

TSCA, REACH and the Lautenberg Act *Chemical Regulation for the 21st Century*

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TSCA, REACH and TSCA 2.0

TSCA

- Toxic Substances Control Act (1976)

REACH

- Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (2006)

Lautenberg Act

- Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016)



Purpose & Intent of TSCA (1976)

To protect against “**unreasonable risks**” posed by exposure to chemical substances



Manufacturers should develop “**adequate data**”



Federal government should have “**adequate authority**”



Government should **not** “**unduly impede**” innovation



Key Provisions of TSCA Title I

§ 4 – Existing Chemicals

§ 5 – New Chemicals & New Uses

§ 6 – Restricting Chemicals Posing Unreasonable Risk

§ 8 – Information Requirements

§ 12 / § 13 – Exports/Imports

§ 14 – Confidential Business Information

§ 18 / § 26 – Preemption / Fees



TSCA § 4 – Testing Existing Chemicals

EPA may require testing on an existing chemical that:

- may present an **unreasonable risk**, or
- is produced in **substantial quantities**



To require testing, EPA must promulgate a rule




Implementation of TSCA § 4

Test Rules + Voluntary Testing Agreements =

 266 chemicals tested

($< 0.5\%$ of chemicals listed on inventory)

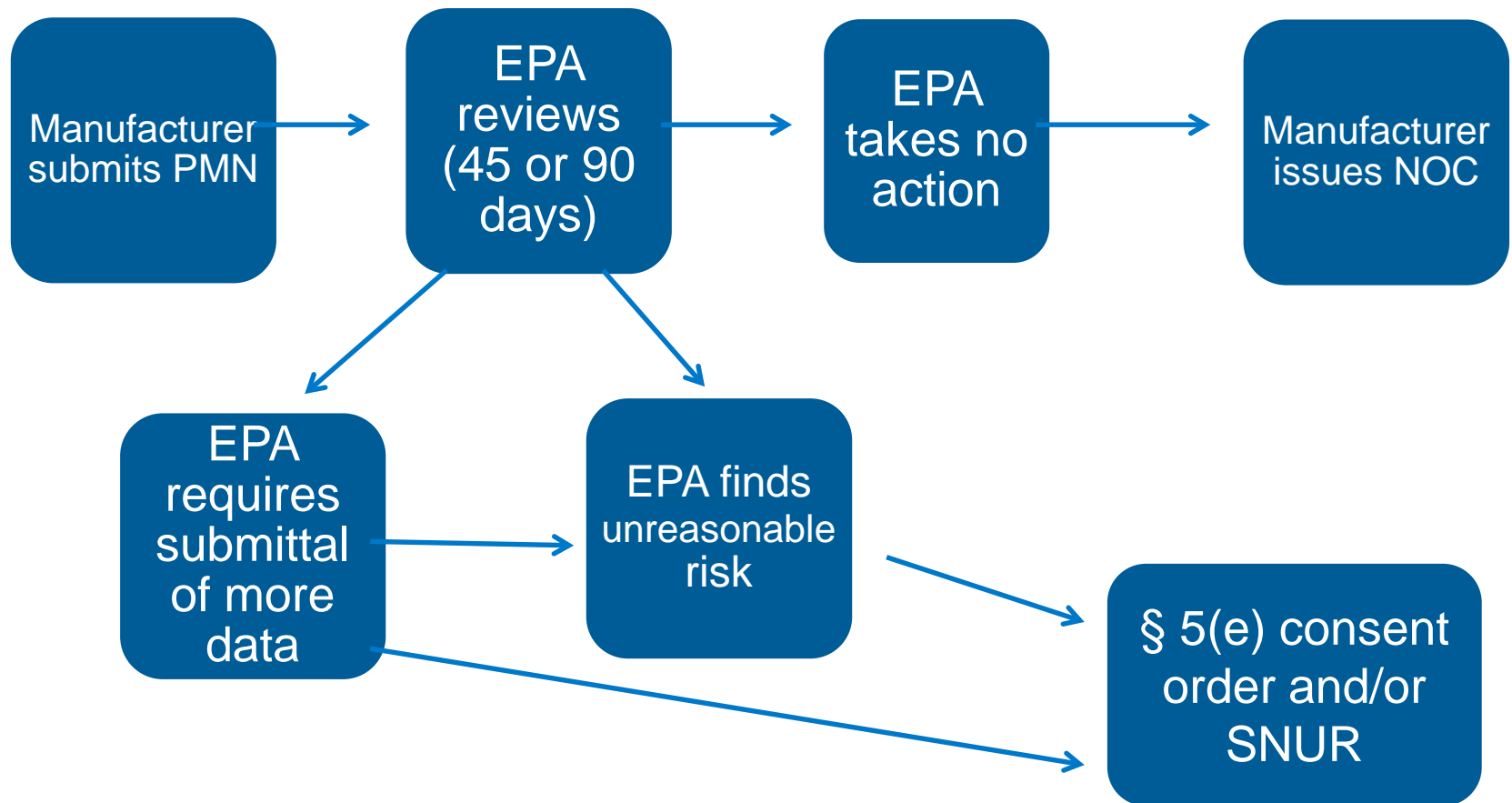
High Production Volume Challenge Program =

