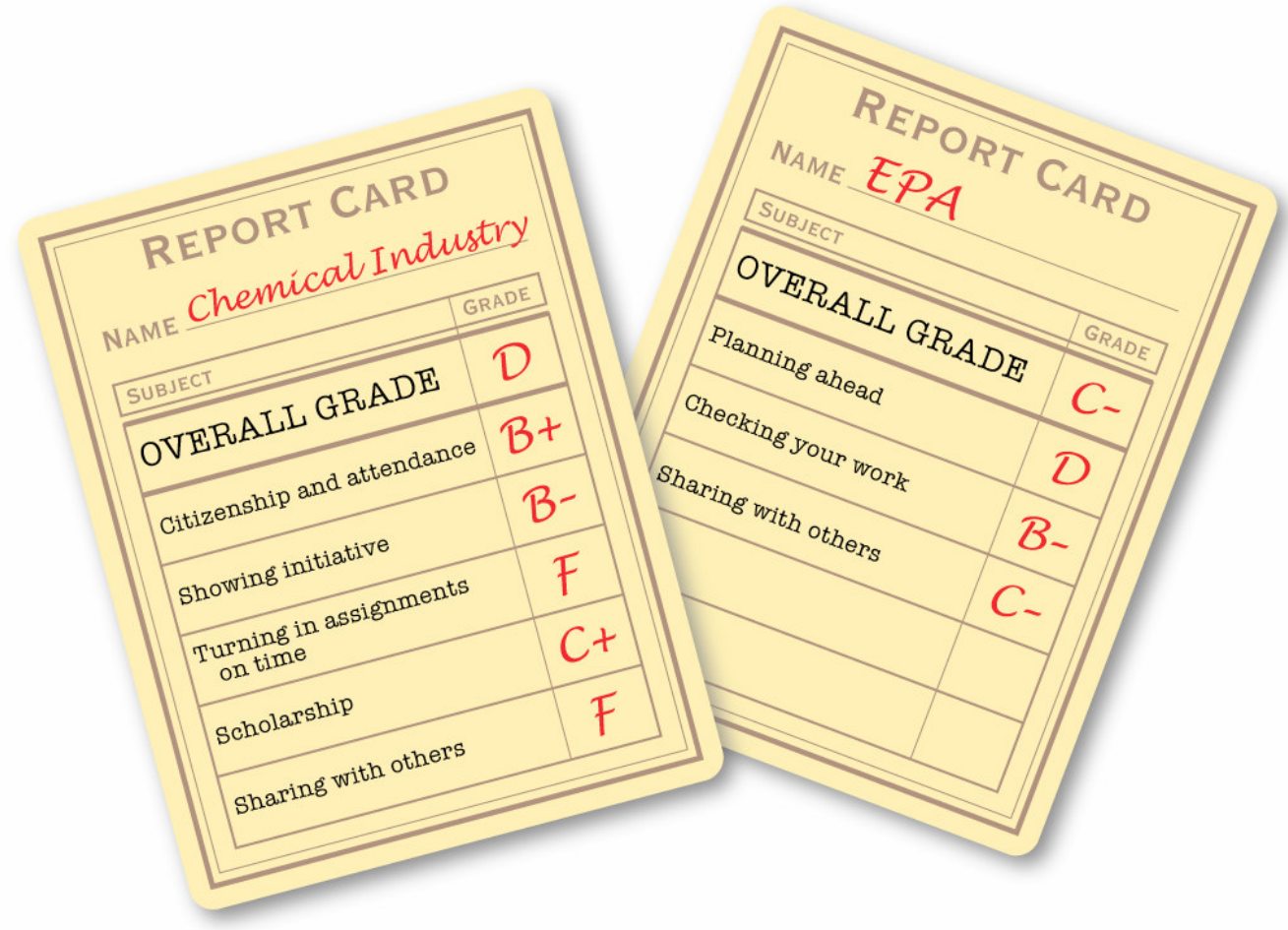
# High Hopes, Low Marks

## A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE





ENVIRONMENTAL DEFENSE

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# High Hopes, Low Marks

## A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE

JULY 2007

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ENVIRONMENTAL DEFENSE
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## Executive Summary

More than a year-and-a-half after it was to have been completed, the High Production Volume (HPV) Chemical Challenge is still well away from delivering on the promises it made.

The Challenge was launched in 1998, spurred by a series of studies – beginning with one by The National Academy of Sciences in 1984 – that documented the paucity of publicly available data on the potential hazards posed by the highest-volume chemicals in production and use in the US. As a response to these studies – and with tacit acknowledgment of the limited authority available to it under the Toxic Substances Control Act (TSCA) to compel testing through regulation – EPA established the voluntary Challenge. Its aim was to enlist manufacturers of HPV chemicals – those produced in or imported into the US in amounts equal to or exceeding one million pounds annually – to develop and make publicly available a "base set" of screening-level hazard information on their chemicals.

The Challenge represents the only systematic effort by the US Environmental Protection Agency (EPA) to foster the development of and public access to basic hazard data on a relatively large number of chemicals in commerce. The program is developing and making public basic hazard information for more chemicals in much less time than any prior effort, and it represents the first significant step taken in the US toward closing the gap between what we know and what we should know about widely used chemicals.

Because the Challenge is voluntary, it side-steps the onerous findings EPA must make to exercise its authority under Section 4 of TSCA to compel hazard testing of chemicals. However, for the same reason, EPA also has limited recourse to ensure full participation by manufacturers or the timely submission and high quality of hazard data sets developed for HPV chemicals.

### Limping toward the finish line

This report – our final assessment of the HPV Challenge – comes more than two-and-a-half years after the original 2004 deadline for the chemical industry to have developed and submitted final data sets, and more than 18 months after the 2005 deadline for EPA to have made all data available to the public. While acknowledging the progress made to date, our report also identifies both serious shortcomings and "lessons learned" that are relevant not only to completion of the Challenge, but also to the design and execution of voluntary environmental initiatives in general.

The Challenge is noticeably limping as it approaches the finish line, with considerable amounts of the data it promised to deliver yet to be made available. Its major success is that manufacturers of the great majority of eligible HPV chemicals did in fact "accept the challenge" by committing to *sponsor* their chemicals, that is, to develop and make public a basic set of hazard data for each of them. However, for many hundreds of these chemicals, sponsors have yet to meet one or both of the two major milestones that constitute fulfillment of those commitments:

- *Initial submission* of robust study summaries of existing data, along with a test plan indicating how remaining information gaps were to be filled; and
- *Final submission* of a data set deemed complete by the sponsor.

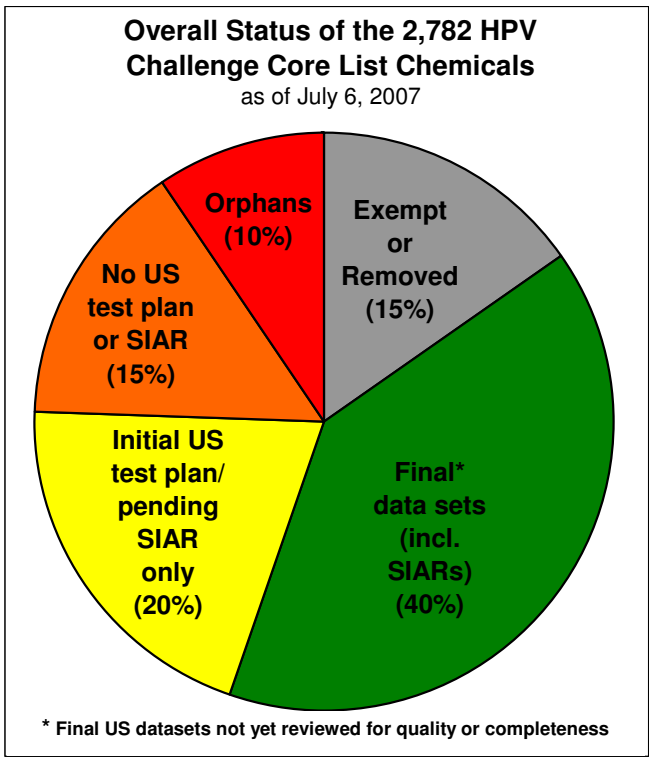
Of the nearly 1,900 HPV chemicals sponsored under the Challenge:

- One-third of those with initial submissions still lack final data sets.
- More than one-fifth lack even initial submissions.

In addition, 10% of the chemicals eligible for sponsorship remain unsponsored "orphans," with no near-term prospect for hazard data to be developed.

Figure 1 shows the status of the nearly 2,800 HPV chemicals originally included in the Challenge.

FIGURE 1
**Overall Status of the 2,782 HPV Challenge Core List Chemicals**




## Additional drawbacks of the Challenge

### OVER-RELIANCE ON ALTERNATIVES TO DIRECT TESTING

The Challenge framework allowed sponsors to use alternatives to new testing, such as relying on unpublished data and applying estimation methods and category approaches – are allowed under the Challenge. However, sponsors have made such extensive use of these alternatives that more than 80% of sponsored chemicals were grouped into proposed categories and fewer than 10% of the base set data elements were proposed to be filled through new testing.

EPA's and Environmental Defense's reviews of these proposals strongly suggest that sponsors tended to over-rely on such alternatives: One or both of us raised non-trivial concerns about the data provided or methods proposed to fill data gaps for a significant majority of the initial submissions, although many of these concerns appear to have been addressed in revisions.

### DECLINING QUALITY OF SUBMISSIONS

The average quality of initial submissions of test plans and robust study summaries, while originally quite good, has declined considerably over the course of the Challenge, especially in the past 18 months.

DELAYED EPA REVIEWS

EPA has fallen behind in its review of initial submissions, exacerbating further the tardiness of sponsors' final submissions under the Challenge.

SLOW DEVELOPMENT OF TEST RULES FOR ORPHAN CHEMICALS

EPA's development of test rules to compel data development for unsponsored "orphan" chemicals has proceeded exceedingly slowly, with only 16 (6%) of the 265 orphans subjected to such rules to date.

LATE LAUNCH OF THE HPV REPOSITORY DATABASE

While EPA's development of the HPV Information System, the repository database for the HPV data, was finally jumpstarted after years of delay, much work remains to fully populate it and make it functional and user-friendly.

POOR EXTENT OF SPONSORSHIP OF NEWLY EMERGED HPV CHEMICALS

Of nearly 600 newly emerged HPV chemicals – those that have reached HPV levels of manufacture since the Challenge was launched – eligible for sponsorship, only 40% have been sponsored through the chemical industry's Extended HPV Program. Wide gaps in publicly available hazard data for these chemicals exist. These findings indicate that the chemical industry is not making the development of and public access to hazard data on all HPV chemicals "evergreen" practices.

**Status of critical next steps**

Critical next steps to be taken by EPA – determining the quality and completeness of the data developed under the Challenge, and using the data to assess the hazards of HPV chemicals – have only just begun. Initial indications are that some final submissions will present data quality problems and still contain data gaps. The ultimate measure of the value of the Challenge will, of course, be the extent to which EPA as well as industry and the public use the new information to drive hazard and risk reduction.

In recent months, rather than noting the successes achieved under the Challenge to date and acknowledging the considerable work that remains to be done, representatives of the chemical industry have regrettably chosen instead to distort both the status of the Challenge and the extent to which the data it is providing address the critical need that led to the launch of the Challenge in the first place: ensuring society's ability to identify and address the risks posed by the tens of thousands of un- or under-assessed chemicals that are produced and used in this country and around the world. The last section of our report is devoted to refuting these claims about the Challenge, in keeping with the overall purpose of this study: to provide an honest reckoning of what the Challenge has, and has not, achieved.

Figure 2 is our summary assessment of the Challenge, in the form of industry and EPA report cards.

FIGURE 2

**HPV Challenge report card**

| CHEMICAL INDUSTRY | | USEPA | |
|---|---|---|---|
| *OVERALL GRADE* | *D* | *OVERALL GRADE* | *C-* |
| *Extent of sponsorship of HPV chemicals* | *B+* | *Extent of test rule development for orphans* | *D* |
| *Extent of initial submissions* | *B-* | *Extent of EPA review of initial submissions* | *B-* |
| *Extent of final submissions* | *F* | *Providing public access to information* | *C-* |
| *Quality of initial submissions* | *C+* | | |
| *Providing public access to information* | *F* | | |

## Introduction

More than 30 years ago, in the Toxic Substances Control Act (TSCA) of 1976, Congress declared:

> "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 and those who process such chemical substances and mixtures."[1]

TSCA gave EPA certain authority to require the development of data sufficient to characterize the hazards posed by chemicals used in commerce – an authority that has proven exceedingly difficult to implement. In a classic *Catch 22*, in order to require testing of a chemical, EPA must first formally find – typically in the absence of much if any data – that: (i) it "may present an unreasonable risk" or is produced in substantial quantities and may enter the environment in substantial quantities or cause significant human exposure, and (ii) relevant data do not exist, and (iii) testing is necessary to provide the needed information.[2] The facts speak for themselves: Over the 30 years since TSCA was enacted, EPA has succeeded in compelling hazard testing for about 200 of the tens of thousands of chemicals in US commerce.[3]

Meanwhile, a series of studies – beginning with one in 1984 by The National Academy of Sciences – consistently identified huge gaps in publicly available hazard data even for those chemicals used in the largest amounts.[4]

In response to these studies – and with tacit acknowledgment of its limited ability under TSCA to compel testing – EPA launched the US High Production Volume (HPV) Chemical Challenge in 1998.[5] Its aim was to voluntarily enlist manufacturers[6] of HPV chemicals – those produced in or imported into the US in amounts equal to or exceeding one million pounds annually – to develop and make publicly available a "base set" of screening-level hazard information[7] on their chemicals.

EPA allowed companies to participate in one of two ways: either directly through the Challenge Program, or indirectly through the International Council of Chemical Associations' (ICCA) HPV Initiative,[8] which operates under the Organization for Economic Cooperation and Development (OECD) Screening Information Date Set (SIDS) Program, a related international effort.[9] Under either program, individual companies or consortia of companies made commitments to "sponsor" HPV chemicals they produce.

- For commitments made directly under the Challenge, sponsors agreed first to identify the extent of available hazard data for a given chemical, and then to develop and submit *robust study summaries* of the existing data, along with a *test plan* that indicated how remaining information gaps were to be filled.[10] These initial submissions were then made available for public and EPA review and comment. Following consideration of comments received, sponsors then were to conduct any needed testing or data development, summarize all of the data and make a final submission, including a final *data set*, to EPA, also made available to the public.

- For chemicals sponsored through the ICCA Initiative under the OECD SIDS Program, submission of initial test plans is not a formal requirement, nor is there a public review opportunity. Instead, sponsors determine what data already exist, fill any identified gaps, and then

summarize and analyze the existing and new data in a draft SIDS Initial Assessment Report, or *SIAR*.[11] SIARs, accompanied by a full set of robust study summaries (termed a dossier), are first submitted to and reviewed by an OECD member country, designated the sponsor country. After agreement between the sponsor company and sponsor country, SIARs are then submitted to a larger group of OECD country representatives for review at a SIDS Initial Assessment Meeting, or *SIAM*. Once discussed and agreed at a SIAM, the final SIAR is made publicly available.[12]

As stipulated in the original program framework, under both routes sponsors were to provide their final submissions by the end of 2004, and EPA was to have made all data publicly available by the end of 2005.[13]

*The HPV Challenge has been EPA's only systematic effort to foster the development of basic hazard data on a relatively large number of existing chemicals. Because it is voluntary, the Challenge side-steps the onerous findings EPA must make to exercise its authority under TSCA Section 4 to compel hazard testing. However, for the same reason, EPA also has limited recourse to ensure participation or the timely completion and high quality of sponsor submissions.*

## What's in this report

This report examines the extent to which the HPV Challenge – now more than a year after its intended end date – has fulfilled its promises. It also identifies what has worked and what hasn't. Finally, the report describes steps that must be completed if the program is to be judged a success.

First, the report lists some of the strengths and limitations inherent to the design of the HPV Challenge, to provide context for both managing expectations.

The report then assesses the status of the program using a number of "metrics" – direct measures by which the progress and extent of completion of the Challenge can be measured. For each of these metrics, we assign a letter grade to summarize the performance in that area to date. These metrics include the extent to which:

- Manufacturers sponsored their HPV chemicals;
- Program commitments (initial and final submissions) were met;
- EPA has compelled information development for unsponsored HPV chemicals;
- Initial submissions were reviewed by EPA;
- Information submitted by sponsors is complete and of high quality; and
- Submitted information has been made publicly accessible, readily retrievable and usable.

Equally important, but beyond the original confines of the Challenge, is the extent to which EPA assesses and acts on the information it receives to ensure sound management of HPV chemicals, and the extent to which the chemical industry commits itself to routinely provide information on chemicals once they reach high-volume levels of production or import. This report also examines the status of these activities.

The report also offers some lessons learned relating to the strengths and limitations, as well as the design and execution, of this and other voluntary information development programs.

Finally, the report responds to unfortunate and misleading characterizations of the program and its degree of completion or success that have recently been offered by representatives of the chemical industry.

## Strengths and limitations of the HPV Challenge

### Some pluses of the HPV Challenge

FULL PUBLIC ACCESS

As a key part of EPA's Chemical Right-to-Know Initiative, the Challenge's primary goal was to make hazard data on high-volume chemicals widely publicly available. As EPA states: "The HPV Challenge Program, a collaborative partnership whose goal was to ensure that the American public had access to the type of information that would allow it to actively participate in environmental decision-making at all levels – federal, state, and local."[14] Despite the slower-than-intended pace at which final data sets are being submitted and the repository database developed and populated, this objective is being achieved.

