

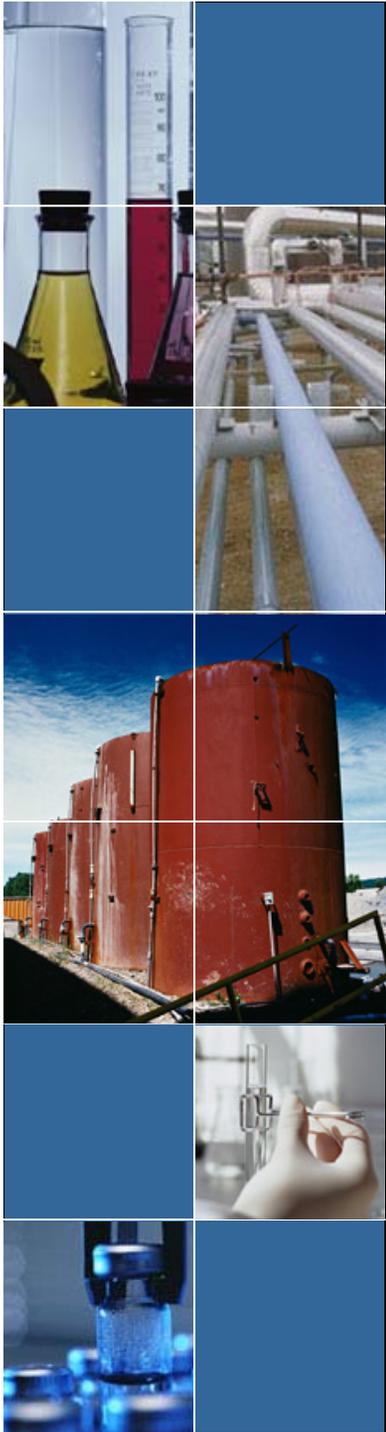
Prioritization of HPV Chemicals under the Chemical Assessment and Management Program (ChAMP)

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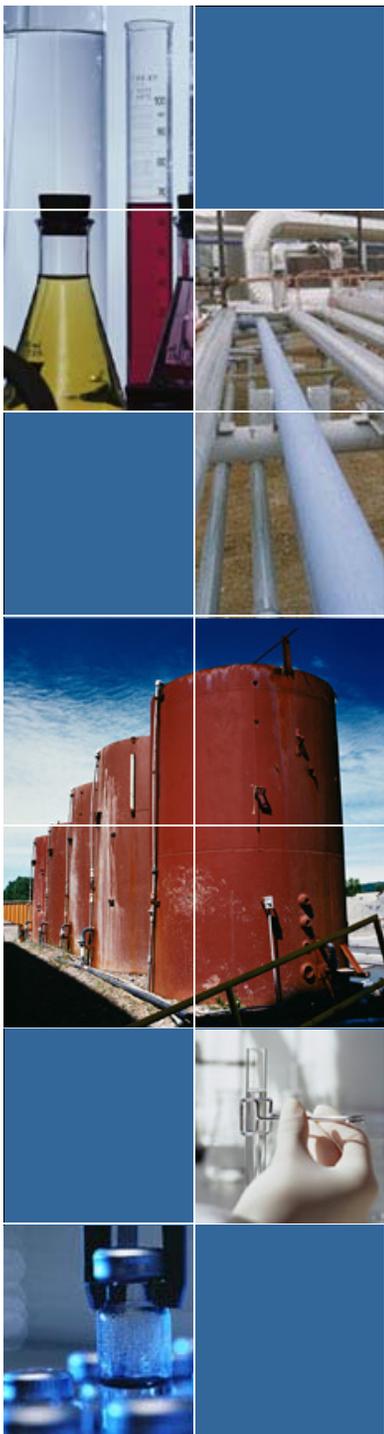
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Part I: ChAMP





Overview

- ChAMP is EPA's new Chemical Assessment and Management Program
- ChAMP was created to implement commitments under the Security and Prosperity Partnership (SPP) of North America

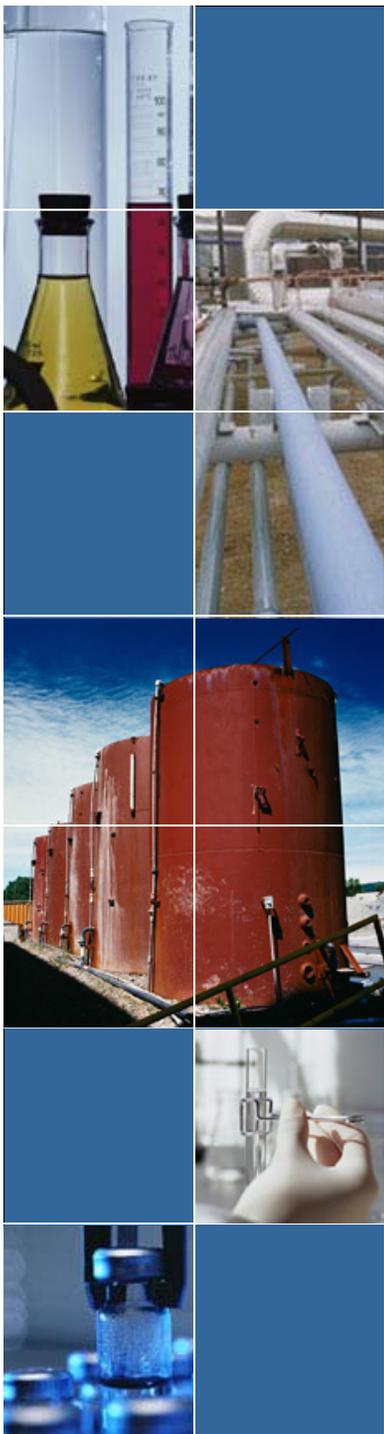




Background on SPP

- SPP was launched in March 2005
- SPP is a trilateral effort to increase security and enhance prosperity among the three North American countries through cooperation and information sharing
- The United States, Canada, and Mexico work together to ensure the safe manufacture and use of industrial chemicals

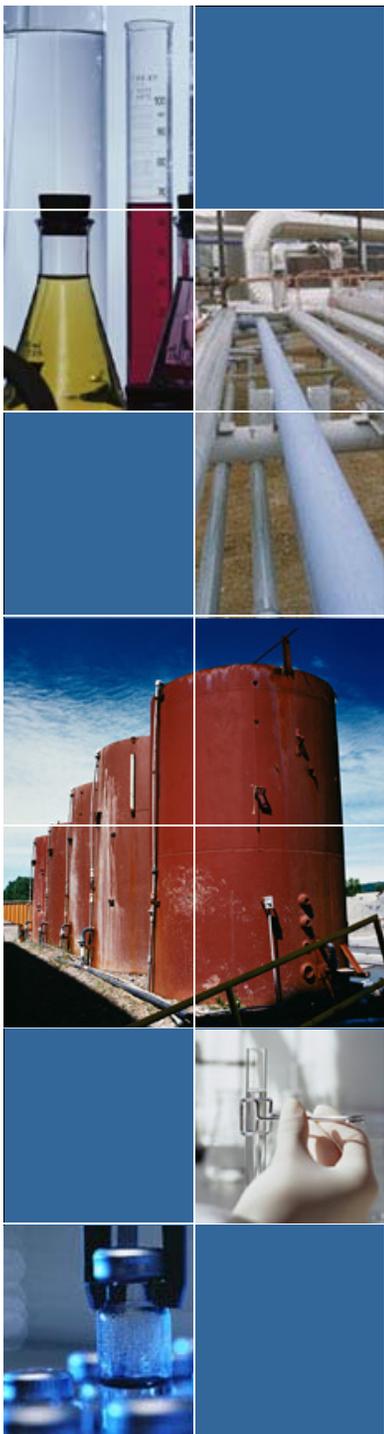




Background on SPP (*cont'd*)

- At the SPP Summit in August 2007, leaders from the three countries committed to specific goals to:
 - Accelerate and improve effectiveness of actions to safeguard health and environment
 - Provide cost-effectiveness for business and government
 - Retain national regulatory authority
- SPP is building on each country's ongoing efforts to assess industrial chemicals, make environmental and health information available to the public, and take risk management actions as appropriate





SPP Commitments (by 2012)

- United States: Assess and initiate needed action on about 6,750 existing chemicals
- Canada: Complete assessment and take regulatory action on the Canadian highest priority substances and initiate assessment of medium-priority substances
- Mexico: Establish a chemical inventory



