Chemical Assessment and Management Program (ChAMP)

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North American Cooperation on Chemical Management

- At Security, Prosperity and Partnership (SPP) Summit in August 2007, President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon 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 with Mexico to establish, by 2020, a Mexican chemical inventory, Inventory updates, strengthened North American chemical regime
  - Research and development on new approaches to testing and assessment.
    - EPA and Canadians have begun collaborating
  - Create mechanisms to share domestic scientific information and best practices for chemical assessment and management. Coordinate approaches to develop international standards.
  - 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 6,750 chemicals
  - Canada: Realize its Chemical Management Plan
  - Mexico: Establish a chemical inventory

Chemicals Assessment and Management Program (ChAMP)

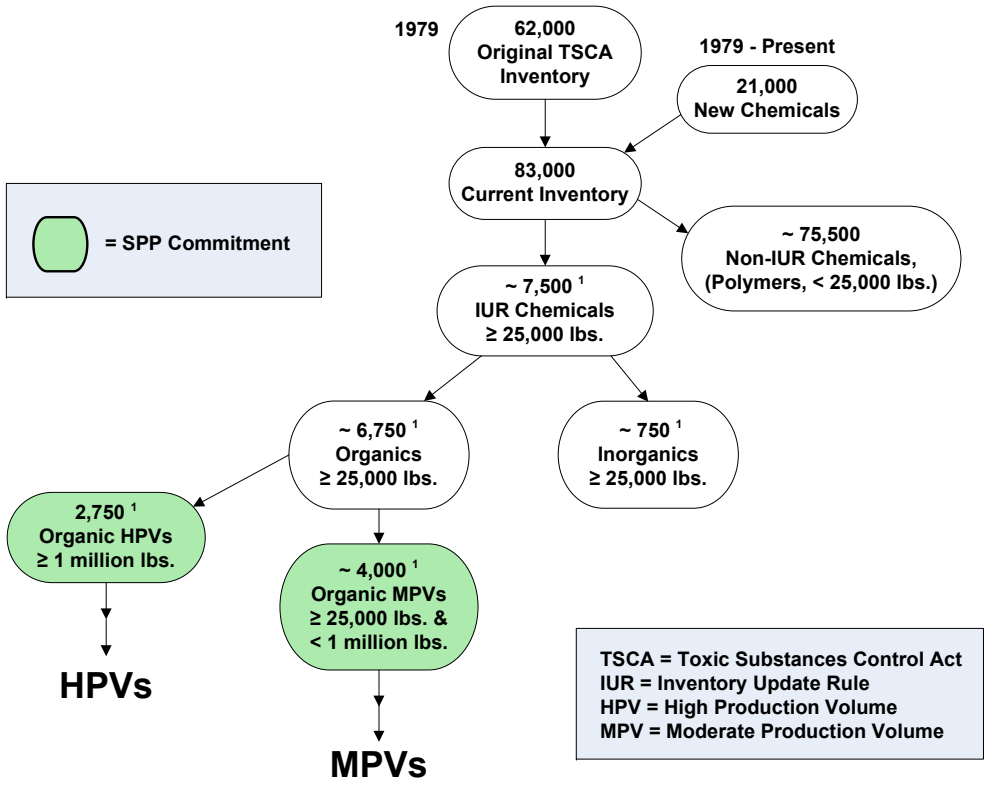
- New title encompasses U.S. SPP commitments and possible enhancements to EPA's existing chemical program which include:
  - HPV Challenge type program for high production volume "inorganic" chemicals
  - Resetting the TSCA Inventory

U.S. Commitments Under SPP

- By the end of 2012:
  - Assess and initiate needed action on the over 6,750* existing chemicals produced above 25,000 lbs/yr the U.S.
  - Includes High Production Volume (HPV) and Moderate Production Volume (MPV) chemicals
    - Includes work under U.S. HPV Challenge
    - MPV work builds off Canadian categorization effort
  - Make and publicly release screening level decisions and initiate needed action

