TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act: **Prioritization Procedural Rule**

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August 10, 2016

Purpose of the Meeting

- EPA is seeking early public input on procedural rulemaking for prioritization under new TSCA
- All oral and written comments will be considered
- A summary of meeting and written comments will be included in docket
- EPA will be providing a brief background presentation on the prioritization approach taken before TSCA amendments

**This is not a proposal for the new procedural rule*

The New Law

- The "Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed by the President and went into effect on June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976

Major Improvements Related to Existing Chemicals

- Mandatory duty on EPA to evaluate existing chemicals with clear and enforceable deadlines
- Chemicals assessed against a risk-based safety standard
- Unreasonable risks identified in the risk evaluation must be eliminated
- Expanded authority to more quickly require development of chemical information when needed

Key Milestones

	New Chemicals	Existing Chemicals	Inventory / Nomenclature	CBI	Other	Fees
Day 1	Implement for all	- §6 rules under development will address new standards - Risk Assessments – will address new standards		- Review CBI claims for chem ID w/in 90 days		
6 Months		-Publish List of 10 Risk Assessments underway for WP Chemicals -January 1st of each year – updated plan for Risk Evaluations **** Proposed rule – prioritization and evaluation**	Proposed rule – Active/Inactive		-Determine whether review small business definition warranted -Report to Congress on Capacity to Implement	**Proposed Rule
1 Year		**-Final Rule: Prioritization Process** -Final Rule: Risk Evaluation Process (including guidance for manufacturer requests) - Publish scope of first 10 risk evaluations	-Final Rule: Active/Inactive		--Establish SACC	**Final Rule
2 Year		-Negotiated Proposed Rule – Byproduct Reporting	-2½ years: Get active/inactive reports	-Rules re: CBI substantiation – 2.5 years -Guidance re: generic names	-Strategic Plan: Promote Alternative Test Methods -All policies, procedures, guidance needed	
3 Year		-3½ years -- 20 Risk Assessments underway (1/2 from WP, min) -20 Low Priorities identified -Proposed Rule – WorkPlan PBTs -Final Rule: Byproducts		-3½ years: Rule to establish plan for reviewing all CBI claims for active chemical IDs		
5 Year		-4 ½ years – Final Rule: PBTs		-Complete review of CBI claims for all active ChemIDs	-Report to Congress re: implementation of plan re: Alternative Methods	**Not a statutory deadline

Prioritization Requirements

- EPA must establish a risk-based process to identify whether a substance is a "high" or "low" priority for risk evaluation
  - *High-Priority.* The chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and potential route of exposure, including to susceptible subpopulations
    - Subject to Risk Evaluation
  - *Low-Priority.* The chemical does not meet the standard for High-Priority
    - No further action; may move to high priority if new information

Prioritization Requirements

- Criteria and Considerations
  - 50% of High-Priority chemicals must come from Work Plan
  - Preference for those with persistence and bioaccumulation scores of 3, and known human carcinogens with high acute/chronic toxicity
  - Hazard, exposure, persistence, bioaccumulation, storage near drinking water, conditions of use and volume, and significant changes in conditions of use and volume
- Opportunities for Public Participation
  - Statute requires two 90-day public comment periods - one following Initiation and one following Proposed Designation
- Timing
  - Prioritization process - from initiation to final designation - must take between 9 and 12 months

❖ EPA must have the Prioritization procedural rule established by June 2017.

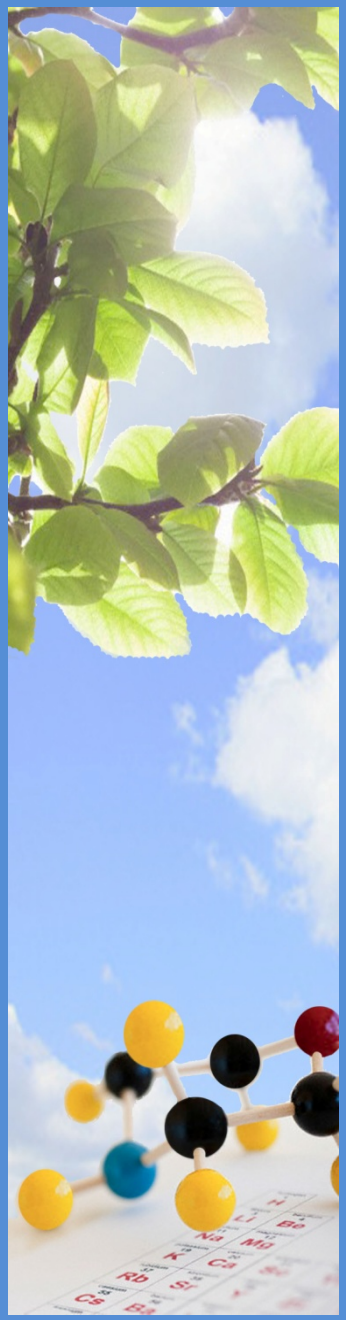
- Interim milestone – proposed rule mid-December 2016

