

Overview of the New Chemicals Premanufacture Process

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Toxic Substances Control Act (TSCA) - An Overview

- Provides basic authority for chemicals in US
- TSCA provides broad authority to:
 - Gather information on new and existing chemical substances and mixtures
 - Require testing of certain chemicals
 - Screen and control new and existing chemicals
 - Control existing chemicals that present risk
 - Coordinate with other Federal and State agencies

TSCA - An Overview

- an “existing” chemical substance is on the TSCA Chemical Substances Inventory as being manufactured or imported in the U.S.
- a “new” chemical substance is one that does not appear on the TSCA Chemical Substances Inventory

Section 5 of TSCA

The Toxic Substances Control Act (TSCA), Section 5, requires a manufacturer or importer of a new chemical substance to submit a “premanufacture notice” (PMN) to EPA 90 days before the date of intended start of production or import of the subject chemical.

Role of New Chemicals Program

■ Gatekeeper Responsibilities

- Designed to prevent health and/or environmental risks before they occur

■ Advocate for Environmental Stewardship

- Designed to encourage the development by Industry for safer and greener new chemicals

■ International Cooperation

- Participating with global partners in areas of mutual interest

Gatekeeper Responsibilities

Process Overview

- Evaluation of risks from new chemicals are considered throughout their product life cycle
- Focus is on determining “unreasonable risk” - if found, EPA identifies needed risk management or other actions.
- Such new chemicals can enter commerce but the company must meet any regulatory requirements.
- If EPA does not take an action, without additional restrictions the new chemical may enter US commerce

Notifications

- PREMANUFACTURE NOTIFICATION (PMN)
 - New industrial chemicals not otherwise excluded are subject to new chemical notification requirements
- INTERGENERIC MICROORGANISM NOTIFICATION
 - Intergeneric microorganisms are subject to new chemical notification requirements

Is Your Substance Subject to a PMN?

- Intent to Manufacture (Import) for Commercial Purpose
- Not Excluded by Statute or Regulation
- Not on the TSCA Inventory
- Defined as Chemical or Microorganism

Exclusions – By Statute

- FOOD, FOOD ADDITIVES, DRUGS, COSMETICS OR DEVICES
- PESTICIDES
- TOBACCO AND TOBACCO PRODUCTS
- FIREARMS, NUCLEAR SOURCE MATERIALS

Exclusions – By Regulation

- MIXTURES
- BYPRODUCTS / IMPURITIES
- NON-ISOLATED INTERMEDIATES
- SUBSTANCES IMPORTED AS COMPONENTS OF AN ARTICLE

Who Submits A PMN?

- U.S. Manufacturer
- U.S. Principal Importer
- Manufacturer, Processor, or User of Excess R&D substance for Non-Exempt Commercial Purpose

Types of TSCA Section 5 Submissions

- Premanufacture Notification (PMN)
- Consolidations
- Joint Submission
- Letter of Support
- Exemption Applications

PMN Exemptions

	Application	Time for Review	User Fee Costs	Results	Workload (EPA Resources)
Low Volume (Regulatory)	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team
Low Releases/ Low Exposure (Regulatory)	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team
Polymer (Regulatory)	Postcard Notification	Must be submitted by 01/31 of the year subsequent to initial manufacture	None	Not Applicable	Notification Management of Postcards
Research & Development (Statutory)	Record-Keeping (Industry)	Not Applicable	None	Submitter must meet definition	None
Test Market (Statutory)	EPA Form preferred	45 days	None	Grant or Deny	New Chemicals Review Team

Definition of a Polymer

- *A polymer is a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weight wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.*

Polymer Exemption

- Ineligible Polymers
 - Degrade, decompose, or depolymerize
 - Chemical identity (monomers and other reactants greater than 2%) included in a “new” chemical substance
 - Water-absorbing polymers with number-average molecular weight equal to or greater than 10,000 daltons

