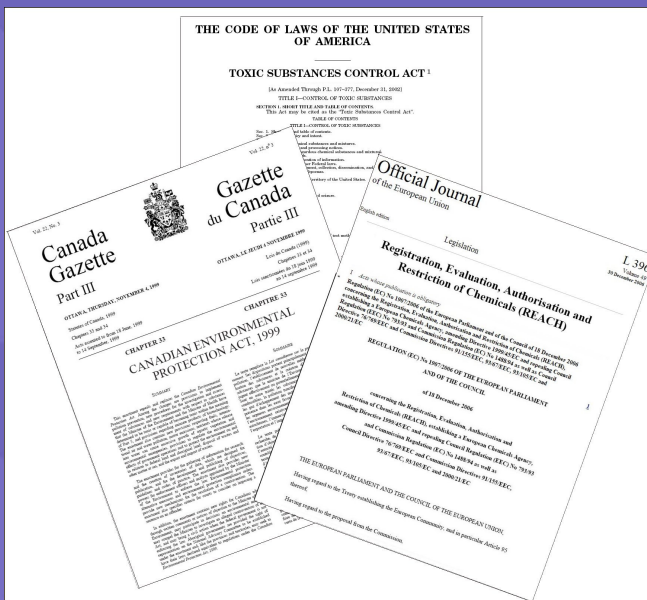


## Not That Innocent

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

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Report available at [www.environmentaldefense.org/go/chempolicyreport](http://www.environmentaldefense.org/go/chempolicyreport) 1

## 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
- 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
- Compelling evidence of harm needed for govt. to regulate an existing chemical

3

## Shifting to “evidence of no harm” policies

- *Knowledge-driven* system rather than continued “toxic ignorance”
- Does not have to mean zero-risk or endless testing
- *Shifts burden of proof* to producers to provide basis for establishing a “reasonable assurance of safety”

4

## Who should bear responsibility for

- developing risk information?
- assessing it to decide whether or not it indicates significant risk?
- deciding what risk management to employ and whether it is adequate?
- REACH is revolutionary in assigning all three tasks to industry, with govt. having an oversight role

## Policies/statutes to be 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 6/07)
- The Canadian Environmental Protection Act (CEPA), 1999

## Areas for policy comparison

- Identifying / prioritizing chemicals of concern
- Tracking chemical production / use
- Facilitating or requiring the reporting and generation of risk-relevant information
- Assessing information to determine hazard/exposure/risk
- Imposing controls to mitigate risk
- Sharing and disclosing information and protecting confidential business information

## *Identifying and prioritizing chemicals of concern*

## US

- “Chemicals of concern” largely limited to those posing an “unreasonable risk”
  - must broadly consider socio-economic factors
  - proposed control must be least onerous
  - must demonstrate that no other statute could address the concern
- TSCA provides no other criteria

## Canada

Core conceptual criterion is “CEPA-toxic”:

- “A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:
  - (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
  - (b) constitute or may constitute a danger to the environment on which life depends; or
  - (c) constitute or may constitute a danger in Canada to human life or health.”

## Canada

### Two key distinctions from TSCA

- Determining whether a chemical is CEPA-toxic, and hence requires regulatory or other risk management action, is separate from determining how risk should be managed.
- CEPA-toxic encompasses the potential to cause adverse effects or constitute a danger, as well as actually doing so.

11

## Canada

- DSL Categorization applied to 23,000 existing unassessed chemicals
  - Specific criteria for:
    - Persistence
    - Bioaccumulation
    - Inherent toxicity ( $iT_{\text{human}}$  and  $iT_{\text{eco}}$ )
    - Exposure potential

12

## REACH

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
- Used to: require Registration sooner; require more information; prioritize chemicals for Evaluation, Authorization or Restriction

13

## Best practice

- Chemicals policies should be underpinned by clear criteria for identifying chemicals of concern, determining information requirements, prioritizing chemicals for assessment, and deciding whether and what risk management is needed.
- Hazard- and exposure-specific, as well as risk-based criteria, should be articulated.
- Government should be authorized and required to impose risk management on chemicals that meet the criteria.

