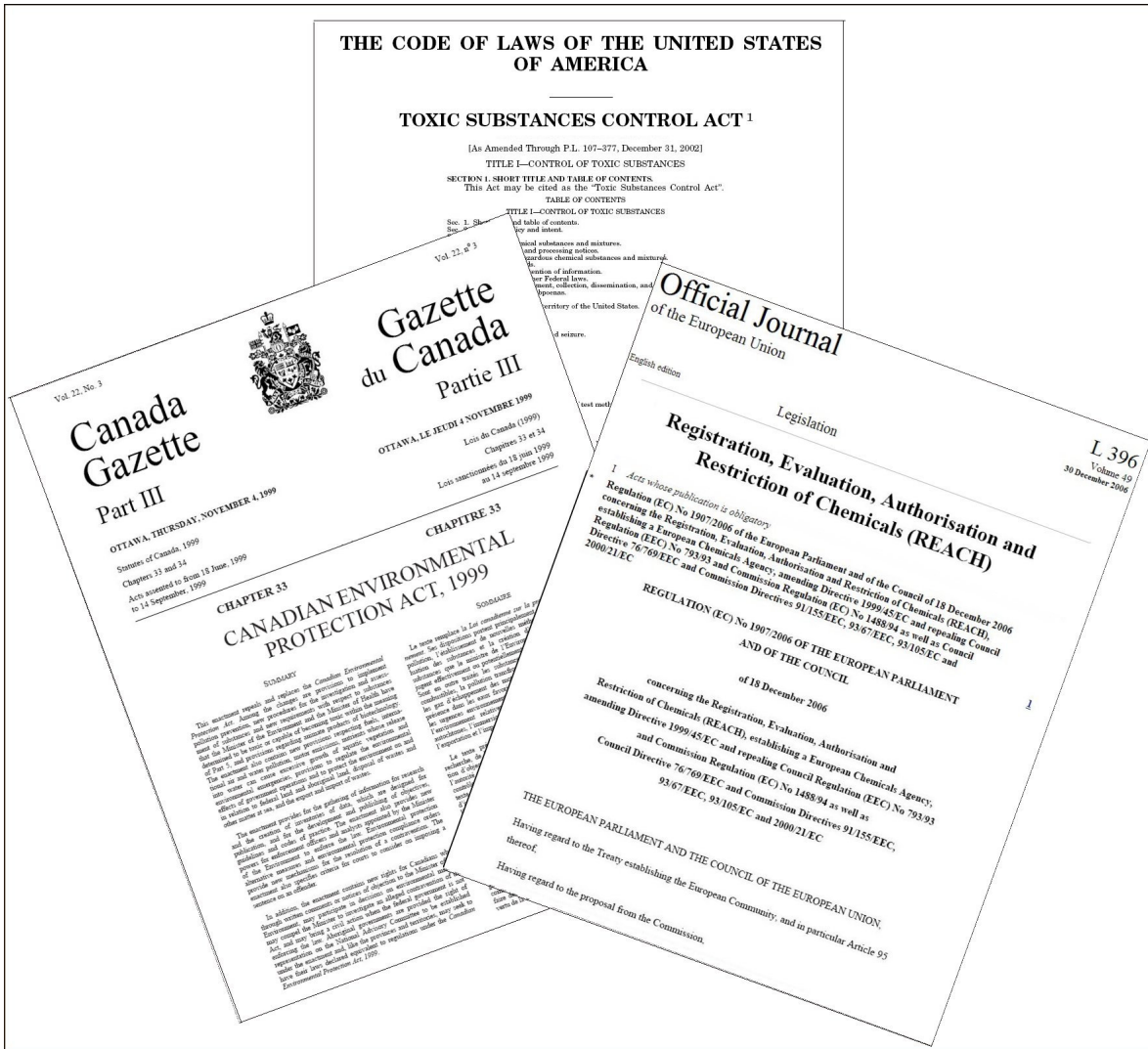


# Not That Innocent

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



APRIL 2007

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AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS

APRIL 2007

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In cooperation with Pollution Probe

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## Acknowledgments

Many people helped me enormously in the preparation of this report, providing advice and guidance, directing me to needed sources of information, educating me and explaining the complexities of the various policies, serving as reviewers of the initial draft, assisting in the development and fact-checking of the comparison tables, editing the report for clarity, providing support and encouragement and countless other ways. Rather than try to identify—and remember—all of the specific ways in which people helped, I simply list them below, with sincere thanks, and apologies to anyone I may have inadvertently omitted.

Of course, the views expressed herein, as well as any mistakes and omissions, are solely my responsibility.

Finally, I wish to gratefully acknowledge funding and travel support from Health Canada and Environment Canada, through a Contribution Agreement with Pollution Probe. My time was also generously supported by the Beldon Fund.

Thanks to the following individuals (in alphabetical order):

John Arseneau, Andrew Beck, Hugh Benevides, Mark Blainey, Ronald Boyd, Morley Brownstein, Steve Clarkson, Allison Cobb, Anna Coutlakis, Fé de Leon, Daryl Ditz, Danie Dubé, George Enei, Rick Findlay, Aaron Freeman, Lori Fryzuk, Johanne Gélinas, Joe Guth, Bjorn Hansen, Virginia Harel, Kathryn Hughes, Laurie Hunter, Kapil Khatter, Louis L'Arrivée, Gordon Lloyd, Patricia MacLellan, Bernard Madé, Cathy Malina, Bette Meek, David Miller, John Moffet, Ken Ogilvie, Louise Power, James Riordan, Shaunalea Savard, Jacinthe Séguin, Eric Sevigny, Melissa Shaw, Jacqueline Sitwell, Bill Smith, Mary Taylor, Joel Tickner, Ken Traynor, Kees van Leeuwen, James Van Loon, Mike Wilson, Anne Woodsworth and Cynthia Wright.

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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.

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## List of Acronyms

4CA	Four Corners Arrangement
ACC	American Chemistry Council
B	Bioaccumulation
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAS	Chemical Abstract Service
CBI	Confidential business information
CEPA	Canadian Environmental Protection Act
CMRs	Carcinogens, mutagens, and reproductive toxicants
ComET	Complex Exposure Tool
ComHaz	Complex Hazard Tool
CSR	Chemical Safety Report
DNEL	Derived no-effect level
DSL	Domestic Substances List
EC	Environment Canada
ECA	Enforceable Consent Agreements
EIA	Extended Impact Assessment
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	U.S. Environmental Protection Agency
EU	European Union
GHS	Globally Harmonized System
GLP	Good Laboratory Practice
GPE	Greatest potential for exposure
HC	Health Canada
HPV	High Production Volume
IPE	Intermediate potential for exposure
iT	Inherently toxic
ITC	Interagency Testing Committee
IUR	Inventory Update Reporting
LPE	Lowest potential for exposure
NDSL	Non-Domestic Substances List
NOC	Notice of Commencement
NOEQ	Notice of Excess Quantity
NOMI	Notice of Manufacture or Import
NPEs	Nonylphenol ethoxylate surfactants
NSN	New Substances Notification
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
OPPT	U.S. EPA Office of Pollution Prevention and Toxics
P	Persistence
PAIR	Preliminary Assessment Information Reporting Rule

## List of Acronyms , continued

PBDEs	Polybrominated diphenyl ethers
PBiT	Persistent, bioaccumulative and inherently toxic
PBT	Persistent, bioaccumulative and toxic
PCBs	Polychlorinated biphenyls
PFOA	Perfluorooctanoic acid
PMN	Premanufacture Notification
PNEC	Predicted no-effect concentration
POPs	Persistent organic pollutants
PSL	Priority Substance List
QSAR	Quantitative structure-activity relationship
R&D	Research and development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SAR	Structure-activity relationship
SIDS	Screening Information Data Set
SimET	Simple Exposure Tool
SimHaz	Simple Hazard Tool
SNAc	Significant New Activity Notice
SNUN	Significant New Use Notice
SNUR	Significant New Use Rule
SVHCs	Substances of Very High Concern
TSCA	U.S. Toxic Substances Control Act
UVCBs	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
VOC	Volatile organic compound

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## I. Introduction

Historically, policies governing industrial chemicals have granted them a “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. When countries first enacted statutes governing industrial chemicals and their management beginning in the mid-1970s, this laissez-faire approach was most directly codified through the decision to “grandfather in” the tens of thousands of chemicals in commerce at time of enactment (the so-called existing chemicals), allowing them to continue to be made and used without restriction. Implicit in this decision was the presumption that the chemicals were safe—surely, we would have discovered by now if it were otherwise—even though very few had been tested or reviewed for possible health or environmental effects.

A corollary consequence of these policies relates to who shoulders the burden of proof. Under current policies, it is government (and hence the public) that must demonstrate a chemical is or could be harmful before any action can be taken, rather than those who produce and use chemicals bearing the burden of demonstrating, or even providing the information necessary to determine whether, they are safe.

This hands-off approach contrasts sharply with the scheme—closer to “presumed guilty until proven innocent”—adopted for other classes of chemicals such as pharmaceuticals and pesticides, generally regulated under different statutes; for these substances, producers have the burden of providing information to government demonstrating their safety, at least when used as intended. These classes of chemicals have been considered more likely to pose risks because they are intentionally designed to be biologically active, whereas most industrial chemicals are not. Nonetheless, there is sufficient evidence of the potential for many industrial chemicals to pose risks, certainly enough to warrant gathering basic information to be able to judge which are likely to be harmful. The European Commission noted that about 70% of all new substances assessed under existing European Union (EU) legislation have at least one dangerous property. It concludes that “[a]n unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects.”<sup>1</sup> The recently completed Domestic Substances List (DSL) Categorization process mandated under the Canadian Environmental Protection Act (CEPA) that examined all 23,000 previously unassessed existing chemicals on the DSL identified more than 4,300 substances possessing hazard or exposure characteristics sufficient to warrant further assessment.<sup>2</sup>

Even if one believes that only a small number of existing chemicals pose any risk, the key is to identify them; the fact that they are already in use should not excuse them. Yet only a few

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<sup>1</sup> European Commission, *Extended Impact Assessment*, COM(2003)644 final, SEC(2003)1171/3, 29 October 2003, p. 27, available at [http://ec.europa.eu/enterprise/reach/eia\\_en.htm](http://ec.europa.eu/enterprise/reach/eia_en.htm).

<sup>2</sup> See “Summary of Government of Canada Categorization Decisions for Substances on the DSL,” available at [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_gc\\_decisions.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_gc_decisions.cfm). As noted by Environment Canada: “The purpose of categorization is not to establish the risks to the environment or human health. Any such risk must be additionally investigated through a screening assessment of the substance.” See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_background.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm). Nonetheless, sufficient evidence of potential risk based on available information has been found for these chemicals to warrant their further investigation, including development of more and better information about them.

hundred of the tens of thousands of industrial chemicals in use have been subjected to formal assessment, and at most a few thousand to requests for data relating to their potential risks.

One reason that so few chemicals have been identified as posing sufficient risk to warrant assessment or control under the current policies is the enormous difficulty in determining whether any given chemical poses a problem in actual use. This is itself a reason to require more testing under controlled laboratory conditions, however, rather than continue what amounts to an uncontrolled, large-scale experiment in the real world. Among the major challenges to documenting and quantifying the contribution of chemicals to human disease and environmental impacts are:

- isolating the contribution of chemicals generally, let alone any single one, to observed human or environmental health problems, given the multifactorial nature of most diseases and environmental impacts; and
- translating any observed correlations into evidence of causation.

Typically, these obstacles have been overcome only after damage is done—once widespread and long-term exposures have occurred—and then only through large-scale and very expensive epidemiological study.<sup>3</sup> It would be far better to ensure that an appropriate degree of data development and assessment is conducted to identify those chemicals that pose sufficient concern to warrant more scrutiny, and those unlikely to pose significant risk, which may well become candidates to replace riskier ones.

Government must already have information sufficient to document potential risk, or at the very least extensive exposure, in order to require development of information sufficient to determine whether there is actual risk.

These policies, which dictate how we manage the tens of thousands of industrial chemicals in commerce, bear two other hallmarks in practice. First, by allowing action only once there is clear evidence of harm, they do not reward, and may well provide a sizeable disincentive against, the gathering of better information about chemicals. A company is likely to view undertaking this activity as only increasing the likelihood that evidence of harm will be uncovered. Existing policies place significant burdens on governments that must be met even before they can request such information of industry. 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 development of information sufficient to determine whether there is actual risk. In the U.S. the burden is sufficiently high that, in the 30 years since the Toxic Substances Control Act (TSCA) was enacted, the U.S. Environmental Protection Agency (EPA) has required testing for fewer than 200 chemicals.<sup>4</sup>

Second, such 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

<sup>3</sup> European Commission, EIA, pp. 24-25.

<sup>4</sup> U.S. Environmental Protection Agency, *Overview: Office of Pollution Prevention and Toxics Programs*, January 2007, prepared by OPPT (“OPPT Overview, 2007”), p. 4, available at [www.epa.gov/oppt/pubs/oppt101c2.pdf](http://www.epa.gov/oppt/pubs/oppt101c2.pdf).

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.

Current policies essentially say: “We’ll consider developing a better understanding only of those chemicals for which we already have good reason to believe they pose a risk.” Not only is this approach plagued by the Catch-22 just noted, it is rather like the old adage about looking for lost car keys at night only under the streetlight because the light is better there. Society remains largely ignorant about the risks of the great majority of chemicals, because we only investigate those about which we already know something. That means we fail to learn not only which chemicals pose risks, but also which chemicals pose little or no risk. So when it comes to choosing among several available options to provide a desired chemical function, or to replacing a problematic chemical, we are often in the dark and run the risk of simply “replacing the devil we know with the devil we don’t.” The potentially enormous benefit of adopting a more comprehensive approach that seeks to develop risk profiles for most or all chemicals would be the ability to select safer chemicals with confidence.

Only for so-called new chemicals—those industrial chemicals brought into production or commerce after such laws were passed—do existing policies mandate any routine scrutiny by government, either as a precondition for commencing manufacture or marketing (the U.S. and Canadian systems) or a condition for continuing to do so (the Canadian system and the EU system that preceded REACH). Even with new chemicals, the requirements imposed on manufacturers to provide advance information and to update that information as production and use change vary considerably among countries. There is extensive debate about how high the burden should be on government to show evidence of harm in order to prevent a chemical from entering the market or restricting its use.<sup>5</sup>

In recent years, the wisdom of a reactive rather than proactive approach to chemicals policy has been increasingly questioned. What has led to this? First is a growing recognition that the manufacture and use of chemicals can play a role as a causative agent of human disease and environmental impacts and as a source of contamination of human tissues, wildlife and environmental media (air, water, soil, sediment). Numerous chemicals are documented as disease agents in occupational settings, and are major contributors to the high incidence of certain diseases among workers. These causative links are well established because of the frequently high exposures and the extensive epidemiological study done of such exposures. But even outside workplaces, chemical exposures have been implicated, though definitive proof is often lacking, as contributors to certain human diseases.<sup>6</sup> The ability of certain chemicals to exert effects, e.g., to

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<sup>5</sup> Ironically, it is often argued that the “more onerous” review required for new chemical approval serves as a disincentive to innovation, by placing such chemicals at a disadvantage in relation to those un- or under-assessed existing chemicals they might be able to replace.

<sup>6</sup> The European Commission (EIA, p. 25) cited and summarized a 2001 World Bank study (K. Lvovsky et al., “Health and Environment Strategy Papers,” No. 1, World Bank Working Paper 24096, 2001) as follows: “[The study] estimates that in established market economies pollution from agro-industrial chemicals and chemical pollution from diffuse sources cause

disrupt the endocrine systems of wildlife, even at very low concentrations is a further indicator of the potential for certain chemicals to cause harm.<sup>7</sup>

Equally disturbing is the accumulation of certain chemicals in wildlife and the environment, even in regions remote from sites of production and use, and the detection of a diverse array of chemicals, albeit often in low concentrations, in human tissues and fluids. Chemicals widely used in consumer products and thought to be safely embedded in polymers or other matrices and hence posing no risk of exposure—including phthalates used as plasticizers, polybrominated diphenyl ethers (PBDEs) used as flame retardants, and several families of perfluorinated chemicals used in coatings for textiles, cookware and food packaging—are now present in the bodies of virtually all people on earth. The ubiquity of such observations—coupled with the inability of our chemicals assessment systems to have predicted or prevented them, or to explain how such chemical exposures have become so widespread—has lent urgency to the calls for major reforms.

The heated debate over the significance of these trends and the contribution of chemicals manufacture and use to them highlights the dearth of information available to resolve such questions. Perhaps the most glaring failure of existing policies is their inability to generate reliable information on the vast majority of industrial chemicals in use today. In most cases we lack the information needed to determine which chemicals are safe, whether the observed accumulation of chemicals in the environment and human bodies poses serious risk, and whether the methods employed to manage chemicals are sufficient to minimize the risks.

Decades of this passive approach allowed the largely unquestioned use of tens of thousands of industrial chemicals without evidence of their safety. Today, however, efforts are finally beginning to address this legacy of un- or under-assessed chemicals. For example:

- In the U.S., the voluntary High Production Volume (HPV) Chemical Challenge is well along in developing and making public a basic set of hazard information on some 2,000 HPV chemicals—defined as those produced at one million pounds or more annually; these data will be used to conduct screening-level hazard assessments and prioritize HPV chemicals for further scrutiny.
- Under a mandate enacted in the 1999 revisions to CEPA, the Canadian government completed a categorization of the roughly 23,000 previously unassessed chemicals on its DSL. Using available information, the exercise identified those chemicals that pose the greatest potential for exposure of the general population in Canada, as well as persistent or bioaccumulative substances considered "inherently toxic" to humans or to nonhuman organisms. A follow-up program to generate or collect additional information and

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between 0.6% and 2.5% of the total burden of disease (that is, deaths and general ill health) with a central estimate of 1.5%. These estimates were based on conservative (5% of the total burden) and liberal (20% of the total burden) percentages of the amount of disease related to around 15 diseases (that is, not all health end-points were included). The degree of imprecision in these assumptions, which still represent expert estimates, by itself indicates that we do not have a robust feel for the impact of chemicals on the general health of the population."

<sup>7</sup> See, for example, European Environmental Agency, *Europe's Environment: The Third Assessment*, State of Environment report No. 1/2003, Chapter 12: "Environment and Human Health," available at [http://reports.eea.europa.eu/environmental\\_assessment\\_report\\_2003\\_10/en/kielv\\_chapt\\_12.pdf](http://reports.eea.europa.eu/environmental_assessment_report_2003_10/en/kielv_chapt_12.pdf).

conduct screening-level risk assessments has been initiated to address the more than 4,000 substances that meet one or more of these criteria.

- Most ambitious of all is the EU's new regulation called REACH, which stands for Registration, Evaluation, Authorization and Restriction of Chemicals. Adopted in December 2006, REACH will set up a relatively comprehensive system for registering the estimated 30,000 chemicals produced or imported in quantities of one metric ton (1,000 kilograms [kg] or about 2,200 pounds) or more per year per producer or importer.<sup>8</sup> Base sets of production, use, hazard and, in some cases, exposure data are required for registration. Government can then evaluate registered substances and, for chemicals identified as “substances of very high concern,” allow only those uses that are explicitly authorized. REACH replaces an array of EU legislation and regulation roughly resembling that in place in the U.S. and Canada.

As described in the remainder of this report, these examples serve as microcosms of the chemicals policies in their respective jurisdictions, and provide insight into the opportunities and limitations offered by each.

#### **Statutes forming the basis for the chemicals policies examined in this report**

This report focuses on so-called industrial chemicals, which typically exclude chemicals regulated under use-specific statutes. Hence chemicals used only as pharmaceuticals, cosmetic ingredients, pesticides or food additives, which are regulated under other statutes, are generally not considered “industrial chemicals.” The term is not intended to mean that such chemicals are used only in industry; many “industrial chemicals” are also present in consumer products.

The statutes that comprise the basis for our comparison are:

- The Canadian Environmental Protection Act (CEPA), as amended in 1999.<sup>9</sup>
- The United States Toxic Substances Control Act (TSCA), 1976.<sup>10</sup>
- The European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation, adopted in December 2006 and to take effect on June 1, 2007. Some aspects of other current EU chemicals regulations, as well as the previous regulations that REACH has supplanted, are cited where appropriate.<sup>11</sup>

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<sup>8</sup> An estimated 30,000 chemicals are produced or imported in amounts of one metric ton or more and are expected to be eventually registered under REACH. See European Commission, Joint Research Center, “Assessment of additional testing needs under REACH,” September 2003, Table 1, p. 12, available at [http://ecb.jrc.it/documents/REACH/PUBLICATIONS/REACH\\_testing\\_needs\\_final.pdf](http://ecb.jrc.it/documents/REACH/PUBLICATIONS/REACH_testing_needs_final.pdf).

<sup>9</sup> CEPA 1999 is available at [www.ec.gc.ca/CEPARegistry/the\\_act/Contents.cfm](http://www.ec.gc.ca/CEPARegistry/the_act/Contents.cfm). In addition to industrial chemicals, which are the focus of this paper, CEPA applies to pharmaceuticals and cosmetic ingredients with respect to their environmental impacts and any health impacts resulting from environmental exposures. Primary authority for these substances is provided under the Food and Drugs Act.

<sup>10</sup> TSCA is available at [http://www4.law.cornell.edu/uscode/html/uscode15/usc\\_sup\\_01\\_15\\_10\\_53.html](http://www4.law.cornell.edu/uscode/html/uscode15/usc_sup_01_15_10_53.html).

<sup>11</sup> The final text of REACH was published in the European Union's *Official Journal*, Volume 49, 30 December 2006, and is available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_396/l\\_39620061230en00010849.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf).



In considering the comparisons of these policies made throughout this report, it is important to keep in mind that REACH, unlike TSCA and CEPA, has yet to be implemented. Many critical elements of REACH remain to be developed, and how all of its provisions will work in practice remains to be seen.

Nonetheless, the intense interest that has surrounded the development and adoption of REACH over most of the last decade is warranted: REACH represents an enormous sea change in chemicals policy, arising out of a view that current policies toward industrial chemicals were largely failing.<sup>12</sup> Among the most revolutionary aspects of REACH are the following:

REACH, unlike TSCA and CEPA, has yet to be implemented. Many critical elements of REACH remain to be developed, and how all of its provisions will work in practice remains to be seen.

- “No data, no market”: REACH seeks to directly address the legacy of the large number of chemicals in commerce that were grandfathered into existing chemicals policies without requiring information to assess their potential risks. REACH’s registration process will require that, in order to enter or remain on the market, all nonexempt chemicals manufactured or imported in amounts of one metric ton or more per year per producer or importer must be registered and must meet specific data requirements.
- Burden shifting: REACH recasts the roles and relationship between government and industry by assigning industry the responsibility to develop risk information, assess it for indication of significant risk, and determine what risk management measures are needed and justify their adequacy. Government plays an oversight role. (Box 1 explores some of the implications of this shift in responsibility.)
- Information flow in chemical supply chains: REACH compels the bidirectional flow of information along the chain that links chemical producers, processors, distributors and users. It requires suppliers to inform their customers about the hazards and risks of their chemicals and about risk management measures that need to be applied. In turn, it requires users to give their suppliers sufficient information on their use(s) of a substance so the supplier can evaluate exposure and identify risk management measures that are then communicated back to the users.
- Authorization for use of substances of very high concern (SVHCs):<sup>13</sup> REACH will disallow the use of high-concern substances except when explicitly authorized, and will only authorize a use where the producer or user has demonstrated its risks are “adequately controlled,” or that its benefits outweigh the risks and no feasible safer alternatives exist. (Box 5 explores the role that substitution plays in REACH’s authorization process.) The

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<sup>12</sup> See European Commission, *White Paper: Strategy for a future Chemicals Policy*, 2 February 2001, Brussels, available at [http://ec.europa.eu/environment/chemicals/pdf/0188\\_en.pdf](http://ec.europa.eu/environment/chemicals/pdf/0188_en.pdf).

<sup>13</sup> SVHCs include chemicals classified as carcinogens, mutagens or reproductive toxicants (CMRs) and certain persistent, bioaccumulative and toxic chemicals (PBTs).

burden to make these showings is on the applicant for authorization, a major shift from policies that place the burden of demonstrating the converse on government.

This report will explore these and other novel elements of REACH, and will also highlight the uncertainties about how REACH will work in practice.

### **Key elements of chemicals policies**

U.S., Canadian and EU chemicals policies include elements related to tracking chemicals, developing risk information, assessing it for indication of significant risk, and acting to address any identified risks. These policy elements, which serve as the structure for the body of this report, include:

- 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

This report will seek out lessons to be gleaned from a comparative look at the U.S., Canadian and EU (REACH) approaches to chemicals assessment and management, identifying “best practices”<sup>14</sup> for each of the core functions above that draw on one or more of these approaches. The aim is to help move our societies 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 in the best position to internalize such information and use it to minimize risk from their products. (For more discussion of who should bear responsibility, see Box 1.)

#### **Box 1: Who should bear responsibility?**

One fundamental difference among the current and emerging policies discussed in this report—and a key decision to be made in any chemicals policy—concerns the roles and responsibilities assigned to government and industry. REACH is truly revolutionary in its recasting of the social contract between these entities. REACH assigns to industry the core responsibility—and considerable authority—for the trifecta of chemicals policies: developing risk information, assessing it for indication of significant risk and deciding what risk management to employ and whether it is adequate. REACH’s preamble puts it like this:

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<sup>14</sup> The term “best practices” is used somewhat loosely because REACH has yet to go into practice.

“Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. ...Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures.”<sup>15</sup>

Under REACH, government largely plays an oversight role, with authority—but only limited obligation—to evaluate industry’s assessments, require more information or testing, or impose controls. Although REACH mandates that criteria for prioritizing chemicals for risk evaluation be developed, government is not required to evaluate the risks of registered chemicals, including the information submitted by registrants, within a given timeframe. *Unless government selects a substance for in-depth evaluation under REACH, the only information and recommended risk management available for the substance is that provided by the registrant, subject to little more than a completeness check by government.*

Many existing systems for industrial and other types of chemicals assign responsibility to industry to generate risk data, but it is virtually unprecedented for government to assign the core responsibilities of risk assessment and decisions about risk management to industry.

Few would argue with the practical necessity of assigning the testing burden to industry. The U.S. Toxic Substances Control Act states: “It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that *the development of such data should be the responsibility of those who manufacture [defined by the statute to include import] and those who process such chemical substances and mixtures.*”<sup>16</sup>

Can industry be trusted to generate reliable data? Some argue that having industry generate risk information is the only way to move toward “green chemistry,” where industry develops the needed expertise and integrates safety considerations into the core functions of developing new chemicals and products, and reviewing and assessing existing products. Otherwise, what incentive would it have to design safer chemicals? Others argue that only data generated by the government or by independent laboratories can be trusted, and that industry should be involved only as far as footing the bill. Although such data may be more reliable, who would decide when a new chemical is sufficiently close to commercialization to hand it over to government for testing? And where would liability lie if such testing proved inaccurate or missed something? (See Box 4 for further discussion of steps to ensure the credibility of industry-generated information.)

This debate notwithstanding, REACH goes much further. There are clear philosophical and practical attractions to placing the burden of chemical risk assessment and management on the producers of chemicals. But its implications with regard to accuracy of information and adequacy of risk management are also essential to consider:

<sup>15</sup> REACH Preamble, paragraphs 18 and 19.

<sup>16</sup> TSCA §2(b)(1). Emphasis added.

- If government is sufficiently resourced to conduct prompt reviews and to address any deficiencies in industry's assessments and management, such an approach may succeed. (It is debatable, however, whether it would be more cost-effective than a system wherein government retains the responsibility to conduct assessments and impose risk management requirements. Advocates for the REACH approach argue that it requires industry to fully document and be legally accountable for the veracity of its information and the soundness of its actions. They also believe that reviewing that documentation should require less effort than creating it. But in practice it is often more difficult—with respect to both political and resource commitments—to rebut a standing assessment than to defend one's own.)
- If government is insufficiently resourced—as could occur if those setting budgets believe that the bulk of the burden has been shifted to industry, or if in times of tight budgets they cut oversight programs—then it must be asked whether industry's assessments and self-designed risk management plans are better than none. REACH will produce more risk assessments and management plans per unit of time than government has; indeed, a major motivation for REACH was the exceedingly slow pace of government assessment and action on chemicals.<sup>17</sup> But it is difficult to imagine that many of the assessments submitted by industry will indicate significant risk of the chemicals in question.

It is evident that a strong government capability dedicated to chemical risk assessment and management is an essential element of any sound chemicals policy. Clear rules are needed that ensure transparency and accountability for the generation of data, its assessment and the resulting actions, regardless of who conducts these activities.

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<sup>17</sup> See European Commission, *White Paper: Strategy for a future Chemicals Policy*, 2001, p. 6.

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## II. Identifying and prioritizing chemicals of concern

The U.S., Canadian and REACH systems differ in their criteria for identifying and prioritizing chemicals of concern regarding potential hazards or risks to human health and the environment. These criteria form the backbone of the policies, influencing all other aspects of how chemicals are assessed and managed. This section compares the criteria underpinning each of the three systems.

### UNITED STATES

TSCA articulates a core conceptual criterion of “unreasonable risk.” This criterion is laid out in §2(b), which places it squarely within the overall policy approach under TSCA:

“POLICY.—It is the policy of the United States that—

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

The unreasonable risk criterion is further elaborated in other sections of TSCA. For EPA to take regulatory action to control any chemical in commerce, it must first find that the chemical “*presents or will present* an unreasonable risk of injury to health or the environment.”<sup>18</sup> Before initiating any regulatory action, EPA must consider more than whether the chemical is harmful and if there are significant exposures to it. It must also consider the economic and social costs of imposing controls on the chemical, including the benefits of the chemical, the availability of alternatives, and the impact of regulation on the economy, small businesses and innovation.<sup>19</sup> It must demonstrate that the proposed control is the least burdensome it could have proposed.<sup>20</sup> Finally, it must demonstrate that no other statute could address the concern.<sup>21</sup>

According to EPA, “The unreasonable risk finding can be characterized as a judgment that the risk of health or environmental injury from the substance/mixture outweighs the burden to society of potential regulations.”<sup>22</sup>

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<sup>18</sup> TSCA, §6(a). Emphasis added.

<sup>19</sup> TSCA, §6(c)(1).

<sup>20</sup> TSCA, §6(a).

<sup>21</sup> TSCA, §§6(c) and 9.

<sup>22</sup> See EPA, “EPA Authorities under TSCA,” OPPT, 11 July 2005, p. 18, available at [www.epa.gov/oppt/npptac/pubs/tscaauthorities71105.pdf](http://www.epa.gov/oppt/npptac/pubs/tscaauthorities71105.pdf), citing 59 *Federal Register* 11138 (9 March 1994).

A somewhat lesser burden is imposed under TSCA in two other cases: first, when EPA finds that insufficient information is available on a new chemical to assess its potential risks and seeks to prohibit or limit its pending development of more information, and second, when EPA seeks to require testing of new or existing chemicals. In these cases, EPA must demonstrate that the chemical:

- “*may present* an unreasonable risk of injury to health or the environment,” or
- “is or will be produced in substantial quantities,” and
  - “enters or may reasonably be anticipated to enter the environment in substantial quantities,” or
  - “there is or may be significant or substantial human exposure” to the substance.<sup>23</sup>

This determination does not necessarily require that both the effects of a chemical and the magnitude of exposure be considered, and it does not introduce the other factors discussed earlier. To require testing, however, EPA must also demonstrate that:

- there is insufficient information to determine the effects of the chemical on health or the environment,<sup>24</sup> and
- testing is necessary to develop such information.<sup>25</sup>

Any prohibition or limitation on a new chemical issued by EPA only applies pending submission of the specified information;<sup>26</sup> any permanent regulation of a new chemical still requires EPA to find that it “presents or will present an unreasonable risk.”<sup>27</sup>

Beyond this broad criterion, TSCA does not specify other criteria for identifying chemicals of concern; EPA has articulated more specific criteria in only a few cases.

In 1999, EPA published a policy statement that set forth criteria it would use to identify persistent (P) and bioaccumulative (B) substances, in the context of reviewing new chemicals under TSCA.<sup>28</sup> These criteria are used to identify putative persistent, bioaccumulative and toxic (PBT) chemicals, which would be confirmed or negated by requiring additional testing. Two tiers of criteria were established:

- Half-life greater than two months and a bioconcentration or bioaccumulation factor (BCF/BAF) greater than or equal to 1,000: For chemicals exceeding these criteria, the outcome of new chemical review could be a TSCA §5(e) Consent Order that allows manufacture to commence but imposes exposure or release controls and testing requirements (see Section VIA below); and

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<sup>23</sup> TSCA, §4(a)(1)(A)(i) and §5(e)(1)(A). Emphasis added.

<sup>24</sup> In practice, this requirement can be extremely onerous and consume substantial resources, as it compels an extensive search for information. It can also be viewed as effectively having to prove the nonexistence of sufficient information.

<sup>25</sup> TSCA, §4(a)(1)(A)(ii) and (iii).

<sup>26</sup> TSCA, §5(e).

<sup>27</sup> TSCA, §5(f).

<sup>28</sup> See [www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm](http://www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm).

- Half-life greater than six months and BCF/BAF factor greater than or equal to 5,000: For chemicals exceeding these criteria—which EPA notes are equivalent to those used internationally to identify persistent organic pollutants (POPs)—the outcome of new chemical review could be a TSCA §5(e) ban pending testing.

However, TSCA does not require manufacturers to submit a minimum data set when they notify EPA of their intent to produce a new chemical (see Section IVA). Unless the manufacturer chose to submit data relevant to assessing P and B, it is unclear how EPA would identify a chemical as a putative PBT. Estimation models using structure-activity relationships (SARs) exist for predicting these parameters, although they require certain input physical-chemical data that may not always be available for a new chemical. Where EPA is able to determine, “based upon available test data, SAR and professional judgment,” that a chemical is a possible PBT, this policy sets forth a testing strategy that EPA would likely impose on the manufacturer, first, to confirm that the chemical has P and B characteristics, and second, to test for certain toxicity endpoints. No criteria for the latter are established, however, and such a determination would be made on a case-by-case basis.

EPA has articulated two different sets of criteria for “substantial” production or release and “significant or substantial” human exposure: one in the context of developing regulations mandating testing of a chemical already in commerce under TSCA §4,<sup>29</sup> as discussed in Section IVB; and the other in the context of imposing testing requirements on certain new chemicals under TSCA §5,<sup>30</sup> as discussed in Section IVA.

EPA has no other specific hazard or exposure criteria for use in a regulatory context to identify chemicals of concern, although it has agreed to use certain criteria from the Globally Harmonized System (GHS) for the Classification and Labeling of Chemical Substances<sup>31</sup> to screen data generated by its HPV Chemical Challenge Program; see Section VB.

## CANADA

The core conceptual criterion under CEPA 1999 for identifying chemicals of concern is the definition of the term “toxic” under §64:

“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.”

<sup>29</sup> See [www.epa.gov/opptintr/chemtest/pubs/sct4rule.htm](http://www.epa.gov/opptintr/chemtest/pubs/sct4rule.htm).

<sup>30</sup> See [www.epa.gov/oppt/newchems/pubs/expbased.htm](http://www.epa.gov/oppt/newchems/pubs/expbased.htm).

<sup>31</sup> Organization for Economic Cooperation and Development (OECD), Series on Testing and Assessment, Number 33, 14 August 2001. *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures*, available at [www.oecd.org/LongAbstract/0,2546,en\\_2649\\_34365\\_2671862\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/LongAbstract/0,2546,en_2649_34365_2671862_1_1_1_1,00.html).

A substance may be “suspected” of being toxic if either its hazards or exposure potential are of concern.<sup>32</sup> CEPA’s definition makes clear that “toxic” encompasses consideration of both hazard and exposure, and hence is an indication of risk.

There are two key distinctions between CEPA’s “toxic” criterion and TSCA’s “unreasonable risk” criterion. First, under CEPA, the determination of whether a chemical is CEPA-toxic and requires regulatory or other risk management action is separate from the determination of how risk should be managed.<sup>33</sup> The former decision does not require consideration of economic and social factors, the benefits of the chemical or the availability of alternatives, although these types of factors do influence the latter decision about what risk management measures to impose.

Second, whereas taking regulatory action requires a finding that a chemical is CEPA-toxic, the definition of that term is broad, encompassing both the potential and actuality for a chemical to cause adverse effects or constitute a danger. In this regard, the term more closely resembles the TSCA “may present an unreasonable risk” formulation.

As a result of these distinctions, the difference between the burdens on government to take action of existing vs. new chemicals does not appear to be as large under CEPA as it is under TSCA.

With respect to identifying substances of concern, CEPA’s new chemicals program utilizes production quantity and release or exposure criteria to trigger specific information requirements for notifiers of new chemicals; see Section IVA.

As described in more detail in Section IVB, when CEPA was reauthorized in 1999, it mandated that Environment Canada and Health Canada categorize the roughly 23,000 chemicals on its Domestic Substances List (DSL). Categorization entailed developing and applying specific criteria to identify which chemicals were: a) persistent, b) bioaccumulative, c) inherently toxic to humans or nonhuman organisms, or d) of greatest potential for exposure to humans, based on available information. These criteria have also been used to further prioritize among those found to meet the criteria.

