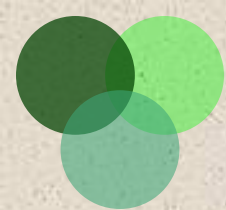


Green Chemistry
An Interdisciplinary Approach to Sustainability
Sustainable Biofuels Development
Chem, ESPM, SPH 234

**Class 19: The European Union's REACH legislation
and the Precautionary Principle**

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Wingspread Statement of the Precautionary Principle (1998)

When an activity raises **threats of harm to human health or the environment**, **precautionary measures should be taken** even if some cause and effect relationships are not fully established scientifically.

In this context **the proponent of an activity**, rather than the public, **should bear the burden of proof**.

The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. **It must also involve an examination of the full range of alternatives, including no action.**



Elements of the Precautionary Principle

1. Preferentially avoids threats of harm to human health or the environment.
2. Acts on early warnings of harm even if some cause and effect relationships are not fully established scientifically.
3. The proponent of an activity, rather than the public, should bear the burden of proof.
4. The process of applying the Precautionary Principle must be open, informed and democratic, must include potentially affected parties.
5. It must also involve an examination of the full range of alternatives, including no action.



Precautionary Principle Decision-making Structures

- 1. Safety standard: move away from cost-benefit test toward health/safety/technology standards**
- 2. Burden of proof: Switch from government to industry**
- 3. Level of certainty required: move from definitive evidence to acting on early warnings**

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)



REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

- Went into force June 1, 2007
- First deadline December 1, 2008 (pre-registration)
- Europe's response to a similar situation as ours