 2,200 chemicals tested

(95% of U.S. commercial market by volume, per ACC)



TSCA § 5 – New Chemicals



TSCA § 5 – New Uses

SNURs for existing chemicals:

Manufacture must submit SNUN 90 days prior to manufacture for new use

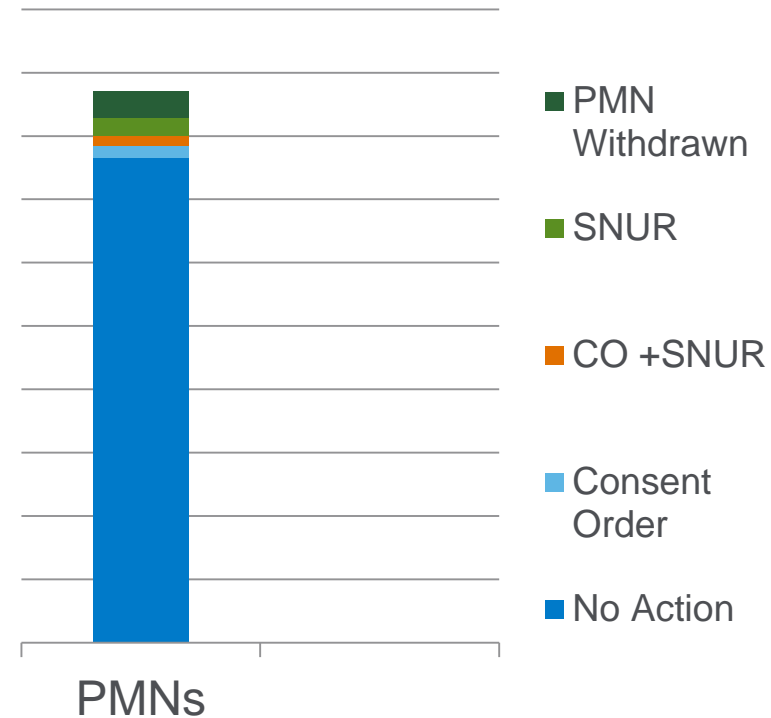
SNURS for new chemicals:

- If EPA enters § 5(e) consent order with PMN submitter, may follow with SNUR for other manufacturers
- EPA can also issue SNUR on new chemical for uses other than use proposed by the PMN submitter



Implementation of TSCA § 5

Category	Approximate Number
PMNs submitted to EPA since 1976	40,000
§ 5(e) consent orders issued by EPA	1,710
SNURs issued following §5(e) consent orders	740
SNURS issued following PMN	1,460
PMNs withdrawn in face of action	2,070



TSCA § 6 - Restrictions

➤ Authorizes EPA to impose risk management measures – **restrictions on manufacture or use of a substance**

➤ **BUT** EPA must:

- impose the “**least burdensome**” restrictions necessary to mitigate the risk
- consider economic consequences
- meet different judicial standard: “**substantial evidence**” rather than “arbitrary and capricious”



Implementation of TSCA § 6



1976-1990: EPA issues § 6 restrictions on:

- PCBs
- Halogenated chlorofluoroalkanes
- Dioxin
- Asbestos
- Hexavalent chromium