PUBLIC REVIEW OPPORTUNITY

From the outset, the Challenge provided for internet-based public access to industry sponsors' submissions and an opportunity to review and comment on them, with the comments also made public. With few exceptions, however, only Environmental Defense and a coalition of animal protection organizations took advantage of this opportunity. In retrospect, this process would have been enhanced by requesting that sponsors respond in writing to all public comments, which did not routinely occur.

USE OF WELL-ESTABLISHED GUIDELINES AND RELIABILITY MEASURES

The program called for adherence to, and sponsors generally appear to have abided by, internationally accepted guidelines governing, for example, acceptable test protocols, study summary format and content, reliability scoring of experimental studies, and guidance on the appropriate use of unpublished data, estimation techniques and category-based approaches. Study summaries of experimental data also typically indicated whether good laboratory practice (GLP) was followed. Ultimately, EPA's review of final submissions, still to come, will determine the extent to which the data submitted is complete and of high quality. A tradeoff engendered by the decision to utilize well-established guidelines is that emerging concerns such as endocrine disruption potential were not considered.

RESTRICTION OF INDUSTRY'S ROLE TO PROVIDING HAZARD DATA

The program intentionally limited the scope of industry commitments to compiling existing and developing new hazard data, not to assessing these data or potential risk. This was done both to expedite the development and public access to hazard data by avoiding protracted arguments over hazard, exposure and risk assessment, and to appropriately assign those tasks to a public agency rather than private companies. While many sponsors opted to provide limited information regarding use and exposure, and in some cases provided their own assessment of hazard, exposure and risk, EPA has committed to conduct its own independent evaluation of these important questions.

INCLUSION OF THE MAJORITY OF INDUSTRIAL CHEMICALS IN COMMERCE, BY TONNAGE

Because of their high manufacturing volumes, HPV chemicals comprise the bulk of industrial chemicals in commerce when measured by tonnage. Indeed the vast majority (>99%) of industrial chemical tonnage is contributed by a tiny fraction of all such chemicals in commerce: about 300 industrial chemicals produced in annual quantities exceeding one billion pounds per year.[15] However, not all of these chemicals, or of HPV chemicals more broadly, are now included in the HPV Challenge, due to exemptions, removals due to apparent reductions in production levels, lack of sponsorship, etc. Moreover, many chemicals (e.g., pesticides, drugs, many inorganics and polymers) are either exempted or excluded from coverage or reporting requirements under TSCA, and therefore not counted in such estimates. Nonetheless, it can be stated with reasonable assurance that the

Challenge is providing basic hazard data on the subset of industrial chemicals that constitute the bulk, by tonnage, of all such chemicals in commerce.

**Some minuses of the HPV Challenge**

SCREENING-LEVEL DATA ONLY

Hazard data being collected under the Challenge are limited to a subset of the SIDS, developed under the auspices of the OECD. The SIDS data are generally acknowledged to be insufficient to provide the basis for a full hazard assessment, let alone a risk assessment, for a chemical. It relies primarily on testing of acute or subchronic toxicity, for example, and its ecological endpoints only include toxicity to aquatic organisms.

FOCUS LIMITED TO HAZARD DATA

By design, the Challenge did not call for submission of use and exposure information, as already noted, although some sponsors did submit some such information. As a result, the program will provide little if any reliable, comprehensive information about the use of and exposure to HPV chemicals.

LITTLE RECOURSE IF DATA QUALITY IS POOR OR DATA ARE INCOMPLETE

Because the program is voluntary, EPA has very limited ability to ensure that the data submitted by sponsors are of high quality and complete. While EPA and other commenters have often identified deficiencies in initial submissions, there is no legal or binding obligation on the part of sponsors to heed those comments. EPA has agreed to conduct a quality and completeness review on final submissions, and to make known the results, but cannot compel sponsors to address any problems that are identified.

WEAK REGULATORY "BACKSTOP"

As noted above and described in more detail later in this report, EPA's authority under TSCA to compel testing of the 10% of HPV Challenge chemicals that were not voluntarily sponsored is seriously constrained; to date, EPA has issued test rules for only 16 (6%) of the 265 orphan HPV chemicals.

"OLD" TOXICOLOGY

While enjoying the advantage of international consensus, having been developed nearly 20 years ago, the SIDS does not address new concerns such as endocrine disruption potential or developmental neurotoxicity.[16] Its test methods, some of which are even older, may not always incorporate the latest in toxicological testing.

EXCLUSION OF THE MAJORITY OF CHEMICALS IN COMMERCE

While HPV chemicals constitute the bulk of chemicals in commerce when measured by tonnage, non-HPV chemicals far outnumber HPV chemicals. The TSCA Inventory contains more than 82,000 chemicals that have been in commerce at some point since 1979. Under the TSCA Inventory Update Rule, EPA reports some 5,400 chemicals manufactured in amounts above 10,000 pounds per year but below the HPV threshold in 2002; an unknown number of chemicals below that threshold are in commerce in the US.[17] The European Union (EU) estimates that about 30,000 chemicals are produced there in quantities at or above one metric ton (2,200 pounds) per year, fewer than 3,000 of which are HPV chemicals.[18]

## Assessment of key HPV Challenge "status metrics"

### Extent of sponsorship of HPV Challenge chemicals

*Summary*
The original core list of HPV chemicals included in the Challenge – those deemed to be manufactured at HPV levels in 1990 – comprised 2,782 substances. Some of these chemicals were exempted or otherwise removed from the scope of the Challenge by EPA, either at the outset or over its course, leaving 2,164 HPV chemicals.

The overall level of sponsorship of these chemicals under the Challenge is as follows:

- 68% of the original program list
- 88% of the HPV chemicals remaining within the scope of the HPV Challenge.

In addition, 10% of the chemicals on the original list are unsponsored orphans.

*Letter grade for extent of sponsorship*: **B+**[19]

*Details*
Of the 2,782 chemicals on the original core list included in the Challenge, 425 chemicals (15%) were exempted or otherwise removed by EPA, either initially or during the course of the Challenge.[20] The reasons were as follows:

- 45 were not considered candidates for testing because the SIDS data would not further understanding of the chemical's hazards.[21]
- 53 were polymers or inorganics that were erroneously included in the initial list as they were to be excluded.[22]
- 327 were found to be no longer manufactured at HPV levels.

An additional 193 (9%) chemicals are being sponsored directly under the OECD SIDS Program by OECD member governments, rather than by industry under the ICCA Initiative.[23]
Of the remaining 2,164 HPV chemicals under the HPV Challenge:

- 1,899 are sponsored by industry, 1,165 directly under the HPV Challenge, and 734 through the ICCA Initiative under the auspices of the OECD SIDS Program.
- 265 are unsponsored "orphan" chemicals.[24]

Appendix 1 provides a list of the companies that reported manufacturing the 265 orphan chemicals in the 2002 reporting cycle of the TSCA Inventory Update Rule (IUR), but have failed to sponsor them.[25] It is important to note that this list excludes any companies that designated their association with particular chemicals to be confidential business information (CBI), and may include companies that have ceased manufacturing an orphan chemical since reporting it under the 2002 IUR.

In addition to the original 1990 HPV program list, 373 chemicals beyond that list are sponsored:

- 101 chemicals are from the 1994 HPV list.
- 272 chemicals are not HPV chemicals, but typically are sponsored as members of categories containing Challenge Program chemicals.

**Extent to which sponsors' program commitments (initial and final submissions) were met**

As noted earlier, two major milestones were to be met in order to fulfill commitments made under the HPV Challenge:

- *Initial submission* of robust study summaries (RSS) of existing data, along with a test plan (TP) indicating how remaining information gaps were to be filled
- *Final submission* of a data set deemed complete by the sponsor

INITIAL SUBMISSIONS

*Summary*

Initial submissions have been received for 80% of the sponsored chemicals. For 20% of sponsored chemicals, no initial submissions have been made.

*Letter grade for extent of initial submissions:* **B-**[26]

*Details*

More than 400 initial submissions of RSS and TPs have been received for chemicals sponsored directly under the Challenge, about a third for proposed categories of multiple chemicals and two-thirds covering individual HPV chemicals.

In addition to these direct submissions of RSS and TPs, EPA also allowed sponsors of HPV chemicals to meet their commitments under the ICCA Initiative to the OECD SIDS Program, provided that they committed to completing all work no later than the end of 2004.[27] SIARs are the primary assessment documents prepared by sponsors under the OECD SIDS Program. They are prepared initially in draft form, and are posted to an electronic discussion group (EDG) for review by OECD member governments. Hence, for these ICCA Initiative chemicals, the initial submission milestone to be tracked is the posting by OECD of a draft SIAR.[28]

For the 1,899 sponsored core-list HPV chemicals, as of July 2007:

- 1,250 are covered by initial submissions of RSS and TPs
- 265 are covered by draft SIARs
- 384 are covered by neither

➢ *Hence, initial submissions have been received for 80% of the sponsored chemicals (TPs/RSS for 66% and draft SIARs for 14%). For 20% of sponsored chemicals, no initial submissions have been made.*

The breakdown of these numbers for chemicals sponsored directly under the Challenge and those sponsored under the ICCA Initiative via the OECD SIDS Program is as follows:

- Of the 1,165 core-list HPV chemicals sponsored directly under the Challenge:
    - 1,125 are covered by initial submissions of RSS and TPs
    - 9 are covered by SIARs
    - 31 are covered by neither
- Of the 734 core-list HPV chemicals sponsored via ICCA/OECD:
    - 125 are covered by initial submissions of RSS and TPs[29]
    - 256 are covered by SIARs
    - 353 are covered by neither

➢ *Hence, initial submissions have been received for 97% of the HPV chemicals sponsored directly under the Challenge, but only 52% of those sponsored under the ICCA Initiative through the OECD.*[30]

Appendix 2 provides a list of the companies and consortia that have sponsored, directly under the Challenge, the 31 HPV chemicals for which even initial submissions have not been made, despite an original program deadline of 2003 for their receipt. These companies, despite enjoying the benefit of being identified and lauded by EPA for voluntarily sponsoring their HPV chemicals, have failed to meet even the initial program milestone – *more than three-and-a-half years after they were expected to have done so*.

Appendix 2 does *not* include the many companies and consortia sponsoring the 353 chemicals under the ICCA Initiative that have yet to make SIARs available for OECD SIDS Program review. Sponsors working through that channel arguably have less control over timing, because generally the sponsor OECD country must review a SIAR before it is made available for OECD review. Nonetheless, submissions for these chemicals must be considered long overdue, as EPA made clear from the outset of the Challenge that sponsors that chose to meet their commitments under the ICCA Initiative rather than directly under the Challenge also had to commit to complete all work no later than the end of 2004.[31]

## FINAL SUBMISSIONS

*Summary*

Final submissions have been received for 51% of the sponsored chemicals. For the other 49% of sponsored chemicals, no final submissions have been made.

*Letter grade for extent of final submissions:* **F**[32]

*Details*

For assessing "completion" of a sponsorship commitment under the Challenge, we have considered either remittance of what the sponsor has designated a final submission, or any other indication (e.g., in the initial or a revised submission) by the sponsor that it considered data development to be complete, to be a final submission for the purposes of tracking this milestone. It is important to understand, however, that *EPA has only begun to review such submissions for completeness or quality, and in some cases actual final submissions have not yet been posted or received by EPA*. (Initial indications are that some final submissions will present data quality problems and still contain data gaps; see "EPA assessment of HPV Challenge data," page 22).

For sponsors meeting their commitments through the ICCA Initiative/OECD SIDS Program, the final submission milestone to be tracked is the approval by OECD of a SIAR considered under its program.[33]

For the 1,899 core-list HPV chemicals sponsored under both programs, as of July 2007 – two-and-a-half years after final data sets or SIARs were to have been submitted:

- 704 have been deemed complete by their sponsors
- 255 have final SIARs
- 940 have neither

➢ *Hence, final submissions have been received for 51% of the sponsored chemicals (TPs/RSS for 37% and SIARs for 13%). For the other 49% of sponsored chemicals, no final submissions have been made.*

The breakdown of these numbers for chemicals sponsored directly under the Challenge and those sponsored under the ICCA Initiative via the OECD SIDS Program is as follows:

- Of the 1,165 core-list HPV chemicals sponsored directly under the Challenge:
    - 620 have been deemed complete by their sponsors
    - 9 have final SIARs
    - 536 have neither

- Of the 734 core-list HPV chemicals sponsored via ICCA/OECD:
    - 84 have been deemed complete by their sponsors
    - 246 have final SIARs
    - 404 have neither

➢ *Hence, final submissions have been received for only 54% of the HPV chemicals sponsored directly under the Challenge, and only 45% of those sponsored under the ICCA Initiative through the OECD.*[34]

In addition to HPV chemicals the original 1990 HPV program list, the status of the 373 chemicals beyond that list that are sponsored is as follows:

- Initial submissions (TPs/RSS or posted SIARs) have been received for 267 (72%) of them, while the remaining 106 (28%) lack initial submissions.
- Final submissions have been received for 236 (63%) of them, while the remaining 137 (37%) lack final submissions.

Figure 3 provides a detailed breakdown of the status of the original chemicals included in the HPV Challenge, including both those sponsored directly under the Challenge and those being handled under the OECD SIDS Program.

**Extent to which EPA has compelled information development for unsponsored HPV chemicals**

*Summary*

EPA's development of test rules to compel data development for unsponsored "orphan" chemicals has proceeded exceedingly slowly, with only 16 (6%) of the 265 orphans subjected to such rules to date. This initial rule took more than five years to finalize. EPA hopes to propose a second rule in 2008 covering up to about 40 additional orphan chemicals, which will still leave more than 200 unaddressed. While EPA has initiated efforts to develop a better evidentiary basis for these chemicals, because of the onerous nature of findings EPA must make to compel testing under TSCA, data development for many HPV Challenge orphan chemicals will likely not occur.

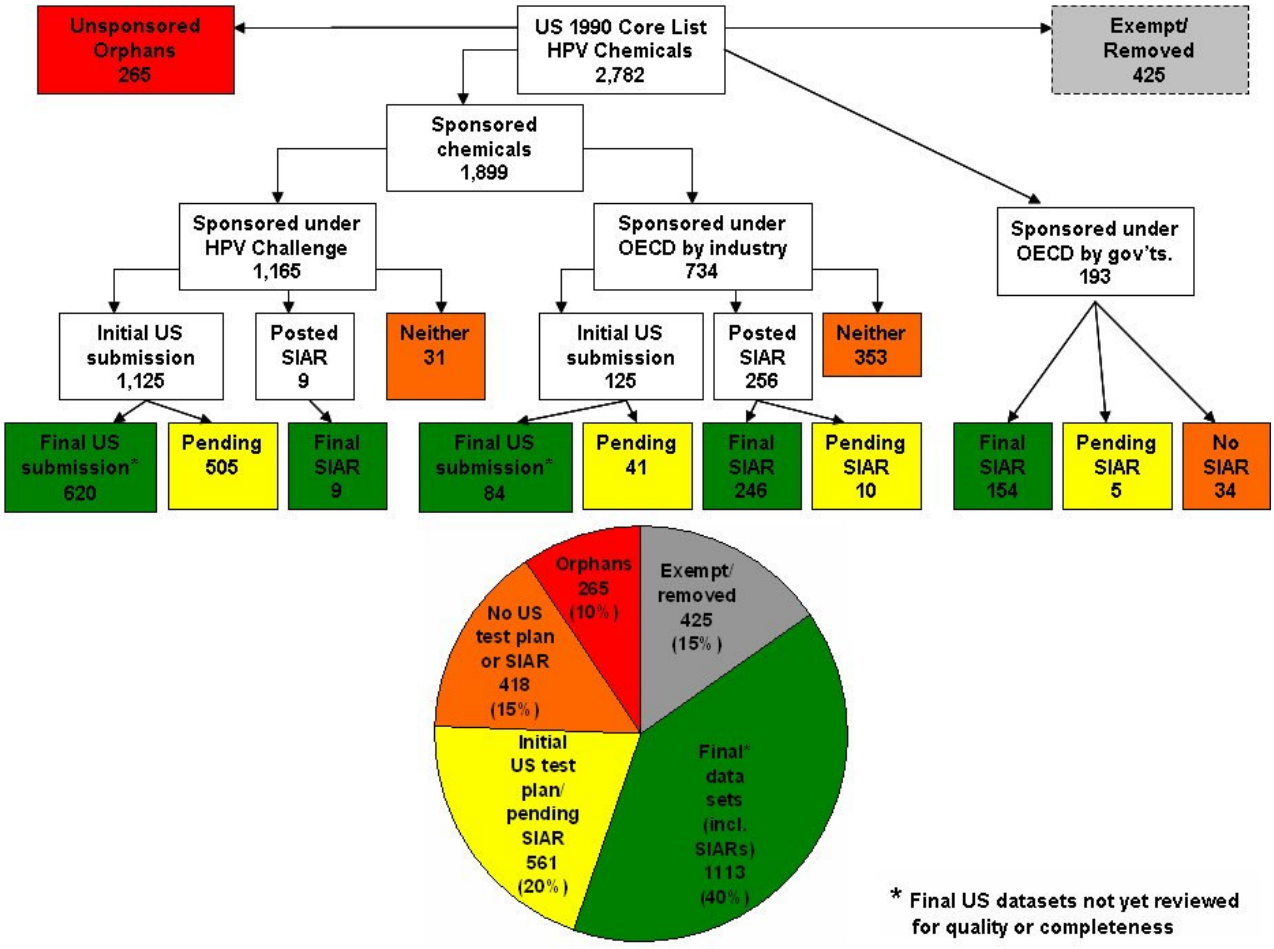
*Letter grade for extent of test rule development:* **D** [35]

*Details*

In launching the HPV Challenge, EPA stated its intention to compel testing and data development for chemicals not voluntarily sponsored.[36] Yet this intent is far from being realized: An initial TSCA Section 4 test rule covering 37 unsponsored HPV chemicals proposed in December 2000[37] was not

FIGURE 3

**Detailed Status of the 2,782 HPV Challenge Core List Chemicals**



finalized until March 2006, more than five years later, by which time it covered only 17 HPV chemicals.[38] Subsequently, EPA revoked the testing requirements for one of these.[39] For the remaining 16 chemicals, final SIDS data was to have been submitted by May 17, 2007 (barring an extension).

