

# Proposed Approach for the Inorganics HPV Challenge Program (IHPV)

Oscar Hernandez, Director  
Louis Scarano, Toxicologist  
Risk Assessment Division  
Office of Pollution Prevention and Toxics

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# Overview

- Inorganics – Definition
- IHPV Proposal
  - General
  - Specific Issues (To Include Using Existing Information & Approaches)
- Next Steps



# Inorganics - Definition

Inorganic chemical substances are defined according to the TSCA Inventory Update Rule (IUR) as chemical substances that **do not contain carbon, or contain carbon only in the form of carbonato [ $=\text{CO}_3$ ], cyano [ $-\text{CN}$ ], cyanato [ $-\text{OCN}$ ], isocyano [ $-\text{NC}$ ], or isocyanato [ $-\text{NCO}$ ] groups, or the chalcogen analogues of such groups**



# IHPV Challenge Program-General

- The IHPV Challenge Program was recently announced as one of the enhancements to EPA's Chemical Assessment and Management Program (ChAMP)
- This effort is intended to:
  - characterize the toxicity, environmental fate and physical-chemical properties of inorganic chemicals that are manufactured or imported into the U.S. at volumes of greater than one million pounds per year and thereby
  - Enable assessment and initiation of needed follow-up action



# IHPV Challenge Program- General

- The HPV Challenge Program (1998-2008) focused on ~2800 organic chemicals
- 2006 Inventory Update Rule (IUR) included first reporting of inorganics – allowing identification of Inorganic HPVs
  - Production volume only (use/exposure info submitted in 2011)
  - **763** Inorganic submissions:
    - 446 Inorganic HPV\* chemicals
    - 317 Inorganic MPV\* chemicals

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\*H= High production volume (> 1 million pounds)

\*M = Moderate production volume (>25,000 and < 1 million pounds)



# IHPV Challenge Program - General

- EPA's current thinking is 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](http://www.regulations.gov) : EPA-HQ-OPPT-2008-0807)
  - EPA is interested in oral and written comments on its thinking
- Includes commitment to identify and work with stakeholders to develop and implement program/process/approach



# IHPV Challenge Program - General

- Phase 1: “Challenge” - Develop, Launch & Sign-Up
  - **Now Through December 2009**
- Phase 2: Implement the Challenge - Receive/Review Data
  - **~ 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
  - **~ 2013 – 2015**
  - **MPV inorganics would subsequently be assessed and prioritized**



# Specific Issues

- Design a program that takes full advantage of the OECD, Canadian Categorization and REACH work
- Use the cluster approach from the U.S. MPV effort
- Use information available from other sources, including feedback from this meeting and written comments



# Using Information from the OECD HPV Program

- OECD = Organization for Economic Cooperation and Development
- OECD HPV Program established in 1991 and served as basis for U.S. HPV Challenge Program
- Developed an internationally agreed upon Screening Information Data Set (SIDS)
- To date, there are 887 completed assessments (616 of which are posted) on international HPV chemicals



# Using Information from the OECD HPV Program

- There are approximately 160 inorganics in the OECD HPV Program
  - 51 are in the info-gathering/data review phase
  - 109 have gone through the process
- 115 (74 of which are HPVs)/756 2006 IUR inorganics are in the OECD HPV program
- OECD's existing guidance is a useful starting point for IHPV approach
- Inorganics that have gone through the OECD HPV process provide useful examples and input to the IHPV program



# Examples of OECD HPV Inorganic Cases

7440666	Zinc	Zinc metal and salts
7646857	Zinc chloride	Zinc metal and salts
7733020	Zinc sulfate	Zinc metal and salts
7779900	Zinc orthophosphate $Zn_3(PO_4)_2$	Zinc metal and salts
7705080	Iron trichloride	Iron salts and hydrates
7720787	Iron sulfate	Iron salts and hydrates
7758114	Dipotassium hydrogenphosphate	
7775099	Sodium chlorate	
7782630	Sulfuric acid, iron(2+) salt (1:1), heptahydrate	Iron salts and hydrates
10025771	Iron chloride, hexahydrate	Iron salts and hydrates
10028225	Iron (III) sulfate	Iron salts and hydrates
13463439	Ferrous sulfate hydrate, unspecified ( $FeSO_4 \cdot xH_2O$ )	Iron salts and hydrates
13520564	Ferric sulfate nonahydrate	Iron salts and hydrates
15244107	Ferric sulfate hydrate, unspecified ( $Fe_2(SO_4)_3 \cdot xH_2O$ )	Iron salts and hydrates
17375416	Ferrous sulfate monohydrate	Iron salts and hydrates
24290402	Ferric chloride hydrate, unspecified ( $FeCl_3 \cdot xH_2O$ )	Iron salts and hydrates
1066337	Ammonium hydrogencarbonate	
1333864	Carbon black	
2551624	Sulfur hexafluoride ( $SF_6$ )	



