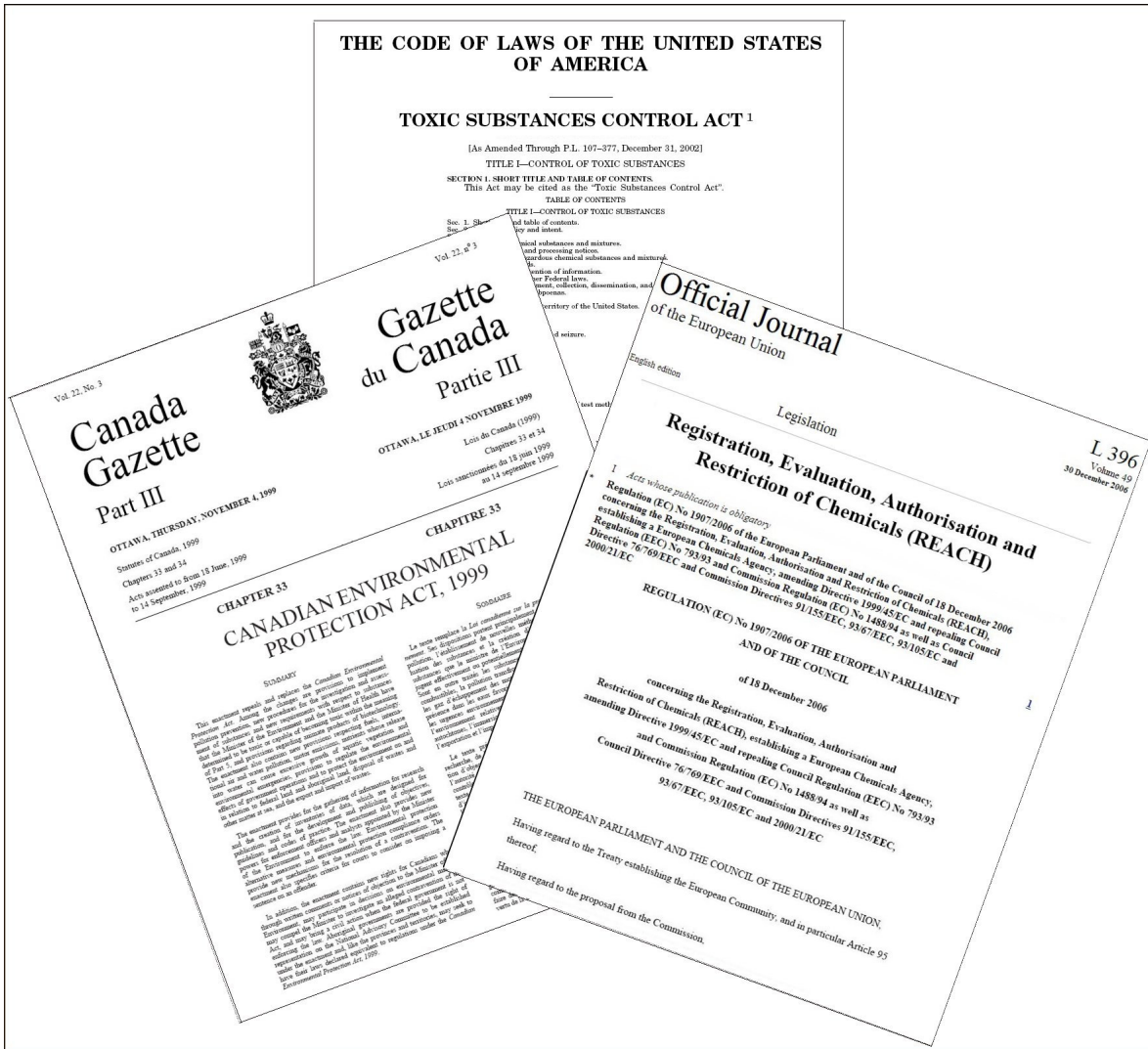


Not That Innocent

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



APRIL 2007

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In cooperation with Pollution Probe

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Executive Summary

Industrial chemicals are ubiquitous in our world today. They are the feedstocks and intermediates that propel the manufacture of virtually every material we use, and the ingredients in the tens of thousands of consumer and commercial products we consume every day. But in recent years, evidence for another kind of ubiquity of such chemicals has begun to emerge. Despite their widespread use, until recently the prevailing wisdom was that exposure to most industrial chemicals was unlikely, especially outside of occupational settings. We now know that some of these chemicals have accumulated in the bodies of virtually all people, and in wildlife and the ecosystems of the remotest regions on Earth. Yet we are only beginning to understand how they got there and what their presence means to our—and our planet’s—health.