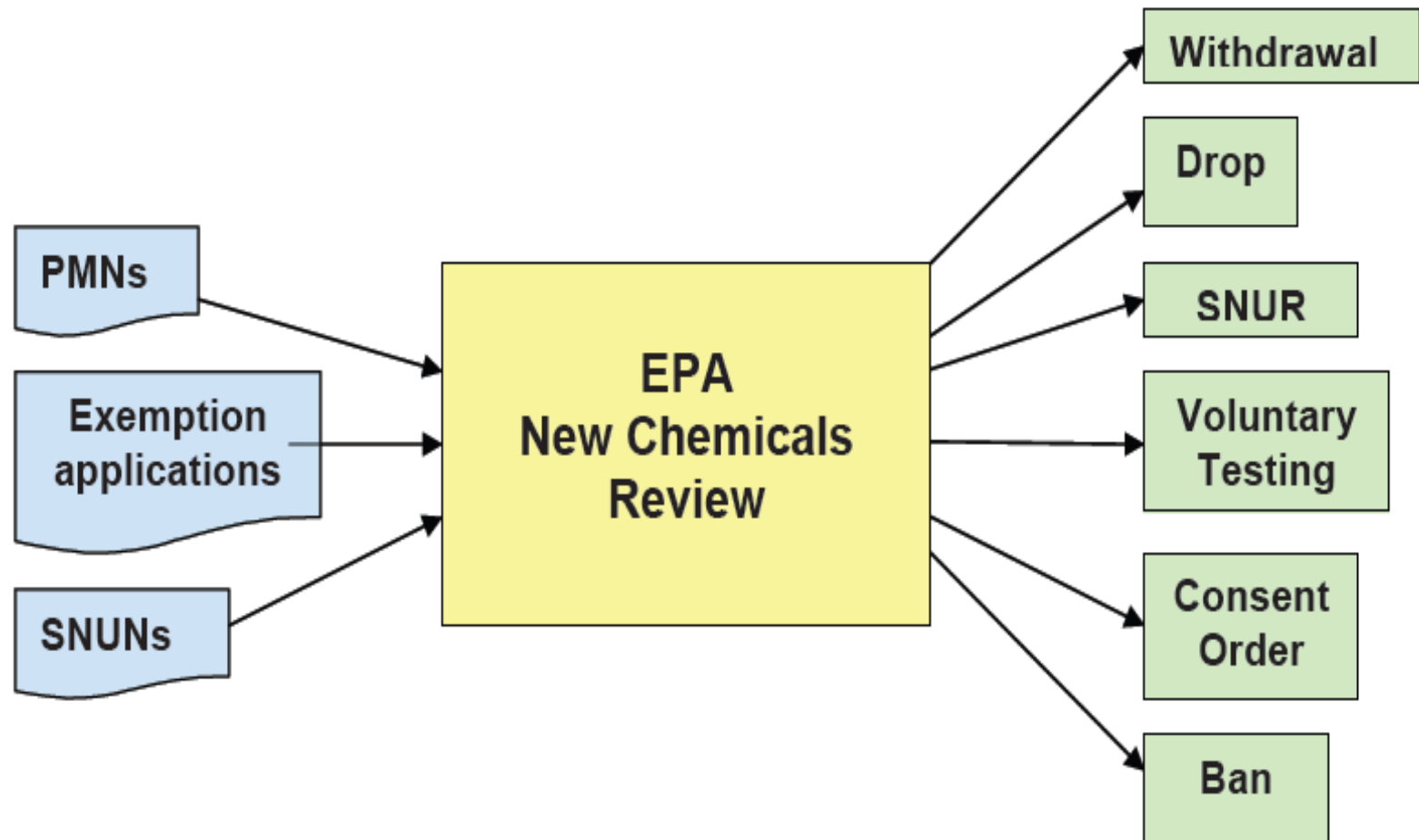
Since 1977...