1991: *Corrosion Proof Fittings v. EPA*

Fifth Circuit Court of Appeals strikes down EPA's proposed asbestos ban



1992-2006: No further § 6 restrictions



TSCA § 8 – Information Requirements

➤ TSCA Inventory

- ~ 84,000 substances
- unknown how many remain in production or use

➤ Information submittal requirements

- CDR
- Unpublished health and safety studies
- Substantial Risk Notifications

TSCA § 14 – Confidential Business Information

- ▲ Submitters can designate data as CBI
- ▲ EPA must protect CBI from public disclosure
(except health and safety studies, unless disclosure would reveal chemical process/composition)
- ▲ No time limit on CBI claims
- ▲ EPA must initiate formal administrative action to challenge CBI claim



Implementation of TSCA § 14

As of 2010, CBI claimed for

> 20,000 chemical substance identities



TSCA § 18 – Preemption

TSCA § 26 – Fees

▲ **State Preemption:** applies when EPA has issued a rule or order under § 5 or § 6, unless –

- Identical to the federal requirement
- Implements another federal law
- Prohibits use of the substance/mixture within the state

▲ **Fees:**

- EPA can require a “reasonable fee” (<\$2,500) from parties required to submit data under § 4 or § 5
- Revenue directed to the general treasury



Calls for TSCA Reform

General consensus on TSCA weaknesses:

- Existing chemicals not sufficiently reviewed
- Rulemaking process too burdensome
- Role of economic criteria in risk evaluation
- Burden of proof (e.g. for PMNs) on EPA
- CBI claims excessive
- Barriers to restriction too high

Basic Structure of REACH

To “ensure a high level of protection of human health and the environment”

Based on the **Precautionary Principle**:

**Considered
unsafe until
proven safe**

vs.

**Considered
safe until
proven
unsafe**



REACH Registration

“No data, no market.”

Must register all substances
manufactured/imported at > 1 T/y

“One substance, one registration.”

