

*Fueling the GC Revolution:
Promoting the development and sharing
of robust chemical information*

Green Chemistry Symposium II:
Chemicals Policy for a Sustainable California

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ENVIRONMENTAL DEFENSE

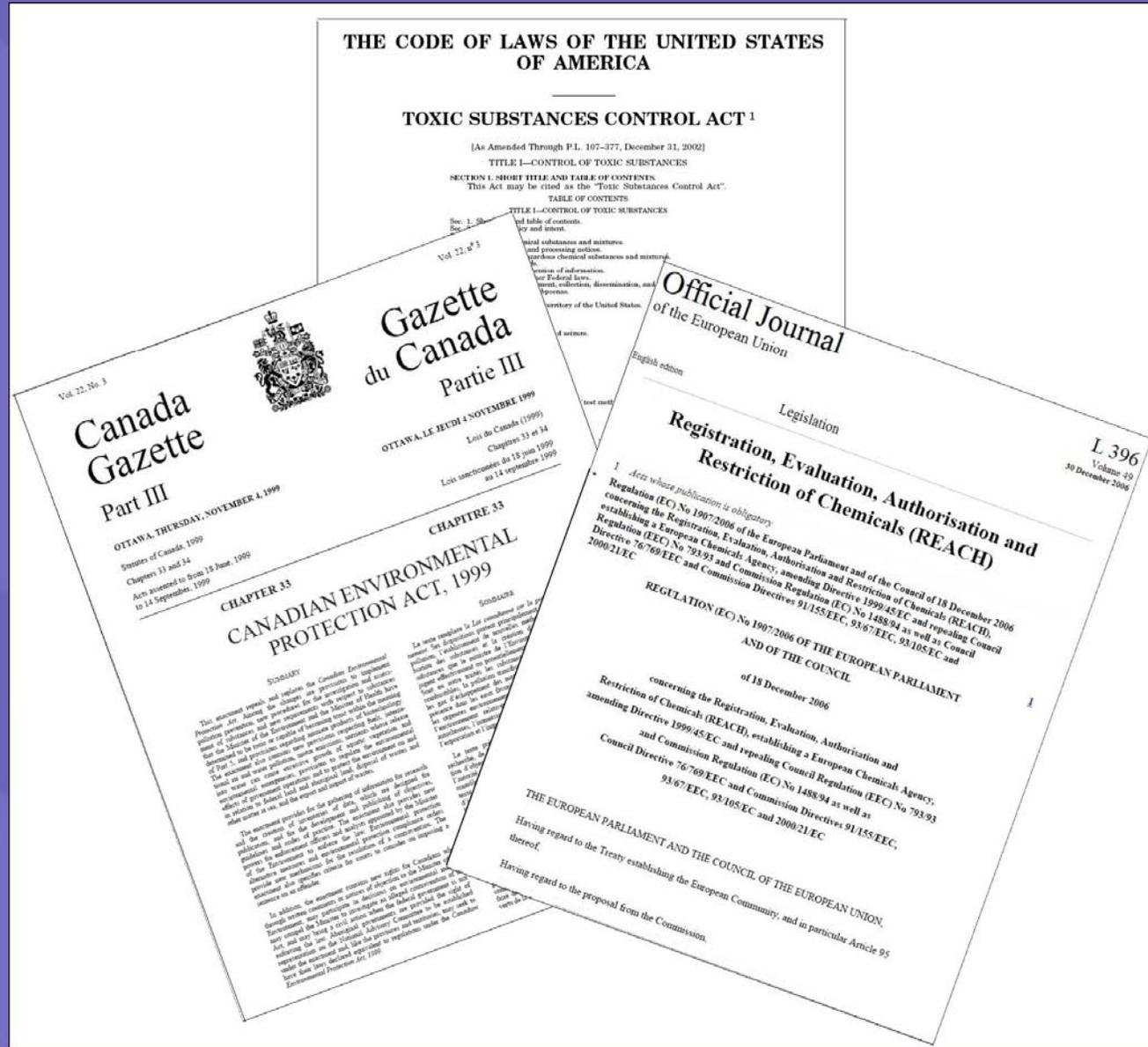
finding the ways that work

Not That Innocent

A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS

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Policies/statutes compared

- The US Toxic Substances Control Act (TSCA), 1976
- The European Union's Registration, Evaluation and Authorization of Chemicals (REACH), 2006
 - Not yet implemented (effective date 6/1/07)
- The Canadian Environmental Protection Act (CEPA), 1999

Paradigm shift underway in chemicals policies

Current policies toward existing chemicals based on “presumption of innocence” – despite the dearth of information

- Grandfathered in 10,000s of “existing” chemicals
- Government shoulders burden of proof
- 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
- Hampers efforts to identify safer chemicals
 - potential substitutes
- Prevents market from working properly – much deeper/broader info base essential

Why the commotion about REACH?

- “No data, no market”
 - Addresses legacy of grandfathered chemicals
 - Requires data to enter/remain on market
- Access to information
 - Compels two-way flow in chemical supply chains
 - Suppliers > customers: risk, risk mgmt info
 - Customers > suppliers: use info
 - Pushes chemical information into public domain
 - CBI allowances tightly prescribed
 - Most submitted info and decisions made public

Why the commotion about REACH?

- Burden shifting
 - REACH assigns responsibility to industry to:
 - develop risk information,
 - assess it for indication of significant risk, and
 - determine risk mgmt. needs and adequacy.
 - Government plays an oversight role.
- Authorization for use of SVHCs
 - SVHC = substance of very high concern (CMR,PBT,vPvB)
 - Applicant bears burden to show:
 - risks are “adequately controlled” OR
 - benefits outweigh risks and no alternatives exist.

Key structural constraints in US chemical information 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

Tracking chemicals in commerce

- TSCA Inventory Update Rule
 - 25,000 lb/yr threshold
 - Many exemptions (e.g., polymers, small businesses)
 - 5-year reporting cycles; single-year info
 - Hides major fluctuations, e.g., ~33% of chems change from one cycle to the next
 - Some processing/use info req'd – HPVs only

New chemicals

- Pre-Manufacture Notification (PMN) required
- EPA usually has only a single 90-day review
- No up-front minimum data set required
 - 67% of PMNs contain no test data
 - 85% of PMNs contain no health data
 - >95% of PMNs contain no ecotoxicity data
- EPA relies on estimation models (QSARs)
- Can require testing but rarely does so

Existing chemicals

- Reporting rules – limited to existing info
 - Co's. must immediate report “substantial risk” info; otherwise:
 - Case-by-case, one-time reporting only of unpubl. tox studies or use/exposure info
 - Generally requires full notice-and-comment rulemaking
 - Used for ~1,100 chemicals in 30 years

Existing chemicals (cont'd)

- Test rules
 - High burden/Catch 22: Must find chemical “may present unreasonable risk” OR significant exposure AND sufficient data do not exist AND testing necessary
 - Done for ~200 chemicals in 30 years
- Voluntary HPV Challenge – data on 2,200 chemicals to be developed (not yet done)
 - EPA to prioritize HPVs for further work

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
- How to balance cutting-edge science vs. routine application of validated methods to many chemicals?

CBI

- Broad ability for submitters to claim CBI
- Health and safety studies not eligible, but chem and submitter ID are
- EPA not req'd. to review, approve claims
- Upfront justification rarely required
- EPA must challenge claims case-by-case
- Claims never expire
- EPA cannot disclose CBI to foreign or state govts

What can California do?

- Ensure access to info gathered by others
 - Negotiate with EU 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

What can California do?

- Develop and share 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)

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

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