Chemical Assessment and Management Program

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Background

Security & Prosperity Partnership

North American Cooperation on Chemical Management

- At the Security and Prosperity Partnership (SPP) Summit in August 2007, the U.S. President, Canadian Prime Minister and Mexican President committed to specific goals to enhance regulatory cooperation among Canada, Mexico, U.S.
  - Accelerate and improve effectiveness of actions to safeguard health and environment
  - Provide cost-effectiveness for business and government
  - Retain national regulatory authority

SPP Commitments

- Regional Commitments
  - Canada & U.S. work will with Mexico to establish a Mexican chemical inventory and a strengthened North American chemical regime
  - Research and development on new approaches to testing and assessment.
    - US and Canada have begun collaborating
  - Create mechanisms to share domestic scientific information and best practices for chemical assessment and management.
  - Enhance Mexico's capacity for chemical assessment and management
  - Reaffirmed: WSSD 2020 goal; Regional SAICM implementation

SPP Commitments

- National Commitments
  - U.S.: Assess and initiate needed action on over 6,000 chemicals
  - Canada: Realize its Chemical Management Plan
  - Mexico: Establish a chemical inventory

ChAMP

Scope & Chemical Universe

Chemicals Assessment and Management Program (ChAMP)

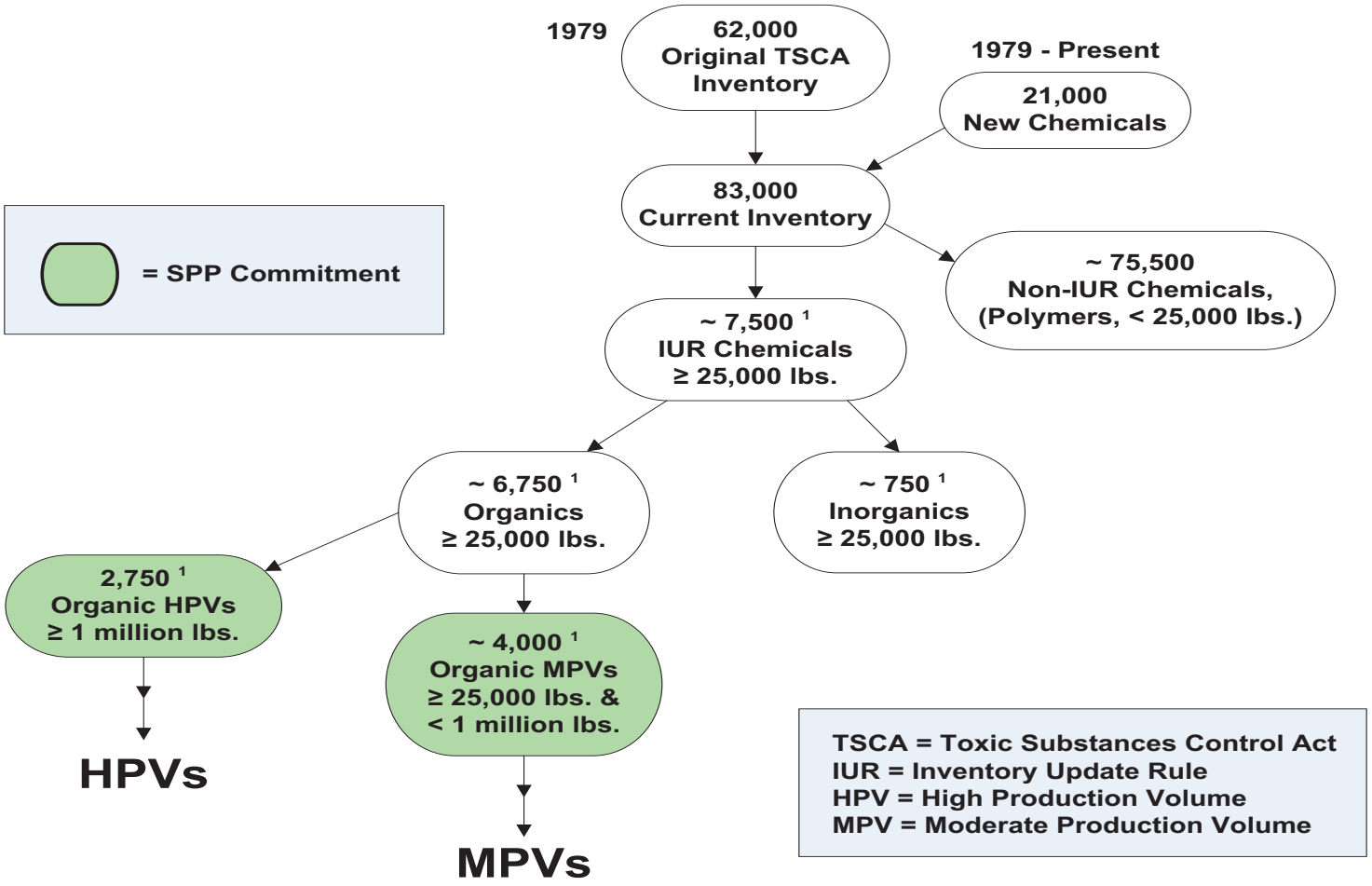
- ChAMP encompasses U.S. SPP commitments and enhancements to U.S. EPA's existing chemical program which include:
  - Resetting the TSCA Inventory
  - HPV Challenge type program for high production volume "inorganic" chemicals