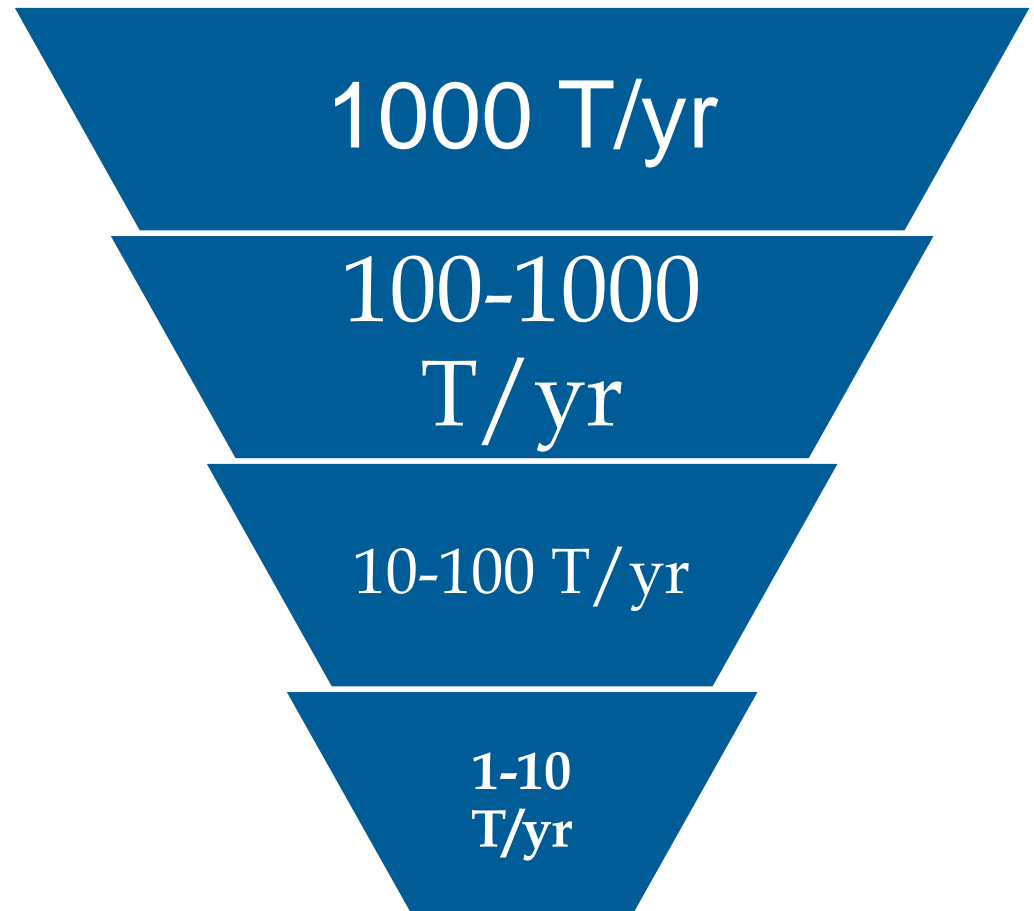
Must submit registrations jointly



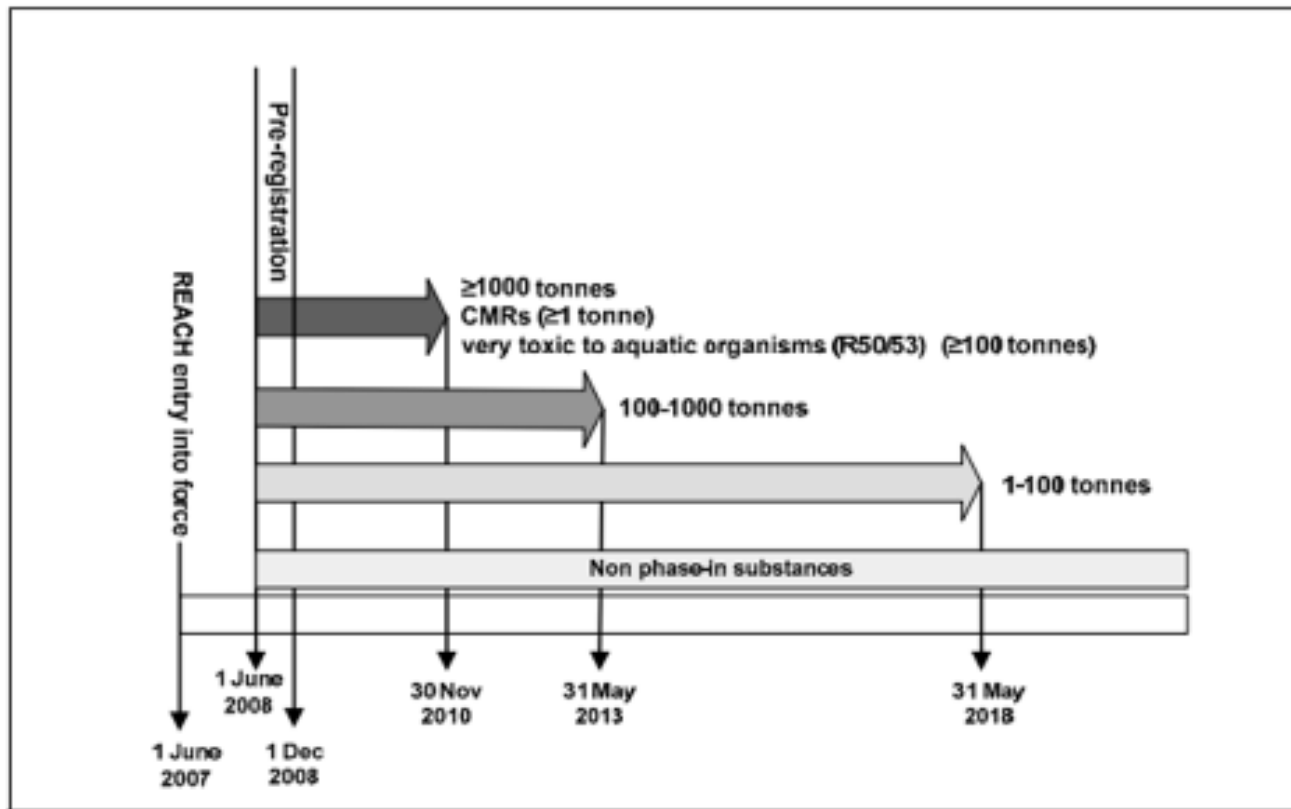
REACH – Registration Requirements

Registration Dossier

- submitted electronically via IUCLID
- Technical dossier
 - extent of data required depends on tonnage band
- Chemical Safety Report (if > 10 T/yr)



