total	number	% of total		
Sumitomo Chemical America, Inc.	1	0	0%	0	0%	1	100%	0	0%	0	0%
Clariant Corporation	11	1	9%	1	9%	8	73%	0	0%	1	9%
R. T. Vanderbilt Company, Inc.	5	0	0%	0	0%	3	60%	0	0%	2	40%
ATOFINA Chemicals, Inc.	21	6	29%	0	0%	12	57%	0	0%	3	14%
Dover Chemical Corporation	8	4	50%	0	0%	4	50%	0	0%	0	0%
Baerlocher USA	5	3	60%	0	0%	2	40%	0	0%	0	0%
3M	3	0	0%	2	67%	1	33%	0	0%	0	0%
International Flavors & Fragrances, Inc. (IFF-US)	3	0	0%	1	33%	1	33%	0	0%	1	33%
DSM	3	1	33%	0	0%	1	33%	0	0%	1	33%
International Specialty Products (ISP)	6	4	67%	0	0%	2	33%	0	0%	0	0%
Morflex, Inc.	3	0	0%	0	0%	1	33%	0	0%	2	67%
Troy	10	7	70%	0	0%	3	30%	0	0%	0	0%
Zeneca Ag Products, Inc.	4	0	0%	0	0%	1	25%	0	0%	3	75%
Phillips Petroleum Company	68	40	59%	0	0%	16	24%	0	0%	12	18%
Lonza, Inc.	5	1	20%	0	0%	1	20%	0	0%	3	60%
Rohm and Haas Company	5	2	40%	0	0%	1	20%	0	0%	2	40%
Mallinckrodt, Inc.	6	5	83%	0	0%	1	17%	0	0%	0	0%
Kao Specialties Americas LLC (formerly High Point Chemical Corporation)	31	26	84%	0	0%	5	16%	0	0%	0	0%
Celanese Ltd.	8	6	75%	0	0%	1	13%	0	0%	1	13%
The Goodyear Tire & Rubber Company	10	9	90%	0	0%	1	10%	0	0%	0	0%
Shepherd Chemical Company	13	12	92%	0	0%	1	8%	0	0%	0	0%
Akzo Nobel	40	29	73%	3	8%	3	8%	0	0%	5	13%
Sasol North America, Inc.	26	22	85%	1	4%	1	4%	0	0%	2	8%
Arizona Chemical Company	42	32	76%	8	19%	1	2%	0	0%	1	2%
Blackman Uhler Chemical Company	1	0	0%	1	100%	0	0%	0	0%	0	0%
Cardolite Corporation	1	0	0%	1	100%	0	0%	0	0%	0	0%
Citrus and Allied Essences, Ltd.	1	0	0%	1	100%	0	0%	0	0%	0	0%

APPENDIX B (CONTINUED)

Performance through 2002 of chemical companies in meeting commitments under the U.S. HPV Challenge Program

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002				DUE AFTER 2002					
		Submitted early/on time		Submitted late		Not submitted <1 year overdue		Not submitted >1 year overdue			
		number	% of total	number	% of total	number	% of total	number	% of total		
Eastman Kodak Company	3	2	67%	0	0%	0	0%	0	0%	1	33%
Eliokem, LLC	3	3	100%	0	0%	0	0%	0	0%	0	0%
Emulsion Products of Alaska, Inc.	5	5	100%	0	0%	0	0%	0	0%	0	0%
Enterprise Products Company	6	6	100%	0	0%	0	0%	0	0%	0	0%
ESCO Company Limited Partnership	5	0	0%	0	0%	0	0%	0	0%	5	100%
Fina Oil and Chemical Company	1	0	0%	0	0%	0	0%	0	0%	1	100%
Finch, Pruyn & Company	1	1	100%	0	0%	0	0%	0	0%	0	0%
Firmenich, Incorporated	2	2	100%	0	0%	0	0%	0	0%	0	0%
First Chemical Corporation	4	4	100%	0	0%	0	0%	0	0%	0	0%
Formosa	7	7	100%	0	0%	0	0%	0	0%	0	0%
Fuji Hunt Photographic Chemicals	1	0	0%	0	0%	0	0%	0	0%	1	100%
GEO Specialty Chemicals	1	0	0%	0	0%	0	0%	0	0%	1	100%
Georgia Gulf Corporation	1	1	100%	0	0%	0	0%	0	0%	0	0%
Great Lakes Chemical Corporation	8	7	88%	0	0%	0	0%	0	0%	1	13%
Gulf States Asphalt Co., LLP	5	5	100%	0	0%	0	0%	0	0%	0	0%
Gulf States Paper Corporation	1	1	100%	0	0%	0	0%	0	0%	0	0%
Haarmann & Reimer (H&R)	3	3	100%	0	0%	0	0%	0	0%	0	0%
Hatco Corporation	1	1	100%	0	0%	0	0%	0	0%	0	0%
Hickson DanChem Corporation	2	1	50%	0	0%	0	0%	0	0%	1	50%
Hills Materials Company	5	5	100%	0	0%	0	0%	0	0%	0	0%
INDSPEC Chemical Corporation	1	0	0%	0	0%	0	0%	0	0%	1	100%
Inland Paperboard and Packaging	1	1	100%	0	0%	0	0%	0	0%	0	0%
Inolux Chemical Company	5	5	100%	0	0%	0	0%	0	0%	0	0%
Inspec USA, Inc.	2	0	0%	0	0%	0	0%	0	0%	2	100%
J. Manheimer, Inc.	1	1	100%	0	0%	0	0%	0	0%	0	0%
Kemin Industries, Inc.	1	1	100%	0	0%	0	0%	0	0%	0	0%
King Industries, Inc.	4	0	0%	0	0%	0	0%	0	0%	4	100%
Konica Graphic Imaging International, Inc.	1	0	0%	0	0%	0	0%	0	0%	1	100%
KoSa	2	2	100%	0	0%	0	0%	0	0%	0	0%
Loctite Corporation	1	1	100%	0	0%	0	0%	0	0%	0	0%
Louis Marsch, Inc.	5	5	100%	0	0%	0	0%	0	0%	0	0%