U.S. Commitments Under SPP

- Assess and initiate needed action on the over 6,000* existing chemicals produced above 25,000 lbs/yr the U.S.
- Includes High Production Volume (HPV) and Moderate Production Volume (MPV) chemicals
- Builds off of prior efforts:
  - HPV Challenge
  - IUR Reporting
  - Canadian categorization, etc.
- Make and publicly release screening level decisions and initiate needed action

*Based on preliminary statistics from 2006 IUR Data

SPP Commitments Under ChAMP



[1] Statistics are based upon preliminary 2006 IUR data; the actual numbers may change slightly when official statistics are available.

Note: The 2006 IUR introduces new reporting thresholds.

ChAMP

Risk-Based Prioritization

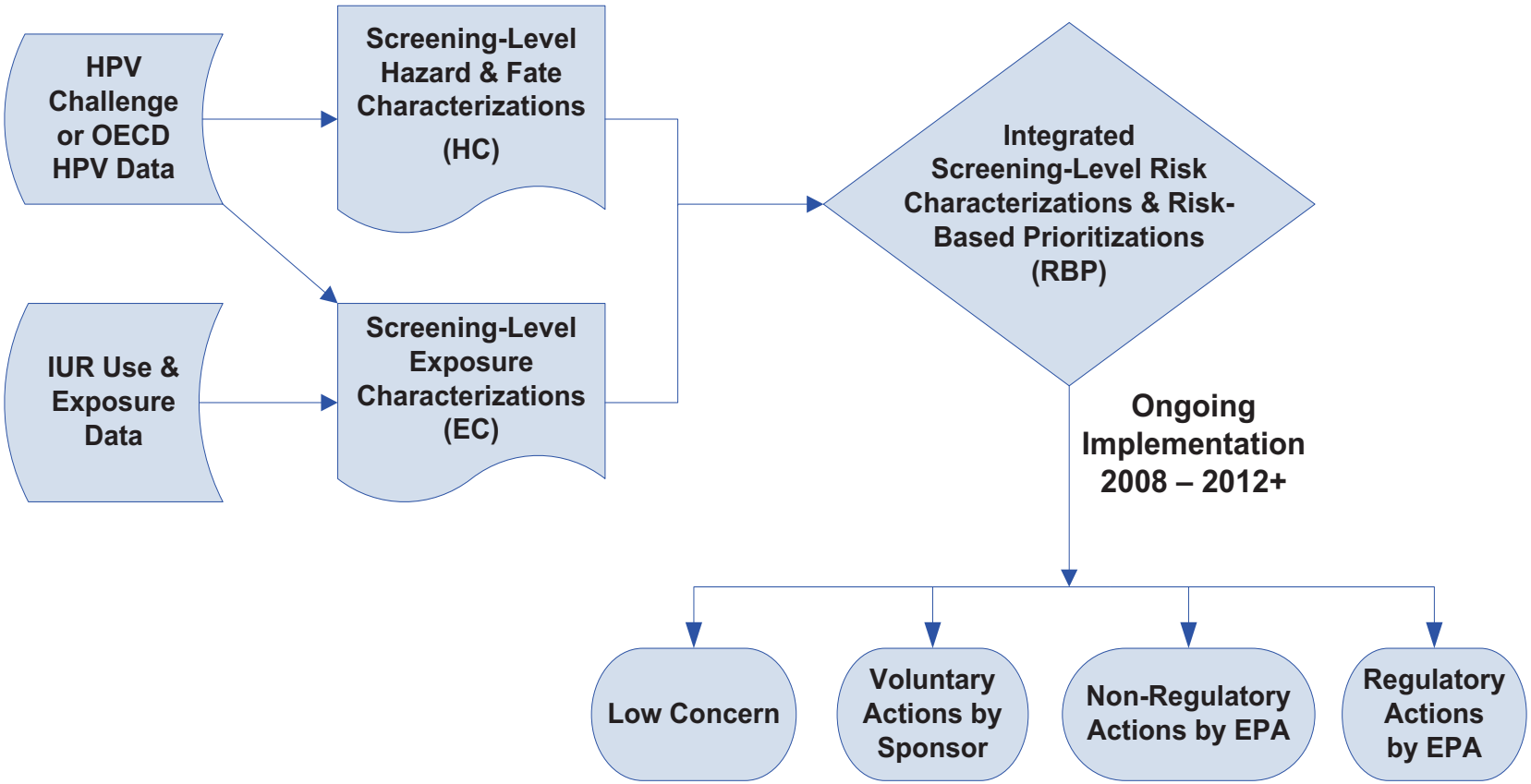
Risk-Based Prioritization Process HPV Chemicals