REACH Registration – Phase-In



REACH Registration – Data Sharing

▲ SIEF – Substance Information Exchange Forum

to facilitate data sharing in a
“fair, transparent and non-discriminatory way”

	Registrations	Unique Substances
TOTAL	45,373	9,472
Phase-in	41,834	7,905
Non phase-in	3,539	1,567



REACH Evaluation

Three types of evaluation:

1. Evaluation of **testing proposals**
2. Registration dossier **compliance checks**
 - **Goal:** Checks on 5% dossiers per year
 - **2015 Results:** 183 dossiers checked, 18% fully compliant
3. **Substance evaluation**
 - **2015 Results:** 16 substance evaluations completed



REACH Authorization

- ▲ To control and progressively replace

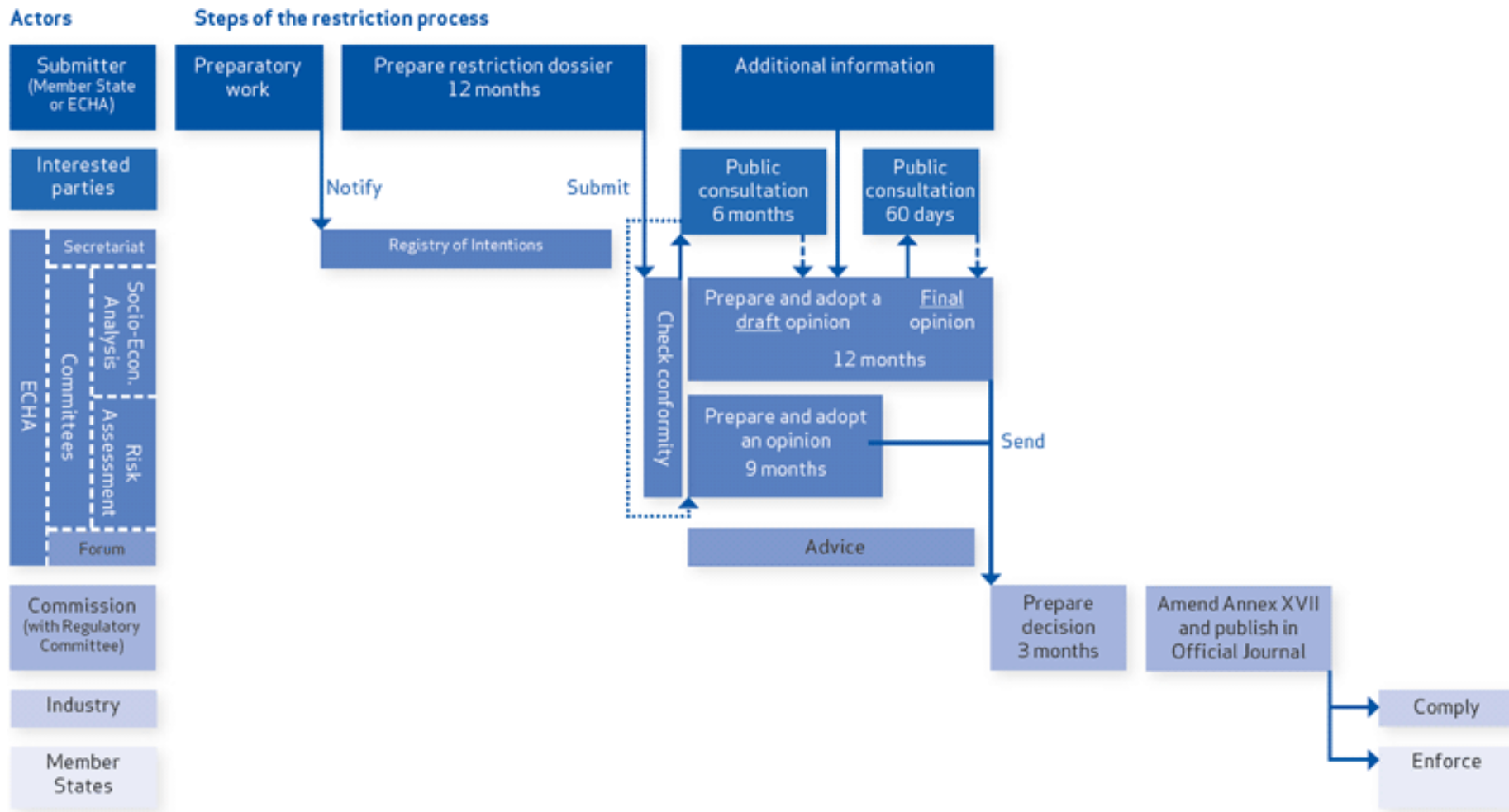
Substances of Very High Concern

- ▲ SVHCs = CMR, PBT Process:



- ▲ 31 substances on Authorisation List

REACH Restriction



REACH Implementation to Date

- ▲ High (and underestimated) cost of implementation
- ▲ Focus to date on massive registration efforts
- ▲ Pace of evaluation, authorization, restriction slow but increasing
- ▲ Significant competitive advantages for large EU chemical manufacturers

Overview of TSCA 2.0

The Frank R. Lautenberg Chemical Safety for the 21st Century Act



Intent of TSCA 2.0

- Establish a credible U.S. program
- Fix what is not working:
 - Review of existing chemicals
 - Barriers to EPA action
 - Lack of restriction authority
 - Scope and continuity of CBI claims
- Also:
 - Protect vulnerable populations
 - Inform public health officials/first responders