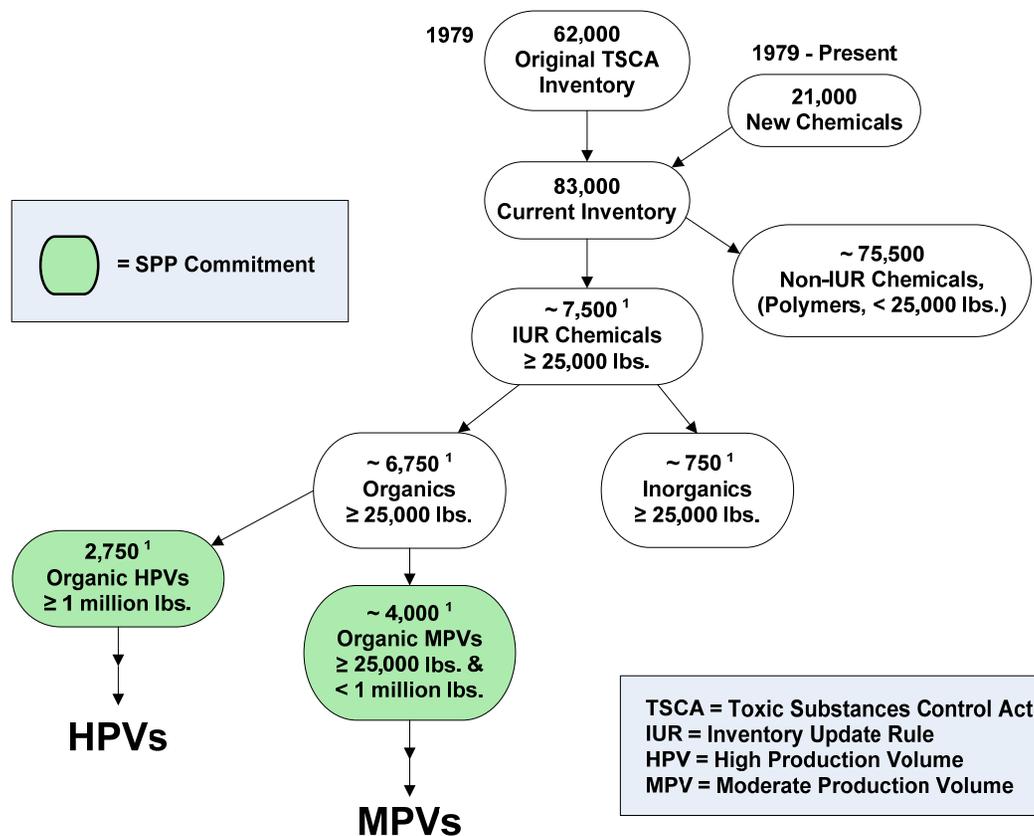


Chemical Assessment and Management Program (ChAMP)

- Encompasses U.S. SPP commitments and possible enhancements to EPA's existing chemical program
- ChAMP will apply the results of EPA's work on HPV chemicals—those chemicals produced or imported in the United States in quantities of 1 million pounds or more/year
- EPA will extend its efforts to moderate-production volume (MPV) chemicals—those produced or imported in quantities above 25,000 and less than 1 million pounds/year



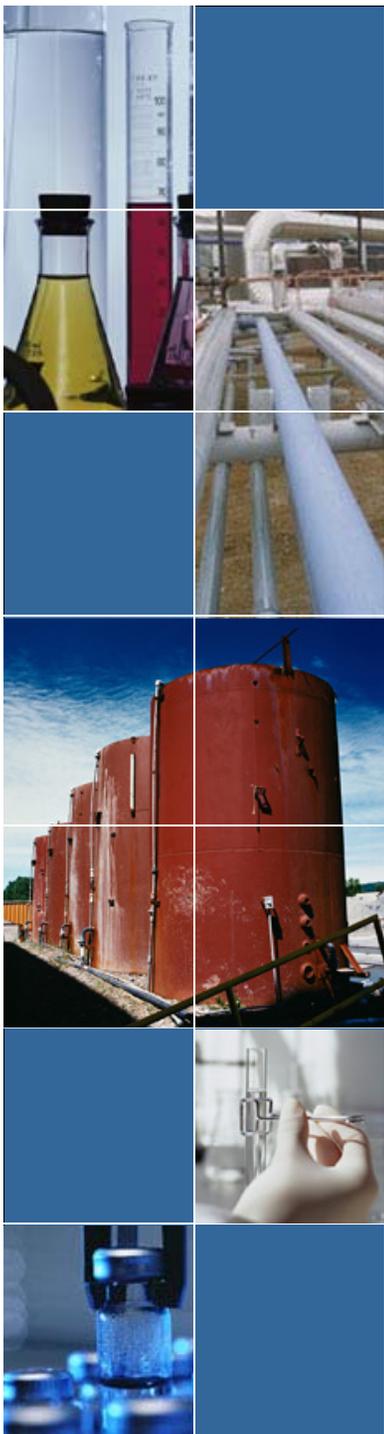
U.S. SPP Commitments - ChAMP



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.

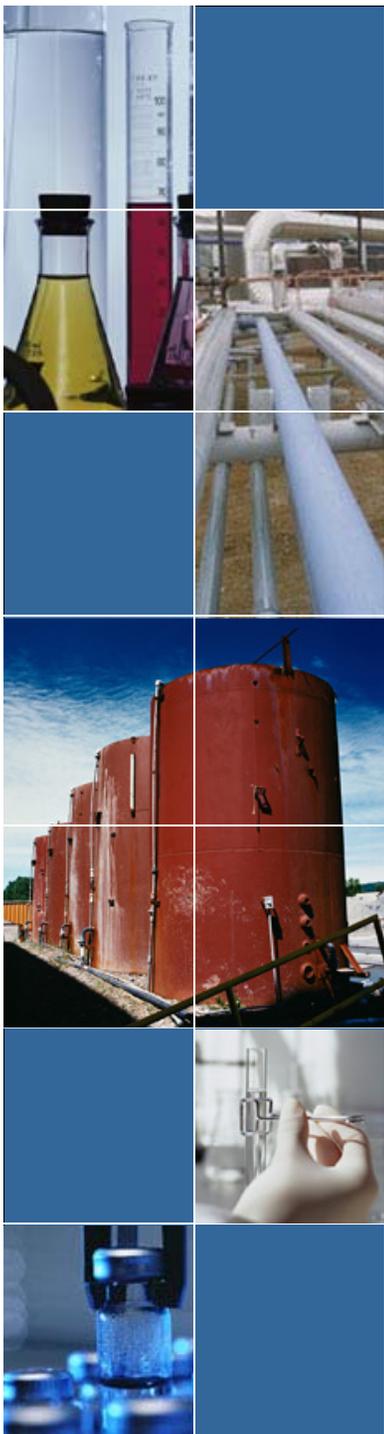




ChAMP Goals under SPP

- ChAMP will build from prior efforts
 - HPV Challenge
 - Inventory Update Reporting (IUR)
- 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





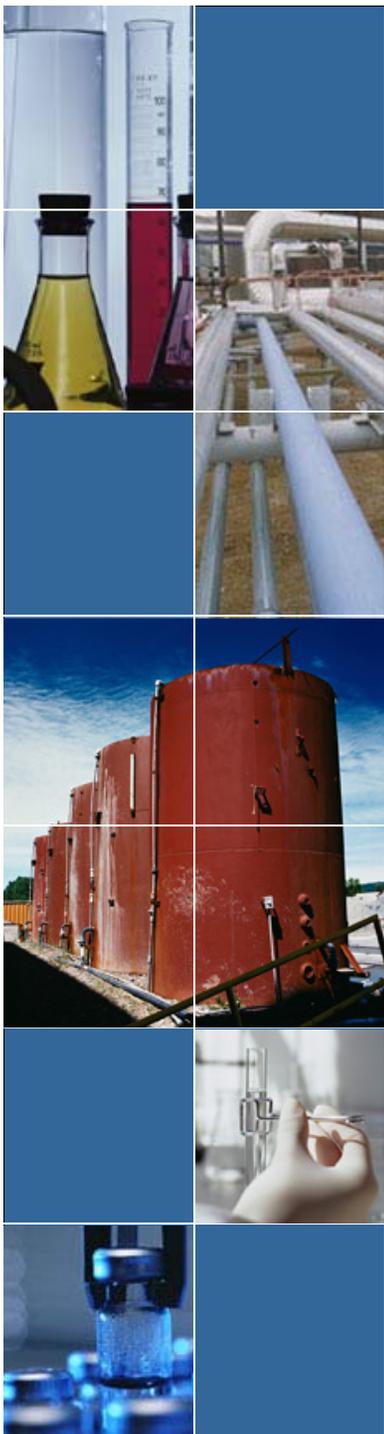
ChAMP Goals under SPP (cont'd)

- 2008
 - Posted HCs for about 340 chemicals
 - Posted RBPs for 150 chemicals
 - Continue developing and posting HCs and RBPs
 - Post initial MPV HCs

- 2009
 - Continue posting RBPs for HPV chemicals and significantly ramp up posting MPV HCs

- By the end of 2012:
 - Assess and initiate needed action on about 6,750 existing chemicals produced above 25,000 lbs/yr in the U.S. (includes HPV and MPV chemicals)
 - Make and publicly release screening-level decisions and initiate needed action

