



Overview of TSCA Work Plan Methodology

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Public Process

- Public Process steps in development of Work Plan Methods document
 - August 2011 EPA published online Discussion Guide
 - Explained 2-step process to identify chemicals
 - September 7, 2011
 - Stakeholder meeting
 - Webinar
 - Online discussion forum open through September 21, 2011
 - Modifications based on public comment resulted in TSCA Work Plan Methods document



Methods Document

- Describes the methodology EPA used to identify work plan chemicals
- Step 1 Factors and Data Sources
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 - Step 1 Excluded Chemicals
- Step 2 Criteria
 - Hazard
 - Exposure
 - Persistence and Bioaccumulation
- Step 2 Categorizing Chemicals
 - Work Plan Chemicals
 - Potential Data Gathering Chemicals



Step 1 Factors

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



Step 1 Factors and Data Sources

- Known or probable carcinogen
 - IRIS Classification
 - 1986 A, B1; 1996 Known or probable, 1995/2005 Carcinogenic
 - IARC Group 1 or 2A
 - NTP Classification as Known Carcinogens
- Persistent, Bioaccumulative, Toxic Chemicals
 - TRI PBT Rule
 - Great Lakes Binational PBT
 - Canadian P, B and T (all three criteria met)
 - UNECE LRTAP POPs
 - UNEP Stockholm Convention POPs



Step 1 Factors and Data Sources

- Children's Health
 - IRIS: RfD or RfC for reproductive or developmental effects
 - NTP CERHR: Infants Any Effect, Pregnant Women Any Effect
 - California Proposition 65: Reproductive
- Neurotoxicity
 - IRIS: RfD or RfC based on neurotoxic effects
- Children's Product Use
 - 2006 IUR: Reported in products intended for use by children
 - Washington State Children's List



Step 1 Factors and Data Sources

- Biomonitoring
 - Addressed both human biomonitoring and environmental monitoring indicative of human exposure
 - NHANES
 - Drinking Water Contaminants
 - Fish Tissue Studies
- Step 1 identified 1,235 chemicals



Step 1 Excluded Chemicals

- Pesticides, drugs, radioactives
 - Statutorily excluded under TSCA
- Already the subject of an Action Plan
- Subject to regulation under development
- Complex process streams, other highly variable batches
- Polymers
- Common oils, fats, plant extracts
- Gases, naturally-occurring (only) chemicals, combustion products
- Explosive, pyrophoric, extremely reactive or corrosive
- Metals principally toxic to the environment
- **Remaining 345 chemicals entered Step 2**



Step 2 Criteria

- Chemicals scored using numerical algorithm based on combination of 3 characteristics
 - Hazard
 - Exposure
 - Persistence and Bioaccumulation
- Data available for all three factors
 - Chemical was binned as High, Moderate or Low
- Chemical could not be scored for hazard, or not for exposure (but high or moderate for hazard or persistence and bioaccumulation)
 - Chemical was binned for potential data gathering



Step 2 Hazard

- Highest hazard score for any single human health or environmental toxicity endpoint became chemical hazard score
- Hazard classification criteria based on *DfE Alternatives Assessment Criteria for Hazard Evaluation*, August 2011
- Score based on readily available data
 - Screening-level review
 - If high score for any endpoint, identified as high



Step 2 Hazard

- Endpoints scored as High (3) Moderate (2) or Low (1)
 - Acute Mammalian Toxicity
 - Carcinogenicity (High includes presumed, suspected, likely)
 - Mutagenicity/Genotoxicity
 - Reproductive Toxicity
 - Developmental Toxicity
 - Neurotoxicity
 - Chronic Toxicity
 - Respiratory Sensitization
 - Acute Aquatic Toxicity
 - Chronic Aquatic Toxicity



Step 2 Exposure

- Exposure Score based on combination of:
 - Use Type
 - Likelihood of potential exposures based on use
 - Consumer products: consider form, how widespread use
 - Industrial/commercial uses: consider dispersives
 - General Population and Environmental Exposure
 - Measured data in biota, environmental media
 - Release to Environment
 - Toxics Release Inventory data
 - Where no TRI, calculation using IUR/CDR production volume, number of sites, release potential from type of use



Step 2 Persistence/Bioaccumulation

- Persistence and bioaccumulation
 - Chemicals that are persistent and bioaccumulative are of particular concern because they can build up in the environment and organisms
- Used TRI and TSCA New Chemicals Program PBT criteria for ranking each factor separately
- Where no data, used EPI Suite 4.10 estimate
- Individual P and B scores were summed, then normalized to generate a P/B score (3, 2, 1)



Step 2 Categorizing Chemicals

- Normalized Hazard, Exposure and P/B scores were summed
 - High: 7 to 9
 - Moderate: 4 to 6
 - Low: 1 to 3
- Work Plan Chemicals are chemicals that scored high
 - 83 chemicals
- Chemicals that could not be scored were classified as Potential Data Gathering Candidate
 - 45 chemicals



2014 Update to Work Plan Chemicals List

- In 2014, EPA updated the TSCA Work Plan
- Using same methodology with newer data received as part of the Chemical Data Reporting Rule and the Toxics Release Inventory
 - Production volume and uses of some chemicals have changed
- Screened the 345 chemicals identified in 2012, the Action Plan chemicals, and several flame retardants



2014 Update to Work Plan Chemicals List

- Changes to the Work Plan chemicals identified in 2012:
 - 15 chemicals removed (Most no longer in production)
 - 1 chemical consolidated into a category
 - 23 chemicals added
 - 10 had 'moderate' score before; now have 'high' score generally based on new exposure information
 - 13 were chemicals screened for the first time
- Chemicals that scored high in 2014
 - 90 Work Plan chemicals



Thank you!