- Total PMN submissions \approx 35,300
- Total PMN exemptions \approx 13,000
- New chemicals added to the TSCA Inventory >21,000

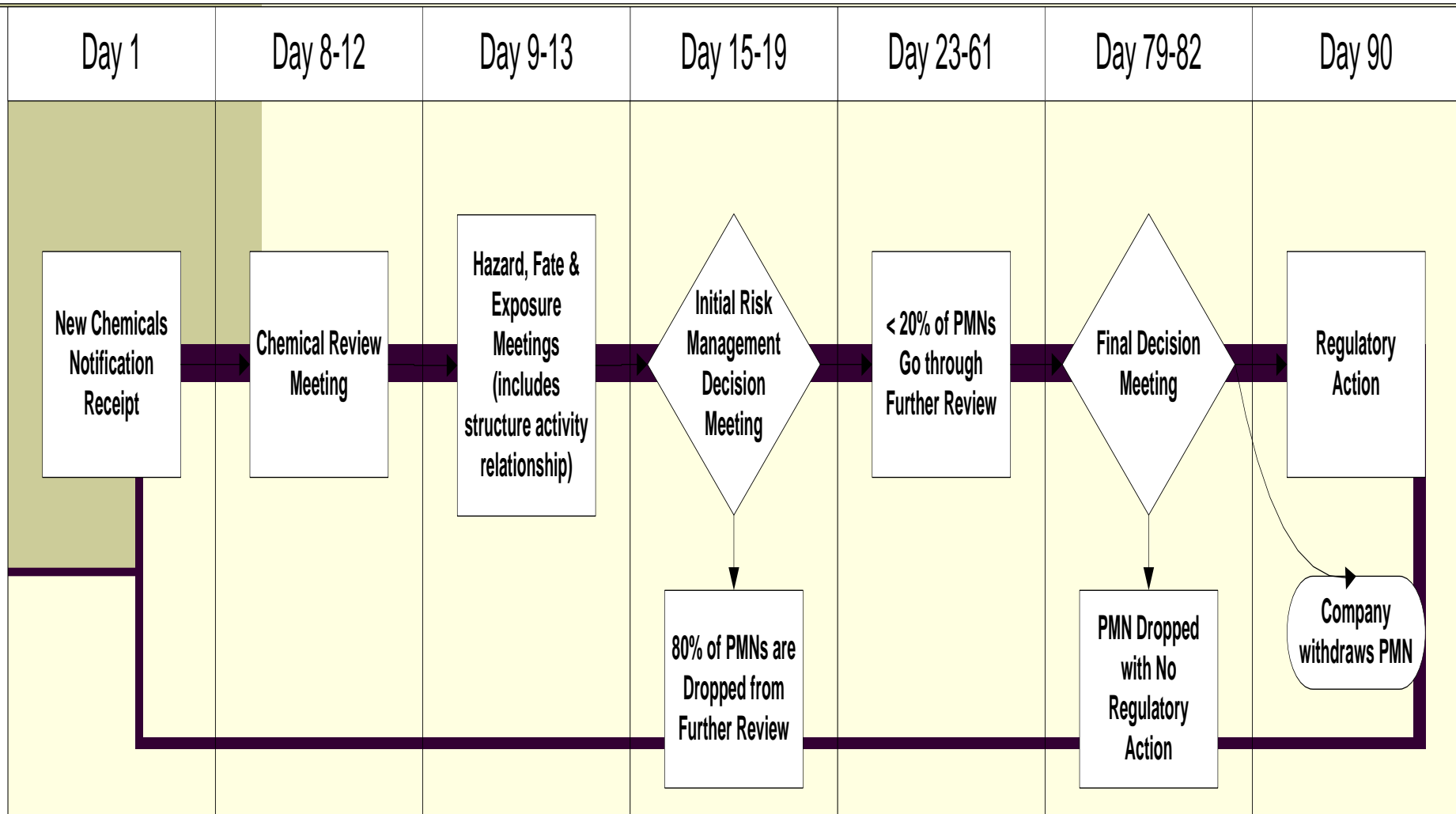
Information Required in Submissions

- Chemical identity
- Byproducts
- Production/Import volume
- Description of uses
- Description of human exposure
- Description of disposal practices
- Available test data:
 - About 50% of PMNs received contain no test data
 - About 15% of PMNs received contain toxicity data
 - Minimal environmental effects/fate data submitted