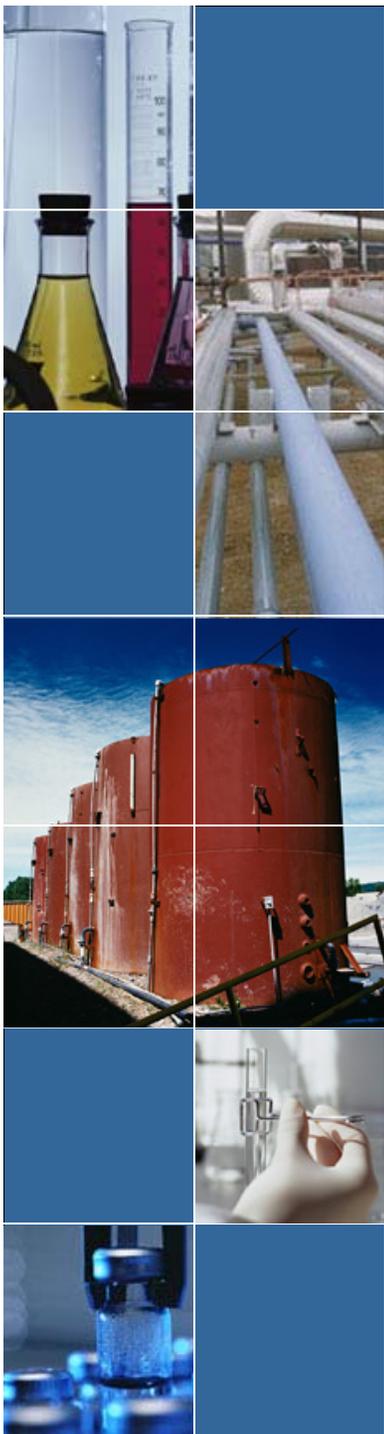




Future Work

- EPA will implement enhancements to ChAMP including:
 - Developing an HPV Challenge-type program for inorganic HPV chemicals
 - Resetting the Toxic Substances Control Act (TSCA) Inventory to reflect the true number of chemicals in use



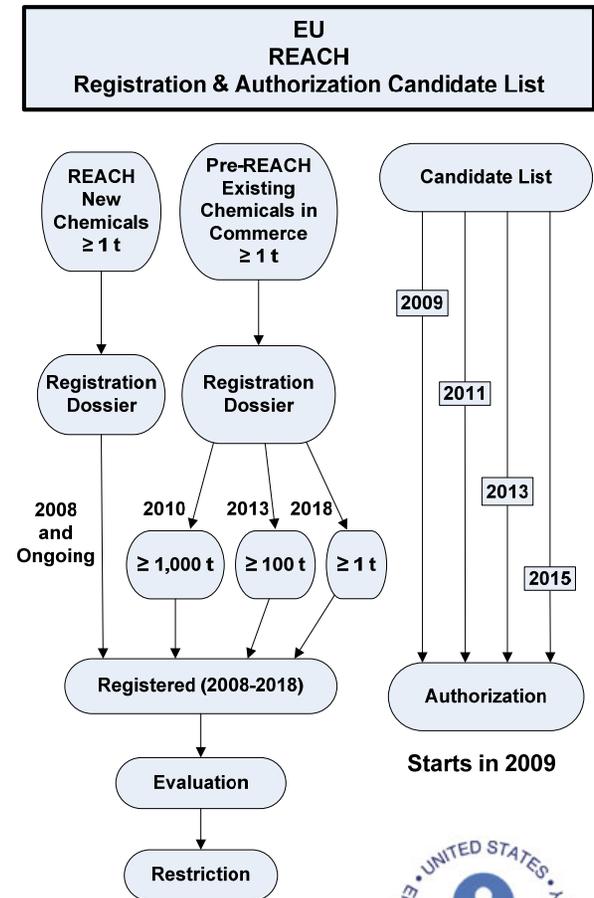
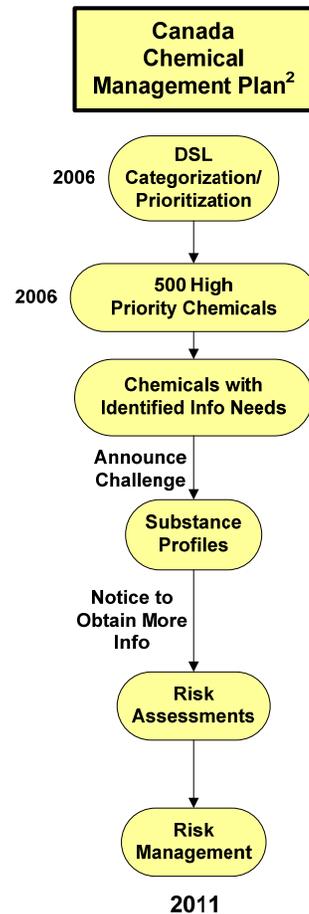
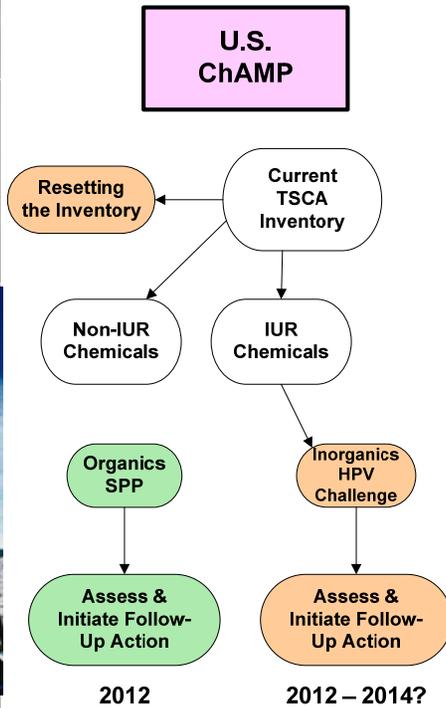
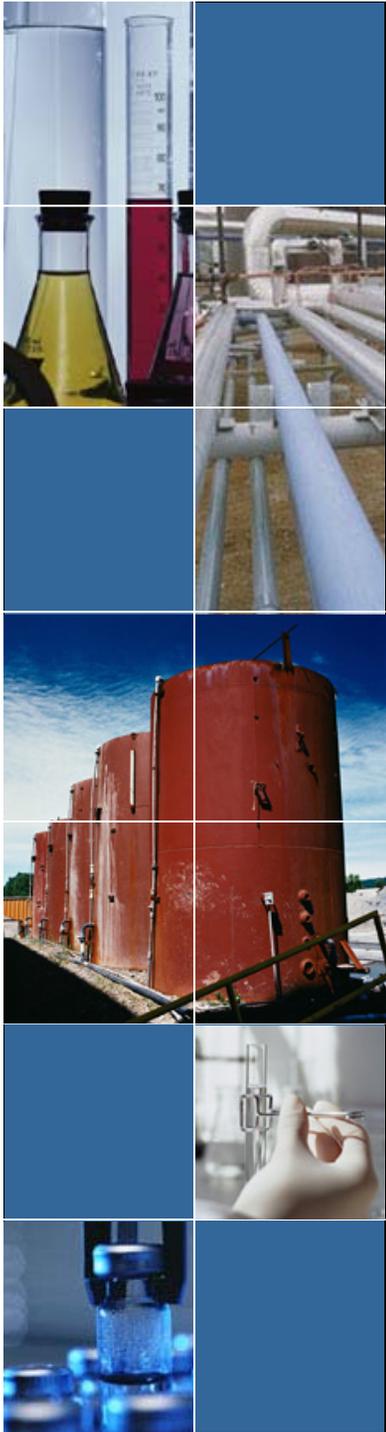


Program Enhancements – Inorganic HPV Challenge

- Inorganics first included on IUR in 2006; no exposure data reporting until 2011
 - EPA estimates that there are likely to be between 400 and 500 HPV inorganic chemicals reported
- EPA will develop IHPV Challenge Program Mirroring HPV Challenge Design
 - Identify and work with stakeholders to develop program/process/timing.
 - Apply established EPA, OECD guidance to determine inorganics data needs
- Assess, priority, and initiate needed action on IHPV chemicals (2012-2014)



Comparing U.S., Canada and EU Approaches

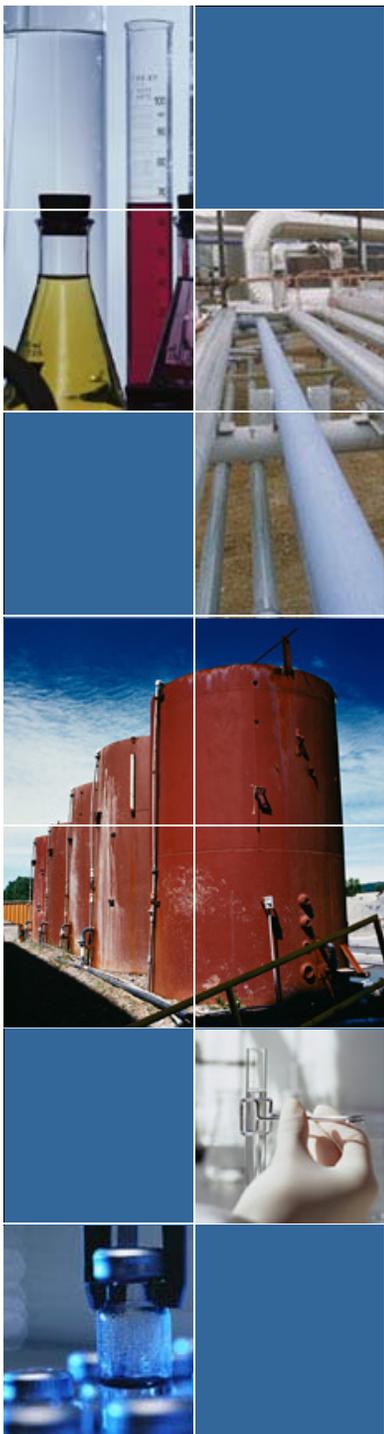


¹ DSL = Canadian Environmental Protection Act Domestic Substances List

² Other aspects of the CMP are not shown on this figure.