REACH vs. TSCA



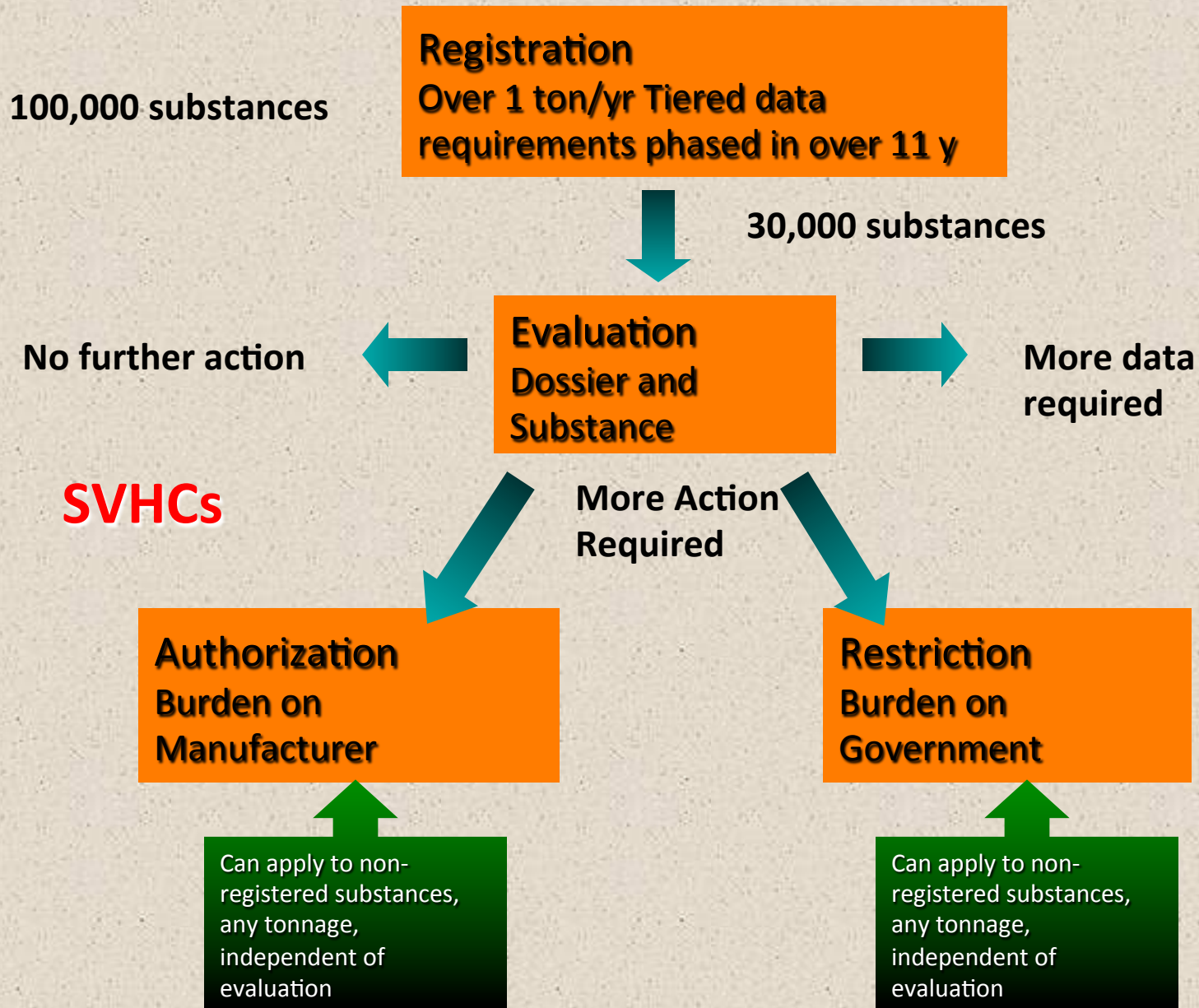
Data Gap

- Mandatory Data disclosure for 30,000 chemicals
- Level playing field for new and existing chemicals
- Public access to information
- Two-way communication in supply chain

Safety Gap

- Burden of proof placed on industry under Authorization for “substances of very high concern”

