Regulation of Chemical Risks: Lessons for TSCA Reform from Canada and the European Union

Adam Abelkop, Indiana University - Bloomington
John D. Graham, Indiana University - Bloomington

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Lessons for TSCA Reform from Canada and the European Union

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Adam D.K Abelkop*
John D. Graham†

School of Public and Environmental Affairs
Indiana University-Bloomington

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Please address correspondence to Adam Abelkop at abelkop@indiana.edu.

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* Associate Instructor and Doctoral Student, Joint Ph.D. in Public Policy, Indiana University School of Public and Environmental Affairs & Department of Political Science; J.D., University of Iowa College of Law, 2010; B.A., Wake Forest University, 2007.
ABSTRACT

The United States Congress is considering reform of the Toxic Substances Control Act (TSCA) of 1976. This Article compares recent reforms in Europe and Canada in order to draw lessons for TSCA reform. In 2006, the European Union enacted the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation while Canada used existing authority under the Canadian Environmental Protection Act (CEPA) of 1999 to initiate the 2006 Chemicals Management Plan (CMP). Focusing on the tens of thousands of industrial chemicals now in use in the US, we offer several suggestions for TSCA reform based on the European and Canadian experiences. Congress should consider applying the Canadian approach to prioritization, where high-priority chemicals are identified for assessment and regulation based on limited data and modeling/screening exercises. To facilitate more expedient safety determinations, TSCA reform legislation should separate risk assessment from risk management decisions. Under either approach, improved chemicals governance will require significant new public and private investments in safety information and deliberations. Finally, Congress should consider applying European-style chemical registration to high-priority substances, placing the burden of generating data and proving the safety of specific uses on industry. In summary, an industry obligation to register high-priority chemicals and defend the safety of specific uses would bring new life to TSCA, enhance public health and environmental protection, and buttress public confidence in federal regulation of industrial chemicals.
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INTRODUCTION

Industrial chemicals are ubiquitous. There are ~100,000 chemical substances in commerce around the world.\(^1\) About 30,000 substances are produced at a quantity greater than one metric tonne per year.\(^2\) In the United States, of the 84,000 chemicals listed on the federal government’s inventory, approximately 8,000 (non-polymeric) chemicals are produced in volumes greater than eleven tonnes per year.\(^3\) A relatively small fraction of chemicals account for the vast majority of production volume, but consumers are nonetheless exposed to thousands of chemicals through products that they use every day. They are used in electronics, clothing, furniture, and carpets. They make up products such as cosmetics, detergents, paints, adhesives, and surfactants.

Chemicals provide many benefits to consumers, but they also present risks. Identifying which uses pose significant risks can be a difficult process, as is deciding what should be done when significant risks are identified. Of the chemicals in commerce that have been tested, the majority have been shown to not be hazardous, but industry and government lack even basic data on the intrinsic properties, uses, and exposure pathways for a large number of substances.\(^4\) For decades nations around the world have been updating their regulatory programs to address this

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2 Id.
worrisome gap in information because it hampers the effectiveness of regulatory risk management and impairs public confidence in the safety of the chemical industry.\(^5\)

Regulation of industrial chemicals is in a period of global maturation.\(^6\) In 2002, the United Nations World Summit on Sustainable Development (WSSD) established the goal that “by 2020, . . . chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment . . . .”\(^7\) The WSSD goal constitutes one of several international responses to the need for coordinated assessment and management of the potential adverse effects from chemical exposures. In 1999, the government of Canada revised the Canadian Environmental Protection Act (CEPA) to accelerate the processes of chemical assessment and management. CEPA (1999)\(^8\) mandated that the government categorize its inventory of existing substances to identify priorities for assessment, and the government completed the categorization on schedule in 2006. That year, the Canadian government launched its Chemicals Management Plan (CMP) to meet the WSSD goal.\(^9\)

Also in 2006, the European Union (EU) enacted the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation to address gaps in data, to go beyond prior EU Directives in the control of industrial chemicals, to protect human health and

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\(^8\) Canadian Environmental Protection Act of 1999, http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=24374285-1. The two laws are referred to as “CEPA 1988” and “CEPA 1999.” For our purposes, we use the acronym “CEPA” to refer to the 1999 legislation and specify “CEPA 1988” when referring to the earlier law.

the environment, and to enhance the sustainability and competitiveness of the European chemical industry.\textsuperscript{10}

Japan enacted revisions to its chemicals law in 2003 and 2009, along with South Korea in 2008 and 2013, and China in 2010 and 2013, to name only a few.\textsuperscript{11} Additionally, US states, prominently California, have enacted new programs aimed at assessing and reducing the potential for adverse effects from chemical exposures.\textsuperscript{12}

Meanwhile, the US Congress has been slow to modernize the Toxic Substances Control Act of 1976 (TSCA), despite a broad consensus that the current design of TSCA is outmoded.\textsuperscript{13} Recently, there have been some signs of progress in the TSCA reform effort. In May 2013, the late Senator Frank Lautenberg (Democrat–New Jersey) and Senator David Vitter (Republican–Louisiana) released a bill entitled the Chemical Safety Improvement Act—the most significant of several recent TSCA reform bills because of its bipartisan sponsorship.\textsuperscript{14} The House of Representatives has recently held hearings on TSCA reform, and a draft reform bill has been circulated for comment.\textsuperscript{15} Although it is far from clear that Congress will pass TSCA reform in


\textsuperscript{14} Chemical Safety Improvement Act, http://cen.acs.org/content/dam/cen/91/web/S-1009-113th-Congress.pdf.

\textsuperscript{15} Chemicals in Commerce Act, Discussion Draft, Apr. 22, 2014,
the near future, there is more legislative momentum for reform than there has been since 1976 as evidenced by the serious bipartisan negotiations under way in both chambers of the US Congress.16

As the market for industrial chemicals is global, and because chemical releases can cross borders, future legislation and regulations will likely have international effects on industry management practices, trade patterns, and the global distribution of risks to human health and the environment. Thus, the TSCA reform effort is not an isolated national effort but can be viewed in the context of the global trend toward modernization of chemicals management. US policymakers have the opportunity to learn from the experiences of other nations to craft legislation that will work in harmony with ongoing regulatory efforts.

The cross-national diffusion of environmental policy innovation has been well documented.17 While one country rarely adopts verbatim the environmental reforms of another, key concepts and procedures are often borrowed and tailored.

In that spirit, the purpose of this Article is to compare the regulatory systems in Canada and the EU, and use comparative insights to draw some lessons that may be of interest to US


policy makers engaged in TSCA reform. CEPA and REACH are seen by stakeholders as the state of the art in chemicals assessment and management, and thus the US may draw useful insights from them. Indeed, the European Union and Canada have each been urging other countries to join in a globalization of the REACH or Canadian programs, respectively. Regardless of what TSCA reformers choose to learn from the Canadian and European experiences, a secondary objective of the Article is to provide comparative information that may be of interest to reformers in Canada, Europe, or other countries and regions where chemical risk management is under consideration for reform. Thus, the Article’s long-term value extends beyond the current US debate over TSCA reform.

The Article is organized in three Parts. In Part I, we describe the scope of our analysis, our research methods, and our analytical approach. In Parts II and III, we compare CEPA and REACH across two significant dimensions: (1) prioritization of existing chemicals for assessment and regulation; and (2) placement of the burdens to produce data and demonstrate safety of specific chemical uses. We conclude by summarizing the possible lessons for TSCA reform and highlighting some future research needs.

I. COMPARATIVE ANALYSIS OF RISK REGULATION IN CEPA AND REACH

Regulation of chemicals generally seeks to prevent or reduce adverse effects to human health and the environment. In a variety of ways, regulation facilitates the generation of safety-related information and ensures that such information is made available to regulators and, where permissible, to the public. Safety information is also disseminated via material safety data sheets and labels throughout supply chains where chemicals are processed, transported, and used. Such

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information facilitates informed safety decisions and stimulates green market forces by encouraging safety in the design and selection of chemicals for use in products. Safety information also may spawn risk management measures that can range from guidance on safe handling practices and spill prevention measures to limitations or prohibitions on certain substances or particular uses of those substances.19

Regulatory programs often pursue safety objectives through a process that includes some mechanism for identification of chemicals of concern, assessment of the environmental releases, exposures, and risks posed by those chemicals in specific uses, and management of those releases, exposures, and risks.20 If substitution of a different chemical is considered in the management phase, the risks of the target chemical may be compared to the risks of possible substitutes, including an evaluation of the utility of various chemical alternatives in accomplishing the function needed by industry and consumers. Thus, the management phase of chemical regulation entails a variety of analyses that go beyond an inquiry into the intrinsic properties of a chemical.

A. Risk Assessment and Safety

Risk is present when there is a hazard and sufficient exposure to that hazard. Risk assessment, the primary tool used to make safety determinations, includes four primary components.21 We offer some depth in the review of the four components because it is critical

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20 Andreas Klinke & Ortwin Renn, Risk Governance: Contemporary and Future, in Regulating Chemical Risks: European and Global Challenges 13–22 (J. Eriksson et al. eds., 2010).
for the reader to appreciate (a) how complex a comprehensive risk assessment can be and why rudimentary assessments are useful, (b) the significant degree of uncertainty that can accompany the findings of even well-done risk assessments, and (c) the role of risk assessment in assessing the effectiveness of alternative risk management measures. Since there are good textbooks on the basics of chemical risk assessment,\textsuperscript{22} we simply summarize the four basic components to set the stage for the comparison of CEPA and REACH with regard to risk assessment and management practices.

First, hazard identification evaluates inherent chemical properties to determine the capacity of a substance to cause adverse effects in humans or the environment. Since regulatory resources are limited, governments tend to target chemicals that exhibit particularly troubling properties. Of special concern for human health are chemicals that have toxic effects at relatively low doses, or are known to be carcinogens, mutagens, or reproductive (CMR) toxins. More recently, emphasis has been given to chemicals that are known or suspected to disrupt the endocrine system of the body—endocrine-disrupting chemicals (EDCs).\textsuperscript{23} Greater priority for environmental wellbeing is also given to chemicals that may persist (P) in the environment rather than breaking down, that may bioaccumulate (B) in organisms, and that may be toxic (T). Chemicals that have all three properties are called PBTs.\textsuperscript{24} Chemicals that are very persistent and very bioaccumulative are sometimes referred to as vPvBs and may also be regulated as a special class.

\textsuperscript{23} Laura N. Vandenberg et al., Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses, 33 Endocrine Reviews 378 (2012).
The Fifteenth Century German scientist Paracelsus (credited for founding the discipline of toxicology) explained that “the dose makes the poison.” Alcohol can kill people if ingested in excessive amounts, but alcohol can also improve health if consumed in moderation. All substances can cause toxic effects, but some cause toxic effects at much lower exposure levels than others. There is some evidence suggesting that some EDCs and reproductive toxins may cause effects at low doses that were previously considered safe. Thus, the hazard identification process, by itself, does not provide meaningful information about risk because knowledge of risk also requires knowledge of the amount of exposure in the real-world environment.

The second step of risk assessment is dose-response assessment, where the level of exposure to a substance (e.g., the dose) is related to the frequency and/or severity of adverse effects (the response). Sometimes the level of exposure is simply compared to the level of exposure that is considered safe, with the ratio of the exposure level to the safe dose serving as an indicator of risk. The dose-response relationship is influenced by how the chemical is taken up, distributed, and metabolized by the body and the biological mechanisms that relate dose to adverse effects. As dose to an organism increases, other factors held constant, the probability (or severity) of adverse effects is expected to increase. If large numbers of people are exposed to substances that exhibit toxic effects at relatively low doses, the number of adverse health outcomes in the population can be substantial.