*Based on preliminary statistics from 2006 IUR Data

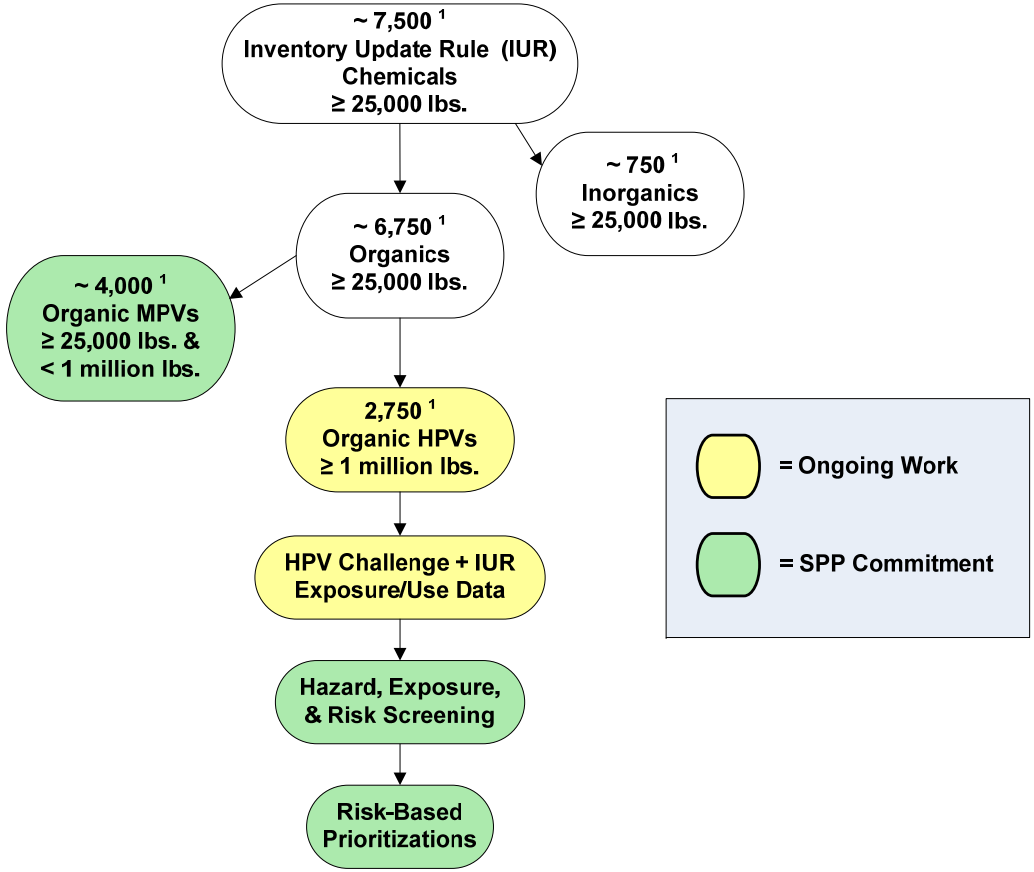
U.S. SPP Commitments



[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.