To this end, Environment Canada used the following criteria:<sup>34</sup>

• <i>Persistence:</i>	<u>Medium</u>	<u>Half-life</u>
	Air	≥ 2 days
	Water	≥ 182 days
	Sediment	≥ 1 year
	Soil	≥ 182 days

<sup>32</sup> *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Pursuant to Section 69 of the *Canadian Environmental Protection Act, 1999*. Copublished by Environment Canada and Health Canada. Version 2005–EPS M-688, Section 9.4.2, p. 97, available at [www.ec.gc.ca/substances/nsb/pdf/cpguidem688.pdf](http://www.ec.gc.ca/substances/nsb/pdf/cpguidem688.pdf).

<sup>33</sup> See General Accounting Office Report GAO/RCED-94-103, *Toxic Substances Control Act – Legislative Changes Could Make the Act More Effective* (1994), p. 26, available at <http://archive.gao.gov/t2pbat2/152799.pdf>.

<sup>34</sup> See “DSL Categorization under CEPA 1999 Section 73: Ecological Categorization Criteria and Process,” available at [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_criteria\\_process.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria_process.cfm). The criteria for persistence and bioaccumulation are identical to those used under Canada’s *Toxic Substances Management Policy* to identify chemicals of very high concern (described further in Section VIB); see Table 1, p. 8, available at [www.ec.gc.ca/toxics/TSMP/en/tsmp.pdf](http://www.ec.gc.ca/toxics/TSMP/en/tsmp.pdf).



- *Bioaccumulation:* Bioaccumulation factor (BAF)  $\geq 5,000$  or  
Bioconcentration factor (BCF)  $\geq 5,000$  or  
 $\text{Log } K_{\text{ow}}^{35} \geq 5$
- *Toxicity:* Acute and chronic toxicity to aquatic organisms (fish, invertebrates, algae):  
LC50 or EC50  $\leq 1$  mg/L or  
NOEC  $\leq 0.1$  mg/L<sup>36</sup>

Health Canada (HC) used the following criteria:<sup>37</sup>

- *Greatest potential for exposure (GPE) to humans:* As further described in Section IVB, HC first ranked all DSL chemicals on the basis of the production quantity, number of submitters and expert-derived use code indices that correlated type of use with expected level of exposure. This step used data collected in 1984–1986, when the DSL was first being developed. HC then used the following criteria for each of these three parameters to identify substances with greatest (GPE), intermediate (IPE) and lowest (LPE) potential for exposure:

	<i>Quantity (kg/year)</i>	<i># of submitters</i>	<i>Sum of expert ranked use code indices</i>
GPE	>100,000	Top 10%	Top 10%
IPE	>10,000	All	Top 30%
LPE	All	All	All

Only substances meeting all three of the highest-tier criteria were considered GPE.

- *Inherent toxicity:* As further described in Section IVB, HC developed specific criteria for each of the health endpoints it considered; these criteria are shown in Table 1.

## EUROPEAN UNION

Two sets of criteria will play pivotal roles in REACH. One is inherited from another EU regulation: classifications of chemicals as “dangerous” using criteria specified under the EU’s Directive on Dangerous Substances.<sup>38</sup> Sixteen classes of dangerous substances, and specific criteria for each (not included here), have been delineated:

<sup>35</sup>  $K_{\text{ow}}$  = octanol-water partition coefficient

<sup>36</sup> LC50 is the concentration of a substance in water causing 50% of the experimental organisms in the water to die within the duration of the test. EC50 is the concentration of a substance in water that induces toxic effects in 50% of the experimental organisms within the duration of the test. NOEC is the no-observed-effect concentration, the highest concentration of a substance at which there is no adverse effect observed in a toxicological study.

<sup>37</sup> See Part C (Tools) of the *Proposed Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999*, available at [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index_e.html).

<sup>38</sup> See a description of the Directive at [http://ec.europa.eu/environment/dansub/home\\_en.htm](http://ec.europa.eu/environment/dansub/home_en.htm). Annex VI of that Directive contains the actual classification criteria, available at [http://ec.europa.eu/environment/dansub/pdfs/annex6\\_en.pdf](http://ec.europa.eu/environment/dansub/pdfs/annex6_en.pdf).

TABLE 1

**ComHaz Endpoint-Specific Qualitative and Quantitative Criteria**

Endpoint	Type of criteria	Sources of information	Description of criteria
Carcinogenicity	Qualitative	Data or (Q)SAR	First hit, weight of evidence
Genotoxicity	Qualitative	Data or (Q)SAR	First hit, weight of evidence
Regulatory/ reference values	Quantitative	Assessments from international/national agencies	Oral: $\leq 0.1$ mg/kg bw per day Inhalation: $\leq 0.4$ mg/m <sup>3</sup> Dermal: NA
Developmental toxicity	Quantitative	Data	Oral/dermal: LO(A)EL $\leq 270$ mg/kg bw per day NO(A)EL $\leq 90$ mg/kg bw per day Inhalation: LO(A)EC $\leq 810$ mg/m <sup>3</sup> NO(A)EC $\leq 270$ mg/m <sup>3</sup>
	Qualitative	(Q)SAR	Sufficient positive evidence <sup>a</sup>
Reproductive toxicity	Quantitative	Data	Oral/dermal: LO(A)EL $\leq 30$ mg/kg bw per day NO(A)EL $\leq 10$ mg/kg bw per day Inhalation: LO(A)EC $\leq 90$ mg/m <sup>3</sup> NO(A)EC $\leq 30$ mg/m <sup>3</sup>
Longer-term toxicity	Quantitative	Data or (Q)SAR (where appropriate)	Oral/dermal: LO(A)EL $\leq 30$ mg/kg bw per day NO(A)EL $\leq 10$ mg/kg bw per day
			Inhalation: LO(A)EC $\leq 90$ mg/m <sup>3</sup> NO(A)EC $\leq 30$ mg/m <sup>3</sup>
Short-term toxicity	Quantitative	Data	Oral/dermal: LO(A)EL $\leq 90$ mg/kg bw per day NO(A)EL $\leq 30$ mg/kg bw per day Inhalation: LO(A)EC $\leq 270$ mg/m <sup>3</sup> NO(A)EC $\leq 90$ mg/m <sup>3</sup>
Acute toxicity	Quantitative	Data or (Q)SAR (where appropriate)	Oral/dermal: LD <sub>50</sub> $\leq 500$ mg/kg bw Inhalation: LC <sub>50</sub> $\leq 1500$ mg/m <sup>3</sup> IP injection: <sup>b</sup> LD <sub>50</sub> $\leq 219$ mg/kg bw IV injection: <sup>b</sup> LD <sub>50</sub> $\leq 154$ mg/kg bw

<sup>a</sup> Substances that satisfy the ComHaz criteria for developmental toxicity based on quantitative structure–activity relationship (QSAR) model predictions are prioritized for the generation of data on developmental toxicity.

<sup>b</sup> These routes of administration (intraperitoneal [IP] and intravenous [IV]) are considered only in the absence of data on more relevant routes (i.e., oral, dermal or inhalation).

Source: Part C (Tools) of the *Proposed Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999*, pp. 23-24, available at [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index_e.html).

### Classification on the Basis of Physicochemical Properties

- Explosive
- Oxidizing
- Extremely flammable
- Highly flammable
- Flammable

### Classification on the Basis of Toxicological Properties

- Very toxic
- Toxic

- Harmful
- Corrosive
- Irritant
- Sensitization

#### Classification on the Basis of Specific Effects on Human Health

- Carcinogenic substances
- Mutagenic substances
- Substances toxic to reproduction

#### Classification on the Basis of Environmental Effects

- Aquatic environment
- Nonaquatic environment

The second set of criteria under REACH defines “substances of very high concern” (SVHCs), which include:

- Substances classified as Category 1 and 2 carcinogens, mutagens and reproductive toxicants (CMRs), using the classification criteria under the Directive on Dangerous Substances just described.
- Substances that meet REACH’s criteria for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); the criteria for identifying these chemicals are in Annex XIII of REACH, which is reproduced in its entirety in Appendix D of this report.
- Substances, termed “equivalent level of concern substances”—such as those having endocrine disrupting properties, or those having PBT or vPvB properties that do not meet REACH’s criteria but for which there is scientific evidence of probable serious effects to human health or the environment—that are identified on a case-by-case basis.<sup>39</sup>

As noted throughout this report, these criteria are used for a variety of purposes under REACH, including the following:

- For dangerous, PBT or vPvB substances manufactured at ten metric tons or more per year, the chemical safety report required for registration must include an exposure assessment and risk characterization (Article 14(4)).
- CMRs manufactured at one metric ton/year or more, and substances manufactured at 100 metric tons/year or more that are classified under the Directive on Dangerous Substances as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment, must be registered within three years, sooner than other substances in their tonnage ranges (Article 23(1)).

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<sup>39</sup> REACH, Article 57.

- Substances meeting these criteria are expected to be prioritized for substance evaluation (Article 44).
- SVHCs are expected to be subject to authorization (Articles 57 and 58(3)).
- Most SVHCs are not eligible to be authorized based on demonstration of “adequate control” (Article 60(3)).
- CMRs that could be used by consumers on their own or in preparations or articles can be directly proposed for restriction by the European Commission, and the restriction approved using an expedited procedure not available for other substances (Article 68(2)).

### **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.*

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 EPA makes decisions as to which chemicals it is concerned about, how they are to be identified or prioritized, or when risk assessment or 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.

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### III. Identifying and tracking chemicals and their production and use

#### A. Chemical inventories

Each of the three systems maintains a list or “inventory” of industrial chemicals. Each inventory was originally populated with those chemicals that were manufactured or in commerce in the respective jurisdictions at the time of their establishment: 1979 for the U.S.’ TSCA Chemical Substances Inventory, 1981 for the EU’s EINECS (European Inventory of Existing Commercial Chemical Substances) and 1986 for Canada’s DSL (the Domestic Substances List). A basic comparison of these three “existing substance” inventories is provided in Table 2.

Canada maintains a second existing substances inventory, the NDSL or Non-Domestic Substances List, which contains chemicals found on the U.S. TSCA Inventory but not on the DSL (more detail to follow). Europe maintains a separate inventory, the European List of Notified Chemical Substances (ELINCS), of “new” chemicals that have been introduced (“notified”) since the EINECS inventory was established. Some information about these additional inventories is shown in Table 2.

These inventories are also used to distinguish between “existing” and “new” substances. New substances are generally defined as those chemicals not on the existing substances inventory. Whether and how new substances get added to these inventories differs significantly among the three systems. A brief description of these processes follows.

#### UNITED STATES

In the U.S., producers or importers<sup>40</sup> of new chemicals must submit a Premanufacture Notification (PMN) to EPA at least 90 days prior to commencing their manufacture. As a rule, EPA must decide within those 90 days whether to deny the request to manufacture and use the chemical, to impose conditions such as implementation of controls or additional testing requirements, or to take no action; if EPA takes no action and does not issue an extension of the assessment period (up to 90 additional days), the notifier can begin production or import.

Once production or import commences, the manufacturer must file a Notice of Commencement (NOC) within 30 days, at which point the chemical is added to the TSCA Inventory; if a NOC is not filed, no one but the original submitter may commence manufacture of the chemical without first filing a PMN.<sup>41</sup> Once a chemical is listed on the Inventory, it becomes an “existing” chemical. Any conditions EPA imposes through PMN review apply only to the original notifier, unless EPA also promulgates a Significant New Use Rule (SNUR) specific to that chemical. SNURs typically extend the same conditions imposed on the original notifier to any other manufacturer; anyone else who begins producing or using the chemical in a manner that does not abide by those conditions is required to file a Significant New Use Notification (SNUN), which

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<sup>40</sup> TSCA defines “manufacture” to include production and import. TSCA §(3)(7) and 40 CFR 720.3(q). We will therefore generally use the term manufacture in the same manner, and use “manufacturer” to refer both to producers and to importers.

<sup>41</sup> EPA, OPPT, *Draft Q&A for the New Chemicals Program*, undated, answer to Question 121-1, available at [www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf](http://www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf).

TABLE 2

**Inventory Comparisons and Statutory Exclusions**

		U.S. TSCA Inventory <sup>a</sup>	Canada CEPA DSL <sup>b</sup>	Canada CEPA NDSL <sup>b</sup>	EU EINECS <sup>c</sup>	EU ELINCS <sup>c</sup>
Date of initiation		1979	1986	–	1981	–
Number of chemicals		82,700	>26,000	>58,000	100,200	4,380
on original list		62,000	23,000	–	100,200	–
added via new chemical notifications		20,700	>3,000	–	–	4,380
Polymers		29,500	4,600	NA	0	NA
Nonpolymers		53,400	18,400	NA	100,200	NA
Organics		50,200	16,100	NA	90,200	NA
Inorganics		3,200	2,300	NA	10,000	NA
		<b>TSCA<sup>d</sup></b>	<b>CEPA<sup>e</sup></b>		<b>REACH<sup>f</sup></b>	
Exclusions / regulated under other authorities	nuclear materials	√	√		√	
	munitions	√				
	foods, food additives	√	√		√	
	drugs	√	partial		√	
	cosmetics	√	partial		partial	
	pesticides	√	√			
	fertilizers		√			
	manufactured items (articles)	√	√		partial	

Source: Environmental Defense, based on references in table notes.

**TABLE 2 NOTES**

<sup>a</sup> EPA, OPPT Overview, 2007; and National Pollution Prevention and Toxics Advisory Committee, “Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?” Broader Issues Work Group, 6 October 2005, at [www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf](http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf).

<sup>b</sup> Government of Canada, *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 27 October 2004, at

[www.ec.gc.ca/CEPARegistry/the\\_act/guide04/toc.cfm](http://www.ec.gc.ca/CEPARegistry/the_act/guide04/toc.cfm); *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 3.3; Environment Canada spreadsheets providing categorization decisions for different chemical classes, accessed from the final (September 2006) CD-ROM; see

[www.ec.gc.ca/substances/ese/eng/dsl/cat\\_index.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm); CEPA New Substances Program Statistics, 1994-2006, spreadsheet provided to the author by Bernard Madé, Director, New Substances Branch, Environment Canada, 23 June 2006.

<sup>c</sup> European Chemicals Bureau, “Assessment of Chemicals,” Existing and New Chemicals web pages, accessed 25 February 2007, at <http://ecb.jrc.it/existing-chemicals/> and <http://ecb.jrc.it/new-chemicals/>. Polymers are excluded from EINECS, and instead are listed under their constituent monomers.

<sup>d</sup> TSCA, §3.

<sup>e</sup> CEPA, §81.

<sup>f</sup> REACH, Articles 2, 6, 7, 9.

TABLE 3

**Substances Subject To, Excluded and Exempt from New Substances Notification/Registration**

		TSCA <sup>a</sup>	CEPA <sup>b</sup>	REACH <sup>c</sup>	ELINCS <sup>d</sup>
Notifications		36,600	13,800	–	6,800
unique substances		NA	NA	–	4,520
added via new chemical notifications		18,100	>3,000	–	4,380 <sup>e</sup>
Excluded from notification/registration	naturally-occurring materials	√	√	√	
	incidental/end-use reaction products	√	√	√	
	mixtures (but not mixture components)	√	√	√	
	impurities	√	√	?	
	byproducts	√		√	
	non-isolated intermediates	√	√	√	
	substances manufactured solely for export	√	√	√	
	substances formed during the manufacture of an article	√	?	√	
Exemptions (E) from, or reduced/conditional (RC) notification/registration requirements	research and development	E*	RC	E	
	test marketing	E**	RC	E	
	low volume	E**	E	E	
	low release/exposure	E**		RC	
	certain polymers	E*	RC	E	
	contained site-limited intermediate		RC	RC	
	transported intermediate		RC	RC	
	substances in articles	E	E	RC	

Source: Environmental Defense, based on references in table notes.

**TABLE 3 NOTES**

<sup>a</sup> EPA, OPPT Overview, 2007, pp. 10-11; NPPTAC, "Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" 2005; and EPA, New Chemicals Program, "Is a Filing Necessary for My Chemical?" available at [www.epa.gov/opptintr/newchems/pubs/whofiles.htm](http://www.epa.gov/opptintr/newchems/pubs/whofiles.htm). Notes: \* These exemptions are self-implementing; the polymer exemption requires post-manufacture notification of, but not approval by, EPA. \*\* These exemptions from PMN requirements do require notice submission and approval by EPA.

<sup>b</sup> CEPA New Substances Program Statistics, 1994-2006, spreadsheet provided to the author by Bernard Madé, Director, New Substances Branch, Environment Canada, 23 June 2006; and Government of Canada, "Who Should and How To Notify," available at [www.ec.gc.ca/substances/nsb/eng/notify\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/notify_e.shtml).

<sup>c</sup> REACH, Articles 2, 6, 7, 9.

<sup>d</sup> European Chemicals Bureau, "Assessment of Chemicals," New Chemicals web page, accessed 25 February 2007, at <http://ecb.jrc.it/new-chemicals/>.

<sup>e</sup> Polymers are exempt from notification unless they contain 2% or more of a substance that is not on EINECS; see <http://ecb.jrc.it/new-chemicals/>.

EPA reviews in the same manner and time frame as a PMN. Chemicals with SNURs are flagged as such on the Inventory. (Table 6 shows the number of SNURs issued by EPA since TSCA was enacted.) *In the absence of a SNUR, anyone (other than the original notifier, who is bound by any conditions imposed through EPA review of its PMN) may manufacture any chemical on the Inventory by any means, for any purpose and in any amount, without any notification to EPA that it is doing so.*<sup>42</sup>

EPA does not maintain a separate inventory of “new” substances that have undergone PMN review, but it does flag such substances on the TSCA Inventory.

#### CANADA

In Canada, new chemicals must also be notified, but with notification required prior to their production or import reaching specified quantity thresholds (set at 100 kg per year or more, depending on the class of chemical). As in the U.S., only new chemicals that have been reviewed by the authorities are placed on the Domestic Substances List (DSL). Hence, like the TSCA Inventory, the DSL is a combination of chemicals that were placed on it because they were in commerce in Canada in 1984–1986,<sup>43</sup> plus “new” chemicals that were notified and assessed by the authorities and have begun manufacture or entered commerce since that time (the latter bear flags on the DSL to distinguish them from non-notified substances).

Like the U.S. system, new substances are placed on the DSL only after they have been assessed, and any substances placed on the DSL without condition may be used without notification. However, there are some key differences in the assessment process that dictate whether and when notified substances are placed on the DSL.

First, Canada applies a tiered notification process. There are several tiers of information requirements that must be met by notifiers, depending (among other factors) on the quantity to be produced or imported and whether significant environmental release or human exposure is expected. A notifier of a new substance must either submit at the outset the full complement of information called for at the highest applicable tier, or submit the information required for a given tier prior to reaching that level of production or import. Only after the full complement of information, including that required at the highest applicable tier, has been submitted and assessed, and government authorities determine that risk management measures need not be imposed, is a notified substance eligible to be placed on the DSL. Unless this full review occurs and the chemical is actually placed on the DSL,<sup>44</sup> any additional producer or importer of the same substance must also notify it and

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<sup>42</sup> Government Accountability Office, Report GAO-05-458, *Chemical Regulation—Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program*, 2005, pp. 15-16, available at [www.gao.gov/new.items/d061032t.pdf](http://www.gao.gov/new.items/d061032t.pdf).

<sup>43</sup> The DSL actually includes “substances that were, between January 1, 1984, and December 31, 1986, in commercial use in Canada, or were used for commercial manufacturing purposes, or were manufactured in or imported into Canada in a quantity of 100 kg or more in any one calendar year.” See *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, p. 6, available at [www.ec.gc.ca/CEPARegistry/the\\_act/guide04/toc.cfm](http://www.ec.gc.ca/CEPARegistry/the_act/guide04/toc.cfm).

<sup>44</sup> Additional DSL listing requirements apply even after government review. Within 30 days of reaching the production or import level for the highest applicable tier, a Notice of Excess Quantity (NOEQ) must be filed; alternatively, any notifier who has submitted the full complement of information for a substance and has begun to manufacture or import the substance may submit a Notice of Manufacture or Import (NOMI) at any time prior to reaching the quantities that trigger the highest tier. Once the full complement of information has been reviewed and approved without condition, the assessment period has expired and either a NOMI or NOEQ has been filed, DSL listing is mandatory.



this notification must be separately reviewed and assessed. Between 1994 and June 2006, a total of 2,845 substances were added to the DSL via the New Substances Notification (NSN) process.<sup>45</sup>

Second, unlike the U.S. system, the outcome of a substance review dictates whether and how it is placed on the DSL and whether notification by other producers or importers is required. The notification review process and outcomes are discussed in Sections V and VI.

Canada's second inventory of existing substances, the Non-Domestic Substances List or NDSL, is a list of substances not included on the DSL that "are accepted as being in commercial use internationally."<sup>46</sup> The NDSL is based on substances that have been on the public (non-confidential) portion of the U.S. TSCA Inventory for a minimum of one year. Substances listed on the confidential portion of the TSCA Inventory are only listed on the NDSL if a company requests the listing and documents that the chemical has been present on the confidential TSCA list for at least one year.<sup>47</sup> Under a U.S.-Canada bilateral agreement called the Four Corners Arrangement (4CA), substances can be added to the NDSL sooner. If a new chemical has been assessed by the EPA, Canada's New Substances Program can review that assessment and decide to add the substance to the NDSL, with an "FC" flag.<sup>48</sup> Chemicals for which either EPA or Canada's New Substances Program have imposed risk management requirements are not eligible for listing on the NDSL.

Producers or importers of chemicals on the NDSL are still subject to notification and information requirements, which are triggered when their domestic quantities approach certain production, import or release/exposure thresholds. Information requirements at each tier are lower than for chemicals not on the NDSL. This means that an NDSL substance, once it has met its highest tier of information requirements, can be added to the DSL after a government review has been conducted that was based on less information than is required for a non-NDSL chemical.<sup>49</sup>

## EUROPEAN UNION

In the EU, the existing chemical inventory, EINECS, is essentially a fixed list (changing only to incorporate corrections), as it represents chemicals that were in commerce as of 1981. New chemicals are separately inventoried on the ELINCS, which has been periodically updated to incorporate newly notified chemicals, and hence is a cumulative listing. In contrast to the U.S. and Canadian systems—but as was the case under the prior regulations' notification process—REACH's

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<sup>45</sup> CEPA New Substances Program Statistics, 1994-2006, spreadsheet provided to the author by Bernard Madé, Director, New Substances Branch, Environment Canada, 23 June 2006.

<sup>46</sup> See *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, p. 15.

<sup>47</sup> See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 2.2.3.

<sup>48</sup> See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 2.2.3.3 and Appendix 9.

<sup>49</sup> This lesser information requirement is presumably based on an assumption that NDSL chemicals pose lower potential for risk than non-NDSL chemicals, either because: a) it is assumed that NDSL chemicals have already been assessed to some extent outside of Canada; this will only be the case, however, for the minority of chemicals that have in fact been assessed, comprised of those chemicals that were reviewed as new chemicals under the U.S. or EU systems or the much smaller number of existing chemicals assessed under such systems; or b) it is assumed that, because NDSL chemicals have already been in use somewhere, they are more likely to have already evidenced any potential risk than would chemicals not yet in use; this assumption is questionable as well, given that history demonstrates that, in the absence of formal assessment, chemicals typically take many years to cause and display adverse effects at levels sufficient to be detected.

registration process for new chemicals<sup>50</sup> does not entail any government review. Under REACH, producers or importers must register their substances at least 21 days prior to placing a chemical on the European market in an amount exceeding one metric ton (1,000 kg) per year.<sup>51</sup> Once notified, and after the waiting period to allow a completeness check expires, marketing and manufacturing of the chemical can commence.<sup>52</sup> Hence—unlike both the U.S. and Canadian systems—because government evaluation of new chemical registrations takes place on a track that is independent of registration itself, such evaluation is not a prerequisite for commencement of manufacture.

In contrast to the U.S. system, however, under REACH all subsequent producers or importers of the same chemical must also file a registration, although they may refer to any earlier registration and utilize information submitted by the earlier registrants with their permission. (For chemicals already on the market, whereas each producer or importer of a chemical must register it, multiple producers or importers of the same substance may co-register and jointly submit the required information.)

REACH, like the Canadian system, will effectively be a tiered notification system, with submission of additional information required prior to reaching specified levels of production or import (see Section IVA). Beyond a simple completeness check, however, no government review or decision is needed in order to continue and increase manufacture.

Unlike both the U.S. and Canadian systems, under REACH, government evaluation of new chemicals is not a prerequisite for commencement of manufacture.

#### MAJOR DIFFERENCES

In Canada, if a notified chemical: a) has less than the full complement of information submitted, b) is found to be CEPA-toxic or suspected of being CEPA-toxic and has conditions (either risk management or additional information requirements) imposed on it, or c) is found to be CEPA-toxic or suspected of being CEPA-toxic and is prohibited but not yet regulated, it cannot be added to the DSL, and hence notification is required by any other producer or importer. In the U.S., a chemical goes onto the Inventory after EPA's first (and usually only) review; any conditions imposed apply only to the original notifier unless EPA also issues a SNUR. There is no specified up-front information requirement, no formal finding about toxicity is required and even chemicals found or suspected to be toxic are still placed on the Inventory, with no notification by a new manufacturer required unless EPA has issued a SNUR. In the EU, under REACH, the review process for a new chemical is separate from the registration process; the listing of a chemical on ELINCS has no bearing on the requirement that subsequent producers or importers register the substance. Like Canada's system, however, a tiered set of data requirements apply as a chemical's production increases.

<sup>50</sup> Under REACH, new chemicals are termed "non-phase-in substances," to distinguish them from existing chemicals, known as "phase-in substances" because the applicable registration requirements for the latter will be phased in over time.

<sup>51</sup> REACH only applies to substances produced or imported in annual quantities of one metric ton (1,000 kg) or more by a single producer or importer, so notification presumably will only be required once this level is approached. This represents a significant change from prior EU regulations, under which the threshold for notification was much lower: 10 kg/year or more.

<sup>52</sup> In contrast to the U.S. system, which is a premanufacture notification scheme, the Canadian and REACH systems do not require notification until a certain level of actual manufacture is reached, and hence their requirements come into effect later than is the case under TSCA. They also establish multiple notification triggers based on reaching each of several specified levels of production or import.

## **Best practice**

*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.

## **B. Updating information on chemical manufacture and use**

Another key difference among the three systems is whether and how government can require chemical manufacturers to update information on manufacture and use over time.

### UNITED STATES

Using TSCA authorities, EPA has developed the Inventory Update Reporting (IUR) Rule,<sup>53</sup> which requires manufacturers of each nonexempt<sup>54</sup> existing chemical to report basic information on how much is manufactured during the reporting year and at which facilities. Reporting of "reasonably ascertainable" information is required, but only: a) for chemicals produced or imported at or above 25,000 (recently raised from 10,000) pounds per year per manufacturing site, b) once every five years (recently raised from four years), and c) of information for the reporting year, i.e., for one of the five years. In addition to quantity and location, the following must be reported for each site:

- number of workers reasonably likely to be exposed to the chemical substance at the site;
- physical form(s) of the chemical substance as it leaves the submitter's possession, along with the associated percent of total production volume; and

<sup>53</sup> See [www.epa.gov/opptintr/iur/](http://www.epa.gov/opptintr/iur/).

<sup>54</sup> Certain chemicals on the TSCA Inventory are fully or partially exempted from IUR reporting. Full exemptions apply to most polymers, and also to chemicals that are: produced in small quantities for research and development; imported as part of an article; impurities, byproducts (under certain circumstances), or nonisolated intermediates; and manufactured by a small manufacturer as defined in the regulations. Partial reporting exemptions apply to certain petroleum processing streams, other chemicals deemed to be of "low current interest" and specifically listed in the regulations, and inorganic chemicals (the latter will be subject to full reporting starting in 2011). See EPA, "Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database," answers to questions 30-37, available at [www.epa.gov/opptintr/iur/pubs/guidance\\_qanda.pdf](http://www.epa.gov/opptintr/iur/pubs/guidance_qanda.pdf).

- maximum concentration of the chemical substance as it leaves the submitter's possession.

If manufacturing quantities equal or exceed 300,000 lbs/year/site, additional information that is “readily obtainable” is required to be reported concerning downstream processing and use sites, types of commercial and consumer uses, amounts in each use category and maximum concentrations in commercial and consumer products.<sup>55</sup>

Under TSCA §8(a), EPA can use case-by-case rulemaking to require manufacturers and processors of specified chemicals to report basic manufacture and use information.<sup>56</sup> Each such request requires a separate rulemaking, although a single rule can cover multiple chemicals. EPA has standardized this type of regulation in the form of a Preliminary Assessment Information Reporting (PAIR) Rule, which requires one-time reporting. As of September 2006, approximately 33 PAIR rules had been issued for about 1,200 chemicals.<sup>57</sup>

The only other circumstances under TSCA requiring reporting of changes in manufacture or use would be for a new chemical subject to such a condition as part of the review of its PMN, or a chemical subject to a SNUR that included such a requirement (called a “volume SNUR”<sup>58</sup>).

The infrequent reporting under the IUR can mask significant changes that occur between reporting cycles. EPA has found that, whereas the number of chemicals reported is relatively constant from one cycle to the next, about 33% of the specific chemicals reported in one cycle are not reported in the next cycle, and are “replaced” by a roughly comparable number of chemicals not reported in the previous cycle.<sup>59</sup> Presumably this reflects changes in manufacturing levels that cause chemicals to fall below or bring them above the reporting threshold.

Under the U.S. HPV Challenge, some 2,800 chemicals were identified as being produced at HPV levels (one million pounds or more annually) based on data reported for the 1990 IUR reporting cycle. Based on data received in the last two reporting cycles, for 1998 and 2002, EPA has determined that production or import levels for about 500 of these chemicals dropped to levels below HPV. But during the same period (1990–2002), EPA estimates that more than 1,100 chemicals may have become HPV chemicals—that is, their production or import levels have risen to above one million pounds annually.<sup>60</sup>

Appendix A contains an analysis of the extent of fluctuation in stated manufacturing levels for chemicals that are reported in both of two successive cycles. Because manufacturing quantities for chemicals in the IUR are publicly reported only in broad ranges, the analysis examined how

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<sup>55</sup> See EPA, TSCA Inventory Update Rule Amendments, *Federal Register*, 7 January 2003, Vol. 68, No. 4, pp. 847-906.

<sup>56</sup> See EPA, “EPA Authorities under TSCA,” 2005, p. 23.

<sup>57</sup> EPA, OPPT Overview, 2007, p. 16.

<sup>58</sup> EPA, “EPA Authorities under TSCA,” 2005, p. 16.

<sup>59</sup> National Pollution Prevention and Toxics Advisory Committee, “Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?” Broader Issues Work Group, 6 October 2005, at [www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf](http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf), pp. 3-4.

<sup>60</sup> See EPA, “Status and Future Directions of the High Production Volume (HPV) Challenge Program,” Office of Pollution Prevention and Toxics, December 2004, p. 98, at [www.epa.gov/chemrtk/pubs/general/hpvreport.pdf](http://www.epa.gov/chemrtk/pubs/general/hpvreport.pdf).

many chemicals had their amounts change by one or more ranges, whether up or down. From 1998 to 2002:

- the range changed for 52% of all chemicals reported in both cycles, increasing for 18% and decreasing for 34%; and
- the range changed by more than one for 40% of the chemicals: 13% increased by two or more ranges, and 27% decreased by two or more ranges.

These data demonstrate that infrequent reporting yields a blurry snapshot, one that paints a highly inaccurate picture of actual manufacturing levels over time.

#### CANADA

Under CEPA, there is no equivalent to the TSCA IUR reporting requirement for existing chemicals already listed on the DSL. Reporting would occur only for a notified new chemical, if and when the chemical reaches the next highest quantity trigger level under the tiered notification scheme. The highest tier is generally reached at only 10,000 kg/year (see Section IV), at which point the chemical is typically placed on the DSL, meaning that no further quantity information is routinely collected after a chemical reaches this quite modest production level (many thousands of DSL chemicals were originally reported as exceeding 10,000 kg/year<sup>61</sup>).

CEPA §71(1)(b) does provide general authority to require submission of manufacture and use information, via publication of a notice in the *Canada Gazette*. As in the U.S., reporting may also occur for chemicals subject to such reporting conditions that are placed on them through the new chemicals review process or issuance of a Significant New Activity (SNAc) Notice.

How many chemicals that were not made or used in significant quantities in the mid-1980s are today, and hence pose a risk of significant exposure not captured through the DSL Categorization?

The lack of a routine reporting requirement means that for the great majority of DSL chemicals, production, import and use information is extremely dated, reflecting the situation at least 20 years ago at the time of their initial listing, ca. 1984–1986. This problem has plagued the DSL Categorization process called for under CEPA 1999, which required Health Canada to identify DSL chemicals posing the Greatest Potential for Exposure (GPE) to Humans. Health Canada was forced to rely on 20-year-old data in its process, and is expecting to find that many chemicals tentatively identified as of high or intermediate exposure concern, based on manufactured quantity, are no longer manufactured or used in Canada. Unfortunately, the same data gap raises the converse critical question: How many chemicals that were not manufactured or used in significant quantities in the mid-1980s are today, and hence pose a risk of significant exposure not captured through the DSL Categorization?<sup>62</sup>

<sup>61</sup> Health Canada, *Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for Human Exposure*, 2003, Table 1, p. 6, available at [www.hc-sc.gc.ca/ewh-semt/alt\\_formats/hecs-sesc/pdf/contaminants/existsub/greatest\\_potential\\_human\\_exposure.pdf](http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/greatest_potential_human_exposure.pdf).

<sup>62</sup> Health Canada did attempt to determine, for about 100 chemicals, whether the quantities reported in the mid-1980s were still current. See Doyle, E. and Patterson, H., “A Study to Determine Currency of DSL Quantity Data for Use in Categorization of DSL

## EUROPEAN UNION

REACH also has no direct counterpart to the TSCA IUR periodic reporting requirement. Under its tiered registration scheme (described further in Section IVA), however, reporting will occur as both new and existing chemicals move to the next highest manufacturing quantity-triggered tier, because an updated registration that includes reporting of the new production or import quantity is required. In addition, REACH will have what amounts to a generic SNUR/SNAc Notice requirement, applicable to all registered chemicals: Article 22 requires that registrants update and resubmit “without undue delay” their registrations whenever there is any significant change in status, including any new use, as well as any new knowledge of risks; changes in the quantity of a substance manufactured or used in an article that result in a change in tonnage band (whether up or down, and including cessation of manufacture) require submission of an updated registration. Nonetheless, the absence of a regular update requirement means that changes in production or import that do not result in a change in tonnage band (which could be nearly an order of magnitude, e.g., between 10 and 100 metric tons/year) will not be reported.

### **Best practice**

*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 kg/year.

Substances,” Health Canada, August 2001, available at [www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/currency-donnees/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/currency-donnees/index_e.html). That study suggested that, on average and after removing several “outliers,” the manufactured quantities of these chemicals had increased about 37% between 1986 and the late 1990s, which was said to be roughly consistent with the estimated 30% growth in chemical production in Canada between 1986 and 1996. However, wide fluctuation among the individual chemicals was seen, with many chemicals’ production dramatically falling and others’ rising over the time period; calculating an average of these disparate values has little value with respect to whether any given chemical’s manufacture has changed significantly since the mid-1980s. In any event, Health Canada made no adjustment (not even a 30% adjustment) to the mid-1980s quantities reported for DSL chemicals. This analysis also does not address the likelihood that chemicals not reported to be manufactured in the mid-1980s have since come into significant production or import, or vice versa. The analysis in Appendix A of the fluctuation in chemicals reported on the U.S. TSCA Inventory from one reporting cycle to the next shows that even reporting every four years, let alone a single snapshot represented by the DSL data, provides a highly inaccurate picture of actual manufacture and use.

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## IV. Facilitating or requiring the generation and submission of risk-relevant information

The U.S. and Canadian systems approach new and existing chemicals quite differently regarding the extent of information required to be generated or submitted; REACH aims to eliminate the distinction. To understand the differences among systems, we discuss how each system treats new vs. existing chemicals, with respect to data development.

### A. New chemicals information requirements

All three systems require notification by producers and importers of all “new” chemicals, except for those excluded or exempted from such requirements. Tables 2 and 3 compare the three systems with respect to what types of chemicals are statutorily excluded, exempted from notification or have reduced or conditional notification requirements. A brief description and comparison of the notification process and the associated data requirements for new chemicals follows.

