# Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment

This discussion guide is intended to be used to help structure public input during the September 2011 webinar and discussion forum addressing the prioritization factors and data sources EPA plans to use to identify priority chemicals for review and assessment under the Toxic Substances Control Act (TSCA). This effort is part of EPA's comprehensive approach to enhance the Agency's current chemicals management program.

This discussion guide provides the following information:



## Goal of Prioritization

EPA intends to identify priority chemicals for review and possible risk management action under TSCA. Identification of a chemical as a priority chemical for review would not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment. Rather, identification of a chemical as a priority chemical would indicate only that the Agency intends to review it on a priority basis. The Agency believes that identifying these chemicals early in the review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency's attention in order to further inform the review. In order to take risk management actions on a chemical substance under various sections of TSCA, the Agency would have to make the appropriate findings required by the specific provisions of the statute.

Identification of some chemicals as priority chemicals for review does not mean that EPA would not consider other chemicals for risk assessment and potential risk management action. EPA will consider other chemicals if warranted by available information. In addition, EPA may subsequently identify other priority chemicals for review in addition to this initial group. Further, while the chemicals identified as priority chemicals for review will likely be well-characterized for hazard and have information indicating exposure potential, EPA will continue to use its TSCA information collection, testing, and subpoena authorities, including sections 4, 8, and 11(c) of TSCA, to develop needed information on additional chemicals that currently have less robust hazard or exposure databases.

## Two-Step Process

EPA is planning to use a two-step process to identify priority chemicals for review and assessment.

In Step 1, EPA plans to identify an initial group of priority chemicals for review by using a specific set of data sources to identify chemicals that meet one of more of the Action Plan priority factors.

***EPA is seeking public input on two related aspects of Step 1:***
***(a) Prioritization Factors; and (b) Data Sources for Prioritization Factors.***

In Step 2, EPA intends to refine that group by using a broader range of data sources to further analyze and select specific chemicals from the initial group for further assessment.

***EPA is seeking input on the Data Sources for Further Analysis to be used in Step 2.***

As EPA works through the initial set of priority chemicals, the Agency may repeat this two-step process to select subsequent chemicals for review and assessment.

## Step 1: Identify Priority Chemicals for Review

### (a) Prioritization Factors and Discussion Questions for Input

To identify candidate chemicals for review, EPA intends to consider risk-based prioritization factors consistent with the criteria used in selecting the initial chemicals on which EPA prepared chemical Action Plans from December 2009 through April 2011. The Action Plans for these chemicals identified a range of actions the Agency has begun to implement, from voluntary phase-outs and alternatives assessments in cooperation with industry and other stakeholders, to the development of test rules to require the development of additional data under section 4 of TSCA, to controls or use restrictions under sections 5 or 6 of TSCA. These factors are:

- Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects).
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.
- Chemicals used in children's products.
- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.

Children's health issues, PBT chemicals, and carcinogens are among the Agency's highest hazard-based priorities, while use in children's products or other consumer products or detection in biomonitoring programs suggest a potential for exposures to the general population, including vulnerable populations such as children. Of course, the uses of interest must be subject to TSCA (i.e., the chemical is not used only as a pesticide, food additive, cosmetic, pharmaceutical, or other use specifically excluded from TSCA regulation).

Chemicals meeting one or more of these Action Plan prioritization factors would become part of the initial group of priority chemicals for review.

***EPA would like to get public input on these prioritization factors, including:***

- ***What other factors, if any, should the Agency add, and why?***
- ***Please discuss which prioritization factors, if any, should receive greater consideration than others.***

### (b) Data Sources for Prioritization Factors and Discussion Questions for Input

***EPA would like to get public input on the data sources that the Agency intends to use to identify chemicals that meet one or more of the Step 1(a) priority criteria factors, including:***

- ***Which other data sources, in addition to those listed in Table 1 below, should the Agency consider in order to identify chemicals that meet the listed factors? Why should such data sources be added?***
- ***For any additional priority criteria factors you might propose, what data sources should be considered to identify chemicals meeting those factors?***
- ***Please explain your concerns or comments, if any, relating to the data sources featured in Table 1.***