For decades, our policies toward such chemicals have effectively presumed them to be safe, despite the dearth of data available to demonstrate either their safety or adverse impacts. Today there is increasing evidence that certain of these chemicals play a role in human disease and environmental impacts.

These factors—the widespread presence of chemicals in humans and the environment, the growing evidence that some of them can cause harm, and the inability of our policies to have predicted or prevented such impacts—have lent urgency to calls for major reforms in industrial chemicals policies worldwide. A sea change is taking place, driven by a growing recognition that existing policies have failed to effectively identify chemicals of concern, to manage their risks, and to facilitate the needed shift toward development and use of safer chemicals.

For the last several decades, government policies have granted the tens of thousands of industrial chemicals already in commerce a strong “presumption of innocence.” In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals as they’ve seen fit. These policies contrast sharply with the approach—closer to “presumed guilty until proven innocent” —adopted for other classes of chemicals such as pharmaceuticals and pesticides. For these substances, producers have the burden of providing information to government deemed sufficient to demonstrate their safety, at least when used as intended.

By contrast, for industrial chemicals, the opposite is true: Government—and hence the public—shoulders the burden of proof. In what amounts to a classic Catch-22, *government must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require the development of information sufficient to determine whether there is actual risk.* These policies place an even higher burden on government to act to control a chemical based on any information it does manage to obtain that is indicative of significant risk. To extend our courtroom analogy, government must effectively prove beyond all reasonable doubt that a chemical poses a

risk before it can take any action to restrict its production or use. And it must typically make its case despite operating under a highly constrained “right to discovery,” with quite limited options for obtaining or compelling the generation of information from producers or users of the chemical.

One profound consequence of such policies is that government, the public and often the companies that produce and use these chemicals know very little about the potential risks of most of them. Moreover, companies have little or no incentive to develop better information: To undertake such activity voluntarily is likely to be seen by a company as only increasing the likelihood that evidence of harm will be uncovered, triggering government action. The lack of good information means that we do not know which chemicals may pose risks, nor do we know which ones pose little or no risk, and hence might serve as viable substitutes.

After decades of this relatively passive approach, change is in the air. Efforts are finally being mounted to address this legacy of un- or under-assessed chemicals. Among them:

- The voluntary High Production Volume (HPV) Chemical Challenge in the U.S., which is developing basic screening information on the potential hazards of some 2,000 of the highest-volume chemicals in use in the U.S.
- Canada’s recently completed Domestic Substances List (DSL) Categorization, mandated by law in 1999, which for the first time examined information available on the roughly 23,000 previously unassessed chemicals that have been in commerce in Canada over the last two decades, and identified more than 4,300 warranting further scrutiny of their potential risks.
- Most ambitious of all, the European Union’s new regulation called REACH, which stands for Registration, Evaluation, Authorization and Restriction of Chemicals. Adopted in December 2006, REACH will require producers and users of an estimated 30,000 chemicals in commerce in Europe to register them and provide information on their production, use, hazard and exposure potential. For chemicals identified as “substances of very high concern” REACH will allow their use only if explicitly authorized.

These examples serve as microcosms of the chemicals policies in these jurisdictions, and provide insight into both the opportunities and the limitations offered by each.

Best practices for the core functions of chemicals policies

This report identifies “best practices” gleaned from a comparative look at the U.S., Canadian and EU approaches to chemicals assessment and management. These policies include a number of common elements related to the core functions they are intended to serve. This report is structured around the six functional elements listed below:

- Identifying and prioritizing chemicals of concern
- Identifying and 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

“Best practices” in relation to the features of each of the three (U.S., Canadian and EU) policies are summarized here, and are more fully developed in the indicated sections of the body of the report.

