

Rigorous Federal Approval Process Exists for New Chemicals

1

Chemical Innovations Receive Comprehensive Review

Chemical Manufacturers Submit Premanufacture Notices (PMNs) to EPA which include:

- Information about chemical identity, anticipated uses, molecular structure, anticipated byproducts and disposal information
- Any health or environmental effects test data in the company's possession
- Anticipated exposure information and other information to enable EPA to evaluate whether use of the chemical would harm health or the environment

More than a dozen federal laws govern the safe manufacture and use of chemicals. The central law aimed at ensuring the safety of industrial chemicals is the Toxic Substances Control Act (TSCA), which among other things requires that all new chemicals be rigorously evaluated by EPA prior to commercial manufacture.

EPA has broad authority to request information and testing. No new chemical may be manufactured commercially without EPA approval under Section 5 of TSCA.

2

EPA Scrutinizes Company Data

EPA conducts initial review of a company's PMN, including all health and environmental data and information provided

3

EPA Experts Apply Predictive Models

- EPA uses the PMN to develop a "profile" for the chemical
- EPA employs sophisticated computer modeling to predict the chemical's physical and chemical properties
- EPA creates models based on structurally similar chemicals

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EPA Analyzes Chemical's Properties

- EPA scientists evaluate health effects data, environmental effects data, physical properties and other data and estimate potential impacts
- If EPA has questions or needs additional data, it can and does request more information
- EPA identifies health and environmental hazard potential

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EPA Analyzes Exposure Potential

- EPA develops profiles for worker, consumer, general population and environmental exposure/release potentials
- Profile considerations include production volume, environmental persistence, worker safety, bioaccumulation potential, etc.

EPA can demand additional data through a section 5(e) consent order

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Robust Process Leads to EPA Decision

EPA has authority to reject or limit a new chemical's use in appropriate cases, or allow manufacture without restrictions

PASS

If EPA is confident of the new chemical's health and environmental profile, the agency can allow the chemical to be manufactured without added restrictions

LIMIT

If EPA determines the new chemical use presents uncontrolled risks, the agency has authority to prohibit or limit its manufacture or use

RESTRICT

EPA may also allow manufacture of new chemicals for use with restrictions, such as labeling or personal protective equipment requirements

STOP

If EPA believes there are unanswered questions concerning safety, the agency has authority to require the manufacturer to conduct additional testing or provide additional information

When a company moves forward to commercially manufacture the chemical after the PMN review period and it notifies EPA that it has done so, the chemical is added to the TSCA Inventory

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EPA Authority Extends Beyond Initial Manufacturing

Once EPA has allowed a new chemical to be manufactured, it maintains authority to evaluate, require reporting, demand testing and regulate all chemicals on the TSCA Inventory

1979 – 2010
EPA Reviewed 36,623 PMNs

2,589	1,848
EPA Took Regulatory Action	Were Withdrawn