Proposed Approach for the Inorganic High Production Volume (IHPV) Challenge Program

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Background

1. EPA is committed to developing a program to characterize the toxicity, environmental and physicochemical properties of inorganic chemicals that are manufactured or imported into the U.S. at volumes of greater than one million pounds. This is one of the enhancements under the Chemical Assessment and Management Program (ChAMP) and is known as the Inorganic High Production Volume (IHPV) Challenge Program. This effort will also contribute to meeting U.S. commitments to chemical assessment and management in North America.

2. The proposed IHPV Challenge Program follows the successful U.S. HPV Challenge Program for organic chemicals which took place from 1998 to 2008. During this time, industry rose to the challenge of providing largely unpublished hazard information on approximately 2200 organic chemicals and making this information publicly available. The information gained from the HPV Challenge Program has formed the nucleus of the ChAMP effort.

3. EPA believes the inclusion of an IHPV Challenge Program as part of the ChAMP/SPP effort is an important step in characterizing the hazard of inorganic chemicals produced or imported into the U.S. at volumes of greater than one million pounds per year. According to the latest figures from the 2006 Inventory Update Rule (IUR), there are approximately 750 inorganic chemicals in commerce, 400-500 of which are HPV.

4. 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 [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups (see 40 CFR 710.46(b) (3) at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cd705e70bc49caa13112968d68ceab8d&rgn=div5&view=text&node=40:30.0.1.1.5&idno=40). Such chemical substances include metals, ammonia, minerals, and inorganic acids

5. This document provides some details on a proposed approach to developing the IHPV Challenge Program. Briefly, the program will consist of three phases:

- Phase 1: IHPV Challenge – Develop, Launch and Sign-Up (Now Through December 2009)
- Phase 2: Receive/Review Data (~ 2010 – 2013)

  - In addition, after an appropriate period for sponsorship, EPA plans to initiate rulemaking (TSCA §4, §8) to obtain needed information on unsponsored chemicals
- Phase 3: Assessing and Reducing Risks (~ 2013 – 2015)
  - Develop and release Risk Based Prioritizations (RBPs) for HPV inorganic chemicals (taking advantage of the 2011 Inventory Update Rule (IUR) exposure data for inorganic chemicals).
  - Initiate needed action on IHPV chemicals as required based on prioritization.
  - Develop and release Hazard Based Prioritizations (HBPs) for Moderate Production Volume (MPV) inorganic chemicals.

6. This proposal is limited to a discussion of Phase 1.

General Concept of the Proposal

7. The goal of this effort is to characterize the hazard of high production volume inorganic chemicals. The term "hazard" is intended to include the physical-chemical properties, environmental fate, environmental toxicity, and human health toxicity of chemical. The organic HPV program – modeled after the Organization for Economic Cooperation and Development (OECD) HPV program – defined a set of minimal information that could be used to define the hazard of a (organic) chemical (http://www.oecd.org/dataoecd/60/43/1947477.pdf). EPA recognizes that the hazard information needed to characterize inorganic chemicals may be different from data sets used to describe the hazard of organic chemicals. In addition, EPA further expects that the IHPV Challenge Program will gain from past (HPV Challenge Program) and current (Canadian CEPA, OECD HPV Challenge cases with inorganic chemicals, and EU REACH; see below) activities to improve its approach.

8. A number of issues presented below reflect those that EPA believes are important to developing an IHPV Challenge Program.

Activities that EPA is Considering

Gathering Information

9. EPA plans to take advantage of activities that are ongoing in the OECD, Canada and Europe.

10. The OECD HPV Challenge Program started in 1991 and is still ongoing. The OECD program has a master list of HPVs which is much larger than the US HPV organic chemicals list because it is a compilation of HPVs across the more than 30 member countries. This voluntary OECD effort is similar to the U.S. HPV Challenge program in that the hazard information presented in the international forum is in large part due to the voluntary efforts of the private sector. However, the governmental authorities generally determine the cases that are developed and discussed at international meetings. The OECD program has processed a little over 100 inorganic chemical HPV cases and there are approximately 50 that

are in various stages of completion. Importantly, about 100 of the 400-500 U.S. inorganic HPV chemicals are in the OECD HPV program.

11. The Canadian Environmental Protection Act (CEPA) of 1999 required the Canadian government to screen their Domestic Substances List (DSL) for hazard and exposure. During the course of carrying out this mandate, Canada developed guidance for screening which included some information on evaluating inorganic chemicals (http://www.ec.gc.ca/substances/ese/eng/dsl/guidance_document.cfm). In September of 2006, Canada completed their screening activity, the results of which can be seen at http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm .

12. The recently passed European legislation to regulate chemicals in commerce is known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). The law just recently went into effect (June of 2008). The first step in the legal process is the pre-registration of chemicals in commerce. EPA plans to work closely with both U.S. industry and the European authorities to identify among the list of U.S.high production volume inorganic chemicals those which are submitted in the six-month pre-registration period (June – December, 2008) under REACH (http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx). This may help provide information on two fronts: (a) identify U.S. inorganic chemicals which are or are not among those being dealt with under REACH, and (b) help inform understanding whether category approaches are employed.

Learning from the Organic Chemical HPV Challenge Program: The Hazard Data Set

13. EPA is considering the full range of data elements that make up the Screening Information Data Set (SIDS) and examining their applicability for inorganic chemical hazard evaluation (http://www.oecd.org/dataoecd/60/43/1947477.pdf). EPA is considering changes in the minimal hazard data set to reflect the data elements appropriate for characterization of the range of inorganic chemicals included in this proposal(see both EPA, 2007 and OECD, 2007).

Learning from the Moderate Production Volume (MPV) Program: The Use of Clusters

14. Screening-level hazard characterizations for medium production volume chemicals (MPVs) are important contributions to the chemicals cooperation work being done in North America through the ChAMP (see http://www.epa.gov/champ/pubs/abouthbp.htm for a full description of this program). The MPV program began with organizing all organic chemicals into structurally-related clusters (see http://www.epa.gov/champ/pubs/MPV_Hazard_Characterization_Protocol_September_2008.pdf) . This was a useful exercise that EPA plans to use with the inorganic chemical HPV Challenge Program. To the extent allowable by structural similarities, EPA plans to group inorganic chemicals into clusters and to discuss these clusters with the public at a workshop in the fall of 2009. EPA expects that discussions with stakeholders and information gathered through the program to eventually refine the clusters into possible categories for the IHPV Challenge Program.

15. The use of categories (or grouping of chemicals for the purpose of hazard characterization) is an important and pragmatic feature of both the U.S. and OECD HPV Challenge Programs. By starting with cluster arrangements as was done in the MPV program, and considering the recent update of the OECD HPV guidance document on creating categories which includes an improved section on creating categories with inorganic chemicals (see Section 6.6 of in OECD 2007), EPA believes the IHPV Challenge Program will have a strong start.

REFERENCES

U.S. EPA, 2007. *Framework for Metals Risk Assessment.* EPA 120/R-07/0001. March 2007. www.epa.gov/osa .

OECD. 2007 *Guidance on Grouping of Chemicals.* Series on Testing and Assessment No. 80. ENV/JM/MONO (2007)28. pp. 72-77. http://appli1.oecd.org/olis/2007doc.nsf/linkto/env-jm-mono(2007)28