Prioritization and Risk Evaluation Under the New TSCA

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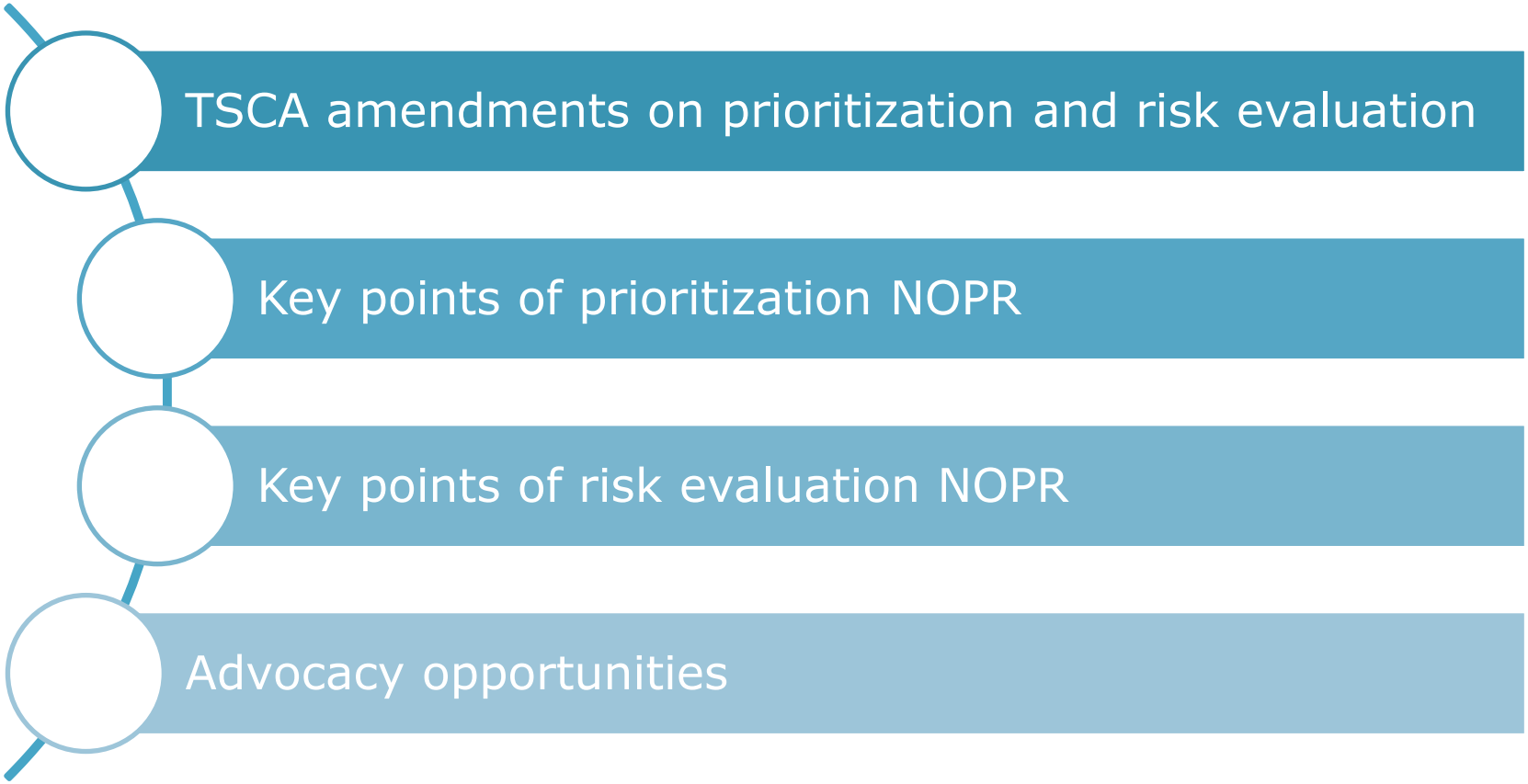
Overview