► IDENTIFYING AND PRIORITIZING CHEMICALS OF CONCERN (SECTION II)

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.

In comparison:

- In the U.S., criteria are few, not clearly articulated and usually presented as general guidelines to be applied on a case-by-case basis. As a result, there is little transparency or clarity regarding how the U.S. Environmental Protection Agency makes decisions as to which chemicals it is concerned about, how they are to be identified or prioritized, or when risk assessment or risk management is warranted. Although flexibility and expert judgment have their place, so do clarity and accountability for decisions.
- In Canada, greater use of hazard and exposure criteria is made, especially in the DSL Categorization process. Canada also uses production quantity and release criteria in determining information requirements for new chemicals. It has articulated relatively clear criteria for defining toxic substances and for listing them as toxic substances or candidates for virtual elimination.
- It is expected that REACH will make extensive use of hazard criteria for the purpose of identifying and managing chemicals of concern.

► IDENTIFYING AND TRACKING CHEMICALS AND THEIR PRODUCTION AND USE
(SECTION III)

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.

In comparison:

- In the U.S., except in the relatively small number 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 or ability to know the practices it is using or the uses of the chemical.
- Canada already has this requirement.
- REACH requires each producer or importer of a chemical to register it, either with other producers or individually.

2. Updating information on chemical manufacture and use: A combination of frequent regular reporting of chemical manufacture, downstream processing, use and exposure information, and a requirement to report at once any significant changes in such information, would provide the best means for government to effectively track chemicals in commerce. Ideally, annual reporting should be required; if actual reporting is done less frequently, annualized quantities and use patterns should still be reported for each year in the reporting cycle.

In comparison:

- The U.S. system 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.
- 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, and only has tiered notifications for new chemicals up to 10,000 kilograms/year.

► FACILITATING OR REQUIRING THE GENERATION AND SUBMISSION OF RISK-RELEVANT INFORMATION (SECTION IV)

1. New chemicals information requirements: A tiered notification or registration scheme should be employed for new chemicals, with increasing information required as production

increases and the extent or diversity of uses expands. Consideration should be given to requiring a first notification at the premanufacturing stage, even in the absence of a significant data requirement, to provide government with an early opportunity to flag potential concerns. Such an approach needs to be coupled with subsequent notifications, however, including one to follow commencement but prior to reaching significant levels of manufacture.

Government should have broad authority to request additional information if it is needed to conduct a thorough assessment. Government should be authorized and required to re-review chemicals as they reach higher tiers, to determine whether potential hazards or exposures have changed and whether additional information or risk management is needed.

In comparison:

- In the U.S., notification is premanufacture, which can allow for potential concerns to be addressed early. The great majority of notifications have virtually no risk data, however, and EPA must negotiate with notifiers on a case-by-case basis to provide information. EPA has no authority to reassess a chemical after it has entered commerce, unless it has imposed a requirement on the producer or importer of a specific chemical to generate and submit additional information at some point after manufacture has commenced.
- A tiered notification or registration approach is already employed in Canada and will be used in the EU under REACH, with specific data requirements delineated at each tier, but applied only after manufacture has begun.
- Unlike notification under the Canadian Environmental Protection Act (CEPA) and the U.S. Toxic Substances Control Act (TSCA), REACH does not tie registration to government review, so that chemicals may begin or continue manufacture even in the absence of review.

2. Existing chemicals—Generation and submission of information: 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 deems necessary to gain a thorough understanding of the potential risks of any chemical of interest or concern. Government should be required to seek such information where it already has evidence of potential risk from an existing chemical.

Producers and users of chemicals 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.

In comparison:

- In the U.S. 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. Given the dearth of such information typically available to government and the difficulty of making the requisite demonstrations without more information, this Catch-22 has meant testing and information development has not been required for the great majority of existing chemicals.

