Approaches to Identifying Potential Candidate Chemicals for Prioritization: **The TSCA Work Plan as a Tool for Identifying Potential Candidates**

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Outline

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  - Use the 2014 Work Plan
  - Augment the 2014 Work Plan with considerations for new data, criteria and factors
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Highlights of the TSCA Work Plan

- Amended TSCA requires that 50% of all High-Priority designations be drawn from the 2014 Update of the TSCA Work Plan.
- The Work Plan is a plan containing chemicals that the Agency intends to consider for risk assessment.
- Identification of a chemical on the TSCA Work Plan does not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment.
- Considered approaches will consider how to integrate Work Plan chemical substances into the prioritization process as a starting point.

Work Plan Methodology Summary‡

- EPA employed a two-step prioritization process that was intended to select an initial group of candidate chemicals for review.
- Step 1
  - EPA used a specific set of data sources to identify chemicals meeting one or more of the Step 1 factors.
  - This group of chemicals was further screened to determine if any chemicals should be excluded because they are not subject to TSCA or there was already significant regulation under TSCA, or due to radioactivity, complex process streams, natural occurrence, or other properties.
- Step 2
  - The chemicals identified as potential candidates for review and assessment under TSCA based on the Step 1 prioritization factors were screened.
  - Score is based on three characteristics: hazard, exposure, and potential for persistence and/or bioaccumulation.

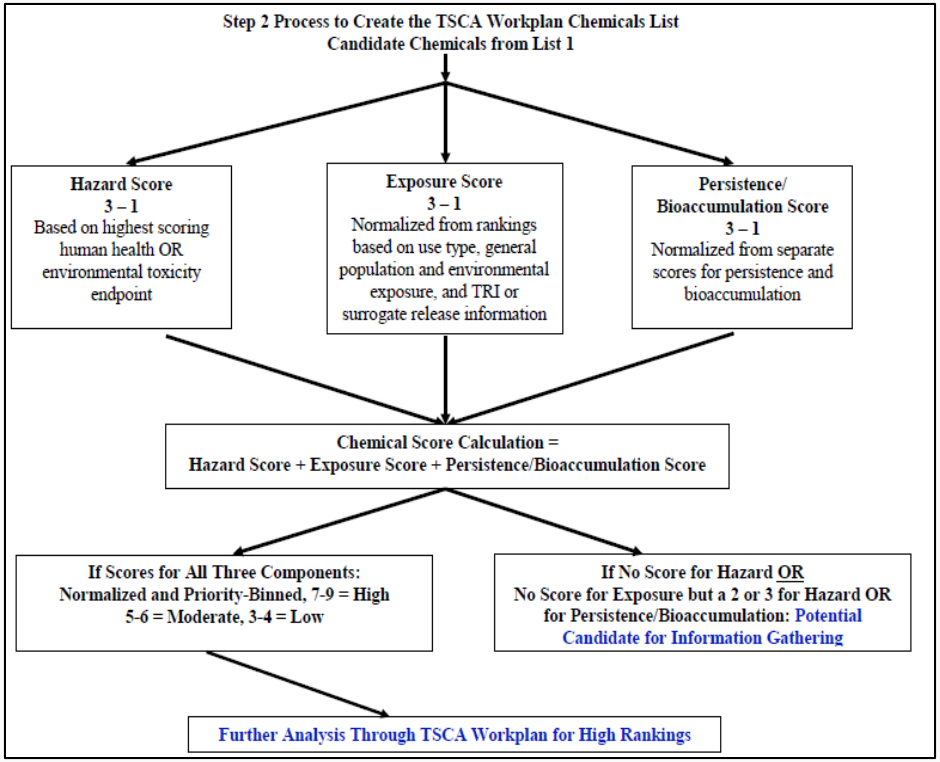
Step 1 Factors considered in 2-step process:

- 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.

‡2012 TSCA Work Plan Methods Document: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-methods-document

Number of Chemicals Identified within the Work Plan Methodology

Work Plan Methodology Step	# Chemicals
Meeting 1 or more of the Step 1 Factors in 2012	1235
Input to Step 2 in 2012 & 2014	345
Output of Step 2 in 2012 – Work Plan chemicals identified	83
Output of Step 2 in 2014 – Work Plan chemicals updated	90



Schematic of Step 2 Process

Considered Approaches‡

A. Use the 2014 Work Plan
B. Augment the 2014 Work Plan with considerations for new data, factors and criteria
C. Use of classification approaches
D. Other considerations

‡Considered approaches described will not change or update the existing chemicals on the 2014 Work Plan and could be used to evaluate *additional* existing chemicals that could be added to a new list to help identify chemicals for prioritization.