- Assess and prioritize HPV chemicals based on hazard/ exposure information
  - **HPV Challenge** hazard data
  - **IUR** exposure/use data
- Develop Risk-Based Prioritization (RBP)
- Identify and initiate needed action, e.g.
  - Gather/generate needed information
  - Take control measures
  - Identify as current low priority and set aside
- Document and post assessments on the web

HPV Risk-Based Screening Decision Process – Components

- Hazard Characterization (HC)
  - U.S. HPV Challenge (test data developed and implemented in 1998-2005)
  - OECD HPV Programme
- Exposure Characterization (EC)
  - 2006 Inventory Update Reporting (IUR)
- Risk Characterization (RC)
  - Combines the Hazard and IUR Exposure/Use data
  - Informs the Risk-Based Prioritization Decision

Risk-Based Prioritization – Components



HPV Challenge Program

- A voluntary initiative launched in 1998 aimed at developing and making publicly available screening-level health and environmental effects information on HPV chemicals.

- A complete data submission contains data or information on 18 internationally agreed to “SIDS” (Screening Information Data Set) endpoints:
  - 5 Human Health Screening Endpoints: Acute, Repeated-Dose, Reproductive, Developmental and Genetic Toxicity
  - 3 Ecological Screening Endpoints: Acute Aquatic Toxicity (Fish, Invertebrates, Plants); Chronic Aquatic Toxicity (case-by-case)
  - 10 P-Chem Properties & Environmental Fate Parameters

- As of 2007, companies have sponsored more than 2,200 HPVs

Screening-Level Hazard Characterization (HC)

- Based on summary of data submitted under HPV Challenge Program, TSCA 8(e) health & safety data and literature search of selected sources conducted by EPA
- Hazards characterized for human health and ecological hazards as high, medium, or low based on *Hazard Characterization Guidance*, which includes toxicity criteria derived and/or used previously:
  - OECD Globally Harmonized System (GHS) for the Classification and Labeling of Chemicals
  - TSCA 8(e) Program – Notices of Substantial Risk

Screening-Level Exposure Characterization (EC)

- Uses information from IUR and a selected number of public sources:
  - IUR – production volume, use, occupational setting concentrations
  - Hazardous Substances Data Bank
  - HPV Challenge submission
  - OECD HPV SIDS Dossier
  - TSCA Test Rules
  - Toxics Release Inventory
- Addresses several exposure scenarios:
  - Occupational
  - Non-occupational exposures, including:
    - Environment (aquatic organisms)
    - General population
    - Consumers
    - Children

Screening-Level Risk Characterization (RC)

- Results from the HC and the EC are integrated to provide the RC.