- In the U.S. and Canada, such risk or exposure findings are not necessary for government to require submission of already-existing information.
- In the U.S., imposition of any information generation or submission requirements typically must be done through full notice-and-comment rulemaking, whereas in Canada this can be done through publication of a notice by the Minister.
- In all three jurisdictions, producers and users of a chemical are obligated to immediately report new information that indicates significant potential risk.
- At the time of registration, REACH will require all manufacturers to submit available information and to generate (or propose to generate) and submit new information specified under the applicable registration requirements. To require a registrant to generate information beyond that specified under the applicable registration requirements, however, an extensive procedure must be followed that includes approval by the Member States or the European Commission and provides the registrant with the right to comment and to appeal the decision.

▀ ASSESSING INFORMATION TO DETERMINE HAZARD/EXPOSURE/RISK (SECTION IV)

1. New chemical review and assessment: Government should be required to review all new chemicals, and should be provided with ample information and time to do so. Consideration should be given to requiring a first notification and review at the premanufacturing stage, even in the absence of a significant data requirement, to provide government with an early opportunity to flag potential concerns. Such an approach needs to be coupled with subsequent notifications, however, including one to follow commencement but prior to reaching significant levels, of manufacture.

In comparison:

- In the U.S. and Canada, government review is required for new chemicals. Short timelines are provided for, however, and if a decision has not been reached before the review period elapses, manufacture of the chemical may commence. In the U.S., the premanufacture timing of new chemical review provides an opportunity for early identification of potential concerns, but the absence of a requirement for a minimum base set of information to be submitted with notifications severely hampers EPA's ability to conduct a thorough and timely review.
- In Canada and under REACH, the first review comes only after manufacture has commenced, but is informed by a required minimum data set.

- Under REACH, new chemical assessment will be conducted by industry, not government. Any government evaluation of these assessments is entirely divorced from the registration process, with the result that new chemicals may commence manufacture or import—and potentially continue to do so indefinitely—without any government review or approval of the information provided by the registrant or of the risk management measures being utilized.

2. Existing chemical review and assessment: Government should provide formal mechanisms by which existing chemicals may be identified as priorities for assessment, including nomination by members of the public, and a transparent process by which decisions to conduct assessments are made within a reasonable timeframe. Decisions by state or provincial governments or international bodies to prohibit or restrict a chemical should trigger a mandatory assessment.

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.

In comparison:

- In the U.S., no such formal processes exist.
- In Canada, such processes are specified.
- Under REACH, government has authority to assess existing chemicals; processes for selecting chemicals for assessment (evaluation) are specified, and once selected, processes and timelines for conducting assessments are also specified. However, no minimum number or indication of the approximate pace at which such assessments must be carried out is specified. Pending such assessments, the only information regarding the chemical, its risks and the appropriateness of any risk management employed is what the registrant has supplied.

► IMPOSING CONTROLS TO MITIGATE RISK (SECTION VI)

1. Risk management for new chemicals: Criteria based on hazard 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.

In comparison:

- In the U.S. 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.

2. Risk management for existing chemicals: The determination as to whether an existing chemical is of sufficient concern to require the imposition of risk management should be based solely on its hazard, exposure or risk characteristics. Socio-economic factors may play a role in determining what measures should be mandated, but should not influence the decision about whether a chemical warrants control.

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.

In comparison:

- In the U.S., socio-economic factors play a central role in the findings EPA must make to regulate an existing chemical, and the burden is much higher for existing chemicals than for new chemicals.
- In Canada, the “whether” vs. “how” decisions are more separate, and potential risk is included in the definition of “CEPA-toxic” used to trigger risk management actions (see Section II of this report). It is unclear, however, whether these factors actually enable Canada to more easily address the risks of existing chemicals.
- On paper at least, REACH appears to meet this best practice, but it does not have an implementation track record to examine.

► SHARING AND DISCLOSING INFORMATION AND PROTECTING CONFIDENTIAL BUSINESS INFORMATION (SECTION VII)

1. Confidential business information (CBI) and information disclosure and access: In order for submitted information to be kept confidential, submitters should be required to:

- *specify precisely what information is requested to be kept confidential;*
- *make such a request at the time of submission and provide a full justification and documentation, in writing; and*
- *specify and justify a time period for which the request is made.*

Government should be required to:

- *specify what information must accompany any confidentiality request, including what grounds constitute acceptable justification and under what conditions such requests are allowed;*
- *review, in a timely manner, all confidentiality requests as part of its action on the submitted information, and determine whether to accept or deny the requests; and*
- *where a request is accepted, set a time period after which disclosure may occur unless a new request is submitted and accepted.*

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.*

Health and safety information should never be eligible for CBI protection. As a rule, the identity of the associated chemical and of the submitter of the information should also be ineligible; government should explicitly state the basis for any exceptions.

