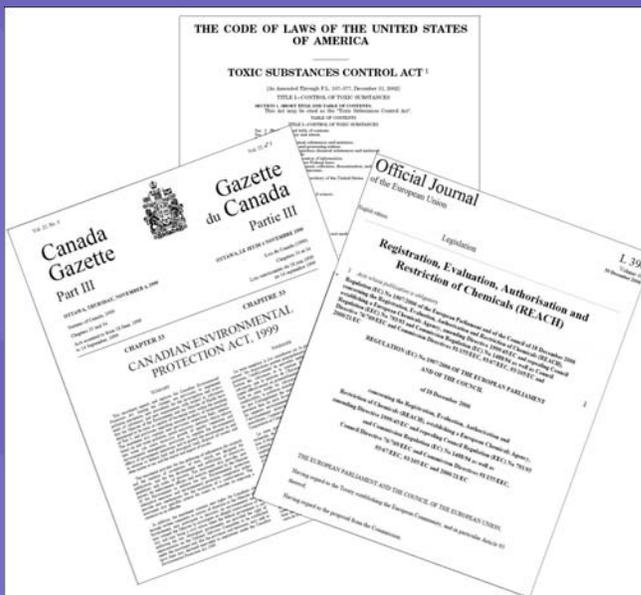


Not That Innocent

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

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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

- Disincentive to develop 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 chemicals about which we already know or suspect something “bad”
 - Impedes efforts to identify safer chemicals

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”

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

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 responsibilities 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!

*Best practices for the core functions
of chemicals policies*

- Identifying and prioritizing chemicals of concern
- Tracking chemicals and their production and use
- Facilitating or requiring the generation and submission 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*

Identifying and prioritizing chemicals of concern

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.

Identifying and prioritizing chemicals of concern

In comparison:

- In US: few criteria, not clearly articulated and 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.
- Although flexibility and expert judgment have their place, so do clarity and accountability for decisions.

Identifying and prioritizing chemicals of concern

- In Canada: Greater use of hazard and exposure criteria is made, especially in the DSL Categorization process.
- Production qty and release criteria used to determine info reqts for new chemicals.
- Relatively clear criteria used to define toxic substances and to list them as toxic substances or candidates for virtual elimination.

Identifying and prioritizing chemicals of concern

- Under REACH: Extensive use of hazard criteria for the purpose of identifying and managing chemicals of concern.
- Used to require Registration sooner; require more information; and prioritize chemicals for Evaluation, Authorization or Restriction

*Tracking chemicals and their
production and use*

*Tracking chemicals and their
production and use*

Best practices:

1. Notification: For new chemicals that are allowed to be manufactured by the notifier only if in compliance with specified conditions, any other company seeking to produce or import the same chemical should be required to go through a full notification and review process.

*Tracking chemicals and their
production and use*

In comparison:

- In US: Except in the 7% of cases where EPA has issued a Significant New Use Rule to accompany its decision concerning a Premanufacture Notification, any subsequent company may produce or import a chemical without EPA's knowledge.

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*Tracking chemicals and their
production and use*

In comparison:

- Canada already has this requirement.
- REACH requires each producer or importer of a chemical to register it, either with other producers or individually.

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Tracking chemicals and their production and use

2. Updating information:

- Should include manufacture, downstream processing, use and exposure information.
- Frequent regular reporting plus a requirement to report at once any significant changes, would be most desirable
- Annual reporting should be required; if less frequent, annualized info should still be reported for each year in the reporting cycle.

Tracking chemicals and their production and use

In comparison:

- The US has regular reporting, but only every five years. It has no generally applicable requirement to report significant changes.
- Some information regarding exposure is required, and for high-volume chemicals, downstream processing and use information must be reported.

*Tracking chemicals and their
production and use*

In comparison:

- REACH will have no regular reporting, but will require reporting of any significant changes and as each registration tier is reached.
- The Canadian system lacks regular reporting, has tiered notifications for new chemicals but only up to 10,000 kgs/year.

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

Facilitating or requiring generation and submission of risk information

Best practice:

1. New chemicals information requirements:

- A tiered notification scheme should be used, more info. req'd. as production, use increase.
- Consider 1st notification premanufacturing to provide government with an early opportunity to flag potential concerns. But:
- Needs to be coupled with subsequent notifications following start of manufacture.