Inputs and Outputs of the New Chemicals Review Process



New Chemicals Review Process



Chemical Review and Search Strategy (CRSS) Meeting

- Chemical Identity
- Structure/Nomenclature
- Analogs/Inventory Status
- Synthesis (includes byproducts and impurities)
- Physical/Chemical properties
- Pollution Prevention

Structure Activity Team (SAT)

- Screening level assessment of potential hazard to human health and the environment and environmental fate
- Hazard profile based on:
 - Physical and Chemical properties
 - Routes of absorption
 - PMN data
 - Structure activity relationship (SAR) analysis
 - Quantitative Structure Activity Relationship estimates
 - Persistent Bioaccumulative Toxic properties

Exposure Assessment

- Entire life-cycle of chemical
 - Workplace
 - Media for releases
- Quantification of releases and exposures
 - Physical and Chemical properties and environmental fate
 - Industrial practices
 - Use practices

Focus Meeting

- Risk management decision meeting by a multi-disciplinary group
- Reporting of hazard and exposure assessments (initial screen)
- Address “low concern” chemicals and chemical categories
- Determination of significant risk for categories, substantial production/significant and/or substantial exposure
- Make decisions on categories and exposure based actions or to initiate Standard Review

Standard Review

- Review and reporting beyond screening level
- Hazard and exposure assessments are in greater detail and depth
- Quantification of potential risk
- Economic analysis on use, substitutes, production volume, and benefits
- Risk management decision meeting

Risk Assessment/Risk Management at Final Decision Meeting

- Consider results of the detailed assessment
- Factor in hazard, exposure, risk, risk/benefit, alternatives, and regulatory history for related PMN cases, etc.
- Outcome
 - Final decisions are made on the 20% of PMN cases continued into this review, of these about $\frac{1}{2}$ are dropped, $\frac{1}{4}$ are withdrawn by submitter in face of regulatory action, and control measures are taken on remaining $\frac{1}{4}$.

Final Risk Management Decisions

- Drop
- Regulate:
 - 5(e) Consent Order (a legal agreement between EPA and the company) which can include:
 - Control exposures/uses
 - Require testing
 - Take other action
 - 5(e) Significant New Use Rule (extends the risk management decisions to any other company interested in the use of the chemical)
 - Non 5(e) Significant New Use Rule (used to control uses other than the ones stated in the submission that could result in increased exposures to, or release, of the PMN substance)
 - Suspension, Ban Pending Upfront Testing

Notice of Commencement

- Submit within 30 days of first manufacture
- Must be submitted by PMN submitter
- Substantiate CBI Claims