U.S. SPP Commitments: HPV Chemicals



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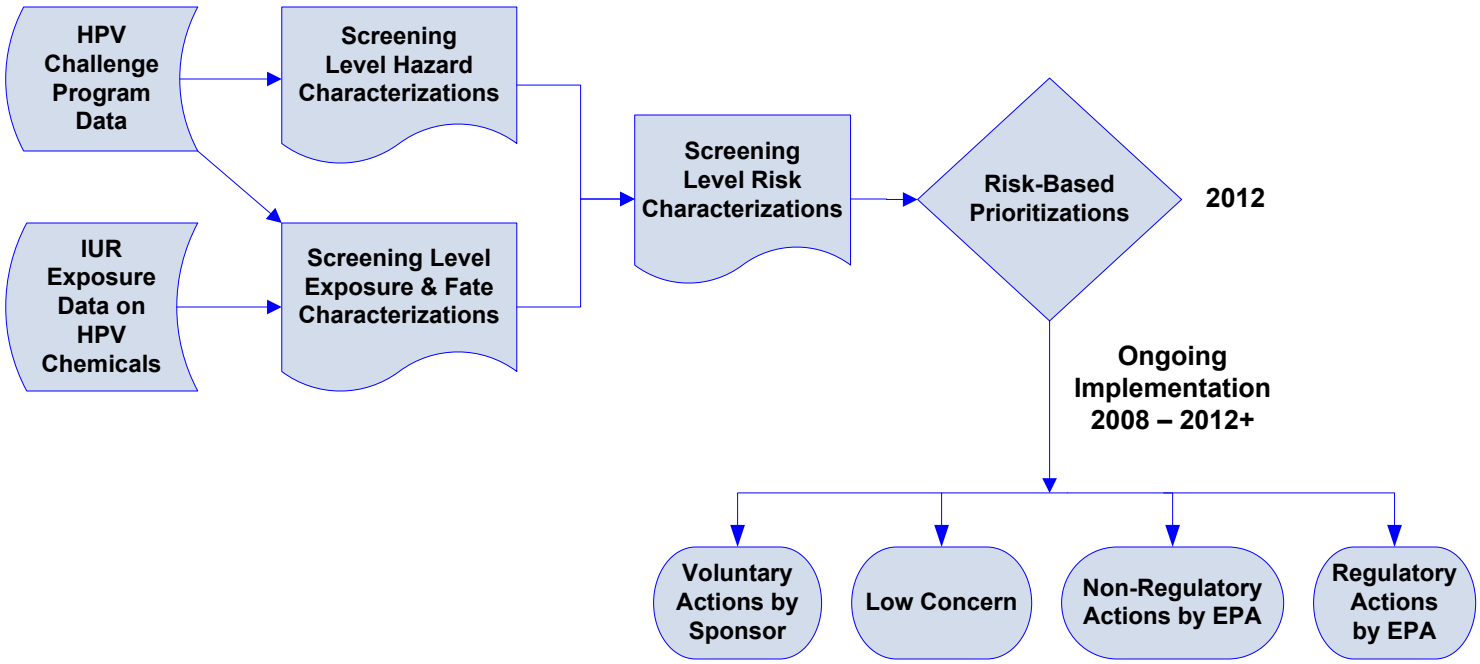
Screening Decision Process – HPV Chemicals

- Assess and prioritize HPV chemicals (1 million lbs/yr) based on hazard/ exposure information
  - HPV Challenge test data
  - IUR Exposure/use reporting
- Evaluate Risks
- 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.

Tools to Implement Risk-Based Prioritizations (RBPs)

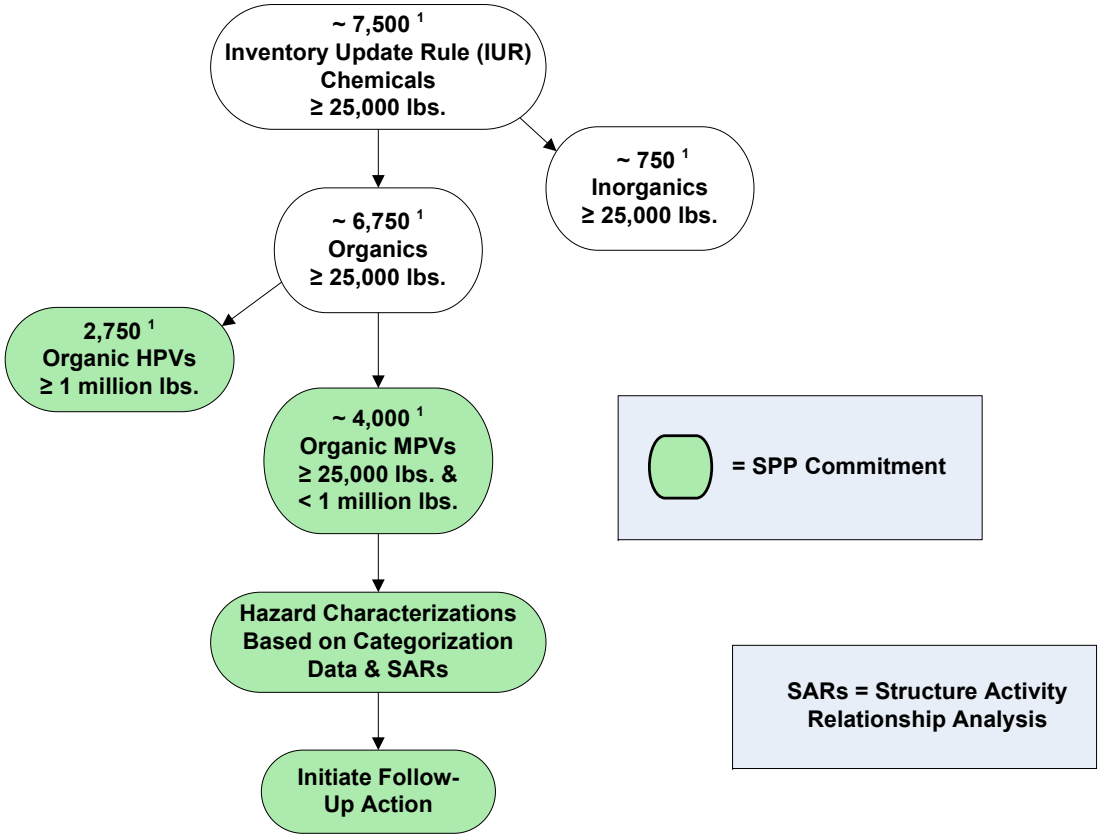
- Where identified as low-concern at this time:
  - Document initial prioritization rationale and post to web

