

This flowchart describes the technical and decision meetings EPA has as part of its 90-day review process following receipt of a premanufacture notice (PMN) on Day 1. Day 1 to 7 involves initial evaluation of the PMN for completeness.

Review Process

Day 8 to 12 Chemical Review and Search Strategy (CRSS)

- Chemical identity
- Structure /Nomenclature
- Analogs/TSCA inventory status
- Synthesis - includes byproducts and impurities
- Use/TSCA jurisdiction as provided by Submitter, literature, analog use
- Physical/chemical properties - physical state, molecular weight, melting point, boiling point, vapor pressure, solubility, octanol water partition co-efficient, and pH
- Pollution prevention aspects: pollution prevention information provided by Submitter, EPA Makes suggestions for Alternate Synthetic Pathways

CRSS decisions: Notice completeness, validity, reportability, eligibility for exemption or exclusion, candidacy for exposure-based review, whether notice meets certain CRSS drop criteria

Day 9 to 13 Structure Activity Team (SAT) Meeting

Interdisciplinary team of chemists, biologists, toxicologists, and information specialists

SAT evaluates potential environmental fate, health effects and environmental hazard through the use of structure activity relationships (SAR), test data on PMN substance, data on analogs, QSAR estimates (Quantitative Structure Activity Relationship: a predictive equation/model derived from a statistical analysis of test data), and expert/judgement

Day 10 to 19 Profile of Exposure and Release

- Occupational exposure
- Releases to the environment
- Environmental/consumer exposure (includes environmental persistence and bioaccumulation or bioconcentration)

Day 15 to 20 Focus Meeting

- Representatives from each discipline involved in assessment
- Delegated decisions for chemical categories, exposure-based reviews, Exemptions

Focus meeting decisions:

For PMNs: Ban pending upfront testing, "drop" from further Agency review, short question, TSCA §5(e) Consent Order and/or Significant New Use Rule (SNUR), standard review.

For Exemptions: Grant, denial, conditional denial or grant options
If regulated, Submitter will be notified by EPA.

Day 21 to 85 Standard Review

Further, in-depth review for non-category/special issue PMN chemicals. The regulatory decision (see Focus meeting decisions, above) is made at the Division Director management level.