- The RC provides a qualitative (High/Medium/Low) risk concern level for each of the five exposure groups assessed.

Risk-Based Prioritization (RBP)

- Low Priority – no follow-up action suggested at this time
- Medium Priority – possible concern – follow-up as needed
- High Priority – promptly begin efforts to better understand and/or address concern

Risk-Based Prioritization (RBP)

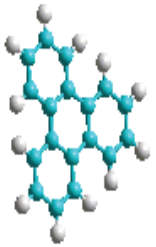
- RBPs and supporting HCs, ECs and RCs are posted on the web: http://www.epa.gov/chemrtk/hpvis/aboutrbd.htm

- A document explaining the procedure and criteria used in preparing RBPs will be posted to the ChAMP website soon: *Methodology for Risk-Based Prioritization Under ChAMP*

Screening Prioritization Process MPV Chemicals

- Produced or imported at quantities ≥ 25,000 lbs/yr and ≤1 million lbs/yr.
- Apply available data and EPA Structure Activity Relationships (SAR) analysis to assess hazard and fate.
- Basic exposure/use data are available only for MPVs produced at ≥ 300,000 lbs at a site
- Use Hazard Characterizations (HCs) to identify MPVs that require follow-up, initiate actions
  - Gather additional data (exposure, testing, etc.)
  - Risk management
- Document and post prioritizations on the web.

Chemical Clustering



Analog Identification Methodology

- Identify analogs using a chemical fragment-based approach with 645 individual molecular fragments

- Database of chemicals with publicly available toxicity data
  - 31,031 potential analogs with publicly available toxicity data
  - On-Line Databases: TSCATS, HSDB, IRIS
  - U.S. Government Documents

