



TSCA Work Plan Methodology and Chemicals



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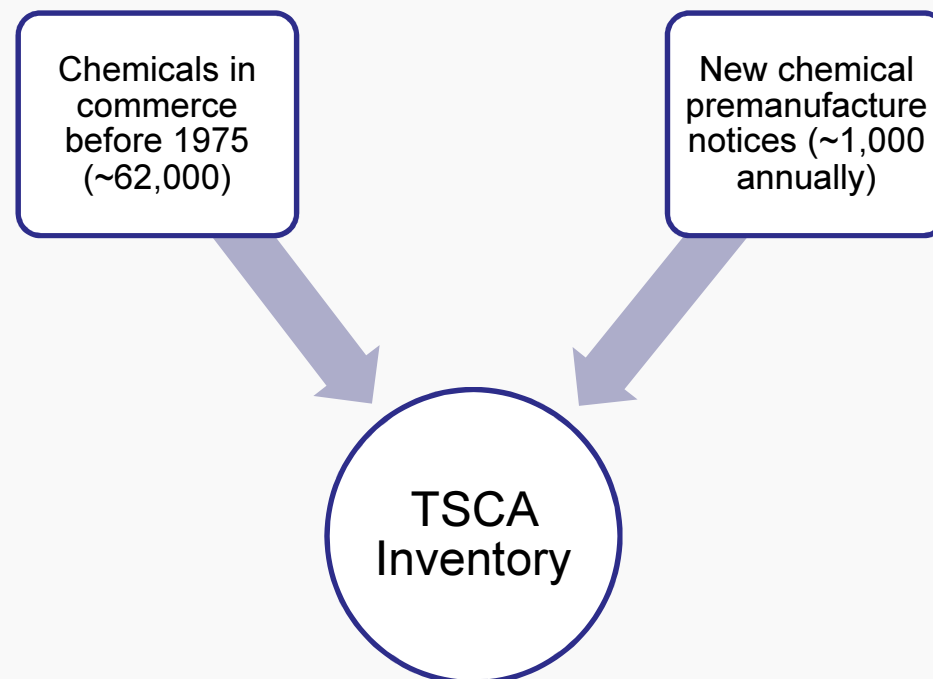
TSCA Work Plan Chemicals

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Background: Existing Chemicals

- Under the Toxic Substances Control Act, EPA is charged with:
 - Assessing the safety of commercial chemicals
 - Taking action if there are unreasonable risks to human health and the environment
- How many chemicals?
TSCA Inventory exceeds 84,000 chemicals





Background: Existing Chemicals

- EPA has adopted a multi-pronged approach to meet statutory requirements for such a large group of chemicals
 1. Risk assessment and risk reduction
 2. Data collection and screening
 3. Public access to chemical data and information