As stated in the final rule:

> "EPA is making the following findings for the 17 *[now 16]* chemical substances under TSCA section 4(a)(1)(B): They are produced in substantial quantities; [and] there is or may be substantial human exposure to them; [and] existing data are insufficient to determine or predict their health and environmental effects; and testing is necessary to develop such data."

All four findings are necessary in order for EPA to compel testing under Section 4, imposing a substantial burden on EPA, which in part explains why proposing and finalizing such rules takes so long.[40] In addition, full notice-and-comment rulemaking procedures must be followed, an economic analysis must be prepared and OMB review and approval is required.

EPA has yet to propose test rules for any of the remaining orphan chemicals, and had hoped to propose a second test rule covering up to about 40 additional HPV orphans in early 2007, but now does not expect to issue the proposed rule until 2008.[41] This would still leave more than 200 orphan chemicals completely unaddressed. For these, EPA has taken some steps to develop a better evidentiary basis for further test rule development. In August 2006, EPA promulgated final rules under TSCA Sections 8(a) and 8)(d) covering 243 unsponsored HPV chemicals that "require manufacturers to submit certain unpublished health and safety data and production/exposure data for these chemicals to EPA."[42] Of these, 35 were subsequently withdrawn, leaving 208 chemicals covered by the reporting rules.[43] The original deadline for submission of the requested information was November 28, 2006.

EPA hopes that information obtained through these rules will help it to make the requisite findings needed to allow it to issue Section 4 test rules for at least some of these chemicals. As of early December, EPA had received and processed only 55 Section 8(a) reports and 50 Section 8(d) submissions.[44] Since then the number of Section 8(a) reports has increased to more than 160.[45]

### Extent of EPA review of initial submissions

*Summary*

While EPA has provided comments on the great majority (>90%) of initial submissions, in the past 18-24 months it has fallen behind. While some of that shortfall has been made up in recent months, EPA has yet to provide comments on a significant number of submissions for which the 120-day comment period had passed, including some for which EPA's comments are more than a year overdue.

*Letter grade for extent of EPA review of initial submissions:* **B–**[46]

*Details*

One of the most significant enhancements to the Challenge since its launch was the 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 could review and comment on the documents. The vast majority of comments provided on initial submissions came from EPA, Environmental Defense, and a consortium of animal

welfare organizations. Most critical to the pace of progress of the program was the timely issuance of EPA's comments, as sponsors were requested not to proceed with any testing until after the comment period had closed and to respond to EPA's comments within 60 days.

While initially EPA provided comments on essentially all initial submissions, typically within or close to within the allotted 120 days, in recent years its performance in this regard has fallen well behind. As of March 2005, EPA had reviewed only eight of 61 submissions for which the 120-day comment period had closed, and had reviewed none of the last 48 submissions for which the comment period had closed. By July 2007, this shortfall had only been partially closed: EPA had yet to provide comments on any of the last 31 submissions for which the 120-day comment period had passed. For 21 of these submissions, EPA's comments are more than six months overdue.[47]

### Extent to which initial submissions by sponsors were of high quality

*Summary*

Sponsors have made extensive use of alternatives to direct testing – reliance on unpublished data and application of estimation methods and category approaches, which is allowed, subject to extensive guidance, under the Challenge. EPA's and Environmental Defense's reviews of sponsors' initial submissions strongly suggest a tendency to over-rely on such alternatives, with one or both of us raising serious concerns about the data provided or methods proposed to fill data gaps for a significant majority of all initial submissions. While many of these concerns appear to have been addressed in revisions, a full accounting of the adequacy and completeness of the data must await EPA's upcoming review of final submissions.

The average quality of initial submissions of test plans and robust study summaries, while originally quite good, has declined considerably over the course of the Challenge, especially in the past 18 months.

*Letter grade for quality of initial submissions:* **C+**[48]

*Details*

The ultimate measure of the Challenge's success, given its original scope and objective, will be the extent to which it yields complete screening-level hazard data of high quality on HPV chemicals. A hallmark of the Challenge has been the extent to which it has allowed or encouraged the use of alternatives to new testing to provide the requested data. Fewer than 10% of the base set data elements have been proposed by industry participants to be filled through new testing. Instead, EPA statistics derived from examination of the initial sponsor submissions indicate that:

- 50-60% of the data elements were proposed by sponsors to be filled using existing experimental data – 20-25% from published studies and 30-35% from "unpublished" studies.
- For the remaining 30-40% of the data elements, sponsors proposed to derive estimated values using structure-activity relationship (SAR) models or so-called "read-across" methods applied to surrogate or analog chemicals or categories of chemicals grouped together, based on apparent structural and functional similarity. In both cases, testing-derived data for one or more chemicals are used to estimate or interpolate/extrapolate data for "related" chemicals that have not been directly tested.[49]

When applied in a scientifically sound manner, use of unpublished data and application of estimation methods and category approaches can reduce the need for testing – thereby reducing both costs to industry and the need to sacrifice laboratory animals and increasing the number of chemicals that can be assessed with limited resources. However, assessing whether estimation and extrapolation techniques are being appropriately applied, as well as judging the reliability of unpublished data, requires considerable and careful oversight. To that end, the program has developed detailed guidance documents.[50]

Proposed use of data derived by such means has also been subject to review and comment. Those reviews have revealed frequent deficiencies. As of July 2007:[51]

- For 83% of the industry submissions that Environmental Defense or EPA has reviewed, one or both of us indicated either that more testing than proposed was clearly needed (usually either because some of the data provided were unreliable or the rationale offered for not providing certain data was insufficient) or might be needed (usually because information accompanying the submitted data was incomplete).
- For nearly half of the category proposals that Environmental Defense or EPA has reviewed, one or both of us disagreed with the submitter's justification for category formation, indicating that industry proposed to over-rely on such methods as a substitute for direct testing. (Note that while about 35% of initial submissions are for proposed categories, those proposed categories contain about 80% of all chemicals sponsored under the Challenge.)

Figure 4 shows the number of initial submissions for which EPA and/or Environmental Defense either called for more information or testing, or disagreed with the justification for or scope of a category proposed by the sponsor.

These data clearly demonstrate the critical importance of the public and EPA review process in identifying deficiencies in sponsors' initial proposals. To the extent that industry heeds these comments, considerably more than the <10% of the required endpoints that sponsors initially proposed to fill by testing will in fact require new data to be generated.

As another measure of the quality of initial submissions, Environmental Defense assigned a letter grade (A to F) to each submission we reviewed.[52] The grades were used to calculate a grade point average (GPA) for the submissions on which we provided comments in each of the past six years of the Challenge; Figure 5 shows the results: a dramatic decline over time in the average quality of the initial submissions. The overall 2001-2006 GPA was 2.52.

It is important to note that these quality measures apply only to the *initial*, not final, submissions of Challenge sponsors. Many sponsors have provided formal responses to comments received (especially to those from EPA), and they and others have no doubt made revisions that are or will be reflected in their final submissions. At this time, however, we have no way to systematically assess the extent to which the concerns raised in comments have been addressed and, hence, the ultimate quality and completeness of data submitted under the Challenge. That task must await EPA's review and assessment of final submissions, which has only just begun; initial indications are that some final submissions will present data quality problems and still contain data gaps (see "EPA assessment of HPV Challenge data," page 22).

FIGURE 4
**Summary of Test Plan Comments**

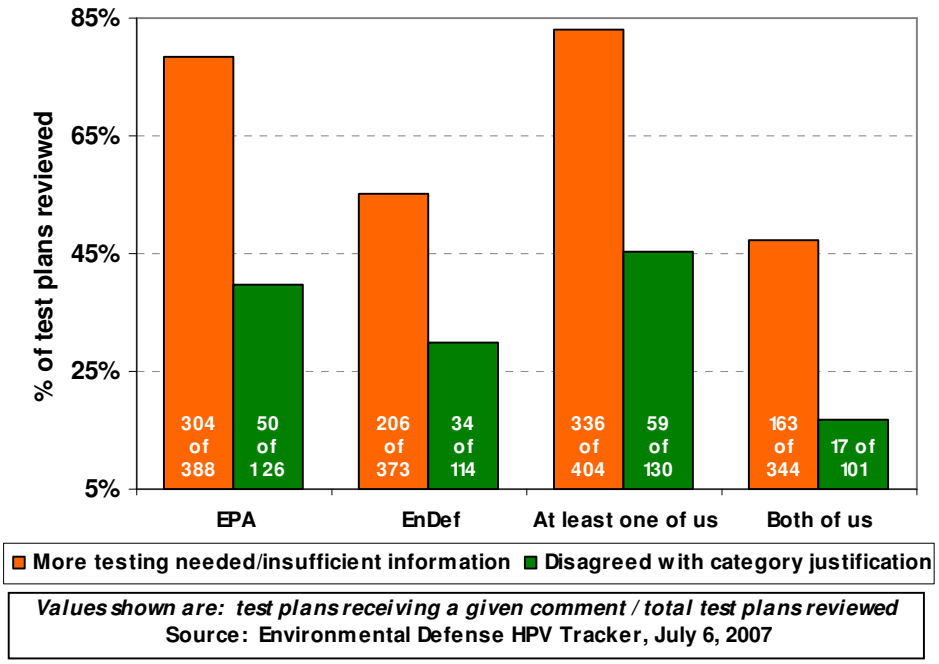
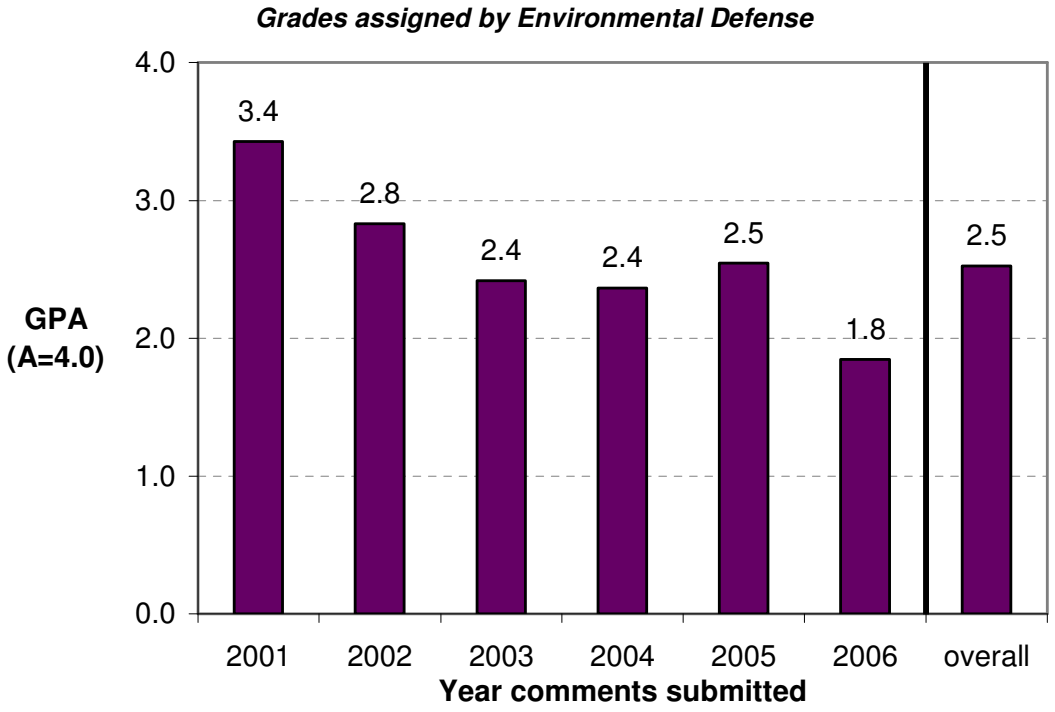



FIGURE 5
**Grade Point Average for Initial Test Plans, by year and overall**



**Extent to which submitted information is publicly accessible, readily retrievable and usable**

*Summary*

Both EPA and industry failed to live up their promises to provide a reasonable means for the public to track the status and progress of the Challenge. While EPA's development of the HPV Information System, the repository database for the HPV data, was finally jumpstarted after years of delay, much work remains to fully populate it and make it functional and user-friendly.

*Letter grade for providing public access to information:* *Chemical Industry* **F**

*USEPA* **C-**[53]

*Details*

One of the three key elements of the Challenge was to be "continuous public access to program status and results." In the *Federal Register* notice describing the program, EPA stated that "[t]he public will be able to follow the status and progress of the chemicals in the voluntary HPV Challenge Program over time. This will be done by making information publicly available on the Internet. EPA and other parties have committed to help the public stay informed about progress in the voluntary HPV Challenge Program, with an emphasis on the status of data collection and testing efforts. EPA will have responsibility for making the data available in ways which are useful to diverse stakeholders."[54] EPA also noted: "Most information associated with the voluntary HPV Challenge Program will be submitted electronically in order to better allow both efficient analysis of the data by EPA and real-time public access to the collected data. Many submissions will be made electronically via the Internet."[55] The chemical industry also committed to manage and track the status of company and consortia commitments to sponsor chemicals, as well as to facilitate public access to test plans and robust summaries.[56]

Unfortunately, such timely and ready access to HPV Challenge data never fully materialized. After initial fledging efforts, the industry abandoned its promise to provide and keep current a web-based "US HPV Chemical Tracking System." EPA did develop a tabular listing of sponsorship commitments, complete with links to the underlying commitment letters; however, given the sheer volume of correspondence and the frequency of revisions, and the non-database format of the listing, it was burdensome both to produce and to use, and was and continues to be updated only infrequently.[57] EPA decided to routinely accept and post sponsor submissions in electronic formats that, while providing for nominal web access, could not be readily searched or analyzed.[58]

The greatest failing regarding transparency was the public's inability to gain any sense of the program's real-time status, outside of the snapshots provided by two status reports issued in 2001 and 2004 by EPA.[59] (As previously noted, Environmental Defense also provided two status reports in 2003 and 2004.[60]) To remedy this, Environmental Defense undertook to develop and maintain its *HPV Tracker*, a web-accessible, searchable and sortable Excel spreadsheet that tracks the status of all sponsors and all sponsored and unsponsored program chemicals under both the Challenge and the OECD SIDS program, including commitments, test plan submissions and revisions, and EPA and public comments. The HPV Tracker also provides summary statistics showing the overall status and pace of progress of the Challenge. The HPV Tracker, which has been updated 17 times over the past three years, remains the only source for such current information.

The repository database for housing and providing public access to the hazard data being developed under the Challenge also got off to a very slow start, despite EPA's promise to provide from the outset "real-time public access to the collected data." Work on the HPV Information System (HPVIS) only began in earnest in mid-2004, and the initial public version was launched in April 2006. While considerable progress has been made, the HPVIS remains incomplete with respect to both content and functionality, due to the late start, budget constraints, the tardiness of many final submissions, the need to manually input and execute quality control procedures on the majority of data that was received in non-database formats, and the complexity of the data themselves. As of April 2007, HPVIS contains data from 348 submissions, representing 873 chemicals, with additional submissions to be added over time.[61]

The accessible data include (but do not readily distinguish between) those drawn from both initial and final submissions. Data have been input in the form received from sponsors, which poses major challenges in using the data, most of which can be traced back to earlier decisions as to acceptable formats for data submission. For example, there are frequently multiple studies of the same chemical for the same hazard endpoint, and hence no "single" selected value is identified or available, leaving to the user the task of selecting or calculating one. The units used to report test values for a given endpoint vary even for the same chemical among the different studies included, and vary even more for a given endpoint across multiple chemicals.

While some of these problems – such as the selection of a single "best" value – may be resolved over time or once EPA reviews and assesses the data, others – such as the disparity in units used for the same endpoint – are likely to continue to limit the utility of the HPVIS.

## Beyond the Challenge: Status of two critical follow-on steps

Two additional related activities that follow directly from, but are beyond the original confines of, the Challenge are the extent to which EPA assesses and acts on the information received to ensure sound management of HPV chemicals, and the extent to which the chemical industry commits itself to routinely provide information on chemicals once they reach high-volume levels of production or import.

### EPA assessment of HPV Challenge data

EPA has only begun to review the final data sets that have been submitted under the Challenge for quality and completeness, but has agreed to review all such submissions. EPA has also agreed to screen the HPV chemicals, prioritize them for further scrutiny based on the hazard data, and develop hazard assessments for high-priority chemicals within two years and for all program chemicals by the end of 2009.[62]

The assessment process EPA intends to apply to HPV chemicals entails several steps:

- Tier I: An automated screening process by which data on key endpoints are compared against predetermined criteria that are derived primarily from those in the internationally accepted "Globally Harmonized System for the Classification and Labeling of Chemical Substances.[63] The automated screening will sort HPV chemicals into first, second and third priority groups for further scrutiny, based on how many, and by how large a margin, the criteria are exceeded.
- Tier II: A manual review and development of a formal screening-level hazard assessment. Data quality and completeness will also be established at this stage, and a description of any available exposure information will be provided.
- Post-Tier II: Follow-up using EPA's existing authorities and procedures, including further assessment and potential regulatory and voluntary actions to develop more information or apply risk management.