Facilitating or requiring generation and submission of risk information

Best practices:

1. New chemicals info requirements (cont'd):

- Government should have broad authority to request additional information needed to conduct a thorough assessment.
- Government should be authorized and required to re-review chemicals as they reach higher tiers, to account for increased exposure potential.

Facilitating or requiring generation and submission of risk information

In comparison:

- In US: Notification is premanufacture, which means few PMNs have risk data.
- EPA must negotiate with notifiers to do testing case-by-case.
- EPA has no authority to reassess a chemical after it has entered commerce, unless it has negotiated to review data submitted later.

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Facilitating or requiring generation and submission of risk information

In comparison:

- Canada, EU: Have tiered notification/registration, but only after manufacture has started.
- Specific data requirements at each tier.
- Unlike CEPA or TSCA, REACH does not tie registration to government review, so chemicals may begin or continue manufacture even in absence of review.

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Facilitating or requiring generation and submission of risk information

2. Existing chemicals:

- Government should have broad authority to require, without having to demonstrate potential or actual risk, industry to generate and submit test data or other information.
- Government should be required to seek such information where it has evidence of potential risk from an existing chemical.

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Facilitating or requiring generation and submission of risk information

2. Existing chemicals (cont'd):

- Producers/users should be required to immediately report information they generate, receive or become aware of that suggests a chemical they produce or use could pose a significant risk.

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Facilitating or requiring generation and submission of risk information

In comparison:

- In Canada and EU: Tiered notification/ registration, is used, but applied only after manufacture has begun.
- Specific data requirements at each tier.
- Unlike CEPA and TSCA, REACH does not tie registration to government review, so chemicals may begin or continue manufacture even in the absence of review.

Facilitating or requiring generation and submission of risk information

In comparison, in the US and Canada:

- Government must have sufficient evidence of potential risk or toxicity of, or extensive potential exposure to, a chemical in order to require industry to generate new risk information (Catch-22).
- Such risk or exposure findings are not necessary for government to require submission of already-existing information.

Facilitating or requiring generation and submission of risk information

In comparison:

- In US: Imposing information generation or submission requirements typically requires full notice-and-comment rulemaking, whereas in Canada it can be done by notice publication by Minister.
- In all three jurisdictions, producers and users must immediately report new information that indicates significant potential risk.

Facilitating or requiring generation and submission of risk information

In comparison:

- Under REACH, manufacturers must submit available information and generate (or propose to generate) new information specified under registration requirements.
- To require further information, however, an extensive procedure must be followed that includes the right to appeal the decision.

*Assessing information to
determine hazard/exposure/risk*

*Assessing information to determine
hazard/exposure/risk*

Best practices:

1. New chemical review and assessment:

- Government should be required to review all new chemicals, and should be provided with ample information and time.
- Consider 1st notification premanufacturing.
- But needs to be coupled with subsequent notifications following commencement of manufacture.

Assessing information to determine hazard/exposure/risk

In comparison:

- In US and Canada: Government review is required, but on a short timeline. If a decision is not reached, manufacture may commence.
- In US: Premanufacture timing provides for early flagging of potential concerns, but absence of a minimum data set severely hampers EPA's ability to conduct a thorough and timely review.

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Assessing information to determine hazard/exposure/risk

In comparison:

- In Canada, EU: First review after start of manufacture, but minimum dataset req'd.
- Under REACH, assessment will be conducted by industry, not government.
- Any government evaluation of these assessments is divorced from the registration process, so new chemical manufacture can start and potentially continue indefinitely without govt review.

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Assessing information to determine hazard/exposure/risk

2. Existing chemical review and assessment:

- Govt should provide means to identify chemicals for assessment, including public nomination process, and a transparent process requiring decisions within a reasonable timeframe.
- Decisions by state/provincial governments, int'l. bodies to prohibit/restrict a chemical should trigger a mandatory assessment.

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Assessing information to determine hazard/exposure/risk

2. Existing chem review/assessment [cont'd]:

- Government should also be required to reach affirmative decisions—which can include a decision that no further action is necessary—and make public those decisions and the basis for them, within a reasonable time period, regarding any assessments it conducts.