- ***Please discuss which data sources, if any, should receive greater consideration than others.***

For each of the Action Plan prioritization factors, these data sources are:

**Table 1**
**Data Sources for Overall Identification of Priority Chemicals**

| Factor | Data Sources | Definition |
|---|---|---|
| PBT | TRI PBT Rule<br>Great Lakes Binational Toxics Strategy<br>Canadian Categorization<br>EPA Region 5 PBT Identification Project (Syracuse Research Corp.)<br>Chemicals proposed to UNECE LRTAP POPs and Stockholm Convention on POPs | P, B, and T as defined in the specific data source |
| Carcinogenicity | Integrated Risk Information System (IRIS)<br>International Agency for Research on Cancer (IARC)<br>National Toxicology Program (NTP)<br>California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) | **IRIS:** A or B1, or known or likely to be carcinogenic to humans<br>**IARC:** 1 or 2A<br>**NTP:** known or reasonably anticipated to be carcinogenic to humans<br>**CA:** Known to the state to cause cancer |
| Potential Children's Health Concern | Voluntary Children's Chemical Evaluation Program<br>California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)<br>IRIS<br>NTP CERHR Monographs | **VCCEP:** Named in program<br>**CA:** Known to the state to cause reproductive toxicity<br>**IRIS:** Non-cancer RfD or RfC is based on repro/dev effects<br>**NTP:** "Some concern," "concern," or "serious concern" for effects on fetuses, infants, or children at current human exposures; or effects on offspring from exposure of pregnant women; or repro effects in exposed adults |
| Children's Product Use | Washington State Children's Safe Product Act<br>Inventory Update Reporting (IUR, 2006) | **WA:** Listed in the Children's Safe Products – Reporting rule<br>**IUR:** Any report that used in products intended for use by children |

| Factor | Data Sources | Definition |
|---|---|---|
| Consumer Product Use | Inventory Update Reporting (IUR, 2006)<br>National Institutes of Health (NIH) Hazardous Substances Data Bank<br>Danish Consumer Product Studies | **IUR:** Any report of "consumer/commercial" use<br>**Others:** Identified as being in consumer product |
| Human Biomonitoring | National Health and Nutrition Examination Survey (NHANES)<br>National Human Adipose Tissue Survey (NHATS)<br>National Human Exposure Assessment Survey (NHEXAS)<br>Total Exposure Assessment Methodology | Reported in any of the data sources |

## Step 2: Select Priority Chemicals For Assessment

### Data Sources for Further Analysis and Discussion Questions for Input

After identifying a group of chemicals for priority review, the second step of EPA's planned process is to use information from additional exposure and hazard data sources to further analyze the chemicals to select specific chemicals for further assessment, including possible risk assessment and risk management action.

***EPA would like to get public input on the data sources that the Agency intends to use in this further analysis, including:***

- ***Should additional data sources beyond those listed in Tables 2 and 3 below be included? What sources, and why?***
- ***Please explain your concerns or comments, if any, relating to the data sources featured in Tables 2 and 3.***
- ***Please discuss which data sources, if any, should receive greater consideration for analysis than others.***

EPA is planning to use the particular sources identified below in Tables 2 and 3. Table 2 lists exposure and use-related information data sources. Table 3 lists hazard data sources.