Communication Exchange



Approaches to Environmental Stewardship

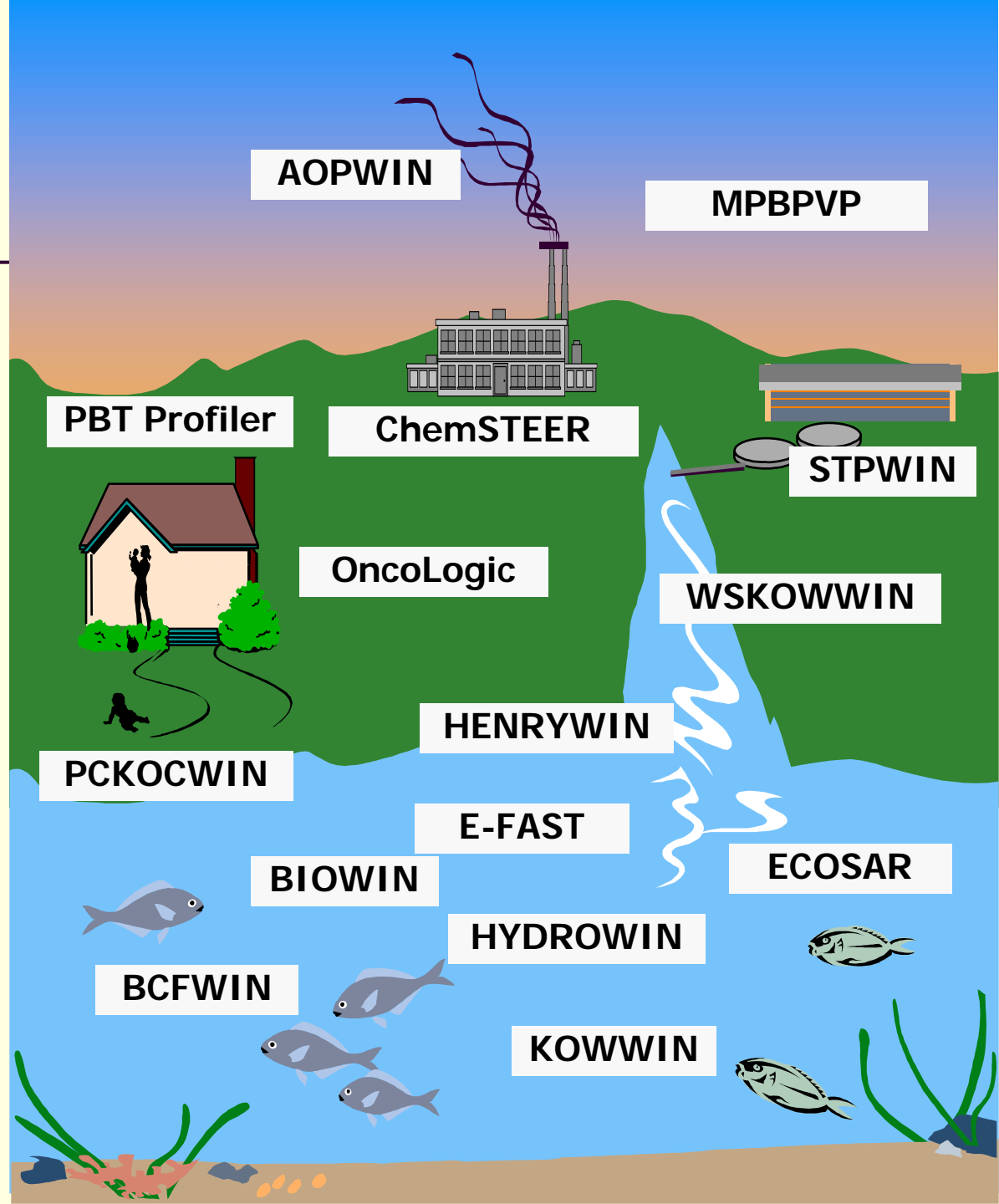
- Pollution Prevention Recognition
 - Promotes source reduction, greener chemistry, and greener engineering practices through recognition
- Sustainable Futures
 - EPA program to make its SAR tools available to Industry for use in research and development in order to design safer and greener new chemicals



