Lessons from the EU's REACH Regulation for California

GC Initiative Stakeholder Meeting

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Richard A. Denison, Ph.D.
Senior Scientist, Health Program

ENVIRONMENTAL DEFENSE

finding the ways that work

Paradigm shift underway in chemicals policies

Current policies toward existing chemicals based on “presumption of innocence”

- Grandfathering-in of 10,000s of “existing” chemicals
- Government shoulders burden of proof
- Compelling evidence of harm needed for govt. to regulate an existing chemical
- Contrast to pesticides, drugs

Implications of such policies

- Impedes devt. of more/better information
  - Companies see little to gain
  - Govts face *Catch 22*: Must have evidence of harm even to require more information
  - Limits efforts only to “bad” chemicals
  - Impedes efforts to identify safer chemicals
- Prevents market from working properly – much deeper/broader info base essential

Key structural constraints in US chemicals policy

Information development:

- Limited tracking of chemicals in commerce
- Upfront data not required for new chemicals
- High hurdle to require chemical testing
- Reliance on “old” toxicology

Information sharing:

- Overly broad allowances for CBI claims
- Few requirements to make information public

Key structural constraints in US chemicals policy

Acting on Information:

- Virtually no criteria to identify chemicals warranting further action; case-by-case
- No mandate to assess existing chemicals
- Only a single, time- and data-constrained assessment opportunity for new chemicals
- Near-impossible hurdle to regulate existing chemicals

Why the commotion about REACH?

- ***"No data, no market"***:
  - Addresses legacy of chemicals grandfathered into existing policies without risk information.
  - Requires registration and specific data as condition to enter or remain on the market.
- ***Burden shifting***: REACH recasts social contract by giving industry responsibility to:
  - develop risk information,
  - assess it for indication of significant risk, and
  - determine risk mgmt needs and adequacy.

  Government plays an oversight role.

Why the commotion about REACH?

- ***Information flow in chemical supply chains***: REACH compels two-way flow
  - suppliers > customers: info about risks of their chemicals and needed risk mgmt.
  - downstream users > suppliers: use info
- ***Authorization for use of substances of very high concern (SVHCs)***:
  - Applicant bears burden to show: risks are "adequately controlled" OR benefits outweigh risks and no alternatives exist.
- But remember–REACH not yet implemented!

Areas for policy comparison

- Identifying / prioritizing chemicals of concern
- Tracking chemical production / use
- Requiring testing or data development
- Assessing chemical risks
- Regulating chemicals of concern
- Sharing and protecting information

Identifying and prioritizing chemicals of concern

REACH: Prioritization Criteria

Two sets of specific criteria:

- Classification criteria for identifying dangerous substances, covering 16 pchem, health and eco endpoints
- Criteria to identify “substances of very high concern” (SVHCs): CMRs, PBTs, vPvB; catch-all for “equivalent concern”
- Used to: require Registration sooner; require more information; prioritize chemicals for Evaluation, Authorization or Restriction

TSCA

- "Chemical of concern" = "unreasonable risk"
- Burden on govt to evaluate:
  - health & environmental effects and exposure,
  - benefits of the chemical,
  - the availability of substitutes, and
  - economic costs, benefits of regulation
- Must also show that:
  - proposed control is least onerous
  - no other statute could address the concern

TSCA

- No statutory and few regulatory criteria; usually presented as general guidelines to be applied on case-by-case basis
- Little transparency or clarity as to how USEPA decides which chemicals are of concern or when risk assessment/ management is needed
- 5 existing chemicals regulated in 30 yrs

Tracking chemicals and their production and use

New chemicals

- REACH: All new chemicals must be registered by all producers.
- TSCA: After EPA review and first manufacture, a new chemical is listed on inventory and then any additional producer can make the chemical without notification, unless EPA has also issued a SNUR (7% of cases).