Need for Prioritization



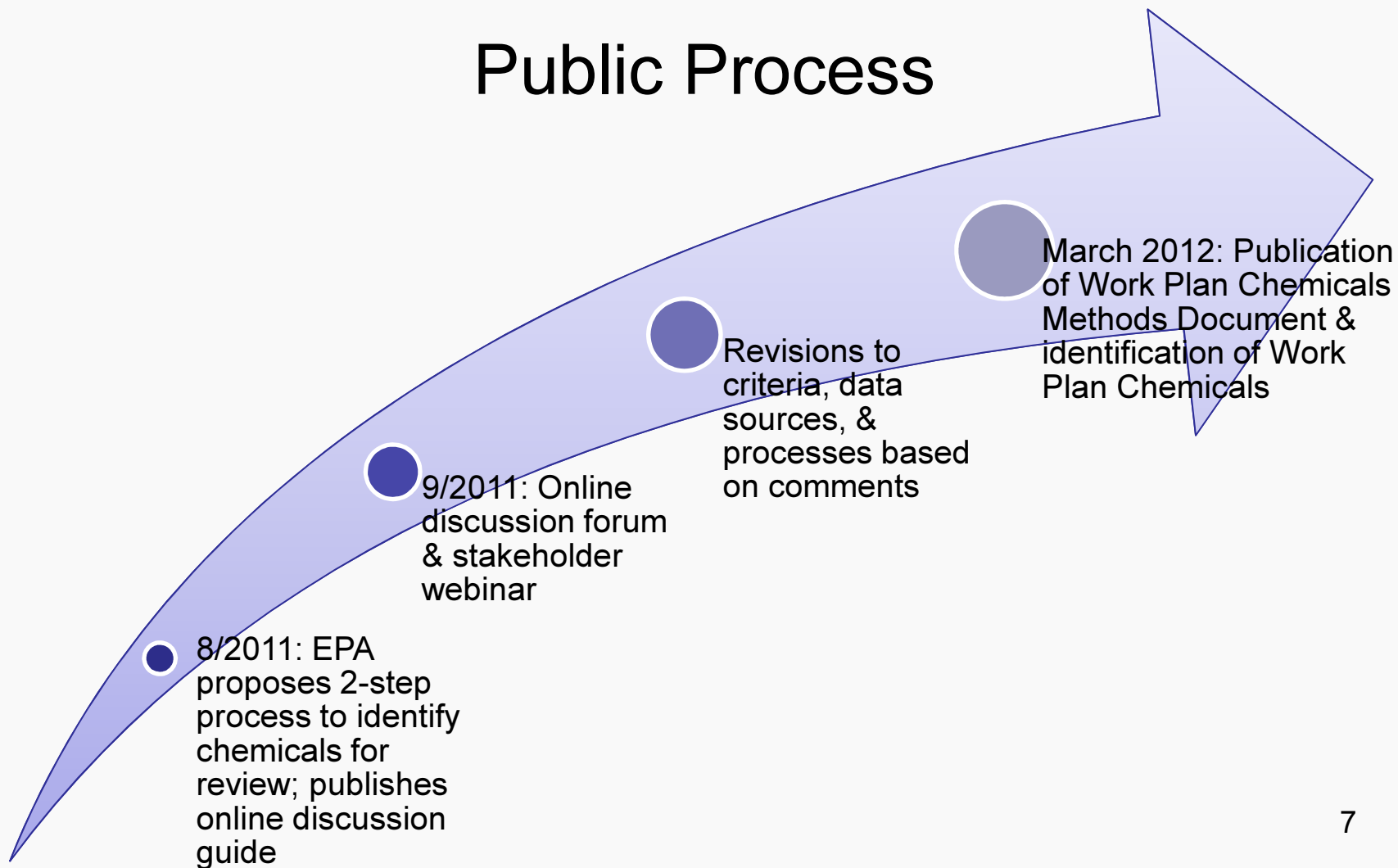


Need for Prioritization

- TSCA Work Plan provides prioritization
 - For chemicals with well-characterized hazards and significant exposure: Risk assessments & appropriate risk management
 - This is a small number of chemicals relative to the TSCA Inventory
 - Other chemicals: screened to determine which warrant future attention
- Methods for screening & prioritization developed with stakeholder participation



Public Process





TSCA Work Plan Methodology

- Step 1: Identification of potential candidate chemicals
 - Key factors
 - Chemicals excluded from Step 2
- Step 2: Screening
 - Hazard
 - Exposure
 - Persistence/Bioaccumulation



Step 1: Overview

- Identification of potential candidate chemicals
 - Known or probable carcinogenicity
 - Persistent, Bioaccumulative, Toxic (PBT)
 - Children's health
 - Neurotoxicity
 - Children's product use
 - Biomonitoring (human and environmental)
- Step 1 identified 1,235 chemicals meeting at least 1 factor



Step 1: Criteria and Data Sources

- Known or probable carcinogenicity
 - IRIS 1986 A, B1; 1996 Known or probable, 1995/2005 Carcinogenic
 - IARC Carcinogens, Group 1, 2A
 - NTP Known Carcinogens
- PBT
 - TRI PBT Rule
 - Great Lakes Binational PBT
 - Canadian P, B and T (all three criteria met)
 - LRTAP POPs
 - Stockholm POPs



Step 1: Criteria 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 effects
- 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: Criteria 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 meeting at least 1 criterion