A. Use the 2014 Work Plan

- A simple approach where EPA could consider identifying 50-100% of potential high-priority candidates from the 2014 TSCA Work Plan.
- Such an approach could be used as an interim method while EPA continues to refine approaches for identifying potential candidates.

B. Augment the 2014 Work Plan with considerations for new data, factors and criteria

- Integrate new hazard, exposure, and potential for persistence and/or bioaccumulation information from new data streams into the Work Plan Methodology.
  - Augment the Work Plan with considerations for re-screening the 345 Step 2 Work Plan Chemicals which would represent the minimal set of chemicals given the exclusions due to TSCA exemptions or other properties considered.
  - Expand the data landscape of the 345 Work Plan chemicals with additional information not available at the time and update scientific methodologies used in the development of these models and technologies for consideration in priority designation.
  - Identify data types (*e.g.*, *in silico*, HTS *in vitro* activity, traditional *in vivo*, *etc.*) as well as data gaps/errors and targeted opportunities to generate data (e.g., *in silico* predictions, *in vitro* and *in vivo* data), if necessary, for conducting risk evaluations.

B. Augment the 2014 Work Plan with considerations for new data, factors and criteria (cont.)

- Consider new/current data sources
  - Historically, chemicals were scored on the basis of readily available data.
  - No judgment was made concerning gaps in or completeness of the available data set for a given chemical.
- Consider or re-evaluate criteria used in determining the Step 2 score based on hazard, exposure, and potential for persistence and/or bioaccumulation
  - For example, Work Plan hazard criteria are based on Alternatives Assessment Criteria for Hazard Evaluation developed by EPA's Design for the Environment Program (DfE).
  - Consider other sources for criteria – e.g., EPA Sustainable Futures/New Chemicals Program, other agencies and sources.

B. Augment the 2014 Work Plan with considerations for new data, factors and criteria (cont.)

- Align and integrate Step 1 factors to be consistent with the Prioritization Rule
  - For example, storage near significant sources of drinking water may be considered as one of many new selection criteria for high-priority candidates and may be considered as one organizing factor to be considered among others.

C. Use of classification approaches

- Classification approaches such as a functional use/sectors approach for identifying and grouping chemicals within the 2014 Work Plan Chemicals would facilitate and inform the development of relevant categories that could be used to streamline approaches in the prioritization and risk evaluation process.
- These categories would provide a basis for similar data needs and would potentially inform streamlined assessments or rapid screening approaches for select categories of chemicals much like those developed by the Government of Canada (e.g., Polymer Rapid Screening I and II)

D. Other considerations

- Consider other modifications or changes through feedback received at this public meeting or during the associated opportunity for comment as part of the ongoing dialogue.
- Suggestions solicited through discussion of other changes that can be made may include new approaches and new data streams not previously considered in the development of the Work Plan Methodology or the presented approaches at this public meeting.

Benefits

- TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires that 50% of all High-Priority designations be drawn from the 2014 Update of the TSCA Work Plan.
  - The 2014 Work Plan chemicals would satisfy this requirement and would represent a pragmatic consideration (time, effort and resources) to begin using these chemicals as a starting point given the efforts and resources already devoted to its development and update.
- The criteria used in the two-step prioritization process already satisfy many of the criteria specified in the Prioritization Rule 40 CFR section 702.9 and TSCA section 6(b)(1)(A).
  - Hazard and exposure potential of the chemical substance, persistence and bioaccumulation, and conditions of use with high exposure potential are accounted for in the methodology.
  - The Work Plan Methodology also has specific criteria to account for potentially exposed and susceptible subpopulations as stated by amended TSCA.

Benefits (cont.)

- Modifying this approach would be responsive to public comments EPA has received since 2014.
  - Considerations for advances in New Approach Methodologies (*e.g.*, data science, *in silico* models, HTS *in vitro* assays, *etc*) may provide mechanisms to fill data gaps that were identified in the original methodology.

Caveats

- The 2014 Work Plan Chemicals represent a static snapshot of the data and priorities (as specified by criteria and factors) at a given time.
  - The data and criteria incorporated into the screening methodology may not be representative of the current state of science or information available at the time of the 2014 Update.
  - Any future approach to update the methodology would need to verify updated data sources and models to ensure harmonization of data with external and internal data and model streams.
  - Need to update factors to account for new criteria specified in the Prioritization Rule.
- The Work Plan Methodology is more aligned towards identifying candidates for High-Priority designation than identifying Low-Priority designations.
  - This will require having an alternative mechanism to identify candidates for Low-Priority designation.

Thank you!