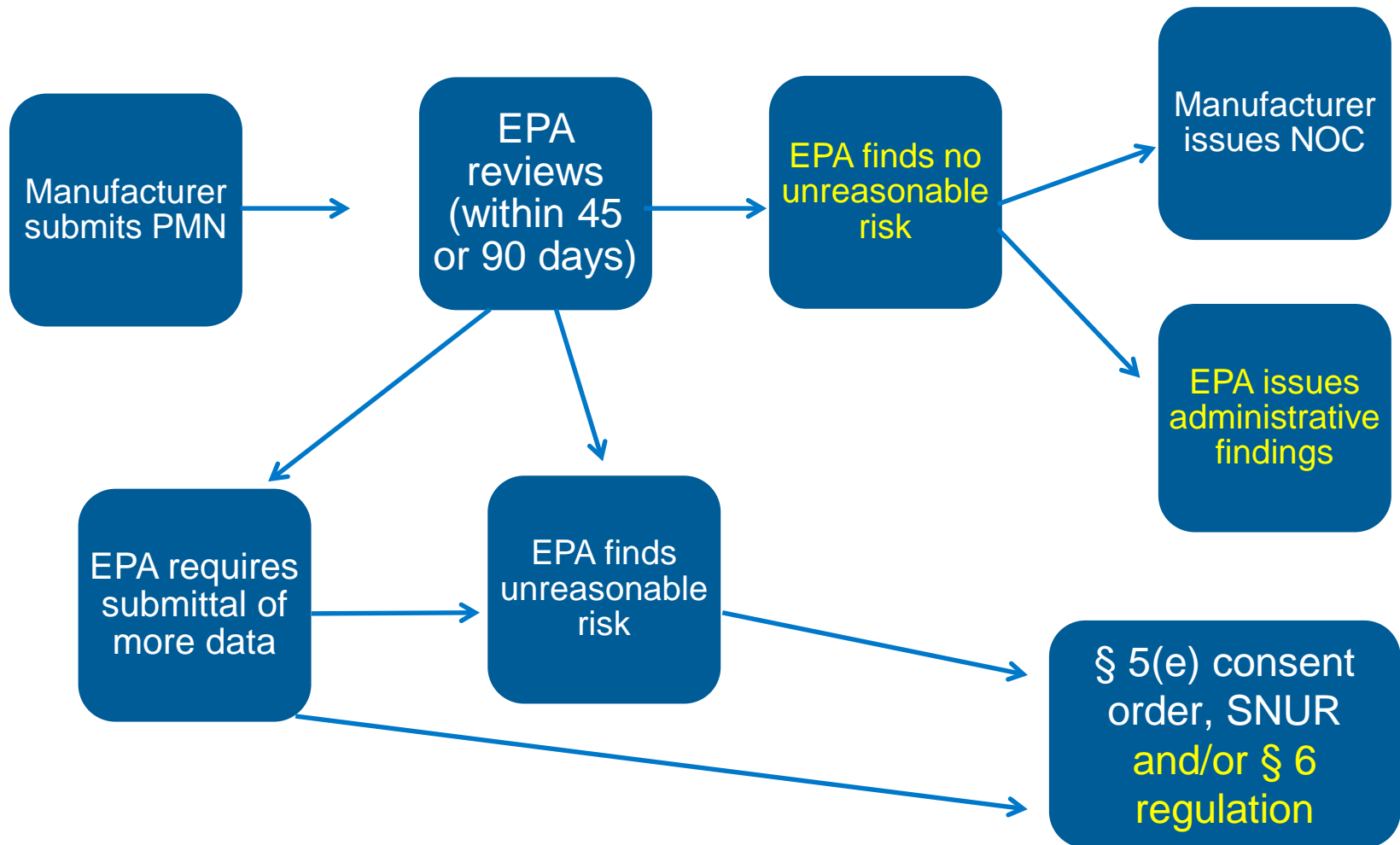


TSCA 2.0 § 4 – Testing of Existing Chemicals

- EPA can require tests through **orders and consent agreements** as well as rules
- EPA to prepare **statement of need** justifying decision to require testing
- Requires **tiered testing** unless available information already justifies more advanced testing
- Requires reduction of testing on vertebrates



TSCA 2.0 § 5 – New Chemicals



TSCA 2.0 § 6 – Prioritization, Risk Evaluation, and Regulation

- Requires EPA to prioritize and systematically conduct risk evaluations of existing chemicals (high- and low-priority)
- Prohibits EPA from considering cost in evaluating risks
- EPA must consider risks to potentially exposed or susceptible populations, and whether a chemical's conditions of use would attain the safety standard
- Requires EPA to issue a risk management rule if it determines a chemical poses an unreasonable risk
- Removes requirement of “least burdensome” restrictions



TSCA 2.0 § 8 – Information Requirements

TSCA Inventory Reset:

- Companies to notify EPA of chemicals manufactured/processed in past 10 years
- EPA to designate all substance as active or inactive



TSCA 2.0 § 14 – CBI

- Manufacturer must substantiate confidentiality claims
- CBI protections expire after 10 years unless re-substantiated
- EPA to review all existing confidentiality claims as to substance identity



TSCA 2.0 § 18 - Preemption

- **“Anti-duplication”** provision on information requests