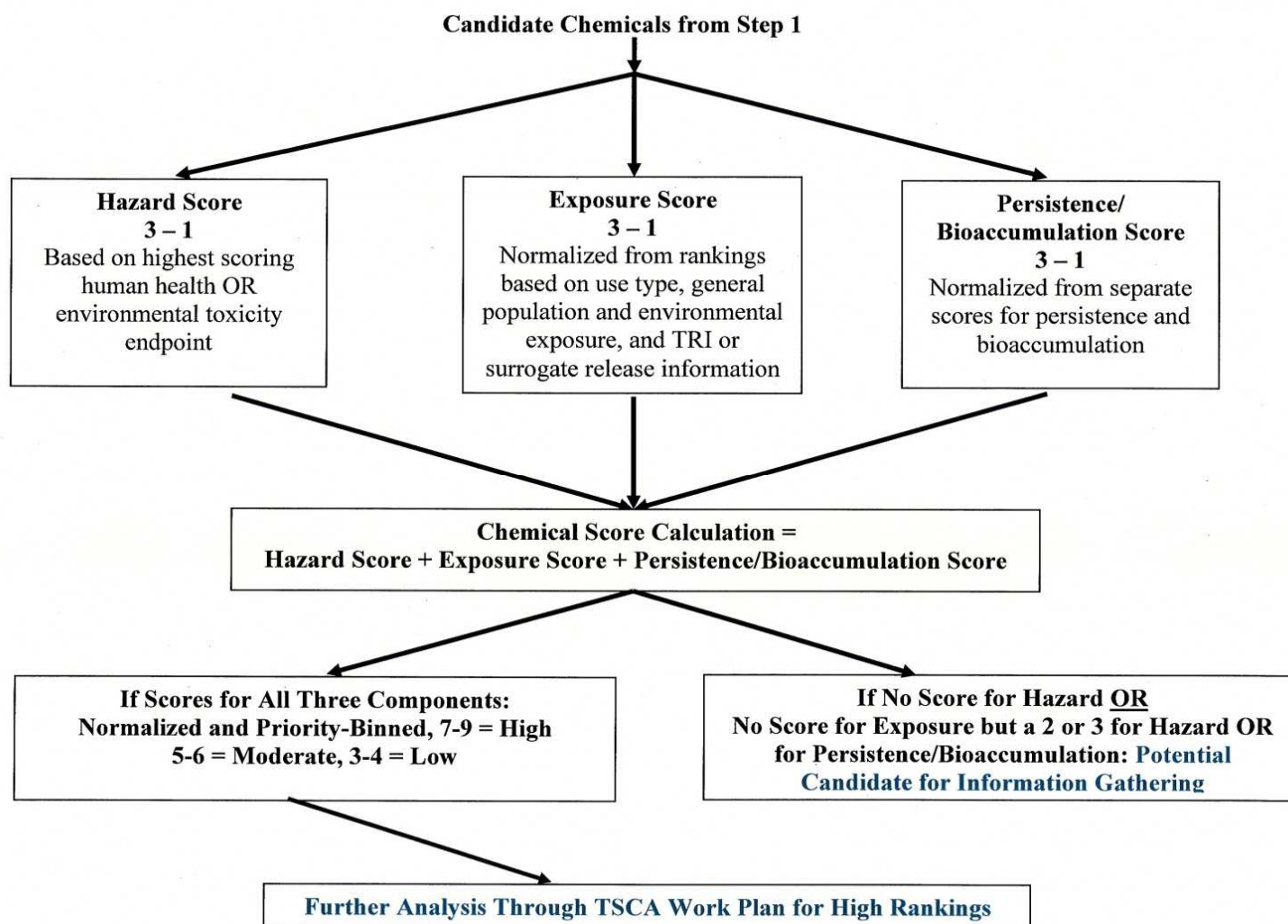


Chemicals Excluded from Step 2 Screening

- Many Step 1 chemicals are not practical for action under TSCA; excluded from further screening
 - Excluded from TSCA: Pesticides, drugs, radioactives
 - Already subject to Action Plans, ongoing regulation
 - Complex process streams, other highly variable batches
 - Polymers, not toxic common oils/fats/plant extracts
 - Gases, naturally occurring, combustion products
 - Explosive, pyrophoric, extremely reactive or corrosive
 - Metals principally toxic to environment, not humans
- Remaining 345 chemicals entered Step 2



Step 2: Overview





Step 2: Overview

- Chemicals were scored with a numerical algorithm based on a combination of 3 characteristics:
 - Hazard
 - Exposure
 - Persistence/Bioaccumulation
- With scores on all 3, chemicals were binned as High, Moderate or Low based on normalized total score
- If scores were missing, the chemical was moved to a separate bin for potential data gathering



Step 2: Hazard

- Hazard score = highest hazard score for any single human health or environmental toxicity endpoint
- Hazard classification criteria based on DfE Alternatives Assessment Criteria for Hazard Evaluation, August 2011
- Score based on readily available data
 - Screening only, not exhaustive. If High score for any endpoint, no other data sought
 - No judgment made concerning gaps in or completeness of available data set for any given chemical



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 dispersion, bystanders
 - General Population and Environmental Exposure
 - Measured data in biota, environmental media
 - Release to Environment
 - TRI data where available
 - Where no TRI, calculation using IUR/CDR production volume, number of sites, release potential from type of use



