



## New Chemicals



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# New Chemicals Program Meetings and Review Process

## New Chemicals Program Meetings and Review Process

The PMN program has evolved into an efficient mechanism by which to identify new chemicals which are of greatest concern early on in the 90-day review process and focus detailed analysis on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA utilizes an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts.

Following receipt of a PMN or exemption notice, the notice undergoes the following steps in the Agency's 90-day review process:

### CHEMICAL REVIEW AND SEARCH STRATEGY (CRSS) MEETING (DAY 8-12)

This meeting examines these aspects of the notice:

- Chemical Identity

- Structure/Nomenclature

- Analogs/TSCA (Toxic Substances Control Act) 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 and boiling point, vapor pressure, solubility, octanol water partition co-efficient, 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.

### STRUCTURE ACTIVITY TEAM (SAT) MEETING (DAY 9-13)

- 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 judgment

### PROFILE OF EXPOSURE AND RELEASE (DAY 10-19)

- Occupational exposure

- Releases

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Basic Information

PMN Forms and Information

Premanufacture Notice Status

New Chemicals Policies

Guidance Materials

Chemical Categories Report

Consent Orders and Significant New Use Rules

ECOSAR: Ecological Structural Activity Relationships

Importing and Exporting New Chemicals

Environmental/consumer exposure (includes environmental persistence and bioaccumulation or bioconcentration)

### **FOCUS MEETING (DAY 15-20)**

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/Significant New Use Rule (SNUR), standard review. For Exemptions: grant, denial, conditional grant or denial.

If regulated, Submitter will be notified by EPA.

### **STANDARD REVIEW (Day 21-85)**

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.

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