#### UNITED STATES

In the U.S., a Premanufacture Notification (PMN) must be submitted to EPA at least 90 days prior to commencing manufacture. EPA receives about 1,500 PMNs annually, and has reviewed about 36,600 since TSCA was enacted.<sup>63</sup> EPA must make a determination whether a chemical warrants prohibition or restriction of its manufacture or use, based on information provided in the PMN or otherwise available. The PMN must include basic information on chemical identity, use, anticipated production volume, exposure and release information, and any pre-existing test data already in the possession of or readily available to the notifier. However—unlike the systems of Canada, the EU and most other developed countries—there is no minimum base set of data required on physical-chemical properties, environmental fate and behavior, toxicity or ecotoxicity.<sup>64</sup> Although EPA encourages such data to be included in the PMN, the great majority of PMNs do not. According to EPA:

- 67% of PMNs contain no test data;
- 85% of PMNs contain no health data; and
- more than 95% of PMNs contain no ecotoxicity data.<sup>65</sup>

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<sup>63</sup> EPA, OPPT Overview, 2007, pp. 8-11; and personal communication to author on 17 November 2006, from Anna Coutlakis, New Chemicals Program, U.S. Environmental Protection Agency. The total and number of specific types of submissions, which include PMNs as well as exemption notices, are indicated in the table below:

<u>Type of Submission</u>	<u>Number Submitted 1979-2006</u>
Premanufacturing Notices	34,048
Test Marketing Exemption Applications	730
Low Volume Exemptions	8,827
Low Release/Low Exposure Exemptions	38
Polymer Exemptions (1985-1995)	<u>2,530</u>
Total	46,173

<sup>64</sup> As discussed later in this section, this lack of a minimum data requirement in part reflects the fact that notification takes place earlier in the course of developing, manufacturing and marketing a new chemical than under Canadian and EU systems.

<sup>65</sup> The first two statistics are from EPA, OPPT Overview, 2007, p. 8. The third statistic is from EPA, OPPT, *Draft Q&A for the New Chemicals Program*, undated, answer to Question 118-5.

To compensate for the dearth of data, EPA developed several screening tools and approaches, most notably Structure-Activity Relationship (SAR) models, which extrapolate from measured data on tested chemicals to estimate values for new chemicals, based on the extent of structural similarity. EPA can also conclude that insufficient information on the chemical exists and that in its absence the chemical “may present an unreasonable risk.” In such cases, it has authority to request additional information; depending on the case, EPA can suspend review of the PMN pending development of the data, or complete its review but include conditions that require testing prior to manufacture or impose controls pending completion of testing.

EPA typically negotiates with the notifier an agreement to develop and submit more information for substances whose PMN indicates that substantial production and exposure or release may occur. EPA can require such information prior to commencement of manufacturing, but more frequently imposes a limit on production volume or use or other controls pending the completion of specified testing. EPA has delineated specific sets of tests that it may require for chemicals that are anticipated to result in substantial human exposure or environmental release, and to be produced:

- at or above 100,000 kg/year —> Exposure-based Core Data Set
- at or above one million pounds/year —> High Production Volume Data Set

The specific tests that EPA may require are shown in Table 4, and are compared with data requirements under the EU and Canadian systems.<sup>66</sup>

In the limited number of cases where EPA determines during the PMN review process that it requires more data, it usually negotiates an agreement with the notifier to conduct testing, under what is called a Voluntary Testing Action, or more formally, a TSCA §5(e) Regulation Pending Development of Information. Under such agreements, PMN submitters voluntarily agree to suspend the notice review period and conduct testing. Often, however, faced with the additional costs, notifiers take the option of withdrawing instead of performing the testing. Through the end of September 2005, EPA had negotiated about 300 Voluntary Testing Actions.<sup>67</sup>

## CANADA

Between 1994 and June 2006, Canadian officials received and processed 13,800 New Substances Notifications (NSNs) for chemicals, with 500–1,000 received annually.<sup>68</sup> NSNs must be submitted prior to exceeding specified quantity thresholds of production or import, and must include types and amounts of information specified in associated schedules or provisions of the New Substances Notification Regulations.<sup>69</sup> The information requirements vary with the type of

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<sup>66</sup> See EPA, *Draft Q&A for the New Chemicals Program*, undated, answer to Question 100-12. The criteria EPA uses to define substantial production, exposure and release are specified in its Exposure-based Policy, available at [www.epa.gov/oppt/newchemicals/pubs/expbased.htm](http://www.epa.gov/oppt/newchemicals/pubs/expbased.htm), and the testing elements of the data sets are available at [www.epa.gov/oppt/newchemicals/pubs/expbasedtesting.htm](http://www.epa.gov/oppt/newchemicals/pubs/expbasedtesting.htm).

<sup>67</sup> EPA, OPPT Overview, 2007, p. 11.

<sup>68</sup> CEPA New Substances Program Statistics, 1994-2006, spreadsheet provided to the author by Bernard Madé, Director, New Substances Branch, Environment Canada, 23 June 2006.

<sup>69</sup> New Substances Notification Regulations (Chemicals and Polymers), published in Canada Gazette, 21 September 2005, available at <http://canadagazette.gc.ca/partII/2005/20050921/html/sor247-e.html>.



substance and whether it is listed on the NDSL. For chemicals that are not polymers, R&D substances, contained site-limited substances or contained export-only substances (each of which has its own notification specifications), the time periods, quantity thresholds and associated references to data requirements are as follows:<sup>70</sup>

- Substances listed on the NDSL:
  - 30 days before exceeding 1,000 kg/year → Schedule 4
  - 60 days before reaching 10,000 kg/year → Schedule 5
  - 75 days before reaching 50,000 kg/year
    - If release exceeds 3 kg/day per site → addl. info. in subsec. 7(2)
    - If significant public exposure → addl. info. in subsec. 7(3)
- Substances not listed on the NDSL:
  - 5 days before reaching 100 kg/year → Schedule 4
  - 60 days before reaching 1,000 kg/year → Schedule 5
  - 75 days before exceeding 10,000 kg/year → Schedule 6

Hence a given substance can be notified more than once by the same party and undergo more than one round of review, with successive reviews based on increasing amounts of information. Table 4 shows these information requirements in comparison to those required under REACH, and those EPA can but is not required to impose (applicable only to high-production and high-exposure or release substances).

## EUROPEAN UNION

One of the hallmarks of REACH is it seeks to eliminate most of the practical distinctions between “new” and “existing” chemicals with respect to information requirements and how they are assessed. This has led to a reduction in certain requirements applicable to new chemicals relative to those under the prior new substances directive (Council Directive 92/32/EEC). Most notably, the prior regulations required notification of all new substances marketed in quantities equal to or greater than 10 kg/year per manufacturer or importer, whereas REACH’s registration requirements only apply to new substances marketed at or above one metric ton/year (1,000 kg/year) per manufacturer or importer. Data requirements for new chemicals have also been reduced somewhat, in exchange for creating a more level playing field by routinely imposing data requirements on existing chemicals for the first time.

Notification of new chemicals under the prior legislation has been replaced under REACH with a registration requirement.<sup>71</sup> Registration entails submission of a technical dossier containing information on the identity, manufacture and use of the substance, guidance on its safe use, and

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<sup>70</sup> New Substances Notification Regulations (Chemicals and Polymers), Sections 7 and 8.

<sup>71</sup> Chemicals already notified under existing EU regulations will be automatically considered registered under REACH. However, if or when the next highest tonnage tier is reached, information required at that tier and any information required at lower tiers that has not already been provided through notification, must be provided. See Article 24.

summaries of studies conducted and testing plans proposed to meet data requirements specified in the annexes. The scope and amount of information required is based on the tonnage manufactured or imported at the time of registration.

Additional data requirements apply as the quantity placed on the market increases. REACH states that “as soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the [European Chemicals] Agency immediately of the additional information.”<sup>72</sup> Hence registration under REACH resembles the tiered notification scheme under CEPA.

The tiers of data requirements under REACH based on tonnage bands are specified in the following annexes:<sup>73</sup>

- 1–10 metric tons/year      Annex VII
- 10–100 metric tons/year      Annexes VII–VIII
- 100–1,000 metric tons/year      Annexes VII–VIII and testing proposals for Annex IX
- >1,000 metric tons/year      Annexes VII–VIII and testing proposals for Annexes IX–X

Table 4 shows these information requirements in comparison to those required under CEPA, and those that EPA can but is not required to impose (applicable only to high-production and high-exposure/release substances).

Among the three systems, an important distinction must be emphasized: Under the U.S. system, the notification requirement applies *premanufacture*, whereas the Canadian and REACH systems do not require notification until a certain level of actual manufacture is reached. The U.S. system does not impose a minimum data requirement for notification, which is a major point of contrast with the other systems. This reflects in part the fact that notification takes place at a relatively early point in the course of developing, manufacturing and marketing a new chemical, when it may not be realistic to expect a company to have conducted much testing. Government intervention at this stage has the advantage of flagging potential concerns before manufacturing has commenced and before significant financial investment has been made by the producer. It also has the potential to allow redesign of the manufacturing process or the chemical itself to eliminate or reduce the concern in advance of commercialization.<sup>74</sup> However, the lack of data on a chemical’s hazards and other properties, and the more speculative nature of information on its potential uses, releases and exposures can severely limit the robustness of any risk evaluation conducted at this stage.<sup>75</sup> This limitation is especially pronounced under the U.S. system, where typically there is only one opportunity for EPA review of a new chemical.

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<sup>72</sup> REACH, Article 12(2).

<sup>73</sup> Tonnages are per manufacturer or importer. For phase-in substances that have been produced or imported for at least three consecutive years, quantities are to be based on the average of the preceding three calendar years; see Article 3(30).

<sup>74</sup> One possible indication of these potential effects of early review is the fact that Notices of Commencement that signify the start of actual manufacturing are filed for only about half of notified chemicals that undergo PMN review; see EPA, OPPT Overview, 2007, p. 10.

<sup>75</sup> See GAO, 2005, pp. 10–16.

### Best practice

*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 CEPA and TSCA, REACH does not tie registration to government review, so that chemicals may begin or continue manufacture even in the absence of review.

TABLE 4

**Comparison of Required Hazard Information Elements for All Chemicals under REACH and New Chemicals under CEPA, Optional Elements for New Chemicals under TSCA, and Voluntary Elements under US HPV/OECD SIDS<sup>3</sup>**

<p><i>NOTES FOR REACH: Most information requirements are caveated and made conditional on many factors, such as chemical type or properties, or results of preceding tests or availability of higher tests specified in the production volume-based hierarchy. Some of the most important ones are described in the notes accompanying certain entries to this table.</i></p> <p><i>At Registration, all relevant data required under Annexes VII-VIII are to be submitted, but only test proposals for any additional tests (based on production volume) under Annexes IX-X. Determination by Agency or a member state as to which Annex IX-X tests are to be done is made as part of Evaluation.</i></p> <p><i>In addition, numerous alternatives to direct testing are allowed, including use of estimation techniques, category-based extrapolation, etc. (see REACH Annex XI).</i></p> <p><b>Grey highlights indicate tests that can be waived if exposure potential is demonstrated to be low.</b></p>												
REACH section ID	Called for under HPV/SIDS	Endpoint	REACH Annex VII 1 to 10 t/yr		REACH Annex VIII 10 to 100 t/yr	REACH Annex IX 100 to 1000 t/yr	REACH Annex X > 1000 t/yr	CEPA new chem Sch. 5 NDSL >10,000 kg/yr; Non-NDSL >1,000 kg/yr	CEPA new chem Sch. 6 Non-NDSL >10,000 kg/yr	CEPA new chem. NSNR (C&P) §7(2) NDSL >50,000 kg/yr	CEPA new chem. NSNR (C&P) §7(3) NDSL >50,000 kg/yr	TSCA new chem >100,000 kg/yr and sign. env. release or human exposure
			phase-in chem	new chem or phase-in chem + SVHC or dang. w/ disp. use								
8.		<b>Mammalian Toxicological Data</b>										
8.1		Skin Irritation and Skin Corrosion in Vitro		√	NA	NA	NA		√ <sup>b</sup>			
8.1.1		Skin Irritation in vivo			√	√	√					
8.2		Eye Irritation in vitro		√	NA	NA	NA					
8.2.1		Eye Irritation in vivo			√	√	√					
8.3		Skin Sensitization in vivo		√	√	√	√		√			
8.4		Genetic Toxicity										
8.4.1	√	In vitro Gene Mutation in Bacteria		√	√	√	√	√	√	√	√	√
8.4.2	√	In vitro Cytogenicity/Chromosomal Aberrations in Mammalian Cells or Micronucleus Study			√	√	√		√		√	√
8.4.3		In vitro (Gene Mutation) in Mammalian Cells			(√) <sup>c</sup>	(√) <sup>c</sup>	(√) <sup>c</sup>					
8.4.X		Further in vivo Mutagenicity Studies			(√) <sup>d</sup>	(√) <sup>d</sup>	(√) <sup>d</sup>		√			
8.5	√	Acute Toxicity										
8.5.1		By Oral Route		√	√	√	√	√ <sup>e</sup>	√ <sup>f</sup>	√ <sup>e</sup>	√ <sup>e</sup>	√
8.5.2/3		By Inhalation Route and/or by Dermal Route			√	√	√	√ <sup>e</sup>	√ <sup>f</sup>	√ <sup>e</sup>	√ <sup>e</sup>	
8.6		Repeated Dose Toxicity										
8.6.1	√	Short-Term (28 days)			√	√	√		√	√	√	√
8.6.2		Sub-Chronic (90 days)			(√) <sup>g</sup>	√	√					

REACH section ID	Called for under HPV/ SIDS	Endpoint	REACH Annex VII 1 to 10 t/yr		REACH Annex VIII 10 to 100 t/yr	REACH Annex IX 100 to 1000 t/yr	REACH Annex X > 1000 t/yr	CEPA new chem Sch. 5 NDSL >10,000 kg/yr; Non-NDSL >1,000 kg/yr	CEPA new chem Sch. 6 Non-NDSL >10,000 kg/yr	CEPA new chem. NSNR (C&P) §7(2) NDSL >50,000 kg/yr	CEPA new chem. NSNR (C&P) §7(3) NDSL >50,000 kg/yr	TSCA new chem >100,000 kg/yr and sign. env. release or human exposure		
			phase-in chem	new chem or phase-in chem + SVHC or dang. w/ disp. use										
8.6.3		Long-Term (≥12 months)			(√) <sup>h</sup>	(√) <sup>h</sup>	(√) <sup>i</sup>							
8.6.4		Further Studies			(√) <sup>h</sup>	(√) <sup>h</sup>	(√) <sup>j</sup>							
8.7		Reproductive Toxicity												
8.7.1	√	Screening Reproductive/ Development Toxicity			√	NA	NA					(√) <sup>k</sup>		
8.7.2	√	Developmental Toxicity (Pre-Natal)				√ <sup>l</sup>	√ <sup>m</sup>					(√) <sup>k</sup>		
8.7.3		Two-Generation Reproductive Toxicity				√ <sup>l</sup>	√ <sup>m</sup>							
8.8		Toxicokinetics												
8.8.1		Toxicokinetic Behavior, if Information is available			√	√	√							
8.9		Carcinogenicity					(√) <sup>n</sup>							
9.		<b>Ecotoxicological Data</b>												
9.1		Aquatic Toxicity												
9.1.1	√	Aquatic Invertebrates (Daphnia) Acute Toxicity		√	√	√	√	√ <sup>o</sup>	√	√ <sup>o</sup>	√ <sup>o</sup>	√		
9.1.2	√	Aquatic Plants (Algae) Toxicity (Growth Inhibition)		√	√	√	√		√			√	√	
9.1.3	√	Fish Acute Toxicity			√	√	√		√			√	√	
9.1.4		Activated Sludge Respiration Inhibition			√	√	√							
9.1.5	(√) <sup>q</sup>	Aquatic Invertebrates (Daphnia) Chronic Toxicity		(√) <sup>p</sup>	(√) <sup>p</sup>	√ <sup>p</sup>	√ <sup>p</sup>					(√) <sup>q</sup>		
9.1.6		Fish Chronic Toxicity			(√) <sup>r</sup>	√ <sup>r</sup>	√ <sup>r</sup>					(√) <sup>q</sup>		
9.1.6.1		Fish Early-Life Stage Toxicity			(√) <sup>s</sup>	(√) <sup>s</sup>	(√) <sup>s</sup>							
9.1.6.2		Fish Short-term Embryo/Sac-Fry Stage Toxicity												
9.1.6.3		Fish Juvenile Growth												
9.2		Degradation												
9.2.1		Biotic Degradation												
9.2.1.1	√	Ready Biodegradability		√	√	√	√	√	√	√	√	√		
9.2.1.2		Surface Water Simulation				(√) <sup>t</sup>	(√) <sup>t</sup>							
9.2.1.3		Soil Simulation												
9.2.1.4		Sediment Simulation												
9.2.1.5		Further Studies					√							

REACH section ID	Called for under HPV/ SIDS	Endpoint	REACH Annex VII 1 to 10 t/yr		REACH Annex VIII 10 to 100 t/yr	REACH Annex IX 100 to 1000 t/yr	REACH Annex X > 1000 t/yr	CEPA new chem Sch. 5 NDSL >10,000 kg/yr; Non-NDSL >1,000 kg/yr	CEPA new chem Sch. 6 Non-NDSL >10,000 kg/yr	CEPA new chem. NSNR (C&P) §7(2) NDSL >50,000 kg/yr	CEPA new chem. NSNR (C&P) §7(3) NDSL >50,000 kg/yr	TSCA new chem >100,000 kg/yr and sign. env. release or human exposure
			phase-in chem	new chem or phase-in chem + SVHC or dang. w/ disp. use								
--		Soil Biodegradation										√
--		Anaerobic Biodegradation										√
9.2.2		Abiotic Degradation										
9.2.2.1	√	Stability in Water/Hydrolysis as Function of pH			√	√	√		√	√		√
9.2.3		Identification of Degradation Products				√	√	√	√	√	√	
9.3		<b>Fate and Behavior in the Environment</b>										
9.3.1		Adsorption/Desorption Screening			√	√	√		√	√		
9.3.2		Bioaccumulation in Aquatic Species				√	√					
9.3.3		Further Information on Adsorption/Desorption				√	√					
9.3.4		Further Environmental Fate and Behavior Studies					(√) <sup>u</sup>					
–		Fate in Wastewater Treatment										√
9.4		Terrestrial Organisms										
9.4.1		Invertebrates Short-Term Toxicity				√	√					
9.4.2		Soil Micro-Organisms Effects				√	√					
9.4.3		Plants Short-Term Toxicity				√	√					
9.4.4		Invertebrates Long-Term Toxicity					(√) <sup>v</sup>	(√) <sup>w</sup>				
9.4.6		Plants Long-Term Toxicity										
9.5		Sediment Organisms										
9.5.1		Sediment Organisms Long-Term Toxicity					(√) <sup>x</sup>					
9.6		Birds										
9.6.1		Birds Long-Term or Reproductive Toxicity					(√) <sup>y</sup>					
--	√	Photodegradation										√
--	√	Transport/Distribution between Compartments (Fugacity)										
10.		<b>Methods of Detection and Analysis</b>				√ <sup>z</sup>	√ <sup>z</sup>					
7.		<b>Physical-Chemical Data</b>										
7.1		State of the Substance at Standard Temperature and Pressure	√	√	√	√	√					
7.2	√	Melting/Freezing Point	√	√	√	√	√	√	√	√	√	

REACH section ID	Called for under HPV/ SIDS	Endpoint	REACH Annex VII 1 to 10 t/yr		REACH Annex VIII 10 to 100 t/yr	REACH Annex IX 100 to 1000 t/yr	REACH Annex X > 1000 t/yr	CEPA new chem Sch. 5 NDSL >10,000 kg/yr; Non-NDSL >1,000 kg/yr	CEPA new chem Sch. 6 Non-NDSL >10,000 kg/yr	CEPA new chem. NSNR (C&P) §7(2) NDSL >50,000 kg/yr	CEPA new chem. NSNR (C&P) §7(3) NDSL >50,000 kg/yr	TSCA new chem >100,000 kg/yr and sign. env. release or human exposure
			phase-in chem	new chem or phase-in chem + SVHC or dang. w/ disp. use								
7.3	√	Boiling Point	√	√	√	√	√	√	√	√	√	
7.4		Relative Density	√	√	√	√	√	√	√	√	√	
7.5	√	Vapor Pressure	√	√	√	√	√	√	√	√	√	
7.6		Surface Tension	√	√	√	√	√					
7.7	√	Water Solubility	√	√	√	√	√	√	√	√	√	√
7.8	√	Partition Coefficient (n-octanol/water)	√	√	√	√	√	√	√	√	√	
7.9		Flash Point	√	√	√	√	√					
7.10		Flammability	√	√	√	√	√					
7.11		Explosive Properties	√	√	√	√	√					
7.12		Self-ignition Temperature	√	√	√	√	√					
7.13		Oxidizing Properties	√	√	√	√	√					
7.14		Granulometry	√	√	√	√	√					
7.15		Stability in Organic Solvents / Identification of Breakdown Products				√	√					
7.16		Dissociation Constant				√	√					
7.17		Viscosity				√	√					
-		Infra-red, Ultra-violet, Mass or Nuclear Magnetic Resonance Spectrum							√			

Source: Environmental Defense, based on:

**HPV/SIDS:** Identification of SIDS elements called for under U.S. HPV and OECD SIDS Programs: See: (1) EPA's formal announcement of the U.S. HPV Challenge Program, *Federal Register*, 26 December 2000, Vol. 65, No. 248, pp. 81694-5, available at [www.epa.gov/chemrtk/pubs/update/ts42213.pdf](http://www.epa.gov/chemrtk/pubs/update/ts42213.pdf). (2) EPA's program guidance document, "Determining the Adequacy of Existing Data," Appendix A, available at [www.epa.gov/chemrtk/pubs/general/datadfin.htm](http://www.epa.gov/chemrtk/pubs/general/datadfin.htm). Note that the list of the SIDS elements omits those applicable to inorganic substances, as they are not included among HPV chemicals identified by EPA under the HPV Challenge Program.

**REACH:** Final text of REACH, published in the European Union's *Official Journal*, Volume 49, 30 December 2006, Annexes VII-X, available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_396/l\\_39620061230en00010849.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf).

**CEPA New Chemicals:** New Substances Notification Regulations (Chemicals and Polymers), published in Canada Gazette, 21 September 2005, available at <http://canadagazette.gc.ca/partII/2005/20050921/html/sor247-e.html>; see Sections 7 and 8 and Schedules 5 and 6 for NDSL (Non-Domestic Substances List) and non-NDSL chemicals.

**TSCA New High-Volume Chemicals:** The criteria EPA uses to define substantial production, exposure and release are specified in its Exposure-based Policy, available at [www.epa.gov/oppt/newchems/pubs/expbased.htm](http://www.epa.gov/oppt/newchems/pubs/expbased.htm), and the testing elements of the data sets are available at [www.epa.gov/oppt/newchems/pubs/expbasedtesting.htm](http://www.epa.gov/oppt/newchems/pubs/expbasedtesting.htm).

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## TABLE 4 NOTES

<sup>a</sup> Requirements listed in the following sets of columns are ***cumulative***, i.e., they carry over requirements applicable at lower tiers as well as new requirements at that tier: REACH Annexes VII, VIII, IX and X; and CEPA Sch. 5, NSNR §7(2), NSNR §7(3).

Explanation of terms/abbreviations: “HPV” = high production volume; “SIDS” = Screening Information Data Set; “phase-in chem” = a chemical already on the market, to which REACH’s requirements will apply on a phased schedule based on tonnage or certain properties; “t/yr” = metric tons per year per producer or importer; “SVHC” = substance of very high concern; “dang. w/ disp. use” = substance classified as dangerous, with a dispersive use; “Sch.” = Schedule; “NDSL” = Non-Domestic Substances List; “Non-NDSL” = substance *not* on the NDSL; “NSNR” = New Substances Notification Regulations; “(C&P)” = chemicals and polymers; “kg/yr” = kilograms per year per producer or importer; “sign. env. release or human exposure” = significant environmental release or human exposure.

<sup>b</sup> Requirement is for “information sufficient to assess skin irritation, which may be based on in vitro or in vivo skin irritation or skin corrosion studies or alternative methods.

<sup>c</sup> To be conducted only if negative results found in Annex VII 8.4.1 and Annex VIII 8.4.2.

<sup>d</sup> To be conducted if positive results found in any of the other genotoxicity studies in Annexes VII and VIII.

<sup>e</sup> Data for one route of exposure is required, selected as the most significant route.

<sup>f</sup> Data required for an additional route of exposure, selected as the next most significant route, unless the chemical boils below 0°C and was already tested by the inhalation route.

<sup>g</sup> To be proposed by the sponsor if frequency and duration of human exposure and nature of potential effect indicate a longer-term study is appropriate, or there is evidence of accumulation of the substance or its metabolites.

<sup>h</sup> Further studies shall be proposed or may be required if shorter-term studies do not detect an expected effect, there is a more specific expected serious effect, the route of exposure used in shorter-term studies was inappropriate or there is particular concern about exposure.

<sup>i</sup> May be proposed by the sponsor or required if frequency and duration of human exposure and nature of potential effect indicate a longer-term study is appropriate.

<sup>j</sup> Shall be proposed by the sponsor or may be required where there is evidence of toxicity of particular concern or of a specific type (e.g., neurotoxicity), or particular concern over exposure.

<sup>k</sup> This element may be required for chemicals anticipated to be produced at or above HPV levels (1 million pounds/year, or 455 metric tons/year), for which high worker exposure or exposure to consumers or the general population is expected.

<sup>l</sup> To be performed initially on one species, with the decision as to whether to perform on a second species at this tonnage level or the next highest based on the results of the first test and other available information.

<sup>m</sup> To be performed initially on one species, with the decision as to whether to perform on a second species based on the results of the first test and other available information.

<sup>n</sup> May be proposed or required if the substance has wide dispersive use or frequent or long-term exposure is expected, and the substance is classified as a category 3 mutagen or there is evidence of induction of hyperplasia and/or preneoplastic lesions; if the substance is already classified as a category 1 or 2 mutagen, it is presumed to be a genotoxic carcinogen, so testing would not be required.

<sup>o</sup> Data from a test on any one of the three organisms is required.

<sup>p</sup> A chronic test shall be considered if the substance is poorly water soluble.

<sup>q</sup> May be required if the substance is expected to be chronically toxic.

<sup>r</sup> A chronic test shall be considered if the substance is poorly water soluble or the safety assessment indicates the need to further investigate aquatic toxicity.

<sup>s</sup> These longer-term studies shall be considered if the chemical safety assessment indicates concern for effects on aquatic organisms. If a decision is made to conduct such tests, only one of the tests specified in 9.1.6.1, 9.1.6.2 and 9.1.6.3 need be provided.

<sup>t</sup> These studies shall be considered if the chemical safety assessment indicates concern for effects on aquatic organisms. Which tests to conduct depends on the results of the chemical safety assessment.

<sup>u</sup> Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate environmental fate and behavior. Which tests to conduct depends on the results of the chemical safety assessment.

<sup>v</sup> In particular for substances with a high potential for soil adsorption or that are very persistent, long-term testing shall be considered instead of short-term.

<sup>w</sup> Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate effects on terrestrial organisms. Which tests to conduct depends on the results of the chemical safety assessment.

<sup>x</sup> Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate effects on sediment organisms. Which tests to conduct depends on the results of the chemical safety assessment.

<sup>y</sup> Any proposal or requirement to test for these endpoints should first carefully consider the large mammalian database that is usually available at this tonnage level.

<sup>z</sup> To be provided upon request for the relevant compartments for which studies were performed that used the method(s).



## B. Existing chemicals: Generation and submission of information

### UNITED STATES

Several authorities are available under TSCA for requiring the submission or generation of risk-relevant information on existing chemicals.

*TSCA §4 Test Rules:* EPA can, through full notice-and-comment rulemaking, require manufacturers of specified chemicals to conduct testing. However, EPA must make certain findings in order to issue a §4 test rule. EPA must find that:

- the substance “may present an unreasonable risk,” based on evidence of more than a theoretical risk of exposure,

OR:

- it is or will be produced in “substantial” quantities and either:
  - it is entering or may enter the environment in “substantial” quantities, or
  - there is or may be “significant or substantial” human exposure to the chemical,

AND that:

- insufficient information exists to assess potential risk,

AND that:

- testing is necessary to develop the needed data.

In practice, EPA has found that it rarely has enough information to make the “may present an unreasonable risk” finding,<sup>76</sup> and instead is usually forced to rely on making the exposure-based finding. EPA has defined through regulation the specific criteria it uses for what constitutes “substantial” production and release and “significant or substantial” human exposure.<sup>77</sup>

Since 1979, EPA has used its §4 test rule authority to require testing of about 200 chemicals. For about 60 of these chemicals, the data were obtained through §4 Enforceable Consent Agreements (ECAs), which it uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing.<sup>78</sup>

*TSCA §8:*<sup>79</sup> EPA has several authorities under TSCA §8 that it can use to require industry to submit pre-existing information; however, these authorities cannot be used to require generation of data not already available. Each such request requires a separate rulemaking, although a single rule can

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<sup>76</sup> This requirement is a classic Catch-22: EPA must already have information sufficient to document potential risk in order to ask for information sufficient to determine whether there is actual risk.

<sup>77</sup> Substantial production/importation: 1 million pounds or more per year, and  
Substantial environmental release: 1 million pounds or more or 10% of production/importation, or  
Substantial human exposure: 1,000 workers or 10,000 consumers or 100,000 general population, or  
Significant human exposure: case-by-case basis. See [www.epa.gov/opptintr/chemtest/pubs/sct4rule.htm](http://www.epa.gov/opptintr/chemtest/pubs/sct4rule.htm).

<sup>78</sup> EPA, OPPT Overview, 2007, p. 15.

<sup>79</sup> See EPA, OPPT Overview, 2007, pp. 16-17; and EPA, “EPA Authorities under TSCA,” 2005, pp. 23-30.

cover multiple chemicals. EPA typically uses these authorities when it has other evidence suggesting there is potential cause for concern about a chemical or group of chemicals, or to develop information to support issuance of a §4 test rule or risk management actions under §6. Most recently, it has issued §8(a) and §8(d) rules covering 243 “orphan” chemicals that were not sponsored for data development under the voluntary U.S. HPV Challenge (see below),<sup>80</sup> because it lacked sufficient information to be able to make the statutory findings required to issue §4 test rules for these chemicals.

- §8(a), General Information Gathering: As previously noted, under TSCA §8(a), EPA can require manufacturers and processors of specified chemicals to report basic manufacture and use information. EPA has standardized this in the form of a Preliminary Assessment Information Reporting (PAIR) Rule, which requires one-time reporting. As of September 2006, approximately 33 PAIR rules were issued for about 1,200 chemicals.
- §8(c), Allegations of Significant Adverse Reactions: Under §8(c), companies must record, retain, and when requested by EPA, report “allegations of significant adverse reactions.” EPA has rarely used this authority: two such rules have been issued, covering two individual chemicals and two chemical categories, yielding 31 reports.
- §8(d), Health and Safety Data Reporting: This authority allows EPA to “call in” unpublished health and safety studies that companies may have in their possession. As of the September 2006, EPA had issued 51 TSCA §8(d) rules covering approximately 1,200 chemicals. In response to these rules, EPA received more than 50,000 studies covering a broad range of health and ecological endpoints, as well as information on chemical and physical properties, environmental fate and exposure.
- §8(e), Substantial Risk Reporting Requirement: This self-implementing provision requires producers to submit unpublished data that “reasonably support a conclusion of substantial risk.” As of September 2006, EPA had received 16,500 initial §8(e) submissions and approximately 7,750 supplemental or follow-up §8(e) submissions. EPA receives approximately 200 initial and 100 supplemental §8(e) submissions per year. These submissions are reviewed and action is initiated where deemed warranted.<sup>81</sup>
- FYI Submissions: These submission are a “voluntary adjunct” to mandatory §8(e) reporting, and do not necessarily contain data indicating adverse effects. As of September 2006, EPA had received 1,500 FYI (voluntary) submissions, averaging about 30 per year.

TSCA established the Interagency Testing Committee (ITC), an independent advisory committee comprised of representatives of 16 U.S. government agencies, departments and institutes. ITC is charged with identifying chemicals regulated by TSCA “for which there are suspicions of toxicity

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<sup>80</sup> These §8(a) and §8(d) rules are available at [www.epa.gov/fedrgstr/EPA-TOX/2006/August/Day-16/t13479.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2006/August/Day-16/t13479.htm) and [www.epa.gov/fedrgstr/EPA-TOX/2006/August/Day-16/t13489.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2006/August/Day-16/t13489.htm), respectively.

<sup>81</sup> As noted in Section VB of this report, receipt of such information has been one of the few ways that assessments of existing chemicals have been triggered under TSCA. For more information about the type and extent of information obtained under §8(e) and how EPA utilizes it, see [www.epa.gov/opptintr/chemtest/pubs/sect8e.htm](http://www.epa.gov/opptintr/chemtest/pubs/sect8e.htm).

or exposure and for which there are few, if any, ecological effects, environmental fate or health effects testing data.” The ITC maintains a Priority Testing List of chemicals recommended for testing or information reporting,<sup>82</sup> and also encourages voluntary submission of information by their producers and importers. In response to ITC recommendations of chemicals needing testing, EPA is required either to initiate the development of §4 test rules or to provide reasons for not doing so. Where ITC recommends information reporting, EPA must develop TSCA §8(a) and 8(d) reporting rules, unless otherwise requested by the ITC. Since its inception in 1976, ITC has recommended information reporting or testing for about 4,500 chemicals.<sup>83</sup>

#### *Voluntary data development efforts*

Despite the above authorities or because of the burden associated with using them, EPA has relied on voluntary efforts to obtain more information on existing chemicals. The most notable of these is the U.S. HPV Challenge,<sup>84</sup> which enlists producers of HPV chemicals—those manufactured and used in the U.S. in amounts equal to or exceeding one million pounds annually—to voluntarily develop and make publicly available a “base set” of screening-level hazard information<sup>85</sup> on their chemicals. Unlike all of the above rules, the HPV Challenge is the only systematic effort by EPA to call for basic hazard data on a relatively large number of existing chemicals. Because it is voluntary, it also sidesteps the “unreasonable risk” and other findings EPA must make to compel data development and submission.

1. *Current status of data development:*<sup>86</sup> The genesis of the HPV Challenge dates to 1998, when EPA found that 43% of HPV chemicals had no publicly available screening-level data, and only 7% had a complete screening-level base set.<sup>87</sup> The Challenge was launched with the intention of filling these gaps. Some 2,782 HPV chemicals were initially identified, although EPA subsequently removed or exempted 423 chemicals for various legitimate reasons.<sup>88</sup> Of the remaining 2,359 HPV chemicals, industry “sponsors” volunteered to develop data on

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<sup>82</sup> See <http://tsca-itc.syrres.com/Chemicals/>.

<sup>83</sup> See [www.epa.gov/opptintr/itc/](http://www.epa.gov/opptintr/itc/).

<sup>84</sup> See EPA’s HPV Challenge web site, at [www.epa.gov/chemrtk/index.htm](http://www.epa.gov/chemrtk/index.htm).

<sup>85</sup> The base set selected for the HPV Challenge is based on the SIDS, or Screening Information Data Set, developed by the Chemicals Committee of the Organization for Economic Cooperation and Development (OECD). For a list of the data elements, see EPA’s program guidance document, “Determining the Adequacy of Existing Data,” Appendix A, available at [www.epa.gov/chemrtk/pubs/general/datadfin.htm](http://www.epa.gov/chemrtk/pubs/general/datadfin.htm).

<sup>86</sup> Data reflect all postings to EPA’s HPV Challenge web site through March, 2007. For the most current information about the HPV Challenge, see “Summary Statistics” for Environmental Defense’s *HPV Tracker* ([www.environmentaldefense.org/documents/2734\\_WelcomeTracker.htm](http://www.environmentaldefense.org/documents/2734_WelcomeTracker.htm)) and our latest status report on the program ([www.environmentaldefense.org/page.cfm?tagID=41](http://www.environmentaldefense.org/page.cfm?tagID=41)).

<sup>87</sup> EPA’s 1998 Data Availability Study is available at [www.epa.gov/chemrtk/pubs/general/hazchem.htm](http://www.epa.gov/chemrtk/pubs/general/hazchem.htm). The undertaking of that study and the launch of the HPV Challenge were spurred by a 1997 report, *Toxic Ignorance*, published by Environmental Defense, which examined 100 HPV chemicals and found that more than 70% of them lacked publicly available data sufficient to conduct even a screening-level hazard assessment. *Toxic Ignorance* and other Environmental Defense reports and information on the HPV Challenge are available at [www.environmentaldefense.org/subissue.cfm?subissue=14](http://www.environmentaldefense.org/subissue.cfm?subissue=14).

<sup>88</sup> EPA exempted or removed these chemicals for any of three reasons: 1) EPA determined that testing using the SIDS data set would not further the understanding of the chemical’s properties; 2) the chemical’s production level was deemed to be below the HPV level and hence the chemical was “no longer HPV”; or 3) the chemical is a polymer or an inorganic chemical exempt from TSCA Inventory Update Rule reporting, but was nevertheless reported erroneously in the 1990 reporting cycle that served as the basis for the Challenge program’s initial chemical list.

