



New Chemicals Decision Guidelines Manual Detailed Outline

U.S. EPA Office of Pollution Prevention and Toxics

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Purpose of the Document

- Provide submitters and the broader public with information on how OPPT conducts its new chemicals assessments
- Help stakeholders determine what forms of regulation and restrictions might be imposed on the manufacture, processing, distribution, use, and/or disposal of a new chemical substance



Description of the Document

- Overview of
 - Review of new chemical submissions
 - Process OPPT follows
 - Policies and decision guidelines used in making decisions under TSCA section 5



Description of the Document

- Internal operational reference long in use to be a model
 - Based on the review of 55,000 new chemical submissions since 1979
- Will be updated to reflect amendments to TSCA under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.



High Level Outline

- Introduction
- Pre-notice consultation
- TSCA section 5 applicability
- Conditions of use
- Estimating physical-chemical properties of chemicals
- Characterization of biotechnology submissions



High Level Outline

- Chemical categories
- Hazard assessment
- Environmental fate
- Chemical and biotechnology exposure assessments
- Exposure-based policy for chemicals
- Risk assessment



High Level Outline

- P2 framework
- Risk management
- Appendices
 - Appendix A Chemical Categories
 - Appendix B Exposure Assessment Tools and Models
 - Appendix C Sources of Information
 - Appendix D List of Acronyms



Comment on the Outline

- EPA is requesting comment on the detailed outline for the New Chemicals Decision Guidelines Manual
- Are there other sections that should be added?