Overview of REACH Process



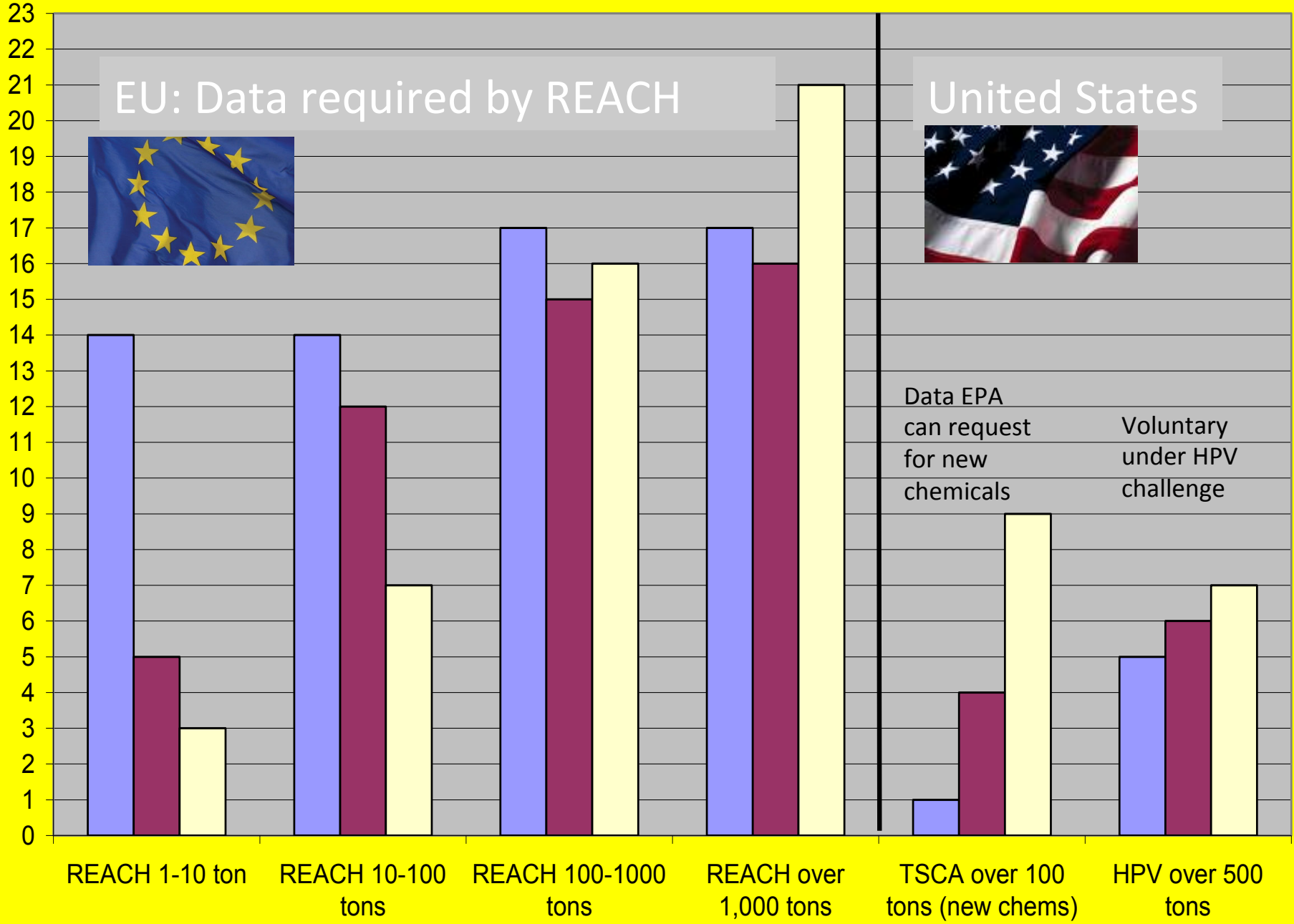
EU: Data required by REACH



United States



Tests



Data EPA can request for new chemicals

Voluntary under HPV challenge

Physical/chemical properties Health effects Environmental effects & fate

Authorization

First Step: Identify Substances of Very High Concern (SVHC)

- a) Carcinogenic
- b) Mutagenic
- c) Toxic for Reproduction
- d) Persistent, Bioaccumulative and Toxic
- e) very Persistent and very Bioaccumulative
- f) Substances of equivalent concern (e.g., EDC's)

Process to place on Annex 14 SVHC list
(138 substances and groups of substances are currently on candidate list)

Authorization

Second step: Apply for Authorization

Manufacturers apply for use-specific authorization and must show:

- a) “Adequate control” (cannot claim “adequate control” for PBT, vPvB, or if cannot establish no-effect threshold); or
- b) Socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and there are no suitable alternative substances or technologies

Status of REACH Implementation

1. Registration

First registration Deadline was November 30, 2010

(Next deadline is May 2013 (for 100-1000 tonnes)

For CMR's, high volume (1000 tonnes/y or more); Env. tox.

4,725 substances registered (26,185 registrations)

Almost exactly what ECHA expected

3480 are phase-in; 1,250 are non-phase-in

Proposals to do 1,548 animal tests for 580 chemicals

400 are CMR's

1,500 registration dossiers have been posted on website

80% of these are on TSCA Inventory

60% were reported in latest TSCA Inventory Update Reporting

2. Authorization

138 chemicals and chemical groups are "Recommended" for inclusion on Annex IV to be made subject to authorization