14

*Facilitating or requiring the reporting and generation of risk-relevant information*

## New chemicals - US

- Pre-Manufacture Notification (PMN) required
- EPA usually has only a single 90-day review
- Once reviewed and mfg starts, new chemical is added to TSCA Inventory
- Anyone may then produce/use for any purpose without condition and without notification, unless ...
  - EPA also issues a Sign. New Use Rule (SNUR), which requires notification for any “new uses”
  - SNURs issued for ~7% of new chemicals



## New chemicals - US

- No up-front minimum data set required
  - 67% of PMNs contain no test data
  - 85% of PMNs contain no health data
  - more than 95% of PMNs contain no ecotoxicity data
- EPA relies on estimation models (QSARs)
- Can require testing but rarely does so

17

## New chemicals - Canada

- Tiered notification scheme
- Base dataset req'd., ↑ based on volume, exposure criteria (start at 100 kg/yr)
- Multiple govt. reviews
  - Only after highest-tier review is a chemical eligible for inventory listing
  - Otherwise new producers must notify

18

## New chemicals - Canada

- Regulated chemicals are ineligible for inventory listing – any new producer/user must notify
- Once listed, notification not req'd unless subject to a SNAc (Significant New Activity) Notice

19

## New/Ex chemicals - REACH

- Registration is analogous to tiered notification – 4 tiers of data req'ts:
  - 1-10, 10-100, 100-1000, >1000 tonnes/yr
- All producers of a chemical must register it (can do so collectively)
- Registration (aka notification)  $\neq$  review:
  - Unlike TSCA and CEPA, NO govt. review before mfg starts (or rises to next tier)

20

## Best practice (1)

- Government should be required to review new chemicals prior to substantial manufacture or import, and should be provided with ample information and time to do so.
- Government should have broad authority to request additional information if it is needed to conduct a thorough assessment.

21

## Best practice (2)

- Companies should be required to notify when they begin manufacture of a chemical they have not made before.
- A tiered notification/registration scheme should be employed for new chemicals, with increasing information required as production increases and the extent or diversity of uses expands.

22

## Best practice (3)

- Consider requiring a first notification at the pre-manufacturing stage, even in the absence of significant data, in order to provide government with an early opportunity to flag potential concerns.
- However, such an approach needs to be coupled with subsequent notifications, including one to follow commencement, but prior to reaching significant levels, of manufacture.

## Existing chemicals - US

- Reporting rules – limited to existing info
  - Immediate reporting req'd of “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 - US

- 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)
  - To be used to prioritize HPVs for further scrutiny

25

## Existing chemicals - Canada

- Regulations very similar to US
- DSL Categorization – 23K chemicals/7 years
  - CEPA-mandated: most ambitious initiative anywhere to examine existing chemicals
  - criteria for GPE; P or B and iT (human, eco)
  - based on existing info, confirmed big gaps
  - identified >4,000 chemicals for further assessment, 500 priorities for action

26

## Existing chemicals - REACH

- Phase-in over 11 years
- Data reqts. ↑ with tonnage, hazard
- Only test proposals – not test data – required for higher tiers at Registration
  - driven by animal welfare concerns

27

## Existing chemicals - REACH

- Two other important caveats
  - Many conditions where test data “may be omitted, replaced with other information, provided at a different stage or adapted in a different way”
    - Rationale must be provided
  - Latitude to waive higher-tier testing reqts. based on “demonstration of low exposure”
    - Criteria yet to be developed

28

## Best practice

- Government should have broad authority to get information it needs without having to first demonstrate potential or actual risk.
- Government should be required to seek such information where it already has evidence of potential risk.

