



***U.S. High Production Volume (HPV)
Challenge Program and U.S. Commitments
Under the Securities and Prosperity
Partnership (SPP)***

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September 27, 2007

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**
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- **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 Structure Activity Relationships (SARs)/category approaches modeled after Organization of Economic and Cooperative Development (OECD) HPV Screening Information Data Sets (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 use of animals**





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**

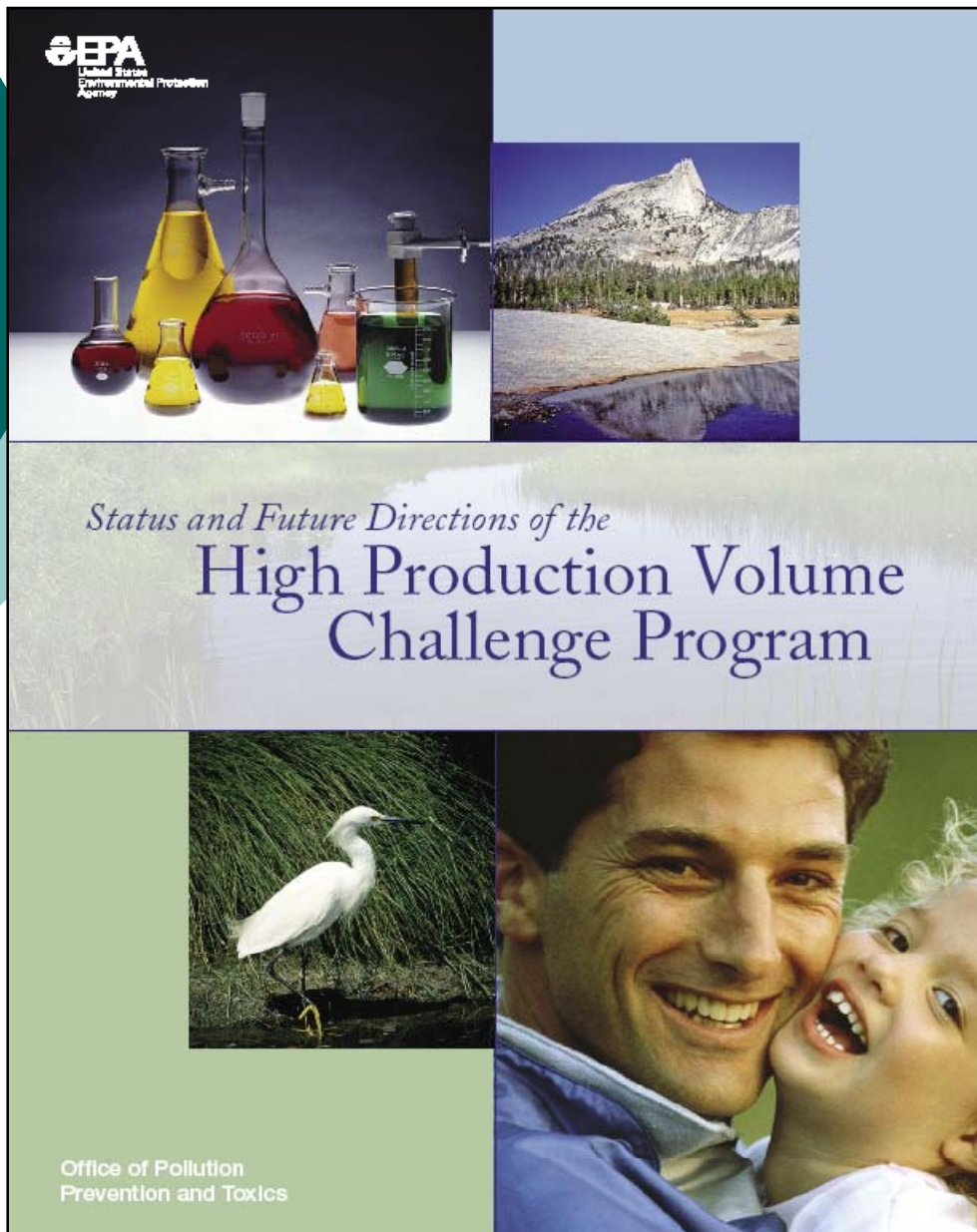




HPV Challenge Program Success

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





- **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 September, 419 Test Plans and Robust Summaries have been submitted covering 1,404 total chemicals**
 - **127 Test Plans are for categories**
 - **292 Test Plans are for individual chemicals**
 - **Submissions have been received for 97% of the chemicals that were sponsored directly in the HPV Challenge Program**





Security & Prosperity Partnership: U.S. Chemical Cooperation Commitments