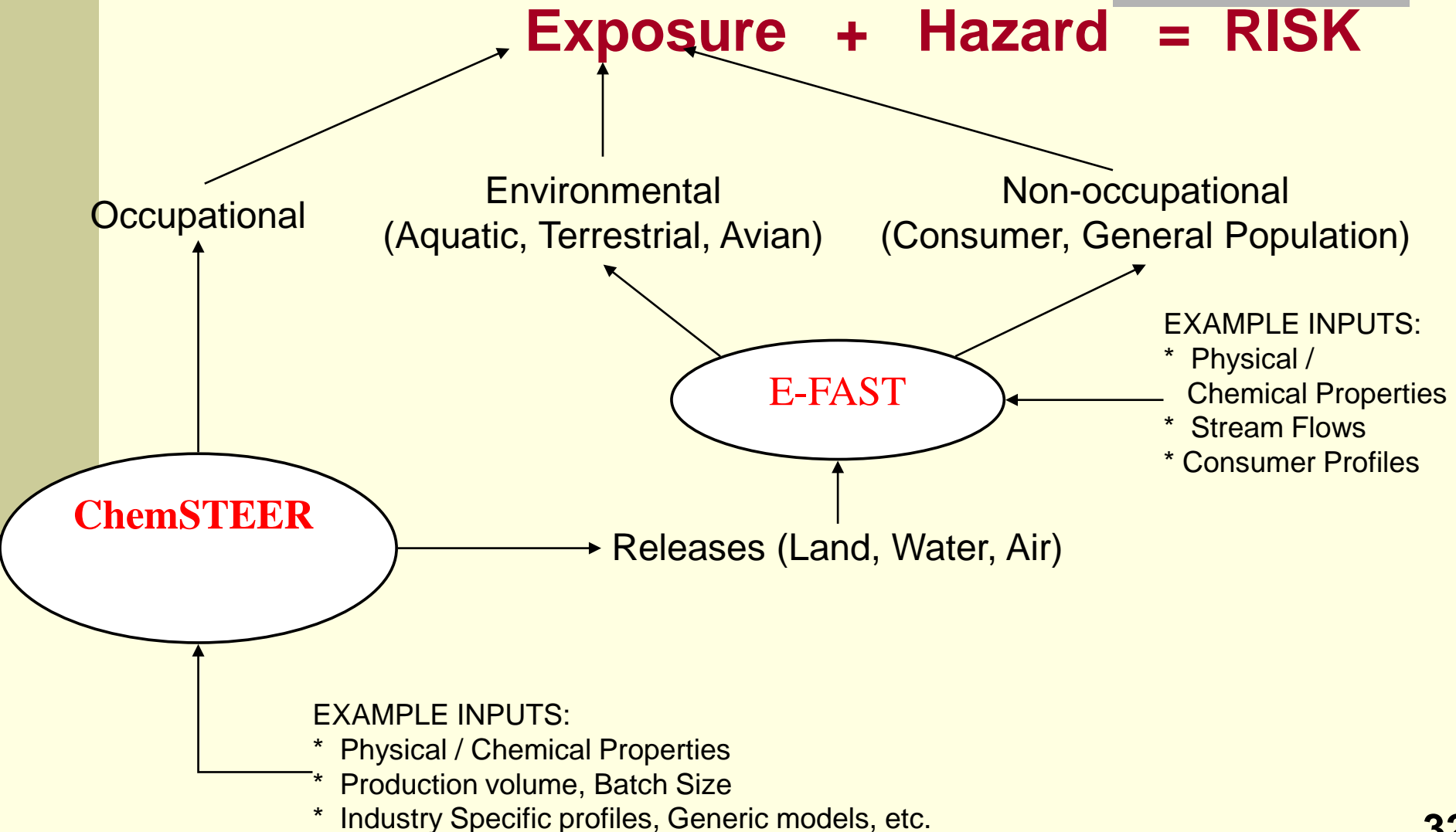
Process Improvements

New Chemicals Models

- Once released, will the chemical go to air, water, soil, sediment?
- How long will the chemical stay in media?
- Will the chemical present a hazard?
- Could this be a PBT?
- Who will be exposed and for how long?



Exposure Information Flow in New Chemicals Risk Screening



Chemical Categories

- Currently 55 categories - human health and ecotoxicity
- Based on analogue test data
- Identifies endpoints of concern
- Provides testing recommendations
- Delegated authority on structural analogues of these category compounds
- EPA needs relevant data to refine concerns

Policy on Persistent, Bioaccumulative, and Toxic (PBT) New Chemicals

- Policy Statement published in 1999
- TSCA Section 5(e) action where:
 - Persistence (transformation half-life) is > 2 months
 - Bioaccumulation (Fish BCF or BAF) is $\geq 1,000$
 - Identification of a potential hazard to human health/environment
- Approximately 7% of notices received since 2001 have been designated as a PBT