Existing chemicals

- REACH: Registration updated as each volume trigger is reached or with any significant change in use/exposure ("universal SNUR").
- TSCA: Reporting of single-year production once every 5 years, if:
  - above 25,000 lbs/yr and not exempt
  - use/exposure info required only for HPV chemicals
  - no requirement to notify of significant changes in production or use

Requiring testing or data development

New chemicals

- REACH: Tiered registration, with a base set of information required up front that increases as each subsequent tier is reached.
- TSCA: No minimum data set required; as a result:
  - 67% of PMNs contain no test data
  - 85% of PMNs contain no health data
  - >95% of PMNs contain no ecotoxicity data
  - Can but rarely does require testing, case-by-case

Existing chemicals

- REACH: Again, tiered registration and data requirements – no distinction between new, existing chemicals
- TSCA: Govt must show evidence of harm in order to require testing – Catch 22
  - Full notice-and-comment rulemaking
  - EPA has required testing for only ~200 chemicals in 30 years under TSCA

Assessing chemical risks

New chemicals

- REACH: Tiered system mean more than one assessment as production expands.
- TSCA: Only a single assessment occurs, before manufacture begins.
  - usually in 90 days (one extension possible)
  - little or no data provided
- Key differences
  - TSCA: Govt review required before manufacture
  - REACH: Industry does the assessment and govt review is not required!

Existing chemicals

- REACH: Same as for new chemicals
- TSCA: No routine assessment
  - No list of priorities for assessment
  - No means to identify/nominate chemicals
  - EPA has assessed <2% of ex. chemicals, triggered mostly by receipt of “substantial risk” information
  - EPA intends to assess HPV chemicals

Regulating chemicals of concern

Existing chemicals

- REACH: Authorization places burden of proof on industry to demonstrate:
  - adequate control, or
  - for SVHCs, that socio-economic benefits outweigh risks, and there are no suitable alternative substances or technologies
  - ~1000 substances expected to be subject to authorization
- TSCA: 5 chemicals regulated in 30 yrs

Sharing and protecting information

Information in the supply chain

- REACH: Mandates flow of risk-relevant information in both directions along the supply chain:
  - Suppliers to customers: risk information, risk management
  - Customers to suppliers: use information
- TSCA: MSDS is essentially only instrument

CBI and public access

- REACH:
  - Requires public access to much of submitted information – and government decisions made based on that information
  - Delineates information to be: a) kept confidential, b) always made public, and c) made public unless justification provided and deemed warranted by govt.
  - Provides for foreign governments to have access to CBI submitted under REACH

CBI and public access

- TSCA:
  - Health & safety study results can't be claimed CBI, but submitter and chemical identity can be
  - Up front justifications not usually required
  - Review, approval of CBI claims not required
  - EPA must challenge CBI claims case-by-case, lacks resources to do so
  - No expiration date for CBI claims, nor a requirement to reassert or rejustify them
  - EPA cannot disclose CBI to foreign, state, local or tribal governments

For more information on REACH in relation to US and Canadian chemicals policies, see:

Not That Innocent: *A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*

www.environmentaldefense.org/chempolicyreport

What can California do?

- Ensure access to info gathered by others
  - Negotiate for access to CBI submitted under REACH
  - Require companies making/importing chemicals in CA that are subject to REACH to submit the same info to CA officials
  - Enhance existing IT infrastructure to receive and share the large volumes of REACH data
- Set clear criteria to identify chemicals of concern
  - Can be hazard-based (e.g., PBTs) and exposure-based (e.g., chemicals detected through biomonitoring)

What can California do?

- Map the flow of chemicals in California by developing and sharing production/use info
  - Require CA producers/importers and users to submit and update info on amounts, facility locations and uses (incl. in products)
  - Require updating of MSDS to reflect all available data (HPV, REACH, Canada)
  - Require disclosure of chems in consumer products
    - Could focus initially on priority chemicals (Canada priority list, REACH SVHC list)

Reliance on "old" toxicology

- HPV, REACH data sets use 20+ yrs. old tests
- Fail to account for:
  - Emerging issues, e.g., ED, DNT
  - Emerging science, e.g., low-dose effects, timing of exposure during development
  - Emerging methods, e.g., toxicogenomics, high-throughput screening and mechanistic assays
  - Perpetual concerns: e.g., cumulative, aggregate exposures, susceptible subpopulations

What can California do?

- Advance the science
  - CA well-positioned to help move toxicology into the 21st century
  - Help to develop, road-test and share new methods, testing strategies – incl. via ITRC*?
  - Utilize biomonitoring data and methods to advance dose and exposure measurement
  - Press industry, federal govt. to move forward
  - Collaborate with universities

* Interstate Technology & Regulatory Council

Why do all this?

- Casts a broad net – to identify not only “bad actors” but also chemicals of low concern
- Influences and informs chemical and product design decisions
- Identifies and fill gaps – info and technology
- Empowers a range of actors – government, industry, academics, public – to advance knowledge and make better decisions about chemicals