Industry Opportunities and Challenges Under TSCA Reform

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Opportunities for Comment on Implementation

Senate version

- Policies, procedures, and guidance needed to implement sections 3A, 4, 4A, 5, and 6, and updates
- Rules on safety assessment / safety determination / risk management process
- Active substances notification process
- Processor requirements under CDR
- Fees

House version

- Policies, procedures, and guidance (no requirement for comment)
- Fees

Good Science Provisions

Senate version – EPA must:

- Make decisions "in a manner consistent with the best available science" and "based on the weight of the scientific evidence"
- Establish policies on use of science, incorporating current policies as appropriate

House version – EPA must:

- Consider the adequacy of the science and make decisions "based on the weight of the scientific evidence"

IRIS issues – NAS recommendations, House inquiry

Impact: Policies, advocacy, judicial review

- FDA's handling of BPA studies

Testing

Expect more

Senate version

- Statement of need (for safety assessment, etc.)
  - Significant data gap – anticipate the need
- Rule, consent order, or order

House version

- "May pose an unreasonable risk" or volume-based
- Rule, consent order, or order

May be unilateral order; consent order preferable

- Negotiate tests, protocols
- FIFRA § 3(c)(2)(B) model (data call-ins)
- Joint testing consortia, cost sharing

PMNs and SNURs

Senate version

- Must submit all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures
- Likely / not likely to meet the safety standard
  - More than "may present an unreasonable risk"
  - Affirmative finding required, or else testing

No House version

Increased importance of anticipating and addressing EPA concerns

Articles – speedbump

Nominate Chemicals for Review

Senate version

- Manufacturer or processor of an active chemical may request EPA to designate it as high priority
- Quota: 25-30% of those designated

House version

- Manufacturer of a chemical may request a risk evaluation for it

Fees – requestor must pay cost of review

Why nominate?

- May get your chemical reviewed many years earlier than otherwise
- Potential for "meets the safety standard" and preemption

Participate in Risk Review Process for Particular Chemicals

Senate version – opportunities to comment:

- On proposed designations as high or low priority, or deferral for more information
- On requests by manufacturer or processor for designation
- By providing additional information for deferrals
- On proposed safety assessments and safety determinations
- On proposed risk management rules

House version – opportunities to comment:

- On preliminary finding of no unreasonable risk
- On proposed risk management rules

Unreasonable Risk

Senate version

"A standard that ensures, **without taking into consideration cost or other nonrisk factors**, that **no unreasonable risk** of injury to health or the environment will result from exposure to a chemical substance **under the conditions of use** …."

House version

"determines through a risk evaluation under this subsection, **without consideration of costs or other non-risk factors**, that the chemical substance presents or will present, in the absence of such requirements, an **unreasonable risk** of injury to health or the environment."

Intended conditions of use to be considered in risk evaluation

Unreasonable Risk

- Precedents consider economic, social, and environmental costs and benefits – so this is new
- Policy judgment by EPA – but not zero risk
- Industry involvement in safety assessment process is critical, because an unreasonable risk must be regulated
- Judicial deference to EPA on scientific questions (hazard) likely, subject to substantial evidence standard of judicial review
- Focus comments particularly on conditions of use (exposure), including applicable restrictions (e.g., OSHA), and affected subpopulations
- Timing, substitutes, economic impact to be addressed in risk management rulemaking

Advocacy at the State Level

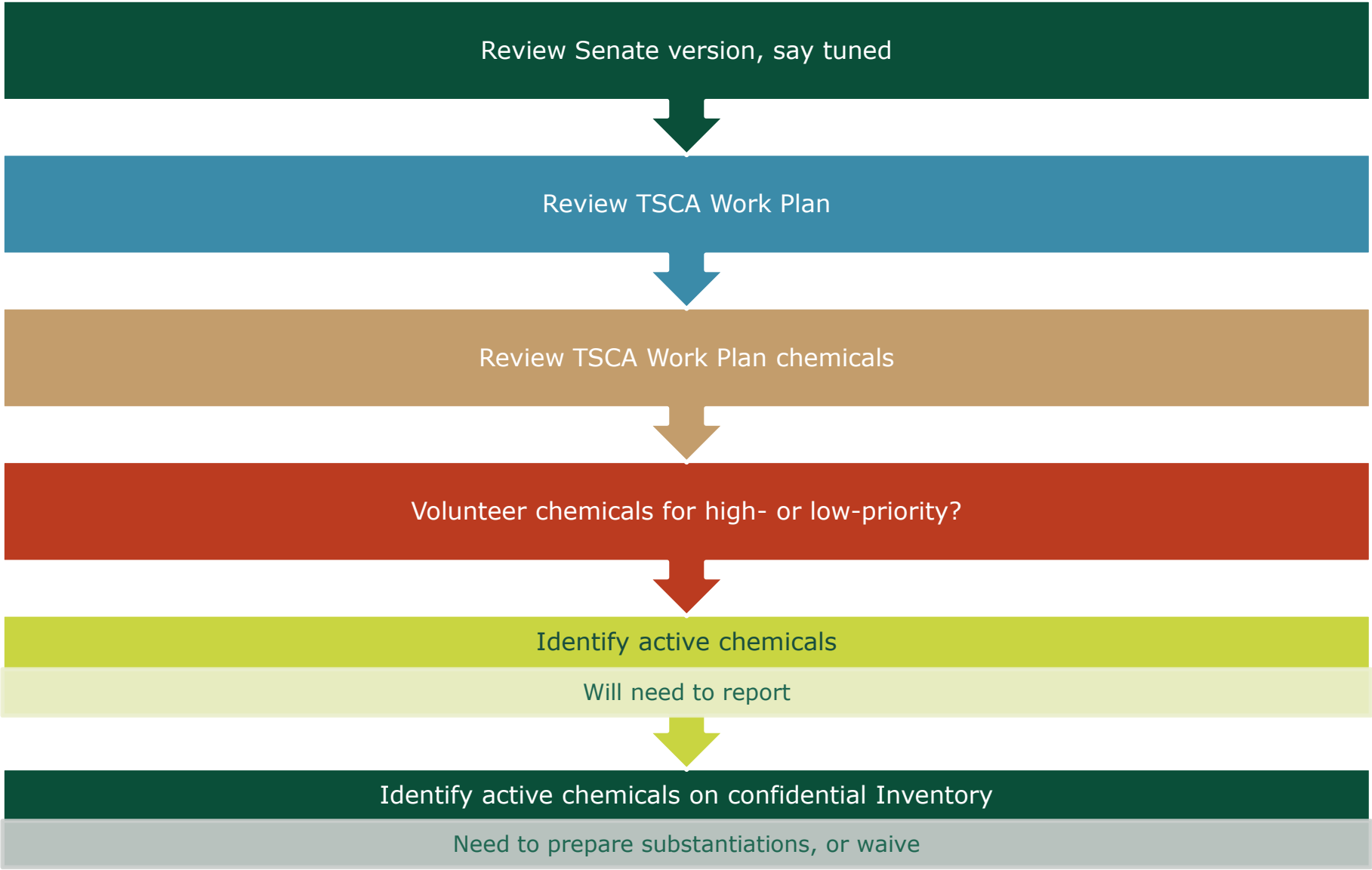
No need for states to fill a federal vacuum

- Limited state resources
- National impact of federal action

If EPA is not currently planning to evaluate a chemical of concern to a state:

- Senate bill would authorize state governor or agency to recommend chemicals for EPA review, and EPA prioritization criteria would require EPA to consider such recommendations
- Manufacturer (or processor) can request EPA review

Preparing for Implementation



Questions?

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