Next Steps

- EPA will consider oral feedback received today and written comments in the docket as we develop a proposal for the prioritization procedural rulemaking

- Next: background presentation on prioritization approach under TSCA prior to amendments; used to create the TSCA Work Plan

- *Not a proposal for the new procedural rule*



United States Environmental Protection Agency

Work Plan Methodology for Chemical Assessments

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August 10, 2016

TSCA Work Plan: Methodology

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

TSCA Work Plan: Step One

Focus of Work Plan: 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 (PBT)
- Chemicals identified as probable or known carcinogens
- Chemicals used in children's products
- Chemicals used in consumer products
- Chemicals detected in biomonitoring programs

TSCA Work Plan: Step One

Factors and Authoritative 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

TSCA Work Plan: Step One

Factors and Authoritative 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

TSCA Work Plan: Step One

Factors and Authoritative 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

TSCA Work Plan: Step One

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

TSCA Work Plan: Step Two

- Screening Exercise
- Weighed three factors equally
  - Hazard
  - Exposure
  - Persistence and Bioaccumulation
- Used readily available data
- Modeling, when needed
- Chemicals scored using numerical algorithm based on combination of these 3 characteristics

TSCA Work Plan: Step Two

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

TSCA Work Plan: Step Two

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

TSCA Work Plan: Step Two

Exposure

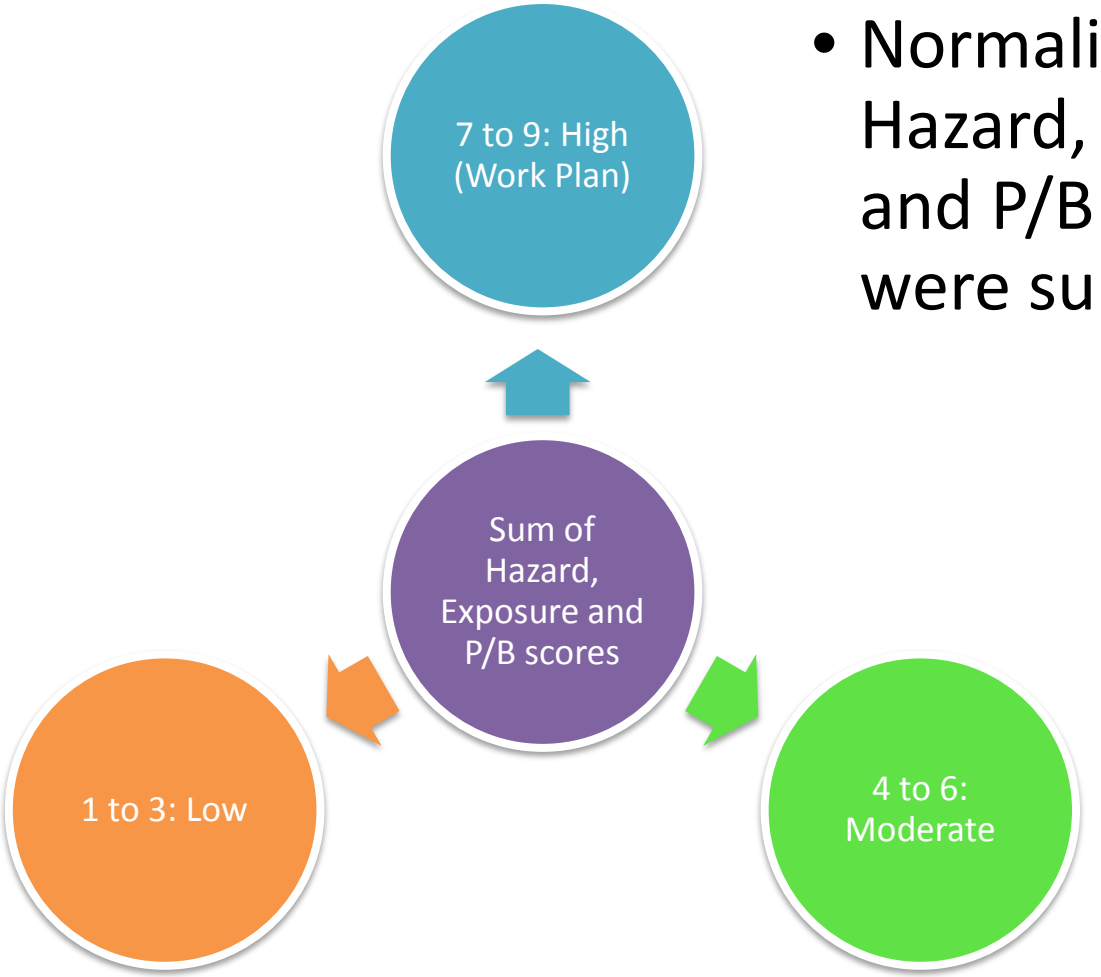
- Exposure Score based on combination of:
  - Use Type
    - Likelihood of potential exposures based on use
      - Consumer products: consider form, how widespread use
      - Industrial/commercial uses: consider dispersives
  - General Population and Environmental Exposure
    - Measured data in biota, environmental media
  - Release to Environment
    - TRI data
    - Where no TRI, calculation using IUR/CDR production volume, number of sites, release potential from type of use
- Individual scores were summed and normalized to generate a use score (3, 2, 1)

