

New Chemical Review under Amended TSCA

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Background



- New law requires EPA to make an affirmative finding on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market
- Chemicals under review at time of enactment were considered “resubmitted” and review period restarted; additional notices continued to come in, resulting in the need to re-review and “backlog”
- Backlog was eliminated in August 2017
- Current focus is to continue to improve processes to meet new requirements in law



Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

Information is insufficient to permit a reasoned evaluation of the risk.

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient Information to permit a reasoned evaluation and may present unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required



Where the conditions of use identified in submissions raise risk concerns, if the submitters provide timely written amendments to their submissions addressing those concerns, in general EPA will consider the conditions of use in those amended submissions to be the intended conditions of use.



Where EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use as described in a submission (original or amended), EPA will assess whether those concerns can be addressed through significant new use rules (SNURs).

Decision Framework



As described in the risk evaluation rule, the identification of any reasonably foreseen conditions of use will be fact- or knowledge-specific: that is, it will be based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission.

Decision Framework



Questions on the Decision Framework