Workers should have access to all available information, whether or not CBI-protected, concerning chemical identity, properties, hazards and workplace exposures for any substance with which they work or to which they could be exposed during work.

Other governments, whether those of domestic states, provinces, municipalities, Tribes or foreign countries, should be given access to CBI for the purpose of administration or enforcement of a law, under appropriate agreements and where the recipient takes appropriate steps to keep the information confidential.

Governments should ensure they have access to chemical information, including CBI, that is submitted to other governments, which may be needed or useful in their administration or enforcement of domestic laws. Means to accomplish this should include:

- *instituting a requirement that companies submit any risk-related information they submit to another government for chemicals they produce, import or use domestically;*
- *negotiating agreements with their counterparts in other governments for full access to chemical information, including CBI, submitted or otherwise available to those governments; and*
- *ensuring that sufficient resources are made available to establish or enhance existing information technology infrastructure so that it is capable of receiving, processing, utilizing and providing access to large volumes of chemical information.*

Policies should include explicit requirements that government make readily and publicly available as much information as possible about chemicals as well as documentation of decisions and the basis for them.

In comparison:

- *In the U.S., disclosure of CBI is generally prohibited except where necessary to protect human health or the environment. EPA is not required to review and either accept or deny CBI requests, and upfront justifications are not routinely required. While it has developed criteria for what constitute legitimate CBI claims, it must challenge them on a case-by-case basis, which is highly*

resource-intensive. CBI claims have no expiration date, nor is there a requirement that they be reasserted and re-justified. Health and safety studies cannot be claimed as CBI—but the associated chemical and submitter identity generally can be. TSCA prohibits the disclosure of information claimed as CBI to anyone outside the federal government (other than contractors), including state, local, Tribal or foreign governments. TSCA does not generally mandate or encourage public disclosure of information not deemed confidential.

- In Canada, CBI may only be disclosed where it is in the public interest and that interest is found to clearly outweigh any private loss. CEPA calls for CBI claims to be supported by information prescribed by implementing agencies, which has been done in the guidelines for the notification of new substances. These guidelines require upfront justification to be provided and require government review and acceptance or denial of CBI claims. CEPA provides no specific exemption from CBI protection for health and safety information. For requests to consider chemical identity as CBI, the guidelines require relatively extensive information to be provided, which government is able to use to decide whether to grant such requests. CBI claims do not expire or require reassertion. Unlike TSCA, CEPA provides broad authority for the sharing of CBI with other governments, domestic and foreign. As in the U.S., CEPA does not generally mandate or encourage public disclosure of information not deemed confidential.
- REACH prescribes three classes of information: that generally to be considered CBI, that always to be made public, and that to be made public unless an acceptable justification for its protection as CBI is submitted and approved. Upfront justifications of CBI claims must be submitted at the time a claim is made. For new chemicals, the chemical identity can be claimed as CBI for up to six years; otherwise, REACH does not provide for the expiration of CBI status. In contrast to both TSCA and CEPA, REACH includes numerous provisions calling for public access to non-confidential information—including government decisions and the basis for them—and it mandates that most such information be made available on the internet, free of charge. As under CEPA, REACH provides broad authority to share CBI with other domestic and foreign governments.

2. Information flow in the chemical supply chain: Government should act aggressively to facilitate, and where needed, require improved flow of information along chemical supply chains in both directions. These provisions of REACH should be carefully examined for applicability and adaptation to other jurisdictions.

Conclusion

Implementation of the “best practices” identified in this report can facilitate a shift toward policies that are *knowledge-driven*, that motivate and reward, rather than impede and penalize, the development of information sufficient to provide a reasonable assurance of safety for chemicals. Such policies would also place more of the burden of providing and acting on that information on those who stand to profit financially from the production and use of chemicals, and are arguably in the best position to internalize such information and use it from the outset to design out risk from their products.