- Where additional info or action is needed, the options include:
  - Contact producers with request for info, informal action
  - Data from other offices, Canada, OECD
  - TSCA §8(a) reporting rules (e.g., exposure, release data)
  - TSCA §5(a)(2) Significant New Use Rules (SNURs)
  - Engage with stakeholders (e.g. DfE, voluntary action, etc.)
  - TSCA §4 test rules
  - Develop/implement Challenge programs, other risk reduction actions
  - Initiate creation of TSCA §5(b)(4) list

Section §5(b)(4) “Risk List”

- Chemicals with risk concerns could be considered for Sec. 5(b)(4) risk list
  - Requires rulemaking and minimum of a “*may present an unreasonable risk*” finding;
    - may be possible with HPV and IUR data
  - Risk list approach could provide incentive for stewardship

U.S. SPP Commitments: MPV Chemicals



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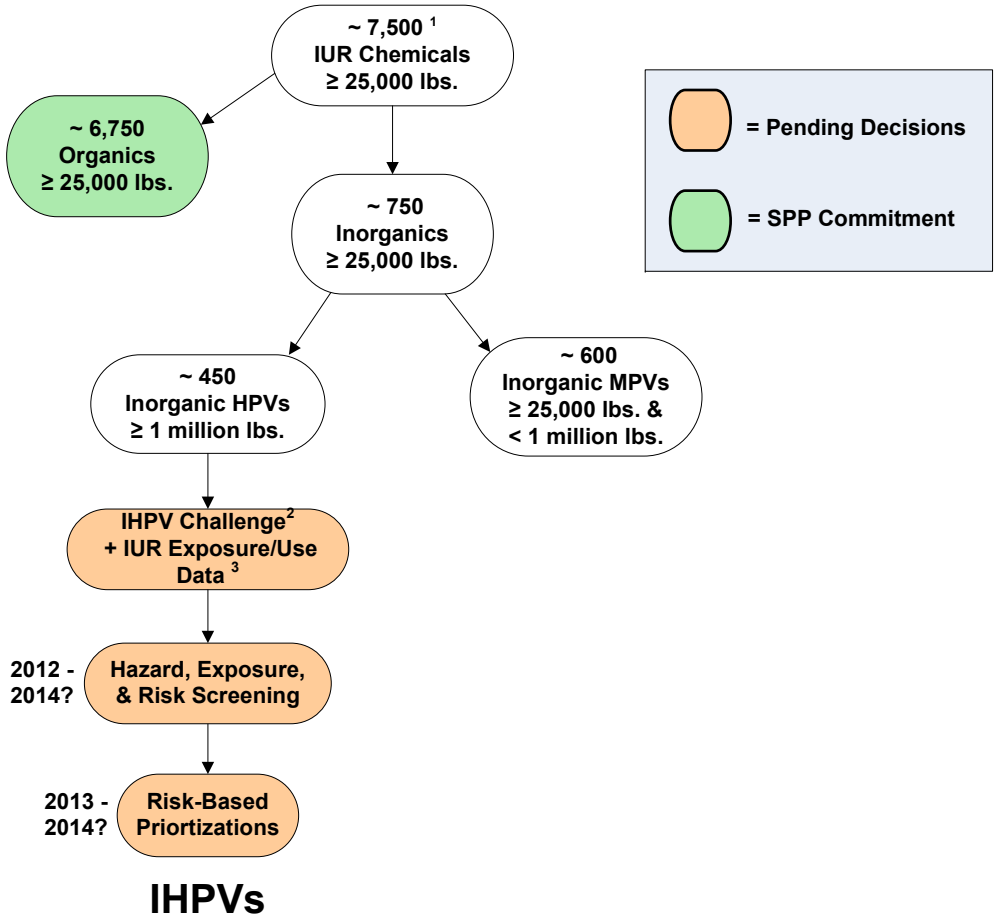
Screening Decision Process – MPV Chemicals