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25 Applegate et al., supra note 21, at 4.
26 See generally Ted Schettler, Gina Solomon, Maria Valenti & Annette Huddle, Generations at Risk: Reproductive Health and the Environment (1999); Vandenberg et al., supra note 23.
28 The low-dose effects of bisphenol-A, the primary component of many plastics, are a matter of intense scientific and public debate. See Wargo, supra note 23, at 272–76; Sarah A Vogel, Is It Safe? BPA and the Struggle to Define the Safety of Chemicals (2013).
The concept of dose-response assessment applies to non-human species as well as people, but the unit of analysis may be different. When dose-response analysis is performed to protect humans, the protection is modeled at the level of the individual human being (or even an organ or tissue). When applied ecologically, dose-response analysis is designed to inform protection at the population level, except in rare cases such as an endangered or threatened species.

When there is an exposure level that is sufficiently small to effectively eliminate any possible adverse effects on an organism, that dose is called a threshold. Since some individuals are more sensitive to chemical risks than others, the strict threshold for an entire population of human beings is the threshold for the most susceptible person in the population. In practice, sensitivity to chemical exposure is usually analyzed for groups of people rather than on an individual-by-individual basis. The “safe” dose of a chemical in humans is typically assumed to be a fraction of the presumed threshold in laboratory animals because margins of safety—also known as uncertainty factors or assessment factors—are applied to account for possible uncertainties, including the imperfections in data quality, the extrapolation of data from the test species to humans, the extrapolation of effects from high experimental doses to low doses, and intra-species variability (e.g., some humans are more sensitive than others). Historically,

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29. On the distinction between the individual and population dose-response function, see NATIONAL RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 141–43 (2009).
30. The term safe is in quotation marks because laboratory tests with limited numbers of animals cannot demonstrate safety in the strict sense that such a term may be understood by some citizens. In practice, toxicologists find a dose where there is no observable adverse effect, though there may by some effects that are not statistically significant or not adverse. A more modern procedure is to use the dose-response data in the animal test to calculate a lower confidence limit on the dose predicted to produce a defined incidence rate of adverse effect—usually about 10% or so—or a change in a continuous physiological parameter of a pre-set magnitude. The important point is that a negative test result at a particular dose does not necessarily mean that the dose is completely safe. For a classic introduction to the issues in using animal data in risk assessment and safety determinations, see David P. Rall, The Use of Laboratory Animal Carcinogenicity Data in Occupational Risk Assessment, in CHEMICAL RISK ASSESSMENT AND OCCUPATIONAL HEALTH: CURRENT APPLICATIONS, LIMITATIONS, AND FUTURE PROSPECTS 105–11 (C. Mark Smith, David C. Christiani & Karl T Kelsey eds., 1994). For a basic statistical treatment of the issues, see CHARLES D. HOLLAND & ROBERT L. SIELKEN, QUANTITATIVE CANCER MODELING AND RISK ASSESSMENT (1993).
31. For a classic introduction to the determination of “safe” doses, see JOSEPH R. RODRICKS, CALCULATED RISKS: THE TOXICITY AND HUMAN HEALTH RISKS OF CHEMICALS IN OUR ENVIRONMENT (2d ed., 2006).
thresholds have been assumed to exist for non-cancer effects but not for cancer; however, recent reviews suggest that this distinction is too simple since some non-cancer effects may not exhibit thresholds while some cancer effects may exhibit thresholds.\textsuperscript{32}

Third, exposure assessment aims to determine the extent to which human and non-human species will come into contact with a substance, whether via respiration, ingestion, or dermal contact. To quantify the exposure for a population of interest, the exposure assessor usually works with information on the production quantity of a chemical, the amount of the chemical dedicated to various uses, the quantity released into the environment (air, water, soil) during specific uses, the transport and fate of the chemical in the environment, and the ultimate population distribution of exposure. The behaviors of people on a day-to-day basis (e.g., dietary habits and indoor versus outdoor activity) can significantly influence the level of human exposure to a substance. Exposures may be measured directly (e.g., with air and water quality measurements or with personal exposure monitors) or estimated through the use of mathematical models. A key statistic of growing importance to risk assessment is the “intake fraction,” the proportion of a released chemical that ultimately is taken in by people via ingestion, respiration, or dermal absorption.\textsuperscript{33}

Fourth, risk characterization generates a (usually) quantitative estimation of the magnitude of risk to human health and the environment from specific uses of a chemical.\textsuperscript{34} A simple version of characterization may be the ratio of an exposure from a specific use to a safe level. A more complex characterization is a quantitative indication of risk such as a probability of an adverse effect or a projected incidence rate of adverse effect in an exposed population.

\textsuperscript{32} NRC 2009, supra note 29, at 177.
\textsuperscript{33} Deborah H. Bennett et al., \textit{Defining Intake Fraction}, 36 \textbf{ENVIRONMENTAL SCIENCE AND TECHNOLOGY} 207A (2002).
\textsuperscript{34} \textit{Id.}
Characterization requires the examination of hazard and exposure data together, accounting for uncertainties and assumptions in test data, monitoring data, and data generated from computer modeling programs.

The same chemical may be characterized as high risk or low risk depending on how it is used by industry, how much of the chemical is released near population centers or downwind or downstream of population centers, or how much of the chemical may reach consumers via the use of specific products (e.g., dishwashing, detergents, paints, and flame retardants). Thus, for an industrial chemical with numerous uses, the risk characterization—and especially the exposure assessment—can be quite complex. The adoption of risk management measures also influences the risk characterization by reducing the exposures to the target chemical. Thus the risk characterization may portray not only the current level of risk, but the projected levels of risk under alternative risk management measures.

Recently, the scientific committees of the European Commission’s Directorate-General for Health and Consumers produced an important document on the need for refinement of risk assessment procedures. For ecological risk assessment, the document recommends moving toward approaches capable of better understanding and quantifying actual damages to the structure and functioning of ecosystems. For human risk assessment, the recommendation is to move from a substantially hazard-driven approach toward more exposure-driven assessments.

Exposure assessments on a chemical-by-chemical basis have an important limitation: they do not account for simultaneous exposure to more than one chemical. There may be adverse effects from cumulative exposure to multiple chemicals or even synergistic effects (e.g., where

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35 On the complexities in exposure assessment, see ALISON C. CULLEN & H. CHRISTOPHER FREY, PROBABILISTIC TECHNIQUES IN EXPOSURE ASSESSMENT: A HANDBOOK FOR DEALING WITH VARIABILITY AND UNCERTAINTY IN MODELS AND INPUTS (1999).
exposure to one chemical causes biological changes that render an organism vulnerable to exposures to another chemical). Thus, exposures to more than one chemical complicate the risk assessment process.\(^{37}\)

Any form of risk assessment may leave some questions unanswered due to the current limitations in scientific knowledge. For example, when humans are exposed to very small doses of chemical carcinogens, the doses may be too small to detect a possible elevation of cancer risk through either animal testing or epidemiological observation. More generally, uncertainties arise with regards to both the proper interpretation of hazard data on specific substances (e.g., scientific synthesis or interpretation of multiple studies concerning the toxicology and/or epidemiology of adverse effects from chemical exposures). The biological mechanisms that give rise to adverse effects may provide important clues to the shape of the dose-response curve at low doses and to the reliability and relevance of animal test data for human risk determination. It is not always easy to determine whether only one biological mechanism is at work or whether multiple mechanisms are contributing to adverse effects.

Since risk assessments are often conducted in the face of incomplete data and imperfection in basic scientific understanding, assumptions—based on professional judgment and policy values—are made throughout the process.\(^{38}\) There are a surprisingly large number of methodological choices (~50)\(^{39}\) in chemical risk assessment that can drastically affect the outcomes of the assessment, and those choices are associated with greater uncertainty for some


\(^{39}\) For a tabular presentation of the 50+ analytic choices in chemical risk assessment, see GOVERNMENT ACCOUNTABILITY OFFICE, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES’ PROCEDURES, ASSUMPTIONS, AND POLICIES, GAO-01-810, Appendix II, Table 5, 120–50 (2001).
chemicals than for others. Some of these choices are determined by a regulatory agency’s science-policy guidance (e.g., a general presumption has been established that chemicals shown to cause cancer in laboratory animals are an indication of potential human cancer risk) while others are left for professional judgment on an assessment-by-assessment basis (e.g., when should an assessment focus on the inhalation route of exposure, and omit detailed consideration of the potential for dermal contact or ingestion of the substance).

Risk assessments contain inherent uncertainty but risk assessors can still perform better in priority setting than lay citizens with no scientific training. Indeed, insights from risk assessments—like much of the knowledge in clinical medicine—arise from professionals who have learned about real-world experiences with multiple chemicals in the past. Moreover, risk assessments become even more informative as critical data gaps on chemicals in commerce are filled and uncertainties reduced.

Finally, the need for risk assessment does not end when it becomes clear that the risks of an existing chemical in specific uses are significant. Some form of risk assessment is also essential to inform the innovative process of green chemistry. Regulators and industry cannot be certain that replacing one chemical with another contributes to lower levels of health and environmental risk without carefully examining the relative risks of the target and substitute chemicals. Professional judgments about risk tradeoffs also play an important role in the process of chemical substitution.

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Since the science underpinning risk assessment is maturing and new data are constantly being collected on individual chemicals, real-world risk assessment should be a dynamic process. The results in one risk assessment report may need to be updated in response to new information. Sometimes the new information suggests greater risk than previously projected;42 in other cases the new information is reassuring because it suggests less risk than previously predicted.43 Thus, risk assessment is a process that unfolds with changes in the available information base, in the amounts of chemicals used in different applications, and in scientific advancements.44 Although such adaptive approaches to risk assessment and management have appeal, they are not easy to incorporate into the adversarial legal environment that has characterized implementation of the Toxic Substances Control Act.

B. Balancing Risk and Benefits in Various Uses

The risk assessment process is designed to inform industrial managers as well as regulators about safety and the possible need for—and effectiveness of—risk management measures. The applicability of management measures will vary depending on how industry is using a chemical.

There are a wide variety of measures that may reduce risk: application of new technologies to industrial processes to prevent or reduce emissions, leaks, and spills;
performance standards that limit volume, concentration, or releases over time; information or educational interventions that alert consumers, workers, or other market actors to potential risks and greener alternatives; stricter handling and waste-disposal practices; restrictions on specific chemical uses; and complete prohibitions on the manufacture and importation of substances. When regulators are considering a ban, it is not uncommon for manufacturers and users to undertake voluntary measures to either reduce risk with the existing chemical or to implement chemical substitution.45

Since the benefits and risks of a chemical vary enormously by use, it is rare that useful chemicals are prohibited in all applications. Even a chemical such as dichloro-diphenyl-trichloroethane (DDT), which has been known for decades to cause toxicity to wildlife when released into the environment, is still used in the developing world to control vectors for malaria.46 But this is the only residual use of DDT permitted under the Stockholm Convention on Persistent Organic Pollutants, and the present uses of DDT on a global basis are less than 1% of the global use of DDT prior to the ban.47 The argument is that the benefits of DDT use for malaria control justify the environmental risk.48 Risk-reduction measures may be preferred to bans in situations where there are no effective, safe, or affordable substitutes and where the benefits of the chemical to industry, consumers, and the public are significant.49

45 The wisdom of relying on substitute chemicals is spawning an entire new field of analysis sometimes called “alternatives assessment.” Cheryl Hogue, Assessing Alternatives to Toxic Chemicals, CHEMICAL & ENGINEERING NEWS, at 19–20, December 16, 2013. Alternatives assessment is a close cousin of risk-tradeoff analysis. See Gray & Graham, supra note 41, at 178–89.
46 On the harmful effects of DDT (from its breakdown product DDE), see Jeffrey L. Lincer, DDE-Induced Eggshell Thinning in the American Kestrel: A Comparison of the Field Situation and Laboratory Results, 12 JOURNAL OF APPLIED ECOLOGY 781 (1975).
The regulatory approaches in Canada and the EU share much in common but also differ in significant ways. We thus turn to a comparison of the two regulatory systems, keeping in mind this background on how risk assessment is used to inform risk management.