1,901 of them, with all data to have been submitted by the end of 2005, while 193 are being addressed by member countries of the Organization for Economic Cooperation and Development (OECD) under its sister HPV program. As of the end of March 2007:

- 39% have final submissions;<sup>89</sup>
- 21% have initial submissions of data and test plans, but not yet final data sets;
- 15% do not yet have even initial submissions;<sup>90</sup> and
- 10% are unsponsored “orphans”; of these 265 chemicals, EPA has issued TSCA §4 test rules to require data development for only 16.<sup>91</sup>

2. *Emerging HPV chemicals*: Since the HPV Challenge was launched, more than 700 additional chemicals have reached HPV levels, based on manufacturing volume data reported in the most recent (2002) reporting cycle of the TSCA IUR. EPA, Environmental Defense and the American Chemistry Council (ACC) jointly identified 574 of these chemicals that had not been included or exempted from the Challenge, and were not otherwise sponsored under the Challenge, the OECD Screening Information Data Set (SIDS) program or other related programs.<sup>92</sup> These “emerging HPV chemicals” are supposed to be addressed under the Extended HPV Program that industry unilaterally announced in 2005.<sup>93</sup> According to the American Chemistry Council, companies have agreed to sponsor only 231 of the 574 chemicals, despite a December 2005 deadline for commitments to be made.<sup>94</sup>

EPA recently examined the extent of screening-level hazard data that is publicly available on 235 of these emerging HPV chemicals, and found the following:

- 52% of them had no screening-level hazard data publicly available (compared with 43% in the 1998 study of the first set of HPV chemicals).

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<sup>89</sup> Most of these have not yet been evaluated by EPA for completeness and quality.

<sup>90</sup> Most of these chemicals, although sponsored by industry, are being addressed, not through the HPV Challenge, but through the sister HPV program under the auspices of the OECD. That program is proceeding at a slower pace with respect to data development, and as a result, data for these chemicals are likely to trickle in over at least the next several years.

<sup>91</sup> On 16 March 2006, EPA issued a final TSCA §4 test rule for 17 HPV orphans chemicals, one of which was subsequently removed; see [www.epa.gov/fedrgstr/EPA-TOX/2006/March/Day-16/t2483.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2006/March/Day-16/t2483.htm) and [www.epa.gov/fedrgstr/EPA-TOX/2006/December/Day-08/t20908.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2006/December/Day-08/t20908.htm). The rule took more than five years to finalize, having been proposed on 26 December 2000. It originally covered 37 chemicals, some of which were subsequently sponsored or had their production quantities fall below HPV levels. The length of time EPA required to finalize this rule is testament to the burden it bears in issuing §4 test rules.

<sup>92</sup> See ACC’s “Questions and Answers on the Extended HPV Program,” at [www.americanchemistry.com/s\\_acc/bin.asp?CID=440&DID=1516&DOC=FILE.PDF](http://www.americanchemistry.com/s_acc/bin.asp?CID=440&DID=1516&DOC=FILE.PDF), especially the answer to Question 12.

<sup>93</sup> See ACC’s press release announcing the EHPV Program, at [www.americanchemistry.com/s\\_acc/bin.asp?CID=199&DID=535&DOC=FILE.PDF](http://www.americanchemistry.com/s_acc/bin.asp?CID=199&DID=535&DOC=FILE.PDF).

<sup>94</sup> This number of sponsorships is indicated on ACC’s web page for the EHPV Program as current through May 2006, but the same number was reported when the web page was accessed on 26 February 2007; see [www.americanchemistry.com/s\\_acc/sec\\_policyissues.asp?CID=432&DID=1493](http://www.americanchemistry.com/s_acc/sec_policyissues.asp?CID=432&DID=1493). The December 2005 deadline for commitments is indicated in ACC’s press release announcing the program. That original program announcement also indicated that data were to be generated and submitted to EPA between 2006 and 2010.

- 2.1% of them had a complete screening-level hazard data set publicly available (compared with 7% in the 1998 study).<sup>95</sup>

The finding that the manufactured quantities of many hundreds of chemicals rose within a few years to HPV levels is further evidence of the volatility of chemical production and commerce. It illustrates the need, not only for a continuous means to ensure data development for HPV chemicals, but also to extend data development efforts beyond a statically defined set of chemicals based on quantity thresholds. Today's niche chemical could become tomorrow's HPV chemical, with a concomitant increase in the need for hazard data. The low availability of hazard data EPA found for newly emerged HPV chemicals indicates that—outside of the structured voluntary program and regulatory test rules that name specific chemicals—little to no hazard data development appears to be independently occurring, or yielding publicly available data, even for high-volume chemicals.

*3. Methods used to provide data on HPV chemicals:* Another key outcome of the HPV Challenge is the extent to which alternatives to direct testing were used to provide the requested data. Fewer than 10% of the base-set data elements have been proposed by industry participants to be filled through new testing. Instead, EPA statistics indicate that:

- Approximately 50–60% of the data elements were to be filled using existing data: 20–25% from published studies and 30–35% from “unpublished” studies.
- For the remaining 30–40%, industry proposed to derive estimated values using structure-activity relationship (SAR) models or “read-across” methods applied to categories of chemicals grouped together based on apparent structural and functional similarity. In both cases, testing-derived data for some chemicals are used to extrapolate or estimate data for “related” chemicals that have not been directly tested.<sup>96</sup>

When applied in a scientifically sound manner, use of unpublished data and application of estimation methods and category approaches can reduce the need for testing—thereby reducing the need to sacrifice laboratory animals and the costs to industry, and increasing the number of chemicals that can be assessed with limited resources. Assessing whether estimation and extrapolation techniques are being appropriately applied, and judging the reliability of unpublished data require considerable expert oversight. To that end, the program has developed detailed guidance documents.<sup>97</sup> Proposals to use data derived by such means are subject to review and comment. Those reviews have revealed frequent deficiencies. As of the end of 2006:

- For 83% of the industry submissions that Environmental Defense or EPA has reviewed, one or both reviewers indicated either that more testing was needed (usually because of unreliable data) or might be needed (because of incomplete information).

<sup>95</sup> See *Fifty-Sixth Report of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency*, 2005, pp. 5–6, available at <http://tscA-itc.syrres.com/Reports/>. Note that, if anything, these numbers overstate the extent to which a full screening-level hazard data set is available, because they group together multiple endpoints and score the endpoint category as available if even a single study was found. Hence, a chemical that has an algae study but no fish or aquatic invertebrate study would still be scored as having ecotoxicity data available.

<sup>96</sup> EPA, *Status and Future Directions of the High Production Volume Challenge Program*, 2004, p. 8.

<sup>97</sup> See [www.epa.gov/chemrtk/pubs/general/guidocs.htm](http://www.epa.gov/chemrtk/pubs/general/guidocs.htm).

- For nearly half of the category proposals reviewed, one or both reviewers disagreed with the submitter’s justification for category formation, indicating that industry proposed to overly rely on such methods as a substitute for direct testing.<sup>98</sup>

To the extent that industry heeds these comments, considerably more than the <10% of the required endpoints that industry initially proposed to fill by testing will require new data.

Despite these shortcomings, the HPV Challenge is well on its way to developing and making public basic hazard information for many more chemicals in less time than any prior effort, and is a first step toward closing the gap between what we know and should know about chemicals in commerce.

## CANADA

§§70–72 of CEPA specify information gathering obligations and available authorities:

- §70 requires anyone who imports, manufactures, transports, processes, distributes or uses a substance for commercial purposes to provide without delay to the Minister of the Environment any information obtained that “reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic.” (This obligation is similar to that under TSCA §8(e).) The criteria that define “toxic” are set out in §64 of CEPA (see Section II of this report for more discussion of the meaning and use of this term).
- §71 authorizes the Minister to require, through notice in the *Canada Gazette*, any person engaged in any activity involving a specified substance during a specified period to:
  - inform the Minister of such activity(ies) during a specified time period (§71(1)(a));
  - provide “available toxicological information, available monitoring information, samples of the substance and information on the quantities, composition, uses and distribution of the substance and products containing the substance” (§71(1)(b)); or
  - conduct toxicological and other tests and submit the results to the Minister for substances identified as toxic or capable of becoming toxic, or suspected of being or capable of becoming toxic, per §72 (§71(1)(c)).

These authorities are analogous to TSCA authorities under §§8(a), 8(d) and 4, respectively. The burden on government to require testing under §71(c) appears somewhat lower, however, with no formal requirement to demonstrate that insufficient information exists to assess potential risk and that testing is necessary to develop the needed data, as required under TSCA.

In addition, §46(1) authorizes the Minister to require, through notice in the *Canada Gazette*, any person described in the notice to submit “any information that may be in the possession of that person or to which the person may reasonably be expected to have access” relating to any of a range of substances, including those on a Priority Substances List, those found to be or suspected of being

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<sup>98</sup> Environmental Defense, *HPV Tracker*, at [www.environmentaldefense.org/go/hpvtracker](http://www.environmentaldefense.org/go/hpvtracker), which is based on data made public by EPA via its HPV Challenge Program web site, [www.epa.gov/chemrtk/index.htm](http://www.epa.gov/chemrtk/index.htm).

CEPA-toxic and those that have not been found to be CEPA-toxic due to insufficient evidence of environmental exposure, but for which the Minister may impose monitoring requirements.

#### *DSL Categorization*

When CEPA was reauthorized in 1999, §73 required the Ministers of the Environment and of Health to “categorize” the ca. 23,000 substances on the DSL<sup>99</sup> to identify those substances that, “on the basis of available information,” either:

- may present, to individuals in Canada, the greatest potential for exposure; or
- are persistent or bioaccumulative and inherently toxic<sup>100</sup> to human beings or to nonhuman organisms.

§74 required that screening-level risk assessments be conducted on substances meeting the categorization criteria to determine whether they are “toxic” or capable of becoming “toxic” as defined in the §64 of CEPA. The categorization was completed by 14 September 2006, within the seven years specified in CEPA 1999. This effort is the most ambitious initiative undertaken to date to examine large numbers of existing chemicals to identify those requiring further data development, assessment and risk management.

The overall categorization approach is depicted in Figure 1. The activities undertaken by the two agencies charged with conducting the categorization, Environment Canada and Health Canada, and the overall results of categorization, are described below.

*1. Environment Canada:* Environment Canada (EC) began its evaluation by identifying available experimental data on DSL chemicals from a variety of databases and other sources. The preference was for experimental data over modeled estimates. It also requested voluntary submission of experimental data from industry and other parties.<sup>101</sup> EC received approximately 700 studies from industry, covering about 3,000 Chemical Abstract Service (CAS) numbers on the DSL. A subset of these studies was used in categorization.<sup>102</sup>

For the more than 11,000 organic substances examined, the searches found:

- experimental bioaccumulation data for 410 substances, and one-quarter of this data was of acceptable quality;

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<sup>99</sup> This number excludes those substances that were added to DSL subsequent to their evaluation by the New Substances Program, presuming that the data development and review process was sufficient to identify any substances needing further assessment or controls.

<sup>100</sup> As noted in CEPA §64, the term “inherently toxic” as used in §73 is distinct from “toxic” as defined under section 64 (the latter is often referred to as “CEPA-toxic”). As stated by Environment Canada: “Inherent toxicity refers to the hazard a substance presents to an organism. It is demonstrated by the concentration of a substance that presents a toxic effect to an organism, tested under laboratory conditions or in other studies.” See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_criteria.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria.cfm).

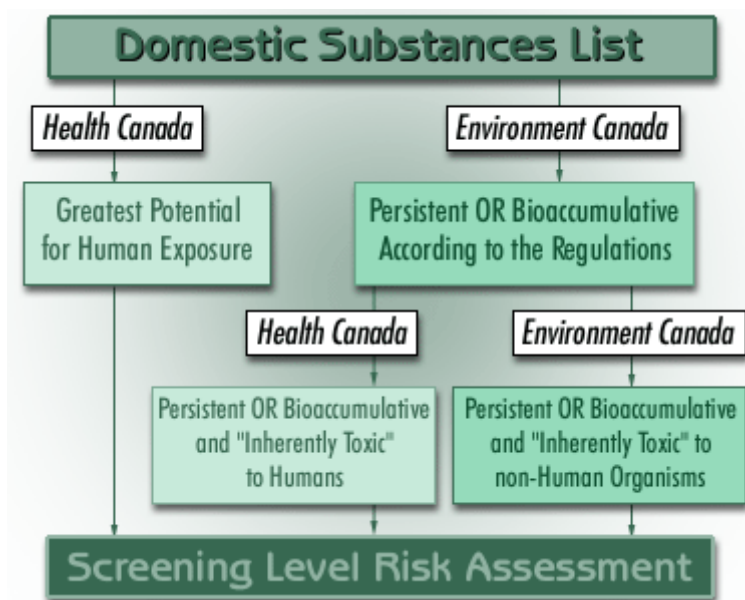
<sup>101</sup> See [https://www.ec.gc.ca/substances/ese/datasubmission/index\\_en.cfm](https://www.ec.gc.ca/substances/ese/datasubmission/index_en.cfm).

<sup>102</sup> Personal communication to author on 20 December 2006, from Danie Dubé, Manager, Chemical Evaluation, Environment Canada.

- experimental persistence data for 850 substances, and one-third of this data was of acceptable quality; and
- experimental data of inherent toxicity to nonhuman organisms for 1,051 substances, and three-quarters of this data was of acceptable quality.<sup>103</sup>

FIGURE 1

**Legislative construct for categorization of Existing Substances on the DSL**



Source: Environment Canada, "DSL Categorization under CEPA 1999 Section 73: Ecological Categorization Criteria and Process," at [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_criteria\\_process.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria_process.cfm).

EC employed estimates derived from quantitative structure-activity relationship (QSAR) models to fill the data gaps and arrive at its preliminary categorization decisions. Using all available information, EC could not categorize 617 organics due to lack of data, and the degree of confidence was deemed low for 416 organics that met the categorization criteria (see Table 5).<sup>104</sup>

For the more than 1,000 inorganic substances on the DSL, EC focused on inherent toxicity to nonhuman organisms. Bioaccumulation was not "systematically evaluated" for inorganics, and metal-containing inorganics were considered to be infinitely persistent. A search identified large gaps in experimental data on physical chemistry (water solubility, physical state, aqueous chemical speciation, log K<sub>ow</sub>), aquatic toxicity to nonhuman organisms, and bioaccumulation and persistence. Therefore, EC generated additional experimental data on acute aquatic toxicity and calculated data for solubility and other physical-chemical parameters. Using all of these data, EC categorized nearly all inorganic DSL substances (see Table 5).<sup>105</sup>

<sup>103</sup> See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_progress\\_organics.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_organics.cfm).

<sup>104</sup> See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_progress\\_organics.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_organics.cfm).

<sup>105</sup> See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_progress\\_inorganics.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_inorganics.cfm).



For these and other classes of DSL chemicals, the number for which low confidence or no determinations could be made is shown in Table 5.

TABLE 5  
**DSL Chemicals for which Low-confidence or No Determinations Were Able to be Made**

Chemical Class	Total # on DSL	# "categorized in" with low confidence level	# unable to be categorized
Organics	11,317	416	617
Inorganics	1,021	0	13
Organic Metal Salts	428	7	3
Organometallics	852	33	12
Polymers	4,017	483	75
UVCBs*	4,734	493	63

Source: Environmental Defense, based on Environment Canada spreadsheets providing categorization decisions for different chemical classes, accessed from the final (September 2006) CD-ROM; [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_index.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm).

\* Substances of Unknown or Variable Composition, Complex Reaction Products, or Biological Materials

EC found approximately 1,100 (about 5%) DSL chemicals that could only be categorized in with a low confidence level, and another 1,420 (about 6%) for which no determinations could be made.<sup>106</sup>

To assess the available data, EC developed procedures to determine data preference, weight of evidence and the selection of “pivotal values,” chosen as most representative from among the available values for a substance for a given endpoint.<sup>107</sup> These values, along with model estimates where experimental data were not available, were compared against specific numeric criteria developed for each categorization parameter: persistence (P), bioaccumulation (B) and inherent toxicity (iT) to nonhuman organisms. The toxicity parameter was limited to aquatic organisms and focused on acute toxicity because more studies and QSAR models are available for such endpoints.<sup>108</sup> Substances with pivotal values exceeding the criteria were identified, and those exceeding either P and iT or B and iT criteria were “categorized in.”

On the September 2006, publicly released CD-ROM that details final categorization results,<sup>109</sup> EC identified those chemicals lacking sufficient information to allow a categorization decision, and indicated the degree of confidence associated with each determination that a chemical met its criteria. EC did not, however, document how many decisions *not* to categorize in a chemical were made with only a low confidence level; this number probably is significantly higher because many more chemicals were not categorized in than were categorized in. Together with the above percentages, this total would better reflect the state of knowledge available to EC on which to base its categorization decisions.

<sup>106</sup> See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_background.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm).

<sup>107</sup> See *Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List*, available at [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_process.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_process.cfm).

<sup>108</sup> See [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_criteria.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria.cfm).

<sup>109</sup> Environment Canada spreadsheets providing categorization decisions for different chemical classes, accessed from the final (September 2006) CD-ROM; see [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_index.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm).

2. *Health Canada*: Health Canada's (HC) charge was to identify DSL chemicals that either: a) pose the greatest potential for exposure (GPE) to humans, or b) possess inherent toxicity to humans (for those chemicals identified by EC as either persistent or bioaccumulative). HC developed a number of tools to aid in the categorization process and the further prioritization of chemicals meeting categorization criteria (see Box 2).

HC used the Simple Hazard Tool (SimHaz) and Simple Exposure Tool (SimET) to develop a "draft maximal list" of 1,896 DSL substances, representing the maximum number of substances that could meet the categorization criteria. The main purpose of the list was to solicit voluntary submissions from industry focusing on substances for which more information on identity, use and toxicity could either: a) clarify categorization decisions—primarily to remove substances from the list, or b) alter their priority for post-categorization screening assessments.<sup>110</sup> HC highlighted two subsets of the list as needing more information:

- 301 substances identified as high hazard (and therefore expected to be categorized in) and of low potential for exposure; HC stated: "Health Canada is soliciting from industry, information or proposal(s) on the use and extent of current and/or potential options for risk management of substances in this group which would reduce their priority for further consideration in screening assessment."
- 388 substances with intermediate exposure potential, for which persistence and bioaccumulation determinations were not available; HC stated: "If these substances are determined to be neither P nor B, they would be moved to the 'low likelihood' group of the maximal list and not considered priorities for screening assessment in 2006."

In late 2004, HC issued an invitation to industry<sup>111</sup> to submit information on the above subsets of the draft maximal list, and on certain GPE and IPE UVCB substances (substances of unknown or variable composition, complex reaction products, or biological materials) and polymers lacking data on composition, production, processing and use needed to assess toxicity and exposure potential. Only a limited amount of information was received.<sup>112</sup>

HC applied the submitted information to further develop its use of the Complex Hazard Tool (ComHaz) and the Complex Exposure Tool (ComET), described in Box 2. HC used ComHaz to finalize the list of chemicals to be categorized in, and is using ComHaz and ComET to prioritize sequencing of the conduct of post-categorization screening assessments.<sup>113</sup>

As described in Box 2, substances not meeting criteria for any of the endpoints—including those lacking sufficient information—were set aside with the decision that no further consideration is

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<sup>110</sup> See [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/max-list/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/max-list/index_e.html).

<sup>111</sup> See [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/max-list/invitation/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/max-list/invitation/index_e.html).

<sup>112</sup> Personal communication to author on 8 February 2007, from Virginia Harel, Safe Environments Programme, Healthy Environments and Consumer Safety, Health Canada.

<sup>113</sup> For a full description of Health Canada's categorization and prioritization procedures, see Health Canada, "The Health-Related Components of Categorization of the Domestic Substances List (DSL): Approach, Results, and Next Steps," available at [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-approche\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-approche_e.html).

needed at this time. Because set-aside decisions can be based on a lack of information for one or more endpoints, any assumption that set-aside chemicals are not of concern is unwarranted; this facet of the DSL Categorization process—its reliance on available information—is a major difference between it and both the CEPA NSN process and REACH, which require data generation to meet minimum information requirements.

A data source hierarchy was employed in applying ComHaz, with authoritative government sources and experimental data preferred over modeled data. This hierarchy is reflected in the degree of confidence HC assigned to a given categorization result, which HC captured in its internal databases.<sup>114</sup> However, on the September 2006, publicly released CD-ROM, HC has not indicated the confidence level associated with its categorization decisions, nor has it identified chemicals which lacked enough information on which to base a categorization decision.

Because set-aside decisions can be based on a lack of information for one or more endpoints, any assumption that set-aside chemicals are not of concern is unwarranted.

### Box 2: Health Canada's tools used to categorize and prioritize DSL chemicals<sup>115</sup>

Primary categorization determinations were made using two tools developed by HC, which were applied to the entire DSL:<sup>116</sup>

- The simple hazard tool, SimHaz, examines whether a substance is found to be of high or low hazard by various domestic and other national or international agencies. The determination is based primarily on whether a chemical is included on various chemical lists. For high hazard, these include lists of carcinogens, mutagens, reproductive or developmental toxicants and sensitizers; for low hazard, these include lists identifying chemicals of low concern.
- The simple exposure tool, SimET, is based solely on production and use data submitted when the DSL was first compiled, dating from 1984–1986. Chemicals are ranked based on quantity, number of submitters and use codes indicative of exposure potential, resulting in greatest, intermediate and lowest potential for exposure groupings (GPE, IPE and LPE, respectively; see further description of criteria in Section II). (The limitations to HC's forced reliance on 20-year-old production and use data were discussed earlier in this report.)

Two other tools were developed to support categorization decisions and prioritize among the categorized chemicals:

<sup>114</sup> Personal communication to author on 1 March 2007, from Louis L'Arrivée, Evaluator, Existing Substances Division, Health Canada.

<sup>115</sup> See *Proposed Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999*, Figure 13, p. 29.

<sup>116</sup> See *Proposed Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999*, Part C (Tools), available at [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index_e.html).

- The complex hazard tool, ComHaz, was developed for application in two stages. The first stage was used to refine the initial categorization list and to set priorities among chemicals meeting the categorization criteria. It was applied to all GPE chemicals and all organic IPE chemicals that were identified as P or B by Environment Canada. Application of this stage began with a sequential, hierarchical search for available information on specific human health endpoints. The first endpoints examined (carcinogenicity, mutagenicity) were those for which no threshold of exposure can be assumed below which there is no effect; positive results led to the substance being “categorized in.” Otherwise, the next endpoint in the hierarchy was examined. The later endpoints (e.g., reproductive toxicity) were those for which no-effect levels can be assumed; quantitative criteria were set for each (presented earlier in Section II), and any information indicating an exceedance of these values led to the substance being “categorized in.” Insufficient information or negative results for a given endpoint led to consideration of the next endpoint down the hierarchy. A positive result halted consideration of later endpoints in the hierarchy, based on the assumption that these endpoints will be examined in the post-categorization, screening-level risk assessment.

Health Canada anticipates that, in a second stage to be employed post-categorization, ComHaz will apply a weight-of-evidence approach to the qualitative endpoints, and will compare exposure-response information for critical endpoints with quantitative exposure estimates generated by the ComET tool (see next paragraph). Since ComET is still under development, however, this comparison of outputs has not yet been conducted.<sup>117</sup>

- The complex exposure tool, ComET, was not used to make categorization decisions but will be used to evaluate and prioritize chemicals found to meet HC’s categorization criteria. HC describes ComET as providing “quantitative plausible maximum estimates of exposure of individuals in the general population by age group based on use scenario (sentinel products and emissions), physical/chemical properties and bioavailability.” When completed, the tool will estimate direct consumer exposure from products and indirect human exposure from the environment. For the former, age-specific “sentinel products” (those expected to result in the highest exposure for individuals in that age group) will be selected. Publicly available information that is not specific to a given substance will be used to provide maximum concentrations of a substance in a given product type to which exposure may occur (e.g., cosmetics, bedding, paints, air fresheners). Then the use profile of specific substances will be developed and used to select appropriate products for exposure estimation, e.g., a chemical that is used as a surfactant would be matched to a “sentinel” cleaning personal care product. Finally, age-specific use factors, including those for frequency, duration and amount of product used will be applied to estimate plausible maximum exposure to a substance.

Environmental exposures include those from air, water, soil and food. Use information and physical-chemical properties are used to estimate “per-unit” emissions and to model distribution among environmental media. The resulting unit concentrations in different media are then

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<sup>117</sup> Personal communication to author on 8 February 2007, from Virginia Harel, Safe Environments Programme, Healthy Environments and Consumer Safety, Health Canada.

scaled to estimate actual concentrations, using “actual emissions, production quantities or use information.”<sup>118</sup> Finally, age-specific exposure factors are used to estimate exposures.

In deriving environmental exposure estimates using ComET, HC may again be forced to rely on production information from the 1984–1986 process used to compile the original DSL. As with SimET, the robustness of these environmental exposure estimates may be significantly compromised by the absence of more current production information. On the other hand, since consumer product exposure estimates by ComET do not rely on production quantities, and information on use patterns will likely be derived from more recent publicly available information, these estimates may not be similarly compromised.<sup>119</sup>

As lists of chemicals to be categorized in by EC and HC neared finalization, both agencies identified a subset deemed “Priority for Action.” These approximately 500 chemicals either: a) exhibited potential for hazard to the environment or human health or greatest potential for human exposure, or b) were substances of emerging concern and international interest. Using CEPA’s §71(1) authority, EC published a notice in March 2006, requiring producers and importers of any of these substances in amounts exceeding 100 kg in 2005 to identify themselves and the quantity produced or imported. The aim of the survey was to determine whether the substances are still being produced in or imported into Canada, and if so, to be able to follow up with producers or importers to obtain more information, including use pattern information.<sup>120</sup> Of the approximately 400 PBiTs included in the survey, about 150 were not reported to be produced in or imported into Canada.<sup>121</sup>

*3. Results of DSL Categorization:* Final results of the DSL Categorization became available in late 2006. More than 4,000 substances have been categorized in: about 1,100 based on meeting the criteria developed by HC,<sup>122</sup> and 2,900 based on meeting the criteria developed by EC.<sup>123</sup> About 350 additional substances were identified by HC as warranting additional review based on evidence of human health concerns identified through the categorization process.

Approximately 500 of the 4,350 chemicals have been assigned highest priority:

- about 400 “PBiTs” possessing properties of persistence, bioaccumulation and inherent toxicity to human or nonhuman organisms; about 150 are no longer produced in or imported into Canada;

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<sup>118</sup> See *Proposed Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999*, Part C (Tools), Figure 13, p. 29.

<sup>119</sup> Personal communication to author on 8 February 2007, from Virginia Harel, Safe Environments Programme, Healthy Environments and Consumer Safety, Health Canada.

<sup>120</sup> The 500 substances in the survey included: a) about 430 substances that were categorized as PBiTs (that is, persistent, bioaccumulative and inherently toxic either to humans or nonhuman organisms); b) about 60 substances that were identified as posing a hazard to human health or otherwise of emerging concern and international interest, but did not meet the categorization criteria; and c) ten that were polymers categorized as having greatest potential for human exposure. See <http://canadagazette.gc.ca/partI/2006/20060304/html/notice-e.html#i3>.

<sup>121</sup> See “Results of surveys” at [www.ec.gc.ca/CEPARegistry/documents/subs\\_list/pbit/148PBiTs.cfm](http://www.ec.gc.ca/CEPARegistry/documents/subs_list/pbit/148PBiTs.cfm).

<sup>122</sup> For a full description of these substances and how they were identified, see Health Canada, “The Health-Related Components of Categorization of the Domestic Substances List (DSL): Approach, Results, and Next Steps,” at [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-proche\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-proche_e.html).

<sup>123</sup> For a full description of these substances and how they were identified, see Environment Canada, “Ecological Categorization of Substances on the Domestic Substances List (DSL),” at [www.ec.gc.ca/substances/ese/eng/dsl/cat\\_index.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm).

- about 75 substances exhibiting high hazard potential to humans and greatest or intermediate potential for exposure; and
- about 20 substances not meeting HC's criteria for categorization but posing significant hazards to human health.<sup>124</sup>

In December 2006, the Canadian government announced a Chemicals Management Plan to address the information, assessment and risk management needs identified through DSL Categorization. (See Box 3.)

### Box 3: The Canadian government's Chemicals Management Plan<sup>125</sup>

In December 2006, the Canadian government announced its Chemicals Management Plan to address the approximately 4,300 chemicals identified through DSL Categorization as needing further review. For the approximately 500 substances identified as "high-priority," the Plan described the following actions:

- For about 50 of these substances, assessment or risk management actions are already underway; these include five substance categories identified as PBiTs that have been placed on the List of Toxic Substances and are being or are to be subject to immediate regulatory controls, with the aim of prohibiting most uses. Among these categories are six polybrominated diphenyl ethers (PBDEs) used as flame retardants, and perfluorooctane sulfonate (PFOS) and its salts, used primarily as water, oil and grease repellents on fabrics and food packaging.<sup>126</sup>
- Significant New Activity (SNAc) Notices have been applied to the 150 PBiT substances found by the survey described above to be no longer in commerce in Canada; these notices will require anyone wishing to begin manufacture or import of any of the substances to undergo government notification, review and assessment.<sup>127</sup>
- For about 200 additional substances, under a "Challenge to Industry,"<sup>128</sup> the government intends to use its CEPA §71(1)(b) authority to require producers and importers to submit information on the quantity and concentration of the substance used or sold and the type of products or other applications in which the substance is used. The information will be used "to complete the assessment as to whether or not the substances meet the criteria [those defining "CEPA-toxic"] set out in section 64 of the Act, to understand the use of the substances, to assess the need for controls and to improve the information available for decision-making." The first Challenge

<sup>124</sup> Personal communication to author on 21 February 2007, from George Enei, Director, Existing Substances Division, Environment Canada.

<sup>125</sup> See the Chemicals Management Plan at [www.chemicalsubstanceschimiques.gc.ca/plan/index\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html).

<sup>126</sup> Personal communication to author on 21 February 2007, from George Enei, Director, Existing Substances Division, Environment Canada. See Order adding these substances to the List of Toxic Substances, at <http://canadagazette.gc.ca/partII/2006/20061227/html/sor333-e.html>.

<sup>127</sup> See the 9 December 2006 Notice at <http://canadagazette.gc.ca/partI/2006/20061209/html/notice-e.html#i3>.

<sup>128</sup> See a full description of the Challenge at [www.chemicalsubstanceschimiques.gc.ca/challenge-defi/notice-avis\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/notice-avis_e.html).

notice was published in February 2007 and covered 13 of the substances.<sup>129</sup> Notices will be issued for additional batches of these chemicals approximately once every three months.

- The remaining substances consist primarily of chemicals in Canadian commerce identified as highly hazardous to humans. Several actions are contemplated: The government intends to issue, in early 2007, SNAc Notices to cover any new or increased uses for some of them. The government believes that “current uses of these substances are considered to be responsibly managed,” but that the notices are needed “to ensure that any new or increased use of these substances is not allowed without informed assessment and appropriate controls.”<sup>130</sup> Others are petroleum streams for which a sector agreement is being considered, or perfluorinated compounds to be addressed under the government’s Perfluorinated Carboxylic Acids and Precursors Action Plan.<sup>131</sup>

As mandated under CEPA, all categorized substances must undergo screening-level risk assessments. Draft assessments of the ca. 150 PBiT substances found to be no longer in Canadian commerce have been made public.<sup>132</sup> Although these substances meet the P, B and iT criteria, because they are not in commerce, the draft assessments conclude that they are “not currently entering, or likely to enter, the environment,” and do not qualify as CEPA-toxic.

Screening assessments will be conducted on all the remaining substances, based on priorities identified either during or after categorization. The other high-priority substances identified above presumably will be assessed early. The Chemicals Management Plan also provides for rapid screening of lower risk chemical substances: “Categorization identified a number of lower risk substances that are unlikely, given current evidence, to pose a threat to the environment. These will be screened quickly, and the results will be released for public comment in the Spring of 2007. ... Our scientists believe that a number of substances, while meeting the categorization criteria, are not likely to pose a risk to the environment in the amounts at which they are found. The accelerated screening approach will apply a worst-case scenario to determine whether further assessment is necessary.”<sup>133</sup>

*One major aspect of the results of categorization that is not explicitly discussed by the Chemicals Management Plan is how the government intends to address the significant data gaps identified through categorization, beyond the small subset of high-priority chemicals. These gaps include the lack of current information on production, import and use, and the dearth of hazard information, especially experimental data, for the great majority of DSL chemicals. These gaps are reflected by the large number of chemicals where no or low confidence categorization decisions were made. Whereas DSL Categorization was limited to using available information, a core element of post-categorization action should be to greatly improve the base of information available on all DSL chemicals.*

<sup>129</sup> See <http://canadagazette.gc.ca/partI/2007/20070203/html/index-e.html>.

<sup>130</sup> See “Restrictions on re-introduction and new uses” under the Chemicals Management Plan at [www.chemicalsubstanceschimiques.gc.ca/plan/index\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html).

<sup>131</sup> Personal communication to author on 21 February 2007, from George Enei, Director, Existing Substances Division, Environment Canada. See also the description of the PFCA Action Plan at [www.ec.gc.ca/nopp/DOCS/rpt/PFCA/en/actionPlan.cfm](http://www.ec.gc.ca/nopp/DOCS/rpt/PFCA/en/actionPlan.cfm).

<sup>132</sup> See [www.ec.gc.ca/CEPARRegistry/documents/subs\\_list/pbit/148PBITS.cfm](http://www.ec.gc.ca/CEPARRegistry/documents/subs_list/pbit/148PBITS.cfm).

<sup>133</sup> See “Rapid screening of lower risk chemical substances” under the Chemicals Management Plan at [www.chemicalsubstanceschimiques.gc.ca/plan/index\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html). A notice in the *Canada Gazette* describing the approach is available at <http://canadagazette.gc.ca/partI/2006/20061209/html/notice-e.html#12>.

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REACH imposes, through its registration process, quite similar data requirements on new and existing chemicals. The primary difference is that the requirements are to be phased in over time for existing chemicals, hence their designation as “phase-in substances” (new chemicals are designated as “non-phase-in substances”). As with new substances, registration of phase-in substances entails submission of a technical dossier containing information on the identity, manufacture and use of the substance; any applicable hazard classifications and labeling requirements; guidance on its safe use; summaries of all relevant hazard information already available to the registrant; and summaries of studies conducted and testing plans proposed to meet data requirements.<sup>134</sup> The scope and amount of information required is based on the tonnage produced or imported at the time of registration, and additional data requirements apply as the quantity placed on the market increases.

### *Substances used in articles*

REACH also requires that manufacturers of articles submit registrations for substances used that meet all three of the following conditions:

- the substance has not already been registered for that use by its manufacturer;
- the substance is present in the article in quantities totaling more than one metric ton per year per producer or importer; and
- the substance is intended to be released from the article under normal or reasonably foreseeable conditions of use.<sup>135</sup>

Independent of the above obligation, if a substance used in an article is on REACH’s candidate list of SVHC substances subject to authorization (see Section VI), the manufacturer of the article must notify the Chemicals Agency and provide further use information if: a) the substance is present in the article in quantities totaling more than one metric ton per year per producer or importer; and b) the concentration of the substance in the article is above 0.1% by weight. This notification obligation does not apply, however, if the manufacturer of the article can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use, including disposal, and provides all recipients of the article with appropriate instructions on use and disposal.<sup>136</sup>

The Agency also has authority to require the registration of any substance in an article that is present in quantities totaling more than one metric ton per year per producer or importer if there are grounds for suspecting that the substance is released and presents a risk to human health or the environment.<sup>137</sup>

Registration deadlines for phase-in substances differ based on tonnage and other factors. Registration must occur:

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<sup>134</sup> REACH, Article 10(a) and Annex VI.

<sup>135</sup> REACH, Article 7, sections (1) and (6).

<sup>136</sup> REACH, Article 7, sections (2), (3) and (4).

<sup>137</sup> REACH, Article 7(5).



- within three and one-half years of enactment (by 1 December 2010) for:
  - CMR substances manufactured at one metric ton/year or more;
  - substances manufactured at 100 metric tons/year or more that are classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment; and
  - substances manufactured at 1,000 metric tons/year or more.
- within six years of enactment (by 1 June 2013) for substances manufactured at 100 metric tons/year or more.
- within 11 years of enactment (by 1 June 2018) for substances manufactured at one metric ton/year or more.<sup>138</sup>

Data requirements are specified in annexes to REACH and also vary by tonnage,<sup>139</sup> as follows:

- 1 metric ton/year or more: information specified in Annex VII must be provided.
  - All of its requirements apply to substances that meet the criteria below.
  - Only physicochemical property data are required for substances manufactured at 1–10 metric tons/year that do not meet the criteria.
  - Criteria: (a) substances that are known or predicted (e.g. using QSARs) to be SVHCs, or (b) substances with dispersive or diffuse uses (e.g., used in consumer products) that are predicted to be classified as dangerous for any human health or environmental effects endpoint under the EU’s classification and labeling criteria.
- 10 metric tons/year or more: information specified in Annexes VII–VIII must be provided.
- 100 metric tons/year or more: information specified in Annexes VII–VIII and testing proposals and time schedules for providing the additional information specified in Annex IX must be provided.
- 1,000 metric tons/year or more: information specified in Annexes VII–VIII requirements and testing proposals and time schedules for providing the additional information specified in Annexes IX–X must be provided.<sup>140</sup>

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<sup>138</sup> REACH, Article 23.

<sup>139</sup> Of the estimated 30,000 chemicals produced or imported in amounts of one metric ton or more that are expected to be eventually registered under REACH, the following numbers fall into each of these tonnage bands:

- >1,000 metric tons/year: 2,700 substances, plus 1,700 transported intermediates with reduced registration requirements;
- 100–1,000 metric tons/year: 2,460;
- 10–100 metric tons/year: 4,980;
- 1–10 metric tons/year: 17,500.