TSCA amendments on prioritization and risk evaluation
Key points of prioritization NOPR
Key points of risk evaluation NOPR
Advocacy opportunities

TSCA Amendments

June 22, 2017 deadline for final rule establishing:

- A risk-based screening process, including criteria for designating high- and low-priority substances
- A process to conduct risk evaluations

Good science provisions

- In carrying out sections 4, 5, and 6, in making decisions based on science, EPA must:
  - Use scientific information in a manner employed in a manner consistent with the best available science
  - Make decisions based on the weight of the scientific evidence

Prioritization NOPR

82 Fed. Reg. 4825 (Jan. 17, 2017)

Objective: guide EPA towards identifying the high-priority substances that have the greatest hazard and exposure potential first

- Also, value in identifying low-priority substances for public and industry

Designate chemical substance as a whole, not specific uses

Not an exact scoring process

Build on TSCA Work Plan process

Which chemicals?

All 90 TSCA Work Plan chemicals and categories – eventually

PMN substances once commercialized – but no rush

Mainly active substances

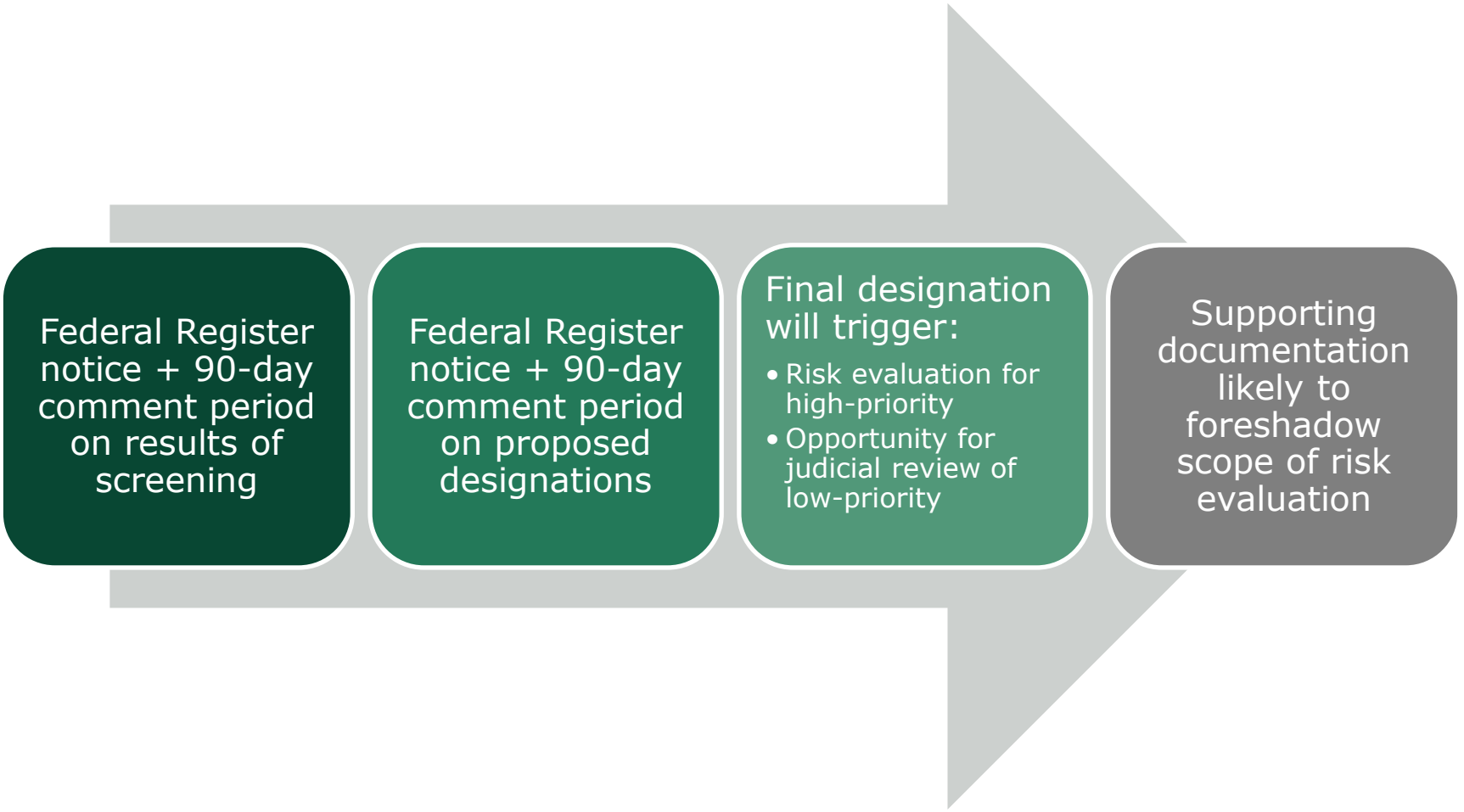
Pre-prioritization

9-12 month timeframe for prioritization creates need for pre-prioritization characterization

- Sufficiency of information for risk evaluation is crucial factor in selection
- Inadequacy of data defaults to high-priority
  - But inadequacy handicaps risk evaluation
- Fill key data gaps through §§ 4, 8, 11; no time deadline
- EPA encourages stakeholders to:
  - Identify prioritization candidates with explanation
  - Provide information, especially on unique uses

No transparency about which chemicals

Formal process



Low-priority substances

§ 6 requires 20 low-priority designations by December 22, 2019

EPA: no obligation to designate additional low-priority substances

- In contrast, high-priority has 1-for-1 substitution
- Contrary view: no quota, but must continue

Likely candidates:

- Safer Chemicals Ingredients List (former DfE)
- 824 entries, including water, vinegar, sunflower oil

Risk evaluation NOPR

82 Fed. Reg. 7562 (Jan. 19, 2017)

Scope of risk evaluation – 6 months after listing

- Not narrow as with TSCA Work Plan assessments