C. CEPA and REACH as a Basis for Comparison

The Canadian and European approaches to chemicals governance lend themselves well to a comparative analysis. The CMP and REACH were both launched in late 2006, and US policymakers can learn from an empirical investigation of how each program has proceeded. Significant work in assessment and management has been completed under both laws. Yet, implementation is not complete, as both have set 2020 as a tentative implementation milestone.50 Open questions remain as to how the CMP will proceed into its final years and how EU Authorities will implement REACH. Therefore, while our primary focus is on drawing lessons to inform the ongoing debate over TSCA reform, our report also sheds light on what Canadian and European lawmakers can learn from each other’s programs.51

Canada and EU Member States are amongst the United States’ largest trading partners, and chemicals management can raise notable trade issues.52 The US is already working to harmonize regulations with Canada and the EU through the Regulatory Cooperation Council and the Transatlantic Trade and Investment Partnership, respectively.53

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opportunity with TSCA reform to design a regulatory program that acts in harmony with both
CEPA and REACH. European and Canadian approaches to chemicals governance also make for
a fruitful comparison because the Nordic countries and Canada have traditionally been among
the most active nations in international chemicals governance due to their concern about adverse
effects of pollutants on Arctic populations and ecology.\textsuperscript{54}

Finally, in congressional hearings on TSCA reform, legislators have shown a keen
interest in regulatory activities in both Europe and Canada.\textsuperscript{55} Testimony, however, has tended to
focus on REACH, with only scant references to CEPA and the CMP. This report therefore fills a
gap in the recent dialogue on TSCA reform by bringing Canadian experiences to the forefront of
the discussion.

There is already a comparative literature on TSCA and REACH. John Applegate, for
example, employs a Hegelian dialectic method, presenting TSCA as the thesis and REACH as its
antithesis (the “anti-TSCA”).\textsuperscript{56} There are also a few reports that include CEPA in their

\begin{footnotesize}
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\item SELIN, supra note 6, at 170–71.
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comparative analyses.\textsuperscript{57} Dr. Richard Denison of the Environmental Defense Fund released a noteworthy report in 2007 reviewing the design of REACH, TSCA, and CEPA.\textsuperscript{58} He provides useful comparative insights on how the design of each program addresses prioritization, data production, risk management for new and existing substances, and information sharing and disclosure. Our Article builds on the work of Applegate, Denison, and others by drawing findings from empirical observations after seven years of CMP and REACH implementation.

\textit{D. Research Method}

We gathered information from primary legislative and regulatory texts, regulatory guidance materials, secondary scientific and policy literatures, and notes from several rounds of interviews with dozens of specialists in government, industry, public interest organizations, and the academic community. We conducted interviews by phone, in person, and through e-mail exchanges. To encourage candor, we assured interviewees that we would not assign specific viewpoints to specific individuals. We list all of the interviewees and their organizational affiliations in Appendix A.

To learn about REACH, we, along with Professor Lois Wise (Indiana University) and Ágnes Botos (REACH consultant in Budapest, Hungary), interviewed 29 individuals, including officials in the European Commission in Brussels (Directorate-General for the Environment and Directorate-General for Enterprise and Industry), the European Chemicals Agency (ECHA) in


\textsuperscript{58} DENISON, supra note 57.

We, along with Professor Todd Royer, Mallory Mueller (both from Indiana University), and an interdisciplinary panel of experts from Europe and the US, gathered more recent data through a second round of 38 interviews conducted between November 2012 and June 2013. This project culminated in the release of a report in 2013 entitled \textit{Scientific and Policy Analysis of Persistent, Bioaccumulative, and Toxic Chemicals: A Comparison of Practices in Asia, Europe, and North America}.\footnote{ABELKOP ET AL., supra note 24.} Although the interviews focused on the science and policy of PBTs, we were also able to gather data from these interviews on the current state of assessment and management practices under REACH and other regulatory programs to inform our analysis.

To learn about CEPA and the CMP, we interviewed 15 individuals in Environment Canada, Health Canada, Canadian industry, academics, and a Canadian public interest organization. One of the authors also attended the 2013 CEPA Update Conference, organized by the Industry Coordinating Group for CEPA, in Mississauga, Ontario in June 2013. The
conference featured detailed presentations from representatives of government and industry on
the administration of CEPA and the CMP.62

Altogether, we interviewed 82 individuals from 2010 to 2014 who offered insight on
chemicals regulation. Thus, our report draws significantly on stakeholder perspectives.

E. Scope and Dimensions of Comparison

While the regulation of new substances is an important and somewhat contentious aspect
of regulatory design (about 600 new industrial chemicals are introduced into US commerce each
year),63 our analysis is limited to existing substances because regulatory programs, prominently
those under CEPA and TSCA as well as EU regulations that pre-date REACH, all treated new
substances with greater scrutiny than existing substances. Historically, existing substances
lacking a significant prior history of major health or environmental risks were simply
grandfathered into acceptance under a presumption of safety, without a full set of basic data on
uses, exposure pathways, and hazardous properties.64 REACH and the CMP are designed to
address this disparity in assessment. The focus of TSCA reform is also on existing industrial
chemicals.65 Moreover, regulation of existing chemicals is even more politically controversial
than new chemicals because there are identifiable companies, workers, and consumers who
derive their livelihood from existing substances. For these reasons, we focus on the legacy of
existing industrial chemicals.

62 Industry Coordinating Group 2013 CEPA Update Conference, Agenda,
63 GAO, supra note 3, at 26.
64 APPLEGATE ET AL., supra note 21, at 281; DENISON, supra note 57, at I-1.
65 See JERRY H. YEN, CONG. RESEARCH SERV., PROPOSED REFORM OF THE TOXIC SUBSTANCES CONTROL ACT
(TSCA) IN THE 113TH CONGRESS: S. 1009 COMPARED WITH S. 696 AND CURRENT LAW 1 (2013),
We concentrate on industrial chemicals because agricultural chemicals, biocides, and pharmaceuticals tend to raise different policy and scientific issues. They are also regulated under different statutory regimes.

Our analysis explores two aspects of regulatory design: prioritization of existing substances for risk assessment and regulation and the allocation of burdens to produce safety data and demonstrate safe use of chemicals. We have chosen these two dimensions for examination because (a) they are central to any chemical regulatory system, (b) they capture some of the most innovative features of the Canadian and European systems, and (c) Canada and Europe differ significantly on these two dimensions.

There are many other features of the two regulatory programs that could be compared: the legal definitions of safety, the treatment of confidential business information, the procedures for regulating new chemicals, the guidelines for measuring the benefits and risks of specific uses including the risks of possible substitutes, and the role of public participation and judicial review in the regulatory processes. We encourage application of a comparative approach to these issues as well.

II. PRIORITIZATION AND SCREENING IN RISK ASSESSMENT

Above we provided some basic information on the general steps involved in risk assessment. In this Part, we compare CEPA and REACH in their approaches to prioritization and risk assessment. We begin by providing additional detail on prioritization and the use of screening techniques in risk assessment. We then deliver empirical descriptions of these processes under CEPA and REACH, followed by lessons for US policy makers.

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66 Though REACH uses the same processes to govern new and existing chemicals.
Risk assessment requires information on hazard and exposure; however, there are wide variations in the amount, type, and level of detail of data that assessors may include in their evaluations. A comprehensive risk assessment includes data on numerous matters such as degradation/persistence, bioaccumulation, toxicity (human health and ecological), dose-response functions for various toxicological endpoints (e.g., reproductive effects and carcinogenicity), production and importation volume, commercial uses, concentrations present in various environmental media, releases from different uses, waste disposal methods, and potential pathways for exposure after release into the environment occurs. Sources of data vary. They may be generated from laboratory tests (e.g., toxicity tests on animals) or field observations (e.g., biomonitoring in human blood or remote sensing of chemicals in the environment). Data may also be estimated based on complicated computer modeling programs that employ statistical techniques.

The information necessary to support a comprehensive risk assessment can be difficult, time consuming, and expensive to obtain. Even a single component of the risk assessment, namely the hazard characterization of a chemical, has taken decades to complete in some cases, and the resulting management decisions have been highly contentious. For example, EPA’s risk assessment process for formaldehyde under TSCA began in the early 1980s. Several draft risk assessments were released for peer review and public comment, including a most recent draft

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released in 2010. Likewise, the EPA assessment of trichloroethylene (a common groundwater contaminant) was begun in the 1980s. Multiple drafts of the risk assessment have been produced, with the final draft issued in 2014. Indeed, both CEPA 1999 and REACH were enacted, in part, because assessment and management decisions under their predecessors were taking too long. TSCA reformers are also looking for a way to accelerate risk assessment and management and reduce the ossification that appears to have plagued EPA decision making under TSCA in the past.

In an ideal world, complete data sets would be available for all chemicals that people and the environment may be exposed to. Yet, industry and regulatory agencies are faced with the legacy of tens of thousands of substances that appear on various inventories of existing chemicals in commerce. Given limited personnel and financial resources, there are two general approaches to streamline the risk assessment process to enable more expedient management decisions: the use of a screening, or tiered, approach to risk assessment and systems for prioritizing which chemicals should be assessed first.

An alternative to comprehensive risk assessment is a screening level assessment. Screening techniques can be accomplished much faster than comprehensive risk assessments since screening assessments require relatively limited data to implement. Screening

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72 NATIONAL RESEARCH COUNCIL, APPLICATIONS OF TOXICOGENOMIC TECHNOLOGIES TO PREDICTIVE TOXICOLOGY AND RISK ASSESSMENT 73 (2007). “A screening test can be defined as one designed to detect a state or property
assessments often rely on modeling and estimation techniques. If new data are generated for screening, tests may use “higher and fewer doses of the compound being studied, fewer test subjects, a shorter time period of observation, and less extensive evaluation” of outcomes. Comprehensive risk assessments, on the other hand, ideally rely on the generation of new data, higher quality tests (e.g., greater number of test subjects over a longer period of time), a wider variety of data, and consider a richer suite of endpoints.

A regulatory system might favor screening level assessment over comprehensive risk assessment to avoid “paralysis by analysis.” Value of information (VOI) analysis is a useful frame for intelligent priority setting and information gathering. “VOI is entirely decision-centric. In a VOI analysis, an information source is valued solely on the basis of the probability and magnitude of its potential impacts on a specific decision at a specific time with a specific state of prior knowledge.” In other words, regulators only need to gather just enough information that allows them to make a risk determination. If additional information would not likely lead to a different determination of risk, then obtaining that information might not be cost-effective.

Whether a chemicals governance regime emphasizes a comprehensive or screening approach to risk assessment, priority setting for assessment and management is essential to maximizing the public health and environmental benefits of regulation. Effective prioritization requires regulators to apply science-based criteria to identify chemicals of concern and further
prioritize among those chemicals—including numerous uses—for purposes of assessment and management.