*Assessing information to  
determine hazard/exposure/risk  
(focus on existing chemicals)*

## Existing chemicals - US

- No routine assessment
- No list of priorities for assessment
- No formal mechanism to identify or nominate chemicals for assessment
- EPA has assessed <2% of ex. chemicals, triggered mostly by receipt of “substantial risk” information
- EPA intends to assess HPV chemicals

31

## Existing chemicals - Canada

- CEPA mandates assessments for:
  - all categorized chemicals (screening-level)
  - Priority Substances (public nominations)
  - chemicals subject to provincial or certain int’l prohibitions/restrictions
- Screening assessments must lead to decision (low frequency of actions taken)

32



## New/Ex chemicals - REACH

- Registrant conducts assessments – major difference from TSCA/CEPA
- Govt. can evaluate registrations
  - Candidate list prioritized based on risk, not hazard
  - BUT: No minimum number or pace at which evaluations are to be undertaken
  - Can lead to authorization/restriction

33

## Best practice (1)

- Government should provide:
  - formal mechanisms to identify chemicals as priorities for assessment, including public nominations, and
  - a transparent process by which decisions to conduct assessments are made within a reasonable timeframe.

34

## Best practice (2)

- Government should be required to reach affirmative decisions – which can include a decision that no further action is necessary – within a reasonable time period.
- Decisions by state/provincial governments or international bodies to prohibit or restrict a chemical should mandate assessment.

*Imposing controls  
to mitigate risk*

*(focus on existing chemicals)*

## Existing chemicals - US

- Extensive regulatory authority – IF burden can be met
- But “presents or will present and unreasonable risk” requires evaluating:
  - health and environmental effects and exposure,
  - benefits of the chemical,
  - the availability of substitutes, and
  - the economic effects (costs and benefits) of rule
- As a result, 5 chemicals regulated in 30 yrs

37

## Existing chemicals - US

- EPA has instead pursued voluntary initiatives:
  - PFOA Stewardship Program
  - Safer Detergents Stewardship Initiative focused on NPEs
  - Furniture Flame Retardancy Partnership focused on penta BDE
  - Sustainable Futures Initiative facilitating companies’ use of EPA new chemical assessment tools

38

## Existing chemicals - Canada

- Toxic Substances Management Policy
  - Track 1 substances (PBTs) – policy aim is virtual elimination, set independent of socio-economics
  - Track 2 substances – policy aim is lifecycle management to prevent or minimize releases
- Numerous risk management measures available under CEPA, but again rarely used
  - 18 final/proposed prohibitions/restrictions

39

## Existing chemicals - Canada

- Non-regulatory options
  - Guidelines, Codes of Practice
  - Environmental Performance Agreements with companies or trade associations
    - Examples: 1,2-Dichloroethane reductions from Dow Chemical facilities; contract with CCPA to monitor and report on 500 chemicals

40

## New/Ex chemicals - REACH

### Authorization

- Candidate list of SVHCs must be developed ...
  - which can then be recommended to be made subject to authorization ...
  - for which final decisions are made case-by-case
- Each step entails extensive review/comment/approval procedures
- Companies then apply for authorizations, which are for specific use(s)

41

## New/Ex chemicals - REACH

- Authorization must be granted if substance is “adequately controlled,” except for certain SVHCs
- Any substance can be authorized if:
  - socio-economic benefits outweigh risks, and
  - there are no suitable alternative substances or technologies

42

## New/Ex chemicals - REACH

- Authorization entails most of the same elements as “unreasonable risk” under TSCA:
  - consideration of significance of risk and ability to “adequately control” it
  - socio-economic benefits vs. risks and
  - availability of alternatives
- But: Burden is on industry, not govt.
- All authorizations to be subject to time-limited reviews, set case-by-case

43

## Best practice

- Determining whether a chemical needs risk management should be based solely on its hazard, exposure and/or risk.
- Socio-economic factors may play a role in determining how, but not whether, to control a chemical of concern.
- Government should be able to impose controls to address potential as well as documented risks.