As of December 2006, EPA had applied the automated screening process to 755 of the chemicals for which some data were available in the HPVIS, with the following results:[64]

| Group Designation | Number of Chemicals |
|---|---|
| Group 1 | 213 (28%) |
| Group 2 | 118 (16%) |
| Group 1 or 2 | 10 (1%) |
| Group 3 | 142 (19%) |
| Unable to assign | 272 (36%) |
| Total | 755 |

In many cases, these assignments are tentative pending receipt of additional data, as some of the chemicals to which the automated screening process was applied did not yet have complete data sets. This factor as well as ambiguities in available data, also explain why nearly a third of the chemicals could not be assigned to a priority group; EPA indicates these chemicals will require a manual examination of the data in order to make an assignment.

EPA has also begun developing draft Tier II screening-level hazard assessments for HPV chemicals. The draft assessment documents include:

- Identification and summarization of critical and supporting studies for human health effects, environmental effects, and environmental fate and behavior;
- A summary of use and exposure information, if available;
- A formal hazard identification; and
- An assessment of data gaps and needs, including whether the SIDS data requirements have been met with data of adequate quality.

In December, EPA released initial drafts of two hazard assessments for public comment on both format and content,[65] and in June circulated three others for review.[66] All five of the draft assessments were based on final submissions for HPV chemicals or categories. *EPA identified remaining data gaps in at least two of these five final submissions, which indicates that data quality problems and data gaps persist in some of the data sets identified by sponsors as complete and final.*

EPA hopes to release assessments for more than one hundred HPV chemicals in the summer of 2007.[67] EPA appears to be getting off to a good start in making good on its promise to develop screening-level hazard assessments of all Challenge chemicals. As EPA staff have stressed, however, receipt of complete final submissions from sponsors will be critical if this effort is to stay on track.[68]

### Emerging HPV chemicals

Since the HPV Challenge was launched, more than 700 additional chemicals have reached HPV levels, based on manufacturing volume data reported in the 2002 reporting cycle of the TSCA IUR. EPA, Environmental Defense and the American Chemistry Council (ACC) jointly identified 574 of these chemicals that had not been included in or exempted from the Challenge, and were not otherwise sponsored under the Challenge, the OECD SIDS program or other related programs.[69] These 574 "emerging HPV chemicals" are supposed to be addressed under the so-called Extended HPV Program that ACC and other chemical industry associations unilaterally announced in 2005.[70]

According to ACC's webpage, last viewed on July 20, 2007, companies have agreed to sponsor only 231 (40%) of these emerging HPV chemicals, despite a December 2005 deadline by which commitments were to have been made.[71] The original program announcement indicated that hazard data on any chemicals sponsored under the EHPV Program are to be generated and submitted to EPA for public posting between 2006 and 2010.[72] To date, however, no EHPV Program submissions have been made publicly available.

EPA recently examined the extent of screening-level hazard data that is publicly available on some of these emerging HPV chemicals, and found the following:[73]

- Of 235 chemicals that were manufactured at HPV levels in 1998 and 2002 (but not 1990):
    - 115 (49%) had no publicly available hazard data for any of the six major hazard endpoint groups examined.
    - Only 2% of them had publicly available screening-level hazard data for at least one endpoint in each of the six major hazard endpoint groups examined.

- Of 286 chemicals that were manufactured at HPV levels in 2002 but not earlier:
    - 166 (58%) had no publicly available hazard data for any of the six major hazard endpoint groups examined.

These findings can be compared to those of EPA's 1998 data availability study conducted on the original 1990 list of HPV chemicals.[74] For those chemicals:

- 43% had no publicly available hazard data for any of the six major hazard endpoint groups examined.
- 7% had publicly available screening-level hazard data for at least one endpoint in each of the six major hazard endpoint groups examined.

In other words, the more recent HPV chemicals appear to have even fewer publicly available hazard data than HPV chemicals did in 1990.

The finding that the manufactured quantities of many hundreds of chemicals increased within a few years to HPV levels illustrates the need for a continuous or "evergreen" means to ensure data development for HPV chemicals. Based on the degree of sponsor interest expressed to date, it appears unlikely that the EHPV Program will fulfill more than a fraction of this need. This finding is also direct evidence of the volatility of chemical production and commerce – hence the need to extend hazard data development efforts beyond a statically defined set of chemicals based on quantity thresholds: Today's "niche chemical" could become tomorrow's HPV chemical, with a concomitant increase in the need for hazard data.

Finally, the very limited publicly available hazard data EPA found for newly emerged HPV chemicals also indicates that – outside of this structured voluntary program and the infrequent issuance of regulatory test rules that name specific chemicals – little to no hazard data development appears to be independently occurring – or at least yielding publicly available data – even for high-volume chemicals. This situation currently falls well short of EPA's expectation for the Challenge's legacy: "EPA expects that, over time, the testing of new HPV chemicals will become routine, and companies may wish to test new HPV chemicals as they appear."[75]

## Lessons learned

### There was a heavy, and likely over-, reliance on alternatives to testing

Experience under the Challenge, as well as other chemical assessment programs, shows that – where provided for – sponsors rely very heavily on alternatives to conducting new tests on their chemicals. These alternatives include: bringing forward unpublished data, deriving estimates using quantitative structure-activity relationship (QSAR) models, and applying "read-across" methods to supply endpoint values for the sponsored chemical either from those for tested surrogate chemicals (also known as analog or supporting chemicals), or from tested members within a category of structurally related chemicals. As noted earlier, under the Challenge, sponsors proposed to fill a significant majority (>90%) of all endpoint values that lack published data by using these methods, rather than conducting new testing. This outcome has several major implications.

First, while a final tally is not yet possible due to lagging final submissions and the still-to-come EPA quality and completeness review, far less new testing took place under the Challenge than was predicted by the chemical industry.[76]

Second, each of these alternative methods has its appropriate use, but each also has significant limitations. Collectively, such extensive use of such methods poses challenges to a program intended to develop a robust understanding of the potential hazards of chemicals.[77] Among the challenges and concerns:

- OVER-RELIANCE
  Clear financial incentives exist to avoid the costs of testing, as do incentives to avoid unnecessary sacrifice of laboratory animals. These incentives may cause those deciding what tests are needed and whether alternatives are sufficient to over-rely on such methods. Indeed, as discussed earlier, this appears to be the case under the Challenge, where EPA and Environmental Defense identified many test plans that proposed to rely on inadequate unpublished data, inappropriate surrogate chemicals, or insufficiently defined or overly broad chemical categories.

- SELECTIVE USE AND REPORTING OF SUCH METHODS
  A corollary concern is the potential for alternative methods to be used, especially by industry, not only as the option of first resort, but also under a "double standard." Sponsors should not be able to argue, for example, that QSAR results are sufficient when they yield "favorable" results, i.e., "exonerate" their chemical, and proceed to conduct actual testing only in cases where the QSAR results indicate a hazard. The key question is who should decide whether and in what settings results from QSARs or other alternative methods are sufficiently reliable. Safeguards to prevent selective use and reporting are needed; for example, there should be a requirement that all results derived using all methods employed must be reported to regulatory officials.

- INAPPROPRIATE USE
  Given the typically greater uncertainty associated with values derived from alternative methods, as a general rule, they are most appropriately used for priority-setting or screening exercises (such as the Challenge), and less so to serve as the basis for more full-blown risk assessments or for risk management decisions. These limitations, however, need to accompany such data as they are carried forward, so that they are not used for purposes for which they are too unreliable.

- DIFFERENT/GREATER EXPERTISE NEEDED
  To appropriately apply and interpret the results of such methods will require additional training and rigorous quality control procedures to ensure that the methods are used correctly and that their limitations (e.g., applicable domains of QSAR models) are fully understood and respected by the users of both the methods and the results. Careful independent expert review is essential.

- JUSTIFICATION AND TRANSPARENCY
  Reliance on alternative methods carries with it an added burden of justification and transparency. There should be requirements both to justify and to document the use of alternative methods and decisions based on such information. The nature, source and means of derivation of each data value needs to accompany it in any subsequent presentation or communication of the data, and should be an integral part of the justification provided for any conclusions or decisions based on such data. Some assessment of the degree of confidence in or reliability of the data is another prerequisite to transparency, and any resulting uncertainty should be captured and communicated through a clear articulation of appropriate qualifications or limitations that apply to conclusions or decisions based on such information.

- CONTINUING NEED FOR EXPERIMENTAL DATA
  There remains a continuing need for generation of experimental data to support the use and refinement of alternative methods. Development and improvement of these alternative methods are highly dependent on having a robust and expanding underlying experimental dataset of values derived from testing. Such data are necessary to refine the algorithms that underpin QSARs and to provide a sufficient basis for interpolation or extrapolation from structurally related chemicals. In other words, these alternatives will only be as good as the experimental data that underpin them. Without continued commitment to enhance databases derived from experimental testing, the applicability and reliability of such alternative methods will not progress to where they can reliably replace direct testing.

Third, clear and comprehensive guidance is needed that delineates the limitations as well as appropriate uses of each alternative method; the acceptable methods; the content of needed justifications for employing the alternatives rather than conducting testing; expectations for interpreting the results; and standards for communicating all of the above. As noted earlier, EPA did develop fairly extensive guidance for most of the methods employed (an exception being the use of surrogate or supporting chemicals), though not all of the aspects noted above were included or emphasized. In addition, some of this guidance (notably enhancements to the category guidance governing final category analyses and reports) arrived too late to allow for its incorporation into many final submissions.[78]

**Thorough expert and public review of sponsors' initial and final submissions is essential**

The Challenge has amply demonstrated how critical expert review is both to the credibility of the program and the quality of the data it generates. As already noted, review of test plans and robust study summaries by both EPA and the public succeeded in identifying many deficiencies in both the existing data provided and the proposals to fill data gaps. This illustrates how important it is to allow for an *interim* review step, in order to allow mid-course corrections to be made.

Thorough review of final submissions – while not formally part of the Challenge – will be equally critical if the data are to be viewed as reliable. Given that the data themselves are public, EPA needs to clearly

identify and transparently communicate any deficiencies, remaining data gaps and disagreement over data interpretation, even as it works with sponsors to address these issues.

**Formal responses to comments received should be required**

While many sponsors provided written responses to EPA's comments, in many other cases no formal response was provided, making it very difficult to understand whether sponsors agreed or disagreed with EPA's comments and what if any changes were made to address these comments. Many fewer sponsors provided responses to public comments received, further frustrating efforts to gauge the ultimate effect of the opportunity for public review and comment on the information generated under the Challenge.

Any such efforts mounted in the future should not only provide for public review and comment, but should also require that sponsors respond in writing to any and all comments received.

**Opportunity for public involvement and full public access added significant value and transparency**

In addition to being a voluntary program, from the outset the HPV Challenge faced another hurdle to being viewed as credible by the public: its reliance on industry to generate the needed data, given the obvious vested interest by companies in maintaining the safety of their chemicals. In addition to relying on well-established test guidelines and other program guidance and providing for EPA review, the fact that all submissions were made fully accessible to the public and could be examined by anyone was important to enhancing credibility and accountability. This importance is not diminished by the fact that only a few public organizations took routine advantage of the opportunity to submit comments; the potential to do so at any time by anyone was essential. Full public access and opportunity for involvement should be considered a bedrock element of any voluntary program.

**The failure to provide for transparent, real-time tracking of program progress was a major shortcoming**

As noted earlier, despite promises to do so, both the chemical industry and EPA failed to provide a reasonable means for the public to understand the status of the Challenge at any given time: how many chemicals were sponsored, had initial or final submissions, etc. This critical task fell to a non-governmental organization to undertake by default: The only effective means available to track program status and progress has been and remains Environmental Defense's HPV Tracker.

The lack of an official tracking system has reduced overall program accountability and transparency. When coupled with inaccurate or at-best premature statements, especially by industry, as to the extent of completion and the amount of data made available through the Challenge (see next section), the unavailability of a transparent means for tracking progress has served to undermine the credibility of both government's and industry's characterizations of the Challenge's achievements.

Going forward, both government and industry must recognize the centrality of transparent tracking of progress in establishing and maintaining the credibility of any voluntary program. An upfront commitment to such a public accountability mechanism, as well as commitment of the necessary resources to ensure it happens, should be an absolute given in any such program.

**Delays in developing and populating a robust, fully functional repository database have set the program back considerably**

As noted previously, this feature of the Challenge was intended to be a core element from the outset. The slow pace in establishing the HPVIS has spawned or exacerbated additional problems: The many challenges being identified by the initial users of HPVIS could have been addressed sooner and more efficiently had they been caught earlier.[79] Some emerging problems with the format of the data themselves (e.g., multiple or inconsistent units), might have been identified sufficiently early so as to be remedied prior to submission by industry sponsors, or workarounds could have been implemented to resolve them.

Any future effort must take all steps necessary to ensure that the public's right to know is not compromised or delayed due to insufficient attention being paid to how, and how quickly, the data are be made public.

## The chemical industry's deceptive "spin" on the Challenge

Even with the incomplete status of the Challenge, the progress to date ought to have provided the ACC with plenty of achievements to which it could point to demonstrate its fulfillment of the commitment industry made to the program's objectives and its contribution toward improving the knowledge base available for chemicals assessment and management. Unfortunately, ACC has instead chosen to distort the facts surrounding the state of knowledge existing both prior to the Challenge's launch and today as a result of the program.

In a variety of forms and fora, ACC is now maintaining that:

- "There never really was any 'toxic ignorance.'" This argument maintains that the chemical industry already had all of the data needed to prove its chemicals were safe, and the Challenge simply gave it the opportunity to demonstrate this. The rash of studies claiming that data gaps existed simply didn't have the tools needed to access the wealth of both public and private data that existed prior to the Challenge.
- "The chemical data gap has been closed." This argument maintains that, even if there were gaps before, they've now been filled and we have ample data not only for HPV chemicals but effectively for all chemicals in commerce today. ACC has also repeatedly claimed that the HPV Challenge is finished and has already provided complete data for more than 2,200 HPV chemicals.[80]

Consider, however, as documented in this report, the following realities regarding our state of knowledge.

### The initial and remaining knowledge gaps for Challenge chemicals

- While the Challenge did unearth considerable amounts of unpublished data, sponsors offered such data to fill only about one-third of the data gaps. Moreover, comments from EPA and Environmental Defense frequently questioned the quality and completeness of these data.
- Much of the remaining data came from the use of read-across among members of chemical categories and the application of estimation methods (QSARs). The vast majority, if not all, of the data derived by sponsors using these means was developed *in response to* the Challenge, not prior to it.
- The HPV Challenge is incomplete: There are still many hundreds of chemicals with initial submissions yet to be finalized, overdue test plans and robust summaries, with uncertain timelines for completion under the OECD program. In addition, 10% of the HPV chemicals are unsponsored orphans.
- Many of the comments provided by EPA and Environmental Defense identified data gaps beyond those identified by sponsors and called for more testing to fill them.
- EPA's assessment of data quality and completeness has only just begun.
- All parties have agreed that the SIDS data comprise only screening-level data, which fall well short of what would be needed to conduct a full hazard or risk assessment. In other words, these data are inadequate to support an assessment that is sufficient to confidently demonstrate either a chemical's safety or likely harm. Nor do these data address emerging concerns such as development neurotoxicity or endocrine disruption potential.

**Knowledge gaps for chemicals not included in the Challenge**

- Beyond the Challenge chemicals, hundreds of other chemicals have risen in production to become HPV chemicals. Even with the greatly enhanced development of and access to online databases relative to the period before the Challenge began, EPA found even larger gaps in publicly available data for these emerging HPV chemicals than was found for the original ones. Industry has managed to achieve only a tepid degree of sponsorship of these chemicals acting unilaterally through its EHPV Program.
- There are tens of thousands of non-HPV chemicals that remain to be addressed, which likely have even larger data gaps than were found for HPV chemicals. Given the dynamic nature of chemical production and use, many of these chemicals may become tomorrow's HPV chemicals. And even today, many of these chemicals may well be used in ways that could pose significant risks – risks we cannot assess (or dismiss, as ACC would have us do) without access to reliable data on their potential hazards.

So even if we were to have complete, high-quality SIDS datasets for all HPV chemicals, we would still have only part of the knowledge needed to assess the potential hazards even of just those chemicals.

ACC's implied claim that industry already possesses sufficient knowledge of its chemicals (HPV and others) to know they are safe is also not supportable: Government programs that have examined large numbers of chemicals have consistently identified many that possess hazardous properties sufficient to warrant further assessment or control. For example:

- The European Commission has noted that about 70% of all new substances assessed under existing EU legislation were found to have at least one dangerous property. It concludes that "[a]n unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects."[81]
- In Canada, the recently completed Domestic Substances List (DSL) Categorization process under the Canadian Environmental Protection Act (CEPA) that examined all 23,000 previously unassessed existing chemicals on the DSL has identified more than 4,300 DSL chemicals warranting further assessment or control.[82]
- As noted earlier, EPA has found that the initial results of applying its automated prioritization screening process to the first 755 HPV Chemicals with data in the HPVIS place about a third of the chemicals in the first-priority group for further assessment, based on their having triggered one or more of the hazard endpoint screening criteria. While these results are certainly preliminary, for reasons including the fact that they take sponsors' data at face value, they suggest that many HPV chemicals will be found to possess one or more hazardous properties that warrant further assessment or control.

In sum, ACC simply can't have it both ways:

- They can't claim that extensive data on their chemicals already exist, even as they project exorbitant costs for testing programs that assume no data exist.[83]
- And they can't claim that all of the needed data on HPV chemicals has now been provided, even as they insist on caution in any use of the data because it represents only screening-level information.[84]

## Conclusion: Is the Challenge a success?

This report shows that the Challenge is noticeably limping as it approaches the finish line, with considerable amounts of data yet to be made available. Of the nearly 2,800 chemicals originally included in the Challenge:

- One-third of those with initial submissions still lack final data sets. More than 500 HPV chemicals sponsored directly under the Challenge that have initial submissions still lack final datasets.
- More than one-fifth lack even initial submissions. Thirty-one HPV chemicals sponsored directly under the Challenge and 387 HPV chemicals proceeding through the OECD SIDS Program lack initial submissions; date development for the latter is proceeding on a much slower track than called for under the Challenge, despite EPA having requested that hazard data on such chemicals be made available by the end of 2004.
- 265 HPV chemicals, 10% of the chemicals eligible for sponsorship, remain unsponsored orphans, with no near-term prospect for data to be developed.