Step 2: Exposure

- Separate scores for each factor were summed, then normalized to provide a single Exposure score (High 3, Moderate 2, Low 1)
- Few chemicals have measured presence data; exposure scores for non-measured chemicals normalized across remaining two criteria (Use Type, Releases) to avoid scoring bias either against or in favor of chemicals with more data available

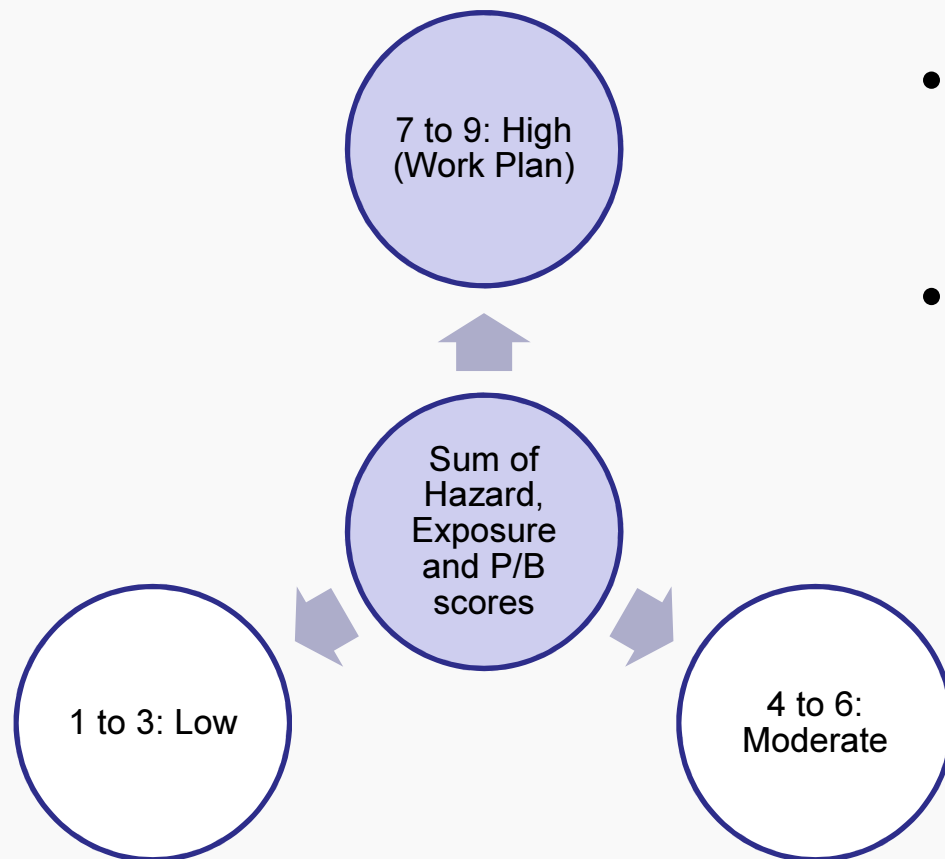


Step 2: Persistence/Bioaccumulation

- P/B scored separately from exposure due to special issues
 - Organisms can remain exposed for a long time
 - Exposures can magnify up food chain
- New Chemicals Program criteria used for ranking each factor separately
 - Where no data, used EPI Suite 4.10 estimate
- Individual P and B scores were summed, then normalized to total P/B score (3, 2, 1)