44

## CBI

45

## US - TSCA

- Broad ability for submitters to claim CBI
- Health and safety studies not eligible for CBI status, but:
  - chem and submitter identity can be CBI
  - process, composition info protected
- EPA not req'd. to review, approve CBI claims

46

## US - TSCA

- EPA has extensive regulatory criteria and authority to challenge claims, but:
  - must do so case-by-case
  - lacks resources, hence rarely done
  - meanwhile cannot disclose
- Upfront justification not routinely req'd.

47

## US - TSCA

- 95% of PMNs contain CBI claims
- No expiration or req't. to reassert CBI, even after chemical is in commerce
- EPA cannot disclose CBI to foreign governments, US States, Tribes, or local governments

48



## Canada - CEPA

- CBI claims must be supported by addl. info “that may be prescribed.”
- Only NSN Guidelines prescribe process:
  - require upfront justification specifying how disclosure would cause economic harm to submitter
  - all such claims must be reviewed and apply only if found acceptable

49

## Canada - CEPA

CBI claims for chemical identity must also indicate its purpose and use, and whether:

- it is or will be present in waste, emissions or effluents
- it is in a product available to the public, and can be identified by analysis
- any domestic or foreign government has ever found that it meets any CEPA-toxic criteria

50

## Canada - CEPA

- No exemption for health/safety studies
- No expiration or time limit
- CBI can be disclosed to domestic or foreign govts and int'l orgs if purpose is to administer or enforce a law and recipient keeps info confidential

51

## EU - REACH

3 classes of information:

1. normally subject to non-disclosure, unless essential to protect HH/env
2. always to be made public
3. public unless upfront CBI claim and justification submitted, approved

52

## EU - REACH

### Class 1 Normally CBI

- Details of preparation's composition
- Precise function/use
- Precise tonnage produced, sold
- Links between supplier/  
distributor/downstream user

53

## EU - REACH

### Class 2 Always public, includes:

- Identity (some exceptions)
- Results of pchem, env fate, tox, ecotox tests, and any no-effect levels/conc's
- Guidance on safe use
- Analytic methods to detect in env, humans (where such info is req'd)

54

## EU - REACH

Class 3 Public unless legit CBI, includes:

- Trade name, and if classified as “dangerous,” the chemical name for
  - certain new substances (up to 6 years)
  - intermediates, R&D (indefinitely)
- Degree of purity, identity of impurities
- Tonnage band (e.g., 10-100 tonnes/yr)
- Actual pchem, tox study summaries

55

## EU - REACH

CBI may be disclosed to any govt or national authority of a country or to an intl org if:

- purpose is to cooperate on implementing or managing legislation for chemicals covered by REACH, and
- the third party protects the confidential information as mutually agreed.

56

## Best practice (1)

CBI claimants should have to:

- make specific request at time of submission
- provide upfront justification, documentation
- specify and justify a time period for which the request is made

57

## Best practice (2)

Government should be required to:

- review and decide on all CBI requests
- where a request is accepted, set an expiration date
- disclose information for which it has rejected a CBI request, after providing a reasonable opportunity for the submitter to rectify the request

58

## Best practice (3)

- Health and safety information should never be eligible for CBI protection.
- As a rule, chemical and submitter identity should also be ineligible; gov't should explicitly state the basis for any exceptions.
- Other domestic, foreign govts should have access to CBI where they agree to keep the information confidential.

## Information Flow

## REACH

- A key innovation of REACH is to mandate the flow of risk-relevant information in both directions along the supply chain that connects producers, processors, distributors and downstream users of chemicals.
- Beyond MSDS, no counterpart in TSCA or CEPA.

61

## REACH

- Many explicit requirements for govt to make public chemical info and documentation of decisions and the basis for them
- Stark contrast to both TSCA and CEPA, which, except in very limited circumstances, neither call for nor facilitate public access to such information.

62

## Best practice

- Require gov't to make public as much information as possible about chemicals as well as gov't decisions.
- Government should act aggressively to facilitate, and where needed, require improved flow of information along chemical supply chains, in both directions.