New Chemicals Decision Guidelines Manual
Detailed Outline

This New Chemicals Decision Guidelines Manual will summarize how EPA reviews new chemical submissions and the policies and decision guidelines used in making decisions under section 5 of the Toxic Substances Control Act (TSCA). This document will provide an overview of both risk assessment and risk management approaches. In addition to providing an overview of the review of new chemical submissions, the manual is intended to help stakeholders determine what forms of regulation and restrictions on the manufacture, distribution, use, and/or disposal of a new chemical substance may arise from an EPA determination.

EPA is providing an outline for the New Chemicals Decision Guidelines Manual for public comment. In particular, EPA is interested in hearing whether there are other sections that should be added to the outline and thus to the document.

Background

EPA has reviewed more than 55,000 new chemical submissions since 1979. During this time, EPA developed several procedures, policies, and decision guidelines to assist OPPT personnel in assessing data obtained during the review and in developing subsequent recommendations, if any, for the regulation of the new chemicals. EPA has codified these procedures, policies, and decision guidelines into draft decision guidelines documents, the most recent of which was developed in 2001 and was intended for internal use by OPPT in the evaluation of new chemical submissions. EPA intends to use the 2001 document as a model for an updated document - the New Chemicals Decision Guidelines Manual, which will be adapted for both internal and external use. EPA is updating its procedures, policies, and decision guidelines to reflect the amendments to TSCA under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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8.1.6 Qualitative Hazard Assessment

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8.2.2 Types of Environmental Hazards

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8.2.3 Use of Models

8.2.4 Selection and Use of Analogs

8.2.5 Assessment Factors

8.2.6 Use of Models

8.2.7 Acute-to-Chronic Toxicity Ratio

8.2.8 Concentration of Concern (CoC)

8.3 Biotechnology Hazard Assessment

8.3.1 Human Health Hazard

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- Toxin production
- Immunological Effects
- Antibiotic resistance

8.3.2 Environmental Effects

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- Ecosystem effects including competition with native species

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9.0.2 Bioavailability

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- Worker Risk Estimates for Cancer
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12.1.2 Non-Cancer Effects

- MOE approach
- Qualitative risk assessments

12.2 Environmental Risk Assessment

12.2.1 Percentile Stream Flow Method

12.2.2 Probabilistic Dilution Method

12.2.3 Acute vs Chronic

12.3 Risk Assessment for Releases Other Than To Streams

12.3.1 Terrestrial Ecosystem

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12.4 Biotechnology Risk Assessment

12.4.1 Human Health Risk Assessment

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- Toxigenicity
- Immunological Effects
- Antibiotic resistance
- Horizontal Gene Transfer (HGT)

12.4.2 Environmental Effects Risk Assessment

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- Horizontal Gene Transfer
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14.0 Overview of Risk Management

14.1 Reasonable vs. Unreasonable Risks

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