In addition:

- Use of alternatives to direct testing – reliance on unpublished data and application of estimation methods and category approaches – are allowed under the Challenge. However, sponsors have made such extensive use of them that more than 80% of sponsored chemicals were grouped into proposed categories and fewer than 10% of the base set data elements were proposed to be filled through new testing.
- EPA's and Environmental Defense's reviews of these proposals strongly suggest that sponsors tended to over-rely on such alternatives: One or both of us raised non-trivial concerns about the data provided or methods proposed to fill data gaps for a significant majority of all initial submissions, although many of these concerns appear to have been addressed in revisions.
- The average quality of sponsors' initial submissions, while originally quite good, has declined over the course of the Challenge, especially in the past 18 months.
- EPA has fallen behind in its review of initial submissions, further exacerbating the tardiness of sponsors' submissions under the Challenge.
- EPA's development of test rules to compel data development for unsponsored orphan chemicals has proceeded exceedingly slowly, with only 16 (6%) of 265 orphans subjected to such rules to date.
- While EPA's development of the HPVIS, the repository database for the HPV data, was finally jumpstarted after years of delay, much work remains to fully populate it and make it fully functional and user-friendly.
- Of 574 newly "emerged" HPV chemicals – those that have reached HPV levels of manufacture since the Challenge was launched – only 231 have been sponsored through the chemical industry's EHPV Program. Wide gaps in publicly available hazard data for these chemicals exist. These findings indicate that the industry is not making the development of and public access to hazard data on all HPV chemicals "evergreen" practices.

Critical next steps that EPA needs to take – determining data quality and completeness, and using the data to assess the hazards of HPV chemicals – have only just begun. Initial indications are that some final submissions will present data quality problems and still contain data gaps. The ultimate measure of the value of the Challenge will, of course, be the extent to which EPA as well as industry and the public use the new information to drive hazard and risk reduction.

## Endnotes

[1] Toxic Substances Control Act of 1976, §2(b)(1), 15 U.S.C. 2601(b)(1), available at www4.law.cornell.edu/uscode/15/ch53.html.

[2] TSCA §4(a)(1), 15 U.S.C. 2603(a)(1).

[3] EPA has used its TSCA §4 authority to require testing of about 200 chemicals, issuing test rules for 140 of them. For the remaining 60, EPA has obtained data through §4 Enforceable Consent Agreements (ECAs), which it uses as an alternative to test rules in cases where there is agreement with industry on the need for, and scope of, testing. U.S. Environmental Protection Agency, *Overview: Office Of Pollution Prevention and Toxics Programs*, January 2007, prepared by OPPT for the National Pollution Prevention and Toxics Advisory Committee ("OPPT Overview"), p. 4, available at www.epa.gov/oppt/pubs/oppt101c2.pdf.

[4] National Research Council, *Toxicity Testing* (Washington, D.C.: National Academy Press, 1984), available at www.nap.edu/catalog/317.html; Environmental Defense Fund (now Environmental Defense). *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States*. New York, NY: Environmental Defense Fund, 1997, available at www.environmentaldefense.org/documents/243_toxicignorance.pdf; 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, DC: U.S. Environmental Protection Agency, April 1998) (available online at 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 (now the American Chemistry Council), Arlington, Virginia, 1998. An analogous study was conducted in 1999 by the European Union (EU), available at ecb.jrc.it/cgi-bin/reframer.pl?A=EX&B=/existing-chemicals/datavail.htm.

[5] See USEPA's HPV Challenge website, at www.epa.gov/chemrtk/index.htm. Also, for descriptions of the origins, purpose, design and implementation of the HPV Challenge, see EPA's status reports on the Challenge, available at www.epa.gov/chemrtk/pubs/general/hpvstltr.htm; and Environmental Defense's earlier status reports: *Facing the Challenge: A Status Report on the US HPV Challenge Program*, March 2003, and *Orphan Chemicals in the HPV Challenge: A Status Report*, June 2004.

[6] TSCA defines manufacture to include both domestic production and import. §3(7), 15 U.S.C. 2602(7).

[7] The base set selected for the HPV Challenge is based on the SIDS, or Screening Information Data Set, developed by the Chemicals Committee of the Organization for Economic Cooperation and Development (OECD). For a description of the Challenge and a list of the data elements, see the December 26, 2000 *Federal Register* notice announcing the Challenge (available at www.epa.gov/chemrtk/pubs/general/frnotics.htm) and USEPA's program guidance document, "Determining the Adequacy of Existing Data," Appendix A, available at www.epa.gov/chemrtk/pubs/general/datadfin.htm.

[8] In 1998, ICCA committed to provide, by 2004, SIDS data sets for 1,000 chemicals that meet the OECD definition of an HPV chemical – produced in one or more OECD countries at a level at or above 1,000 metric tons per year – through the OECD SIDS Program. See www.iccahpv.com/hpvchallenge/HPVChallenge.cfm.

[9] See OECD's webpage for the SIDS Program, Co-operation on the Investigation of Existing Chemicals, available at www.oecd.org/about/0,2337,en_2649_34379_1_1_1_1_1,00.html.

[10] Despite the term "test plan," data under the Challenge can be and have been developed using a variety of means in addition to direct testing, as discussed later in this report.

[11] The OECD SIDS Program differs from the Challenge in another respect as well: SIARs provide not only a summary of SIDS data for an HPV chemical, but an assessment of its potential hazards and a recommendation as to whether further assessment beyond this initial screening level is warranted.

[12] For those chemicals that overlap with the U.S. HPV Challenge list of chemicals, EPA allowed sponsors to make Challenge program commitments through participation in the ICCA Initiative, provided that they committed to completing all work no later than the end of 2004. See EPA's Frequently Asked Questions page for the HPV Challenge, answer to Question 4, available at www.epa.gov/chemrtk/pubs/general/hpvfaqs.htm.

[13] See EPA's original program announcement and description in *Federal Register*, December 26, 2000, Vol. 65, No. 248, p. 81692, available at www.epa.gov/chemrtk/pubs/update/ts42213.pdf, and *Status and Future Directions of the High Production Volume Challenge Program*, Office of Pollution Prevention and Toxics, Washington, DC, December 2004, pp. 14, 40-41, available at www.epa.gov/chemrtk/pubs/general/hpvreport.pdf.

[14] See EPA's website for the HPV Challenge, at www.epa.gov/chemrtk/.

[15] See USEPA National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, "Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" Draft dated October 6, 2005, answer to question 3, p. 4, available at www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf.

[16] The SIDS was formally adopted by the OECD in November, 1989. See OECD's *Manual for Investigation of HPV Chemicals*, Chapter 2, p. 2, available at www.oecd.org/dataoecd/60/43/1947477.pdf.

[17] See EPA National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, "Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" Draft dated October 6, 2005, answer to questions 1 and 2, p. 3, available at www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf.

[18] See REACH Q&A, December 2006, available at europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/488&format=HTML&aged=0&language=EN&guiLanguage=en. The EU defines an HPV chemical to be one manufactured in the EU at or above 1000 metric tons, or about 2.2 million pounds, annually – more than twice the 1 million pound level that defines a U.S. HPV chemical.

[19] This letter grade of B+ was assigned based on the typical percentile grading scale used in academia, where 90-100% is considered an A, 80-90% a B, etc.

[20] See EPA's 1990 HPV Challenge Program Chemical List and associated indicator codes, available at www.epa.gov/hpv/pubs/update/hpvchmlt.htm. There is some overlap among these lists.

[21] Virtually all of these chemicals are natural products like sugars, oils and fatty acids. See chemicals assigned an indicator of "1" on EPA's HPV Challenge Program Chemical List, available at www.epa.gov/chemrtk/pubs/update/hpvchmlt.htm.

[22] Polymers and, until recently, inorganic chemicals have generally been exempted from reporting under the TSCA Inventory Update Rule. See 69 *Fed. Reg.* 40789-90, available at www.epa.gov/fedrgstr/EPA-TOX/2004/July/Day-07/t15205.htm.

[23] Under the OECD SIDS Program, chemicals can be sponsored either directly by member governments or by companies through the ICCA Initiative. For purposes of the Challenge, EPA regarded data development for U.S. HPV chemicals sponsored by OECD member governments as already being addressed and therefore these chemicals did not need to be sponsored by industry directly under the Challenge.

[24] This count of 265 chemicals excludes two chemicals – CAS #s 1445450 and 68479981 – designated as orphans by EPA, which have also been designated by EPA to be "tentatively" sponsored. EPA's list of HPV orphans as of November 30, 2006 is available at www.epa.gov/chemrtk/pubs/general/hpvunspn.pdf. Since then, two additional chemicals – CAS #s 68526829 and 68909182 – have been designated by EPA as orphans, due to withdrawn sponsorships, while two other chemicals – CAS #s 150505 and 3338247 – have been removed from the list due to new sponsorships; personal communications to the author from Jeffrey Taylor, EPA Office of Pollution Prevention and Toxics, June 27 and July 11, 2007.

[25] The data for the 2002 reporting cycle are the most recent that are publicly available; data now being collected for the 2006 reporting cycle are not yet available. Data for the 2002 reporting cycle change over time, however, based on corrections submitted by companies and revisions made by EPA. The 2002 IUR data used for this report were provided to the author by OPPT staff in January, 2007.

[26] This letter grade of C+ was assigned based on the typical percentile grading scale used in academia, where 90-100% is considered an A, 80-90% a B, 70-80% a C, etc.

[27] See endnote 12.

[28] While initial test plans are also sometimes submitted under the OECD program, it is not a routine requirement and hence cannot serve as an interim milestone for the purpose of tracking initial submissions. However, even the initial posting – prior to any OECD review – of a SIAR is counted here as sufficient to have met the initial submission milestone.

[29] For some ICCA Initiative chemicals, sponsors choose to submit a RSS and TP under the Challenge, as well as a SIAR under the OECD SIDS Program. This occurs most commonly when the U.S., an OECD member, is the designated country sponsor for an industry submission to the OECD program.

[30] While one might think that separate letter grades should have been assigned to these two subcategories of sponsorship, given that sponsors had a choice as to which program they used and that EPA's timeline for final submissions was the same for both, it is evident that this milestone should be graded based on the overall performance across both sponsorship categories.

[31] See endnote 12.

[32] This letter grade of F was assigned based on the typical percentile grading scale used in academia, where 90-100% is considered an A, 80-90% a B, 70-80% a C, 60-70% a D and below 60% an F. In addition, final data sets were originally due to have been submitted by the end of 2005, more than two-and-a-half years ago. Even for chemicals sponsored directly under the Challenge, only 54% of final submissions have been received; see text for details.

[33] In some cases, SIARs are not agreed to after an initial discussion at an OECD meeting, and are sent back for further work and subsequent re-review.

[34] See endnote 30.

[35] Both the extent to which, and the rate at which, EPA has developed test rules for Challenge orphans has been dismal, and would warrant a letter grade of F were it not for the fact that EPA's evidentiary burden under TSCA severely constrains its

ability to compel testing. Given those constraints, EPA is making significant efforts using authorities available to it to meet that evidentiary burden wherever it can. But its progress to date and limited ability to deliver on its promise to use test rules to ensure data development for all Challenge chemicals still warrants no better than a grade of D.

[36] See EPA's Frequently Asked Questions page for the HPV Challenge, available at www.epa.gov/chemrtk/pubs/general/hpvfaqs.htm, wherein EPA states: "EPA plans, if necessary, to make those HPV chemicals not sponsored in the Challenge Program subject to a test rule under Section 4 of the Toxic Substances Control Act (TSCA)."

[37] 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."

[38] See www.epa.gov/fedrgstr/EPA-TOX/2006/March/Day-16/t2483.htm. The removal of 20 chemicals from the original list of 37 was due to two factors: sponsorship of 13 chemicals in the face of test rule issuance, and an EPA determination that seven of the chemicals were no longer produced at HPV levels, based on data from the 2002 reporting cycle under the TSCA IUR.

[39] EPA stated it revoked the testing requirements for this substance because it received new information indicating that worker exposure is limited due to product reformulation, and hence the substance no longer meets its criteria for "substantial human exposure," as required under TSCA. See 71 *Fed. Reg.* 71058, available at www.epa.gov/fedrgstr/EPA-TOX/2006/December/Day-08/t20908.htm.

[40] EPA officials have themselves indicated that finalization of a test rule can take two to ten years and consume considerable financial resources; see Government Accountability Office, Report GAO-05-458, *Chemical Regulation – Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, 2005, p. 26, available at www.gao.gov/new.items/d05458.pdf.

[41] The early 2007 date was noted in a presentation by Jim Willis, EPA Office of Pollution Prevention and Toxics, at the HPV Data Users Conference held in Austin, TX on December 12-14, 2006, available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm. The 2008 date was provided by personal communication from Jeffrey Taylor, EPA Office of Pollution Prevention and Toxics, July 11, 2007.

[42] See EPA's TSCA Section 8(a) Preliminary Assessment Information Reporting (PAIR) Rule and its TSCA Section 8(d) "Health and Safety Data Reporting Rule. As explained in these notices, because EPA had first listed the chemicals on the Priority Testing List maintained by the Interagency Testing Committee, it was able to issue these rules as final rules rather than first propose and then finalize them using full notice-and-comment rulemaking procedures.

[43] Of the initial 33 chemicals withdrawn in the face of issuance of the reporting rules, 22 were sponsored directly under the Challenge, four more under the OECD and ICCA efforts and seven were determined by EPA no longer to be manufactured at HPV levels. See Willis, *op. cit.* and *Federal Register*, September 29, 2006, Vol. 71, No. 189, p. 57439, available at www.epa.gov/fedrgstr/EPA-TOX/2006/September/Day-29/t15959.htm. Subsequently, two additional chemicals were withdrawn based on sponsorship; see *Federal Register*, April 30, 2007, Vol. 72, No. 82, p. 21119, available at www.epa.gov/fedrgstr/EPA-TOX/2007/April/Day-30/t2104.htm.

[44] Willis, *op. cit.*

[45] Personal communications to the author from Joseph Nash, EPA Office of Pollution Prevention and Toxics, July 18, 2007.

[46] EPA's overall comment rate exceeding 90% is tempered by the significant number of overdue comments on more recent submissions; see text for details.

[47] See EPA's posting of HPV Challenge submissions and comments, available at www.epa.gov/chemrtk/pubs/summaries/viewsrch.htm.

[48] This letter grade of C+ is based primarily on the overall GPA of 2.52, based on grades we assigned to each initial submission we reviewed. See text for details.

[49] These statistics are drawn from EPA's latest status report on the HPV Challenge: *Status and Future Directions of the High Production Volume Challenge Program*, Office of Pollution Prevention and Toxics, Washington, DC, December 2004, p. 8, available at www.epa.gov/chemrtk/pubs/general/hpvreport.pdf. While they only reflect initial submissions received and compiled by EPA as of that time, there is reason to expect that the statistics are largely representative of subsequent submissions as well; if anything, the extent of testing proposed by sponsors has declined still further for submissions posted in recent months.

[50] See EPA's guidance documents for the Challenge at www.epa.gov/chemrtk/pubs/general/guidocs.htm.