Exposure-based Policy est. 1988

Exposure Parameter	TSCA 5(e) Exposure-Based Policy Criterion
Production Volume	100,000 kg/yr
Significant or Substantial Human Exposure: High Number of Workers Exposed	$\geq 1,000$ workers
Significant or Substantial Human Exposure: Acute Worker Exposure, Inhalation	≥ 100 workers exposed to ≥ 10 mg/day
Significant or Substantial Human Exposure: Chronic Worker Exposure, Inhalation	≥ 100 workers exposed to 1-10 mg/day for ≥ 100 days/yr
Significant or Substantial Human Exposure: Chronic Worker Exposure, Dermal	≥ 250 workers exposed by routine dermal contact for ≥ 100 days/yr
Significant or Substantial Human Exposure: Consumer	Presence in consumer product where exposures are likely
Significant Human Exposure: Ambient General Population	≥ 0.003 mg/kg/day exposure via drinking water, air, or groundwater
Substantial Human Exposure: Ambient General Population	$\geq 10,000$ kg/yr release to environmental media
Substantial Environmental Release	$\geq 1,000$ kg/yr total release to surface water calculated after wastewater treatment

Exposure-based testing

■ Health Testing

- Bacterial reverse mutation (formerly "Ames") test
- Mammalian erythrocyte micronucleus (intraperitoneal route)
- Repeated dose 28-day oral toxicity in rodents
- Acute oral toxicity
- "Prenatal Developmental Toxicity" test
- "Reproduction/Developmental Toxicity Screening Test"

■ Environmental toxicity testing:

- Algal toxicity
- Aquatic invertebrate acute toxicity, freshwater daphnids
- Fish acute toxicity
- Chronic toxicity tests of aquatic organisms

■ Environmental Fate Testing

- Water solubility
- Fate in wastewater treatment - Porous Pot test
- Aerobic biodegradation - Ready Biodegradability test
- Anaerobic biodegradation - Anaerobic Biodegradability of Organic Chemicals
- Soil biodegradation
- Photolysis (photodegradation)
- Hydrolysis as a function of pH (stability in water)



New Chemical Decisions

Possible Decisions

- Drop from further review
- Drop with a concern letter
- Regulate:
 - Suspension, pending upfront testing (under section 5(e) authority)
 - Section 5(e) consent order – Risk-based and Exposure-based
 - Section 5(a)(2) significant new use rule (SNUR)
 - Section 5(f) action -> section 6 ban or rule
 - Unilateral section 5(e) order (ban, pending testing)

“Drop” Decision

- A case is dropped from further review when it:
- Does not meet any of the exposure-based criteria
 - Does not present an unreasonable risk to human health or the environment
 - Does not present increased potential for risk from an increased production volume or other uses

Drop with a Concern Letter

- The notifier is informed by letter of potential hazard or risk.
- Data exist for structurally analogous substances.
- Small population may be affected and potential risk is controllable.
 - Standard industrial practices
 - PPE
 - Environmental controls

Suspension, Pending Upfront Testing

- There is insufficient information, and chemical substance may pose an unreasonable risk
- Risk from exposure or release cannot be controlled
- Testing or other information will provide a more informed risk assessment

TSCA, Section 5(e)

Consent Orders

The information . . . is insufficient . . . to permit a reasoned evaluation . . . such activities . . .

- May present an unreasonable risk of injury to health or the environment, or . . .
- Will be produced in substantial quantities, and . . . enter the environment in substantial quantities or there . . . may be significant or substantial human exposure .

