

# Facing the Challenge



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

### EXECUTIVE SUMMARY

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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.

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

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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.

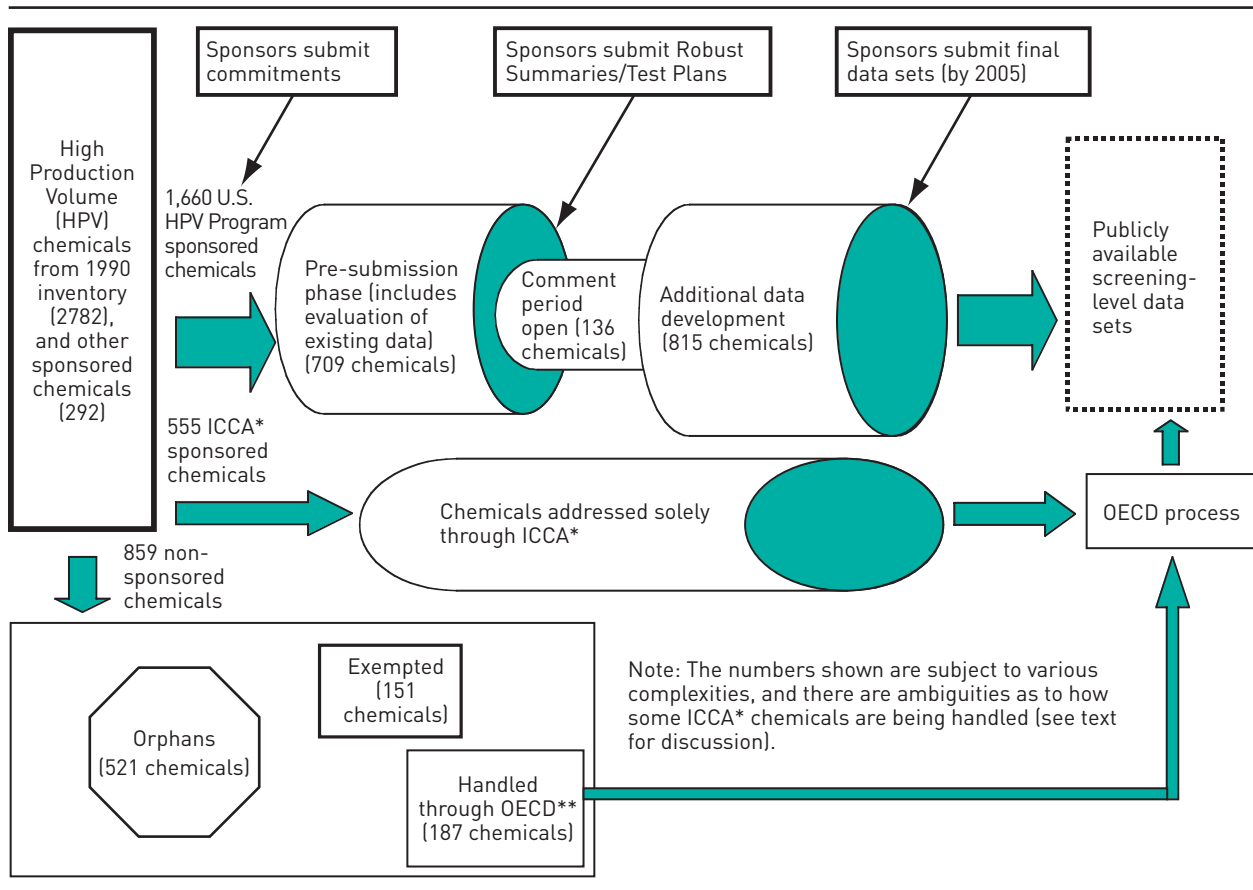
Evaluating an HPV chemical under the program is a multi-stage process (see Figure ES-1). First, the sponsor—a company or consortium of companies that produces a given chemical and has made a commitment for it under the HPV Challenge Program—assesses the extent to which SIDS-relevant hazard data already 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.<sup>1</sup>

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.<sup>2</sup>

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.<sup>3</sup> 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.

<b>Company name</b>	<b># of commitments</b>	<b># &gt; 1 yr overdue</b>	<b>% &gt; 1 yr overdue</b>
<b>10 Best</b>			
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%
<b>10 Worst</b>			
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.<sup>4</sup> 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)

<b>Sponsor name</b>	<b># of submissions</b>	<b># of HPV chemicals</b>	<b>GPA (A=4.0)</b>
<b>TRADE ASSOCIATION/CONSORTIUM SPONSORS</b>			
<b>11 Best</b>			
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
<b>5 Worst</b>			
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
<b>INDIVIDUAL COMPANY SPONSORS</b>			
<b>10 Best</b>			
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
<b>6 Worst</b>			
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.

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## Notes

- <sup>1</sup> 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.
- <sup>2</sup> 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.
- <sup>3</sup> 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.
- <sup>4</sup> 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.



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