- Developing approach to assess MPV Chemicals
  - Produced or imported at quantities ≥ 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 ≥ 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 assessments and conclusions on the web.

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
- 2008
  - Posted additional 50 HCs in January
  - Posted initial set of 19 RBPs in March
  - Continue developing and posting RBPs
  - Post initial MPV HCs
- 2009
  - Continue posting RBPs for HPV chemicals and significantly ramp up posting MPV HCs

Program Enhancements: Inorganic HPV Chemicals



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[2] Implementation of an IHPV Challenge program would take 3 to 4 years
[3] Inorganics IUR exposure/use reporting occurs in 2011.

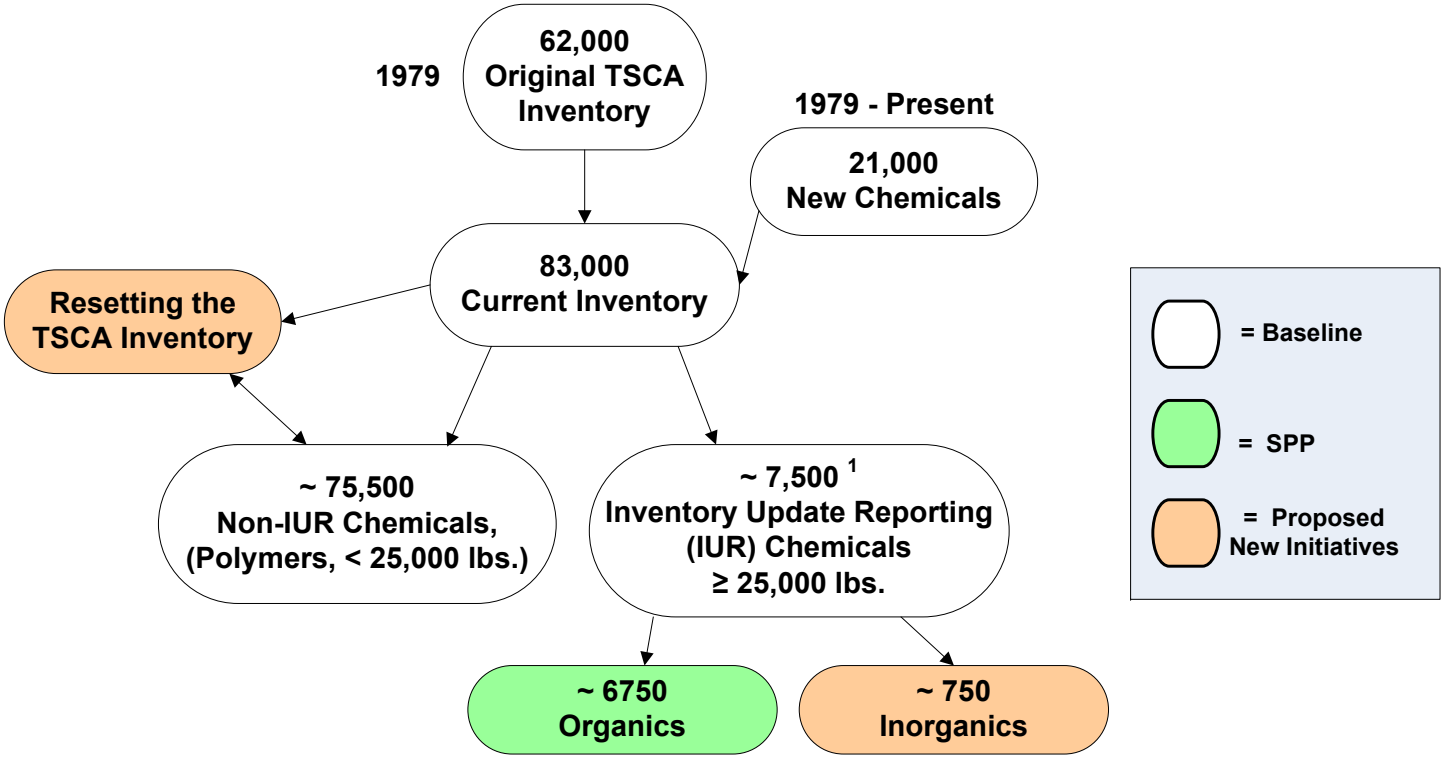
Program Enhancements – Inorganic HPV Challenge