See European Commission, Joint Research Center, “Assessment of additional testing needs under REACH,” September 2003, Table 1, p. 12, available at [http://ecb.jrc.it/documents/REACH/PUBLICATIONS/REACH\\_testing\\_needs\\_final.pdf](http://ecb.jrc.it/documents/REACH/PUBLICATIONS/REACH_testing_needs_final.pdf).

<sup>140</sup> REACH, Article 12.

Reduced information requirements apply to two types of chemicals used only as intermediates: on-site isolated intermediates (where both the manufacture of the substance and its use to make another substance occur at the same site) and transported isolated intermediates (where the manufacture of the substance and its use to make another substance occur at different sites).<sup>141</sup>

Registrants of chemicals produced at 10 metric tons/year or more must also prepare and submit a chemical safety report (CSR) as part of their registrations.<sup>142</sup> The CSR includes assessments of physicochemical, human and environmental hazards and an assessment of whether the chemical qualifies as a PBT or vPvB substance. CSRs for chemicals identified through these assessments as possessing dangerous properties or qualifying as PBTs or vPvBs must also include an exposure assessment and a risk characterization. Registrants of chemicals produced at 1–10 metric tons/year are not required to prepare a CSR, and need only provide a more basic set of information on use and exposure.<sup>143</sup>

In sum, at the time of registration, manufacturers will be required to submit available information and to generate and submit new information—and testing proposals for chemicals in the two highest tiers—specified under the applicable registration requirements. The determination of whether to require generation of information applicable to chemicals in the two highest tiers is made at the evaluation stage. To require a registrant to generate information beyond that specified under the registration requirements, however, an extensive procedure must be followed that includes approval by the Member States or the Commission and provides the registrant with the right to comment and to appeal the decision.<sup>144</sup> Although imposing standardized information requirements on all existing chemicals registered under REACH goes far beyond any provision of CEPA or TSCA, the apparent burden on government to impose any further data generation requirements on registrants is more like that under CEPA and TSCA.

In considering REACH's data requirements, there are two important qualifications that will affect how much and what type of information REACH provides. First, whereas the REACH annexes specify a “standard testing regime” for meeting applicable data requirements, they also provide a plethora of conditions applicable to any required data element, under which standard information “may be omitted, replaced with other information, provided at a different stage or adapted in a different way.”<sup>145</sup> A rationale can be provided for why testing is not needed or feasible. Data not meeting good laboratory practice (GLP) standards or generated using nonstandard methods may suffice. Finally, alternative methods to direct testing can be used, including use of *in vitro* rather than *in vivo* data, qualitative or quantitative structure–activity relationship (SAR) modeling, weight-of-evidence approaches and grouping of substances into categories coupled with read-across approaches.<sup>146</sup> For any given data element, there are additional conditions under which testing

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<sup>141</sup> REACH, Articles 17 and 18.

<sup>142</sup> REACH, Articles 10(b) and 14 and Annex I.

<sup>143</sup> REACH, Article 10(a)(x). The required information elements are specified in Annex VI, Section 6.

<sup>144</sup> REACH, Articles 46(1), 50 and 52.

<sup>145</sup> This language appears in the introduction to each of the Annexes VII–X.

<sup>146</sup> These allowable adaptations are described in REACH, Annex XI, Sections 1 and 2. They are not unlike those that apply to data generation in the U.S. and Canada. Many of these same alternative methods and rationales are allowable under the U.S. HPV Challenge Program (see Section IVB and EPA's web site for the Challenge Program, at [www.epa.gov/chemrtk/index.htm](http://www.epa.gov/chemrtk/index.htm)) and under Canada's New Substances Notification Regulations (see *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 8).

need not be conducted or may be modified. REACH does require that, for each “adaptation” of a testing requirement, the nature of the adaptation and the basis for it must be clearly indicated.

Second, REACH provides considerable latitude for registrants to waive higher-tier testing requirements based on demonstration of low exposure. Under what REACH terms “substance-tailored exposure-driven testing,” a registrant may omit testing for two toxicological endpoints in Annex VIII, and for any endpoint in Annex IX or X.<sup>147</sup> Adequate justification based on the exposure assessment submitted as part of the CSR must be provided, and any conditions on use tied to achieving low exposure must be communicated through the supply chain. The Commission will develop the criteria that will be used to define what constitutes “adequate justification.”

The allowances that REACH provides for all of these adaptations are motivated by a desire to reduce testing, in particular animal testing, both in response to animal protection concerns and to minimize costs to industry. Flexibility and expert judgment are important in determining data needs for a given chemical, and there are situations where use of the allowable derogations or alternative methods is scientifically justifiable. The challenge, however, is to balance those needs with the desire for a robust characterization of the risks posed by chemicals subject to REACH, especially in light of the strong incentives that exist—particularly among chemical producers who bear the costs—to minimize testing requirements.

Without clear guidance and careful oversight, an over-reliance on the use or misapplication of alternatives to animal testing can result, as demonstrated under the U.S. HPV Challenge discussed earlier. Similarly, the inherently dynamic nature of exposure and the often very limited scope and reliability of available exposure information means that any use of such information to claim low exposure must be subject to independent review and verification. Appendices B and C are papers by Environmental Defense that detail the challenges and limitations to applying alternative methods and relying on exposure-driven approaches to chemicals assessment. These papers were presented at recent meetings considering these issues, held under the auspices of the Chemicals Committee of the Organization for Economic Cooperation and Development (OECD).

These issues raise particular challenges in the context of REACH implementation, since any independent evaluation of whether such adaptations, alternative methods or waivers of testing requirements are appropriate and sufficiently justified will not occur unless a substance is selected by the Agency or a Member State for evaluation (see Section V). In the interim, the chemical will be in production and use even though the extent of data available on the chemical may be insufficient. This is one consequence of the approach under REACH (as well as prior EU legislation) where the registration and evaluation (equivalent to notification and assessment) processes operate on independent tracks. Prompt evaluation of all registered substances would minimize this concern (see Section V).

More broadly, given the extent to which all of the chemicals policies discussed in this report rely heavily on data generated by industry and on information derived (whether by government or industry) using alternative methods, it is incumbent on government to ensure that such information is credible and perceived as such. Box 4 provides some proposals.

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<sup>147</sup> REACH, Article 13(1) and Annex XI, Section 3.

### Best practice

*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 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.<sup>148</sup>
- 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.

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<sup>148</sup> Although notice publication is procedurally simpler than notice-and-comment rulemaking, it may be viewed as a political decision under Canada's parliamentary system of government. Procedures now applicable to all regulatory proposals in the U.S. that require review and approval by the White House's Office of Management and Budget (OMB) have introduced political considerations as well, however.

#### **Box 4: Ensuring the credibility of industry-generated data and information developed using alternatives to direct testing**

Where new data on chemicals are required to be generated, essentially all policies affecting chemicals worldwide—whether industrial chemicals or drugs, cosmetics ingredients, pesticides, or food additives—require and rely on chemical producers to generate and submit those data. REACH as well as existing U.S. and Canadian approaches to assessing industrial chemicals rely extensively on such data. It is critical, therefore, that every effort be made to ensure that industry-generated data used to formulate and support public policy are—and are seen as—credible. This need is even more pronounced when one considers the obvious financial incentives industry has in minimizing testing costs and being able to state that its products are safe.

Cost minimization, animal welfare concerns and efficiency objectives are driving an increasing reliance by industry and government on alternatives to direct *in vivo* testing, including use of *in vitro* assays, the use of various estimation and extrapolation methods and weight-of-evidence approaches. These methods have inherent limitations as well as legitimate uses. Industry and regulatory agencies often have less experience with them, and they often require different types of expertise both to properly use and to critically review. Finally, standardization of methodologies and guidance on their appropriate and inappropriate use are less well developed than for standard testing methods.

To ensure a high degree of public trust in the government's assessment and management of chemicals, steps need to be taken to ensure the integrity and appropriate use of industry data and these alternative information sources. Consideration should be given to requiring implementation of the types of measures indicated below:

With respect to industry-generated data or other privately funded research, consider:<sup>149</sup>

- Establishing a registry of health and safety related studies to ensure that results of all initiated studies are reported and made available, along with details of the method utilized in each study. This proposal is quite similar to what already occurs in pharmaceuticals regulation.
- Requiring government access to all records of privately sponsored research used in setting or implementing public policy. Such a requirement already exists for public-funded research.
- Requiring the disclosure of funding sources and the extent of sponsor review or approval, as well as potential financial conflicts of interest, on the part of researchers who are privately funded and whose research is used in public policy settings. A growing number of scientific journals and organizations require such disclosures.
- Requiring independent peer review or certification of studies submitted for use in public policy contexts, along with transparency safeguards to ensure disclosure of the identity of reviewers and any potential conflicts of interest, as well as balanced representation of the scientific community among reviewers.

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<sup>149</sup> These proposals are liberally adapted from a summary of Wagner, W. and Steinzor, R., eds. (2006) *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research*, Cambridge University Press, summary available at [www.progressivereform.org/issue\\_science.cfm#rescue](http://www.progressivereform.org/issue_science.cfm#rescue).

With respect to alternatives to direct testing, consider:<sup>150</sup>

- Avoiding over-reliance on alternatives by creating and adhering to clear, scientifically sound guidance on the appropriate uses (e.g., for initial screening of large numbers of chemicals) and inappropriate uses of each alternative method.
- Requiring justification and appropriate documentation by government and industry for use of and decisions made based on information derived from alternative methods.
- Ensuring careful independent expert review.
- Implementing safeguards to prevent selective use and reporting, for example, by requiring that all results and methods used be reported.
- Requiring that any communication of the data, and conclusions or decisions based on data derived from such methods, clearly indicate the nature, source and specific means used to derive them.
- Requiring that an assessment be made of the reliability of the data, and that any resulting uncertainty be reflected in appropriate qualifications of conclusions or decisions based on such information.

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<sup>150</sup> These concepts are more fully developed in Appendix B.

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## V. Assessing information to determine hazard/exposure/risk

All three systems employ or will employ established procedures to assess the potential risks of chemicals. The nature of the procedures and their extent of application differ for new versus existing substances under the U.S. and Canadian systems, so these will be examined separately. Under REACH, the same procedures will be applied to new and existing substances.

### A. New chemical review and assessment

Under the U.S. and Canadian systems, government authorities review all new chemicals (ineligible for exemptions) that fall under the respective jurisdictions of TSCA and CEPA. Each system uses very similar procedures to review new-use notifications as well (SNURs and SNAcs, respectively). The several important differences are discussed below.

#### UNITED STATES

EPA must review each PMN it receives and make a determination, generally within 90 days, whether a chemical warrants prohibition or any restrictions on its manufacture or use, based on information provided in the PMN or otherwise available. The PMN includes basic information on chemical identity, use, anticipated production volume, exposure and release information, and any pre-existing test data already in the possession of or readily available to the notifier (in practice most PMNs contain few or no actual test data).

After an initial check to ensure the chemical is not already on the TSCA Inventory or eligible for an exclusion or exemption, and that the PMN is complete, EPA evaluates the information to determine whether: a) the chemical's manufacture, processing, distribution, use or disposal "may present an unreasonable risk"<sup>151</sup> (a "risk-based finding"), b) the chemical will be produced in substantial quantities and will result in substantial or significant human exposure or environmental release (an "exposure-based finding"),<sup>152</sup> or c) warrants no concern. If EPA makes a risk-based or exposure-based finding, it can initiate action to reduce potential risk by prohibiting or limiting such activities, or can require more information to be developed and submitted.

PMNs are subjected to varying levels of review, depending on the amount of information available, the extent of structural similarity to known chemicals and initial findings with respect to potential hazard and exposure. EPA indicates that fewer than 5% of PMNs go through a full risk assessment (which, somewhat ironically, EPA terms a "standard review").<sup>153</sup>

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<sup>151</sup> TSCA distinguishes between two levels of findings that EPA must make to take action. The first, that a chemical "may present an unreasonable risk," applies to risk management actions on new chemicals (TSCA §5) and requirements to test new or existing chemicals (§4). The second, that a chemical "presents or will present an unreasonable risk," generally applies to risk management actions on existing chemicals (TSCA §6). See Section II of this report for more discussion of this important distinction.

<sup>152</sup> EPA's criteria for what constitutes substantial production and substantial or significant human exposure and environmental release are detailed in its Exposure-based Policy, at [www.epa.gov/oppt/newchemicals/pubs/expbased.htm](http://www.epa.gov/oppt/newchemicals/pubs/expbased.htm).

<sup>153</sup> EPA, *Draft Q&A for the New Chemicals Program*, undated, answer to Question 106-1.

## CANADA

In Canada, New Substance Notifications (NSNs) must be submitted a specified length of time prior to exceeding specified quantity thresholds of production or import, and must include types and amounts of information specified in associated schedules or provisions of the New Substances Notification Regulations. The specified time periods also correspond to the length of the assessment period, i.e., how long the government has to review the chemical and reach any decisions concerning management or information requirements.<sup>154</sup> The length of time, quantity threshold and information requirements all vary with the type of substance and whether it is listed on the NDSL; see Section IVA.

The assessment period for a notification begins after an initial check is made to ensure that the information provided is complete and the submission has been accepted, at which point an acknowledgment letter is sent to the notifier. Assessment of the submission is a shared responsibility of Environment Canada and Health Canada. The assessment is aimed at making a key determination: whether or not the substance is, or is suspected of being, “toxic” or capable of becoming “toxic,” as defined under §64 of CEPA. This determination involves an assessment of the hazards and potential for exposure to humans and the environment. A substance may be “suspected” of being toxic if either its hazards or exposure potential are of concern.<sup>155</sup>

## EUROPEAN UNION

Except as noted, the following description is the process that will be used under REACH for new and existing substance registration and evaluation.

### *Registration*

REACH's registration process supplants the previous notification scheme for new chemicals. Prior to registration of a new chemical,<sup>156</sup> manufacturers or importers must first inquire with the Chemicals Agency established under REACH whether their substances are already registered.<sup>157</sup> If not (which will be the case with a truly new substance), the inquirer must register the chemical, and can do so either individually or with other potential registrants. (If it has been registered within the preceding ten years, REACH imposes data and cost sharing requirements on the new and earlier registrants primarily as a means to reduce animal testing.)

These data are used by the registrant to meet additional requirements to develop and provide a risk assessment and to propose any relevant classifications for the chemical, based on classification criteria contained in the Classification and Labeling of Dangerous Substances Directive. Manufacturers and importers of chemicals at levels at or above ten metric tons/year must also submit an assessment of the potential risks of the chemicals they are registering, in the form of a

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<sup>154</sup> The assessment period may be extended when more time is needed, but only a single extension is allowed and it cannot exceed the length of the initial assessment period.

<sup>155</sup> *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 9.4.2, p. 97.

<sup>156</sup> REACH terms a new chemical a “non-phase-in substance,” which is any chemical that is not a “phase-in substance,” the latter being any chemical listed on EINECS, or with evidence of having been either manufactured in the European Community but not placed on the market within the last 15 years, or previously marketed and notified within the Community. REACH, Article 3(20).

<sup>157</sup> REACH, Articles 26 and 27.



chemical safety report (CSR). Government then has the authority to evaluate these assessments and take action based on its findings. *(This is a key difference in REACH relative to CEPA and TSCA. Under TSCA and CEPA, assessment activities are conducted exclusively by government. This distinction and its implications are discussed in more detail in the Introduction and Box 1.)*

Once a registration—or an update of a registration either to reflect changes in production levels, uses, etc., or to comply with any decisions requiring that additional information be provided—is received, the Chemicals Agency must perform a completeness check within three weeks. This check specifically excludes “an assessment of the quality or adequacy of any data or justifications submitted.”<sup>158</sup> Unless deemed incomplete, the registrant may immediately commence or may continue manufacture or import. Therefore, under REACH, manufacturers of new chemicals may commence production or import without prior government review of potential risks. This is similar to prior EU chemicals legislation and is in contrast to both TSCA and CEPA notification.

### *Evaluation*

The evaluation phase of REACH is the first point at which the quality, adequacy and implications of information provided in registrations are assessed by government. There are two types of evaluation: “dossier” and “substance.”

Under “dossier evaluation,” the Agency:

- examines (within 180 days of receipt<sup>159</sup>) any testing proposals submitted by registrants and decides to require that the proposed tests be conducted, to modify the proposed test conditions, to require that tests applicable at the relevant tonnage tier but not proposed by the registrant be conducted, or to reject the testing proposal;<sup>160</sup> and
- performs a compliance check that:
  - assesses the adequacy of the submitted information and any justifications provided for modifying or not providing required information;
  - assesses the adequacy of any proposed risk management measures; and
  - requires the registrant to provide any additional information needed to bring the registration into compliance within a specified timeframe.<sup>161</sup>

All testing proposals must be evaluated by the Agency,<sup>162</sup> whereas only a fraction (at least 5% of the registrations received in each tonnage band) is subject to compliance checks.<sup>163</sup>

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<sup>158</sup> REACH, Article 20(2).

<sup>159</sup> REACH, Article 43(1). For phase-in substances, longer review periods are provided (Article 43(2)):

- 2 years for proposals in registrations received by the first deadline (3.5 years after REACH takes effect),
- 3 years for proposals in registrations received by the second deadline (6 years after REACH takes effect),
- 4 years for proposals in registrations received by the third deadline (11 years after REACH takes effect).

<sup>160</sup> REACH, Article 40.

<sup>161</sup> REACH, Article 41.

<sup>162</sup> Testing proposals rather than test data must be submitted at the time of registration for information requirements applicable to substances produced at 100 metric tons per year or more. Priority for testing proposal review is to be given to: a) substances of high concern, and b) substances classified as dangerous, produced or imported at or above 100 metric tons/year, and used in a manner resulting in “widespread and diffuse exposure.” REACH, Article 40(1).

Under “substance evaluation,” selected chemicals are for the first time assessed by government for their potential risks. These evaluations are to be coordinated by the Agency but conducted mostly by competent authorities of the Member States. Substances are to be prioritized for evaluation using “a risk-based approach”<sup>164</sup> according to criteria developed by the Agency that consider:

- hazard information on the substance or its transformation products, including structural similarity to substances of known concern;
- exposure information; and
- aggregate tonnage across all registrants of a given substance.

The Agency is to designate a “rolling action plan” (covering three years and updated annually) that provides a list of substances eligible for evaluation because “there are grounds for considering ... that a given substance constitutes a risk to human health or the environment.”<sup>165</sup> Member states may also nominate substances for inclusion on this list. Member states can then select substances to evaluate, with the Agency responsible for ensuring that any substances not selected by any Member States are evaluated. There is no minimum number of substances specified that must be evaluated, however, nor a timeline that would govern the rate at which evaluations are to be carried out.

Substance evaluations can lead to:

- a draft decision by a Member State to request that the registrant provide more information by a specified deadline, which may require testing and may encompass information beyond that specified in the registration information requirements; such draft decisions must be: a) made within 12 months of the appearance of a substance on the list of substances to be evaluated in that year, b) circulated to the registrant and other Member States for comment, and c) approved by a designated committee of the Member States.<sup>166</sup> Final decisions may be appealed by the registrant or another directly affected party.<sup>167</sup>
- a decision by a Member State to prepare a dossier on a substance that it believes meets one or more of the criteria used to identify substances of very high concern that are subject to authorization.<sup>168</sup>

There is no minimum number of substances that must be evaluated, nor a timeline to govern the rate at which evaluations are to be carried out under REACH.

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<sup>163</sup> REACH, Article 41(5).

<sup>164</sup> REACH, Article 44(1).

<sup>165</sup> REACH, Article 44(2).

<sup>166</sup> REACH, Article 46.

<sup>167</sup> REACH, Articles 91, 92 and 93. According to Article 91(2), any such an appeal “shall have suspensive effect,” so that the decision to require testing does not take effect while the appeal is pending.

<sup>168</sup> REACH, Article 59(3), referring to the criteria in Article 57 used to identify substances of very high concern.

- a decision by a Member State to prepare a dossier on a substance that it believes “poses a risk to human health or the environment that is not adequately controlled” and warrants restriction.<sup>169</sup>

The substance evaluation—but not the preparation of any dossiers by the Member State—must be completed within 12 months of its initiation or receipt of any requested additional information.<sup>170</sup> This requirement, along with the time frames associated with comment on draft decisions and appeals of final decisions,<sup>171</sup> means that a new chemical could be manufactured or imported for several years prior to its evaluation being completed, assuming it is nominated and selected for evaluation in the first place. Unless evaluation takes place, the registrant’s data and assessment are the only official documents regarding the substance under REACH.

### **Best practice**

*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.

<sup>169</sup> REACH, Article 69(3).

<sup>170</sup> REACH, Article 46(4). If it is not completed, it will be deemed to have been completed, which allows another Member State to select it for evaluation. Only one Member State may evaluate a given substance at one time, and there is a process for resolving competing selections. See Article 45.

<sup>171</sup> REACH, Articles 50-52.

## B. Existing chemical review and assessment

### UNITED STATES

In contrast to new chemicals, no routine assessment of existing chemicals is required under TSCA. Differing from both Canada and the EU, the U.S. maintains no list of chemicals warranting priority assessment, and provides no formal mechanism for parties to nominate chemicals for such purposes.<sup>172</sup> Nor does TSCA set forth conditions under which an assessment of an existing chemical must be initiated. Any assessment activities are conducted at EPA's discretion.

The lack of a mandate to identify chemicals warranting assessment, coupled with the dearth of information typically available on existing chemicals that might trigger an assessment, means that the vast majority of such chemicals on the TSCA Inventory have never been assessed. EPA estimates that it has assessed fewer than two percent of the 62,000 chemicals in existence at the time TSCA was enacted.<sup>173</sup> Most of these assessments have been triggered by EPA's receipt of information that indicates a particular chemical or group of chemicals may pose a significant risk. In some cases, this information was submitted under the obligation imposed on companies by the Substantial Risk Reporting Requirement (TSCA §8(e)<sup>174</sup>).

The absence of hazard and exposure information on the great majority of existing chemicals<sup>175</sup>—coupled with EPA's limited authority under §4 to require the generation of data unless it already has some evidence of risk, and the significant time and resources such rules require<sup>176</sup>—severely hampers EPA's ability to initiate an assessment of an existing chemical. (The recent amendments to the TSCA Inventory Update Rule discussed in Section IIIB will, beginning this year, provide EPA with some additional information on production, use and exposure, which could help in the identification of chemicals posing substantial risk of exposure. These reporting requirements are quite limited, however, for chemicals below 300,000 lbs/year. Data will be reported only once every five years and cover only a single year within each reporting cycle. See Appendix A for an analysis indicating why such infrequent reporting will not provide an accurate picture.)

The HPV Challenge, which EPA launched in order to develop more hazard data on high-volume chemicals, should provide EPA with a greater ability to assess the subset of existing chemicals that are produced in the largest volumes. The data sets, some of which have not been submitted, have yet to be reviewed by EPA for quality and completeness. EPA has agreed to do this review, screen

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<sup>172</sup> The closest TSCA comes to mandating such processes is through its establishment of the Interagency Testing Committee (ITC), which recommends chemicals for information reporting or testing, not assessment. ITC is discussed further in Section IVB of this report.

<sup>173</sup> GAO, 2005, p. 18.

<sup>174</sup> For more information about the type and extent of information obtained under §8(e) and how EPA utilizes it, see [www.epa.gov/opptintr/chemtest/pubs/sect8e.htm](http://www.epa.gov/opptintr/chemtest/pubs/sect8e.htm).

<sup>175</sup> As noted in Section IVB, EPA found in 1998 that 43% of HPV chemicals had no publicly available screening-level data, and only 7% had a complete screening-level base set. Data availability for chemicals coming into high production since then appears to be even lower, and EPA has indicated that data availability for lower-volume chemicals is lower still. GAO, 2005, p. 20.

<sup>176</sup> EPA has indicated that a TSCA §4 rule can take between 2–10 years to promulgate and requires significant resources. GAO, 2005, p. 26.

the HPV data, prioritize chemicals based on the hazard data, and develop hazard assessments for high-priority chemicals within two years, and for all program chemicals within four years.<sup>177</sup>

The assessment process EPA intends to apply to HPV chemicals entails several steps:

- An automated screening process by which data on key endpoints are compared against predetermined criteria that are derived primarily from those in the internationally accepted “Globally Harmonized System for the Classification and Labeling of Chemical Substances.”<sup>178</sup> The automated screening will sort HPV chemicals into first, second and third priority groups for further scrutiny.
- A manual review and development of a formal screening-level hazard assessment. Data quality and completeness will also be established at this stage, and a description of any available exposure information will be provided.
- Follow-up using EPA’s existing authorities and procedures, including potential regulatory and voluntary actions to develop more information or apply risk management.

#### CANADA

In contrast to TSCA, CEPA mandates that assessments—formal determinations as to whether substances are or are capable of becoming toxic—must be made in each of three cases:

- for chemicals that have been categorized in through the DSL Categorization process, for which CEPA requires that screening-level risk assessments be conducted;<sup>179</sup>
- for chemicals on the Priority Substances List, the establishment of which CEPA also mandates; and
- for chemicals subject to provincial or certain international decisions to prohibit or restrict them, which CEPA mandates must be reviewed.<sup>180</sup>

The Priority Substances List (PSL), established under CEPA §76, is a list of substances identified by the Ministers to which priority should be given to assess their actual or potential toxicity. CEPA mandates that PSL substances be assessed within five years of the publication of the list.<sup>181</sup> Environment Canada and Health Canada share assessment responsibilities. Two lists

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<sup>177</sup> EPA agreed to implement an HPV chemical screening process within this time frame, as proposed by its federal advisory committee, the National Pollution Prevention and Toxics Advisory Committee. See [www.epa.gov/oppt/npptac/pubs/recommendationfeb2005.pdf](http://www.epa.gov/oppt/npptac/pubs/recommendationfeb2005.pdf).

<sup>178</sup> See OECD Series on Testing and Assessment, No. 33. *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures*, 14 August 2001, available at [www.olis.oecd.org/olis/2001doc.nsf/LinkTo/env-jm-mono\(2001\)6](http://www.olis.oecd.org/olis/2001doc.nsf/LinkTo/env-jm-mono(2001)6).

<sup>179</sup> CEPA §74(a).

<sup>180</sup> §75(3) requires that any decision by the government of a Canadian province or territory, or the government of a member country or of a subdivision of a member country of the OECD, to prohibit or substantially restrict a substance, be reviewed to determine whether the substance is “toxic” or capable of becoming “toxic” as defined under CEPA 1999. This requirement does not apply, however, “to a substance the only use of which in Canada is regulated under another Act of Parliament that provides for environmental and health protection.”

<sup>181</sup> CEPA provides for an extension of this deadline in cases where additional information is needed. See §78(2).

of PSL substances have been established, based on recommendations of a Ministers' Expert Advisory Panel.<sup>182</sup> The first list, published in 1989, contained 44 substances, all of which were assessed. Of these, 25 were determined to be toxic. The second list, published in 1995, contained an additional 25 chemicals. Of these, 23 have been completed, with 18 determined to be toxic; for the two others, the assessment was suspended because insufficient information was found to make a determination, and Health Canada is charged with collecting additional information.<sup>183</sup>

Environment Canada and Health Canada can also identify candidate chemicals for assessment through:

- industry-supplied information;
- public nominations to the PSL;
- assessment of “new” substances similar to existing substances;
- emerging science and monitoring; and
- international assessment or data collection.<sup>184</sup>

Both agencies have published extensive documentation of the procedures and processes they use to conduct screening-level risk assessments<sup>185</sup> and priority substance assessments.<sup>186</sup>

Screening-level risk assessments, whether conducted on chemicals categorized in through the DSL Categorization process or otherwise, and §75 reviews of other jurisdictions' decisions must lead to a proposal by the Ministers specifying one of three outcomes:<sup>187</sup>

- a decision to take no action;
- a decision to add it to the PSL for more in-depth assessment (unless the chemical is already on the PSL); or
- a recommendation that the chemical be added to the List of Toxic Substances, and—where additional requisite findings are made—that it be added to Virtual Elimination List.

The List of Toxic Substances appears as Schedule 1 of CEPA. It includes substances that meet the statutory definition of toxic, and currently contains 85 substances or groups of substances.<sup>188</sup>

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<sup>182</sup> See [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index_e.html).

<sup>183</sup> See *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, p. 9. For the lists themselves and links to the assessment reports for individual substances, see [www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/index_e.html) and [www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/index_e.html).

<sup>184</sup> See [www.ec.gc.ca/substances/ese/eng/overview.cfm](http://www.ec.gc.ca/substances/ese/eng/overview.cfm).

<sup>185</sup> For Health Canada, see [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/screen-eval-prealable/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/screen-eval-prealable/index_e.html) and [www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/index_e.html). For Environment Canada, see [www.ec.gc.ca/substances/ese/eng/dsl/slra.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/slra.cfm).

<sup>186</sup> For Health Canada, see [www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index_e.html) and [www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/index_e.html). For Environment Canada, see [www.ec.gc.ca/substances/ese/eng/psap/psap\\_2.cfm](http://www.ec.gc.ca/substances/ese/eng/psap/psap_2.cfm).

<sup>187</sup> CEPA, §77.

<sup>188</sup> See [www.ec.gc.ca/CEPARegistry/subs\\_list/Toxicupdate.cfm](http://www.ec.gc.ca/CEPARegistry/subs_list/Toxicupdate.cfm). These 85 substances and groups represent more than 1,000 discrete chemicals; see [www.chemicalsubstanceschimiques.gc.ca/manage-gestion/managing-geree/index\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/manage-gestion/managing-geree/index_e.html).

Placement of a substance on the list does not result in controls; rather, it authorizes the government to proceed to regulate it and to require pollution prevention or environmental emergency plans.<sup>189</sup>

The process for adding a chemical to the List of Toxic Substances is quite involved:<sup>190</sup> First an assessment identifying a substance as CEPA-toxic must be developed and finalized. A recommendation from the Ministers of Health and of Environment must then be made and approved by the Cabinet; the recommendation can also include proposing implementation of virtual elimination. Following public comment and finalization of a decision, the Ministers must get the approval of the Governor in Council in order to add the substance to the List of Toxic Substances.

“Virtual elimination” of a toxic substance released into the environment is defined in CEPA §65 as the “ultimate reduction of the quantity or concentration of the substance in the release below the level of quantification specified by the Ministers.” For a toxic substance to be added to the Virtual Elimination List, it must also be found to be persistent, bioaccumulative and inherently toxic to human or nonhuman organisms (i.e., it must be a PBiT); its presence in the environment must result primarily from human activity; and it must not be a naturally occurring radionuclide or inorganic substance. To date, only a single substance—hexachlorobutadiene—has been placed on the Virtual Elimination List.<sup>191</sup> (Twelve other PBiT substances—identified as persistent organic pollutants (POPs) under international conventions—have been banned or restricted or are being managed in accordance with the goal of virtual elimination under Canada’s Toxic Substances Management Policy [see Section VIB].<sup>192</sup>)

Under certain circumstances, a screening-level risk assessment conducted on a chemical categorized in through the DSL Categorization process can lead directly to its listing on the List of Toxic Substances and the Virtual Elimination List, as specified under CEPA §77(3). Requisite findings are that: the substance may have a long-term harmful effect on the environment, it is a PBiT and its presence in the environment results primarily from human activity. As noted in Box 3, as part of the Chemicals Management Plan following DSL Categorization, five substances or groups of substances have recently been added to the List of Toxic Substances, with the aim of prohibiting most uses.<sup>193</sup>

## EUROPEAN UNION

Under the EU’s former Existing Substances Regulations, which have been replaced by REACH, the European Commission, in consultation with the Member States, was charged with regularly drawing up lists of priority substances requiring assessment due to their potential effects on human health or the environment.<sup>194</sup> Four priority lists have been published since 1994, comprising a total of 141 substances.<sup>195</sup> This approach is quite similar to that used in Canada, but there is no counterpart in the U.S.

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<sup>189</sup> See *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, p. 10.

<sup>190</sup> See CEPA §77.

<sup>191</sup> See <http://canadagazette.gc.ca/partII/2006/20061213/html/sor298-e.html>. This listing, first proposed in 2003, was finalized on 13 December 2006.

<sup>192</sup> See [www.ec.gc.ca/CEPARegistry/policies/](http://www.ec.gc.ca/CEPARegistry/policies/).

<sup>193</sup> See Order adding these substances to the List of Toxic Substances, at <http://canadagazette.gc.ca/partII/2006/20061227/html/sor333-e.html>.

<sup>194</sup> See Article 8 of Council Regulation (EEC) 793/93, available at <http://ecb.jrc.it/Legislation/1993R0793EC.pdf>.

<sup>195</sup> See <http://ecb.jrc.it/priority-setting/>.

Priority substances were required to undergo an in-depth risk assessment following procedures specified by regulation and detailed in Technical Guidance Documents. Final risk assessments are available for only about half of these substances.<sup>196</sup> The slow pace of this process was a major motivating factor in the movement toward REACH. The fate of pending risk assessments for priority substances is unclear, given the advent of REACH.

Assessments of existing chemicals under REACH will proceed in the same manner as has already been described for new chemicals, in Section VA.

### **Best practice**

*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 time frame. 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.

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<sup>196</sup> See <http://ecb.jrc.it/esis/index.php?PGM=ora>.



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## VI. Imposing controls to mitigate risk

All three systems have some degree of authority in imposing management measures to mitigate identified risks. There are some differences, however, in the nature and extent of these authorities as they apply to new versus existing substances under the U.S. and Canadian systems, so these will be examined separately. Under REACH, the same procedures will be applied to new and existing substances.

### A. Risk management for new chemicals

#### UNITED STATES

The PMN review and the identical review of a significant new use notice (SNUN), are generally the only times when EPA can use its TSCA §5 authorities to impose risk management requirements on producers or importers of new chemicals or those with new uses subject to a SNUR. Once EPA acts, or decides to take no action and the notification period lapses, the only controls that apply are those imposed through the review. (This differs significantly from the Canadian and REACH systems, where an increase in production volume to the next tier of notification or registration, and in the case of REACH, any significant changes in use, automatically trigger an additional round of information submission. In Canada, this “renotification” must be followed by an additional round of review and consideration of the need to impose risk management measures, and under REACH this can occur if the substance is selected for evaluation.)

The range of outcomes of PMN review is:<sup>197</sup>

- “Drops”—decisions to cease review because a chemical is similar enough to known chemicals of low or no concern, or initial assessment is deemed not to warrant regulation.
- Request for additional information or for further testing, where EPA finds insufficient information exists; depending on the extent of information and length of time needed, this can lead to an agreement to suspend or extend the review.
- Negotiation of a Consent Order with the notifier that allows manufacture subject to certain conditions, which may address exposure or release mitigation (worker protection, controls on disposal, releases to water and other industrial, commercial and consumer activities); testing requirements; or labeling, hazard communication or record keeping requirements. Typically EPA extends the assessment period in these cases.<sup>198</sup> The conditions in such Consent Orders legally apply only to the original notifier, but can be extended to any other manufacturer, processor or user through the concurrent issuance of a Significant New Use Rule (SNUR).
- Issuance of a SNUR without a Consent Order, done when EPA finds that the extent of exposure or risk posed by the notifier’s production and use does not warrant regulation, but

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<sup>197</sup> EPA, OPPT Overview, 2007, pp. 8-10.

<sup>198</sup> EPA has authority under TSCA §5(c) to unilaterally extend the review period for up to 90 days. Alternatively, a consensual “suspension” of the review can be requested by the submitter, under 40 CFR §720.75(b).

that other production or use scenarios could. Such a SNUR requires notification by the original notifier or anyone else who engages in the activities defined by EPA as constituting a significant new use.<sup>199</sup>

- Withdrawal of a PMN by the notifier, usually in the face of EPA action.
- Issuance of an immediately effective regulation under TSCA §5(f) imposing production limits or other controls, or an order prohibiting manufacture or use of the chemical. This has happened only in the rare cases when EPA has been able to make the requisite finding that the activities described in a PMN present or will present an unreasonable risk.<sup>200</sup>

The extent to which EPA used these options since TSCA was enacted through the end of September 2005 is shown in Table 6.<sup>201</sup>

TABLE 6  
**Regulatory (and Voluntary Testing) Actions on 36,600 PMNs Reviewed through 30 September 2005**

<u>Regulatory Action</u>	<u>Number</u>
Consent Orders without SNURs	586
Consent Orders with SNURs	734
Independent SNURs	575
§5(f) Actions	4
PMNs withdrawn, often in face of EPA action	1,705
Approximate Voluntary Testing Actions	300
<b>Total Actions</b>	<b>3,899</b>

Source: Environmental Defense, based on EPA, OPPT Overview, 2007, p. 11.

## CANADA

Under CEPA, the review of a New Substance Notification (NSN) for a substance can yield one of three outcomes:<sup>202</sup>

- No suspicion of being “toxic.” The notifier is informed and can commence manufacture; however, the substance is not placed on the DSL unless the information required at the highest tier has been submitted and its review determines that there is still no suspicion

<sup>199</sup> EPA is not required to make a risk-based finding in order to issue a SNUR, but it must consider a number of factors in determining that an activity constitutes a “significant new use,” including but not limited to the projected production and processing volume of the chemical, and the anticipated extent to which the use increases the type, form, magnitude and duration of exposure to humans or the environment. See TSCA §5(a)(2).