- The Security & Prosperity Partnership (SPP) Agreement & Commitments
- U.S. Existing Chemical Initiatives
- U.S. & Canadian Chemical Cooperation Components
- Next Steps



Security and Prosperity Partnership (SPP)

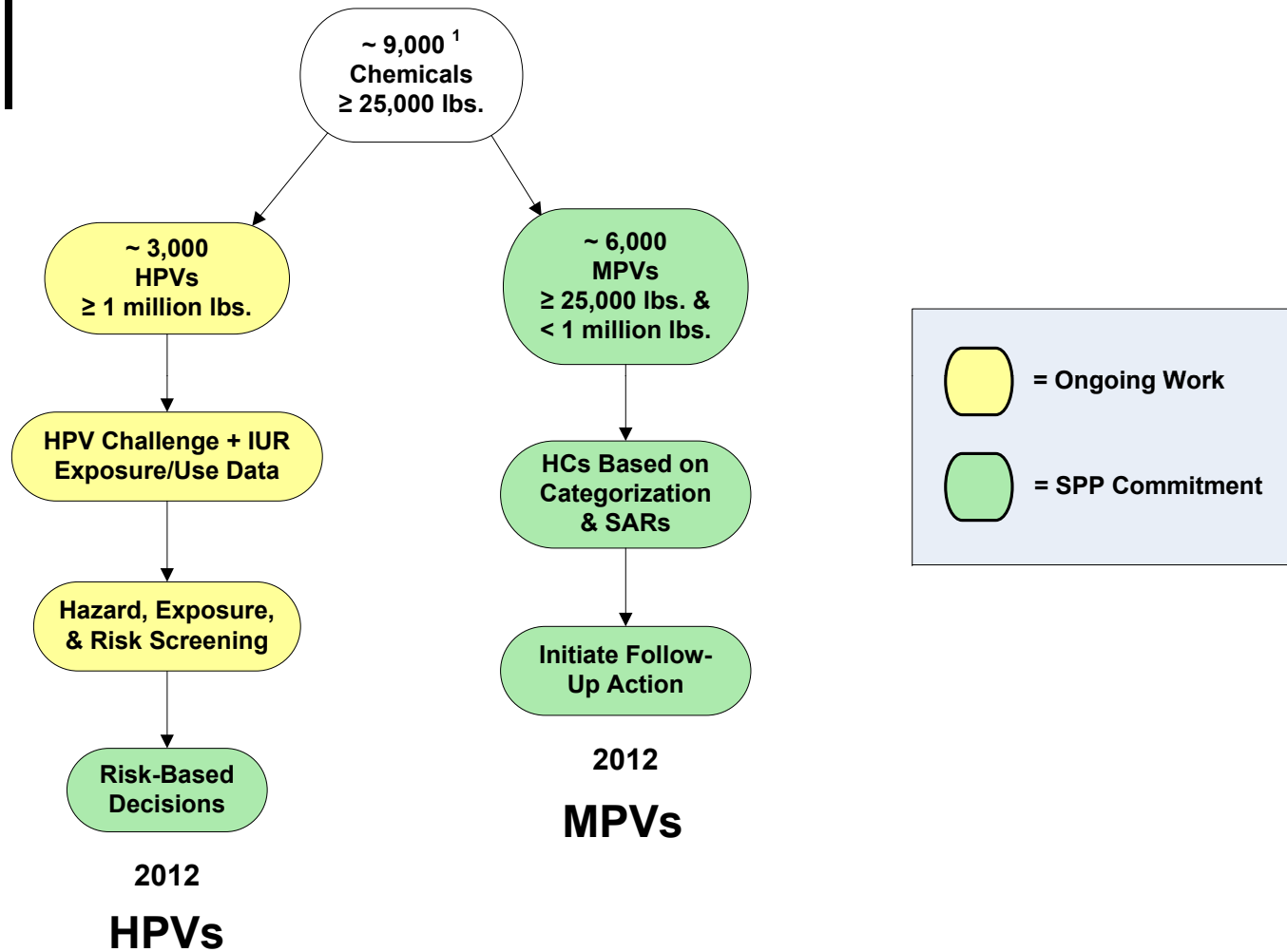
- **Chemical Cooperation Announced August 21, 2007**
- **Goal: enhance regulatory cooperation among Canada, Mexico, U.S.**
 - Accelerate & improve effectiveness of actions to safeguard health & environment
 - Provide cost-effectiveness for business & government
 - Maximize trade in goods & services
 - Retain national regulatory authority
- **Regional Commitments Under SPP**
 - Canada & U.S. work with Mexico to establish, by 2020, a Mexican chemical inventory, Inventory updates, strengthened North American chemical regime
 - Research & development on new approaches to testing & assessment.
 - ORD & Canadians have begun collaborating
 - Create mechanisms to share domestic scientific information & best practices for chemical assessment & management. Coordinate approaches to develop international standards.
 - Enhance Mexico's capacity for chemical assessment & management
 - Reaffirmed: WSSD 2020 goal; Regional SAICM implementation