- Inorganics first included on IUR in 2006; no exposure data reportinng until 2011
  - EPA estimates that there are likely to be between 400 and 500 HPV inorganic chemicals reported
- EPA considering 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 intiate needed action on IHPV chemicals (2012-2014)

Program Enhancements – Resetting the TSCA Inventory

- TSCA §8(b) requires EPA to "compile, *keep current*, and publish" TSCA Inventory"
- Inventory's "83,000 chemicals" are misleading
  - Likely that many chemicals are no longer manufactured/imported; or
  - Are produced only in low or episodic volumes

Program Enhancements: Resetting the TSCA Inventory



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Program Enhancements – Resetting the TSCA Inventory

- EPA will engage stakeholders on regulatory options for making the TSCA Inventory:
  - Better reflect the chemicals in commerce in the U.S.
  - A more meaningful and useable resource

Stakeholder Engagement

- EPA will seek input from a wide range of partners and stakeholders
  - Series of meetings and discussions over March through June period
  - Focus meetings, webinars, pre-established conferences/meetings
  - Industry, NGOs, States and Tribes, Federal Partners
- EPA goal is to provide feedback to Administrator this summer and possibly begin implementing program enhancements by the end of summer.

Relationship to Work by the Commission on Environmental Cooperation

- CEC's Sound Management of Chemicals (SMOC) work group has worked for over a decade to deal with individual chemicals issue in North America
- SMOC is now focused on regional implementation of the Strategic Approach to International Chemicals Management (SAICM) in NA
- The SPP regional and national commitments provides another avenue to complement SMOC's efforts and realize progress