[51] See Environmental Defense, *HPV Tracker*, available online at www.environmentaldefense.org/go/hpvtracker, which is based on data made public by EPA via its HPV Challenge website, www.epa.gov/chemrtk/index.htm.
[52] These grades were assigned by the principal authors of all of the comments on test plans and robust summaries submitted by Environmental Defense: Dr. George Lucier, Director Emeritus of the Environmental Toxicology Program for the National Institute for Environmental Health Sciences, 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.
[53] These letter grades reflect EPA's late start on developing the HPVIS, leading to its current partial population and limited functionality, and the failure of both the chemical industry and EPA to provide a reasonable means for the public to track the status and progress of the Challenge; see text for details.
[54] *Federal Register*, December 26, 2000, Vol. 65, No. 248, p. 81692, available at www.epa.gov/chemrtk/pubs/update/ts42213.pdf.
[55] *Federal Register*, *op. cit.*, p. 81694.
[56] *Ibid.*
[57] The current version of EPA's "HPV Challenge Summary Report (see www.epa.gov/chemrtk/pubs/sumresp.htm) has not been updated since January 20, 2006.
[58] EPA did add very basic search functionality for these documents to its website in early 2004.
[59] EPA's status reports are available at www.epa.gov/chemrtk/pubs/general/hpvstltr.htm.
[60] See endnote 5.
[61] See the HPV Information System (HPVIS) at www.epa.gov/hpvis.
[62] EPA agreed to implement the HPV chemical screening process outlined herein within this time frame, as proposed by its federal advisory committee, the National Pollution Prevention and Toxics Advisory Committee. See www.epa.gov/oppt/npptac/pubs/recommendationfeb2005.pdf.
[63] See OECD Series on Testing and Assessment, No. 33. *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures*, 14 August 2001, available at www.olis.oecd.org/olis/2001doc.nsf/LinkTo/env-jm-mono(2001)6.
[64] See presentation of Meena Sonawane, EPA Office of Pollution Prevention and Toxics, at the HPV Data Users Conference held in Austin, TX on December 12-14, 2006, available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm.
[65] See presentation of Meena Sonawane, *op. cit.* The draft screening assessments are for Primene 81-R Amines and 1,3-Dioxolane.
[66] These three draft hazard assessments were for two categories, Tall oil and related substances and Rosin and rosin salts, and for one individual chemical, Dichloroacetyl chloride. Communication from Charles Auer, EPA Office of Pollution Prevention and Toxics, June 26, 2007.
[67] Communication from Charles Auer, EPA Office of Pollution Prevention and Toxics, June 26, 2007.
[68] See presentation of Mark Townsend, EPA Office of Pollution Prevention and Toxics, at the HPV Data Users Conference held in Austin, TX on December 12-14, 2006, available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm.
[69] See ACC's "Questions and Answers on the Extended HPV Program," especially the answer to Question 12.
[70] See ACC's EHPV webpage, at www.americanchemistry.com/s_acc/sec_policyissues.asp?CID=432&DID=1493. In marked contrast to the HPV Challenge, the chemical industry chose to develop and execute the EHPV Program without significant involvement of EPA or other stakeholders. As a result, basic questions regarding transparency, public access and EPA and public review of sponsors' initial and final submissions remain at issue. At the time of the announcement, Environmental Defense issued a press release that both welcomed the initiative and raised a number of these concerns, several of which have yet to be fully addressed.
[71] See ACC's EHPV webpage, and ACC's press release announcing the EHPV Program, at www.americanchemistry.com/s_acc/bin.asp?CID=206&DID=1711&DOC=FILE.PDF. When accessed on July 20, 2007, the webpage still indicated that "as of May 12, 2006" 231 EHPV chemicals had been sponsored, and the spreadsheet posted on the page also listed that number of commitments.
[72] See ACC's press release announcing the EHPV Program, *op. cit.* In addition to hazard data, companies sponsoring chemicals have also been asked to provide information on use and exposure, both for the EHPV chemicals and for original Challenge chemicals for which it was not provided originally. For the 231 EHPV chemicals and for 462 Challenge chemicals, companies have agreed to provide such information. See ACC's EHPV webpage, *op. cit.*
[73] 58th (2006) and 56th (2005) *Reports of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency*, available at tsca-itc.syrres.com/Reports/; and personal communication to the author from John D. Walker, EPA Office of Pollution Prevention and Toxics, December 2006. Note that, if anything, these numbers overstate the extent to which a full screening-level hazard data set is available, because the search method employed groups

together multiple endpoints and scores the endpoint category as having data available if even a single study for a single endpoint was found. Hence, a chemical that has a single algae study but no fish or *Daphnia* study would still be scored as having ecotoxicity data available.

[74] See EPA's 1998 Data Availability Study, available at www.epa.gov/chemrtk/pubs/general/hazchem.htm.

[75] See www.epa.gov/chemrtk/pubs/update/hpvchmlt.htm.

[76] ACC claimed that the Challenge would cost industry $500 million. See last sentence of the summary paragraph at the top of the following page: www.chemicalawareness.org/background/. (This page, last visited on 7-11-07, is from the website of the Alliance for Chemical Awareness, an industry group of which ACC is a member. The text appearing there is identical to the text Environmental Defense saved from ACC's own website on 3-31-05, which has since been modified to eliminate the reference to the $500 million cost figure. The current version of that page is available at www.americanchemistry.com/s_acc/bin.asp?CID=439&DID=1515&DOC=FILE.PDF).

At the time the Challenge was launched, EPA estimated the total cost to industry (including laboratory, reporting, administrative and export notification costs) would be $250,000 per chemical to provide a full SIDS dataset, assuming no data already existed and all endpoints were filled by new testing (see EPA's Factsheet "High Production Volume Chemicals Frequently Asked Questions," p. 4, available at www.epa.gov/chemrtk/pubs/general/hpvq&a.pdf). Using that figure, $500 million would pay the total costs of fully testing 2,000 chemicals – more than the 1,900 original program chemicals sponsored under the Challenge. More recently, EPA has estimated that the total cost to industry for full SIDS testing would be $237,000; see 71 *Fed. Reg.* 71061, available at www.epa.gov/fedrgstr/EPA-TOX/2006/December/Day-08/t20908.htm. Using that figure, $500 million would cover the total costs for fully testing more than 2,100 chemicals.

[77] This discussion of alternative methods and needed cautions to prevent their overuse or inappropriate use is adapted from Denison, R.A. and Balbus, J.M. "Environmental Defense Perspective on Integrated Approaches to Chemical Testing and Assessment," paper presented at the 39th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Organization for Economic Cooperation and Development, 15-17 February, 2006, available at www.oecd.org/dataoecd/19/34/36286018.pdf.

[78] This supplemental guidance, which was developed by EPA's advisory committee, NPPTAC (see "Guidance for Preparing the Final Category Analysis," pp. 14-17 of the NPPTAC recommendation document, available at www.epa.gov/oppt/npptac/pubs/recommendationfeb2005.pdf), was only communicated to sponsors on July 14, 2005.

[79] As part of the preparation for its HPV Data User Conference, EPA funded several organizations to conduct case studies entailing the use of the HPVIS and its data, both to identify barriers to the use of the database and its data (with the aim of enhancing HPVIS), and to explore potential applications of the HPV data. The reports of those case studies include discussions of the problems the users confronted in carrying out their projects; see the four case study reports available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm.

[80] Variations on these arguments have appeared in numerous written materials authored by ACC staff; e.g.:
(1) ACC, "TSCA Myth vs. Fact," August 2, 2006, available at www.americanchemistry.com/s_acc/bin.asp?SID=1&DID=3384&CID=433&VID=115&DOC=File.PDF;
(2) Conrad, J.W., Jr., ACC's Assistant General Counsel, "Open Secrets: The Widespread Availability of Information about the Health and Environmental Effects of Chemicals," *Law & Contemporary Problems*, Summer 2006, pp. 141-165, available at www.law.duke.edu/journals/lcp/articles/lcp69dsummer2006p141.htm;
(3) Russell, S., Senior Director at ACC, "Views on Success & Future Directions," presentation at EPA's HPV Data Users Conference held in Austin, TX on December 12-14, 2006, available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm;
(4) Walls, M., ACC's Managing Director for Regulatory and Technical Affairs, "Testimony of the American Chemistry Council before the Senate Environment and Public Works Committee on the Toxic Substances Control Act," August 2, 2006, available at epw.senate.gov/public/109th/Walls_Testimony.pdf;
(5) Bond, G., Team Leader for ACC's Health, Product and Science Policy Team, "Taking Responsible Action by Making Chemical Safety Data Public," *Chemistry Business*, September 2004, pp. 17-20, available at www.americanchemistry.com/s_acc/bin.asp?CID=181&DID=334&DOC=FILE.PDF;
(6) Walls, M., in "The Future Of U.S. Chemical Regulation," *Chemical & Engineering News*, January 8, 2007, pp. 34-38, available at pubs.acs.org/cen/government/85/8502regulation.html

[81] European Commission, *Extended Impact Assessment,* COM(2003)644 final, SEC(2003)1171/3, October 29, 2003, p. 27, available at ec.europa.eu/enterprise/reach/eia_en.htm.

[82] CEPA Registry, "Categorization of Existing Substances" at www.ec.gc.ca/CEPARegistry/subs_list/dsl/s1.cfm. As noted by Environment Canada: "The purpose of categorization is not to establish the risks to the environment or human health. Any such risk must be additionally investigated through a screening assessment of the substance." See

www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm. Nonetheless, sufficient evidence of potential risk based on available information has been found for these chemicals to warrant their further investigation.

[83] See endnote 76.

[84] See, for example, Russell, S., Senior Director at ACC, "Views on Success & Future Directions," presentation at EPA's HPV Data Users Conference held in Austin, TX on December 12-14, 2006, available at www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm.

## Appendix 1
## Companies that reported manufacturing orphan chemicals but have not sponsored them

*[NOTE: Because the basis for this list is the non-confidential portion of the 2002 IUR, this list excludes any companies that designated their association with particular orphan chemicals to be confidential business information (CBI). "No company identified" means that no companies in the non-confidential data were identified as associated with the chemical. This list may also include companies that have ceased manufacturing an orphan chemical since reporting it in under the 2002 IUR.]*