A priority-setting system for risk assessment could start with a focus on chemicals with hazardous properties, or it could start with a focus on chemicals that are commonly released into the environment (e.g., due to high-volume production and dispersive uses). If a priority-setting system starts with a focus on chemical properties, it must later consider uses and exposures or it may not address significant risks. If the system starts with an exposure focus, it must later consider hazard or it may also miss significant risks. Conceptually, priority setting for risk assessment could consider both hazard and exposure from the start, but such a risk-based priority-setting process is more complex, data intensive, time-consuming, and expensive for government and industry. Regardless of whether priority setting for risk assessment starts with consideration of hazard, exposure, or both, the result of priority setting is a manageable number of chemicals and/or uses that are subject to risk assessments.

To be efficient, priority setting will necessarily involve some rudimentary form of screening based on priority criteria. However, without hard data, any priority-setting approach will leave a lingering uncertainty about whether the screening techniques have missed a bad actor. Thus, there is a tension between the desire for timely risk management decisions and the need to fill the data gaps that are a source of concern. A classic chicken-egg dilemma plagues the design of any priority-setting scheme. There is a temptation to wait for adequate data, since

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77 In Europe, the hazard aspect is sometimes subdivided into four components: chemicals that threaten human health (e.g., toxic, carcinogenic, genotoxic, reproductive toxin, endocrine disruptor); chemicals that threaten environmental quality (e.g., ecotoxicity, endangered species, ecosystem integrity, purity of air, soil, and water, restriction of land use); chemicals with hazardous traits that could lead to damages over time (e.g., persistency, potential to bioaccumulate, potential to break down into more harmful substances, capability of being transported over long distances); and chemicals that can lead to harm if combined with other chemicals or if used in special contexts in which exposure and damage are likely to occur. Professor Ortwin Renn, University of Stuttgart, Personal communication, April 27, 2014.

78 Ditz, supra note 57 (indicating that risk-based prioritization is problematic if data on risk are not available).
data are needed in order for government to set evidence-based priorities. If risk assessments are delayed until adequate data are available, the resulting risk assessments and regulatory decisions might be made in a more informed and perhaps somewhat less contentious way.\textsuperscript{79} On the other hand, since it would take many years to develop adequate data on thousands of existing chemicals, there is a cogent argument for undertaking preliminary risk assessments promptly, to identify chemicals and uses of likely concern, before adequate data are available on all chemicals.

The precautionary principle, which was introduced in the 1992 Rio Declaration on Environment and Development, supports such an approach and was incorporated into CEPA through its preamble: “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”\textsuperscript{80} CEPA § 76.1 directs EC and HC to consider the weight of evidence and to apply the precautionary principle in conducting and interpreting risk assessments. REACH is also based on precautionary reasoning.\textsuperscript{81} Screening level assessments can be precautionary by applying worst-case scenarios for exposure and conservative assumptions about toxicity (e.g., based on the known toxicity of structurally similar chemicals).

We now assess how prioritization and tiered levels of assessment are incorporated into CEPA and REACH.

A. \textit{CEPA 1999 and the CMP}

The government of Canada regulates industrial chemicals primarily under the authority of the Canadian Environmental Protection Act, which was first enacted in 1988 and revised in

\textsuperscript{79} Id.
\textsuperscript{81} REACH, art. 1(3).
CEPA 1999 formed the basis for present regulatory activities by requiring Environment Canada (EC) and Health Canada (HC) to categorize existing chemicals by the end of 2006 in order to identify priority substances for risk assessment. In 2006, the government of Canada launched the Chemicals Management Plan to submit the identified substances warranting further evaluation to various degrees of screening assessments (less than full risk assessments) to determine whether management is called for. Existing chemicals are listed on the Domestic Substances List (DSL)—a total of about 23,000 substances that were manufactured in or imported into Canada in quantities equal to or greater than 100 kg/yr between January 1, 1984 and December 31, 1986. The categorization identified each substance as a priority or non-priority, based on ecological and health criteria. The CMP further designated priority substances as high, medium, or low priorities. The relationship between categorization and the CMP is depicted in Figure 1.

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82 The Canadian literature refers to the laws as CEPA 1988 and CEPA 1999. Here, we use “CEPA” to refer to the 1999 legislation and specify when we are referring to the earlier law.
83 CEPA § 73.
Figure 1. Overview of Prioritization and Risk Assessment under CEPA

**Categorization**
(1999–2006)

~ 23,000 substances on the Domestic Substances List categorized as high or low priority;
~ 4,300 substances identified as high priority

**Chemicals Management Plan**
(2006–2020)

further prioritization and screening assessment of the ~ 4,300 identified priority substances

- No further action
- **Toxic Substances List**
  provides authority for risk management,
  ~ 30 policy tools
1. Categorization

CEPA § 73(1) established four criteria to categorize chemicals on the DSL: greatest potential for exposure (GPE) to individuals in Canada, persistence (P), bioaccumulation (B), and inherent toxicity (iT) to human beings and non-human organisms.\(^85\) The CMP also uses these criteria for further prioritization—PBiT as ecological criteria, and GPE and iT as human health criteria.\(^86\)

Under CEPA, there is a difference between inherently toxic and toxic. The “inherent toxicity” determination is equivalent to a toxicity determination in other contexts; it is solely a hazard-based determination of whether a substance causes toxic effects at tested doses. Canada uses the iT designation, though, because “toxic”—without the preceding “i” for “inherent”—has a specific legal meaning under CEPA that does not correspond with the general scientific understanding of toxicity.\(^87\) The determination that a substance is “toxic”—often referred to as “CEPA-toxic”—is a purely legal finding and is distinct from whether the substance is “inherently toxic.” A substance is CEPA-toxic “if it is entering or may enter the environment in a quantity or concentration under conditions that” may result in harm to human health or the environment.\(^88\) Thus, while inherent toxicity is a hazard-based determination, the formal “toxic” (CEPA-toxic) determination is based in risk as it incorporates potential for exposure.\(^89\)


\(^87\) Meek & Armstrong, supra note 72, at 594.

\(^88\) CEPA, § 64.

\(^89\) Geoff Granville, Report to the ICG on Screening Assessments under the CMP, Dec. 21, 2012, at 3.
toxicity is a categorization and prioritization criterion while CEPA-toxicity is a legal designation that authorizes the initiation of the risk management process.

Categorization of the DSL under CEPA constitutes an initial prioritization effort. Regulators applied the criteria through chemical-specific hazard profiles—rudimentary analyses based on existing data, modeling, expert judgments, and plausible assumptions. The agencies constructed these profiles by gathering and evaluating data themselves and through submissions by interested parties. The data collection and decision-making steps for EC and HC in the categorization process are depicted in Figure 2.
Figure 2. DSL Categorization Process for Environment and Health Canada

1. DSL Substances
2. Collection of Existing Data
3. Scientific Evaluation of Data
4. Likely or unlikely P or B and iT to human or non-human organisms; greatest potential exposure
5. Data Submission by Interested Parties
6. Evaluation of Additional Data
7. Publication of Final Categorization Decisions

- Not considered P or B and iT to non-human organisms; not considered GPE or iT to humans
  - No further action at this time as a result of this exercise
- Considered P or B and iT to non-human organisms; considered GPE or iT to humans
  - Prioritized for screening assessment under the CMP
EC and HC completed the categorization of the DSL on schedule in September 2006, identifying 3,900 substances that met either or both of the human health and ecology criteria for categorization.\textsuperscript{90} In addition, HC determined that another 400 substances, which met neither the human health nor ecology criteria, nonetheless warranted further attention from a human health perspective, bringing the total number of prioritized substances to 4,300.\textsuperscript{91} That EC and HC completed DSL categorization on schedule is a remarkable achievement, given the scale and complexity of the task. The establishment of strict legislative time frames for prioritization and other assessment tasks is viewed as central to the success story.

Following the initial categorization, EC and HC examined industry data gathered from 2001 to 2006 to determine whether certain priority substances were still in commerce within Canada at or above the 100 kg/year DSL threshold.\textsuperscript{92} Through this process, EC removed 145 PBiTs that did not meet the criteria from priority consideration.\textsuperscript{93} However, these substances are not completely free of regulation because they are subject to requirements under the CEPA Significant New Activity (SNAc) approach, which governs the re-introduction and new uses of existing substances.\textsuperscript{94}


For the remaining priority substances (more than 4,000), further assessment was warranted. The CEPA § 73 “categorization-level” hazard profiles triggered a Screening Level Risk Assessment (SLRA) under § 74. Under CEPA, a SLRA assesses the weight of evidence and applies the precautionary principle to determine whether a substance is CEPA-toxic or capable of becoming so. Recall that the risk-based determination that a substance is CEPA-toxic authorizes the initiation of the risk management process.

The CMP constitutes the government of Canada’s strategy to further prioritize and assess the priority substances by 2020. This represents a gargantuan task considering a single comprehensive risk assessment can take decades to complete. The CMP, therefore, embodies a compromise between making informed decisions and making expedient decisions. As such, the CMP strategy, discussed in greater detail below, is a response to Canada’s experience with conducting comprehensive risk assessments as part of its Priority Substances List mechanism.

2. Priority Substances List

The Priority Substances List (PSL) is a complex process that is no longer used in Canada; however, it is necessary to describe the PSL in order to explain why the government of Canada adopted the more streamlined CMP approach. Whereas the CMP is not formally mentioned in any legislation, CEPA 1988 and CEPA 1999 established and maintained the PSL framework for prioritization and risk assessment of industrial chemicals.

95 CEPA, § 74.
97 CEPA, § 46(1)(a).
Under the PSL, EC and HC subjected listed substances to a more comprehensive risk assessment rather than a SLRA. Both forms of risk assessment are designed to inform the determination as to whether or not a substance is CEPA-toxic, but the SLRA approach tends to be much more focused, less resource-intensive, and more rapidly completed. The level of assessment in a SLRA is flexible and depends on the nature of the information available as well as the potential risks and can range from a lower tier to an in-depth assessment. SLRAs can rely heavily on modeling and estimation techniques and conservative (high) estimates of exposure. Full risk assessments, on the other hand, may require the generation of new data to determine, for example, modes of action and more likely exposure scenarios. Though these more comprehensive assessments conducted for PSL substances provided regulators with much more information than screening assessments, they were much more time and resource intensive, and therefore constrained the number of substances that authorities could evaluate expeditiously.

The first PSL, published in 1989, listed 44 chemicals.98 The PSL includes a five-year timeline to complete risk assessments.99 Risk assessments were completed in early 1994 and 25 substances were identified as CEPA-toxic.100 The government published the second PSL in 1995, this time listing 25 substances for risk assessment. Authorities found 18 of them to satisfy the criteria for CEPA-toxicity.101

Through the CEPA PSL framework, Canada has addressed a number of substances of notoriety, including dioxins, furans, hexachlorobenzene (HCB), hexachlorobutadiene (HCBD),

99 CEPA § 78.
and chlorinated paraffins, to name a few. Nonetheless, the government, industry, and non-governmental organizations (NGOs) all considered the PSL process to be too slow and, ultimately, impractical. The excessive length of the assessment process was a major driver for the creation of the 1999 update of CEPA, with its requirement for a seven-year period to categorize substances on the DSL. Notably, the PSLs were established under the original CEPA 1988 legislation. To date, the PSL mechanism has not been used under CEPA 1999, and it seems unlikely that it will be used in the foreseeable future. The PSL provides an informative contrast to Canada’s successor—the CMP.

3. Chemicals Management Plan

The government of Canada introduced the Chemicals Management Plan in 2006, following the completion of the DSL categorization. The CMP is a strategy that is designed by EC and HC in cooperation with industry and NGO stakeholders. Its primary purpose is to protect human health and the environment while acting as Canada’s plan to achieve the sound management of chemicals in accordance with the WSSD 2020 goal. A secondary purpose is to increase public confidence in the management of chemicals by industry and government.

