

U.S. High Production Volume (HPV) Challenge Program

U.S. EPA, Office of Pollution Prevention and Toxics

December 12, 2006

Topics Covered

- Why the HPV Challenge Program Was Needed?
- HPV Challenge Program Goals and Approach
- HPV Challenge Program Design Features
- HPV Challenge Commitments
- Orphan Chemicals
- How Has EPA Contributed to the HPV Challenge Program?
- Regulatory Component
- Next Steps



Why Was the HPV Challenge Program Needed?

Three Separate Studies

- Toxic Ignorance 1997 (Environmental Defense, or ED – formerly EDF)
- Data Availability Study 1998 (EPA)
- Data Availability Study 1998 (American Chemistry Council, or ACC – formerly CMA)



Why Was the HPV Challenge Program Needed?

- 43% of the U.S. HPV chemicals had no publicly available studies for any of the 6 basic endpoint groups
- Only 7% of the U.S. HPV chemicals had a full set of publicly available studies for the 6 basic endpoint groups



HPV Challenge Program Launches

- The HPV Challenge Program began in 1998 as a collaborative effort between EPA, the American Chemistry Council (ACC), the American Petroleum Institute (API), and Environmental Defense (ED).
- Goal of the program:
 - Make basic health and environmental effects data for HPV chemicals available to the public by the end of 2005



HPV Challenge Program Design Features

- Voluntary program for companies to make basic hazard data on their HPV chemicals publicly available by 2005
- Public involvement at every step
- Incorporate animal welfare considerations and encourage use of SAR/category approaches Modeled after OECD HPV SIDS
- SIDS: An agreed upon basic set of heath and environmental hazard and environmental fate information



HPV Challenge Program Design Features

- Screening Information Data Set (SIDS)
 - Physicochemical Properties: melting & boiling pts.,
 vapor pressure, water solubility, partition coeff.
 - Environmental Fate: photodegradation, stability in water, biodegradation, transport (model)
 - Environmental Effects: acute toxicity in fish, aquatic invertebrates, and aquatic plants
 - Health Effects: acute and subchronic toxicity, genetic toxicity, reproductive and developmental toxicity



HPV Challenge Program Goals and Approach

- Companies asked to volunteer ("commit") to sponsor one or more HPV chemicals
- Commitment consists of identifying the sponsors and chemicals, and indicating the year the test plan and existing information will be made publicly available



HPV Challenge Program Goals and Approach

- Participation includes developing robust summaries of scientifically adequate existing studies and a Test Plan describing what sponsors plan to do if adequate data are not available for a given endpoint
- FR Notice issued December 26, 2000 (65 FR 81686)



Categories/SAR

- "a group of chemicals whose properties are likely to be similar or follow a pattern as a result of structural similarity"
- "These structural similarities <u>may</u> create a predictable pattern <u>in any or all</u> of the following parameters: physicochemical properties, environmental fate, environmental effects, and/or human health effects."



Categories and SAR

- Why Use Categories and SAR Approaches?
 - Faster and more efficient than chemical by chemical approach – provides means to "extend existing data"
 - Results in reduced costs and animal usage



HPV Challenge Program Success

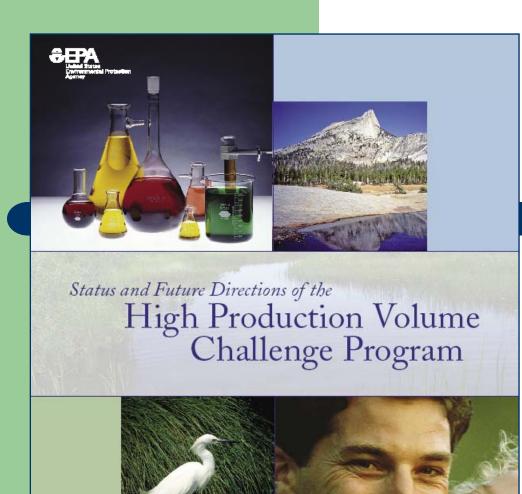
- 373 companies and 104 consortia have pledged to voluntarily provide data for approximately
- 1,400 chemicals included in the U.S.
 Challenge Program



HPV Challenge Program Success

- An additional approximately 800 chemicals are sponsored in the International Council of Chemical Associations (ICCA) HPV Initiative
- Total Commitments = approximately 2,200 chemicals







- Report Highlights
- Final Status Report to Be Developed



Orphans

• Over 260 chemicals remain as "unsponsored" or orphan chemicals



How Has EPA Contributed to the HPV Challenge Program?

- Availability of guidance documents such as:
 - Data Adequacy
 - Developing Robust Summaries
 - Developing Categories
 - All guidance documents can be located at: http://www.epa.gov/hpv/pubs/general/guidocs.htm
- Posting of data and soliciting comments
- Providing a publicly available database
 - High Production Volume Information System (HPVIS)



Regulatory Component

- HPV Chemicals not sponsored in the Voluntary Component are subject to the Regulatory Component of the program
- Issued TSCA Section 4 Final Test Rule
- Issued TSCA Section 8 Rules



HPV Challenge Test Plans and Robust Summaries

- As of December 1, 2006, 404 Test Plans and Robust Summaries have been submitted covering 1,404 total chemicals
 - 124 Test Plans are for categories
 - 280 Test Plans are for individual chemicals
 - Submissions have been received for 1,351 (97%) out of 1,387 chemicals that were sponsored <u>directly</u> in the HPV Challenge Program



Next Steps

- Continue to refine HPVIS
- Screening of completed data sets
- Prepare "Tier 2" hazard assessments
- Develop information products that will suit a broader audience
- Continue to address "orphan" chemicals
- Develop approach to deal with post HPV Challenge data needs/actions
- Develop final report on HPV Challenge Program



For More Information

Visit the HPV Challenge Website: www.epa.gov/hpv or

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