<sup>200</sup> This §5(f) authority authorizes EPA to take action equivalent to that under §6, which applies primarily to existing chemicals. In both cases, the finding that must be made by EPA is that the activity “presents or will present an unreasonable risk.” The difference in this case is the ability to impose controls that are effective immediately, rather than through a full notice-and-comment rulemaking procedure. EPA has exercised this authority only four times in the history of TSCA. GAO, 2005, p. 17 and Appendix V.

<sup>201</sup> EPA, OPPT Overview, 2007, p. 11.

<sup>202</sup> See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 9.5.

of the substance being toxic. Meanwhile any additional manufacturers must submit a notification.

- No suspicion of being “toxic” based on the activities indicated in the NSN, but a “significant new activity” involving the substance beyond those in the NSN may result in the substance becoming toxic. In this case, a Significant New Activity (SNAc) Notice (akin to the U.S.’s SNUR) is usually issued specifying: a) activities that require notification (or renotification if undertaken by the original notifier) prior to initiating them, b) activities that are allowed without notification, or c) both. Activities requiring notification are those deemed able to significantly increase the amount or concentration of a substance in the environment or significantly alter the type or magnitude of exposure to it. A SNAc Notice applies to the original notifier and any users of the substance. If a substance covered by a SNAc Notice meets all applicable information requirements and is still not suspected of being toxic based on the notified activities, it is placed on the DSL with an “S” flag, and subsequently the SNAc Notice applies to any manufacturer, importer or user.
- Suspicion of being or capable of becoming “toxic.” The government may then:
  - permit manufacture or import subject to certain conditions (limiting, for example, the quantity, physical form, use or disposal of the substance);
  - prohibit manufacture or import for up to two years, at which time the prohibition lapses unless regulation of the substance has been proposed; in the latter case, the prohibition lapses once the regulation takes effect; or
  - prohibit manufacture or import pending submission by the notifier and assessment by the government of additional information.

In such cases, the assessment period is usually extended to allow time for the development and approval of the risk management measures or information requirements to be imposed. Substances subject to conditions or whose production is prohibited cannot be placed on the DSL, and must continue to be notified by any new manufacturer or importer. Regulated substances may be placed on the DSL, with their production and use subject to the regulatory requirements.

Between 1994 and June 2006, the following number of actions was taken on NSNs for chemicals:<sup>203</sup>

- 7 ministerial prohibitions, 6 of which were maintained by proposal of a regulation<sup>204</sup>
- 87 ministerial conditions
- 41 SNAcs
- 5 prohibitions pending testing

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<sup>203</sup> CEPA New Substances Program Statistics, 1994-2006, spreadsheet provided to the author by Bernard Madé, Director, New Substances Branch, Environment Canada, 23 June 2006.

<sup>204</sup> Personal communication to author on 5 January 2007, from Bernard Madé, Director, New Substances Branch, Environment Canada.

## EUROPEAN UNION

Two distinct authorities exist under REACH through which risk management can be required of producers, importers or their downstream users. These are the authorization and restriction processes, and they apply in the same manner to new and existing substances.

### *Authorization*

Manufacturers and users of chemicals subject to REACH's authorization provisions can only make or use the chemical if specifically authorized to do so. Authorizations are use based, that is, they apply only to specifically designated uses of a chemical.

1. *The burden of proof for authorization:* REACH imposes certain burdens of proof on applicants for an authorization: They must demonstrate that the use of the chemical is “adequately controlled,” or for substances that either cannot meet this burden or are ineligible for such a designation (certain SVHCs), applicants must demonstrate that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies. (Box 5 explores the role that substitution plays in REACH's authorization process.)

Under TSCA (and to a lesser extent CEPA), to prohibit or restrict the production or use of a chemical, the government must demonstrate risk, that benefits outweigh costs and that viable alternatives exist.

In contrast, under TSCA (and to a lesser extent CEPA), in order to prohibit or restrict the production or use of a chemical, the government must demonstrate risk (i.e., lack of adequate control), that the benefits of the regulation outweigh the costs and that viable alternatives exist. If, in practice, REACH succeeds in actually reversing the burden of proof, this will represent a major paradigm shift in chemicals policy.

### **Box 5: The role of substitution in REACH authorization**

REACH states that the aim of its authorization requirement is to assure that “the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies when these are economically and technically viable.”<sup>205</sup> The role of substitution of SVHCs has been one of the most contentious aspects of REACH. The preamble sets forth the principle that substitution should be required when a substance poses an unacceptable risk—but also that any such decision must take into account the availability and safety of alternatives and the socio-economic benefits of the substance in question.<sup>206</sup> REACH stops short of mandating substitution, instead requiring that those applying for authorizations analyze the availability, viability and risks of alternatives. If viable alternatives are identified, a substitution plan and timetable for implementation are required.

<sup>205</sup> REACH, Article 55.

<sup>206</sup> REACH Preamble, paragraphs 73 and 74.

Requiring an applicant to analyze whether alternatives are technically and economically viable for that applicant<sup>207</sup> begs the question, however, as to what motive the applicant has to actually find suitable alternatives—when that would require development and implementation of a plan to replace the very chemical for which authorization is being sought.<sup>208</sup> Herein lies a core dilemma within REACH, or in any chemicals policy that seeks to mandate or drive substitution. Producers or users of a chemical are the ones who know the most about the functionality, performance characteristics and needs, and the economics of their chemical. On the other hand, they also have the highest vested interest in maintaining their ability to continue to produce or use that chemical and are likely to dispute the viability of a claimed substitute. To what extent is it possible for government to insert itself into such a process—and deliver the necessary expertise and objectivity?

REACH could also provide incentives for substitution in less direct ways.<sup>209</sup> These include:

- public, customer, consumer and competitor access to information identifying, for example, those substances expected to be subject to authorization, the risks of these and other potentially safer chemicals, the extent to which these substances are present in consumer products and those substances for which applications for authorization have been submitted (see Section VIIA); and
- the requirement to demonstrate the ability to control risks, both in registering a substance and in applying for authorization to use a SVHC; and
- the authority for government, and to a lesser extent the ability of other parties, to scrutinize and independently assess the information and documentation submitted by producers and users in both the registration and authorization processes.

REACH's approach to promoting substitution of the most dangerous chemicals through these means will be tested as it is implemented over the coming years. It provides an important and untried experiment in the debate over chemicals policy.

The REACH authorization process itself is quite involved, as described below.

*2. Identifying chemicals to be subject to authorization:* The Chemicals Agency is responsible for developing and maintaining a list of substances identified as being of very high concern and therefore candidates to be subject to authorization. Such substances include the following:

- substances that meet REACH's criteria for persistent, bioaccumulative and toxic (PBT);
- substances that meet REACH's criteria for very persistent and very bioaccumulative (vPvB);
- Category 1 or 2 carcinogens;

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<sup>207</sup> See REACH, Article 60(5).

<sup>208</sup> Government can consider information in addition to that provided by the applicant, and under REACH it will publicize uses of a chemical for which applications for authorizations have been submitted, and seek public comment on the availability of alternatives. See REACH, Article 64(2).

<sup>209</sup> This potential of REACH is explored in more detail in Lahl, U., "REACH – Assessment of the Political Agreement," 2006, available at [www.bmu.de/english/chemical\\_safety/downloads/doc/38542.php](http://www.bmu.de/english/chemical_safety/downloads/doc/38542.php).

- Category 1 or 2 mutagens;
- Category 1 or 2 reproductive toxins; and
- substances—such as those having endocrine disrupting properties, or those having PBT properties or vPvB properties that do not meet REACH’s criteria but for which there is scientific evidence of probable serious effects to human health or the environment—that give rise to “an equivalent level of concern” to the other substances listed above, identified on a case-by-case basis.<sup>210</sup>

Dossiers must be prepared on substances proposed to be added to the candidate list, which can be undertaken by Member States or by the Agency in response to a request from the European Commission. The dossiers are subject to comment from the Agency, Member States and all other interested parties. If no comments are received, or if an agreement to list the substance is reached by a designated committee of the Member States after consideration of comments received, the substance is placed on the Agency’s candidate list.<sup>211</sup>

From this candidate list, the Agency recommends substances to be subject to authorization, giving priority to substances that have PBT or vPvB properties, wide dispersive use or high volumes. Each recommendation of a substance must include: a) “transitional arrangements”: i) the “sunset date,” or the date after which marketing and use of the substance is prohibited unless authorized; and ii) a date at least 18 months earlier than the sunset date by which applications for authorization must be received; any uses included in such applications may continue even after the sunset date until a final decision on the application is reached; b) review periods for certain uses, if appropriate; and c) uses or use categories to be exempted, if any, and the conditions for such exemptions.<sup>212</sup>

The number of substances recommended by the Agency is to “take account of the Agency’s capacity to handle applications in the time provided for.”<sup>213</sup> The list of recommendations is then made available for comment, with specific solicitation of views on any uses of a given substance that should be exempted from the authorization requirement. The Agency’s recommendations, amended based on comments received, are forwarded to the Commission. Initial recommendations are to be made within two years of REACH enactment, and further recommendations made at least every two years thereafter.

Final decisions to designate a substance as subject to authorization are made by the Commission, using a formal regulatory procedure that entails referral to and approval by a regulatory committee comprised of Member State representatives.<sup>214</sup> Once final, “a manufacturer, importer or downstream user cannot place the substance on the market for a use or use it himself, unless the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorized.”<sup>215</sup>

*3. Grounds for granting authorizations:* Under REACH, the Commission is assigned the authority

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<sup>210</sup> REACH, Article 57.

<sup>211</sup> REACH, Article 59.

<sup>212</sup> REACH, Article 58.

<sup>213</sup> REACH, Article 58(3).

<sup>214</sup> REACH, Article 58(1), referring to Article 132(3), in turn referring to Articles 5 and 7 of Council Decision 1999/648/EC, which describe the formal regulatory procedure to be followed.

<sup>215</sup> REACH, Article 56(1).

to grant authorizations.<sup>216</sup> REACH specifies that, in general, authorizations are to be granted “if the risk to human health or the environment from the use of a substance ... is adequately controlled.”<sup>217</sup> However, an authorization based on this “adequate control” provision cannot be granted for the following substances:

- substances meeting the criteria used to identify PBTs or vPvBs;
- substances for which it is not possible to determine a threshold of effect<sup>218</sup> and that are:
  - Category 1 or 2 carcinogens;
  - Category 1 or 2 mutagens;
  - Category 1 or 2 reproductive toxins; or
  - “equivalent level of concern” substances; and
- PBT or vPvB substances that do not meet the specified criteria but are deemed on a case-by-case basis to pose an equivalent level of concern.<sup>219</sup>

Use of substances that cannot be established to be “adequately controlled” or are ineligible for such a designation (those just listed) may nevertheless be authorized “if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.”<sup>220</sup> In judging whether there are “suitable alternative substances or technologies,” the Commission must consider whether shifting to alternatives would reduce overall risk to human health and the environment as well as “the technical and economic feasibility of alternatives *for the applicant*” for authorization.<sup>221</sup>

*4. Applying for authorization:* Applications for authorization may be submitted to the Agency by manufacturers, importers or downstream users of a substance. They must include “an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution,” and may include a socioeconomic analysis supporting the requested use of the substance. If the analysis of alternatives identifies any suitable ones, then a substitution plan and timetable must be proposed.<sup>222</sup> Public notice of the applications will be made to provide an opportunity for interested parties to submit information on alternative substances or technologies.<sup>223</sup>

Two Agency committees—the Committee for Risk Assessment and the Committee for Socio-economic Analysis—review the applications and any related information submitted by other parties and issue draft opinions within ten months of receipt of the application. The Risk Assessment Committee’s opinion is to address the risks arising from use of the substance, as well

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<sup>216</sup> REACH, Article 60.

<sup>217</sup> REACH, Article 60(2). “Adequate control” is further defined in Annex I, Section 6.4.

<sup>218</sup> Such a threshold would be established through the assignment of a derived no-effect level (DNEL) for a human health effect or a predicted no-effect concentration (PNEC) for an environmental effect. See REACH, Annex I, Section 6.4.

<sup>219</sup> REACH, Article 60(3).

<sup>220</sup> REACH, Article 60(4).

<sup>221</sup> REACH, Article 60(5). Emphasis added.

<sup>222</sup> REACH, Article 62(4)(e) and (f).

<sup>223</sup> REACH, Article 64(2).

as any proposed alternatives. The Socio-economic Analysis Committee's opinion is to address the availability, suitability and technical feasibility of proposed alternatives where such information was submitted. These draft opinions are provided to the applicant for comment, and then finalized and forwarded to the Commission and the Member States. The Commission makes a final decision on the authorization, using a formal regulatory procedure that entails referral to and approval by a regulatory committee comprised of Member State representatives.<sup>224</sup>

For an authorization granted to a manufacturer or importer, downstream users of the substance may use it in accordance with the conditions of the authorization, but must notify the Agency of such use within three months of receiving the substance.<sup>225</sup> Conversely, for an authorization granted to a downstream user for a particular use, the upstream manufacturer or importer of the substance may place it on the market for that use.<sup>226</sup>

All authorizations, which can include conditions on use and monitoring requirements, are to be subject to a time-limited review, with the review period to be set on a case-by-case basis.<sup>227</sup> A review may be initiated by the Commission at any time if significant changes have occurred, environmental quality standards or other environmental objectives are not met, or new information on possible substitutes for the substance becomes available. An authorization may be amended or withdrawn under certain circumstances, including if new information or the emergence of viable alternatives means that the authorization would not have been granted.<sup>228</sup>

### *Restriction*

In addition to authorizations for a substance, restrictions may be imposed “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis”<sup>229</sup> and is not adequately controlled.<sup>230</sup> Restrictions can apply even to substances not subject to registration, for example, chemicals produced or imported below one metric ton/year or otherwise exempted from registration, or chemicals not yet registered.

There are three means by which the restriction process can be initiated:

- For CMR substances that could be used by consumers, the Commission may directly propose a restriction on such consumer use.
- For other substances:
  - The Commission is to request that the Agency, within 12 months, prepare a dossier on the substance and propose restrictions it deems needed, taking into account all available information on the substance.

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<sup>224</sup> REACH, Article 64. The formal regulatory procedure used is that referred to in Article 132(3), which in turn refers to Articles 5 and 7 of Council Decision 1999/648/EC.

<sup>225</sup> REACH, Articles 56(2) and 66(1).

<sup>226</sup> REACH, Article 56(1)(e).

<sup>227</sup> REACH, Article 60(8).

<sup>228</sup> REACH, Article 61(2) and (3).

<sup>229</sup> REACH, Article 68(1).

<sup>230</sup> REACH, Article 69(1).



- Alternatively, a Member State may prepare such a dossier on its own initiative.

All such dossiers are to be made publicly available and open for comment, and information germane to a socio-economic analysis of the restrictions is to be solicited.

For the restriction proposals on CMR substances made directly by the Commission, the proposal is immediately referred to a regulatory committee, comprised of Member State representatives, for review and approval, using a formal regulatory procedure.<sup>231</sup> This approval process, which bypasses much of the more involved procedure that otherwise applies, is considered warranted for substances of such high concern.

For proposed restrictions on other substances initiated through dossier preparation, a procedure similar to that used for authorizations is followed. Two Agency committees—the Committee for Risk Assessment and the Committee for Socio-economic Analysis—review the proposed restrictions and any related information submitted by other parties and issue draft opinions.<sup>232</sup> Within nine months of the receipt of the proposal, the Risk Assessment Committee is to formulate an opinion that addresses whether the proposed restrictions are appropriate to reduce the risks of the substance. Within 12 months, the Socio-economic Analysis Committee is to formulate a draft opinion on the socio-economic impacts of the proposed restrictions. This draft opinion is to be provided for public comment and revised accordingly. Both final opinions are to be made public and forwarded to the Commission. The Commission makes a final decision on the restriction, explaining any deviation from the original proposal, using a formal regulatory procedure that entails referral to and approval by a regulatory committee comprised of Member State representatives.<sup>233</sup> Decisions concerning restrictions must consider the socio-economic impact, including the availability of alternatives.<sup>234</sup>

### **Best practice**

*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 nontransparent manner.
- REACH will establish such criteria.

<sup>231</sup> REACH, Article 73. The formal regulatory procedure used is that referred to in Article 132(3), which in turn refers to Articles 5 and 7 of Council Decision 1999/648/EC.

<sup>232</sup> REACH, Articles 70 and 71.

<sup>233</sup> REACH, Article 73. The formal regulatory procedure used is that referred to in Article 132(3), which in turn refers to Articles 5 and 7 of Council Decision 1999/648/EC.

<sup>234</sup> REACH, Article 68(1).

## B. Risk management for existing chemicals

### UNITED STATES

EPA's regulatory authorities for existing chemicals are specified in TSCA §6. It can issue regulations to:<sup>235</sup>

- §6(a)(1): prohibit (or limit) the manufacture, processing or distribution in commerce of a substance;
- §6(a)(2): prohibit (or limit) the manufacture, processing or distribution in commerce of substance for a particular use or for a particular use at a particular concentration;
- §6(a)(3): require a substance, or any article containing the substance, to be labeled or accompanied by warnings and instructions for use, distribution or disposal;
- §6(a)(4): require manufacturers and processors of a substance to keep records of manufacturing or processing methods and conduct reasonable monitoring or testing necessary to assure regulatory compliance;
- §6(a)(5): prohibit or otherwise regulate commercial use of a substance;
- §6(a)(6): prohibit or otherwise regulate disposal of a substance, or any article containing the substance, by manufacturers, processors, or anyone who uses it or disposes of it for commercial purposes; or
- §6(a)(7): require manufacturers or processors to notify distributors, other persons in possession of the substance and the general public of the risk of injury, and replace or repurchase the substance.

To issue a regulation under TSCA §6, EPA must determine that activities involving a substance “present or will present an unreasonable risk of injury to health or the environment.” As discussed in more detail in Section II of this report, this is a significant burden. EPA must evaluate not only health and environmental effects and exposure, but also the benefits of the chemical, the availability of substitutes and the economic effects of a rule. In order to do so, EPA must prepare analyses of hazard and exposure, conduct a risk assessment, develop a substitution analysis, provide a full economic (cost-benefit) analysis and assess the consequences of the regulation on technological innovation. EPA must also develop and finalize its regulation through full notice-and-comment rulemaking.

Not surprisingly, these authorities have seldom been used: Since adoption of TSCA in 1976, EPA has succeeded in developing TSCA §6 rules for only five substances: polychlorinated biphenyls (PCBs), by virtue of a mandate from the U.S. Congress; fully halogenated chlorofluoroalkanes used as aerosol propellants; dioxin in certain wastes; asbestos (limited to products no longer in commerce, because the initial rule was vacated by U.S. courts after legal challenge); and hexavalent chromium used in water treatment chemicals in comfort cooling towers.<sup>236</sup>

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<sup>235</sup> This list is taken virtually verbatim from EPA, “EPA Authorities under TSCA,” 2005, p. 23 .

<sup>236</sup> GAO, 2005, p. 58.

### *Voluntary initiatives*

In part because of the onerous nature of rulemaking under TSCA §6, EPA has increasingly pursued voluntary agreements with industry to implement risk management for chemicals of concern.<sup>237</sup> A recent example involves perfluorooctanoic acid (PFOA) and related fluoropolymers and fluorotelomers used to make nonstick cookware, stain-resistant textile treatments, grease-resistant food packaging and many other industrial applications. Concerns about PFOA include its high persistence in the environment, its widespread detection both in the environment and in the blood of the general U.S. population, and its implication in developmental and other adverse impacts seen in laboratory studies. Last year, the majority of the members of an expert panel convened by EPA's Science Advisory Board concluded that PFOA should be considered "likely to be carcinogenic."<sup>238</sup>

Responding to these concerns, EPA announced in January 2006, the "2010/15 PFOA Stewardship Program,"<sup>239</sup> which challenged the eight major U.S. producers of PFOA and related chemicals to make two commitments:

- achieve no later than 2010, a 95% reduction measured from a year-2000 baseline, in facility emissions to all media and product content levels of PFOA, precursor chemicals that can break down to PFOA and related higher homologue chemicals; and
- work toward the elimination of these chemicals from emissions and products by five years thereafter, or no later than 2015.

All eight companies have accepted the challenge.<sup>240</sup>

Other examples of voluntary efforts include:

- The Safer Detergents Stewardship Initiative, which recognizes companies that phase out or reduce the manufacture or use of nonylphenol ethoxylate surfactants (NPEs). These surfactants and their breakdown products, including nonylphenol, are toxic to aquatic organisms.<sup>241</sup>
- The Furniture Flame Retardancy Partnership, which seeks to identify, assess and implement safer chemical and non-chemical substitutes for pentabromodiphenyl ether (pentaBDE) used as a flame retardant in furniture foam. The partnership includes furniture makers and an environmental nongovernmental organization, as well as producers of flame retardant chemicals.<sup>242</sup>
- The Sustainable Futures Initiative, which EPA indicates is "an approach that encourages pollution prevention in new chemical development through the transfer of EPA's chemical risk screening methodologies." Companies participating in the initiative receive

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<sup>237</sup> See generally information on EPA's Design for the Environment and Green Chemistry Programs, available at [www.epa.gov/opptintr/dfe/](http://www.epa.gov/opptintr/dfe/) and [www.epa.gov/greenchemistry/](http://www.epa.gov/greenchemistry/), respectively.

<sup>238</sup> See EPA-SAB-06-006, *SAB Review of EPA's Draft Risk Assessment of Potential Human Health Effects Associated with PFOA and Its Salts*, 30 May 2006, available at [www.epa.gov/sab/panels/pfoa\\_rev\\_panel.htm](http://www.epa.gov/sab/panels/pfoa_rev_panel.htm).

<sup>239</sup> See [www.epa.gov/oppt/pfoa/pubs/pfoastewardship.htm](http://www.epa.gov/oppt/pfoa/pubs/pfoastewardship.htm).

<sup>240</sup> See [www.epa.gov/opptintr/pfoa/pubs/commitments.htm](http://www.epa.gov/opptintr/pfoa/pubs/commitments.htm).

<sup>241</sup> See [www.epa.gov/opptintr/dfe/pubs/projects/formulat/sdsi.htm](http://www.epa.gov/opptintr/dfe/pubs/projects/formulat/sdsi.htm).

<sup>242</sup> See [www.epa.gov/opptintr/dfe/pubs/projects/flameret/index.htm](http://www.epa.gov/opptintr/dfe/pubs/projects/flameret/index.htm).

training and agree to employ the same suite of tools EPA uses to assess new chemicals. In exchange, participants can qualify for expedited review of their new chemical submissions, receive public recognition, and for small businesses, gain access to technical assistance from EPA. Through the initiative, several companies have screened their new chemicals using EPA's methodologies, and screened their existing chemical inventories to identify, and in some cases eliminate or reduce their use of, PBTs.<sup>243</sup>

## CANADA

As described in more detail below, CEPA authorizes a number of risk management measures to be taken for existing substances. In order for regulations or requirements for pollution prevention plans or environmental emergency plans to be imposed, however, the chemical must be on or recommended to be added to the List of Toxic Substances.<sup>244</sup>

Once listed, government has two years to develop and propose a management strategy, and a further 18 months to finalize the strategy. Canada's *Toxic Substances Management Policy*<sup>245</sup> lays out two tracks for management of such chemicals of concern:

- For Track 1 substances—chemicals on the List of Toxic Substances that are found to be CEPA-toxic, persistent and bioaccumulative, and whose presence in the environment results primarily from human activity—the policy aim is virtual elimination from the environment. The risk management emphasis is on the prevention of releases, rather than their control or remediation (unless the chemical is already in the environment). The end aim is set independent of socio-economic factors, although deciding how it is to be met (e.g., interim targets, timelines) will consider such factors.
- For Track 2 substances—chemicals of concern that do not meet all of the above criteria—the policy aim is life-cycle management to prevent or minimize environmental releases. Pollution control and pollution prevention measures are to be pursued. Socio-economic factors are expected to play more of a role in setting objectives. Virtual elimination is not ruled out, but would be pursued only for specific products or uses where the chemical “poses unacceptable risks to the environment or human health.”<sup>246</sup>

According to the *Policy*, producers and users of a Track 1 substance bear the burden of proof of demonstrating that the substance can be managed throughout its lifecycle without measurable release. Monitoring requirements are to be applied. Track 1 substances for which such risk

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<sup>243</sup> See [www.epa.gov/oppt/newchems/pubs/sustainablefutures.htm](http://www.epa.gov/oppt/newchems/pubs/sustainablefutures.htm).

<sup>244</sup> See *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, p. 11.

<sup>245</sup> See [www.ec.gc.ca/toxics/TSMP/en/execsum.cfm](http://www.ec.gc.ca/toxics/TSMP/en/execsum.cfm).

<sup>246</sup> See *Toxic Substances Management Policy*, pp. 5-7, available at [www.ec.gc.ca/toxics/TSMP/en/tsmp.pdf](http://www.ec.gc.ca/toxics/TSMP/en/tsmp.pdf). The great majority of substances on the List of Toxic Substances are designated Track 2, and most of the Track 1 substances have already been banned in Canada or other countries. See links to individual substances at [www.ec.gc.ca/TOXICS/EN/mainlist.cfm?par\\_actn=s2#1](http://www.ec.gc.ca/TOXICS/EN/mainlist.cfm?par_actn=s2#1).

management measures are unable to reduce releases below the level of detection (with quantitative limits set by the government) are to be targeted for phaseout of production and use.<sup>247</sup>

Risk management measures available under CEPA 1999 include:<sup>248</sup>

- establishing regulations to impose restrictions on an activity related to a substance, or to set limits on the concentrations of a substance that can be used, released to the environment or be present in a product;<sup>249</sup>
- mandating preparation and implementation of pollution prevention plans outlining actions to prevent or minimize the creation or release of pollutants and waste;
- mandating preparation and implementation of environmental emergency plans addressing prevention, preparedness, response and recovery from an environmental emergency;
- setting environmental quality objectives, including goals for pollution prevention or control of toxic substances and ambient environmental quality targets or maximum acceptable levels;
- developing environmental codes of practice recommending procedures, practices, or quantities of releases relating to facilities and activities during any phase of development and operation involving a substance, and any subsequent monitoring activities;
- developing environmental quality guidelines that recommend a concentration for toxic substances in surface water, agricultural water, soil, sediment, or human or animal tissue; developing environmental release guidelines, including standards expressed as concentrations or quantities, for the release of substances into the environment from facilities or activities;
- negotiating cooperative agreements with provincial, territorial, aboriginal or foreign governments or any person addressing the creation, operation and maintenance of a system for monitoring environmental quality; and
- developing administrative agreements for work sharing between the federal government and provincial, territorial, or aboriginal governments or aboriginal peoples to administer CEPA 1999.

Regulatory prohibitions and restrictions have been used to a limited extent under CEPA. Nine substances, including DDT and mirex, have been prohibited altogether, and another five have been subject to use restrictions or concentration limits in mixtures or products.<sup>250</sup> Recently a

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<sup>247</sup> See *Toxic Substances Management Policy*, pp. 5-6, available at [www.ec.gc.ca/toxics/TSMPE/en/tsmp.pdf](http://www.ec.gc.ca/toxics/TSMPE/en/tsmp.pdf). As noted earlier, the first substance – hexachlorobutadiene – was formally added to the Virtual Elimination List in December 2006. In addition, twelve PBiT substances – identified as persistent organic pollutants (POPs) under international conventions – have been banned or restricted or are being managed in accordance with the goal of virtual elimination as Track 1 substances under Canada's *Toxic Substances Management Policy*. See <http://www.ec.gc.ca/CEPARegistry/policies/>.

<sup>248</sup> This list is taken virtually verbatim from *A Guide to Understanding the Canadian Environmental Protection Act, 1999*, 10 December 2004, pp. 11-12.

<sup>249</sup> For a list of current and proposed regulations, see [www.ec.gc.ca/CEPARegistry/regulations/](http://www.ec.gc.ca/CEPARegistry/regulations/).

<sup>250</sup> See the Prohibition of Certain Toxic Substances Regulations, at <http://canadagazette.gc.ca/partII/2005/20050309/html/sor41-e.html>; and Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes), at <http://canadagazette.gc.ca/partII/2006/20061129/html/sor279-e.html>.

proposed regulation was issued to prohibit production, import, use or sale of four fluorotelomer-based substances except when present in manufactured items (articles).<sup>251</sup>

Sector-specific regulations that restrict the use of certain toxic substances have also been used, covering, for example, chlorinated solvents in degreasing and dry cleaning.<sup>252</sup>

Requirements for companies to develop and implement pollution prevention plans, authorized under CEPA §56, have been imposed for seven substances, groups of substances or specific uses (e.g., wood preservatives).<sup>253</sup> The plans must incorporate certain standard elements, and a notice of implementation and, in some cases, interim progress reports are required, but these plans need be submitted only upon request. Although certain measures of effectiveness are to be incorporated into individual plans, there does not appear to be a mechanism by which government assesses the overall effectiveness of pollution prevention plans.

Finally, non-regulatory approaches include Guidelines and Codes of Practice, which have been developed in some cases for specific substances or groups of substances used in specific applications or sectors. Guidelines can recommend quantitative limits for certain substances in products, emissions or environmental media; for example, there are Guidelines for volatile organic compounds used in consumer products and for ethylene oxide used in sterilization operations.<sup>254</sup> Codes of Practice offer broader principles and recommendations for appropriate practices and procedures, addressing for example, the reduction of chlorofluorocarbon emissions from refrigeration and air-conditioning systems, and the reduction of dichloromethane emissions from the use of paint strippers in commercial furniture refinishing.<sup>255</sup> Given their non-regulatory nature and the lack of any reporting elements, the extent to which the Guidelines and Codes have been adopted and achieved the intended reductions is not known.

### *Voluntary initiatives*

Although not a formal risk management instrument under CEPA, voluntary Environmental Performance Agreements between government and industry have become the primary tool used to reduce industrial releases (and in a few cases, use) of certain CEPA-toxic substances.<sup>256</sup> Agreements can be negotiated with an individual company, but more typically involve a trade association and seek involvement of multiple member companies. Design elements common to all such Agreements include:

- senior-level commitment from participants;
- clear environmental objectives and measurable results;
- clearly defined roles and responsibilities;
- consultation with affected and interested stakeholders;
- public reporting;

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<sup>251</sup> See Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances), at <http://canadagazette.gc.ca/partI/2006/20060617/html/regle2-e.html>. The exception for manufactured items is proposed because of practical difficulties in identifying the substances in such items when imported; see <http://canadagazette.gc.ca/partI/2006/20060617/html/regle1-e.html>.

<sup>252</sup> See list of current regulations at [www.ec.gc.ca/CEPARRegistry/regulations/](http://www.ec.gc.ca/CEPARRegistry/regulations/).

<sup>253</sup> See list of Notices requiring pollution prevention plans at [www.ec.gc.ca/nopp/p2p/en/p2notices.cfm](http://www.ec.gc.ca/nopp/p2p/en/p2notices.cfm).

<sup>254</sup> See a list of existing Guidelines at [www.ec.gc.ca/CEPARRegistry/guidelines/Guidelines.cfm](http://www.ec.gc.ca/CEPARRegistry/guidelines/Guidelines.cfm).

<sup>255</sup> See a list of Codes of Practice at [www.ec.gc.ca/CEPARRegistry/guidelines/Codes.cfm](http://www.ec.gc.ca/CEPARRegistry/guidelines/Codes.cfm).

<sup>256</sup> See [www.chemicalsubstanceschimiques.gc.ca/manage-gestion/managing-geree/index\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/manage-gestion/managing-geree/index_e.html) and [www.ec.gc.ca/epa-epe/en/index.cfm](http://www.ec.gc.ca/epa-epe/en/index.cfm).

- verification of results;
- incentives and consequences; and
- continual improvement.<sup>257</sup>

Agreements have specific terms of duration, but are monitored by government after their expiration to ensure their objectives continue to be met; if they are not met, options include development of a regulation or imposition of pollution prevention planning requirements. The mandatory options can serve as a regulatory “backstop” for the Agreements should they not meet their stated objectives, and as an incentive for participation in the Agreement. (In at least one case, the government agreed not to advance a regulation of a particular substance only if 100% of the affected companies signed on to the Agreement, which was achieved.)

Currently, there are four active agreements, five that have expired after being carried out and two more in “consultation phase” (i.e., open for public comment).<sup>258</sup> Examples include:

- An Agreement to control emissions of 1,2-dichloroethane (a CEPA-toxic substance) from two Dow Chemical facilities.<sup>259</sup> Under the Agreement, Dow implemented a plan to identify, monitor, repair and prevent future fugitive emission sources. Emission reduction goals were set and reports submitted on an annual basis. Achieved reductions through 2004 (data for 2005 and 2006 are still to come) were 30–44% at one facility (against a 2006 goal of 48%) and 50–60% at the other (2006 goal of 49%). Dow also undertook ambient monitoring for the chemical. A third-party audit of implemented management systems and emissions reductions was conducted, with a second audit to occur this year.
- An Agreement to achieve verifiable reductions in the use, generation and release of specified priority substances in the automotive parts sector.<sup>260</sup> To date, this agreement extends to five automotive-parts manufacturing companies and about 35 facilities, which have committed to:
  - achieve a 20% reduction per unit of output of VOC emissions, and a 3% reduction of carbon dioxide emissions per unit of output, between the 2000 baseline year and 2007;
  - achieve a verifiable reduction in the use, generation and release of specific substances including greenhouse gases, metals and certain categories of halogenated and nonhalogenated hydrocarbons; and
  - screen their inventories and implement pollution prevention plans for these substances.

Results are not yet publicly available. The extent of participation is significant with respect to achieving the VOC objective of the Agreement (35 of about 40 targeted facilities), but less than desired for the other objectives (greenhouse gas emissions

<sup>257</sup> See [www.ec.gc.ca/epa-epe/en/stRpt.cfm](http://www.ec.gc.ca/epa-epe/en/stRpt.cfm).

<sup>258</sup> Personal communication to author on 28 February 2007, from Lori Fryzuk, Head, Regulatory Innovation and Management Systems, Environment Canada; and [www.ec.gc.ca/epa-epe/en/agr.cfm](http://www.ec.gc.ca/epa-epe/en/agr.cfm).

<sup>259</sup> See Agreement at [www.ec.gc.ca/epa-epe/1\\_2-DCE-Dow/en/details.cfm](http://www.ec.gc.ca/epa-epe/1_2-DCE-Dow/en/details.cfm). This five-year Agreement expired in October 2006.

<sup>260</sup> See Agreement at [www.ec.gc.ca/epa-epe/apma/en/details.cfm](http://www.ec.gc.ca/epa-epe/apma/en/details.cfm). This is an active five-year Agreement with a term expiring at the end of this year.

reductions and reduction in use and release of other substances), which are relevant for most of the roughly 300 facilities in Canada.<sup>261</sup>

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Risk management of existing chemicals under REACH will proceed in the same manner as has already been described in Section VIA for new chemicals.

### **Best practice**

*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). 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.

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<sup>261</sup> Personal communication to author on 28 February 2007, from Lori Fryzuk, Head, Regulatory Innovation and Management Systems, Environment Canada



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## VII. Sharing and disclosing information and protecting confidential business information

This section of the report focuses on the aspects of chemicals policies that facilitate or impede the sharing or disclosure of chemical information, including between: government and members of the public, national governments and other levels of government, and actors in chemical supply chains.

### A. Confidential business information (CBI) and information disclosure and access

#### UNITED STATES

TSCA §14 states that, with limited exceptions, information considered to be “trade secrets and commercial or financial information obtained from a person and privileged or confidential” that is reported to or otherwise obtained by EPA “shall not be disclosed” except to federal government employees or their designated contractors, or to law enforcement officials.<sup>262</sup>

Exceptions allow that information:

- shall be disclosed if the EPA Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; and
- may be disclosed when relevant in any TSCA proceeding, except that the disclosure shall be made so as to preserve confidentiality to the extent practicable without impairing the proceeding.

In addition, the general prohibition on disclosure:

- does not prohibit disclosure of health and safety studies or data from such studies, but
- does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

Although health and safety studies and associated data are not eligible for CBI protection, chemical and company identity can be eligible.<sup>263</sup> This allowance can lead to perverse outcomes, such as that a chemical’s adverse effects on mammalian reproduction must be disclosed, but identification of which chemical causes the effect may be kept a secret. An example of where this frequently occurs is in EPA’s public listings of submissions received under TSCA §8(e), which requires the submission of information indicative of substantial risk; whereas a generic name for the substance must be supplied, its specific name and other identifiers such as Chemical Abstract Service

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<sup>262</sup> TSCA §14, citing a provision of the Administrative Procedure Act, §552(b)(4) of Title 5, United States Code,

<sup>263</sup> See, for example, such allowance in EPA’s PMN regulations, 40 CFR §720.85(a), at [www.access.gpo.gov/nara/cfr/waisidx\\_06/40cfr720\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr720_06.html). Elsewhere, EPA regulations state that EPA considers chemical identity to be part of the underlying data to a health and safety study; see, for example, 40 CFR §716.3 and 40 CFR §720.3(k).