1,000 t = 2.2 M lbs.; 100 t = 220k lbs.; 1 t = 2.2k lbs.



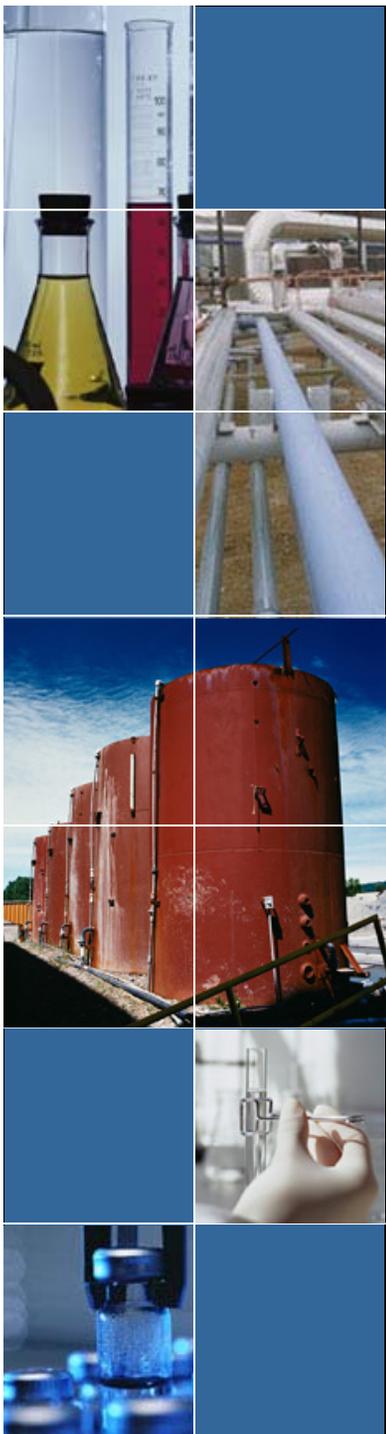


Additional Information

- For more information, please visit EPA's Chemical Assessment and Management Program (ChAMP) website:

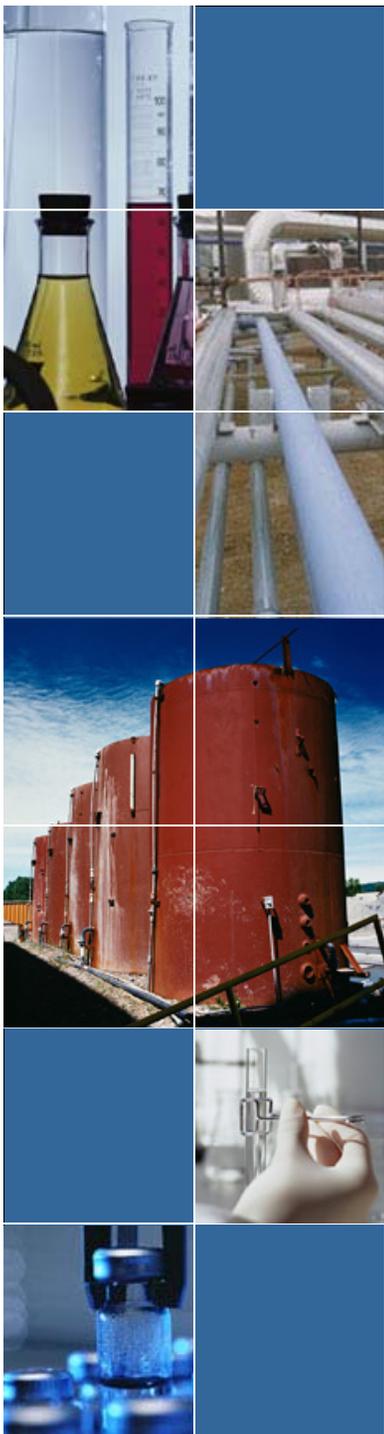
<http://www.epa.gov/champ/>





Part II. Risk Based Prioritization of HPV Chemicals

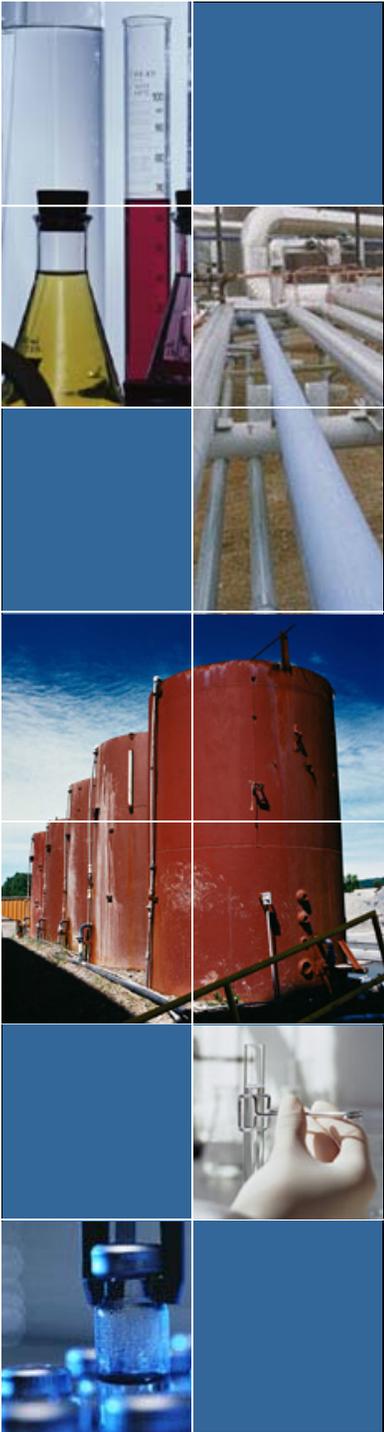




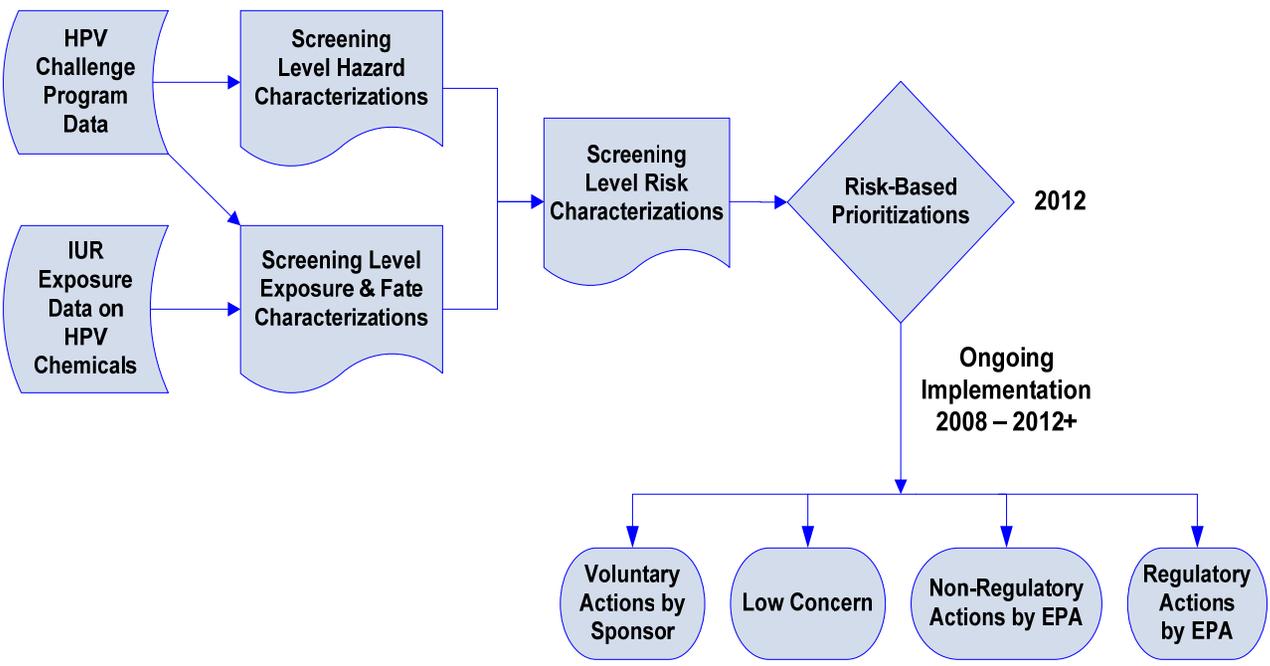
Screening Decision Process – HPV Chemicals

- Assess and prioritize HPV chemicals
(1 million lbs/yr) based on hazard/ exposure information
 - HPV Challenge test data
 - IUR Exposure/use reporting
- Develop Risk-Based Prioritization (RBP) documents
- Identify and initiate needed action
 - Gather/generate needed information
 - Take control measures
 - Identify as current low priority and set aside
- Document and post assessments and conclusions on the web





Taking Action on HPV Chemicals: Risk-Based Prioritization Process



* The first 200 Hazard Characterizations on HPV chemicals have been posted to EPA's website. The first set of Risk-Based Prioritization documents will be posted soon.