U.S. Commitments Under SPP

- **By the end of 2012:**
 - Assess & initiate needed action on the over 9,000 existing chemicals produced above 25,000 lbs/yr in the U.S.
 - Includes organic High Production Volume (HPV) & Moderate Production Volume (MPV) chemicals
 - Screening level prioritization decisions

Ongoing Work & SPP Commitments



¹ Statistics are based upon 2002 IUR, and may change when updated 2006 IUR statistics are available in Fall 2007.



Screening Decision Process Development: HPVs

- Prioritize HPV chemicals based on available risk/hazard/exposure information
 - Where No Further Action Needed At This Time:
 - Document decision rationale and post to web
 - Likely to be most common decision
 - Where Additional Info or Action Is Needed:
 - Simple Measures:
 - Contact producers with request for info, informal action
 - Literature search, data from other offices, Canada, OECD
 - Mid-Range:
 - Batch TSCA §8 rules for exposure, release data
 - Engage with stakeholders on voluntary action
 - More Complicated:
 - TSCA §4 test rules
 - Develop/implement more formal risk reduction actions



Screening Decision Process

Development: MPVs

- Exploring approach to assess Moderate Production Volume Chemicals
 - Produced or imported at quantities $\geq 25,000$ lb/yr and < 1 million lb/yr
 - Apply available data, Canadian categorization plus SAR, & HPV Challenge categories to assess hazard & fate
 - Basic exposure/use data are available only for MPVs produced at $\geq 300,000$ lb at a site
 - Use hazard characterization to identify MPVs that require follow-up, initiate actions
 - Gather additional data
 - Risk management
- Initiate stakeholder dialogues on both HPV & MPV assessment processes



Next Steps

- Implementation of U.S. Commitments under SPP
 - Initiate stakeholder meetings to discuss implementation details starting Fall 2007
 - Work with Canada to share information & approaches for assessing & managing chemicals
 - Continue to develop U.S. approach for assessing chemicals to meet the SPP commitments

For More Information

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

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