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Assessing information to determine hazard/exposure/risk

In comparison:

- In US: No such formal processes exist.
- In Canada: Such processes are specified.
- Under REACH:
 - Government has authority to assess chemicals, but no minimum number or pace at which evaluation must be done.
 - Pending evaluation, only information on the chemical's risks and adequacy of risk mgmt. employed is that of registrant.

Imposing controls to mitigate risk

Imposing controls to mitigate risk

Best practices:

1. Risk management for new chemicals:

- Criteria based on hazard and/or exposure characteristics should be established to identify chemicals of high concern, and government should be authorized and required to impose risk management measures on chemicals that meet the criteria.

Imposing controls to mitigate risk

In comparison:

- In US and Canada: Few if any such criteria have been developed, with the result that risk management actions on new chemicals are taken almost entirely on a case-by-case basis, relatively infrequently, and in a non-transparent manner.
- REACH will establish such criteria.

*Imposing controls to mitigate risk*Best practices:2. Risk mgmt for existing chemicals:

- Determining whether an existing chemical is of concern and needs risk mgmt should be based solely on its hazard, exposure or risk characteristics.
- Socio-economic factors may play a role in deciding how – but not whether to control a chemical.

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*Imposing controls to mitigate risk*Best practices:2. Risk management for existing chemicals (cont'd):

- The burden on government to manage the risks of existing chemicals should not be higher than for new chemicals, and government should be able to impose controls to address potential as well as documented risks.

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Imposing controls to mitigate risk

In comparison:

- In US: Socio-economic factors must be core part of decision whether to regulate an existing chemical, and the burden to show actual risk is much higher for existing than for new chemicals.
- In Canada: “Whether” vs. “how” are more separate; potential risk included in “CEPA-toxic.”
- Unclear whether these factors actually enable Canada to more easily address the risks of existing chemicals.

Imposing controls to mitigate risk

In comparison:

- On paper at least, REACH appears to meet this best practice, but it does not have an implementation track record to examine.
 - Can decide to regulate based on hazard alone.
 - Treats new and existing chemicals the same.

*Sharing and disclosing
information and protecting
confidential business
information*

*Sharing and disclosing information
and protecting CBI*

Best practices:

1. CBI and information disclosure and access:
 - A. Submitters should be required to:
 - specify precisely what information is requested to be kept confidential;
 - make request at time of submission and provide written justification and documentation; and
 - specify and justify a time period for which the request is made.

*Sharing and disclosing information
and protecting CBI*

B. Government should be required to:

- specify documentation to accompany claim, including acceptable grounds;
- review all requests and determine whether to accept or deny them; and
- where accepted, set a time period after which disclosure may occur unless a new request is submitted and accepted.

*Sharing and disclosing information
and protecting CBI*

C. Government should be able to:

- disclose submitted information for which it has rejected a confidentiality request, after providing a reasonable opportunity for the submitter to rectify the request; and
- disclose CBI when it is in the public interest.

Sharing and disclosing information and protecting CBI

- D. Health and safety info should be ineligible. As a rule, so should the identity of the associated chemical and of the submitter; government should explicitly state basis for any exceptions.
- E. Workers should have access to all available risk information for any substance with which they work or to which they could be exposed.

Sharing and disclosing information and protecting CBI

- F. Other domestic, foreign govts should have access to CBI where they agree to keep the information confidential.
- G. Govt should ensure it has access to CBI submitted to other govts, including by:
 - requiring submission of info companies submit to another government for chemicals made or used domestically;
 - negotiating agreements with other govts for full access to CBI available to them.

Sharing and disclosing information and protecting CBI

- H. Policies should require government to make readily and publicly available as much information as possible about chemicals as well as documentation of decisions and the basis for them.
2. Information flow in the chemical supply chain: Government should aggressively facilitate, and as needed, require improved two-way flow of information along chemical supply chains.

US - TSCA

- Broad ability for submitters to claim CBI
- Exception where disclosure is necessary to protect HH/environment
- Health and safety studies not eligible for CBI status, but:
 - chem and submitter identity can be CBI
 - process, composition info cannot be released

US - TSCA

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

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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

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Canada - CEPA

CBI may be disclosed where:

- it is in the interest of public health, safety or the protection of the environment; and
- the public interest clearly outweighs financial or competitive loss to the submitter and any resulting damage to the privacy, reputation or human dignity of any individual.

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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

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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

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

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

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EU - REACH

Class 1 Normally CBI

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

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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)

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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

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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.