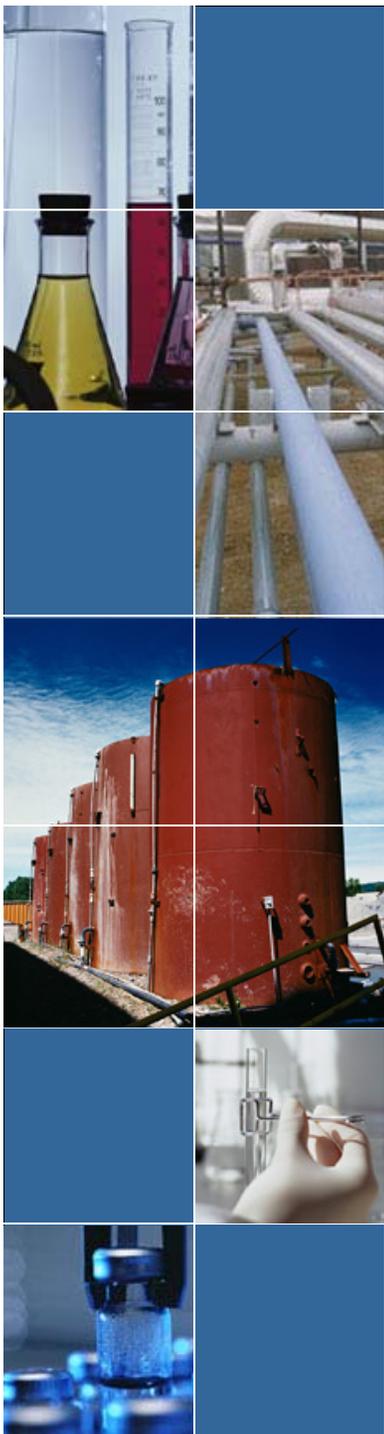




Risk-Based Prioritizations (RBPs)

- EPA's initial RBPs of HPV chemicals are screening-level documents that:
 - Summarize basic hazard, use and exposure information available to EPA on HPV chemicals
 - Identify potential risks
 - Note scientific issues and uncertainties
 - Indicate the initial priority being assigned by the Agency for potential future appropriate action
- Each RBP (for a given chemical or chemical category) contains the following supporting documents:
 - Hazard Characterization (HC)
 - Exposure Characterization (EC)
 - Risk Characterization (RC)

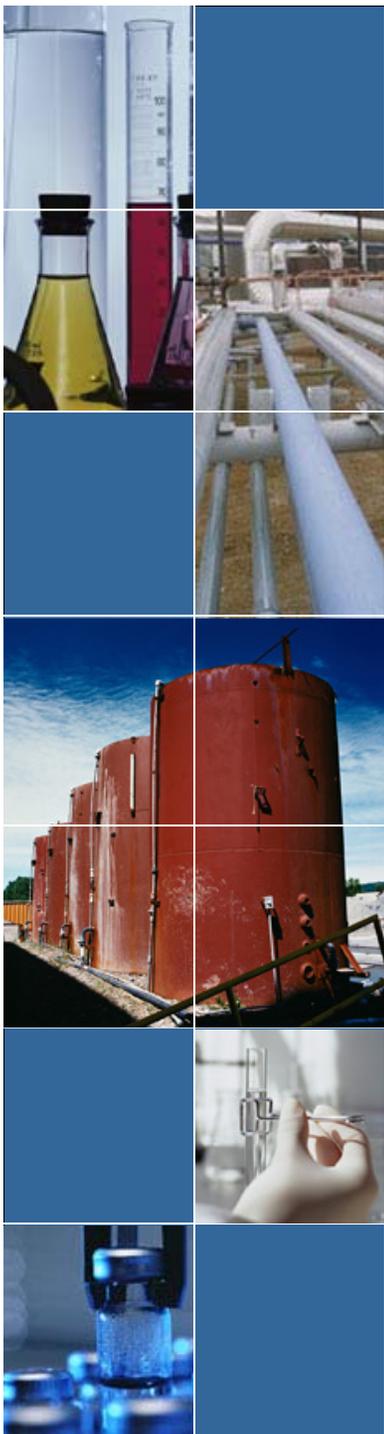




EPA's Initial Prioritization Concern Groupings

- **Low Priority, Follow-up Action Not Suggested at This Time:** Information available to EPA on the chemicals or categories assigned to this priority suggests that they do not present significant risk issues that warrant further Agency consideration at this time. This prioritization category may include chemicals with known risks that are already being controlled or addressed by existing activities or regulations.
- **Medium Priority, Potential Concern:** Information available to EPA on chemicals assigned to this priority suggests possible concerns, including chemicals with risk issues or uncertainties that might be resolved if additional data (e.g. on exposures, controls and/or hazards) were available to provide a basis for evaluating the potential concerns.
- **High Priority:** Information available to EPA on chemicals assigned to this priority suggests that these chemicals appear to have more serious potential risk concerns. Further analysis may result in identifying a need for risk management actions, regulations, and/or more comprehensive data. High Priority chemicals further designated as "chemicals of special concern" will be the focus of expedited attention.

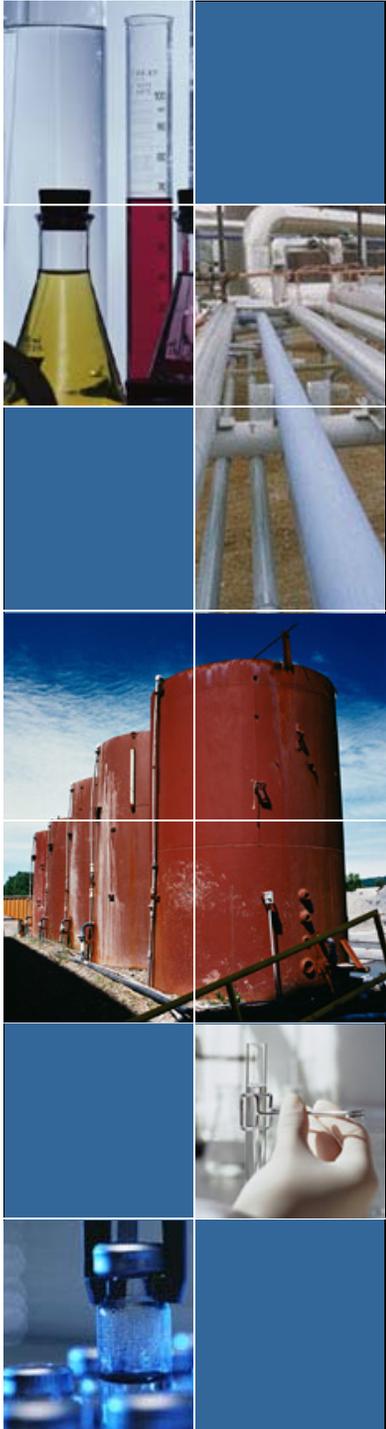




Hazard Characterization (HC)

- 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

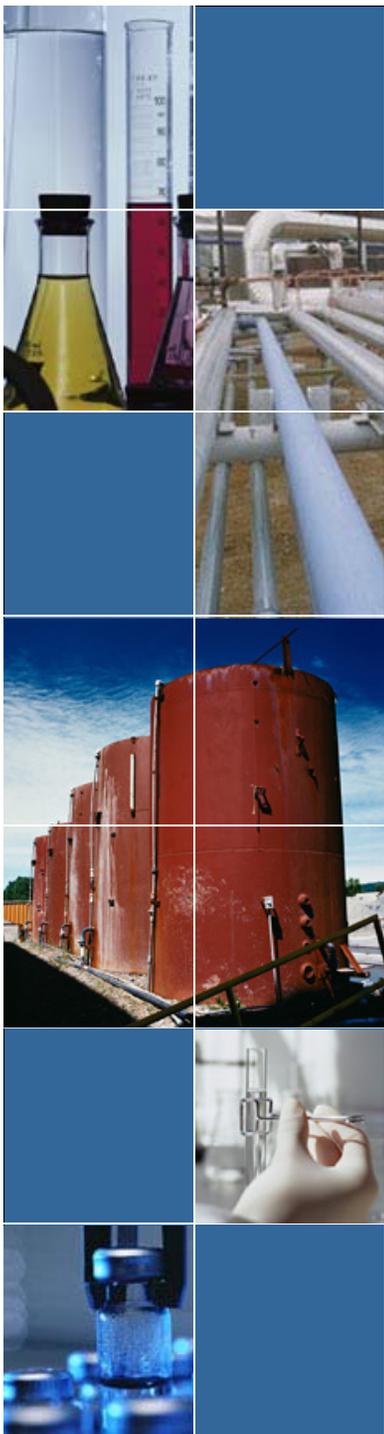




Exposure Characterization (EC)