(CAS) number are often listed as “confidential”—as are the names of the submitters themselves.<sup>264</sup> TSCA provides that “manufacturers, processors or distributors” submitting information may designate any such information as confidential and submit it separately. Such designations are common; for example, about 95% of PMNs for new chemicals submitted under TSCA contain information, including chemical identity, designated by the submitter as CBI.<sup>265</sup> There is typically no requirement to reassert such claims even after these chemicals enter commerce.<sup>266</sup> EPA does not always require submitters to provide a justification for such designations at the time they are made,<sup>267</sup> and it does not require that these claims be reviewed and approved in order to be retained. In addition, such designations are not time limited and hence do not expire, unless the submitter so designates. EPA has developed extensive regulations and criteria that govern CBI claims, and it has authority to challenge any such designations.<sup>268</sup> It must do so on a case-by-case basis, however, which it has rarely done because of the extensive resources required.<sup>269</sup> A 1992 EPA study identified extensive problems with respect to the extent of inappropriate CBI claims.<sup>270</sup> In the absence of a successful challenge by EPA, the information must be held as confidential.

The provision of §14 that allows disclosures only to federal government employees or their designated contractors effectively prohibits EPA from disclosing any information designated by a submitter as CBI to anyone else—including not only the general public but also foreign governments, U.S. states, Tribes and local governments.<sup>271</sup>

## CANADA

Under CEPA, §§313-321 of Part 11 contain the provisions governing disclosure of information and confidentiality with respect to the exercise of authorities under Part 5 (Controlling Toxic Substances) that are the focus of this report. The relevant provisions are as follows:

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<sup>264</sup> For a recent example, see EPA’s compilation of §8(e) submissions received in July 2006, at [www.epa.gov/oppt/tscas8e/pubs/8esub/2006/8ejul2006.htm](http://www.epa.gov/oppt/tscas8e/pubs/8esub/2006/8ejul2006.htm). Oddly, EPA’s guidance for §8(e) submissions reiterates that “EPA considers chemical identity to be part of, the underlying data to, a health and safety study,” citing 40 CFR §716.3 and 40 CFR §720.3(k). EPA goes on to state: “Consequently, the confidential identity of a chemical substance will not be protected by EPA unless otherwise provided for under section 14 of TSCA and the interpreting regulations in 40 CFR part 2.” See [www.epa.gov/fedrgstr/EPA-TOX/2003/June/Day-03/t13888.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2003/June/Day-03/t13888.htm). Either EPA has not been able or willing to challenge such claims made in §8(e) submissions, or the claims have been found to comport with §14 of TSCA and the interpreting regulations in 40 CFR Part 2.

<sup>265</sup> GAO, 2005, pp. 5, 32; OPPT Overview, 2007, p. 10. The fraction of submitters making CBI claims for chemical identity drops to about 65% for chemicals actually entering commerce, i.e., for which NOCs are filed.

<sup>266</sup> An exception is that a claim to keep chemical identity – but not other information – in a PMN confidential does expire once manufacture of the chemical commences, unless in filing the required Notice of Commencement the notifier again asserts that the chemical identity is CBI; in this latter case, in contrast to the case when filing a PMN, a justification for the CBI claim must also be provided. See 40 CFR §720.85(b), at [www.access.gpo.gov/nara/cfr/waisidx\\_06/40cfr720\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr720_06.html).

<sup>267</sup> Examples of cases where up-front justification is explicitly required include CBI claims: a) for chemical identity and facility identification under EPA’s TSCA Inventory Update Rule; see [www.epa.gov/oppt/iur/pubs/guidance/confidentiality.htm](http://www.epa.gov/oppt/iur/pubs/guidance/confidentiality.htm); and b) for “substantial risk” information required to be submitted under TSCA §8(e); see [www.epa.gov/oppt/tscas8e/pubs/confidentialbusinessinformation.htm](http://www.epa.gov/oppt/tscas8e/pubs/confidentialbusinessinformation.htm).

<sup>268</sup> See generally 40 CFR Part 2, Subpart B, at [www.epa.gov/foia/foiaregs.htm](http://www.epa.gov/foia/foiaregs.htm), and more specifically, the special rules applicable to TSCA at 40 CFR §2.306 and the criteria for use in confidentiality determinations at 40 CFR §2.208.

<sup>269</sup> GAO, 2005, pp. 5, 33.

<sup>270</sup> Cited in GAO, 2005, pp. 32-33.

<sup>271</sup> See EPA, OPPT Overview, 2007, p. 21.

- §313 provides that submitted information may be accompanied by a written request that it be kept confidential, along with any supplemental information that may be prescribed.
- §314 prohibits government disclosure of such information, subject to certain exceptions:
  - §315 authorizes disclosure where: “(a) the disclosure is in the interest of public health, public safety or the protection of the environment; and (b) the public interest in the disclosure clearly outweighs in importance (i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and (ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.” The section also requires that all reasonable efforts be made to provide advance notice of the disclosure to the submitter.
  - §316 allows disclosure in order to administer or enforce CEPA, and also to other governments within Canada as well as to foreign governments and international organizations, where:
    - the purpose is administration or enforcement of a law, and
    - the recipient takes appropriate steps to keep the information confidential.
- §319 provides for the development of regulations specifying information that must accompany a confidentiality request.

Whereas regulations governing confidential information pursuant to §319 have not been developed, the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* have laid out more specific requirements for making confidentiality requests as part of New Substances Notifications (NSNs).<sup>272</sup> These provisions require submitters to designate which information is being requested to be kept confidential, and to provide supplemental information, including substantiation that “disclosure of the information may reasonably be expected to cause substantial harm to the competitive position of the notifier; and disclosure of the information may reasonably be expected to result in a material financial loss to the company or a material financial gain to its competitors.”

Where the submitter requests that the substance identity be treated as confidential, an acceptable “masked name” must be provided.<sup>273</sup> The request must also be backed up by a description of “the detrimental effects to the competitive position of the notifier’s company that would result from the identity of the substance appearing on the DSL or in any other publication” and “the manner in which a competitor could use the identity of the substance.” In addition, the submitter must indicate:

- whether the substance for which a masked name is proposed is or will be present in waste, emissions or effluents released to the environment;
- whether the substance is in a product available to the public, and can be identified by analysis of the product;

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<sup>272</sup> See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Section 7, p. 77.

<sup>273</sup> This requirement actually derives directly from the statute: see CEPA §88.

- for what purpose the substance is manufactured or used; and
- whether, to the best of the submitter’s knowledge, any domestic or foreign government has ever found that the substance meets any of the criteria specified in the definition of “toxic” under §64 (if so, details are to be provided).

The intent of requiring this information is to potentially identify circumstances under which disclosure of substance identity may be needed or warranted. For example, information indicating that a substance is already considered toxic by another government, or that the public, consumers or the environment may be exposed to it, is relevant in determining whether to allow the substance identity to be masked or whether it should be disclosed pursuant to §315.<sup>274</sup>

All requests for CBI status are reviewed to determine the acceptability of the claims.<sup>275</sup>

Neither CEPA nor the NSN Guidelines provides that health and safety studies or data are ineligible for CBI status, in contrast to TSCA, nor do they set time limits on CBI claims.<sup>276</sup> Under the tiered notification scheme applicable to new substances, however, confidentiality claims would presumably need to be asserted by the notifier and reviewed by government in each round of notification.

Interestingly, under Part 3 of CEPA, there are different provisions governing confidentiality. Part 3 addresses the conduct of research and environmental assessments, the development of objectives, guidelines and codes of practice, and the development of inventories of environmental data.<sup>277</sup> The confidentiality provisions appear in §§51–53. Although not applicable to information submitted under Part 5, they nevertheless contain some interesting additional features:

- §52 delineates the sole reasons for which a confidentiality request may be made:
  - the information constitutes a trade secret;
  - the disclosure of the information would likely cause material financial loss or prejudice to the competitive position of the person providing the information, or on whose behalf it is provided; and
  - the disclosure of the information would likely interfere with contractual or other negotiations being conducted by the person providing the information, or on whose behalf it is provided.

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<sup>274</sup> Personal communication to author on 23 February 2007, from Bernard Madé, Director, New Substances Branch, Environment Canada.

<sup>275</sup> See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Sections 7.2 and 9.4.1, pp. 77, 97.

<sup>276</sup> Where disclosure of such information is deemed by the Minister to be sufficiently in the public interest, disclosure is authorized under CEPA §315, whether or not the information is health or safety related and regardless of how long it has been kept confidential.

<sup>277</sup> These provisions apply to information gathered under the authority of CEPA §46(1), which is to be used “for the purpose of conducting research, creating an inventory of data, formulating objectives and codes of practice, issuing guidelines or assessing or reporting on the state of the environment.” Information to be requested is limited to that which “may be in the possession of that person or to which the person may reasonably be expected to have access.”

- §53 specifies that the Minister must consider and either accept or reject the request. As in §315, even where the reasons provided are deemed justified, the request may be denied if: “(a) the disclosure is in the interest of the protection of the environment, public health or public safety; and (b) the public interest in the disclosure outweighs in importance (i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and (ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.”<sup>278</sup>

Although they apply in a different context, §§51–53 codify at least two useful requirements not found in §§313–321: the specific delineation of the only acceptable reasons for asserting the need for CBI protection (§52), and the requirement that the Minister must either accept or reject such a request (§53). Whereas the NSN Guidelines incorporate analogous provisions, they are less well ensconced than they would be if included in the statute, and it is not certain that such requirements would be adopted in other contexts beyond the NSN process where §§313–321 govern confidentiality.

Certain provisions of Part 5 of CEPA call for information to be made public: the DSL and NDSL (§66(5)), guidelines for the application of authorities under Part 5 (§69(1)), the Priority Substances List (§76(6)), assessments and proposed and decided measures to be taken in response to the assessments (§77), conditions and prohibitions on a chemical’s manufacture (§84(5)) and proposed and final regulations (§§91 and 92). However, publication of health or environmental data and other information about chemicals, including that received from manufacturers, is not mandated and is not routinely done. (A notable exception has been the interim and final results of DSL Categorization, where extensive information on categorization decisions for individual chemicals and the basis for them has been made public.)

In contrast to TSCA, §316 of CEPA explicitly provides for disclosure of CBI to other governments within Canada as well as to foreign governments and international organizations, as long as two conditions are met: the purpose is administration or enforcement of a law, and the recipient takes appropriate steps to keep the information confidential.<sup>279</sup>

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Articles 118 and 119 of REACH govern access to information. Article 118 delineates the following types of information whose disclosure “shall normally be deemed to undermine the protection of the commercial interests of the concerned person:”

- details of the full composition of a preparation;
- the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;

<sup>278</sup> Interestingly, this language is identical to that in §315 cited above except that, in §315, the word “clearly” precedes “outweighs in importance.” This suggests that §53 carries a somewhat reduced burden of proof relative to §315.

<sup>279</sup> CEPA §§44(3) and 75(2) also authorize cooperation with foreign governments with respect to certain activities. However, the former section applies to sharing of already existing information on environmental quality and related issues (see footnote 277), and the latter is limited to information concerning substances that have already been prohibited or restricted.

- the precise tonnage of the substance or preparation manufactured or placed on the market; or
- links between a manufacturer or importer and distributors or downstream users.

This information can be disclosed “where urgent action is essential to protect human health, safety or the environment, such as emergency situations.”<sup>280</sup>

Article 118 also provides for the development, by the Agency’s Management Board, of procedures for “appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request.”

Article 119 (titled “Electronic public access”) delineates the types of information that are to be made publicly available, and provides that it be made available free of charge, over the Internet. Two categories of information are distinguished:

- Information on specific substances—whether on their own, in preparations or in articles—that is to be made publicly available under any circumstances (i.e., that is effectively ineligible for CBI protection) includes:
  - the name of the substance as given in EINECS, if it is listed there;
  - the classification and labeling of the substance;
  - physicochemical data concerning the substance and on pathways and environmental fate;
  - the result of each toxicological and ecotoxicological study;
  - any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established (in accordance with Annex I);
  - the guidance on safe use provided by the registrant;
  - analytical methods (if requested in accordance with Annexes IX or X) which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.
- Information on specific substances that is to be made public—unless the submitter of the information submits a justification deemed valid by the Agency<sup>281</sup> for why disclosure could harm its or other parties’ commercial interests—includes:
  - the degree of purity of the substance and the identity of impurities or additives which are known to be dangerous, if any of this information is essential to classification and labeling;
  - the total tonnage band (i.e., 1–10 metric tons, 10–100 metric tons, 100–1,000 metric tons or over 1,000 metric tons) within which a particular substance has been registered;

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<sup>280</sup> Article 9(9) provides that any information submitted on a substance produced and used solely for “product and process orientated research and development” must always be kept confidential.

<sup>281</sup> Whereas Article 119(2) states that the justification provided by the submitter must be “deemed valid by the Agency” in order to preclude disclosure – and hence implies that confidentiality requests and justifications are to be reviewed – REACH itself appears to contain no specific mechanism through which the reviews are to occur. Compliance checks (Article 41) conducted under Dossier Evaluation may well extend to this information, but must only be done on a minimum of 5% of registrations received in each tonnage band. It is not clear whether or how the vast majority of such justifications are to be deemed valid or invalid.

- the study summaries or robust study summaries of physicochemical, toxicological and ecotoxicological studies;
- information (other than that listed under the first information category above), contained in the safety data sheet;
- the trade name(s) of the substance; and
- the chemical name for substances which are dangerous as defined under the EU's Directive on Dangerous Substances:
  - for a period of six years, for non-phase-in substances;
  - indefinitely, for substances that are only used as one or more of the following:
    - as an intermediate;
    - in scientific research and development; or
    - in product and process orientated research and development.

For any of the above information to be eligible for protection as CBI, the registrant must make a specific request at the time of registration and must include a justification as to “why publication could be harmful for his or any other concerned party's commercial interests.”<sup>282</sup>

Other information on substances is also to be made available, but only upon request:

- information in addition to that listed above that is included in Agency databases that are to be developed and maintained on a) all registered substances, b) the classification and labeling inventory, and c) the harmonized classification and labeling list, unless the information is precluded from disclosure under Article 118 or a confidentiality request has been granted.<sup>283</sup>

Finally, other information and documents are to be posted on the Agency's public web site:

- a list of pre-registered phase-in substances;<sup>284</sup>
- information relating to testing proposals involving tests on vertebrate animals;<sup>285</sup>
- information on which substances are being and have been evaluated;<sup>286</sup>
- information on which substances are to be evaluated and the Member States assigned to them, and an annual progress report on fulfilling those obligations;<sup>287</sup>
- recommendations by the Agency of substances to be subject to authorization;<sup>288</sup>

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<sup>282</sup> REACH, Article 10(a)(xi).

<sup>283</sup> REACH, Article 77(2)(e).

<sup>284</sup> REACH, Article 28(4).

<sup>285</sup> REACH, Article 40(2).

<sup>286</sup> REACH, Article 77(2)(f).

<sup>287</sup> REACH, Articles 44(2) and 54, respectively.

<sup>288</sup> REACH, Article 58(4).

- the candidate list of substances meeting the criteria for being subject to authorization;<sup>289</sup>
- dossiers prepared on substances proposed for authorization;<sup>290</sup>
- broad information on uses for which applications have been received and for reviews of authorizations;<sup>291</sup>
- Agency committee opinions concerning authorization decisions;<sup>292</sup>
- summaries of final authorization decisions, including the reasons for the decisions, especially where suitable alternatives exist;<sup>293</sup>
- dossiers prepared on substances proposed for restriction, including the proposed restrictions;<sup>294</sup>
- draft and final Agency committee opinions concerning restriction decisions;<sup>295</sup> and
- nominees for Agency committees.<sup>296</sup>

REACH's requirements that government make publicly available significant amounts of information about chemicals and documentation of decisions and the basis for them stand in stark contrast to TSCA and CEPA, which, except in very limited circumstances, neither call for nor facilitate public access to such information.

REACH's requirements that government make publicly available significant amounts of information about chemicals stand in stark contrast to TSCA and CEPA.

Article 35 mandates that workers have access to all information about a substance that they use or may be exposed to, that is required to be included in safety data sheets (detailed in Article 31), or required to be communicated by a supplier of a substance to downstream recipients in cases where a safety data sheet is not required (detailed in Article 32).

With respect to whether other governments can have access to information held as confidential under REACH, Article 120 broadly provides for such access:

“Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned ...,<sup>297</sup> provided that both the following conditions are met:

<sup>289</sup> REACH, Article 59(10).

<sup>290</sup> REACH, Article 59(4).

<sup>291</sup> REACH, Article 64(2).

<sup>292</sup> REACH, Article 64(6).

<sup>293</sup> REACH, Article 64(9).

<sup>294</sup> REACH, Article 69(6).

<sup>295</sup> REACH, Articles 71(1) and 72(2), respectively.

<sup>296</sup> REACH, Articles 85(1) and (2).

<sup>297</sup> The agreements are to be developed under “Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals or under Article 181a (3) of the Treaty.”



- (a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;
- (b) the third party protects the confidential information as mutually agreed.”

This provision is quite similar to that under CEPA and has no counterpart under TSCA.

### **Best practice**

*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.

### **B. Information flow in the chemical supply chain**

One innovative, unique aspect of REACH is the extent to which it requires improved flow of risk-relevant information in both directions along chemical supply chains that connect producers, processors, distributors and users of chemicals. Safe management of chemicals by all actors demands ready access to good information on how chemicals are being processed and used, the hazardous properties of chemicals and risk management practices that need to be implemented. REACH's objective in mandating such information flow is to overcome the formidable disincentives, such as competitive forces, confidentiality and liability concerns, and bottlenecks such as "middlemen" (i.e., distributors, brokers), which serve to block access to information needed to identify and mitigate risks. Suppliers typically have limited knowledge of how or by whom their chemicals are used, and users have limited knowledge of the characteristics of the substances they receive or appropriate risk management measures recommended by the producers.<sup>298</sup>

REACH aims to induce information flow primarily by:

- requiring suppliers to communicate downstream, through safety data sheets or other means, hazard and risk-related information and other information about the substance "that is necessary to enable appropriate risk management measures to be identified and applied;"<sup>299</sup> and
- encouraging downstream users to communicate upstream to their suppliers sufficient information on their use(s) of a substance so that the supplier can develop exposure scenarios or assign the use(s) to exposure categories and identify needed risk management measures that can be communicated back downstream.

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<sup>298</sup> For more discussion of information flow in the context of improved chemicals assessment and management, see Denison, R.A., "Improving Information Flows – In Supply Chains and Beyond," presented at the North American Dialog on "Framing a Future Chemicals Policy," held in Boston, MA, April 2005, available at [www.chemicalspolicy.org/downloads/W3-Informationflow.doc](http://www.chemicalspolicy.org/downloads/W3-Informationflow.doc).

<sup>299</sup> REACH, Article 32(1).

Two entire titles of REACH are devoted to these tasks: Title IV covers “Information in the Supply Chain” and Title V covers “Downstream Users.”<sup>300</sup>

*Information flow down the supply chain*

Articles 31—33 specify the information that suppliers of substances or preparations, and in certain cases suppliers of articles containing certain substances, are to communicate to their recipients:

- A safety data sheet must be prepared and always accompany:
  - any substance or preparation that is classified as dangerous under the EU’s Directive on Dangerous Substances;<sup>301</sup>
  - any substance that is a PBT or vPvB substance; or
  - any substance on the candidate list of substances meeting the criteria for being subject to authorization.
- A safety data sheet must be prepared and provided upon request to any recipient of a preparation containing a substance that:
  - is known to pose health or environmental hazards and is present at 1% or more by weight in solid or liquid preparations, and 0.2% or more by volume in gaseous preparations;
  - is a PBT or vPvB substance and is present at 0.1% or more by weight; or
  - has a workplace exposure limit.

Safety data sheets must be dated and kept current, and are to contain information on:

- the substance’s or preparation’s identity, composition, physical and chemical properties, and physical, health and environmental hazards;
- risk management measures for first aid, firefighting, accidental release, handling and storage, transport, disposal, exposure controls and personal protection;
- regulations applicable to the substance;
- (when a chemical safety report is required of the supplier), exposure scenarios from the CSR that are associated with the relevant downstream use(s) of the substance, as well as conditions on such uses identified as necessary to maintain low exposures.<sup>302</sup>

Where a safety data sheet is not required, the supplier must still provide to recipients of a substance “available and relevant information about the substance that is necessary to enable

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<sup>300</sup> REACH also has extensive provisions to facilitate or require the sharing of data among registrants of the same substance; see Article 11 and Title III. These provisions, although innovative, are beyond the scope of this paper.

<sup>301</sup> A partial exception is provided for such substances or preparations that are offered or sold to the general public and include “sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment. In such cases, the safety data sheet need be provided only upon request. See Article 31(4).

<sup>302</sup> REACH, Article 13(1) and Annex XI, Section 3.

appropriate risk management measures to be identified and applied including specific conditions” identified as needed to maintain low exposures.<sup>303</sup>

Under certain circumstances, suppliers of articles must communicate information on substances to the recipients. If an article contains a substance on the candidate list of substances meeting the criteria for being subject to authorization at a concentration above 0.1% by weight, the supplier of the article must provide the recipient with “sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.” This information must be given automatically to any commercial customer of the article, and upon request to any end consumer.

#### *Information flow up the supply chain*

Article 34 specifies that each actor in the supply chain must communicate certain information to the next actor or distributor up the supply chain, including new information discovered or developed on a substance’s hazardous properties, and any information that “might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him.”

Title V imposes additional requirements on downstream users related to information flow up the supply chain. As specified in Article 37, downstream users have the option of providing a description of their use of a substance sufficient to allow their supplier to prepare an exposure scenario to be included in the registration of the substance, and to identify in the safety data sheet provided to the downstream user those risk management measures needed to safely manage the substance. Such a use becomes an “identified use” and the downstream user must apply the identified risk management measures.

Downstream users must prepare their own chemical safety reports for their use(s) of a substance if: a) they choose not to provide a description of their uses to their suppliers, b) they use a substance outside of the conditions of an identified use, or c) they use a substance in a manner against their supplier’s advice.<sup>304</sup> In such cases, they must also notify the Agency before commencing or continuing that use.<sup>305</sup>

#### **Best practice**

*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.*

<sup>303</sup> REACH, Article 13(1) and Annex XI, Section 3.

<sup>304</sup> See REACH, Article 37(4) for situations under which this requirement to prepare a CSR does not apply.

<sup>305</sup> REACH, Article 38. See subsection 5 for situations under which this notification requirement does not apply.

**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.

## APPENDIX A

### Excerpt from comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (70 Fed. Reg. 3658, 26 January 2005)

18 February 2005  
Docket ID No. OPPT-2004-0106

The following comments regard certain of the proposed revisions to the reporting requirements under the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) regulations, (70 Fed. Reg. 3658, 26 January 2005<sup>1</sup>). Currently, the IUR requires certain manufacturers (including importers) of certain chemical substances on the TSCA Chemical Substances Inventory to report data on chemical manufacturing, processing, and use every four years.

- Among the changes EPA is now proposing is to lengthen the reporting cycle from four years to five. Given the enormous fluctuation in production volumes over time, we strongly oppose any further lengthening of the reporting period and believe that annual data should be provided even if reporting is required less than annually.

#### Reporting frequency

EPA is proposing to reduce the frequency – from every four to every five years – of the already infrequent reporting of production volume, use and exposure information required of chemicals producers and importers. The fact is that the actual extent of fluctuation in production and import levels for individual industrial chemicals is so large that more frequent, not less frequent, reporting is needed to adequately characterize the actual levels of these chemical substances in production and use in the U.S. And such information is in turn essential to understanding the potential for releases of and exposures to, and hence risks from, chemical substances.<sup>2</sup>

Consider the change in the number of so-called high production volume (HPV) chemicals<sup>3</sup> produced in the U.S. between subsequent four-year reporting cycles under current IUR requirements. Under the U.S. HPV Challenge, some 2,800 chemicals were identified as being produced at HPV levels based on data reported for the 1990 IUR reporting cycle. Based on data received in the last two reporting cycles, for 1998 and 2002, EPA has determined that production/import levels for about 300 of these chemicals dropped to levels below one million pounds annually. But during the same period (1990-2002), EPA estimates that more than 1,100

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<sup>1</sup> Available online at [www.epa.gov/fedrgstr/EPA-TOX/2005/January/Day-26/t1380.htm/](http://www.epa.gov/fedrgstr/EPA-TOX/2005/January/Day-26/t1380.htm/).

<sup>2</sup> Consistent with TSCA, the focus here is on industrial chemicals and not on pesticides, food additives, drugs and cosmetic ingredients, and a few other specific categories of materials excluded from TSCA's definition of "chemical substance." See 15 U.S.C. Sec. 2602(2)(B), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse\\_usc&docid=Cite:+15USC2602](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2602).

<sup>3</sup> HPV chemicals are those produced and imported in aggregate quantities exceeding one million pounds annually.

chemicals may have become HPV chemicals – that is, their production/import levels have risen to above one million pounds annually.<sup>4</sup>

Because of the infrequent reporting, the uncertainty associated with EPA’s determination of whether a given chemical is produced at HPV levels plagues the HPV Challenge Program, invites endless challenges, wastes EPA resources, and undermines public confidence that data needs for all HPV chemicals are in fact being addressed.

An even greater degree of fluctuation in production levels is found among all chemicals reported on the TSCA Inventory. To illustrate this, we examined those that are included in the publicly available database of TSCA inventory chemicals subject to reporting requirements under the IUR.<sup>5</sup> This database provides non-confidential annual production volume ranges for approximately 14,000 chemicals for each of the last five IUR reporting cycles: 1986, 1990, 1994, 1998 and 2002. The ranges, which are quite broad, are as follows:

- 10,000 pounds - 500,000 lbs.
- >500,000 - 1 million lbs.
- >1 million - 10 million lbs.
- >10 million - 50 million lbs.
- >50 million - 100 million lbs.
- >100 million - 500 million lbs.
- >500 million - 1 billion lbs.
- >1 billion lbs.

If one asks for how many of these chemicals did the chemical’s reported production volume change from one reporting cycle to the next, the answer is remarkable: Of the approximately 10-11,000 chemicals reporting a range for at least one of the two successive cycles being compared, the reporting range changed for more than 50% of the chemicals in each pair of reporting cycles: 1986-1990, 1990-1994, 1994-1998 and 1998-2002. Just looking at the changes from 1998 to 2002:<sup>6</sup>

- the reporting range changed for 52% of chemicals;
- the reporting range increased for 18% of the chemicals and decreased for 34%;
- for 40% of the chemicals, the reporting range changed by more than one range (13% increased by two or more ranges, while 27% decreased by two or more ranges).

The histogram below illustrates these findings.

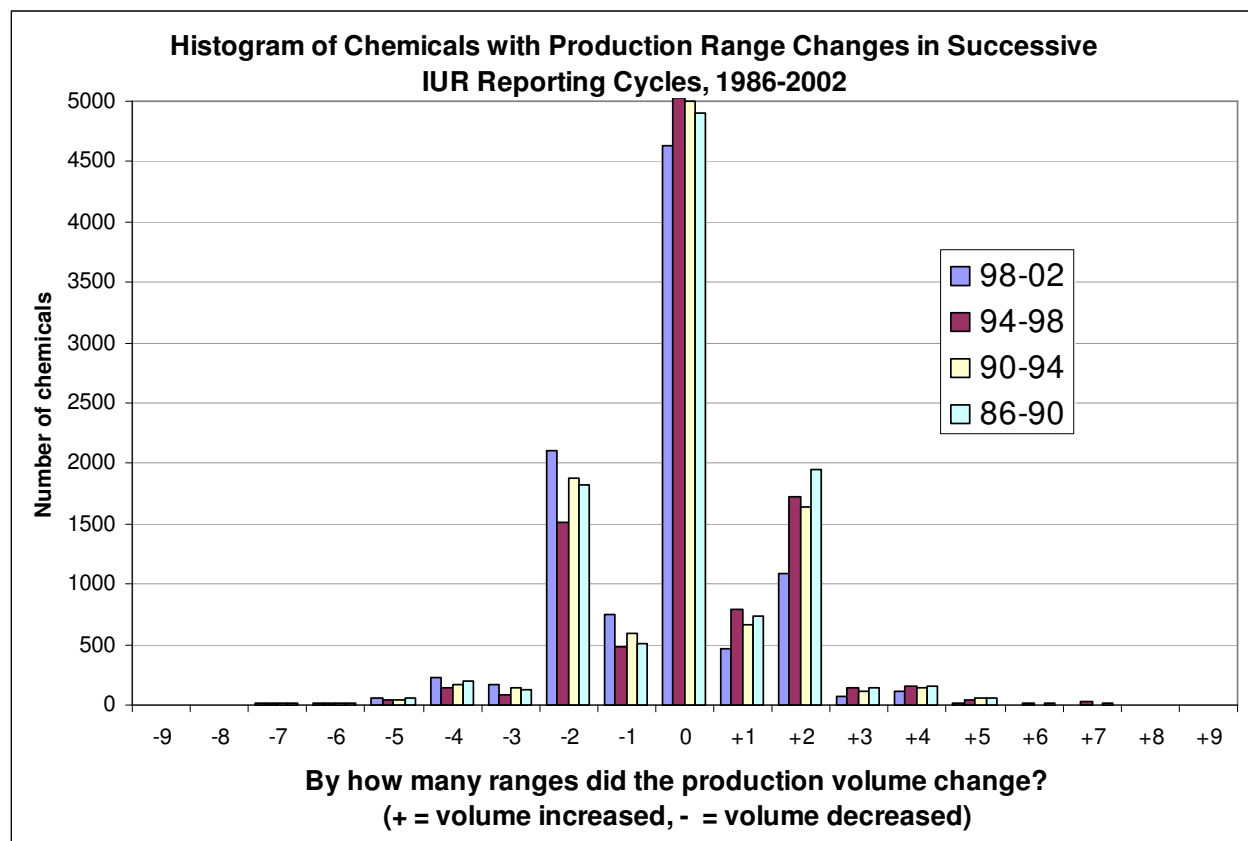
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<sup>4</sup> See USEPA, “Status and Future Directions of the High Production Volume (HPV) Challenge Program,” Office of Pollution Prevention and Toxics, December 2004, p. 98.

<sup>5</sup> See “Non-confidential Production Volume Information Submitted by Companies for Chemicals Under the 1986- 2002 Inventory Update Rule,” available for download at [www.epa.gov/oppt/iur/iur02/search03.htm](http://www.epa.gov/oppt/iur/iur02/search03.htm). Only those chemicals produced or imported in quantities exceeding 10,000 pounds annually (to rise to 25,000 pounds starting in 2006) are subject to the reporting requirement and hence included in the database.

<sup>6</sup> The data for the other pairs of successive reporting periods are similar; see histogram. The full analysis is available on request.





Given how large the individual reporting ranges are, a change of even a single range can represent, and changes of two or more ranges certainly do represent, enormous changes in actual production volume. *Hence, these data reveal that – for thousands of industrial chemicals – there are dramatic fluctuations in the amount of a given chemical produced over a few years.* And while the absence of a requirement (to date) to report use information for these chemicals precludes a definitive statement, it seems likely that there are also comparably dramatic changes occurring in use patterns for chemicals exhibiting such large changes in production level.

The magnitude of the fluctuations seen on a quadrennial basis demonstrates that more – not less – frequent reporting is needed to adequately characterize production and use of industrial chemicals in the U.S. Moving to a five-year reporting cycle simply exacerbates this problem. In our view, EPA should ideally be requiring annual reporting. At the very least, EPA should require that reports include annual quantities for each year of the reporting interval, or annualized data averaged over the reporting period, even if annual submission is not required.

Given that, by law, EPA has to base many of its rules and negotiated agreements on estimated production volumes as well as associated release and exposure estimates, moving to even less frequent reporting of these data will only increase the likelihood that EPA will be relying on outdated data in making its decisions. This in turn means that EPA will be more likely to erroneously include or exclude chemicals from actions it takes, yielding bureaucratic inefficiencies, added costs to industry and potentially increased impacts to human health and the environment. [END]

## APPENDIX B<sup>1</sup>

### Environmental Defense's Perspective on Integrated Approaches to Chemical Testing and Assessment

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February 2006

#### Introduction

Interest in promoting so-called “integrated approaches” to chemical testing and assessment is motivated by a desire to: gain efficiencies in assessing new chemicals prior to market introduction as well as chipping away at the huge backlog of un- or under-assessed chemicals already on the market; reduce the costs associated with traditional testing; and reduce unnecessary use of laboratory animals.

We appreciate and share interest in achieving these objectives, and we are both supportive of and engaged in promoting the development and use of many of the alternative methods that comprise more integrated approaches. At the same time, it is critical that an appropriate balance be struck with other equally important objectives: assuring full protection of human health and the environment; basing decisions on scientifically sound and defensible information; ensuring that all assessment information used to make such decisions is independently verifiable and reproducible; and maximizing transparency in communicating the basis for decisions to stakeholders and the general public.

To achieve all of these objectives, we believe the following “guiding principles” need to be followed:

*Avoid over-reliance.* Precisely because of the large benefits of reducing costs to government and industry and reducing animal use, there can be a strong incentive to over-rely on alternative methods. This potential must be acknowledged and tempered, through:

- the creation of clear, scientifically sound guidance on the appropriate and inappropriate uses of each alternative method;
- requirements for justifying and documenting both use of alternative methods and decisions based on such information; and
- careful independent expert review.<sup>2</sup>

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<sup>1</sup> Denison, R.A. and Balbus, J.M. “Environmental Defense Perspective on Integrated Approaches to Chemical Testing and Assessment,” presented at the 39th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Organization for Economic Cooperation and Development, 15-17 February 2006, available at [www.oecd.org/dataoecd/19/34/36286018.pdf](http://www.oecd.org/dataoecd/19/34/36286018.pdf).

*Avoid selective use and reporting (“double standard”).* A corollary concern is the potential for alternative methods to be used, especially by industry, not only as the option of first resort, but also under a “double standard.” We have already seen some indications of companies, for example, arguing that (Q)SAR results are sufficient when they are favorable, i.e., “exonerate” their chemical, and proceeding to do actual testing only in cases where the (Q)SAR results indicate a hazard. While we consider the latter response wholly appropriate, it begs the question as to who decides whether and in what settings (Q)SAR results are deemed sufficiently reliable. Safeguards to prevent selective use and reporting are needed; for example, there should be a requirement that all results derived using all methods employed be reported to regulatory officials.

*Screening vs. other uses.* Another related question is the use to which information derived from alternatives to direct testing is put. As a general matter, we regard such methods – especially when used individually – to entail sufficient uncertainty as to be most appropriate for priority-setting or screening-level assessments, and less so to serve as the basis for more full-blown risk assessments or for risk management decisions. Exceptions may arise when a “critical mass” is reached, e.g., a sufficient number of mutually-supporting or corroborative results derived using alternative methods. In such cases, there may be a sufficient degree of confidence to support a more definitive conclusion or decision; this situation is akin in some ways to a weight-of-evidence approach, which we discuss in more detail below.

*Transparency.* An approach that relies on information generated through multiple, diverse methods carries with it an added burden of transparency. The nature, source and means of derivation of each data value needs to accompany it in any subsequent presentation or communication of the data, and should be an integral part of the justification provided for any conclusions or decisions based on such data. Some assessment of the degree of confidence in or reliability of the data is another prerequisite to transparency, and any resulting uncertainty should be captured and communicated through a clear articulation of appropriate qualifications or limitations that apply to conclusions or decisions based on such information.

*Continuing need for generation of experimental data.* Another essential point is that development and improvement of many alternative methods is highly dependent on having a robust and expanding underlying dataset of values derived from *in vivo* testing. Such data are necessary either to provide for the development and refinement of the algorithms that underpin mathematical predictive models ((Q)SARs), and to allow correlations to be established between *in vivo* results and those of other systems (*in vitro* testing, toxicogenomics). In short, at least in the near term, these alternatives will only be as good as the *in vivo* data that underpin them; without continued commitment to enhance databases derived from *in vivo* testing, the applicability and reliability of such alternative methods will not progress to the point where they can fully replace *in vivo* test systems.

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<sup>2</sup> Given these needs, we also note that the prospect raised by some that integrated approaches will result in “the simplification and streamlining of existing Test Guidelines and associated testing strategies” is likely overly optimistic.

Integrated approaches will only be as good as the “sum of their parts.” The appropriate and inappropriate uses of each method need to be clearly understood, and their limitations acknowledged and reflected, in choosing the uses to which such approaches are put and in documenting any resulting conclusion or decision.

In the remainder of this paper, we first briefly discuss the closely related issue of weight-of-evidence (WOE) approaches, and then address the more specific issues, opportunities and limitations associated with each of the identified alternative approaches that may comprise the elements of a more integrated approach:

- (Quantitative) Structure-activity relationships [(Q)SARs]
- Read-across methods (using chemical category and analog approaches)
- *In vitro* tests
- Toxicogenomics (and related emerging technologies)
- Exposure information

### Weight of Evidence

Virtually by definition, integrated approaches imply that a weight-of-evidence (WOE) approach is to be used, that is, a variety of information is considered in conducting an assessment or reaching a decision. WOE approaches are, of course, not new and have been used implicitly or explicitly in a variety of settings, especially in the risk assessment arena.