TSCA Work Plan: Step Two

Persistence and Bioaccumulation

- Used TRI and TSCA New Chemicals Program PBT criteria for ranking each factor separately
  - Persistence
    - Half-life > 6 months
    - Half-life ≥ 2 months
  - Bioaccumulation
    - BCF or BAF > 5000
    - BCF or BAF ≥ 1000
- 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)

TSCA Work Plan: Step Two



- Normalized Hazard, Exposure and P/B scores were summed

TSCA Work Plan

- *TSCA Work Plan Chemicals: Methods Document* published in February 2012 (https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf)
- Work Plan published with *Methods Document* in 2012
- Work Plan scores updated in 2014
- Of the 345 chemicals which completed Step 1, 90 scored high after Step 2, based on 2014 update, and are considered Work Plan chemicals

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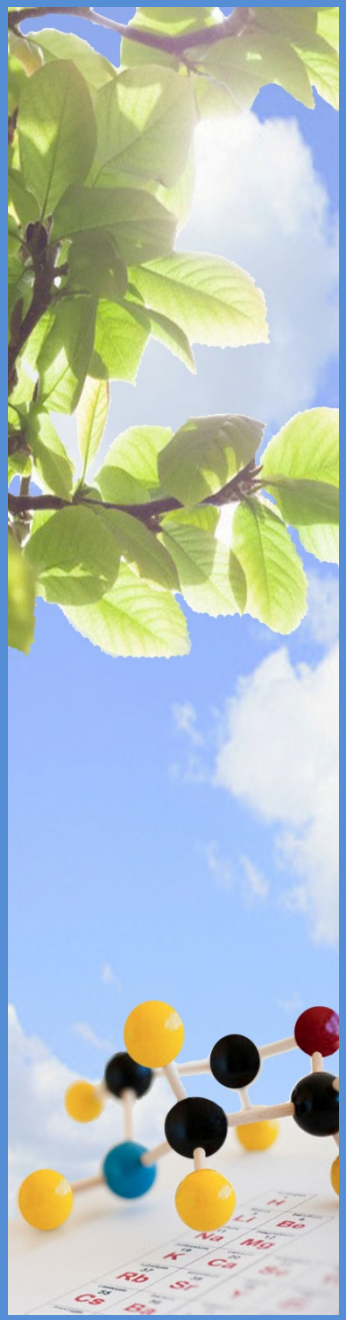
Thank you!

To learn more about
EPA's Chemical Management & Programs:

http://www.epa.gov/oppt



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Public Meeting on the New TSCA Procedural Rulemaking for Chemical Prioritization

EPA will consider comments submitted to docket

EPA-HQ-OPPT-2016-0399

Submit comments at www.regulations.gov by August 24, 2016.