- The screening-level EC considers a selected number of public sources but is primarily based on information from the IUR.
- Other commonly used public data sources:
 - HSDB
 - HPV submission
 - SIDS dossier
 - Test Rule
- Other public data sources searched including:
 - National Institute of Health's (NIH) Household Products Database
 - National Environmental Monitoring and Assessment Program (EMAP)
 - National Emission Inventory (NEI) Database





Exposure Characterization (EC) (cont'd)

- The contents of EC includes the following information:
 - Production Volume and Use
 - Relevant Physical/Chemical and Fate Information
 - Potential Environmental Release
 - Potential general population and environmental exposure
 - Potential occupational exposure
 - Potential consumers exposure
 - Potential children's exposure
 - Non-confidential IUR data summary
 - Uncertainties

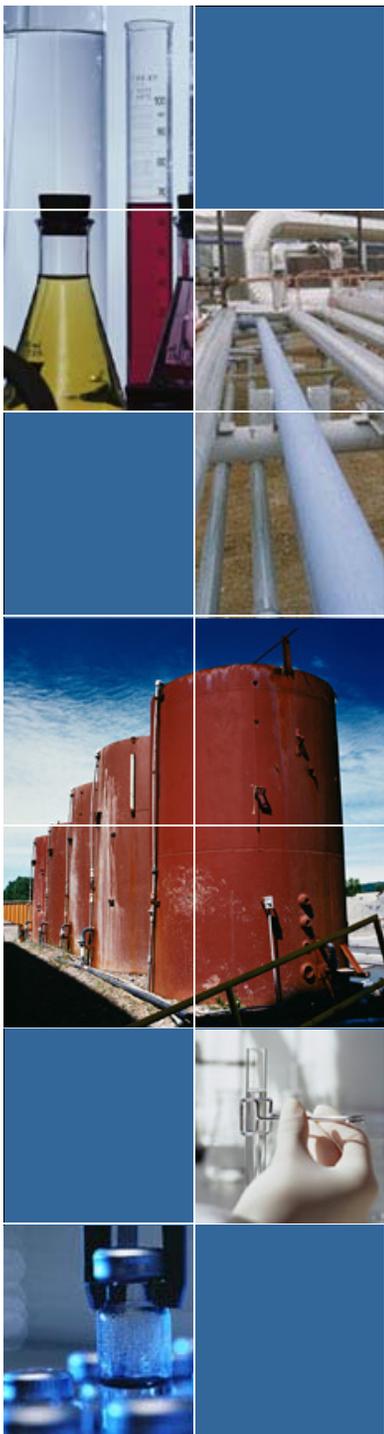




Production Volume and Use Information

- Production volume (PV) and use information are extracted from the IUR and masked to protect confidential business information (CBI)
- Information presented includes:
 - Aggregated PV reported in ranges
 - Non-CBI sites and companies
 - Summary of industrial processing and use
 - Summary of commercial and consumer use

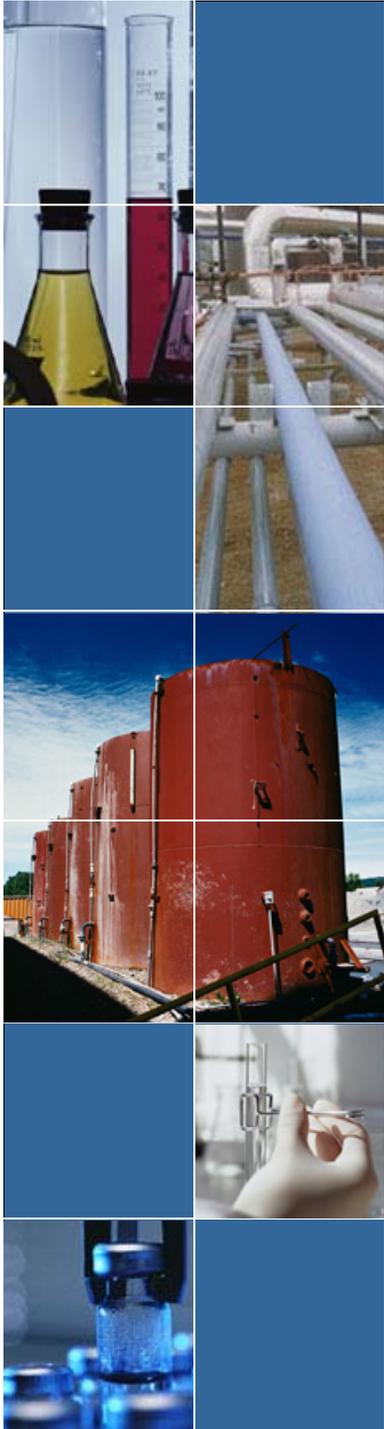




Physical-Chemical Properties and Environmental Fate

- Basic physical-chemical properties and information on the transport of chemicals in the environment are used to help characterize potential exposures
- Relevant information includes:
 - Selected physical/chemical properties that affect potential exposure
 - Vapor pressure and physical state
 - Reactivity
 - Persistence and bioaccumulation statement

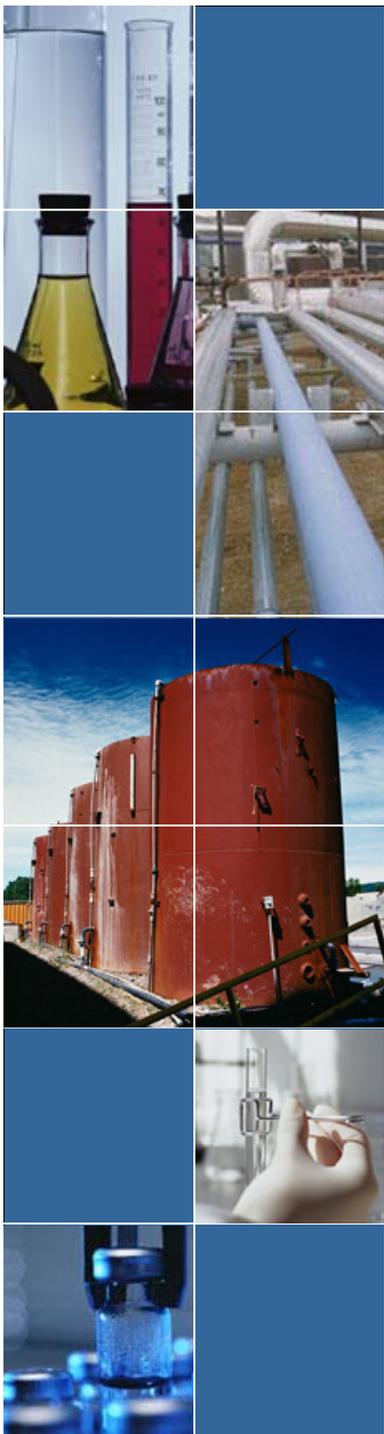




Environmental Releases

- The EC discusses the potential releases to various media
- Information presented includes:
 - Release statements based on non-confidential IUR use codes related to industrial processing and use
 - Release statements based on information from other selected public sources
 - Releases from other sources such as Toxic Release Inventory (TRI)
 - Readily available data from the Hazardous Substances Data Bank (HSDB), including affected media

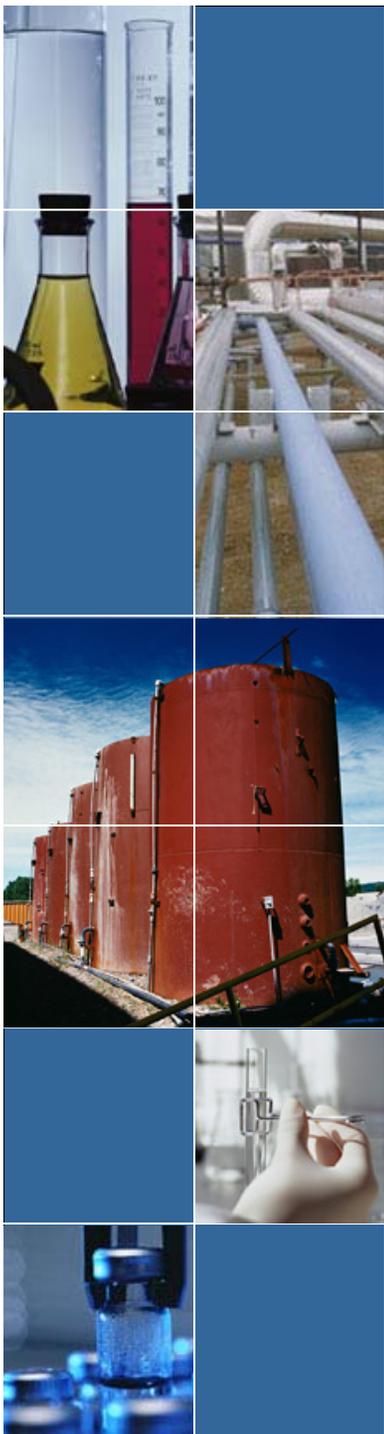




Potential Exposures

- The EC also identifies relative rankings for potential exposure to following populations:
 - The Environment
 - The General Population
 - Workers
 - Consumes
 - Children
- Statement on relative ranking will be based on the totality of information considered (including IUR, HPV, and other selected data sources) and in combination with professional judgment.