APPENDIX C

Performance through 2002 of trade associations and consortia in meeting commitments under the U.S. HPV Challenge Program

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002						DUE AFTER 2002			
		Submitted early/on time number	% of total	Submitted late number	% of total	Not submitted <1 year overdue number	% of total	Not submitted >1 year overdue number	% of total		
All consortia	1214**	729	60%	63	5%	202	17%	76	6%	144	12%
Toluenesulfonamide Testing Group	1	0	0%	0	0%	0	0%	1	100%	0	0%
Society of the Plastics Industry	11	1	9%	1	9%	1	9%	8	73%	0	0%
European Fluorocarbon Technical Committee	2	0	0%	0	0%	1	50%	1	50%	0	0%
International Institute of Synthetic Rubber Producers, Inc. (IISRP)	3	0	0%	0	0%	1	33%	1	33%	1	33%
American Petroleum Institute (API)	406	249	61%	7	2%	53	13%	37	9%	60	15%
American Chemistry Council (ACC)	418	319	76%	16	4%	7	2%	26	6%	50	12%
Synthetic Organic Chemical Manufacturers Association, Inc.	30	27	90%	0	0%	0	0%	1	3%	2	7%
The Flavor and Fragrance High Production Volume Consortia	59	39	66%	15	25%	4	7%	1	2%	0	0%
ETAD North America Stilbene Fluorescent Brighteners	7	0	0%	0	0%	7	100%	0	0%	0	0%
Consumer Speciality Products Assn./ADBAC Steering Cmte.	5	0	0%	0	0%	5	100%	0	0%	0	0%
LAB Sulfonic Acids Coalition	3	0	0%	0	0%	3	100%	0	0%	0	0%
BPD/BPA Coalition	2	0	0%	0	0%	2	100%	0	0%	0	0%
BTBP Consortium	1	0	0%	0	0%	1	100%	0	0%	0	0%
Dimethyl Sulfide Producers Assn.	1	0	0%	0	0%	1	100%	0	0%	0	0%
Dimethyl Sulfoxide Producers Assn.	1	0	0%	0	0%	1	100%	0	0%	0	0%
Isocyanurate Industry Ad Hoc Committee (IIAHC)	1	0	0%	0	0%	1	100%	0	0%	0	0%
The MBOCA Consortium	1	0	0%	0	0%	1	100%	0	0%	0	0%
The Soap and Detergent Assn.	112	7	6%	0	0%	105	94%	0	0%	0	0%

APPENDIX C (CONTINUED)

Performance through 2002 of trade associations and consortia in meeting commitments under the U.S. HPV Challenge Program

Ranked *worst to best*, based on % of all commitments >1 year overdue* (includes only direct commitments under the U.S. program)

	Total # of commitments	DUE IN OR BEFORE 2002						DUE AFTER 2002			
		Submitted early/on time		Submitted late		Not submitted <1 year overdue		Not submitted >1 year overdue			
		number	% of total	number	% of total	number	% of total	number	% of total		
Sodium Formaldehyde Bisulfite Manufacturers Association	1	0	0%	0	0%	0	0%	0	0%	1	100%
The DCB Coalition	1	0	0%	0	0%	0	0%	0	0%	1	100%
American Forest & Paper Assn.	1	1	100%	0	0%	0	0%	0	0%	0	0%
American Methanol Institute Testing Group (AMITG)	1	1	100%	0	0%	0	0%	0	0%	0	0%
Dioxolane Manufacturers Consortium	1	1	100%	0	0%	0	0%	0	0%	0	0%
Ethanol HPV Challenge Consortium	1	1	100%	0	0%	0	0%	0	0%	0	0%
Hexamethoxymethylmelamine (HMMM) Coalition	1	1	100%	0	0%	0	0%	0	0%	0	0%
U.S. Nitroglycerin Producers Consortium (USNPC)	1	1	100%	0	0%	0	0%	0	0%	0	0%

See Table 5 for a ranked list of all company consortia and trade associations with at least 5 commitments.

* Primary ranking based on values in shaded column. Consortia with the same percentage of commitments >1 year overdue are ranked by the percentage of commitments <1 year overdue, then by percentage of commitments that were submitted late.

** Total number of commitments across all consortia is higher than total number of chemicals with commitments because some chemicals have more than one sponsoring consortium.



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finding the ways that work

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