Though the CMP is not formally mentioned in legislation, CEPA provides the primary legal authority for actions under the CMP. The CMP is designed to facilitate coordination between CEPA and other laws, including those that govern food and drugs, cosmetics, and pesticides. To that end, EC and HC also draw legal authority for CMP actions from a variety of laws in addition to CEPA. Though many decisions have been politically contentious, thus far,
government, industry, and some NGO stakeholders seem to be pleased with the design and progression of the CMP.\(^\text{106}\) As such, the CMP has all but displaced the PSL as a prioritization mechanism for the assessment of chemicals in Canada.

Authorities are scheduled to work through the CMP in phases from 2006 to 2020. The phases are somewhat overlapping but also address some distinct sectors.

Phase I of the CMP included three primary initiatives. The first initiative of CMP Phase I was the industry “Challenge.” It targeted nearly 200 of the substances identified in the categorization as highest priority.\(^\text{107}\) EC and HC first divided the challenge substances into twelve “batches” to be addressed sequentially.\(^\text{108}\) CEPA § 71 provides government the authority to compel businesses to provide information about the substances that they manufacture, import, and use.\(^\text{109}\) EC and HC published a list of each batch in the Canada Gazette approximately every three months beginning in February 2007, using authority under § 71 to challenge industry to provide data on the chemicals in the batch within six months of the publication.\(^\text{110}\) Much of the submitted information consisted of release and exposure data, since industry had only six months to provide it—generally not enough time to plan and carry out new laboratory tests.\(^\text{111}\) In some cases, however, additional data were supplied. After receiving the data, EC and HC conducted SLRAs, which they released for public comment.

\(^\text{106}\) ENVIRONMENTAL DEFENCE, supra note 92.


\(^\text{109}\) CEPA, § 71.


\(^\text{111}\) Dayna Nadine Scott, Testing Toxicity: Proof and Precaution in Canada’s Chemicals Management Plan, 18 REVIEW OF EUROPEAN, COMPARATIVE & INTERNATIONAL ENVIRONMENTAL LAW 59, 66 (2009). However, the categorization process did provide industry with an indication of the substances that would be subject to risk assessment, giving businesses time to gather data.
The ministries used the SLRA for each substance to determine whether or not it satisfied the criteria for CEPA-toxicity. When the assessment led the ministries to conclude that the substance is CEPA-toxic, they developed a risk management proposal, which they finalized after considering public comments. In addition to being a vehicle to determine whether risk management is necessary, the Challenge also encouraged companies to voluntarily reduce emissions of high-priority substances and substitute, if possible, safer alternatives.

The second initiative of CMP Phase I was a Rapid Screening Assessment of potential PiTs and BiTs that were manufactured or imported in quantities less than 1,000 kg/yr (under the 1986 DSL)—a total of 1,066 substances.\textsuperscript{112} EC evaluated whether these substances were already being assessed through other programs, searched for red flags by determining if the substances appeared on priority or regulatory lists in other jurisdictions, and applied conservative ecological exposure scenarios to determine if further assessment was warranted. When the ecological exposure estimates were not of concern, then HC applied a rapid screening framework from a human health perspective. Through this process, EC and HC have determined that 472 potential substances required further assessment, 533 required no further action because their estimated exposures were not of concern, and 61 were withdrawn from rapid screening either because they had been removed from DSL (were no longer in commerce) or, the opposite, they were found to be manufactured or imported in quantities exceeding 1,000 kg/yr.\textsuperscript{113}

The third initiative of CMP Phase I, which now extends into Phase II, is the Petroleum Sector Stream Approach.\textsuperscript{114} EC and HC divided 164 high priority petroleum substances into five

\textsuperscript{113} Id.
streams and have proceeded to gather information from industry, conduct SLRAs, and propose risk management options where applicable or as necessary through the same processes as in the Challenge. As of June 2014, Phase I is nearly complete.

Phase II was announced in 2011. It includes an additional rapid screening effort based on exposure-related information, an approach to address polymers, and the Substance Groupings Initiative (SGI). Under the SGI, EC and HC have placed an additional 500 substances into nine groups of similar chemicals—organic flame retardants, for example—and will proceed in the same spirit as in the Challenge and the Petroleum Sector Stream Approach. The rationale for assessing substances in groups is that they may share similar chemical properties or may be used in similar ways. This approach emphasizes the use of the “read-across” technique, whereby the characteristics of a chemical (without direct data) are estimated based on the characteristics of previously examined chemicals with similar molecular structures. Assessing like chemicals together, therefore, could facilitate the identification of safer substitutes and create efficiencies for risk assessment and management, and this appears to be the case, with a number of draft assessments on various groupings being announced on the CMP website. However, an aggressive use of this approach might test the limits of the read-

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115 To date, 117 substances have been identified that may not require further risk assessment because of low exposure potential. Environment Canada, Rapid Screening of Substances from Phase One of the Domestic Substances List Inventory Update: Results of the Final Screening Assessment, March 2014, at 4–5, http://www.ec.gc.ca/ese-ees/7340E1B7-1809-4564-8C49-F05875D511CB/FSAR_RSII_EN.pdf.
118 Steven J. Enoch, Chemical Category Formation and Read-Across for the Prediction of Toxicity, in RECENT ADVANCES IN QSAR STUDIES 209 (2010).
119 Government of Canada SGI, supra note 117.
across screening technique, which could ultimately undermine confidence in the assessment process.\textsuperscript{120}

Following the first two phases of the CMP, the Canadian government will still have to conduct SLRAs for about 1,700 priority substances identified in categorization.\textsuperscript{121} How the ministries will execute the next phase of the CMP is uncertain, but it seems clear that, regardless of the outcomes of the next prioritization activities, the government will proceed in the same fashion as in the Challenge, Petroleum Sector Stream Approach, and SGI, with information gathering, screening assessment, and risk management. The CMP and DSL categorization embody VOI principles by soliciting a limited amount of information on a specific, manageably sized group of prioritized substances with a strict deadline for information submission. Each phase of the CMP is presented in Figure 3.


\textsuperscript{121} Galatone, supra note 117, at 4.
Figure 3. Chemicals Management Plan

**Phase 1: 2006 – 2012**

<table>
<thead>
<tr>
<th>Industry Challenge</th>
<th>Rapid Screening</th>
<th>Petroleum Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening level risk assessments of ~ 200 substances in 12 batches</td>
<td>1,100 substances examined</td>
<td>160 high priority petroleum sector substances, assessed together using, for example, “read across” methods</td>
</tr>
<tr>
<td>52 substances concluded “toxic” and 48 proposed as “toxic”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Phase 2: 2012 – 2016**

<table>
<thead>
<tr>
<th>Rapid Screening</th>
<th>Substance Grouping Initiative</th>
<th>Polymers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of remaining lower concern substances based on updated exposure information</td>
<td>~ 500 substances organized into nine groups of similar substances (e.g., organic flame retardants)</td>
<td>~ 600 substances no action yet, but proposal for phased information gathering</td>
</tr>
<tr>
<td>140 substances examined</td>
<td>117 require no further action (low exposure estimates)</td>
<td>Will carry over to Phase 3 as necessary</td>
</tr>
</tbody>
</table>

**Phase 3: 2016 – 2020**

~ 1700 substances remain to undergo screening level risk assessments
The various initiatives under the CMP are designed to further prioritize substances to undergo SLRAs, which in turn are designed to determine whether or not a substance satisfies the criteria for CEPA-toxicity. There are three potential outcomes if a SLRA leads authorities to determine that a substance is CEPA-toxic. First, the government may opt to take no further action. In practice, this has been a rare conclusion and appears to be avoided if possible. Second, the ministries may add the substance to a PSL, triggering a more detailed and comprehensive risk assessment. As noted above, this approach has been all but abandoned because it is seen as an unnecessary iteration. Third, the ministries may recommend that a substance be added to Schedule 1 of CEPA, the Toxic Substances List (TSL), and where applicable, the Virtual Elimination List (VEL) as well.

Not all outcomes of the SLRA process, however, are discretionary. If the government finds that a substance “may have a long-term harmful effect on the environment,” satisfies the PBiT criteria, and its presence in the environment “results primarily from human activity,” it must be recommended for addition to the TSL. For any substance recommended for addition to the TSL—discretionary or mandatory—the government may also have to recommend it for addition to the VEL if it meets certain criteria.

The addition of a substance to the TSL provides the ministries with the authority to propose and initiate risk management, including a possible phase out of the substance. If a substance is also added to the VEL, the ministries must enact a restriction on its emissions by “prescribe[ing] the quantity or concentration of the substance that may be released into the

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122 CEPA, § 77(2).
123 CEPA, § 77(2)(c).
125 CEPA, § 77(4).
environment . . . from any source. . .” In practice, if a SLRA indicates that a substance is CEPA-toxic, it is routinely added to the TSL. As of July 2014, there are 132 substances on the TSL and only two substances on the VEL. We elaborate on some risk management techniques below in Part III.A as part of our discussion of how CEPA allocates the burdens of producing data and proving safety. In the following sub-Section, we continue the discussion of prioritization and assessment processes by introducing the European Union’s REACH regulation.

**B. REACH**

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation is a compilation of four separate bodies of regulation that govern the cradle-to-grave manufacture, importation, and use of industrial chemicals in the EU. REACH is administered by the European Chemicals Agency (ECHA) in cooperation with Member State Governments and the European Commission. Though each of the components of REACH are related to one another, each serves a distinct function and is somewhat independent of the others.

The prioritization processes under REACH are not analogous with those under CEPA. While Canada’s categorization and CMP identified a subset of chemicals that warrant further assessment, the underlying principle of REACH is that almost all chemicals warrant further assessment. Context is important here: Europe’s political environment is different from Canada’s (and the United States’), and REACH serves the entire EU marketplace rather than that of a

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126 CEPA, § 65(3).
single nation. Whereas Canada’s DSL lists about 23,000 existing substances, there are about 100,000 substances listed on the EUs various chemicals inventories.\(^{129}\) REACH is designed to facilitate assessment and subsequent voluntary management by industry through registration, to identify Substances of Very High Concern (SVHCs) for authorization, and to identify uses of concern for restriction. The following sub-sections discuss prioritization for assessment and management under registration, evaluation, authorization, and restriction.

1. Registration

Registration is based on the principle of “no data, no market”\(^{130}\)—the notion that nearly all chemicals on the market warrant complete risk assessments. Given that there are more than 100,000 substances in commerce in the EU, and many of them lack even basic data sets on hazard characteristics and potential exposure pathways, the development of data constitutes a gargantuan task. The REACH registration process does set some priorities. As explained below, the schedule for registration is sequenced by firm production level and by certain hazard characteristics.

The general registration provision requires that “any manufacturer or importer of a substance . . . in quantities of 1 tonne or more per year shall submit a registration to the [European Chemicals] Agency.”\(^{131}\) Downstream users—often small or large companies that make use of a chemical in consumer products or services—may also provide use and safety


\(^{130}\) REACH, art. 5.