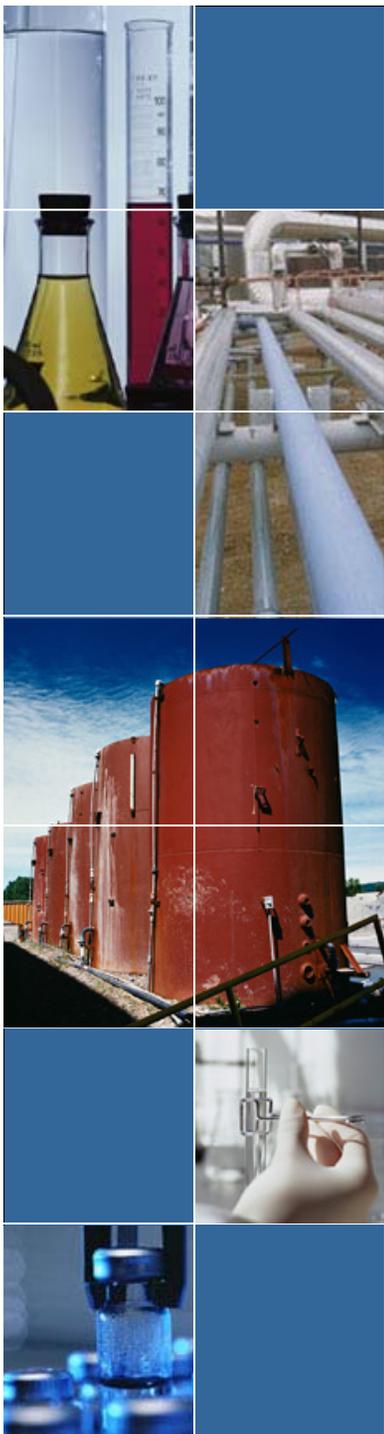




Non-Confidential IUR Data Summary

- The EC presents IUR data in a manner that allows CBI data to be protected
- Non-confidential IUR data summary includes:
 - Combined manufactured and imported PV – aggregated and in ranges
 - Non-confidential company names
 - Number of potentially exposed workers in one of three ranges: <100, between 100 and 999, or greater than 1,000
 - Non-confidential physical form(s)
 - Non-confidential maximum concentration
 - Non-confidential industrial processing and use information (three-code combination of processing activity, industrial sector, and industrial function category)
 - Non-confidential commercial and consumer use information including the associated maximum concentration and an indication of whether the chemical is used in children's products





Contents of Full RBP

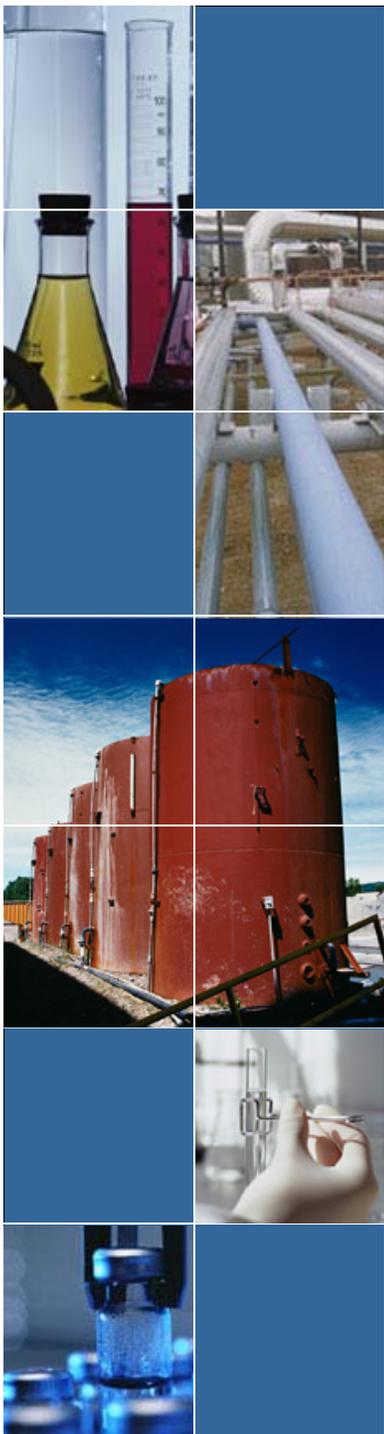
- Hazard and Fate Summary
 - Toxicity to the human health and environment
 - Persistence and bioaccumulation
- Exposure Summary
 - PV and uses
 - Ranking for potential exposures to environment and general population, workers, consumers and children
- Risk Characterization Summary
 - Potential risks to the aquatic organisms, general population and environment, workers, consumers and children
- Regulatory and Related Information Summary
 - Regulation related information (e.g. chemical is listed under TSCA)



Content of Full RBP (cont'd)

- Assumptions and Uncertainties
- Rationale Leading to Prioritization Decision
 - Summary of relevant information related to exposure, release and toxicity
- Prioritization Decision
 - States whether the chemical is of high, medium or low priority based on available information
- Supporting Documents
 - Screening level RC, HC and EC





Example 1: Exposure Summary for Primene™ 81-R Amines (CASRN 68955-55-3)

- **PV:** This chemical is an HPV chemical manufactured and/or imported into the US with an aggregate volume of 1 million to 10 million pounds/yr
- **Uses:** The non-confidential IUR uses include processing of the chemical as a fuel in organic chemicals manufacturing. The HPV Challenge submission for this chemical indicates that it is used as a fuel and lubricant additive, and in surfactants, dyes, refinery processing and metal working fluids
- **General Population and the Environment:** It is likely there would be some releases to water and air during manufacturing, processing and use. EPA identifies a high potential that the general population and the environment might be exposed.





Example 1: Exposure Summary for Primene™ 81-R Amines (CASRN 68955-55-3) (con't)

- **Workers:** EPA identifies a high relative ranking for the potential worker exposure. The high relative ranking is based on the potential for dermal exposure to liquids and inhalation exposure to vapors, use operations; the high concentrations of the chemical used; the potential for exposure to mist at high concentrations during industrial and commercial uses; and the potentially high number of workers during commercial activities.
- **Consumers:** Depending on the consumer product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers may be exposed from products containing this chemical based on IUR data and information from public data sources that indicate this chemical is found in household products.
- **Children:** No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. Therefore, EPA identifies a medium potential that children might be exposed.

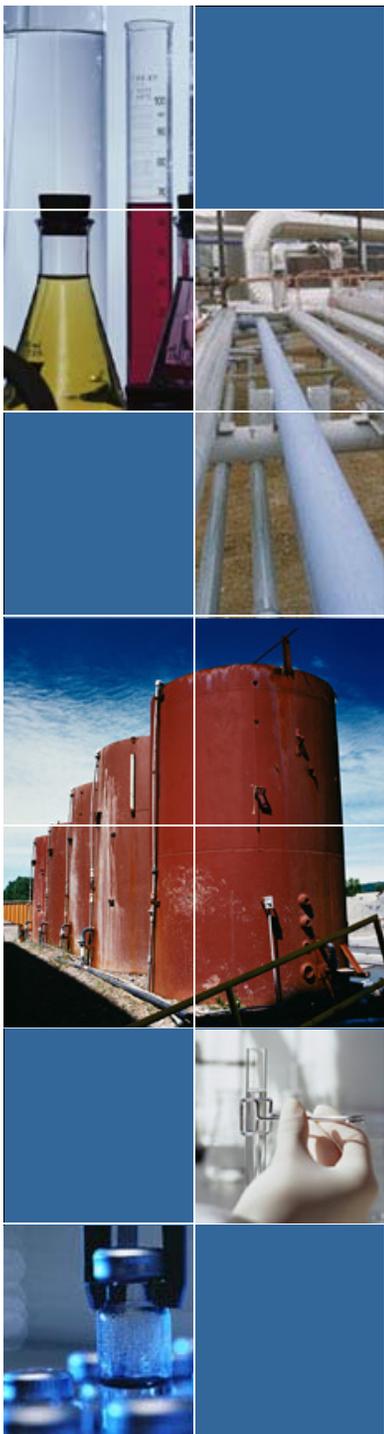




Example 1 (con't): Risk Characterization Summary for Primene™ 81-R Amines (CASRN 68955-55-3)

- Potential Risk to Aquatic Organisms from Environmental Releases: Medium/High Concern
- Potential Risk to the General Population from Environmental Releases: Low
- Potential Risk to Workers: Low Concern
- Potential Risk to Consumers from Known Uses: Low Concern
- Potential Risk to Children: Medium Concern





Example 1 (con't): Prioritization Decision for Primene™ 81-R Amines (CASRN 68955-55-3)

- **MEDIUM PRIORITY, POTENTIAL CONCERN:** In order to further evaluate the medium to high concern for potential risk to aquatic organism and the medium concern for potential risk to children from this chemical, EPA has identified possible next steps involving efforts to develop a better understanding of exposure to and uses of this chemical. Examples of information that would assist EPA in its analysis include, but are not limited to:
 - Information concerning potential release to water from manufacturing, use and disposal of the chemical and products containing this chemical.
 - Information concerning the use of this chemical in household products; and
 - Other information pertinent to environmental exposures to this chemical.