**Table 2**
**Exposure Data Sources for Screening Priority Chemicals for Assessment**

| **Exposure and Use Information** | |
|---|---|
| **Data Type** | **Data Source** |
| Uses | Inventory Update Reporting and Chemical Data Reporting (IUR/CDR)<br>Premanufacture Notice (PMN) Database (confidential)<br>High Production Volume (HPV) Challenge Submissions<br>Screening Information Data Sets (SIDS) Documents<br>National Institutes of Health (NIH) Household Product Database<br>NIH Hazardous Substances Data Bank |
| Environmental releases | Toxics Release Inventory (TRI)<br>National Emission Inventory (NEI) Database U.S. EPA<br>Preliminary Assessment Information Reporting (PAIR)<br>Organization for Economic Cooperation and Development (OECD) Emission Scenario Documents<br>NIH Hazardous Substances Data Bank |

| Exposure and Use Information | |
|---|---|
| **Data Type** | **Data Source** |
| General human exposures, including indoor air contaminants | Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study<br>Brown et al., *Indoor Air*, 4:123-134, 1994.<br>Daisey et al., *Atmospheric Environment*, 28 (22): 3557-3562, 1994.<br>Kelly et al., *Environmental Science & Technology*, 28(8): 378A-387A, 1994.<br>NOPES Final Report, EPA/600/3-90/003 (NTIS PB90-152224), January 1990.<br>Samfield, M.M. Indoor air quality data base for organic compounds. Govt. Reports Announcements & Index (GRA&I), Issue 12. EPA-600-R-92-025 (NTIS PB92-158468), 1992.<br>Shah and Singh, *Environmental Science & Technology*, 2(12): 1381-1388, 1988.<br>Sheldon et al., *Indoor Pollutant Concentrations and Exposures*, California Air Resources Board, Contract A833-156, Final Report, January 1992.<br>Shields, et al., *Indoor Air*, 6:2-17, 1996. |
| Worker exposures | Inventory Update Reporting and Chemical Data Reporting (IUR/CDR)<br>National Occupational Exposure Survey (NOES)<br>Occupational Safety and Health Administration (OSHA) monitoring studies<br>Preliminary Assessment Information Reporting (PAIR)<br>OECD Emission Scenario Documents<br>NIH Hazardous Substances Data Bank |
| Environmental exposures | Contaminant Exposure and Effects-Terrestrial Vertebrates database (CEE-TV)<br>EPA Environmental Monitoring and Assessment Program (EMAP)<br>EPA's Databases on Monitoring and Assessing Water Quality<br>List of Drinking Water Contaminants and their Maximum Contaminant Levels (MCLs)<br>National Air Quality System (AQS) U.S. EPA<br>National Contaminant Occurrence Database (NCOD) U.S. EPA<br>Current National Recommended Water Quality Criteria U.S. EPA<br>National Water-Quality Assessment Program (USGS NAWQA)<br>EPA Fish Tissue Studies<br>National Sediment Inventory (NSI) Tissue Data<br>National Status and Trends Program (NSTP)<br>National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data U.S.G.S. |

**Table 3**
**Hazard Data Sources for Screening Priority Chemicals for Assessment**

| **Hazard Information (Data on all toxicological endpoints)** | |
|---|---|
| **Providers/ Data Source** | **Description** |
| National Library of Medicine Databases | http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp<br>Accessed through ChemID Plus, searching on a chemical name or ID produces results that are linked to all NLM databases, including:<br>Biomedical Citations From PubMed<br>Toxicology Citations From PubMed<br>Registry of Toxic Effects of Chemical Substances (RTECS)<br>NLM TOXLINE on TOXNET<br>Agency for Toxic Substances and Disease Registry (ATSDR) Medical Management Guidelines<br>ATSDR Public Health Statements<br>ATSDR Toxicological Profiles<br>ATSDR ToxFAQS |
| TSCATS | The Toxic Substance Control Act Test Submission Database<br>http://www.syrres.com/esc/tscats.htm |
| USEPA - Office of Pesticide Programs | http://www.epa.gov/pesticides/reregistration/status.htm<br>http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html |
| USEPA - Ambient Water Quality Criteria Documents | http://www.epa.gov/waterscience/criteria/wqcriteria.html |
| USEPA - Drinking Water Standards Health Effects Support Documents | http://www.epa.gov/safewater/standards.html |
| USEPA - ECOTOX Database | http://www.epa.gov/ecotox |
| IPCS Concise International Chemical Assessment Documents (CICADs) | http://www.inchem.org/pages/cicads.html |