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 56406 | Glycine | CHARKIT CHEMICAL CORPORATION |
| | | CHATTEM CHEMICALS, INCORPORATED |
| | | GNC GROUP, INC. |
| | | TESSENDERLO KERLEY, INC. |
| | | THE DOW CHEMICAL COMPANY |
| 62237 | Benzoic acid, 4-nitro- | CAMBREX CHARLES CITY, INC. |
| | | PHT INTERNATIONAL, INC. |
| | | R.W. GREEFF & CO., L.L.C. |
| 62566 | Thiourea | CHEM ONE LTD |
| | | SAKAI TRADING NEW YORK INC. |
| 75070 | Acetaldehyde | CELANESE CHEMICALS, INC. |
| | | CELANESE LTD. |
| | | DAK AMERICAS, LLC |
| | | EASTMAN CHEMICAL COMPANY |
| | | THE DOW CHEMICAL COMPANY |
| 75365 | Acetyl chloride | CHARKIT CHEMICAL CORPORATION |
| | | TESSENDERLO KERLEY, INC. |
| 75876 | Acetaldehyde, trichloro- | GEMCHEM INC. |
| 77769 | Propane, 2,2-dimethoxy- | no company identified |
| 78002 | Plumbane, tetraethyl- | no company identified |
| 78115 | 1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester) | BESTON CHEMICAL CORP. |
| | | DYNO NOBEL, INC. |
| | | ENSIGN-BICKFORD INDUSTRIES, INC. |
| | | INTERNATIONAL SPECIALTY CHEMICALS, INC. |
| 81072 | 1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide | CINCINNATI SPECIALTIES, LLC |
| | | HENKEL LOCTITE CORP. |
| 81163 | 1-Naphthalenesulfonic acid, 2-amino- | OMNISPECIALTY CORPORATION |
| | | SUMITOMO CORPORATION OF AMERICA |
| 81845 | Naphthalic anhydride | no company identified |
| 83410 | Benzene, 1,2-dimethyl-3-nitro- | BASF CORPORATION |
| 84651 | 9,10-Anthracenedione | CHEMICAL PRODUCTS CORP. |
| | | MITSUBISHI INTERNATIONAL CORPORATION |
| | | SHANCO INTERNATIONAL, INC. |
| | | SUNBELT CORPORATION |
| 84695 | 1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester | BOEHME FILATEX, INC. |
| | | KIC CHEMICALS, INC. |
| | | UNITEX CHEMICAL CORP. |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 85405 | 4-Cyclohexene-1,2-dicarboximide | no company identified |
| 89327 | 1H,3H-Benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone | E. I. DU PONT DE NEMOURS AND CO., INC. |
| | | JAYHAWK FINE CHEMICALS |
| 91532 | Quinoline, 6-ethoxy-1,2-dihydro-2,2,4-trimethyl- | CINCINNATI SPECIALTIES, LLC |
| | | FLEXSYS AMERICA, LP |
| 91689 | Phenol, 3-(diethylamino)- | MITSUI & CO. (U.S.A.) INC. |
| 94962 | 1,3-Hexanediol, 2-ethyl- | DIXIE CHEMICAL COMPANY, INC. |
| 96220 | 3-Pentanone | BASF CORPORATION |
| | | EXXON MOBIL CORP. |
| | | THE DOW CHEMICAL COMPANY |
| 97007 | Benzene, 1-chloro-2,4-dinitro- | no company identified |
| 98099 | Benzenesulfonyl chloride | GNC GROUP, INC. |
| | | UNIVAR USA INC. |
| 98168 | m-Toluidine, .alpha.,.alpha.,.alpha.-trifluoro- | no company identified |
| 98566 | Benzene, 1-chloro-4-(trifluoromethyl)- | CHEMCENTRAL CORP. |
| | | E. I. DU PONT DE NEMOURS AND CO., INC. |
| | | MITSUBISHI INTERNATIONAL CORPORATION |
| | | PHT INTERNATIONAL, INC. |
| | | R.W. GREEFF & CO., L.L.C. |
| | | UNIVAR USA INC. |
| 100538 | Nicotinonitrile | CHEVRON PHILLIPS CHEMICAL COMPANY LP |
| 101348 | 9-Octadecenoic acid, 12-(acetyloxy)-, 1,2,3-propanetriyl ester, (9Z,9'Z,9''Z,12R,12'R,12''R)- | CASCHEM, INCORPORATED |
| 104665 | Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis- | SPECIALTYCHEM PRODUCTS CORPORATION |
| 104916 | Phenol, p-nitroso- | no company identified |
| 104938 | Benzene, 1-methoxy-4-methyl- | HAARMANN & REIMER |
| | | JAYHAWK FINE CHEMICALS |
| 107391 | 1-Pentene, 2,4,4-trimethyl- | no company identified |
| | | no company identified |
| | | no company identified |
| 107404 | 2-Pentene, 2,4,4-trimethyl- | no company identified |
| 108190 | Imidodicarbonic diamide | CF INDUSTRIES, INC |
| 109875 | Diethylamine | AMERIBROM, INC. |
| | | THE DOW CHEMICAL COMPANY |
| | | TICONA |
| 110032 | t-Butyl peroxide | AIR PRODUCTS AND CHEMICALS, INC. |
| | | AKZO NOBEL POLYMER CHEMICALS LLC |
| 110189 | N,N,N',N'-tetramethyl-1,2-ethanediamine | no company identified |
| 110338 | Adipic acid, dihexyl ester | no company identified |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 110441 | 2,4-Hexadienoic acid, (2E,4E)- | DOW CORNING CORPORATION |
| | | MITSUI & CO. (U.S.A.) INC. |
| | | SAKAI TRADING NEW YORK INC. |
| | | TOMEN AMERICA, INC. |
| | | UNIVAR USA INC. |
| 111444 | Ethane, 1,1'-oxybis[2-chloro- | E.T. HORN CO. |
| 111853 | Octane, 1-chloro- | LONZA INC. |
| 111911 | Methane, bis(2-chloroethoxy)- | no company identified |
| 112527 | Dodecane, 1-chloro- | LONZA INC. |
| 118821 | Phenol, 4,4'-methylenebis[2,6-di-tert-butyl- | no company identified |
| 118901 | o-Toluic acid | no company identified |
| | | no company identified |
| | | no company identified |
| 119335 | p-Cresol, 2-nitro- | no company identified |
| 119619 | Methanone, diphenyl- | ATOFINA CHEMICALS, INC. |
| | | BERJE INC. |
| | | CIBA SPECIALTY CHEMICALS CORPORATION |
| | | COGNIS CORPORATION |
| | | MORRE-TEC IND. INC. |
| | | SARTOMER COMPANY, INC. |
| | | VELSICOL CHEMICAL CORPORATION |
| 121697 | Benzenamine, N,N-dimethyl- | BASF CORPORATION |
| | | BUFFALO COLOR CORPORATION |
| 121824 | 1,3,5-Triazine, hexahydro-1,3,5-trinitro- | ALLIANT TECHSYSTEMS INC. |
| | | BAE SYSTEMS ORDNANCE SYSTEMS INC. |
| | | BESTON CHEMICAL CORP. |
| | | TRW VEHICLE SAFETY SYSTEMS, INC.. |
| 124630 | Methanesulfonyl chloride | ATOFINA CHEMICALS, INC. |
| | | PHT INTERNATIONAL, INC. |
| 127684 | Benzenesulfonic acid, 3-nitro-, sodium salt | BASF CORPORATION |
| | | COLOR RESOURCES INTERNATIONAL |
| 131577 | Methanone, (2-hydroxy-4-methoxyphenyl)phenyl- | DOW CORNING CORPORATION |
| 137166 | Disulfide, bis(dimethylthiocarbamoyl) | THE DOW CHEMICAL COMPANY |
| 137202 | Taurine, N-methyl-N-oleoyl-,sodium salt | no company identified |
| 138250 | Isophthalic acid, 5- | no company identified |
| 139402 | s-Triazine, 2-chloro-4,6-bis(isopropylamino)- | no company identified |
| 140932 | Carbonodithioic acid, O-(1-methylethyl) ester, sodium salt | ALKEMIN |
| | | UNIVAR USA INC. |
| 142303 | Oleic acid, butyl ester | AIR PRODUCTS AND CHEMICALS, INC. |
| 142734 | Glycine, N-(carboxymethyl)- | no company identified |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 144627 | Ethanedioic acid | CHEM ONE LTD |
| | | JLM MARKETING, INC. |
| | | UNIVAR USA INC. |
| 149440 | Methanesulfinic acid, hydroxy-, monosodium salt | THE GOODYEAR TIRE & RUBBER COMPANY |
| 330541 | Urea, 3-(3,4-dichlorophenyl)-1,1-dimethyl- | no company identified |
| | | no company identified |
| | | no company identified |
| 460004 | Benzene, 1-bromo-4-fluoro- | DIAZ CHEMICAL CORP |
| 506514 | 1-Tetracosanol | SASOL NORTH AMERICA INC. |
| 506525 | 1-Hexacosanol | SASOL NORTH AMERICA INC. |
| 513746 | Carbamic acid, dithio-, monoammonium salt | no company identified |
| 515402 | Benzene, (2-chloro-1,1-dimethylethyl)- | CLARIANT LSM (AMERICA) INC. |
| 529339 | 1-Naphthol, 1,2,3,4-tetrahydro- | no company identified |
| 529340 | 1(2H)-Naphthalenone, 3,4-dihydro- | no company identified |
| 542927 | 1,3-Cyclopentadiene | CYMETECH, LLC |
| | | SUMITOMO CORPORATION OF AMERICA |
| | | VELSICOL CHEMICAL CORPORATION |
| 553264 | Ethanol, aluminum salt | SYNGENTA CROP PROTECTION, INC. |
| 557619 | 1-Octacosanol | no company identified |
| 563724 | Oxalic acid, calcium salt (1:1) | no company identified |
| 590192 | 1,2-Butadiene | EXXON MOBIL CORP. |
| | | JLM MARKETING, INC. |
| 592450 | 1,4-Hexadiene | no company identified |
| 594423 | Methanesulfenyl chloride, trichloro- | no company identified |
| 598721 | Propanoic acid, 2-bromo- | CLARIANT LSM (MISSOURI) INC. |
| 617947 | Benzenemethanol, .alpha.,.alpha.-dimethyl- | GEO SPECIALTY CHEMICALS, INC. |
| 624839 | Isocyanic acid, methyl ester | no company identified |
| 628137 | Pyridine, hydrochloride | no company identified |
| 628966 | 1,2-Ethanediol, dinitrate | DYNO NOBEL, INC. |
| 630206 | Aluminum stearate | OXY VINYLS, LP |
| | | THE DOW CHEMICAL COMPANY |
| 645625 | 2-Hexenal, 2-ethyl- | THE DOW CHEMICAL COMPANY |
| 693958 | Thiazole, 4-methyl- | no company identified |
| 756809 | Phosphorodithioic acid, O,O-dimethyl ester | no company identified |
| 870724 | Methanesulfonic acid, hydroxy-, monosodium salt | EASTMAN KODAK COMPANY |
| 928723 | Glycine, N-(carboxymethyl)-, disodium salt | MONSANTO COMPANY |
| | | SOLUTIA INC. |
| | | STERLING CHEMICALS, INC. |
| 939979 | Benzaldehyde, p-tert-butyl- | no company identified |
| 1000824 | Urea, (hydroxymethyl)- | BASF CORPORATION |
| | | BORDEN CHEMICAL, INC. |
| 1002693 | Decane, 1-chloro- | LONZA INC. |
| 1111780 | Carbamic acid, monoammonium salt | BASF CORPORATION |
| | | CF INDUSTRIES, INC |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 1323655 | Phenol, dinonyl- | DOVER CHEMICAL CORP. |
| 1324761 | Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- | BASF CORPORATION |
| | | MICRO INKS |
| | | TOYO INK AMERICA, LLC. |
| 1401554 | Tannins | no company identified |
| 1498517 | Phosphorodichloridic acid, ethyl ester | no company identified |
| 1738256 | Propanenitrile, 3-(dimethylamino)- | AIR PRODUCTS AND CHEMICALS, INC. |
| 1912249 | s-Triazine, 2-chloro-4-(ethylamino)-6-(isopropylamino)- | no company identified |
| 2152649 | C.I. Solvent Blue 23, monohydrochloride | no company identified |
| 2210799 | Oxirane, [(2-methylphenoxy)methyl]- | DYNACHEM, INC |
| | | RESOLUTION PERFORMANCE PRODUCTS |
| | | VANTICO INC. |
| 2372454 | Butyl alcohol, sodium salt | no company identified |
| 2409554 | Phenol, 2-(1,1-dimethylethyl)-4-methyl- | MERISOL ANTIOXIDANTS LLC |
| 2425549 | Tetradecane, 1-chloro- | LONZA INC. |
| 2494895 | Ethanol, 2-[(4-aminophenyl)sulfonyl]-, hydrogen sulfate (ester) | CIBA SPECIALTY CHEMICALS CORPORATION |
| 2524030 | Phosphorochloridothioic acid, O,O-dimethyl ester | AVECIA INC. |
| 2524041 | Phosphorochloridothioic acid, O,O-diethyl ester | DOW AGROSCIENCES |
| 2691410 | 1,3,5,7-Tetrazocine, octahydro-1,3,5,7-tetranitro- | BAE SYSTEMS ORDNANCE SYSTEMS INC. |
| | | BESTON CHEMICAL CORP. |
| 2814202 | 4(1H)-Pyrimidinone, 6-methyl-2-(1-methylethyl)- | CIBA SPECIALTY CHEMICALS CORPORATION |
| 2905626 | Benzoyl chloride, 3,5-dichloro- | OCCIDENTAL CHEMICAL CORPORATION |
| 2915539 | Maleic acid, dioctyl ester | no company identified |
| | | no company identified |
| 2941642 | Carbonochloridothioic acid, S-ethyl ester | SYNGENTA CROP PROTECTION, INC. |
| 3039836 | Ethenesulfonic acid, sodium salt | AIR PRODUCTS AND CHEMICALS, INC. |
| | | BASF CORPORATION |
| | | HUNTSMAN PETROCHEMICAL CORPORATION |
| 3132998 | Benzaldehyde, 3-bromo- | CLARIANT LSM (AMERICA) INC. |
| 3386332 | Octadecane, 1-chloro- | LONZA INC. |
| 3724650 | Crotonic acid | no company identified |
| 3779633 | 1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(6-isocyanatohexyl)- | LYONDELL CHEMICAL COMPANY |
| 3965557 | 1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt | E. I. DU PONT DE NEMOURS AND CO., INC. |
| 4035896 | Imidodicarbonic diamide, N,N',2-tris(6-isocyanatohexyl)- | BASF CORPORATION |
| 4170303 | 2-Butenal | SASOL CHEMICALS NORTH AMERICA LLC |
| 4316738 | Glycine, N-methyl-, monosodium salt | BASF CORPORATION |
| | | THE DOW CHEMICAL COMPANY |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 4719044 | 1,3,5-Triazine-1,3,5(2H,4H,6H)-triethanol | BORDEN CHEMICAL, INC. |
| | | CHAMPION TECHNOLOGIES, INC./EH&S |
| | | CORSICANA TECHNOLOGIES INC. |
| | | MARCHEM TECHNOLOGIES |
| | | P CHEM, INC. |
| 4860031 | Hexadecane, 1-chloro- | LONZA INC. |
| 5026744 | Oxiranemethanamine, N-[4-(oxiranylmethoxy)phenyl]-N-(oxiranylmethyl)- | VANTICO INC. |
| 5216251 | Toluene, p,.alpha.,.alpha.,.alpha.-tetrachloro- | no company identified |
| 5460093 | 2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-, monosodium salt | CIBA SPECIALTY CHEMICALS CORPORATION |
| 5915413 | s-Triazine, 2-(tert-butylamino)-4-chloro-6-(ethylamino)- | no company identified |
| 6381777 | D-erythro-Hex-2-enonic acid, .gamma.-lactone, monosodium salt | CHEM ONE LTD |
| | | PMP FERMENTATION PRODUCTS, INC. |
| | | UNIVAR USA INC. |
| 6473138 | 2-Naphthalenesulfonic acid, 6-[(2,4-diaminophenyl)azo]-3-[[4-[[4-[[7-[(2,4-diaminophenyl)azo]-1-hydroxy-3-sulfo-2-naphthalenyl]azo]phenyl]amino]-3-sulfophenyl]azo]-4-hydroxy-, trisodium salt | CIBA SPECIALTY CHEMICALS CORPORATION |
| 7795951 | 1-octanesulfonyl chloride | no company identified |
| 8001589 | Creosote | COOPERS CREEK CHEMICAL CORPORATION |
| | | CROWLEY TAR PRODUCTS CO., INC. |
| | | RAILWORKS CORP. |
| | | SUMITOMO CORPORATION OF AMERICA |
| | | TRENTON SALES, INC |
| 8005025 | C.I. Solvent Black 7 | E. I. DU PONT DE NEMOURS AND CO., INC. |
| | | FORMULABS |
| | | INTERNATIONAL BUSINESS MACHINES |
| | | ORIENT CORPORATION OF AMERICA |
| | | USR OPTONIX, INC. |
| 8007452 | Tar, coal | ERIE COKE CORP. |
| | | REILLY INDUSTRIES, INC. |
| | | TONAWANDA COKE CORP. |
| 10265697 | Glycine, N-phenyl-, monosodium salt | BUFFALO COLOR CORPORATION |
| 13749945 | Acetohydroximic acid, thio-, methyl ester | no company identified |
| 13826352 | Benzenemethanol, 3-phenoxy- | CLARIANT LSM (AMERICA) INC. |
| | | FMC CORPORATION |
| 17103310 | Urea, sulfate (2:1) | AGRIUM U.S. INC. |
| 17321470 | Phosphoramidothioic acid, O,O-dimethyl ester | no company identified |
| 17976431 | 2,4,6,8,3,5,7-Benzotetraoxatriplumbacycloundecin-3,5,7-triylidene, 1,9-dihydro-1,9-dioxo- | HALSTAB DIVISION, HAMMOND GROUP, INC. |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 19438610 | Phthalic anhydride, 4-methyl- | no company identified |
| 19525598 | Glycine, N-phenyl-, monopotassium salt | BUFFALO COLOR CORPORATION |
| 20068024 | Crotononitrile, 2-methyl-, (Z)- | no company identified |
| 20227536 | Phosphorous acid, 2-(1,1-dimethylethyl)-4-[1-[3-(1,1-dimethylethyl)-4-hydroxyphenyl]-1-methylethyl]phenyl bis(4-nonylphenyl) ester | ZEON CHEMICALS L.P. |
| 21351393 | Urea, sulfate (1:1) | AGRIUM U.S. INC. |
| 22527635 | Propanoic acid, 2-methyl-, 3-(benzoyloxy)-2,2,4-trimethylpentyl ester | VELSICOL CHEMICAL CORPORATION |
| 24615847 | Hydracrylic acid, acrylate | no company identified |
| 24634615 | 2,4-Hexadienoic acid, potassium salt, (2E,4E)- | MITSUI & CO. (U.S.A.) INC. |
| | | SAKAI TRADING NEW YORK INC. |
| | | TOMEN AMERICA, INC. |
| | | UNIVAR USA INC. |
| 24794589 | Formic acid, compd. with 2,2',2''-nitrilotris[ethanol] (1:1) | W.R. GRACE, PERFORMANCE CHEMICALS |
| 25154385 | Piperazineethanol | no company identified |
| 25168052 | Toluene, ar-chloro- | no company identified |
| 25168063 | Phenol, isopropyl- | no company identified |
| 25321419 | Benzenesulfonic acid, dimethyl- | DYNACHEM, INC |
| | | RUTGERS ORGANICS CORPORATION |
| 25377735 | Olein, mono-Octadecenoic acid, 1,2,3-propanediol monoester | DIXIE CHEMICAL COMPANY, INC. |
| 25383997 | Stearic acid, ester with lactic acid bimol. ester, sodium salt | no company identified |
| 25646713 | Methanesulfonamide, N-[2-[(4-amino-3-methylphenyl)ethylamino]ethyl]-, sulfate (2:3) | AGFA CORPORATION |
| 26377297 | Phosphorodithioic acid, O,O-dimethyl ester, sodium salt | no company identified |
| 26401274 | Phosphorous acid, isooctyl diphenyl ester | GENERAL ELECTRIC CO. |
| 26544387 | Phosphorous acid, cyclic neopentanetetrayl bis(2,4,di-tert-butylphenyl) ester | HEICO CHEMICALS INC |
| | | LONZA INC. |
| | | MILLIKEN CHEMICAL |
| 26680546 | 2,5-Furandione, dihydro-3-(octenyl)- | LONZA INC. |
| | | MILLIKEN CHEMICAL |
| 27193288 | Phenol, octyl- | no company identified |
| 27859581 | Phthalic acid, diisononyl ester | MILLIKEN CHEMICAL |
| 28106301 | Benzene, ethenylethyl- | THE DOW CHEMICAL COMPANY |
| 28188241 | Stearic acid, triester with pentaerythritol | no company identified |
| 28908001 | Benzothiazole, 2-[(chloromethyl)thio]- | no company identified |
| 30574971 | 2-Butenenitrile, 2-methyl-, (2E)- | E. I. DU PONT DE NEMOURS AND CO., INC. |
| 31138655 | D-gluco-Heptonic acid, monosodium salt, (2.xi.)- | MILPORT ENTERPRISES, INC. |
| | | VULCAN PERFORMANCE CHEMICALS |
| | | W.R. GRACE, PERFORMANCE CHEMICALS |
| 34689468 | Phenol, methyl-, sodium salt | MERISOL USA LLC (FORMERLY MERICHEM-SASOL USA LLC) |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 35203066 | Benzenamine, 2-ethyl-6-methyl-N-methylene- | MONSANTO COMPANY |
| 35203088 | Benzenamine, 2,6-diethyl-N-methylene- | MONSANTO COMPANY |
| 37734455 | Carbonochloridothioic acid, S-(phenylmethyl) ester | SYNGENTA CROP PROTECTION, INC. |
| 37764253 | Acetamide, 2,2-dichloro-N,N-di-2-propenyl- | SYNGENTA CROP PROTECTION, INC. |
| 38185067 | Benzenesulfonic acid, 4-chloro-3,5-dinitro-, potassium salt | no company identified |
| 38321185 | Ethanol, 2-(2-butoxyethoxy)-, sodium salt | no company identified |
| 39515510 | Benzaldehyde, 3-phenoxy- | CLARIANT LSM (AMERICA) INC. |
| | | FMC CORPORATION |
| | | SYNGENTA CROP PROTECTION, INC. |
| 40630635 | 1-octanesulfonyl fluoride | no company identified |
| 40876980 | Butanedioic acid, oxo-, diethyl ester, ion(1-), sodium | no company identified |
| 51632167 | Benzene, 1-(bromomethyl)-3-phenoxy- | no company identified |
| 52184197 | Phenol, 2,4-bis(1,1-dimethylpropyl)-6-[(2-nitrophenyl)azo]- | no company identified |
| 52556420 | Propanesulfonic acid, 2-hydroxy-3-(propenyloxy)-, Na salt | no company identified |
| 52663577 | Ethanol, 2-butoxy-, sodium salt | no company identified |
| 56803373 | Phosphoric acid, (1,1-dimethylethyl)phenyl diphenyl ester | no company identified |
| 57693148 | Chromate(3-), bis[3-(hydroxy-.kappa.O)-4-[[2-(hydroxy-.kappa.O)-1-naphthalenyl]azo-.kappa.N1]-7-nitro-1-naphthalenesulfonato(3-)]-, trisodium | CIBA SPECIALTY CHEMICALS CORPORATION |
| | | ORGANIC DYESTUFFS CORPORATION |
| 61788441 | Phenol, styrenated | CAPITAL RESIN CORPATION |
| | | COGNIS CORPORATION |
| | | DUREZ CORPORATION |
| | | FLEXSYS AMERICA LP |
| | | THE GOODYEAR TIRE & RUBBER COMPANY |
| 61788769 | Alkanes, chloro | DOVER CHEMICAL CORP. |
| 61789853 | Sulfonic acids, petroleum | no company identified |
| 61790134 | Naphthenic acids, sodium salts | WILLIAMS REFINING & MARKETING, L.L.C. |
| 63302498 | Phosphorochloridous acid, bis(4-nonylphenyl) ester | no company identified |
| 64743028 | Alkenes, C>10 .alpha.- | MITSUBISHI CHEMICAL AMERICA INC. |
| 64743039 | Phenols, (petroleum) | FARMLAND INDUSTRIES, INC. |
| 65652417 | Phosphoric acid, bis[(1,1-dimethylethyl)phenyl] phenyl ester | no company identified |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 65996783 | Light oil, coal, coke-oven | ACME STEEL COMPANY |
| | | CITIZENS GAS & COKE UTILITY, MFG. DIVISION |
| | | DRUMMOND COMPANY, INC. |
| | | EMPIRE COKE COMPANY |
| | | GREAT LAKES DIVISION, NATIONAL STEEL CORPORATION |
| | | ISG WARREN INC. |
| | | KOPPERS INDUSTRIES, INC. |
| | | NATIONAL STEEL CORP. |
| | | TONAWANDA COKE CORP. |
| | | UNITED STATES STEEL CORP. |
| | | USS CLAIRTON WORKS |
| | | WHEELING-PITTSBURGH STEEL CORPORATION |
| 65996794 | Solvent naphtha, coal | HEMPEL (USA) |
| | | KOPPERS INDUSTRIES, INC, CM&C |
| 65996829 | Tar oils, coal | HONEYWELL INTERNATIONAL, INC |
| | | KOPPERS INDUSTRIES, INC, CM&C |
| | | KOPPERS INDUSTRIES, INC. |
| | | REILLY INDUSTRIES, INC. |
| 65996830 | Extracts, coal tar oil alk. | KOPPERS INDUSTRIES, INC, CM&C |
| | | MERISOL USA LLC (FORMERLY MERICHEM-SASOL USA LLC) |
| 65996863 | Extract oils, coal, tar base | KOPPERS INDUSTRIES, INC, CM&C |
| 65996874 | Extract residues, coal, tar oil alk. | KOPPERS INDUSTRIES, INC, CM&C |
| 65996896 | Tar, coal, high-temp. | ACME STEEL COMPANY |
| | | BETHLEHEM STEEL CORPORATION |
| | | COOPERS CREEK CHEMICAL CORPORATION |
| | | DRUMMOND COMPANY, INC. |
| | | EMPIRE COKE COMPANY |
| | | GREAT LAKES DIVISION, NATIONAL STEEL CORPORATION |
| | | HONEYWELL INTERNATIONAL, INC |
| | | ISG WARREN INC. |
| | | KOPPERS INDUSTRIES, INC, CM&C |
| | | KOPPERS INDUSTRIES, INC. |
| | | NATIONAL STEEL CORP. |
| | | ORMET PRIMARY ALUMINUM CORPORATION |
| | | REILLY INDUSTRIES, INC. |
| | | UNITED STATES STEEL CORP. |
| | | WHEELING-PITTSBURGH STEEL CORPORATION |
| 65996910 | Distillates, coal tar, upper | HONEYWELL INTERNATIONAL, INC |
| | | KOPPERS INDUSTRIES, INC, CM&C |
| | | KOPPERS INDUSTRIES, INC. |
| | | REILLY INDUSTRIES, INC. |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 65996921 | Distillates, coal tar | COOPERS CREEK CHEMICAL CORPORATION |
| | | KOPPERS INDUSTRIES, INC. |
| | | RAILWORKS CORP. |
| 66241110 | C.I. Leuco Sulphur Black 1 | no company identified |
| 67763148 | Phosphoric acid, mono(2-ethylhexyl) ester, compound with tert-dodecanamine | EXXON MOBIL CORP. |
| 68081867 | Phenol, nonyl derivs. | no company identified |
| 68082780 | Lard, oil, Me esters | no company identified |
| 68131135 | Amides, coco, N-(hydroxyethyl) | no company identified |
| 68153606 | Fatty acids, tall-oil, reaction products with diethylenetriamine, acetates | CORSICANA TECHNOLOGIES INC. |
| | | P CHEM, INC. |
| 68187417 | Phosphorodithioic acid, O,O-di-C1-14-alkyl esters | no company identified |
| 68187575 | Pitch, coal tar-petroleum | KOPPERS INDUSTRIES, INC. |
| 68187597 | Coal, anthracite, calcined | UCAR CARBON CO. INC. |
| 68187768 | Castor oil, sulfated, sodium salt | COGNIS CORPORATION |
| | | FREUDENBERG - NOK, GP |
| 68187848 | Castor oil, oxidized | CASCHEM, INCORPORATED |
| | | WERNER G. SMITH, INC. |
| 68188181 | Paraffin oils, chlorosulfonated, saponified | BASF CORPORATION |
| 68308747 | Amides, tall-oil fatty, N,N-di-Me | no company identified |
| 68309160 | Fatty acids, tall-oil, 2-(2-hydroxyethoxy)ethyl esters | no company identified |
| 68309273 | Fatty acids, tall-oil, sulfonated, sodium salts | no company identified |
| 68334010 | Disulfides, alkylaryl dialkyl, petroleum refinery spent caustic oxidn products | MERISOL USA LLC (FORMERLY MERICHEM-SASOL USA LLC) |
| 68441667 | Decanoic acid, mixed esters with dipentaerythritol, octanoic acid and valeric acid | no company identified |
| 68442604 | Acetaldehyde, reaction products with formaldehyde, by-products from | no company identified |
| 68442773 | 2-Butenediamide, (E)-, N,N'-bis[2-(4,5-dihydro-2-nortall-oil alkyl-1H-imidazol-1-yl)ethyl] derivs. | no company identified |
| 68457749 | Phenol, isobutylenated methylstyrenated | THE GOODYEAR TIRE & RUBBER COMPANY |
| 68513622 | Disulfides, C5-12-alkyl | no company identified |
| 68515899 | Barium, carbonate nonylphenol complexes | BAERLOCHER USA LLC |
| 68526829 | Alkenes, C6-10, hydroformylation products, high-boiling | STERLING CHEMICALS, INC. |
| 68527026 | Alkenes, C12-24, chloro | DOVER CHEMICAL CORP. |
| 68527220 | Naphtha, petroleum, clay-treated light straight-run | CHEVRONTEXACO CORPORATION |
| 68584258 | Benzenesulfonic acid, C10-16-alkyl derivs., compds. with triethanolamine | HUISH DETERGENTS INC. |
| 68602813 | Distillates, hydrocarbon resin prodn. higher boiling | SARTOMER COMPANY, INC. |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 68607283 | Quaternary ammonium compounds, (oxydi-2,1-ethanediyl)bis[coco alkyldimethyl, dichlorides | CHAMPION TECHNOLOGIES, INC./EH&S |
| 68608593 | Ethane, 1,2-dichloro-, manuf. of, by-products from, distn. lights | no company identified |
| 68609041 | Cyclohexane, oxidized, non-acidic by-products, distn. residues | BASF CORPORATION |
| 68609052 | Cyclohexane, oxidized, non-acidic by-products, distn. lights | BASF CORPORATION |
| 68610902 | 2-Butenedioic acid (2E)-, di-C8-18-alkyl esters | VULCAN PERFORMANCE CHEMICALS |
| 68611643 | Urea, reaction products with formaldehyde | AGRIUM U.S. INC. |
| | | CF INDUSTRIES, INC |
| | | FARMLAND INDUSTRIES, INC. |
| | | ROYSTER-CLARK NITROGEN, INC |
| | | TERRA NITROGEN, LP |
| | | TRIAD NITROGEN, L.L.C. |
| 68647609 | Hydrocarbons, C>4 | no company identified |
| 68649423 | Phosphorodithioic acid, O,O-di-C1-14-alkyl esters, zinc salts | EXXON MOBIL CORP. |
| | | FORD MOTOR COMPANY |
| 68650362 | Aromatic hydrocarbons, C8, o-xylene-lean | CONOCOPHILLIPS |
| 68782978 | Distillates (petroleum), hydrofined lubricating-oil | no company identified |
| 68815509 | Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol | BURLINGTON CHEMICAL CO., INC. |
| | | KAO SPECIALTIES AMERICAS LLC |
| 68909182 | Pyridinium, 1-(phenylmethyl)-, Et Me derivs., chlorides | CHAMPION TECHNOLOGIES, INC./EH&S |
| | | LONZA INC. |
| | | P CHEM, INC. |
| 68909773 | Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. Residues | HUNTSMAN PETROCHEMICAL CORPORATION |
| 68915059 | Fatty acids, tall-oil, low-boiling, reaction products with ammonia-ethanolamine reaction by-products | ARR-MAZ PRODUCTS, L.P. |
| 68915399 | Cyclohexane, oxidized, aq. ext., sodium salt | BASF CORPORATION |
| 68918161 | Tar, coal, dried and oxidized | no company identified |
| 68919175 | Hydrocarbons, C12-20, catalytic alkylation by-products | COASTAL EAGLE POINT OIL COMPANY |
| | | THE GOODYEAR TIRE & RUBBER COMPANY |
| 68920649 | Disulfides, di-C1-2-alkyl | TPI PETROLEUM, INC., A COMPANY OF VALERO |
| 68937291 | 1,6-Hexanediol, distn. residues | BASF CORPORATION |
| 68937699 | Carboxylic acids, C6-18 and C5-15-di- | no company identified |
| 68938965 | Benzene, phenoxytetrapropylene- | no company identified |
| 68953800 | Benzene, mixed with toluene, dealkylation product | CONOCOPHILLIPS |
| 68955373 | Chlorides, tallow, hydrogenated | no company identified |