As an initial step in developing this understanding, companies that manufacture, process, or use this chemical are encouraged to provide available information on a voluntary and non-confidential basis.

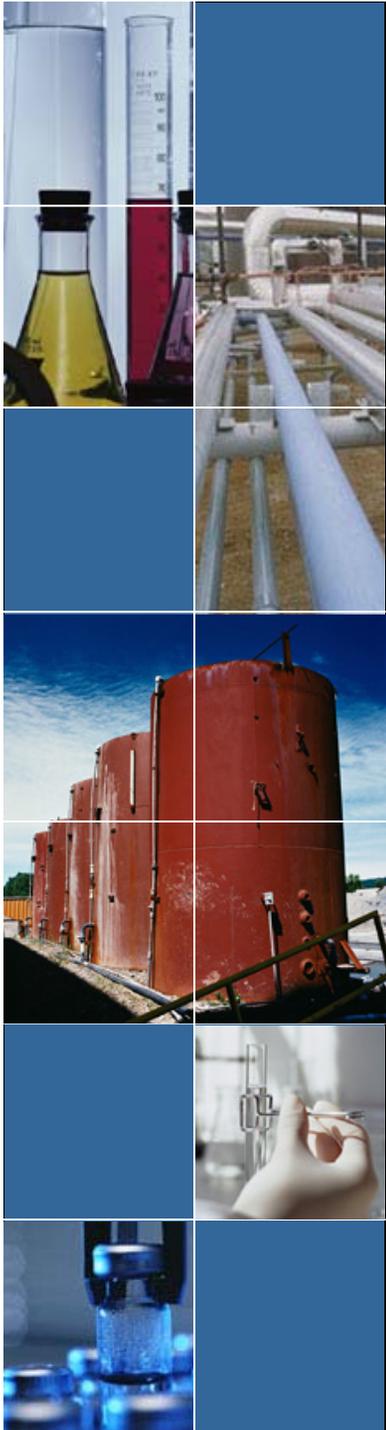




Example 2: Exposure Summary for Allyl Alcohol (CASRN 107-18-6)

- **PV:** This chemical has an aggregated production and/or import volume in the US of 100 million to 500 million pounds/yr
- **Uses:** According to IUR submissions, the primary industrial are claimed confidential information provided to EPA under the HPV Challenge Program indicates the chemical is used as an intermediate in the production of 1,4-butanediol and 2-methyl-1, 3-propanediol and in the manufacture of water treatment chemicals, coating resins, and plasticizers. The Hazardous Substances Data Bank indicates the chemical is used to manufacture glycerol, acrolein, military poison gas, water treatment chemicals, allyl compounds, resins, plasticizers, fire retardants, pesticides and herbicides.
- **General Population and the Environment:** It is likely there would be some releases to water and/or air during manufacturing, processing and use. This chemical is on the Toxics Release Inventory (TRI). Total releases reported in 2006 from all 40 reporting sites is 544,330 pounds, which include air releases of 44,612 pounds from on-site fugitive and point sources in addition to on-site water releases of 19,133 pounds. The remaining volume of release was deep-well injected. EPA identifies a high potential that the chemical may be released to the environment and that the general population and the environment may be exposed.





Example 2: Exposure Summary for Allyl Alcohol (CASRN 107-18-6)

- **Workers:** EPA identifies a medium relative ranking based on relatively high volatility and the likelihood that workers would wear adequate personal protective equipment (PPE) due to severe dermal and respiratory irritation at higher concentrations. The extent of PPE worn by workers who may be exposed at lower concentrations is not known. This chemical has an OSHA Permissible Exposure Limit (PEL) of 2 ppm time weighted average, with a skin notation.
- **Consumers:** EPA identifies a low potential that consumers might be exposed based on information from IUR and public data sources that indicates this chemical is not present in commercial and consumer products.
- **Children:** EPA identifies a low potential that children might be exposed based on information from IUR and public data sources that indicates this chemical is not present in commercial and consumer products.

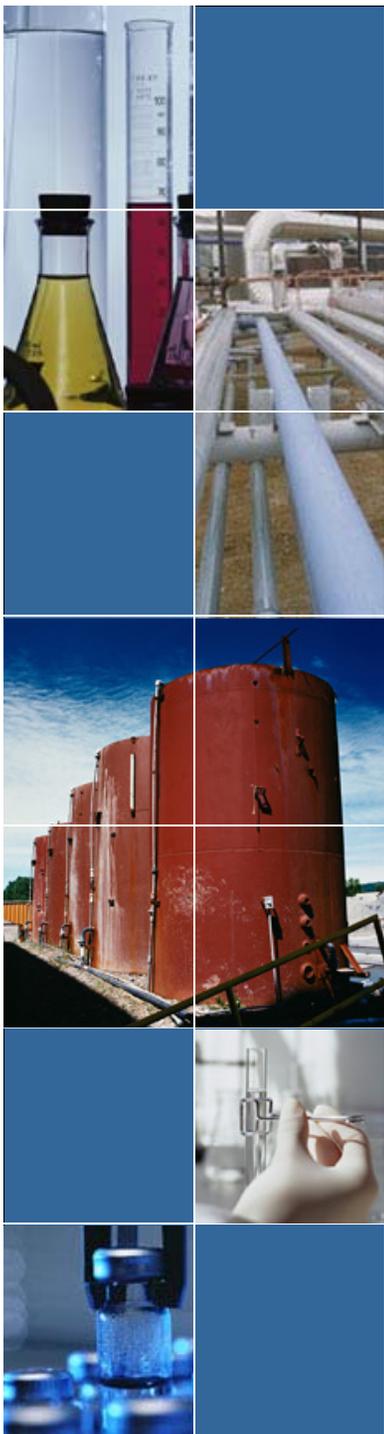




Example 2 (con't): Risk Characterization Summary for Allyl Alcohol (CASRN 107-18-6)

- Potential Risk to Aquatic Organisms from Environmental Releases: Medium/High Concern
- Potential Risk to the General Population from Environmental Releases: High
- Potential Risk to Workers: Low Concern
- Potential Risk to Consumers from Known Uses: Low Concern
- Potential Risk to Children: Low Concern





Example 2 (con't): Prioritization Decision and Rationale for Allyl Alcohol (CASRN 107-18-6)

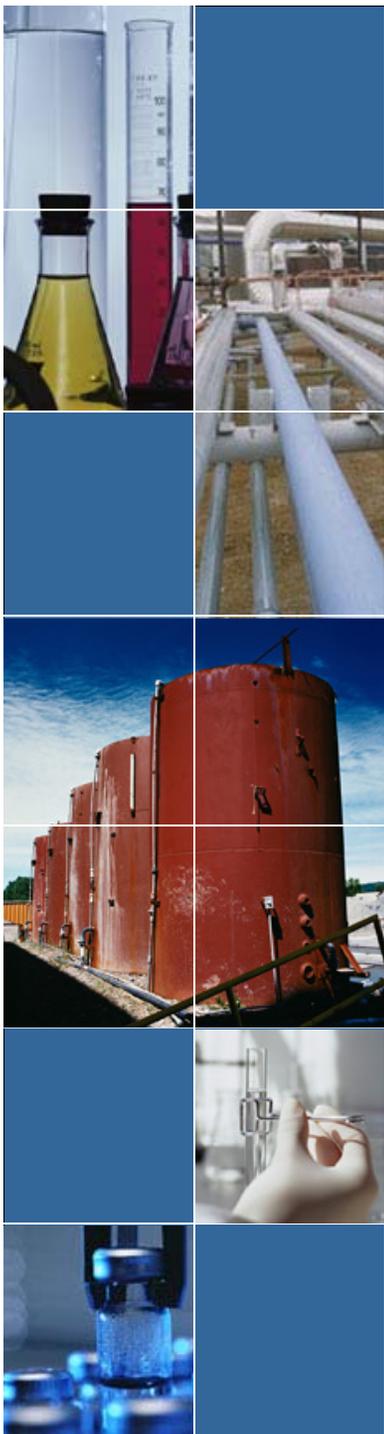
Rational Leading to Prioritization Decision:

- The hazards of this chemical are well characterized and understood
- Existing regulations in the US are expected to control the potential risks to all populations

Prioritization Decision:

- **LOW PRIORITY** – Follow-up action not suggested at this time.





Screening Decision Process – MPV Chemicals

- Developing approach to assess MPV Chemicals
 - Produced or imported at quantities $\geq 25,000$ lbs/yr and ≤ 1 million lbs/yr.
 - Apply available data, Canadian categorization results, and EPA Structure Activity Relationships (SAR) analysis to assess hazard and fate.
 - Basic exposure/use data are available only for MPVs produced at $\geq 300,000$ lbs at a site
 - Use Hazard-Based Prioritizations (HBPs) to identify MPVs that require follow-up, initiate actions
 - *Gather additional data (exposure, testing, etc.)*
 - *Risk management*
- Document and post assessments and conclusions on the web.



RBP and Supporting Documents

- The RPB and supporting documents (EC, HC, and RC) will be posted on EPA's Web site @

www.epa.gov/champ/