\(^{131}\) REACH, art. 6(1).
information on their own or assist in the preparation of registration dossiers through a lead registrant.\textsuperscript{132}

The registration must take the form of a technical dossier, which includes information on: the identity of the manufacturer, importer, or producer; the identity, including chemical and physical properties, of the substance; the manufacture and uses of the substance; environmental fate and pathways; (eco)toxicological information; guidance on safe use; and research summaries.\textsuperscript{133} Ideally, registration dossiers including this data will contain comprehensive risk assessments. Empirical investigations of the amount and quality of information included within registration dossiers, however, suggest that some dossiers leave much to be desired and may be more analogous to screening level assessments due to their heavy reliance on modeling and estimation techniques rather than hard data.\textsuperscript{134}

REACH contains a tiered phase-in period for registration that is based partly on production volume of individual firms (rather than the marketplace as a whole) and partly on toxicity. The first registration deadline in November 2010 applied to companies that manufactured or imported any substances at volumes greater than 1,000 tonnes per year, substances that are “very toxic” to aquatic organisms greater than 100 tonnes per year, and CMRs at volumes greater than 1 tonne per year.\textsuperscript{135} In response to this first deadline, ECHA received roughly 25,000 registration dossiers covering about 4,000 substances.\textsuperscript{136} The second registration deadline was in May 2013 and applied to companies that manufactured or imported substances at volumes greater than 100 tonnes per year. The third and last registration deadline is

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{132} REACH, art. 37.
\item \textsuperscript{133} REACH, art. 10(1)(a).
\item \textsuperscript{134} See, e.g., Greta Stieger, Martin Scheringer, Carla A. Ng & Konrad Hungerbühler, \textit{Assessing the Persistence, Bioaccumulation Potential and Toxicity of Brominated Flame Retardants: Data Availability and Quality for 36 Alternative Brominated Flame Retardants}, CHEMOSPHERE (2014).
\item \textsuperscript{135} REACH, art. 23(1).
\end{itemize}
\end{footnotesize}
June 2018, when all substances manufactured or imported in quantities of 1 tonne or more are to be registered. As of July 2014, the REACH database contains information on 12,585 substances from 48,575 registration dossiers.137

The registration dossier under REACH must contain a minimum set of data, or the substance may not be put on the market in Europe. The tiers in the registration process influence the data requirements that are applicable. Chemicals produced or imported in higher volumes and chemicals that exhibit certain hazardous properties (e.g., CMR properties and aquatic toxicity) have not only earlier registration deadlines, but also more demanding data requirements.138 For example, once the 10-tonne threshold is reached for a registrant, the registration dossier must include a Chemical Safety Report (CSR), which details potential exposure scenarios and risk management measures.139 Additional information on potential exposures and risk characterization is also required for PBT, vPvB, and other substances classified as “dangerous” under the European Council’s Dangerous Substances Directive relating to the classification, packaging, and labeling of dangerous substances.140

2. Evaluation

REACH contains two distinct evaluation processes: substance and dossier evaluation.141 Dossier evaluation entails ECHA evaluation of a specific registration dossier. Dossier evaluation is a compliance check that is meant to verify that the registration dossiers submitted by industry

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138 REACH, art. 12(1); 23.
139 REACH, art. 10(1)(b); 14(1), (3).
141 See Herbatschek et al., supra note 128, at 126–33.
fulfill all of the registration data requirements.\textsuperscript{142} REACH mandates that ECHA must conduct a compliance check on no less “than 5\% of the total [number of dossiers] received by the Agency for each tonnage band . . . .”\textsuperscript{143} REACH does not obligate ECHA to examine the other 95\% of registration dossiers for substantive compliance. From this 5\% baseline, ECHA prioritizes its selection of dossiers to examine through random selection (25\%) as well as a mix of hazard and exposure characteristics and technical concerns (75\%), including potential PBT, vPvB, or CMR characteristics; wide dispersive use; or excessive confidentiality claims.\textsuperscript{144}

The compliance check process is procedurally straightforward but can be scientifically intensive. When ECHA carries out an overall compliance check, it assigns the task to a team of about five specialists, including physical chemists, environmental experts, and human health experts. Experts are responsible for a substantive examination of the portions of the dossier in their area of specialization. First, the experts determine whether the registrant provided the required and appropriate data. Second, they analyze the quality of the data by evaluating the reliability and validity of the study reports included within the dossier. Third, the team examines any exposure scenarios, which are required for PBTs, vPvBs, CMRs, and all “classified” (dangerous)\textsuperscript{145} substances manufactured or imported at volumes greater than 10 tonnes per year (i.e., those classified under the EU’s version of the Globally Harmonized System for one hazardous property or another). Finally, the team evaluates the risk management measures described in the dossier and may consider whether the measures are likely to be sufficient to

\textsuperscript{143}REACH, art. 41(5).
\textsuperscript{144}REACH, art. 41(5).
achieve “adequate control” of exposures.\textsuperscript{146} The team may request more data to support the effectiveness of risk management measures or suggest that alternative measures be considered.

Not all compliance checks review the entire dossier. Targeted compliance checks are also employed frequently by ECHA. They are typically automated (i.e., through use of screening of dossiers with information technology tools) and focused on portions of the dossier that are of special concern to ECHA (e.g., substance identification information or nano-materials). In many cases, only a small fraction of a dossier is reviewed during a compliance check and only those experts necessary for the targeted review are employed.

Substance evaluation is an altogether different process, carried out by Member States in collaboration with ECHA and the European Commission.\textsuperscript{147} It involves evaluation of a specific substance rather than a specific dossier. Substance evaluation is not itself a regulatory process, but the outcomes of a substance evaluation can trigger regulations under other provisions of REACH or other EU legislation.

The aim of the substance evaluation process is to clarify the risks to human health and the environment associated with the use of specific chemical substances.\textsuperscript{148} As a result, it is expected that the substance evaluation processes will be triggered by risk-based or hazard-based concerns. A Member State is expected to draw from registration dossiers prepared by industry but may also request additional information from registrants that extends beyond the minimum data requirements that REACH specifies for registration.\textsuperscript{149} If a registration dossier is missing information on certain hazards (e.g., types of toxicity), the substance evaluation process may be

\textsuperscript{146} REACH Annex I, § 6.4 indicates that risk is adequately controlled if the estimated exposure levels will not exceed the derived no effect level or the predicted no effect concentration for the substance, and the likelihood and severity of an event occurring due to a physiochemical property of the substance (e.g., flammability, explosivity) is negligible.


\textsuperscript{148} Id. at 1.

\textsuperscript{149} Id. at 6–7.
employed to obtain the necessary information from industry, which can then be used for both classification and labeling. Substance evaluation is important because it can lead to enactment of new risk management measures through the authorization or restriction processes in REACH or instruments under other European chemicals legislation. For example, substance evaluation could lead to the setting of a new occupational exposure limit to protect workers throughout Europe or it could lead to a proposal for harmonized classification of the substance under the EU Classification, Labelling and Packing (CLP) Regulation.\textsuperscript{150}

ECHA, through its Member State Committee, determines which substances will undergo substance evaluation, and lists them on the Community Rolling Action Plan.\textsuperscript{151} The selection of substances is based on criteria that are related to human health and environmental quality, including the chemical’s hazardous properties, the potential for exposure, and aggregated tonnage of production (registration data).\textsuperscript{152} Political concerns may play a role in a Member State’s decision to nominate a chemical or substance for evaluation.\textsuperscript{153} Compared to the registration process, the substance evaluation process under REACH has been the subject of very limited practical implementation by EU Authorities, although this could change due to recent commitments in the Community Rolling Action Plan for substance evaluation.\textsuperscript{154}

3. Authorization

\textsuperscript{151} REACH, art. 44(2).
\textsuperscript{153} Herbatschek et al., supra note 128, at 152–55 (indicating that political preferences of Member States influence the prioritization of substances for consideration of inclusion on the Candidate List).
The authorization process is intended to protect human health and the environment by facilitating the substitution of SVHCs with suitable, safer alternatives. A SVHC is defined by Article 57 as a CMR, a PBT, a vPvB, or a substance of equivalent concern, such as an endocrine disruptor. A variety of priority-setting issues have arisen in the assessment and management of these substances given the number of potential SVHCs—about 1,500—and legislative ambiguity in how to prioritize substances at various stages of the authorization process and other risk management processes.

Under authorization, a SVHC is placed on a Candidate List, denoting that the substance is a “candidate” to be placed on the formal Authorization List (REACH Annex XIV). Substances on the Authorization List must be phased out, though exceptions for specific uses may be authorized based on certain socioeconomic and risk factors, depending on the characteristics of the substance. ECHA, at the request of the Commission, or a Member State government may request that a substance be placed on the Candidate List by submitting a dossier in accordance with Annex XV of REACH to identify the substance as a SVHC. ECHA’s Member State Committee, a committee of experts comprised of representatives from the Member States, evaluates each substance that has been proposed for inclusion on the Candidate List. A unanimous decision of the Committee places the substance on the Candidate List while a split

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155 REACH, art. 55, 58, 59.
156 REACH, art. 55, 56(1), 57 (laying out the parameters for what constitutes a substance of very high concern). For a description of potential harm to human health and the environment from endocrine disruptors, see Patricia Hunt, Toxins All Around Us, SCIENTIFIC AMERICAN, Oct. 11, 2011, http://www.scientificamerican.com/article.cfm?id=toxins-all-around-us.
157 REACH, Annex XIV.
158 REACH, art. 55.
vote turns the listing decision over to the Commission.161 ECHA may then recommend substances on the Candidate List for inclusion on the Authorization List to the Commission, which may place substances on the Authorization List through comitology.162 Comitology is the process by which the Commission adopts implementing acts to apply uniformly throughout the EU without each individual Member State government having to adopt implementing legislation.163

The authorization process begins with the identification of SVHCs. As of July 2014, there have been 165 Annex XV dossiers submitted to formally identify substances as SVHCs, 155 substances have been placed on the Candidate List, and 22 substances have been placed on the Authorization List.164 Based on existing classifications of substances under various EU regulations, the CLP Regulation for example, early estimates indicated that there might be as many as 1,500 substances eligible for classification as a SVHC.165 In 2013, the Commission has estimated that, at most, 440 substances will have to be assessed for SVHC classification by 2020.166 Each SVHC may undergo a rudimentary or screening-level assessment prior to a management decision on how to proceed.

To determine which potential SVHCs should be studied and listed first, REACH specifies prioritization criteria in Article 58 as PBT and vPvB characteristics, wide dispersive uses,

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161 To date, all Member State Committee decisions on candidate listing have been unanimous, with contentious negotiation occurring prior to voting. Herbatschek et al., supra note 128, at 157.
163 Regulation (EU) No 182/2011. Under comitology, the Commission drafts an implementing act for submission to a committee of representatives of the Member States referred to as the REACH Comitology Committee (distinct from the ECHA Member State Committee). The comitology committee then decides whether an implementing act should be adopted through a majority vote.
165 Herbatschek et al., supra note 128, at 152. See also, various lists of chemical inventories, including those with hazardous properties, http://esis.jrc.ec.europa.eu/index.php?PGM=cla
166 SVHC Roadmap, supra note 50, at 12.
significant market level production and importation volume, and ECHA’s capacity to deal with the authorization applications.\textsuperscript{167} However, no comprehensive, formal procedure has been specified for setting priorities among potential SVHCs.\textsuperscript{168} ECHA guidance also refers to factors such as whether the substance is already being addressed under another REACH process (e.g., restrictions), whether the substance is listed in the Community Rolling Action Plan for substance evaluation, whether the substance is under consideration by Member States for further regulatory risk management, and whether the substance should first be addressed under classification criteria defined in the CLP Regulation.\textsuperscript{169} The lack of clarity in REACH about how to set priorities among numerous potential SVHCs has been a source of confusion for government and stakeholders.\textsuperscript{170}

To further complicate the process, the full implications of placing a substance on the Candidate List is partially an open question. Inclusion on the Candidate List does trigger some unambiguous legal requirements on companies (e.g., notification requirements throughout the supply chain).\textsuperscript{171} Placement of a chemical on the Candidate List may also elicit some market de-selection of the chemical due to the stigma of being listed as well as the potential for further regulation. Many believed that REACH envisioned that all substances placed on the Candidate List would—with perhaps only a few exceptions—eventually be placed on the Authorization List, but that perception may not prove to be a reality. Figure 4 below depicts the authorization listing process.