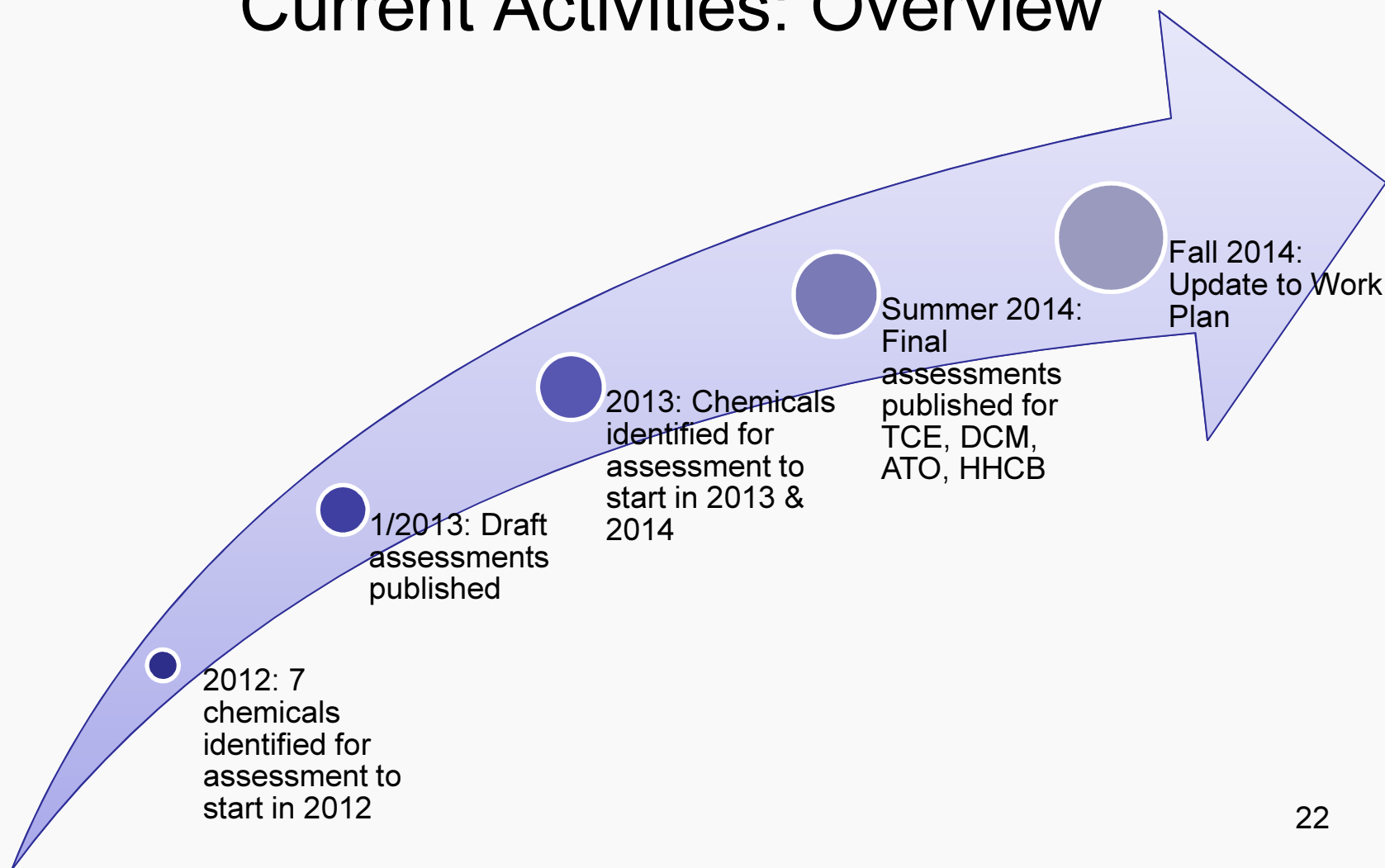
TSCA Work Plan Chemicals



- Normalized hazard, exposure, and P/B scores were summed
- Of the 345 chemicals, 83 scored high
 - These were placed on the TSCA Work Plan
 - Work Plan published with methodology in 2012



Current Activities: Overview





Current Activities: Assessments

Final assessments

- Trichloroethylene (TCE)
- Methylene Chloride (DCM)
- Antimony & Antimony compounds
- HHCB

Draft assessment

- N-Methylpyrrolidone (NMP)

Ongoing assessments

- Peer review: Medium-chain chlorinated paraffins (MCCP), long-chain chlorinated paraffins (LCCP), 1-bromopropane
- Also in progress: TBB, TBPH, TCEP, HBCD, D4, 1,4 dioxane

Flame retardant chemicals

- Chemicals for assessment include 20 flame retardants in 3 groups of structurally similar compounds: Brominated phthalates, chlorinated phosphate esters, cyclic aliphatic bromides
- Flame retardants for which assessments are underway represent their group



Current Activities: 2014 Update

- EPA is updating the TSCA Work Plan for Chemical Assessments
- 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
 - Some chemicals will be removed
 - Other chemicals will be added



Participating in the Work Plan Process

- Public comments were received on the TSCA Work Plan methodology and draft risk assessments
- Continuing opportunity for consultation and comment as EPA develops future risk assessments



Finding More Information

- EPA's Chemical Management Program:
www.epa.gov/oppt/existingchemicals
- Contact: Maria Doa, Director, Chemical Control Division
 - doa.maria@epa.gov



Thank You!