The largest concerns about the application of WOE, and by extension, integrated approaches, are the absence of a rigorous definition of what constitutes WOE, or clear guidance and standards for the use of WOE and associated documentation and communication needs. A recent paper<sup>3</sup> by Douglas L. Wood of the US National Cancer Institute provides empirical evidence for such concerns. He conducted an extensive survey of the published risk assessment literature, finding the following wide diversity of types of “uses” of WOE:

- “(1) metaphorical, where WOE refers to a collection of studies or to an unspecified methodological approach;
- (2) methodological, where WOE points to established interpretative methodologies (e.g., systematic narrative review, meta-analysis, causal criteria, and/or quality criteria for toxicological studies) or where WOE means that “all” rather than some subset of the evidence is examined, or rarely, where WOE points to methods using quantitative weights for evidence; and
- (3) theoretical, where WOE serves as a label for a conceptual framework.”

Clearly, if integrated approaches that rely on WOE are to meet even basic tests for transparency, objectivity and accountability, addressing this lack of consistency must be a first priority. As noted by Dr. Wood, among the problems to be remedied are:

- the multiplicity of definitions and uses;

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<sup>3</sup> Weed, D.L. (2005) “Weight of Evidence: A Review of Concept and Methods,” *Risk Analysis*, Vol. 25, No. 6, pp. 1545-1556.

- the multiplicity of weighting schemes and criteria for applying them; and
- defining the role of judgment in applying WOE approaches.

Wood goes on to offer an important recommendation: “The WOE concept and its associated methods should be fully described when used. A research agenda should examine the advantages of quantitative versus qualitative weighting schemes, how best to improve existing methods, and how best to combine those methods. ... The goal of this approach is to work toward a consensus on the meaning and methods of weight of evidence, such that a recognizable standard can be created and accepted.”

We consider this recommendation, extended to integrated approaches to chemical testing and assessment, to be an appropriate starting point for the OECD’s further consideration of such approaches.

### **(Quantitative) Structure-activity relationships [(Q)SARs]**

While development and use of (Q)SARs holds considerable promise to reduce testing needs, at present there are significant limitations to their use. Reliable models are available for only a subset of relevant endpoints, and are in particular lacking for most human health-related endpoints, especially chronic ones. The question of validation continues to be a contentious one, with no clear agreement on what constitutes sufficient validation. Public access to underlying algorithms and training datasets has yet to be assured for many (Q)SARs, despite such access being identified as key to providing needed transparency and accountability in the application of (Q)SAR approaches, especially in regulatory contexts. Existing (Q)SARs have limited “domains” of applicability, with many common types of chemicals falling outside. Finally, the accuracy and reliability of (Q)SAR-derived estimates vary from one (Q)SAR and endpoint to another, and the estimates they generate often vary considerably from available experimental values.

At SIAM 21, a “(Q)SAR application pilot project” was proposed (see Document ENV/JM/EXCH/SIAM(2005)9), generally agreed to and forwarded to the Existing Chemicals Task Force. Under the pilot, sponsors would apply selected (Q)SAR models for selected SIDS endpoints to the chemicals for which they are also preparing a SIDS Initial Assessment Report, thereby allowing a direct comparison of experimental and predicted values for the same endpoints. We support this proposal: In addition to facilitating an increase in OECD experience with the application of (Q)SARs, the project would help to illustrate both the opportunities for and limitations of using (Q)SARs as an alternative to direct testing.

Having a full understanding of both the appropriate application and the limitations of (Q)SARs is essential to ensuring their appropriate use. OECD has recently focused appropriate attention on the need for validation of (Q)SARs, as a means to gain greater acceptance for their use. Two case studies presented at the 2nd Meeting of the ad hoc Expert Group on (Q)SARs (held 20-21 September, 2004 in Paris) are useful to consider in this context.

The first case study, from the U.S.,<sup>4</sup> described its view of problems arising from too rigidly applying validation principles to (Q)SARs the USEPA uses to assess new chemicals. (Unlike most other OECD countries, U.S. law does not require that chemical manufacturers provide a “base set” of hazard data when notifying authorities of their intent to make a new chemical, and hence the great majority of new chemical notifications submitted in the U.S. lack such data. In addition, EPA is given only 90 days to decide whether a chemical needs any restrictions placed on its manufacture or use; if it fails to act, manufacture can commence. For this reason, EPA has developed and made extensive use of (Q)SARs to predict the hazards of chemicals it reviews that lack actual test data.) EPA argued that whether a (Q)SAR is “valid” depends in part on how and for what purpose it is used; e.g., used as a means to rapidly screen and prioritize many chemicals to identify those in most need of further scrutiny, a higher degree of uncertainty may be accepted than, say, for risk assessment purposes. Hence, EPA argued that both (Q)SAR use and concepts of validity need to be flexible and tailored to the regulatory needs of each country.

While this argument has merit, and the constraints faced by EPA are indeed considerable, I would raise two concerns:

- Where such constraints do not exist (i.e., the rest of the OECD), the larger question needs to remain whether and when (Q)SAR-generated estimates can reliably replace experimental data and hence serve as a scientifically sound alternative to testing.
- (Q)SAR estimates generated by or submitted to regulatory agencies for use in such a context-specific manner cannot be assumed to be “valid” universally, and hence should not simply be adopted for use by other countries that do not face the same constraints and may need or wish to develop a more certain basis for regulating chemicals.

An EU country participant contrasted the EPA’s use of (Q)SARs versus that contemplated under REACH: In the former case, the government develops, applies and interprets (Q)SAR results; under REACH, industry would utilize (Q)SARs, and governments would have to be in a position to be able to judge the validity of the results. This difference, it was argued, suggests a greater need for rigorously validating (Q)SARs in advance, at least for this type of use.

The second case study, provided by Denmark,<sup>5</sup> compared experimental data and (Q)SAR estimates for chemicals assessed at SIAMs 11-18 held over the previous several years. Only five endpoints were able to be compared: biodegradability; acute toxicity to fish, aquatic invertebrates and algae; and mutagenicity. These are the endpoints for which the “best” (Q)SARs exist – those that are based on large sets of experimental data and have been considered to provide the most reliable estimates. The results are summarized below:

- The (Q)SAR models were able to identify 80-90% of the chemicals that actually tested as readily biodegradable, but (depending on the specific model) only 46-80% of the chemicals that actually tested as not biodegradable.
- The fraction of chemicals for which the (Q)SAR predictions for acute toxicity “agreed” (defined as being within an order of magnitude of the test result) with the experimental

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<sup>4</sup> “Regulatory Application of (Q)SARs: A U.S. EPA Case Study,” ENV/JM/TG(2004)25/REV2.

<sup>5</sup> Comparison of SIDS Test Data with (Q)SAR Predictions for Acute Aquatic Toxicity, Biodegradability and Mutagenicity on Organic Chemicals Discussed at SIAM 11-18,” ENV/JM/TG(2004)26/REV1.

data were: 4/5 of the chemicals for fish; 3/4 for invertebrates (specifically, crustaceans); and 2/3 for algae.

- The (Q)SAR models were able to identify 95% of the chemicals that actually tested as negative for mutagenicity, but (depending on the specific model) only 60-80% of the chemicals that actually tested as mutagenic. However, the comparison included so few substances that tested positive that the latter conclusion must be viewed as tentative.

As with studies describing scientific validation efforts for specific (Q)SAR models, these results suggest both the utility of certain (Q)SARs but also some important limitations to their accuracy and reliability. As with the other methods discussed in this paper, appropriate use of (Q)SARs can play an important role in supplementing and extending the base of information available for use in chemical assessment – as long as their shortcomings are kept in mind and clearly communicated. While we believe that relying solely on (Q)SAR-derived information will be sufficient only in relatively rare cases, such information considered as part of an integrated approach may well be able to help compensate for weaknesses or resolve conflicting results found in data derived from other methods, thereby strengthening the overall assessment.

#### **Read-across methods (using chemical category and analog approaches)**

We support efforts to promote scientifically appropriate use of category approaches, and are pleased to see the enhancements made recently to OECD guidance governing: category definition and justification, the process to be followed for verifying category soundness once data have been developed; and the specific methods to be used to assign specific hazard values to individual members of a category that have not been directly tested. Continuous refinement and enhancement of this guidance will be needed to incorporate experience in real-world application of the guidance.

Equally important, even with clear guidance in place, careful expert review of all category-based assessments is essential, as demonstrated by experience with chemical categories under the US HPV Challenge Program, in which about 80% of all sponsored chemicals are being assessed as members of categories rather than individually. In comments filed on the initial industry submissions for these categories, USEPA and public comments identified concerns or deficiencies in the category justifications about half of the cases. For example, some categories were found to be overly broad or ill-defined, or a whole category or the inclusion of specific chemicals was found not to be supported by available data. While many or most of these concerns were addressed in subsequent revisions, the experience highlights the critical role that expert review plays in applying category-based approaches.

Presentation of the results of applying category-based approaches must be transparent. Assuming that a category is still found to be justified once all data development has been completed and evaluated, the final dataset needs not only to provide all required data elements for each category member, but also to clearly indicate those values that are extrapolated rather than experimentally measured, together with clear explanations as to how each value has been derived.

## *In vitro* tests

*In vitro* tests comprise a gamut of different assays, ranging from relatively simple protein or receptor binding assays to the complex simulation of heterogeneous tissues outside of living organisms. In comparison to the similarly wide range of *in vivo* tests, *in vitro* tests offer certain advantages and disadvantages. Advantages include reduced cost, reduced or no sacrifice of animals, generally rapid results, and the ability to perform multiple replications or parallel experiments simultaneously. The primary disadvantage of *in vitro* testing is increased uncertainty in interpreting results, due to difficulties correlating binding profiles or cytotoxicity with *in vivo* effects, and the inability to account for metabolism or other complex interactions that can moderate or exacerbate toxicity *in vivo*.

While some *in vitro* tests, such as the Ames test, have long been incorporated into predictive toxicology, there are still large knowledge gaps that must be filled before *in vitro* tests can begin to replace *in vivo* tests in most applications. As those knowledge gaps are filled, however, it is likely that there will be specific applications in which *in vitro* tests can form part of an integrated assessment. One such possibility would be the inclusion of high-throughput binding assays for an array of different endocrine receptors, in order to be able to categorize compounds' or mixtures' ability to stimulate various endocrine pathways. Such studies are common in the published literature,<sup>6</sup> but these methods are not yet common in regulatory use.

*In vitro* methods hold great promise for more rapid screening of chemical compounds and environmental samples, but they also present many of the same limitations as the use of QSAR models mentioned above. Because *in vitro* findings are several steps removed from whole animal histopathology, they are more easily discounted when they suggest a problem. Indeed, many in industry argue that *in vitro* methods should not be relied upon because they are invariably more "sensitive" than the corresponding *in vivo* studies; even where this is the case, however, that property might well be *desirable* if such tests are used as a first-line screen for chemicals. More generally, whether *in vitro* methods are always more sensitive remains to be seen; there simply are not enough correlative data with *in vivo* studies to know at this point. Given this, just as many in industry are concerned about an over-reliance on positive findings from *in vitro* studies, an over-reliance on negative results from *in vitro* methods, in the absence of documentation of their sensitivity, could also lead to erroneous decisions and to inadequate public health protection.

As mechanisms of toxicity continue to be elucidated, the utility of *in vitro* testing may well increase, initially for screening of chemicals but ultimately, perhaps, for use in more definitive assessments. In order for this to occur, an intensive effort to determine and map out the relevant mechanisms for a wide variety of types of toxicity is necessary. In addition, regulatory toxicology

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<sup>6</sup> See, e.g., Oh SM, Park K, Chung KH, "Combination of *in vitro* bioassays encompassing different mechanisms to determine the endocrine-disrupting effects of river water." *Sci. Total Environ.* 1 February 2006;354(2-3):252-64. Epub 19 March 2005; or Araki N, Ohno K, Nakai M, Takeyoshi M, Iida M., "Screening for androgen receptor activities in 253 industrial chemicals by *in vitro* reporter gene assays using AR-EcoScreen cells." *Toxicol. In Vitro.* September 2005; 19(6):831-42.



agencies and laboratories will need to run selected *in vitro* assays in parallel with traditional *in vivo* toxicological tests on a range of chemicals so that databases that correlate *in vitro* findings with relevant adverse health outcomes can be populated. Initial attempts to incorporate *in vitro* assays into larger, integrated assessments should focus on limited applications with the greatest knowledge base, such as endocrine or metabolic disruptors. Confidence gained in these limited applications may foster increased investment and confidence in broader development and use of *in vitro* assays. As with all of the methods discussed in this paper, such confidence will also be dependent on transparency of methods, materials, and interpretation.

### **Toxicogenomics (and related emerging technologies)**

The term toxicogenomics has developed as an umbrella term describing a number of different technologies that measure global or large-scale gene, protein and metabolite expression within biological systems and systematically analyze the resulting data. Thus, DNA and RNA microarrays, proteomic and metabolomics assays, and the bioinformatics systems needed to record and analyze such complex datasets are all part of “toxicogenomics.”

To date, most of the development of toxicogenomics methods has taken place in the pharmaceutical industry, driven by a desire to improve the screening and culling of drug candidates early in the research and development process. The requirements for screening of drug candidates differ significantly from the requirements for screening environmental chemicals. These differences include: 1) a relatively selective focus on a few types of toxicity, especially hepatotoxicity, to eliminate unsuitable drug candidates; in contrast, environmental chemicals to which children and other susceptible populations may be exposed must be assessed more comprehensively, including for carcinogenic, developmental and reproductive effects; 2) drug candidates can be usefully screened out based just on acute or sub-acute toxicity; environmental chemicals must be screened for potential chronic toxicity; 3) false negative results in drug screening can be detected in later, rigorous pre-clinical testing regimens, while there is essentially no backstop for false negative results in environmental chemical screens. Thus, even with successful use of toxicogenomics methods to screen for toxicity by the pharmaceutical industry, substantial development of knowledge and data will be necessary before toxicogenomics methods can be safely and broadly applied to screen environmental chemicals. Early efforts to develop this capability are underway in various government and academic research centers around the world.

Despite these limitations, toxicogenomic data may be a very useful adjunct within an integrated assessment framework long before such data can be reliably used as the basis for regulatory decisions. As understanding of toxicity mechanisms continues to accrue, short-term toxicogenomic assays may be able to confirm or exclude the ability of specific chemicals or mixtures to act by certain mechanisms.

A second potentially useful near-term application of toxicogenomics assays could be in testing the validity of proposed chemical categories being increasingly employed in large-scale chemical screening initiatives such as the OECD HPV SIDS program and the US HPV Challenge, and

expected under the European Union's emerging REACH initiative.<sup>7</sup> At present, there are relative few objective data used to justify most proposed category classifications. *In vivo* studies of acute toxicity and 28-day repeat dosing are the most commonly used traditional toxicology tests within the HPV program to support the validity of proposed categories, but results of these tests are often only available for a small subset of chemicals in the category. Submitting all members of a category to a short-term gene or protein expression assay, using either large numbers of markers or a specified subset, could allow more rigorous evaluation of proposed categories, and in particular provide a mechanism to identify potential outliers. For this to be feasible, reliable and inexpensive *in vitro* toxicogenomics assays will need to be further developed and validated. Such assays are likely to be limited in scope, with respect to dose range and time course. It must be recognized that assays with such limitations could not be expected to fully exclude the possibility of differential toxicity within a category, and variability due to technical or random biological factors would have to be accounted for. Toxicogenomic data would not be expected to be the sole basis for category validation, but rather would be considered along with other data as part of a weight-of-evidence approach.

## Exposure information

As documented in detail elsewhere,<sup>8</sup> we have raised concerns for some time within OECD about the serious limitations of available exposure information as a general matter, as well as the more specific tendency toward over-reliance on extremely limited exposure information in OECD's hazard assessment activities. These concerns, briefly summarized here, apply equally to reliance on exposure information in applying more integrated approaches to testing and assessment.

### *Key differences between assessing hazard and exposure*

Hazard is largely inherent to a substance, while exposure changes with place, use and time. This means that hazard (and hazard characterization or assessment) is relevant whatever the setting or use, while exposure is highly site/use-specific. Any exposure assessment is necessarily a "snapshot" of current exposure; the next new use or activity alters the picture. Exposure assessment must therefore be ongoing: scope, frequency of measurement must characterize *variation* in as well as *magnitude* of exposure.

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<sup>7</sup> We note and indicate our strong support for the project proposed by the OECD/IPCS Advisory Group on Toxicogenomics, entitled "Molecular Screening for Characterizing Individual Chemicals and Chemical Categories," which would undertake just such a study. See "Progress report on toxicogenomics: prepared for JM39, ENV/JM(2006)8, paragraphs 10-11, Work Item 1 and Annex 1.

<sup>8</sup> Denison, R., "Environmental Defense's perspective on policy issues related to exposure assessment," paper presented at the OECD Chemical Committee's Policy Dialogue on Exposure Assessment, held 6-7 June 2005, at OECD Headquarters, Paris; Denison, R. and Silbergeld, E., memorandum to the Task Force on Existing Chemicals for its 12<sup>th</sup> meeting, "Environmental Defense's concerns regarding use of exposure information in making recommendations regarding further work on HPV chemicals," 15 August 2003; Denison, R., addendum to memorandum to the Task Force on Existing Chemicals for its 12<sup>th</sup> meeting, "Statistics for all chemicals with SIAPs reviewed for SIAMs 15-16 and to be reviewed at SIAM 17 regarding use of exposure information in making recommendations regarding further work on HPV chemicals," 26 September 2004; Denison, R., memorandum to the Task Force on Existing Chemicals for its 13<sup>th</sup> meeting, "Further Proposal Re Use of Exposure Information in SIAM Recommendations," 17 September 2004.

Mechanisms for generating and evaluating hazard data are far more advanced and accepted than for exposure data. Extensive international-consensus standards exist for generating hazard data; they also address quality/reliability, interpretation, and reproducibility/verifiability. In contrast, standardized and routine collection of exposure data is rare and infrequent, and public access to such data is even rarer.

Differential access to both exposure data and the means to generate them can severely limit the “reproducibility” of such data. Most exposure data and the means to generate them reside virtually exclusively with industry. Industry’s interest in claiming low exposure must be acknowledged, and means that having the ability to independently verify such information is essential. It must also be acknowledged that direct access to exposure “settings” is limited even for government officials. In addition, confidential business information (CBI) restrictions limit public access to exposure-relevant data; in contrast, hazard data are typically ineligible for CBI protection. Finally, supply-chain impediments to sharing exposure-relevant information abound, where for competitive reasons both suppliers and their customers have only limited access to information in the possession of the other party.

*Implications for integrated approaches that incorporate exposure information*

There is a critical need to develop international consensus guidelines governing the generation and use of exposure information, addressing:

- scope, completeness and quality;
- means of collection, analysis, QA/QC, verification, validation and reporting/ presentation transparency; and
- representativeness (accounting for both spatial and temporal variability).

Equally important is to ensure the capacity exists and is used to provide adequate expert review of any reliance on exposure information, to ensure that resulting conclusions or decisions:

- explicitly assess the information’s scope, completeness and quality;
- sufficiently acknowledge limitations and the degree of uncertainty; and
- fully qualify conclusions.

Chemical assessment policies must acknowledge and directly address the variable nature of exposure. This means that exposure must be periodically reassessed to account for changes over time in production, use patterns. A corollary need is that requirements for the prompt reporting of such changes needs to be in place.

With respect to the differential access to exposure-related information, government officials need to be provided with authority and be able to demonstrate their ability to independently verify exposure data submitted by industry. Industry should itself commit to mechanisms such as third-party review and public release of all such data. Steps to de-bottleneck supply-chain flows

of exposure-relevant information need to be instituted, by both industry and government. Finally, the allowed scope of CBI claims for such information should be as limited as possible.

Reliance even on reliable and complete exposure information does not preclude the need to develop a hazard characterization for a chemical, which has value independent of exposure and will virtually inevitably be needed as the exposure situation changes.

[END]

## APPENDIX C<sup>1</sup>

### Environmental Defense's perspective on policy issues related to exposure assessment

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April 2005

While both hazard and exposure are clearly relevant in determining chemical risks, there are critical differences between our ability to assess hazard and exposure that have implications for the development and application of exposure assessment policies. And real-world experience in chemical assessment programs that have attempted to rely on exposure information to prioritize chemicals also offers lessons for exposure assessment. In this paper I first address these issues, and then discuss their implications for exposure assessment policies.

#### *Critical differences between assessing hazard and exposure*

Approaches to integrating exposure assessment into regulatory decision-making need to acknowledge and account for a number of critical differences between the nature of hazard and exposure information and their relative extent of availability. While both hazard and exposure are clearly relevant in determining risk, certain characteristics of exposure information pose serious challenges to sound decision-making:

1. Hazard is largely inherent to a chemical, and doesn't fundamentally change over space or time, whereas any exposure information necessarily represents only a "snapshot" in both space and time.

A chemical's *hazard* is relatively intrinsic, largely or entirely independent of how the chemical is used, where or how it enters the environment, or other factors that vary with time and place. Hazard data are therefore relevant (i.e., necessary though not sufficient) in characterizing risk whatever the use of a chemical, and hence are useful in understanding any and all potential uses of or exposures to a chemical -- and what kind of exposure-reducing efforts may need to be taken.

Just the opposite is true for *exposure*, the potential for which changes depending on how a chemical is produced, used, transported and discarded. Conditions that determine exposure can and often do differ enormously for every setting and point in time that a chemical is present.

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<sup>1</sup> Denison, R.A. "Environmental Defense's perspective on policy issues related to exposure assessment," in *OECD Series On Testing And Assessment, No. 51, Approaches to Exposure Assessment in OECD Member Countries: Report from the Policy Dialogue on Exposure Assessment in June 2005*, Chemicals Committee, Organization for Economic Cooperation and Development, p. 109, available at [http://appli1.oecd.org/olis/2006doc.nsf/linkto/ENV-JM-MONO\(2006\)5](http://appli1.oecd.org/olis/2006doc.nsf/linkto/ENV-JM-MONO(2006)5).

And even if a “snapshot” of current exposure were able to be assembled, the next new use or activity leading to a release would alter the exposure picture.

The variable nature of exposure poses a major challenge to exposure (and risk) assessment: It means that exposure assessment must be an ongoing activity, with the scope and frequency of its measurement sufficient to characterize the variation in as well as magnitude of exposure.

2. Voluntary and regulatory mechanisms for generating and collecting exposure information are undeveloped relative to those for hazard information.

Extensive international consensus exists as to how to test a chemical for most hazardous properties. Detailed government-sanctioned procedures, guidelines, criteria and standards are already in place for conducting hazard tests, for assuring the quality and reliability of the results, and for determining whether the results constitute evidence of a particular hazard. Moreover, these measures allow that results are reproducible and can be independently verified.

In contrast, virtually none of these mechanisms are in place to assure that exposure information is complete and accurate. Debates over what constitutes adequate exposure assessment and how to address the “moving target” nature of such information are far from resolved. Government-sanctioned procedures for generating, evaluating the adequacy of and interpreting exposure data have yet to be developed or validated, including testing and measurement standards, guidance, methods and tools.

Even use and exposure information reported in sufficiently qualitative terms or sufficiently aggregated form so as to eliminate any confidential business information (CBI, see next bullet) concern is rarely systematically collected and made public. For the first time, beginning in 2006, USEPA will begin to require the reporting of basic information relevant to understanding uses of and exposure to chemicals, although it will be limited to several thousand chemicals, and will be collected only once every five years – despite enormous documented variability in these chemicals’ production volumes<sup>2</sup> that presumably reflects changes in their underlying use patterns.

3. Differential access to both exposure data and the means to generate them severely limit the “reproducibility” of such data.

In addition to the variability and absence of agreed-upon procedures noted above, other factors limit “reproducibility,” that is, the ability to readily and independently measure or verify exposure data. Most exposure data and the means to generate them reside virtually exclusively with industry. It must be acknowledged that industry has a strong interest in maintaining that

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<sup>2</sup> Environmental Defense’s analysis of production volume data reported under the Toxic Substances Control Act Inventory Update Rule, comparison of data for 1986, 1990, 1994, 1998 and 2002. Available on request. Analysis shows that from one reporting cycle to the next one four years later, the production volume of about 40-50% of reported chemicals changed significantly, likely by one or more orders of magnitude.

exposure to its products is low, so the ability to independently measure and verify exposure data is critical. Yet physical access to many exposure “settings” (e.g., workplaces) is very limited and infrequent at best, even for government officials.

Broader access to exposure-relevant information is even more restricted: Wide latitude is typically provided to claim chemical use and exposure information as CBI, preventing even its review outside government; this situation is often in contrast to that applying to hazard data, which is more likely to be deemed ineligible from designation as CBI.

Finally, even chemical manufacturers have incomplete access to and information on their customers and how their chemicals are used. Intermediaries (vendors, brokers, distributors) are a formidable information flow bottleneck, as is the often-proprietary nature of information concerning downstream use and competition among suppliers. These factors serve to impede information-sharing even within supply chains, which in turn affects the extent and accuracy of exposure-relevant information that any one entity in a supply chain can provide if asked or required to do so.

For all of these reasons, we believe that exposure assessment at this time is simply too uncertain and unreliable for it to serve as a basis for deciding for which chemicals hazard data should be developed. While ultimate decisions concerning risk identification and management need to account for exposure as well as hazard, in all but the most exceptional cases, chemical prioritization approaches should be hazard-, not exposure-driven.

*Difficulty of using exposure information in chemical priority-setting: OECD experience as a real-world example*

The ongoing work of the OECD Existing Chemicals Program vividly illustrates the limitations to available exposure information – and to efforts to prioritize chemicals based on such information. In that program, chemical-by-chemical assessments of high-production volume (HPV) chemicals are conducted. Typically, industry collects existing information and conducts any testing needed to fill gaps in the required set of hazard information. Industry then prepares draft assessment documents, which are reviewed by health and environmental agency officials in member countries. While the primary emphasis is on hazard assessment, program procedures currently allow for exposure information to be included to “place the hazard information into context.” As we have documented in detail elsewhere,<sup>3</sup> in practice this exposure information is routinely being used to decide that chemicals that have been identified as possessing clearly

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<sup>3</sup> Denison, R. and Silbergeld, E., memorandum to the Task Force on Existing Chemicals for its 12<sup>th</sup> meeting, “Environmental Defense’s concerns regarding use of exposure information in making recommendations regarding further work on HPV chemicals,” 15 August 2003; Denison, R., addendum to memorandum to the Task Force on Existing Chemicals for its 12<sup>th</sup> meeting, “Statistics for all chemicals with SIAPs reviewed for SIAMs 15-16 and to be reviewed at SIAM 17 regarding use of exposure information in making recommendations regarding further work on HPV chemicals,” 26 September 2004; Denison, R., memorandum to the Task Force on Existing Chemicals for its 13<sup>th</sup> meeting, “Further Proposal Re Use of Exposure Information in SIAM Recommendations,” 17 September 2004.

hazardous properties are nevertheless low priorities for further work based on “anticipated low exposure.”

Unfortunately, the exposure information typically being relied upon has truly massive deficiencies with respect to scope, quality and completeness.<sup>4</sup> Such information typically is:

- very limited in scope, and hence incomplete or even haphazard in its coverage of potential exposures, because it:
  - covers only a portion of known production and use;
  - covers only a subset of relevant activities, e.g., production, transport, storage, processing, use by customers, use in consumer products, product disposal, waste management;
  - covers only a subset of exposed entities, e.g., workers, consumers, the general population, sensitive populations, and wildlife;
  - addresses only a subset of relevant routes of exposure, e.g., by inhalation, ingestion or dermal contact; through food, water, air;
  - rarely is based on ongoing or sufficiently frequent measurement to address variation or changing conditions;
- unverified, unpublished, rarely peer-reviewed and of uncertain or undetermined quality;
- frequently based on judgment or speculation, rather than on actual measurements, monitoring or validated methods of exposure modeling.

Some of these deficiencies are related to the limited requirements under the program governing what exposure information is to be provided. However, others reflect the fundamental characteristics of exposure information described in the first section of this paper, as well as limitations on the extent and quality of information actually available and the capacity for effective review, and the lack of agreed-upon measures of scope, quality and completeness.

The Existing Chemicals Program has wrestled repeatedly with this problem over its history. Indeed, because of what many saw as an over-reliance on exposure-related considerations in the absence of an agreed-upon approach, the program went through a major refocusing to return to a primary focus on hazard characteristics as the primary driver for the program. However, despite the refocusing effort, inconsistent and insufficient exposure-related information – more than any other factor – drives the recommendation process for chemicals being assessed through the program.

### *Implications for exposure assessment policy*

All of the factors discussed above mean that assembling a complete and reliable exposure picture even for a single point in time faces obstacles and has proven exceedingly difficult in practice. So how should exposure assessment policies – and practices – address these current realities?

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<sup>4</sup> See prior footnote.



*Guidelines development:* We continue to strongly support the development of comprehensive guidelines for collection, analysis, validation and presentation of exposure information, as the much-needed foundation of any exposure assessment policy and practice. In our view, the OECD program needs to invest at least the same effort in developing a process for exposure assessment as was invested in developing the SIDS. There remain a number of substantial obstacles that must be solved in order to ensure that adequately robust data on exposure can be gathered. Resolving these challenges will not be easy. These obstacles include:

- lack of agreement as to what exposure information is relevant and needed;
- lack of consensus as to the framework and methodologies needed to conduct an exposure assessment;
- limited availability of and access to internationally accepted, comprehensive measured exposure information or models for predicting exposure; and
- limited information available on all uses and other exposure pathways of chemicals.

Guidelines need to ensure that the measured and modeled or estimated data address and are representative of the full range of actual and potential exposures that can or do occur. Procedures are needed to govern, for example, the minimum number of samples, the frequency of sampling, and other parameters so as to ensure that the results of any exposure measurements are both statistically meaningful and representative of the spatial and temporal variations present in the sampled environment. Quality assurance/quality control procedures to ensure data quality are needed. Where data are available for only a subset of production sites/release points/exposure sources, procedures are needed to determine whether and if so how extrapolations from available data can be used to characterize exposures arising from the missing sources.

*Adequate expert review:* Policies need to provide for thorough review of exposure information. This starts with ensuring exposure-related expertise among reviewers is sufficiently diverse to address each of the various relevant exposure settings (workplace, consumer, environmental), and data generated through direct measurement as well as modeling. The review process should yield an explicit assessment of the **scope, completeness and quality** of the exposure information, in which any conclusions are qualified to accurately reflect the actual extent and nature of exposure information provided and hence the degree of associated uncertainty. Specific factors to be assessed should include:

- **Scope and Completeness:** geographic, temporal extent of applicability and associated limitations; to what fraction of total production and use, to what uses, and to which specific facilities, processes, activities and products the provided information applies; which activities associated with the chemical's full lifecycle (production, processing, storage, transport, use and disposal) are covered; whether information on releases and exposures relate to workers, consumers, public or the environment; whether information is based on measurements, modeling, judgment, extrapolation.
- **Quality:** extent of documentation provided/cited; reference to/description of procedures used; representativeness of sampling underlying any measured data; validation of any model used; peer review and extent of access to underlying data; assignment of measures of reliability; reproducibility.

*Accounting for the variable nature of exposure:* Policies need to acknowledge and account for the inherent variability in exposure over time as well as space. For example:

- For new chemicals, the nature or extent of production, use and exposure needs to be tracked and revisited/reassessed over time, not only as a chemical enters commerce but as its production level and range of uses change. During the initial review/approval process, conditions should be included that require reporting of any changes in the nature and extent of production and use and other exposure-relevant factors, and such reports should trigger a reassessment of exposure potential.
- For existing chemicals, policies should also be responsive to changes in the production level or use profile of a chemical. One recent illustration of this need in the U.S. is the change that has accompanied the phase-out of pentabromodiphenyl ether and its replacement with a different chemical, the production and use of which has increased dramatically as a result.

*Data verification and model validation:* To the extent data from industry are relied on, policies need to incorporate mechanisms to ensure and demonstrate that such data are accurate and representative, and wherever possible, to be able to independently verify such data.

To the extent that modeled as opposed to measured data are relied on to provide exposure estimates, policies need to outline procedures to be employed to validate the models, provide public access to the models and their underlying data sets. Just as for measured data, policies also need to ensure that models effectively account for variation in exposure over time.

*Differential access:* The differential access to exposure-related information (as discussed above) is a serious barrier to public confidence in both industry- and government-derived exposure assessment. In addition to adopting and abiding by comprehensive guidelines covering all aspects of exposure assessment, government needs to develop and implement mechanisms to demonstrate that it can independently verify the reliability of industry-generated exposure information; and industry needs to be encouraged or required to implement its own measures to increase confidence in the information it provides, including routine third-party review and a commitment to make information public whether exculpatory or not.

In addition, policies need to consider means to break through the supply-chain bottlenecks that effectively prevent development of a full understanding of chemical processing and use. In our view, one of the key innovations offered by the European Union's REACH proposal is its intent to compel information-sharing up and down the chemical supply chain.

Finally, in our view, serious reconsideration of the currently overbroad allowances for CBI claims related to exposure-relevant information is warranted.

*Transparency:* Policies should ensure that any descriptions of exposure information are clear and transparent in describing the scope and nature of the information and its limitations, including by addressing all of the elements specified above under Scope and Completeness and Quality.<sup>5</sup>

Policies should require that conclusions or recommendations be carefully written and explicitly qualified so as to limit their perceived and actual applicability to those settings for which information has been provided and deemed sufficient to warrant the conclusion or recommendation. Furthermore, the degree of uncertainty associated with a conclusion or recommendation should be stated and should reflect the extent of exposure information available. Lastly, policies should ensure that in the absence of good exposure information, exposure should be assumed possible or likely.

### *Additional challenges*

*Cumulative and aggregate exposures:* A common limitation of exposure assessments in practice is to examine exposures only to single chemicals at single points in time, or from single sources or products, as if they occur in isolation from other exposures that are in fact relevant to understanding the true nature and magnitude of exposure. While understandable given the complexity involved in going further, this frequent failure to consider or even acknowledge the need to ultimately examine cumulative and aggregate exposures undermines the credibility of an exposure assessment. Policies, therefore, need to ensure that an accurate context is provided within which to judge a particular exposure assessment, one that accounts for factors such as:

- production, processing and use of the same chemical by multiple entities;
- multiple uses of the chemical leading to actual or potential exposures;
- multiple routes of exposure (direct, indirect) to a chemical;
- continuous or periodic release of or exposure to a chemical; and
- exposure to multiple chemicals producing the same/similar effects and/or acting by the same/similar mechanism(s)

*Biomonitoring/environmental monitoring/health tracking:* The ultimate arbiter of the value of exposure assessment is the extent to which its findings comport with reality. It is relatively rare for extensive data from actual environmental and biomonitoring to be available, and rarer still for health tracking statistics to be available that can be linked to particular exposures. Nonetheless, exposure assessment policies should ensure that such data are examined and incorporated where available, and should encourage the development of and public access to such data.

*Susceptible subpopulations:* In addition to variation over time and space, exposure to a chemical or the effects arising from such exposure may differ among particular subsets of human or ecological populations. This variation may be due any number of factors, such as inherent differences in the subpopulations themselves (e.g., children's respiratory rates are higher than those of adults), differences with respect to proximity to, or reliance on activities associated with, particular sources of exposure (e.g., occupational exposure, dependence on a diet high in fish or

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<sup>5</sup> Revisions proposed at SIAM20 to the *Manual for Investigation of HPV Chemicals* incorporate many of these suggestions, and are an excellent starting point for consideration of clarity and transparency in reporting exposure information.

groundwater as a drinking water source), or differences in sensitivity to a substance (e.g., sensitization, genetic susceptibilities). (Less understood at present are the analogous differences in ecological subpopulations.) Policies need to account for such variations and ensure protection of the most susceptible and sensitive sectors of potential exposed populations.

[END]

## APPENDIX D

### Annex XIII of REACH<sup>1</sup>

#### Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances

This Annex lays down the criteria for the identification of:

- (i) persistent, bioaccumulative and toxic substances (PBT-substances), and
- (ii) very persistent and very bioaccumulative substances (vPvB-substances).

A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3.

A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2. This annex shall not apply to inorganic substances, but shall apply to organo-metals.

#### 1. PBT-substances

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

##### 1.1. Persistence

A substance *fulfils* the persistence criterion (P-) when:

- the half-life in marine water is higher than 60 days, or
- the half-life in fresh- or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh- or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

##### 1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B-) when:

- the bioconcentration factor (BCF) is higher than 2 000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

##### 1.3. Toxicity

A substance fulfils the toxicity criterion (T-) when:

- the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0,01 mg/l, or
- the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

#### 2. vPvB – substances

A substance that fulfils the criteria of the sections below is a vPvB substance.

##### 2.1. Persistence

A substance fulfils the very persistence criterion (vP-) when:

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<sup>1</sup> This excerpt is from the final text of REACH, published in the European Union's *Official Journal*, Volume 49, 30 December 2006, at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_396/l\\_39620061230en00010849.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf).

- the half-life in marine, fresh- or estuarine water is higher than 60 days, or
- the half-life in marine, fresh- or estuarine water sediment is higher than 180 days,  
or
- the half-life in soil is higher than 180.

2.2. Bioaccumulation

A substance fulfils the very bioaccumulative criterion (vB-) when:

- the bioconcentration factor is greater than 5 000.