    NTP, ATSDR, HPV Challenge Program
  - Other Sources: RTECS, IUCLID, AEGLS

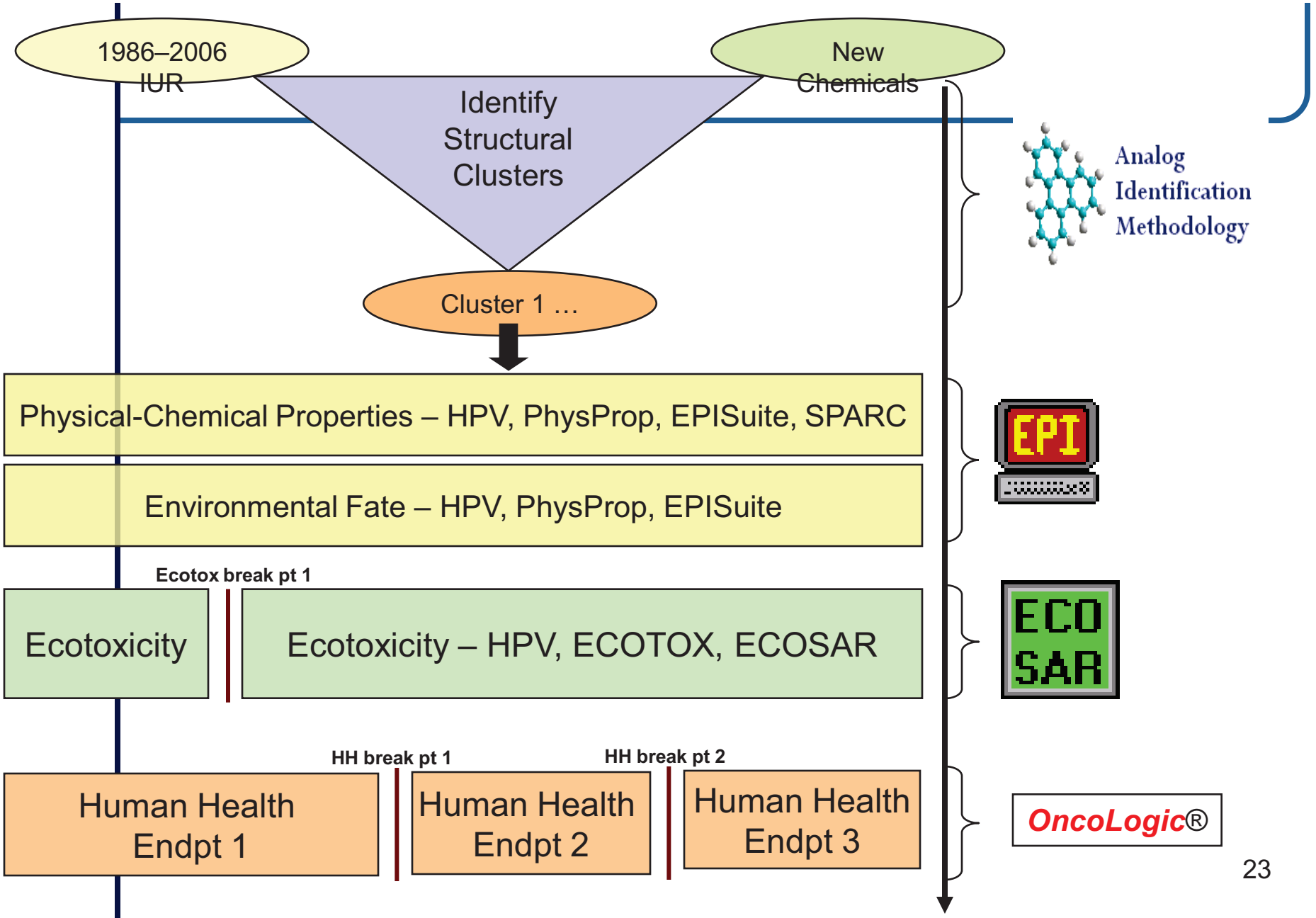
Data Gathering & Modeling

- Endpoints Included – Similar, but more than HPV:
  - Pchem/Fate
  - Ecotoxicity
    - Fish/Invert/Plant – Acute & Chronic
  - Health
    - Quantitative (LC_{50}, NOAEL/LOAEL): Acute, Repeated-Dose, Reproductive, Developmental
    - Qualitative (+/-): Genetox, Cancer, Neurotox, Immunotox, Irritation, Sensitization

- Data Sources – Similar to HPV:
  - OECD & US **HPV** Dossiers, Section 4, Section 8(e)
  - IRIS, NTP, ATSDR, ECOTOX, HSDB, PhysProp, EFDB
  - Canadian DSL

- Models Employed – much more than HPV:
  - EPISuite, SPARC (pKA), ECOSAR, OncoLogic, OECD QSAR Toolbox

Approach for MPV Hazard Characterization



Hazard-Based Prioritization (HBP)

- A document explaining the procedure and criteria used in preparing HBPs is posted on the ChAMP website:

http://www.epa.gov/champ/pubs/abouthbp.htm

- HBPs and supporting HCs are posted on the web:

http://www.epa.gov/champ/pubs/hbpdocs.htm

Tools to Address Concerns

- When additional information or action is needed to address concerns, the options include:
  - Contact producers with request for information, informal action
  - Collect and review data from other EPA offices, Agencies, States, Canada, EU, and OECD
  - Issue TSCA § 8(a) reporting rules (e.g., exposure, release data)
  - Issue TSCA § 5(a)(2) Significant New Use Rules (SNURs)
  - Engage with stakeholders (e.g. Design for the Environment, or DfE, voluntary action, etc.)
  - Issue TSCA § 4 test rules
  - Develop/implement Challenge programs, other risk reduction actions
  - Consider other TSCA actions (e.g., § 5(b)(4) list, § 6)

Meeting the SPP Goals

- 2007
  - Developed process for screening-level Hazard Characterizations (HCs) and Risk Characterizations (RCs), and Risk-Based Prioritizations (RBPs) on HPV chemicals
  - Posted over 150 HCs (precursor to RBP)
- 2008
  - Posted RBPs for 151 chemicals
  - Developed process for screening-level Hazard-Based Prioritization (HBP)
  - Posted initial MPV HBPs for 55 chemicals
- 2009
  - Continue posting RBPs and HBPs

ChAMP Enhancements

TSCA Inventory Reset

Inorganic HPV (IHPV) Challenge

TSCA Inventory Reset

ChAMP Enhancements

- Following an extensive stakeholder engagement effort during the Spring of 08, EPA announced in September 2008 the decision on two ChAMP Program enhancements. EPA intends to:
  - Update the current Toxic Substances Control Act (TSCA) Inventory of industrial chemicals by "resetting“ it to better reflect the chemicals actually in commerce in the U.S.
  - Develop a phased approach to challenge the U.S. chemical industry to develop health and safety data on inorganic HPV chemicals.
- EPA outlined and solicited stakeholder input on both of these efforts at a one-day public meeting held on December 8, 2008.