- Prohibition on state restrictions once EPA finds no unreasonable risk or issues a § 6 rule
- **“Regulatory pause”** while EPA conducts risk evaluation
- State laws in effect 8/31/2003 and state actions taken before 4/22/16 are **grandfathered**



TSCA 2.0 § 26 - Administration

- Fees for activities under §§ 4a, 5, 6, and 14:

25% of the cost to EPA of carrying out activities,
or a maximum of
\$25M (subject to adjustment)



TSCA 2.0 – Key Deadlines

6 months after enactment

- EPA must have 10 chemicals under risk evaluation

1 year after enactment

- EPA must:
 - 1) establish screening process for designating high- and low-priority substances
 - 2) publish final rule regarding TSCA inventory reset
 - 3) develop guidance for manufacturers on draft risk evaluations
 - 4) establish Science Advisory Committee on Chemicals

2 years after enactment

- EPA must develop strategic plan to promote toxicity testing methods that reduce or replace vertebrate animal testing while providing information of equivalent or better quality and relevance

3 ½ years after enactment

- EPA must be evaluating risks of 20 high-priority chemicals and have designated 20 chemicals as low priority



Observations & Comparisons

- ▲ REACH v. Lautenberg Act – phase-in of programs
- ▲ Program credibility – trade and economic implications
- ▲ Risk-based TSCA v. hazard-based REACH
- ▲ Differing methods of fostering innovation
- ▲ Difficulty and cost of chemical evaluation
- ▲ Complexity of data sharing under REACH