Establishing Annex XIV

Substances Subject to Authorization

Identify SVHC
CMR, PBT, vPvB, or equivalent concern

Hundreds

Propose for the Candidate List
Prepare Annex XV dossier

Establish Candidate List

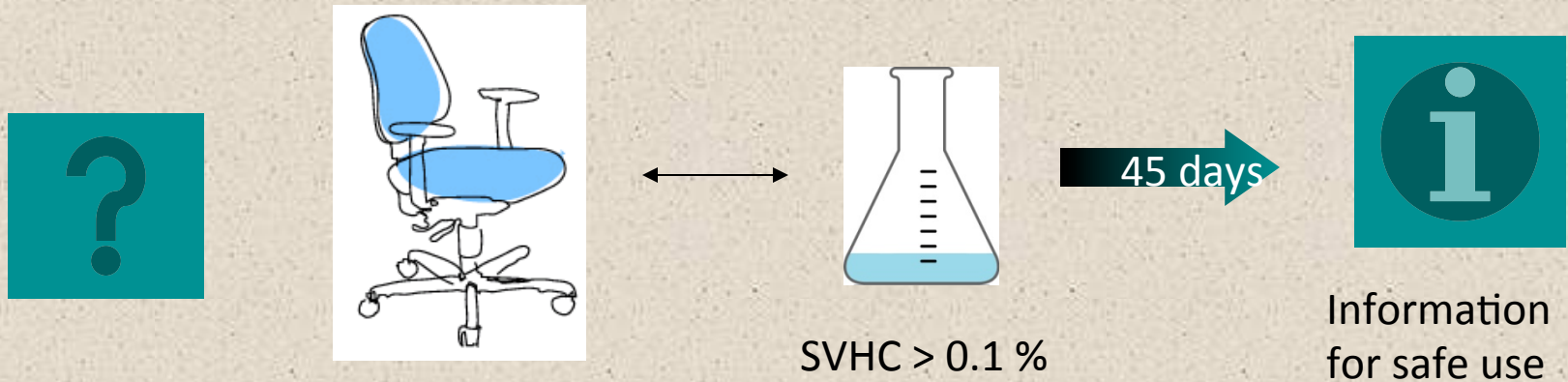
15 + rolling admissions

Prioritize Substances
Propose for Annex XIV

?

Include in Annex XIV
Use prohibited unless authorized or exempted

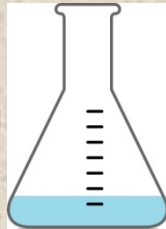
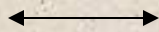
Obligations Linked to Candidate List: Communicate with Users



From date of substance inclusion on Candidate list:

- Automatically to downstream user, or on request from consumer, suppliers must provide "sufficient information to ensure safe use" of article
- For articles containing a Candidate SVHC above 0.1% (by weight)
- Minimum information is substance name

Obligations Linked to Candidate List: Notify ECHA



SVHC
> 0.1%
> 1 tpa



Notify
Agency

Beginning 2011:

- Any producer or importer of articles
- Containing a Candidate SVHC above 0.1% (by weight)
- In quantities over 1 tpa
- Must notify the Agency

New Chemicals Policy in California

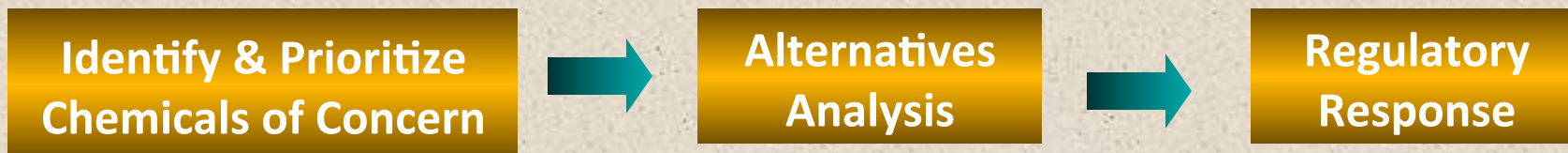


California EPA Green Chemistry Initiative

- Expand Pollution Prevention
- Develop Green Chemistry Capacity
- Create an Online Product Ingredient Network (SB 928)
- Create an Online Toxics Clearinghouse (SB 509)
- Accelerate the Quest for Safer Products (AB 1879)
- Move Toward a Cradle-to-Cradle Economy

SB 509 (Simitian): Create an Online Toxics Information Clearinghouse

AB 1879 (Feuer): Accelerate the Quest for Safer alternatives



SB 928 (Simitian): Product Ingredient Disclosure (2010)



Safe Chemicals Act of 2012

Requires EPA to establish mandatory minimum data set and authorizes EPA to require additional information if necessary

Requires EPA to prioritize chemicals based on likely risk, volume, uses, toxicity, persistence, bioaccumulative potential

Requires expedited action on prioritized chemicals

Requires EPA to evaluate whether industry shows that prioritized chemicals present “reasonable certainty of no harm.”

Establishes a public database of information with narrow CBI provisions
Provisions to promote green chemistry and development of safer alternatives