\textsuperscript{168} Herbatschek et al., supra note 128, at 152–54.
\textsuperscript{169} ECHA, Annex XV Guidance, supra note 159, at 7; Herbatschek et al., supra note 128, at 155.
\textsuperscript{170} REACH, art. 7, 31, 33; Herbatschek et al., supra note 128, at 152.
\textsuperscript{171} ECHA, Summary of obligations resulting from inclusion in the Candidate List of Substances of Very High Concern for authorization, http://echa.europa.eu/candidate-list-obligations.
Figure 4. Process for Inclusion of Substances on the REACH Authorization List

**Technical Dossier in Accordance with Annex XV**
- Submitted by Member State or ECHA (at the request of the Commission)
- Supports identification of substance as SVHC

**Evaluation of Dossiers for Risk Management**
- Screening Assessment
- Risk Management Options
  - Authorization
  - Restriction
  - Other Legislation
  - No Action

**Member State Committee**
- Unanimous Decision to List
- Split Decision

**European Commission**

**Candidate List**

**ECHA Recommendation**
- ECHA recommends to European Commission which SVHCs to place on Authorization List

**European Commission**

**Authorization List: Annex XIV**
A drawback of placing many potential SVHCs on the Candidate List is that the list was intended to send a market signal for de-selection of the substance, even before the substance was placed on the Authorization List.\textsuperscript{172} To avoid unnecessary de-selection, some suggested that a screening assessment should precede placement of a substance on the Candidate List.\textsuperscript{173} An additional motivating factor for pre-Candidate List screening is that REACH does not provide for a de-listing process for Candidate List substances that do not go on to the Authorization List.\textsuperscript{174} In other words, once a substance is placed on the Candidate List, the substance cannot be removed until after it is placed on the Authorization List, and the scientific burden of making the case for removal from the Authorization List has been made.\textsuperscript{175} ECHA and the Commission have taken the position that a substance on the Candidate List can be delisted (using the same criteria for delisting that applies to substances on the Authorization List), but the legal viability of this position is arguable.\textsuperscript{176}

To fulfill the goal of considering all SVHCs for inclusion on the Candidate List by 2020, the Commission released in February 2013 a “Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020.”\textsuperscript{177} In December 2013, ECHA released a “SVHC Roadmap to 2020 Implementation Plan” detailing a proposal for prioritizing SVHCs for screening assessment, conducting screening assessments, and considering various risk management options.\textsuperscript{178}

The roadmap specifies two tiers of assessment. The first tier entails a rudimentary assessment of the hazard and risk factors pursuant to Article 58 and existing data (e.g., from

\begin{footnotesize}
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\item[\textsuperscript{172}] Herbatschek et al., supra note 128, at 133–34.
\item[\textsuperscript{173}] Id. at 135.
\item[\textsuperscript{174}] Id. at 136.
\item[\textsuperscript{175}] Id. at 139 (“Procedure for de-listing” from the Authorization List).
\item[\textsuperscript{176}] Id. at 136.
\item[\textsuperscript{177}] SVHC Roadmap, supra note 50.
\end{itemize}
\end{footnotesize}
registration dossiers). ECHA determines whether there is enough data from the registration dossier to substantiate concern regarding the Article 57 criteria to determine whether the substance is a PBT, vPvB, CMR, or substance of equivalent concern—and hence, a SVHC. If not, then ECHA may submit the dossier to a compliance check, propose substance evaluation to be undertaken by a Member State, or submit the substance for evaluation under the harmonized classification and labeling process.

The second tier of analysis entails an evaluation of risk management options (RMO) to determine if risk management is necessary and, if it is, to determine the most appropriate approach to risk management. This process is shown below in Figure 5. The details of RMO analysis are an open question, but the available documents seem to envision a consideration of whether or not authorization is an appropriate or optimal regulatory strategy, given consideration of hazard and exposure data as well as consideration of the restriction process and other regulations that might already apply.\textsuperscript{179}

\textsuperscript{179} EU Authorities are exhibiting a preference for restrictions over authorization for some chemicals. See EU Commission to Propose Five Substance Restrictions Under RoHS2, CHEMICAL WATCH, Feb. 7, 2014.
Figure 5. SVHC Identification Roadmap

Prioritization

Screening Assessment

If not enough information
- direct contact with registrant(s),
- dossier evaluation, and/or
- substance evaluation

If concern, RMO Analysis

No action
Candidate List
Restriction

Authorization List

Other legislation (e.g., CLP Regulation)

It appears that each substance that is placed on the Candidate List will undergo at least an assessment to determine if it should be placed on the Authorization List.\footnote{ECHA, Prioritisation for Authorisation, supra note 167, at 3–4.} ECHA is responsible for drafting a proposed recommendation for additional listings at least once every two years.\footnote{ECHA, Role of the Member State Committee, supra note 160.} After public consultation and dialogue with the Member State Committee, ECHA forwards a recommendation to the European Commission, which makes final decisions about the Authorization List.\footnote{Id.}

The SVHC Roadmap to 2020 Implementation Plan provides some clarity as to the screening assessments and RMO analyses that substances will undergo prior to risk management. Moreover, updated guidance from ECHA provides some indication of factors that will be considered when evaluating whether to place potential SVHC on the Candidate List.\footnote{ECHA, Annex XV Guidance, supra note 159.} Nonetheless, the European Authorities have a large degree of discretion in how priorities will be set and stakeholders do not have a clear understanding of which substances will undergo screening assessments/RMO analyses first. If a large number of chemicals are placed on the Candidate List, the sequencing of chemicals for possible placement on the Authorization List is another unknown.

The Implementation Plan does mention the criteria by which substances might be prioritized. The criteria include production and importation volume, whether uses are in the scope of authorization, potential PBT, CMR, and endocrine disrupting properties, the time and effort needed to generate information for screening assessments, and structural similarities to substances already on the Candidate List, Authorization List, or in the pool of substances to
undergo RMO analysis. The Implementation Plan lists these criteria, but EU Authorities will likely need to develop a structured approach to apply these prioritization criteria to the ~ 1,500 potential SVHCs.

4. Restriction

The restriction authority under REACH is essentially a carry-forward risk management approach that European Authorities possessed prior to the enactment of REACH. It is seen as the “safety net” under REACH to address risks that are not adequately addressed through registration, evaluation, and authorization.

The European Commission is authorized to issue restrictions on the production, placement on the market, and use of selected chemicals to address unacceptable risks to human health and the environment. The restrictions may entail a wide variety of measures, but are generally applied on a use-by-use basis. When issuing a restriction, the analytic burden of proof rests with the Commission.

The restriction authority is particularly suitable for dealing with risks that arise from the aggregate production and use of a chemical or a group of chemicals by multiple manufacturers and users. The restriction authority has several advantages for the Commission compared to the authorization process. Only substances that are shown to be SVHCs can be listed in the authorization process whereas restrictions can be applied to any chemical and use that poses unacceptable risks to human health and the environment. Moreover, authorization operates on a

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184 SVHC Implementation Plan, supra note 178.
chemical-by-chemical basis whereas the Commission may be able to address groups of chemicals or target narrow uses through the restriction authority.

The Commission has already decided to regulate some chemicals under its restriction authority rather than under authorization. Additionally, the RMO seems to envision that substances on the Candidate List could be subjected to restrictions rather than authorization. Yet, the Commission has not put forward any formal procedure for determining which chemicals and uses should be a priority for regulation under the restriction approach. The following sub-section draws lessons from the Canadian and EU approaches to prioritization and assessment.

C. Lessons

1. Some Form of Formal Prioritization for Risk Assessment and Management is Essential

   Though both CEPA and REACH represent the state of the art in chemicals governance, they take very different approaches. CEPA is designed to facilitate governmental decision making on whether substances are CEPA-toxic. The emphasis of REACH, at its present stage of implementation, is on encouraging adequate control of risk through registration and on identifying SVHCs for management. We must emphasize that those processes are not directly analogous to one another, and a substance that is CEPA-toxic will not necessarily be a SVHC under REACH and vice versa. What’s more, the complexity of these laws is a product of the political contexts within which they are being implemented—REACH in particular with its separate programs and distribution of authority between the Commission, ECHA, and Member States.

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187 Bergkamp & Penman, supra note 10, at 8; Herbatschek et al., supra note 128, at 146.
Nonetheless, the experiences of both Canada and the EU make abundantly clear the desirability and necessity of prioritization in assessment and management.\(^{188}\) Thousands of existing chemicals lack data on basic properties, uses, environmental releases, and exposures. Through its categorization process, Canada identified 4,300 priority chemicals for more in-depth assessment while tens of thousands of substances must be registered with ECHA. The European Commission projects a need to make SVHC decisions on as many as 440 substances by 2020.\(^{189}\)

The approaches to priority setting under CEPA and REACH differed, but both systems recognized a need to focus public and private sector resources on a limited number of chemicals. The priorities set in Canada seem to be manageable, but the tractability of the EU approach is better demonstrated for registration than it is for authorization. Indeed, the resources and workload for the EU Authorities were a major consideration in the development of the EU Roadmap on Substances of Very High Concern.\(^{190}\)

Once large numbers of registration dossiers were submitted under REACH, EU Authorities realized that they needed mechanisms to set some priorities in reviewing registration dossiers. Targeted compliance checks on registration dossiers have a sound priority-setting rationale, since ECHA can focus on those portions of dossiers where the potential value of a compliance check is high. The priority-setting procedures for authorization, substance evaluation, and restriction under REACH are not yet fully worked out.\(^{191}\) NGOs have raised concerns that ECHA and the Commission are too slow at formally listing substances as


\(^{189}\) SVHC Roadmap, supra note 50, at 12.

\(^{190}\) Id. at 12–13.

\(^{191}\) Herbatschek et al., supra note 128, at 152.
SVHCs. The recent 2020 Roadmap and RMO analysis proposed by the EU may help set priorities for authorization in the future.

Interestingly, both Canada and Europe are setting priorities based on hazard and exposure, but they are doing so in different ways. The CMP incorporated information on hazard and exposure in the categorization and CMP prioritization processes. Under REACH, hazard and exposure both play a role in the tiered registration process and in the design of registration dossiers. Hazard characteristics certainly drive decisions about which substances are placed on the Candidate List in the REACH authorization process, but exposure potential is also exerting a subtle role, as described in the SVHC Identification Roadmap and Implementation Plan. Priorities for substance evaluation and restrictions under REACH may also be based on exposure as well as hazard, but the details have not yet been worked out.

Based on the experiences in Canada and Europe, it is apparent how critical priority setting is for practical management of existing chemicals. Any TSCA reform effort would be wise to encourage or require, at a minimum, some rudimentary form of priority setting, presumably a scheme that considers both hazard and exposure. Furthermore, both Canadian and European experiences suggest that the US might do well to either include as much clarity on prioritization criteria and processes as possible in the legislation itself and/or delegate EPA wide authority to determine its own prioritization scheme for assessment and management. Since EPA already has a workable scoring system to assist in priority setting, detailed legislative language may not be necessary. Some legislative clarity would reduce the risk of practical implementation problems and uncertainty that Europe is facing. The Canadian experience,

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193 SVHC Roadmap, supra note 50; SVHC Implementation Plan, supra note 178.
though, is not a perfect guide for the US, as it is unlikely that EPA could enact a strategy analogous to the CMP through rulemaking without years of litigation. A prioritization scheme for assessment and management should be formalized in legislation, be stated plainly and unambiguously, and should provide EPA with a broad degree of technical and policy discretion.