Relationship to Work by CEC/SMOC

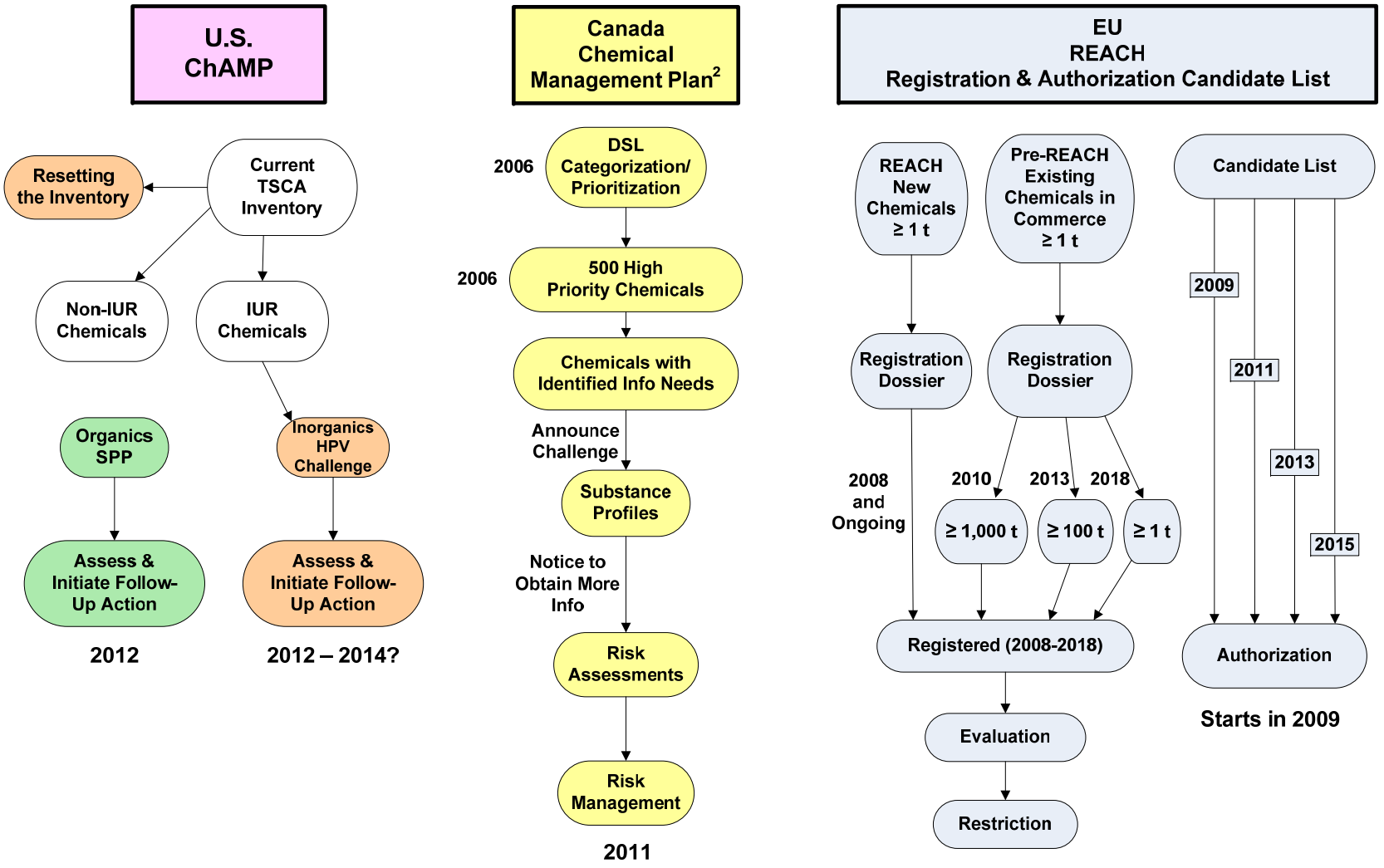
- SMOC has agreed to four major areas for its work:
  - Establish a foundation for chemicals management across North America: Mexican Inventory
  - Develop and implement a sustainable regional approach to monitoring, including biomonitoring: Mexican PRONAME initiative
  - Reduce the risk from chemicals of mutual concern to North America: NARAP chemicals and PBDEs
  - Improve the environmental performance of sectors

*North American Regional Action Plan (NARAP) chemicals include PCBs, mercury, chlordane, DDT, dioxins/furans, etc.

Timing of Actions Under SPP and Their Relationship to Timing Under REACH

- Parallel schedules for priority chemical assessments should allow U.S. and Canada to share/coordinate timing of data and assessments and follow-up action, where appropriate
- Because the REACH 1st registration deadline (HPV chemicals) is Dec. 2010 and the 1st authorization candidate list is expected in late 2008, REACH submitters and evaluators will benefit from U.S. and Canadian work
- REACH registration dossiers can meet future follow-up testing needs for U.S. HPVs/MPVs and IHPVs
- Schedule for completion of North American assessment work (2012) compares favorably to timing of REACH registration schedule (2010-2018)
- U.S. (EPA), Canada (Environment and Health Canada) and EC (DG Environment, DG Enterprise, and European Chemical Agency) officials met in December 2007 to begin consideration of future cooperation and staff exchange opportunities

