C234: Green Chemistry: An Interdisciplinary Approach to Sustainability

Class 17: Law and Policy --- Chemicals Policy Reform

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Review

Neoclassical Economics
- Prevailing school of economics in U.S., global institutions
- Relies on market to provide value-free, objective criterion of welfare
- Under ideal conditions, free market allocates goods “efficiently” and therefore maximizes social welfare
- Environmental economics treats environment as good subject to market allocation, to be used to produce other market goods; seeks optimal level of pollution and environmental damage.

Ecological Economics
- Newly emerging field
- Scale of human economy is constrained by ecological reality; market can allocate efficiently but cannot contain economy to sustainable scale.
- Distribution of wealth must be decided from outside market system.
- Sustainable development distinguishes economic:
  - “growth” (throughput)
  - “development” (qualitative improvements at sustainable scale).
**Prevailing Welfare Maximization Decision-Making Structure**
Economic actors are free to pursue activity, even if it causes damage to human health and the environment, unless Government (or plaintiffs) can carry their burden of proof to demonstrate that harm can be avoided by regulations that have net benefit (i.e., pass a cost-benefit test).

**Exhibit A: Presidential Executive Order 12866**
“Regulatory Planning and Review” (58 FR 51735; October 4, 1993) §§ 1(a), 1(b), 1(b)(6): requires federal agencies to justify rules using cost-benefit analysis wherever statutes permit.

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**Hazard Data Gathering Under TSCA**
1. TSCA §4: EPA may require testing if it shows it has insufficient information to evaluate safety and chemical may present unreasonable risk or there may be high exposure. Has produced information on 200 chemicals.

2. TSCA §5 PMN’s (67% no testing, 85% no health data)
   CBI claims for 90% PMN’s, 67% of NOC’s and Inventory

3. TSCA §8 requires companies to submit information that “reasonably supports conclusion of substantial risk.” EPA has issued rules calling in unpublished information on testing of chemicals. Thousands of submissions.
   CBI claims for chemical identity (not §14 health and safety data).

4. Voluntary programs: HPV Challenge Program (SIDS data for HPV Chemicals);
   Voluntary Children’s Chemical Evaluation Program
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**TSCA §6(a) [15 U.S.C. 2605(a)]:**

“If the Administrator finds that there is a reasonable basis to conclude that... a chemical substance... presents... an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance... to protect adequately against such risk... “

**TSCA §6(c) [15 U.S.C. §2605(c)]:**

(c) PROMULGATION OF SUBSECTION (a) RULES.—(1) In promulgating any rule under subsection (a)... the Administrator shall consider
(A) the effects of such substance... on health and the magnitude of the exposure,
(B) the effects of such substance... on the environment and the magnitude of the exposure,
(C) the benefits of such substance... for various uses and the availability of substitutes for such uses, and
(D) the reasonably ascertainable economic consequences of the rule... .

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**Structural Weaknesses Of TSCA**


**Data Gap:** Producers are not required to investigate and disclose sufficient information on the hazard traits of chemicals to government, the public, or businesses that use chemicals.

**Safety Gap:** Government lacks the legal tools it needs to efficiently identify, prioritize, and take action to mitigate the potential health and environmental effects of hazardous chemicals.

**Technology Gap:** Industry and government have invested only marginally in green chemistry research, development, and education.
Under TSCA, given the three Gaps, what are:

The Position Of Government?
The Position Of Chemicals Manufacturers?
The Position Of Downstream Users?
The Position of Consumers?


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.

Closing the Safety Gap means

Developing new decision-making structures

1. Safety standard: move from cost-benefit test to health/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
Issues raised by closing the Data Gap

- Put old and new chemicals on same footing?
- No data, no market (mandatory). Who should pay for it? How much cost?
- What if multiple manufacturers make the same chemical. Should all provide same data? Share costs? Ethical issue: Animal testing vs. animal rights.
- How much information? Chemical toxicity and use information?
- Tiered testing with screens, if positive result go on to more tests. (CBCRP)
- Should there be priorities for some chemicals over others? How prioritize if you don’t know anything about a chemical?
- Avoid preference for domestic manufacturers vs. importers?
- Confidentiality of information – competitiveness vs. right to know.
Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

- 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

100,000 substances

Registration
Over 1 ton/yr Tiered data requirements phased in over 11 y

30,000 substances

Evaluation
Dossier and Substance

SVHCs

No further action

More data required

More Action Required

Authorization
Burden on Manufacturer

Can apply to non-registered substances, any tonnage, independent of evaluation

Restriction
Burden on Government

Can apply to non-registered substances, any tonnage, independent of evaluation

100,000 substances

30,000 substances

More data required

EU: Data required by REACH

United States

Data EPA can request Voluntary for new chemicals under HPV challenge

Tests

REACH 1-10 ton
REACH 10-100 tons
REACH 100-1000 tons
REACH over 1,000 tons
TSCA over 100 tons (new chems)
HPV over 500 tons

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
(15 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

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Status of REACH Implementation

1. Registration
   First registration Deadline was November 30, 2010
   (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
   15 chemicals and chemical groups are “Recommended” for inclusion
   on Annex IV to be made subject to authorization

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

New Chemicals Policy in California
Accelerate the Quest for Safer alternatives

Systematic process for:
• Evaluating chemicals of concern in consumer products
• Identifying safer alternatives
• Stimulating investment in CA’s product development sector

1. Generate list of Chemicals of Concern (CoC)
2. Identify products containing CoCs
3. Create a list of Priority Products based on exposure potential
4. Perform an alternatives analysis (AA) using a lifecycle approach
5. Complete requirements of a regulatory response

Safe Chemicals Act of 2010

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