



High Production Volume (HPV) Challenge Program – Future Directions

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Main Goal of the Program

- The main goal of the HPV Challenge Program was to collect basic screening-level health and environmental effects data for HPV chemicals and make those data available to the public



Accomplishments - broad participation

- The success of EPA's HPV Challenge Program to date is due largely to the voluntary efforts of industry to sponsor HPV chemicals and meet its commitment
- Additionally, the participation of others (NGO's, Animal Welfare groups) in providing input on test plan and robust summary packages have proved invaluable
- Future success depends on broad stakeholder participation and data use by EPA, other agencies, states, NGOs, industry, international, etc.



Accomplishments – data generation and availability (1)

- The HPV Challenge Program has collected and made publicly available a substantial and growing amount of health and environmental effects data for HPV chemicals
- HPVIS is up and running
- Estimation techniques, such as Structure-Activity Relationships, and other category development tools have provided innovative ways for sponsors to optimize the use of existing data and plans for developing new data
- Around 10% of all HPV Challenge Program data to date have been generated through new testing



Accomplishments – data generation and availability (2)

- 1998 Chemical Hazard Data Availability Study (literature survey)
- Out of 2,863 HPV Chemicals
 - Only 200 (7%) had all 6 major data endpoint groups covered and available to the public
 - 1,217 (43%) had 0 endpoints covered



Accomplishments – data generation and availability (3)

- As of September 2006
- Out of the original 2,683 about 1,400 are in the EPA HPV Challenge Program. The rest are:
 - ICCA HPV initiative or OECD SIDS – about 900
 - “Orphans” – about 300
 - “No longer HPV” – about 250
- EPA is in the middle of conducting a data completeness screen – this is a work in progress
- About ½ of the 1,400 appear complete or updated revisions are pending review
- About ½ appeared to be “incomplete”



Future Directions - Completing “Incomplete” Data Sets

- EPA sent letters in September 2006 to those sponsors where records indicated the sponsored chemicals may have had incomplete data sets
- 215 letters were sent, covering 727 chemicals
- The Agency received 171 responses, covering 667 chemicals (92% of the 727 chemicals)
 - 51 responses yielded new submission materials
 - 30 replies provided a new due date for completing data submissions
 - 73 responses provided other comments, clarifications, and status updates on data submissions
 - 12 replies promised additional research and response
 - 5 replies indicated sponsorships were being withdrawn



Future Directions - Collecting Data on Orphan Chemicals

- EPA will also collect data on unsponsored, or “orphan” chemicals
- For these approximately 300 chemicals, EPA is following a regulatory approach:
 - EPA promulgated a TSCA section 4 test rule for 17 Orphans in March, 2006
 - EPA finalized a section 8(a)/8(d) rule in August 2006 on 243 orphans (33 were withdrawn in September leaving 210 in each rule)
 - 2nd Orphan test rule planned for proposal in early 2007 (40 chemicals under consideration)



Orphan Chemicals – what were the results of the 8(a)/8(d) rule?

- Rule originally covered 243 chemicals, but 33 were withdrawn because:
 - 22 HPV Challenge sponsorship commitments were made
 - 4 OECD SIDS or ICCA HPV Initiative commitments were made
 - 7 were determined to be "no longer HPV"
- As of December 8 EPA has received and processed 55 8(a) reports and 50 8(d) submissions –deadline for submission was November 28th
- What could this mean?
 - EPA is still processing submissions
 - The substances are no longer manufactured or imported, or are produced by small manufacturers who are exempt from 8(a) PAIR reporting (\$30 million/yr and 100,000 pounds)
 - They are produced as non-isolated intermediates, impurities or excluded byproducts



Future Directions – Prioritizing and Screening Chemicals

- EPA has begun to use collected program data to identify and prioritize HPV chemicals for additional data development and/or risk management actions
- Work is being done consistent with NPPTAC recommendations
- EPA will use data on HPV chemicals to support risk-based decisions, as appropriate



Future Directions – Data Use

- EPA is looking towards approaches to provide enhanced/better integrated access of other information, such as IUR exposure-related data, TRI data and additional health and safety data to stakeholders
- EPA is looking to develop/provide tools to enhance the ability of broad range of stakeholders to use data - system functionality
- EPA will maintain a dialogue with stakeholders through a variety of means (e.g., FOSTTA, further data use conferences) on data use issues as well as other HPV-relevant topics



Future Directions – Links to other related initiatives

- The successful framework of the HPV Challenge Program is being considered as a model for other efforts to address further HPV chemicals
- EPA is lending support to these efforts, such as the Extended HPV Program and the Japan HPV Challenge Program that are collecting data on new HPV chemicals



Links to other related initiatives - EHPV and Japan Programs

- Extended HPV (EHPV) Program
 - Launched November 2005
 - Covers 574 U.S. HPV chemicals that were new to the Inventory Update Rule in 2002
 - Designed to secure screening level hazard and fate data, as well as use and exposure data
 - Led by the American Chemistry Council, in cooperation with the Synthetic Organic Chemical Manufacturers Association and the Soap and Detergents Association
- Japan Challenge Program
 - Launched June 2005
 - Covers 665 chemicals produced in Japan
 - Modeled largely after the HPV Challenge Program



Links to other related initiatives - OECD SIDS and ICCA Programs

- EPA will continue to participate in the OECD SIDS Program and the ICCA HPV Initiative, and track those programs' chemicals that are considered covered in the HPV Challenge Program
- The OECD eChem Portal to information on chemical substances
 - Currently under development by OECD
 - Scheduled for public release in April 2007
 - Will offer access to data and assessment reports on chemicals in commerce
 - Users will be offered an opportunity to comment on the format and functionality of the portal to ensure it meets the needs of diverse audiences



Conclusions

- As a result of the HPV Challenge Program, an increasing amount of basic screening-level chemical data are now available to the public and EPA
- EPA remains committed to building upon that program and enhancing its utility to all stakeholders
- The Agency is beginning to utilize the data for its own mission to identify and prioritize HPV chemicals of possible concern for future management actions to protect human health and the environment
- EPA looks forward to continuing to work with all stakeholders to increase access to, and understanding and utility of the data
- Over the near term EPA will focus in particular on working with submitters towards “final” submissions, addressing the orphans and reporting out on progress