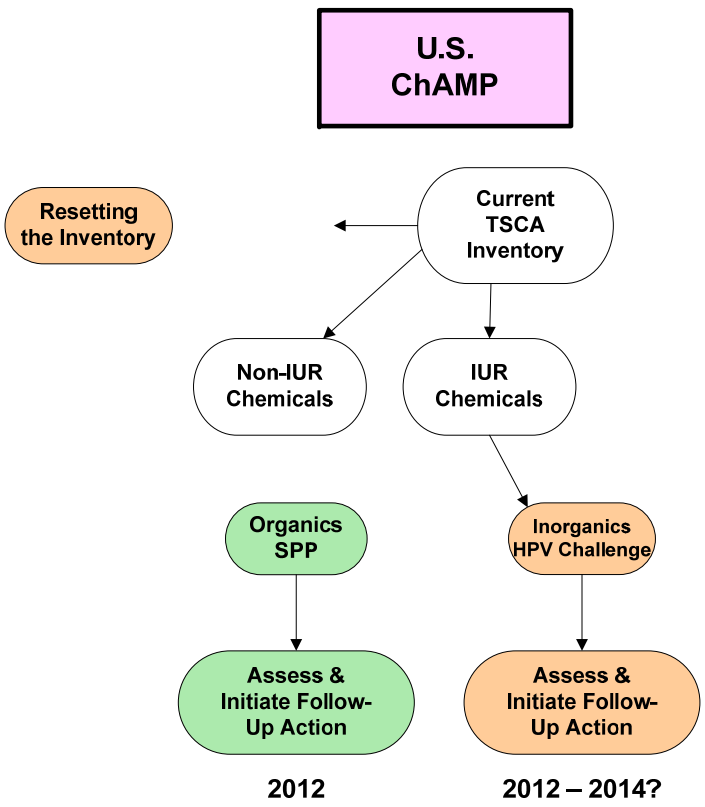
Comparing U.S., Canada, and EU Approaches

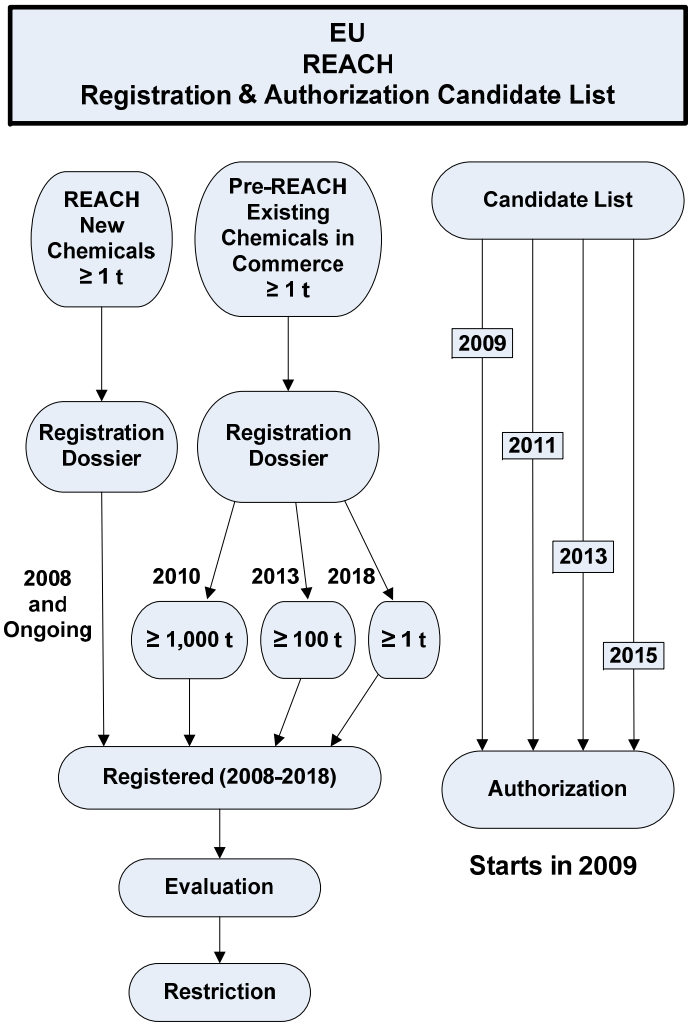


[1] DSL = Canadian Environmental Protection Act Domestic Substances List
[2] Other aspects of the CMP are not shown on this figure.

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

Comparing U.S., Canada, and EU Approaches





Thank you

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

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