



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

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# *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 health 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 may create a predictable pattern in any or all 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**





*Status and Future Directions of the*  
**High Production Volume  
Challenge Program**



Office of Pollution  
Prevention and Toxics

- **Published Interim Report in December 2004**
- **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 directly 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](http://www.epa.gov/hpv) or

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