TSCA Inventory Reset

- Current TSCA Inventory nearly 84,000 chemicals
  - U.S. EPA believes that many chemicals are no longer manufactured/imported; or
  - Are produced only in low or episodic volumes
- TSCA § 8(b) requires EPA to "compile, keep current, and publish" TSCA Inventory.
- Resetting the Inventory would give EPA and others a better understanding of which chemicals are actually in commerce.
- A more accurate Inventory would allow EPA to better plan and execute its mission of protecting human health and the environment.

TSCA Inventory Reset

- EPA will further engage stakeholders but is considering a “clean reset” which would remove chemicals no longer being manufactured or imported.
- A new chemical notice would only be needed if a company decided, at a later date, to produce a chemical no longer on the reset inventory.
- EPA would also anticipate periodic resets in the future to continue to keep the Inventory current.

EPA Proposed "Clean Reset" Approach

- The public version of the Inventory would be posted online, with chemical identities (generic name if claimed CBI) and associated CAS or Accession numbers
- Companies would certify that they have manufactured a chemical listed on the Inventory within a specified timeframe
  - Companies would certify their chemicals online via a secure website, e.g., by flagging.
  - EPA is considering a three year time period for the Inventory reset process.

Coordination with IUR

- EPA proposed to make the “Reset Inventory” available in time for the next TSCA Inventory Update Reporting (IUR) period (to occur June 1 through September 30, 2011, for chemicals manufactured during 2010 calendar year).

- This would help ensure that the IUR reporting is coordinated with an accurate accounting of the chemical substances currently manufactured for commercial purposes at any production volume.

- Subsequent periodic Inventory reset efforts could be timed to occur in conjunction with IUR reporting.

Inorganic HPV Challenge

Inorganic Chemicals

- Inorganics first included on IUR in 2006, allowing identification of Inorganic HPVs
  - Production volume only
  - No exposure data reporting until 2011
- Examples: metals & salts, ammonia & cmpds, minerals & fibers (bentonite, zeolite, asbestos, etc.), inorganic acids (HCl, HNO3, H2SO4), etc.
- Of 750 Inorganics reported on 2006 IUR, approximately 400 - 500 are HPV

IHPV Challenge

- U.S. EPA proposed an approach for an IHPV Challenge Program

- Approach proposes to:
  - Look to OECD guidance and experience on inorganics
  - Apply approaches and procedures similar to those used in HPV Challenge Program (especially categories)
  - Apply established EPA Guidance on inorganics assessment
  - Assess, prioritize, and initiate needed action on IHPV chemicals

IHPV Challenge Approach

- Outlined in the document entitled "*Proposed Approach for the Inorganic High Production Volume (IHPV) Challenge Program*"
- Available in the following docket at www.regulations.gov: EPA-HQ-OPPT-2008-0807
- Also in this docket are the Federal Register Notice announcing the public meeting on IHPV Challenge and the slides presented at that meeting.

IHPV Challenge Program – Proposed Approach

- Phase 1: “Challenge” - Develop, Launch & Sign-Up
  - Now Through December 2009
- Phase 2: Implement the Challenge Receive/Review Data
  - approximately 2010 – 2013
  - Vigorous use of TSCA § 4 test rule authority to deal with “orphans”
- Phase 3: Assess and Initiate Actions – Consider IHPV Data and IUR Exposure/Use Information for Qualitative-Risk Based Prioritization
  - approximately 2013 – 2015
  - MPV inorganics would subsequently be assessed and prioritized