| CAS Number | Chemical name | Producers/importers of each orphan chemical as of 2002, as listed in 2002 Inventory Update and current as of 1/07 |
|---|---|---|
| 68955760 | Aromatic hydrocarbons, C9-16, biphenyl deriv.-rich | CONOCOPHILLIPS |
| 68987417 | Benzene, ethylenated | no company identified |
| 68987666 | Ethene, hydrated, by-products from | no company identified |
| 68988227 | 1,4-Benzenedicarboxylic acid, dimethyl ester, manuf. of, by-products from | ARTEVA SPECIALTIES S.A.R.L. D/B/A KOSA |
| 68990614 | Tar, coal, high-temp., high-solids | BETHLEHEM STEEL CORPORATION |
| | | CITIZENS GAS & COKE UTILITY, MFG. DIVISION |
| | | WHEELING-PITTSBURGH STEEL CORPORATION |
| 68990658 | Fats and Glyceridic oils, vegetable, reclaimed | no company identified |
| 70084989 | Terpenes and Terpenoids, C10-30, distn. residues | IFF CHEMCIAL HOLDINGS INC |
| 70693504 | Phenol, 2,4-bis(1-methyl-1-phenylethyl)-6-[(2-nitrophenyl)azo]- | CIBA SPECIALTY CHEMICALS CORPORATION |
| 70851080 | Amides, coco, N-[3-(dimethylamino)propyl], alkylation products with sodium 3-chloro-2-hydroxypropanesulfonate | no company identified |
| 71077059 | Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine product tower residues | no company identified |
| 72162153 | 1-decene, sulfurized | BP AMERICA INC. |
| 72854274 | Tannins, reaction products with sodium bisulfite, sodium polysulfide and sodium sulfite | no company identified |
| 73665186 | Extract residues, (coal), tar oil alk., naphthalene distn. residues | no company identified |
| | | no company identified |
| 83864022 | Bis(adiponitrile)dicyanobis(triphenylborane)nickel | no company identified |
| 84501860 | Hexanedioic acid, esters with high-boiling C6-10-alkene hydroformylation products | WERNER G. SMITH, INC. |
| 90640805 | Anthracene oil | HEMPEL (USA) |
| 90640861 | Distillates, coal tar, heavy oils | KOPPERS INDUSTRIES, INC, CM&C |
| | | KOPPERS INDUSTRIES, INC. |
| 119345027 | Benzene, 1,1'-oxybis-, tetrapropylene derivs. | no company identified |
| 125997208 | Phosphoric acid, mixed 3-bromo-2,2-dimethylpropyl and 2-bromoethyl and 2-chloroethyl esters | no company identified |

SOURCE: (1) Companies reporting 1990 HPV chemicals in the 2002 TSCA Inventory Update reporting cycle, available at www.epa.gov/oppt/iur/tools/data/2002-comp-chem-records.htm. The data for the 2002 reporting cycle are the most recent that are publicly available; data now being collected for the 2006 reporting cycle are not yet available. Data for the 2002 reporting cycle change over time, however, based on corrections submitted by companies and revisions made by EPA. The 2002 IUR data used for this report were provided to the author by OPPT staff in January, 2007. (2) EPA's list of orphan chemicals as of 11-30-06, available at www.epa.gov/chemrtk/pubs/general/hpvunspn.xls, plus two additional chemicals – CAS #s 68526829 and 68909182 – that have since been designated by EPA as orphans, due to withdrawn sponsorships, and minus two other chemicals – CAS #s 150505 and 3338247 – that have since been sponsored; personal communications to the author from Jeffrey Taylor, EPA Office of Pollution Prevention and Toxics, June 27 and July 11, 2007. (EPA's list includes two other chemicals our table does not include. These are chemicals EPA designates as orphans but for which tentative sponsorships have been made: CAS#s 1445450 and 68479981).

## Appendix 2
## Chemicals sponsored directly under the HPV Challenge lacking even initial submissions, and the companies or consortia that have sponsored them

### A. Listed by chemical

| CAS Number | Chemical Name | Companies/Consortia |
|---|---|---|
| 74953 | Methylene bromide* | Albemarle Corporation |
| 74975 | Chlorobromomethane | Albemarle Corporation |
| 75467 | Trifluoromethane | E.I. du Pont de Nemours and Company |
| 90437 | Ortho-phenyl phenol | The Dow Chemical Company |
| 94757 | 2,4-dichlorophenoxyacetic acid | The Dow Chemical Company |
| 118489 | Isatoic anhydride | Synthetic Organic Chemical Manufacturers Association (SOCMA) Isatoic Anhydride Coalition |
| 122190 | Benzyl dimethyl octadecyl ammonium chloride | Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture |
| 150505 | Tributyl trithiophosphite | Bayer Corporation |
| 288880 | s-Triazole | Bayer Corporation |
| 409029 | Heptenone, methyl- | ExxonMobil Chemical Company |
| 542756 | 1,3-dichloropropene | The Dow Chemical Company |
| 929066 | Diglycolamine | Huntsman Corporation |
| 1333079 | Toluenesulfonamide | Toluenesulfonamide Testing Group |
| 1809194 | Phosphonic acid, dibutyl ester | Rhodia Inc. |
| 1918021 | 4-amino-3,5,6-trichloropicolinic acid | The Dow Chemical Company |
| 1929824 | 2-chloro-6-(trichloromethyl)-pyridine | The Dow Chemical Company |
| 3338247 | Sodium diethyl dithiophosphate | Bayer Corporation |
| 6289469 | 1,4-Cyclohexanedicarboxylic acid, 2,5-dioxo-, dimethyl ester | Color Pigments Manufacturers Association, Inc. (CPMA) |
| 6471789 | Benzenesulfonic acid, 4-amino-5-methoxy-2-methyl- | International Association of Color Manufacturers |
| | | Noveon, Inc. |
| | | Sensient Colors Inc. |
| 61789728 | Benzyl (hydrogenated tallow alkyl) dimethyl ammonium chloride | Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture |
| 61789739 | Benzyl (hydrogenated tallow alkyl) methyl ammonium chloride | Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture |
| 68391015 | Benzyl C12-18 alkyl dimethyl ammonium chloride | Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture |
| 68424851 | Benzyl C12-16 alkyl dimethyl ammonium chloride | Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture |
| 68514410 | Ketones, C12-branched | ExxonMobil Chemical Company |
| 68937724 | Carboxylic acids, di-, C4-11 | The Soap and Detergent Association |
| 68953708 | Oxirane, reaction products with ammonia, distn. residue | Huntsman Corporation |
| 70024678 | Benzenesulfonic acid, C16-24-alkyl derivatives | American Chemistry Council (ACC) Health, Environmental, and Research Task Group (HERTG) |

* This chemical is listed in EPA's final test rule covering 17 HPV orphans issued in March 2006.

| CAS Number | Chemical Name | Companies/Consortia |
|---|---|---|
| 98510895 | Bicyclo[3.1.1]heptanol, 2,6,6-trimethyl | The Flavor and Fragrance High Production Volume Consortia (FFHPVC) Terpene Consortium |
| | | Millennium Chemicals Inc. |
| 102479878 | Gases, (petroleum), extractive, C3-5, butene-isobutylene-rich, reaction products with butene, isobutylene and methanol, distn. residues | ExxonMobil Chemical Company |
| 108083438 | Gases, (petroleum), extractive, C4-6, isopentane-rich, reaction products with methanol, byproducts from | ExxonMobil Chemical Company |
| 108083449 | Gases, (petroleum), extractive, C4-6, isopentane-rich, reaction products with methanol, ether fraction, hydrogenated, cracked, isopentane fraction | ExxonMobil Chemical Company |

## B. Listed by consortium/company

| Companies/Consortia | CAS Number | Chemical Name |
|---|---|---|
| *CONSORTIA* | | |
| American Chemistry Council (ACC) Health, Environmental, and Research Task Group (HERTG) | 70024678 | Benzenesulfonic acid, C16-24-alkyl derivatives |
| Color Pigments Manufacturers Association, Inc. (CPMA) | 6289469 | 1,4-Cyclohexanedicarboxylic acid, 2,5-dioxo-, dimethyl ester |
| Consumer Specialty Products Association (CSPA) ADBAC Steering Committee/Joint Venture | 122190 | Benzyl dimethyl octadecyl ammonium chloride |
| | 61789728 | Benzyl (hydrogenated tallow alkyl) dimethyl ammonium chloride |
| | 61789739 | Benzyl (hydrogenated tallow alkyl) methyl ammonium chloride |
| | 68391015 | Benzyl C12-18 alkyl dimethyl ammonium chloride |
| | 68424851 | Benzyl C12-16 alkyl dimethyl ammonium chloride |
| International Association of Color Manufacturers | 6471789 | Benzenesulfonic acid, 4-amino-5-methoxy-2-methyl- |
| Synthetic Organic Chemical Manufacturers Association (SOCMA) Isatoic Anhydride Coalition | 118489 | Isatoic anhydride |
| The Flavor and Fragrance High Production Volume Consortia (FFHPVC) Terpene Consortium | 98510895 | Bicyclo[3.1.1]heptanol, 2,6,6-trimethyl |
| The Soap and Detergent Association | 68937724 | Carboxylic acids, di-, C4-11 |
| Toluenesulfonamide Testing Group | 1333079 | Toluenesulfonamide |

| *COMPANIES* | | |
|---|---|---|
| **Companies/Consortia** | **CAS Number** | **Chemical Name** |
| Albemarle Corporation | 74953 | Methylene bromide* |
| | 74975 | Chlorobromomethane |
| Bayer Corporation | 150505 | Tributyl trithiophosphite |
| | 288880 | s-Triazole |
| | 3338247 | Sodium diethyl dithiophosphate |
| E.I. du Pont de Nemours and Company | 75467 | Trifluoromethane |
| ExxonMobil Chemical Company | 409029 | Heptenone, methyl- |
| | 68514410 | Ketones, C12-branched |
| | 102479878 | Gases, (petroleum), extractive, C3-5, •utane-isobutylene-rich, reaction products with •utane, isobutylene and methanol, distn. Residues |
| | 108083438 | Gases, (petroleum), extractive, C4-6, isopentane-rich, reaction products with methanol, byproducts from |
| | 108083449 | Gases, (petroleum), extractive, C4-6, isopentane-rich, reaction products with methanol, ether fraction, hydrogenated, cracked, isopentane fraction |
| Huntsman Corporation | 929066 | Diglycolamine |
| | 68953708 | oxirane, reaction products with ammonia, distn. Residue |
| Millennium Chemicals Inc. | 98510895 | Bicyclo[3.1.1]heptanol, 2,6,6,-trimethyl |
| Noveon, Inc. | 6471789 | Benzenesulfonic acid, 4-amino-5-methoxy-2-methyl |
| Rhodia Inc. | 1809194 | Phosphonic acid, dibutyl ester |
| Sensient Colors Inc. | 6471789 | o-Toluenesulfonic acid, 4-amino-5-methoxy- |
| The Dow Chemical Company | 90437 | Ortho-phenyl phenol |
| | 94757 | 2,4-dichlorophenoxyacetic acid |
| | 542756 | 1,3-dichloropropene |
| | 1918021 | 4-amino-3,5,6-trichloropicolinic acid |
| | 1929824 | 2-chloro-6-(trichloromethyl)-pyridine |

* This chemical is listed in EPA's final test rule covering 17 HPV orphans issued in March 2006.

SOURCE: Environmental Defense analysis of data in its HPV Tracker, available online at www.environmentaldefese.org/go/hpvtracker

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