# IHPV Data Set

- OECD's SIDS for organic chemicals:
  - **Physical-chemical properties:** melting & boiling pts., vapor pressure, water solubility, octanol:water partition coefficient.
  - **Environmental fate:** photodegradation, stability in water, biodegradation, transport (model)
  - **Environmental effects:** acute toxicity in fish, aquatic invertebrates and aquatic plants
  - **Health effects:** acute and subchronic toxicity, genetic toxicity, reproductive and developmental toxicity



# IHPV Data Set

OECD has identified a number of parameters that need to be considered in describing the physical-chemical properties of inorganic chemicals:

- Degree of dissociation of metal-containing compound (i.e., the ligand-metal dissociation)
- Chemical speciation and valency
- Crystalline structure
- Particle size
- In vitro solubility



# IHPV Data Set

- EPA expects to consider and refine the OECD's recommended approach and will share that understanding with the OECD. For example:
  - Similar information for physical-chemical properties as on previous slide plus additional considerations for environmental fate
  - bioavailability will play a key role for both aquatic toxicity and mammalian toxicity and EPA is considering building such screens into the IHPV data set.



# Canada's Categorization Information

- As required under the Canadian Environmental Protection Act of 1999, Canada categorized (prioritized) 23,000 chemicals on the DSL (Domestic Substances List; akin to our inventory) in September, 2006
- EPA will look and apply the results of the Canadian categorization where relevant to the IHPV program



# EU/REACH Information

- REACH = Registration, Evaluation, Authorization and Restriction of Chemicals
  - EU law that went into effect in June, 2007
- EPA has discussed collaboration approaches with the European Commission and the European Chemicals Agency and gotten a positive response
- EPA will look at inorganic chemicals submitted to REACH during the pre-registration period (June 1 to December 1, 2008) for information relevant to the IHPV program
- REACH HPV registration data sets would more than meet IHPV Challenge needs



# Cluster Approach

- In ChAMP's Moderate Production Volume (MPV) Hazard-Based Prioritization (HBP) effort, chemicals are grouped by EPA into clusters based on structural analogy
- Relatively 'data-rich' analogs (e.g. HPV Challenge chemicals) are included in clusters for 'data sharing' purposes
- For inorganics, a similar, EPA-initiated cluster approach is being considered



# Potential Inorganic Cluster Example

<b>10361-37-2</b>	<b>Barium chloride (BaCl<sub>2</sub>)</b>
<b>7787-32-8</b>	<b>Barium fluoride (BaF<sub>2</sub>)</b>
<b>17194-00-2</b>	<b>Barium hydroxide (Ba(OH)<sub>2</sub>)</b>
<b>1304-28-5</b>	<b>Barium oxide (BaO)</b>
<b>21109-95-5</b>	<b>Barium sulfide (BaS)</b>
<b>12047-27-7</b>	<b>Barium titanium oxide (BaTiO<sub>3</sub>)</b>



# Other Sources of Information

- EPA Risk Assessment Forum – *Framework for Metals Risk Assessment (2007)* and related issue papers (<http://epa.gov/osa/metalsframework/index.htm>)
- OECD guidance on categories ([http://appli1.oecd.org/olis/2007doc.nsf/linkto/env-jm-mono\(2007\)28](http://appli1.oecd.org/olis/2007doc.nsf/linkto/env-jm-mono(2007)28))



# Next Steps

- Late summer of 2009, EPA will:
  - have reviewed the OECD, Canadian, and available REACH pre-registration information
  - propose clusters for inorganic HPVs
- Fall of 2009, EPA will host a workshop to further elaborate the issues and refine approaches
- EPA plans to subsequently initiate the sponsor sign-up opportunity and implement the IHPV Challenge Program as outlined above



# Thank you and....

## ***Looking forward to your comments***

- EPA will provide a summary of comments made at today's meeting.
- Any further comments should be submitted to the public docket for the Inventory Reset: EPA–HQ–OPPT–2008–0807
- Email to [scarano.louis@epa.gov](mailto:scarano.louis@epa.gov)