US ERA ARCHIVE DOCUMENT

EPA's Chemical Assessment and Management Program UPDATE

Great Lakes Binational Toxics Strategy
Stakeholder Forum

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SPP Commitments

- At the Security and Prosperity Partnership (SPP) Summit in August 2007, President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon committed to enhance regulatory cooperation in North America
 - Canada & U.S. will work with Mexico to establish a Mexican chemical inventory and strengthened North American chemical regime.
 - Research and development on new approaches to testing and assessment.
 - Create mechanisms to share domestic scientific information and best practices for chemical assessment and management. Enhance Mexico's capacity for chemical assessment and management



Chemicals Assessment and Management Program (ChAMP)

- ChAMP encompasses U.S. SPP commitments and possible "ChAMP enhancements" including:
 - HPV Challenge-type program for High Production Volume "inorganic" chemicals
 - Resetting the TSCA Inventory



ChAMP

- By the end of 2012:
 - Assess and initiate needed action on the over 6,750 existing chemicals produced above 25,000 lbs/yr in the U.S.
 - Includes High Production Volume (HPV) and Moderate Production Volume (MPV) chemicals
 - Builds off of prior efforts:
 - HPV Challenge
 - Inventory Update Reporting (IUR)
 - Canadian categorization, etc.
 - Make and publicly release screening level decisions and initiate needed action

^{*}Based on preliminary statistics from 2006 IUR Data



Screening Decision Process – HPV Chemicals

- Assess and prioritize HPV chemicals (1 million lbs/yr) based on available 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 (Risk Based Prioritizations) on the web
- Stakeholders will soon be able to post comments and submit data electronically



Tools to Implement Risk-Based Prioritizations (RBPs)

- Where additional info or action is needed, the options include:
 - Contact producers with request for info, informal action
 - Data from other offices, Agencies, States, Canada, EU, and 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. Design for the Environment (DfE), voluntary action, etc.)
 - TSCA §4 test rules
 - Develop/implement Challenge programs, other risk reduction actions
 - Possible creation of TSCA §5(b)(4) "risk list"
- Where identified as low-concern at this time:
 - Document initial prioritization rationale and post to web



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
- Posted Hazard Based Prioritizations (HBPs) on 38 MPV chemicals.



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 HCs for over 150 chemicals
- 2008
 - Posted HCs for additional 140 chemicals
 - Posted RBPs for 151 chemicals
 - Continue developing and posting RBPs
 - Posted initial set of HBPs for 38 MPV chemicals
- 2009
 - Continue posting RBPs for HPV chemicals and significantly ramp up posting MPV HBPs



ChAMP Enhancements

- On Sept. 24, EPA Assistant Administrator Jim Gulliford announced the Administrator's decisions 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 is currently engaging stakeholders on both of these efforts.



TSCA Inventory Reset

- Current TSCA Inventory contains almost 84,000 chemicals
 - Likely 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.
- An accurate Inventory would allow EPA to better plan and execute its mission of protecting human health and the environment from chemicals that may present risks.
- Complements IUR reporting.



Inventory Reset

- EPA is considering a "clean reset" which would remove chemicals no longer being manufactured or imported from the Inventory.
 - Reset could be achieved by putting the Inventory online and inviting companies to certify that they have manufactured or imported specific chemicals within a certain timeframe.
- A new chemical notice (e.g., PMN) would 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.



Inorganic Chemicals/IHPV

- Inorganics first included on IUR in 2006
 - 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

- EPA considering IHPV Challenge Program Mirroring HPV Challenge Design
 - Identify and work with stakeholders to develop program/process/approach

Proposed approach would:

- Look to OECD guidance and experience on inorganics
- Apply approaches and procedures similar to those used in HPV Challenge Program
- Apply established EPA Guidance on inorganics assessment
- Assess, prioritize, and initiate needed action on IHPV chemicals (2012-2014)



Stakeholder Engagement

- EPA sought 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 is seeking stakeholder input on the ChAMP enhancements (IHPV, reset) at a public meeting on December 8, 2008.



Opportunities for North American Collaboration

- 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.
 - Canada's DSL Challenge has identified and given tentative dates for review of 193 high priority chemicals
 - 66 of Canada's high priorities are also EPA HPVs
 - Additional overlaps are expected among Canada's medium priority chemicals and EPA's MPVs
- EPA and Canada are exploring ways to collaborate on chemicals of mutual interest
 - Sharing data on chemicals under review
 - Monthly conference calls
 - Attendance at brainstorming workshops, etc.



Resources

For more information:

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