- "All conditions of use" to be evaluated (as of scope issuance)
  - Not all will receive same level of evaluation
  - Contrary view: EPA has discretion to review only specific conditions of use
  - Scope of review affects EPA resources
- Reviewing all conditions of use "challenging but manageable"
- Triggers "high-priority pause" preemption of state requirements within scope

Good science considerations

No provisions defining "best available science" or "weight of the scientific evidence"

- Preamble references EPA's Risk Characterization Handbook and other resources
- Section 26 science provisions apply without need for rulemaking
- WoE analysis to be conducted on a case-by-case basis
- Preamble requests comments on the need for regulatory text

Manufacturer requests

25-50% of risk evaluations if qualified

"Qualified" includes submitting:

- "a complete list of the reasonably available information that is consistent with the standards in TSCA section 26 and that is relevant to whether the chemical substance presents an unreasonable risk"
- Explanation as to why the information is adequate for risk evaluation
- Certification that "I have not withheld any relevant information."

Request covers chemical, not specific uses

Fee: 100% or 50% of cost

- Cost estimate: $3,670,890

Conduct of risk evaluation

Rely on reasonably available information

- Not new testing
- May include stakeholder risk evaluations, data

Hazard assessment – health & environment

Exposure assessment

3 years + possible 6-month extension

Proposed risk evaluation

- Describe impacts on subpopulations, etc.
- 30-day opportunity for comment

Final risk evaluation

Presents an unreasonable risk to health or the environment under the conditions of use	Does not present an unreasonable risk
• Immediately proceed to risk management rulemaking (2 years) • High-priority pause ends; no new preemption yet	• Likely for some chemicals, given high threshold for low-priority designation • 60-day period for seeking judicial review in court of appeals • Preemption of existing and new state requirements within scope

Advocacy opportunities

Comment deadlines

- Prioritization: March 20, 2017
- Risk evaluation: March 20, 2017
- Regulatory freeze: March 21, 2017

Questions?

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