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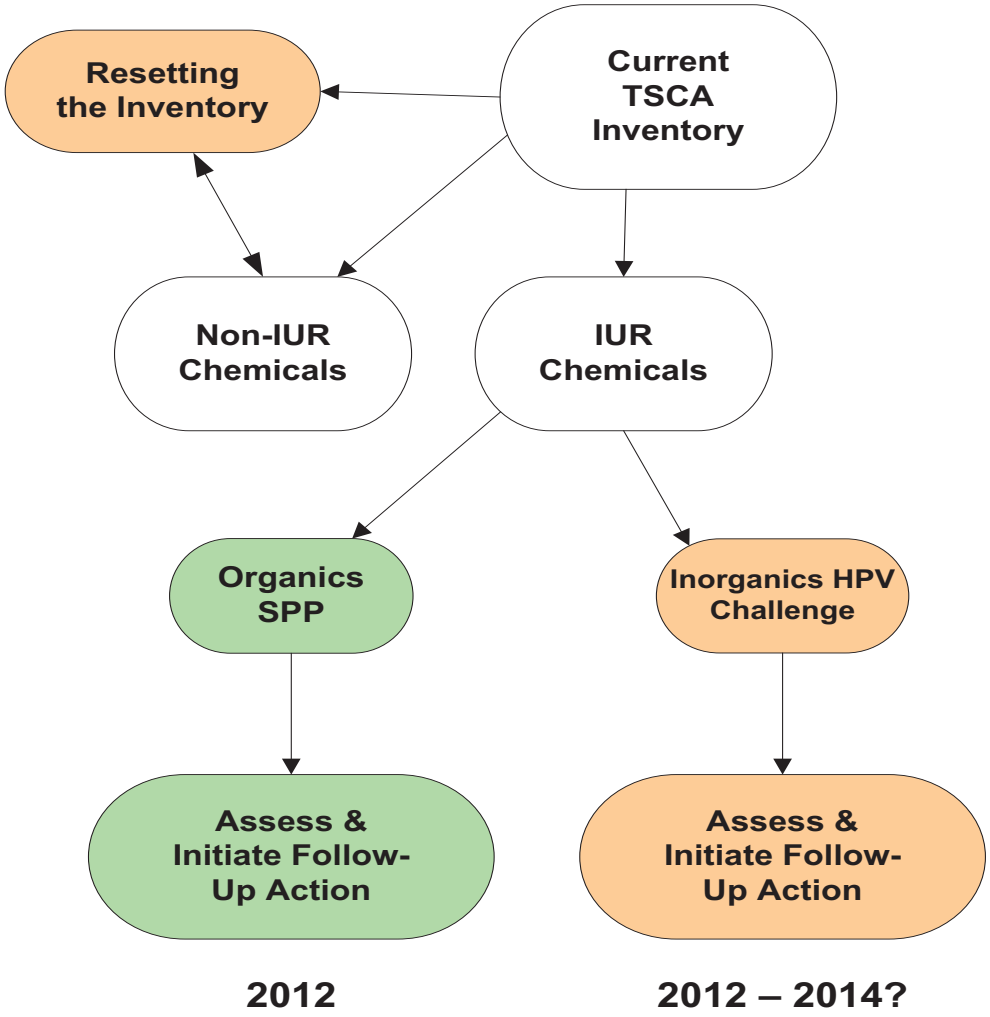

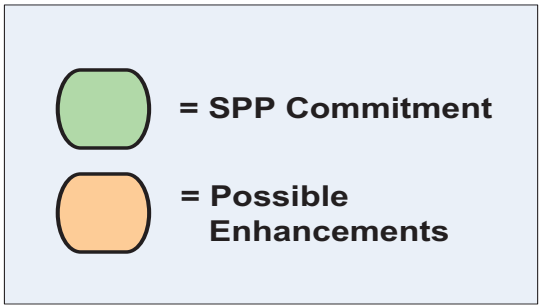

ChAMP Next Steps

- Continue developing Risk-Based Prioritizations for HPV & “Data Available” chemicals.
- Continue developing Hazard-Based Prioritizations for MPVs & “Data Poor” chemicals.
- Finalize approach for IHPV Program and launch the “Challenge”.
- Determine approach for TSCA Reset; propose rule and implement shortly thereafter.

For More Information

ChAMP -- http://www.epa.gov/ChAMP/