5(e) Risk-based Consent Order

- There is insufficient information, and chemical substance may pose an unreasonable risk
- Risk from exposure or release can be controlled
- Manufacturing can commence under specific terms and conditions
- Testing or other information will provide a more informed risk assessment

Potential Control Measures in 5(e) Orders

MAY INCLUDE:

Testing

Protective Equipment Requirements

Worker Training Programs

Distribution/Use/Disposal Restrictions

Labels, MSDS, and Notification Letters

Restrictions on Releases to Water/Air

Recordkeeping Requirements

Production/Importation Volume Testing Trigger

New Chemical Exposure Limit (NCEL)

Product Stewardship Programs

5(e) Exposure-based Consent Order

- $PV \geq 100,000$ kg/yr
- There is insufficient information, and
 - (1) substantial environmental exposure or
 - (2) significant/substantial human exposure criteria are met.
- Manufacturing can commence.
- Testing or other information will provide a more informed hazard assessment.
- Testing is triggered at specified PV.

Significant New Use Rules (SNURs)

- “Section 5(e) SNUR” – extends consent order requirements to other manufacturers and processors
- “Non-section 5(e) SNUR” – provides that standard provisions would apply without use of 5(e) consent order
- Notice and Comment SNUR

Outcomes

- **Drop from further review (before or at the Focus Meeting):** about 80% of PMNs
- **Drop from further review (after the Focus Meeting):** 7%
- **Regulated:** about 8% of PMNs,
 - Unilateral section 5(e) consent order (ban, pending testing)
 - Section 5(e) consent order
 - Section 5(a)(2) significant new use rule (SNUR)
- **Withdrawn:** about 5% of PMNs



Emerging Issues

Approaches for Nanoscale Materials under TSCA

- Many nanoscale materials (NMs) are chemical substances as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are new chemicals and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture
- There is presently no similar requirement for NMs that are existing chemicals, i.e. already on the TSCA inventory
- The limited information currently available indicates that NMs may have different toxicity and/or exposure characteristics than their “macro” counterparts

TSCA New Chemicals Program Experience/Issues

- PMN submissions on nanosized chemicals are being received and reviewed but most have not met other elements of National Nanotech Initiative (NNI) definition -- unique properties or deliberately engineered -- other than:
 - A low release, low exposure exemption has been granted (carbon nanotube)
- There have been several recent company meetings on pending new chemical NMs
- General approach has been to permit limited manufacture of nanosized new chemicals under appropriate controls via use of consent orders and Significant New Use Rules (SNURs)

Emerging Issues: PFOS / PFOA

- EPA incorporated information on PFOS, PFOA into new chemical reviews for related materials and substitute compounds
 - Reviews typically consider decomposition products, fate, transport, bioaccumulation potential, toxicity, use patterns, potential exposures and releases
 - Consent orders under TSCA §5(e) specify additional testing, other controls where necessary on new chemicals that make it through review
- New and Existing Chemical Programs coordinate for consistency in approach, data

Emerging Issues: Biotechnology

- TSCA Biotech regulations published in 1997 (62 FR 17910-17958)
- Covers “new” microorganisms used for commercial purposes
 - Industrial enzymes, biofuels and biofertilizers, breakdown of chemical pollutants in the environment
 - Hazard and exposure assessments are different than for chemicals
 - Colonization and pathogenicity, toxin production, virulence, ability to transfer virulence factor genes, allergic reactions
 - Release and survival of the microorganism

Additional Information

- **New Chemicals Program**
www.epa.gov/oppt/newchems
- **Policies**
www.epa.gov/oppt/newchems/pubs/policies.htm
- **Guidance**
www.epa.gov/oppt/newchems/pubs/guideman.htm
- **International Trade Data System (ITDS) - Automated Commercial Environment (ACE)**
www.itds.gov/xp/itds/home.xml
- **EPA Agency-wide Import-Export Portal**
www.epa.gov/compliance/international/importexport.html
- **OPPT TSCA Import-Export Website**
www.epa.gov/oppt/import-export/index.htm
- **TSCA Section 13 Import Checklist**
www.epa.gov/oppt/import-export/pubs/checklist.pdf
- **Compliance Guide for Chemical Import Requirements of TSCA**
www.epa.gov/compliance/resources/publications/monitoring/tsca/importguidejune2008.pdf



Thank you