

2008/SOM2/CD/010b

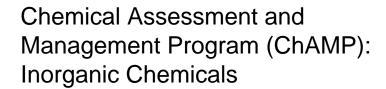
Agenda Item: 5

Chemical Assessment and Management Program (ChAMP): Inorganic Chemicals

Purpose: Information Submitted by: United States



7th Chemical Dialogue Meeting Arequipa, Peru 22 May 2008



Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency May 16, 2008

Inorganics in 2006 IUR

- o Inorganics first included on IUR in 2006
 - Production volume and other manufacturing (including importing) information only
 - No exposure-related data reporting until 2011
- o Examples:
 - metals & salts
 - ammonia & cmpds
 - minerals & fibers (bentonite, zeolite, asbestos, etc.)
 - inorganic acids (HCI, HNO₃, H₂SO₄, etc.)
- o 756 Inorganics
- o 400-500 HPV



Inorganics under ChAMP – IHPV Challenge

- EPA considering IHPV Challenge Program Mirroring HPV Challenge Design
 - Identify and work with stakeholders to develop program/process/approach
 - Proposed approach would apply:
 - o OECD guidance and experience on inorganics
 - Approaches and procedures similar to those used in HPV Challenge Program
 - Established EPA Guidance on inorganics assessment
 - Assess, prioritize, and initiate needed action on IHPV chemicals (2012-2014)

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Organization for Economic Cooperation and Development (OECD) HPV Program

- OECD HPV Program is a global hazard assessment program for HPV chemicals in which the US is a key participant.
- Screening Initial Data Set: Internationally Agreed Data for Hazard Assessment
 - Ecological Endpoints (3): Acute Fish, Aquatic Invertebrate and Aquatic Plants Toxicity: Chronic Toxicity if chemistry indicates.
 - Health Endpoints (5): Acute, Repeated-Dose Reproductive, Developmental and Genetic Toxicity
 - Other Toxicity Data, if available: e.g. eye or skin irritation, sensitization, carcinogenicity, neurotoxicity, etc.
- o OECD Process:
 - Data & Information Gathering
 - Dossier Development: Robust Summaries + SIDS Initial Assessment Report (SIAR) + SIDS Initial Assessment Profile (SIAP)
 - SIAM (SIDS Initial Assessment Meeting) Dossier Reviewed and Agreed
 (Agreed)
 - Dossier published by United Nations Environmental Programme (UNEP)
- ~100 HPV Inorganics are assessed or currently under assessment in the OECD SIDS program

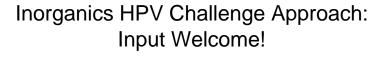


- Organics HPV Challenge developed and implemented in 1998-2005
- Similar Approach/Process would be used for Inorganics:
 - Sponsorship Commitment
 - Gather & Evaluate Available Data using available guidance: literature search, data adequacy, categories, use of QSARs, etc.
 - Prepare HPV Dossier
 - Identify data gaps & justify where testing is/is not needed
 - o Propose Test Plan for filling data gaps
 - Submit Test Plan to EPA for review, posting and public comment
 - Consider comments and revise test plan as appropriate
 - Conduct needed testing and submit revised final dossier to EPA

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Chemical Categories

- US HPV Challenge Program encourages grouping of similar chemicals into categories
- Use of categories:
 - accomplish the goal of obtaining screening- level hazard information through the strategic application of testing to the category;
 - if appropriately justified and supported (e.g. with pchem data and existing test data), interpolation and/or extrapolation can be used to assess the chemicals in lieu of conducting additional screening-level testing.
- o Example OECD Inorganics Categories:
 - Nitrates: ammonium, calcium, sodium, potassium
 - Zinc metal & salts: Zinc, Zinc oxide, Zinc chloride, Zinc sulfate, Zinc orthophosphate
 - Synthetic Crystalline Zeolites



- To submit comments via e-mail regarding the SPP efforts and possible enhancements, send to <u>oppt.ncic@epa.gov</u>; or
- Written comments to USEPA, CBIC, 1200 Pennsylvania Avenue, NW, Mail Code 7404, Room 6428, Washington, DC 20004. <u>Please reference docket</u> <u>number EPA-HQ-OPPT- 2008-0319</u> <u>when submitting comments.</u>