2. Prioritization with Limited Data is Feasible

The most interesting lesson from the Canada-Europe comparison is that it is feasible, based on CEPA’s experience, to undertake a large-scale, credible prioritization process with extremely limited data, thereby avoiding the time and expense associated with the numerous required information submissions under REACH. Instead of waiting for (or requiring) hard data on each chemical in commerce, the Canadian authorities have been making professional judgment in the use of existing data and screening/modeling exercises, in effect allowing information for some chemicals to serve as a basis for predicting information for other chemicals.

Government officials and stakeholders mostly report that Canada’s prioritization effort through the CMP has been effective in identifying chemicals of concern from a risk perspective and in stimulating more in-depth assessments of the risks associated with the specific uses of those chemicals. However, the political environment in Canada may be not as receptive to NGO analysis and critique of chemicals management as it is in the US. Thus, the lack of heavy criticism in Canada of a judgment-laden process may be somewhat misleading. Nonetheless, the stakeholders seem to consider CEPA 1999 and the CMP notable improvements over prior

195 ENVIRONMENTAL DEFENCE, supra note 92; Ditz, supra note 57.
196 See Granville, supra note 89; ENVIRONMENTAL DEFENCE, supra note 92; Letter from Peter Goodhand, CEO, Canadian Cancer Society, Richard Paton, President and CEO, Chemistry Industry Association of Canada, Peter Robinson, CEO, David Suzuki Foundation & Rick Smith, Exec. Dir., Environmental Defence, to James Flaherty, Minister of Finance, Peter Kent, Minister of Environment, Leona Aglukkaq, Minister of Health & Stockwell Day, President Treasury Board and Minister of Asia-Pacific Gateway (Jan. 21, 2011) (on file with author) (supporting funding for CMP Phase 2).
approaches. Key ingredients of the CEPA success in prioritization are the widespread use of screening and modeling techniques, consideration of both health and environmental impacts, the use of rudimentary exposure information as well as hazard characteristics, and strict legislative deadlines in the categorization process.

Based on the CEPA model, a simplified tiered approach to risk assessment of a single chemical might proceed as follows. The first tier is a preliminary assessment that can be performed even if very few data are available, by applying worst-case scenarios for exposure and conservative assumptions about toxicity. If risk is absent using these inputs, there is no need for more detailed information. If risk is present, regulatory authorities may require industry to refine the exposure and toxicity estimates in a second tier, based on hard data or more realistic, validated models. If risk is not present in the second tier, no more information is required. If risk is present, industry is required to implement risk management measures that reduce exposures until safety is accomplished. Under this approach, risk assessment is iterative: simple risk assessments are updated as better data become available.197

Whereas CEPA begins with prioritization of risk assessment based on limited data, REACH first aims to fill the information gap, and then employs a prioritization mechanism for risk management that makes use of risk assessments.198 The CEPA and REACH approaches have advantages and disadvantages from a priority-setting perspective.

An advantage of the CEPA approach is that priorities are set rapidly because they can be based on the limited available data and screening/modeling. Because CEPA is based on the

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198 E. Donald Elliott, draft paper, Central European Policy Center in Brussels, April 9, 2014; Ditz, supra note 57 (indicating that the purpose of registration is to generate data rather than prioritize chemicals for assessment and management).
Precautionary Principle, a lack of data does not constitute a barrier to risk assessment, and the risk assessment process is conducted with conservative assumptions. Industry can respond to conclusions drawn from risk assessments that use estimation techniques by generating additional data. Moreover, the information-collection burdens on industry are limited because they face data-submission requirements only for the small share of existing chemicals that are identified as a priority for risk assessment.

A disadvantage of the CEPA approach in its reliance on screening/modeling techniques is that it does little to address data gaps. REACH, on the other hand, does compile a huge volume of information through the registration dossiers, but the database is so large that much of it may never be fully examined.\(^{199}\) Moreover, during the initial phase of registration, only a small number of chemicals were regulated under REACH (via restrictions or authorization), in part because industry was in the process of preparing dossiers for registration. Now that numerous registrations have been submitted (and many more will be submitted in 2018), ECHA faces a priority setting dilemma in addressing imperfections in the dossiers. For sure, REACH was designed to achieve a level of quality in the dossiers: all companies manufacturing or importing the same chemical are expected to pool their expertise, registrants know they may face quality checks by ECHA, NGOs and the public can review the dossiers on ECHA’s website, ECHA is performing compliance checks, and European Authorities can apply penalties for violations under REACH. Nonetheless, there are already indications that there are significant quality problems with registration dossiers.\(^{200}\)

Another potential disadvantage of the CEPA approach is that some errors will inevitably occur in the priority-setting process because of the heavy reliance on limited data and

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\(^{199}\) Abelkop et al., supra note 60, at 11056.  
\(^{200}\) See, e.g., Stieger et al., supra note 134.
screening/modeling exercises. Both false-positive and false-negative errors are expected to occur.201

A false-positive error occurs when a chemical is treated as a priority or is determined to be CEPA-toxic when it should not be. False-positive errors are of some concern because both government and industry will waste resources evaluating a chemical that does not pose a health or ecological risk. The rapid screening component of the program was introduced to, in part, address this concern. Based on the latest exposure information, substances can enter a streamlined risk assessment process, so that both industry and government resources can be focused on substances of higher potential concern. Beyond the prioritization process, industry can also provide data to aid in further refining risk assessments. Additionally, the affected companies may experience some unjustified market de-selection of their products due to the adverse publicity that the government creates for their products. However, the adverse consequences of false-positive error may be limited and temporary, especially if the process constitutes prioritization of a substance for assessment without placing it on a formal list. The review processes in Canada, which can be buttressed by additional data from industry, may expose any false-positive errors and allow safe chemicals—or at least safe chemical uses—to be removed from the government’s priorities.

A false-negative error occurs when a chemical is classified as low priority when it should be classified as high priority, or determined to not pose a risk when it should be classified as CEPA-toxic. False-negative errors are more serious because they are errors that are less likely to be corrected at a later stage, as industry has little incentive to produce data that are not

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required. Notably, concerns over false-negative errors have been raised about the way that HC and EC conduct SLRAs under the CMP, including insufficient consideration of certain toxicity endpoints and low dose effects (especially endocrine disrupting effects), deficiencies in data, failure to consider differences in exposure to higher risk groups (e.g., women), failure to consider cumulative effects of exposures to multiple chemicals, and inadequate application of precautionary approaches to assessment. These critiques do not seem to be inherent to the way that CEPA is designed, but rather in the way that screening assessments are conducted. Should EPA conduct screening risk assessments under a reformed TSCA, it would do well to perform evaluations with these points in mind.

Reliance on limited hazard data and screening/modeling will suffer from some false-negative errors, but the rate of error is likely to be relatively small if the screening and modeling exercises are conservative (i.e., health protective) in their design, which means that the exercises would be generally biased in favor of pushing borderline cases into the priority category. There are ways to combine multiple screening exercises in order to minimize the false-negative error rate. Moreover, for existing chemicals that have been used for decades without any demonstration of adverse effects, there is a practical upper bound on the possible magnitude of adverse effects.

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203 Dayna Nadine Scott & Sarah Lewis, Regulating Toxics: Sex and Gender in Canada’s Chemicals Management Plan, in OUR CHEMICAL SELVES: TOXICS, GENDER AND ENVIRONMENTAL HEALTH (Dayna Nadine Scott ed., forthcoming); Scott, supra note 111; CSM & CELA, supra note 120.  
204 For a useful case study illustrating the conservatism in Quantitative Structure Activity Relationships (QSARs), see Patricia Ruiz et al., Prediction of Acute Mammalian Toxicity Using QSAR Methods: A Case Study of Sulfur Mustard and Its Breakdown Products, 17 MOLECULES 8982 (2012). But for a skeptical view of the utility of QSAR approaches see SCHETTLER ET AL., supra note 26, at 242–43. An additional concern is that industry-generated risk assessments might be less conservative than government-generated assessments.  
205 Long, supra note 202, at 553, 557. It is important to have flexibility to allow new information to enter the process as science and information evolve and to identify new priorities not identified by particular prioritization criteria. For example, CEPA has various, tiered information feeders for assessment. Environment Canada, Overview of the Existing Substances Program, supra note 86.
impacts from any false-negative error and continued use. There is also a strong body of statistical evidence supporting the use of read-across techniques, in vitro tests, and acute toxicity as surrogates for, or predictors of, chronic toxicity. \(^{206}\) There is a similar body of statistical evidence supporting PBT determinations based on limited data, chemical structure, and modeling. \(^{207}\) To the extent possible, risk assessment should also emphasize assessing groups of similar chemicals together, as in the CMP’s SGI and petroleum sector approaches. Group approaches have a better chance of accounting for cumulative exposures and also build efficiency into the assessment process. Even if SLRA methods improve, the CEPA approach is vulnerable to a higher rate of false-negative error than a system that would operate with full information.

The REACH approach is not, however, a full-information approach because: (1) it is using rudimentary (rather than full) data sets, and (2) REACH is implemented in ways that permit registrants, under certain conditions, to use some of same screening/modeling exercises that were employed in Canada (to reduce the number of animal tests). \(^{208}\) Thus, it seems possible that the REACH approach could have a lower rate of false negatives than the CEPA approach, but it is difficult to know in practice whether such an advantage exists or how large the advantage is.


It is also useful to compare the Canadian and EU approaches from the perspective of public confidence.\textsuperscript{209} CEPA may have an advantage over REACH in the near term, since Canada has moved much faster than Europe to focus on priority chemicals. In the long run, the REACH approach could garner more public trust if the practical difficulties in implementation of assessment and management diminish and if the registration data yield risk assessments that produce meaningful gains in health and environmental protection. Given its purported reliance on hard data, REACH may not require the same degree of public trust in the screening/modeling techniques and associated expert judgments that are inherent to the CEPA approach.

On the other hand, REACH may fail to generate public confidence if it does not meet public expectations for timely conclusions or if it becomes apparent that most of the large volume of information in registration dossiers is never reviewed by public officials through a rigorous process. If some of the registration data prove to be unreliable, which is likely,\textsuperscript{210} and if those errors are not detected and corrected through ECHA’s review processes, then REACH may be perceived as a regulation with significant error, particularly a potential for false-negative error (since registrants are unlikely to submit dossiers with known false-positive errors). The pace of implementation may also become a public-confidence problem, since multiple rounds of registration dossiers and evaluations of potential SVHCs may overwhelm the technical

\textsuperscript{209} On the case for public confidence as a valid criterion to consider in regulatory reform, see generally DAVID VOGEL, THE POLITICS OF PRECAUTION: REGULATING HEALTH, SAFETY, AND ENVIRONMENTAL RISKS IN EUROPE AND THE UNITED STATES (2012).

\textsuperscript{210} Stieger et al., supra note 134; Martin Scheringer, PBT Assessment, Workshop on PBT Science and Policy, December 4, 2013, Brussels, Belgium, at 7; Natasha Gilbert, Data Gaps Threaten Chemical Safety Law, 475 NATURE 150 (2011); Costanza Rovida, Fabiola Longo & Richard R. Rabbit, How are Reproductive Toxicity and Developmental Toxicity Addressed in REACH Dossiers?, 28 ALTEX 273 (2011); Christina Rudén & Sven Ove Hansson, Registration, Evaluation, and Authorization of Chemicals (REACH) Is but the First Step—How Far Will It Take Us? Six Further Steps to Improve the European Chemicals Legislation, 118 ENVIRONMENTAL HEALTH PERSPECTIVES 6 (2010); Nicholas Ball et al., The Challenge of using Read-Across within the EU REACH Regulatory Framework; How Much Uncertainty is Too Much? Dipropylene glycol methyl ether acetate, an Exemplary Case Study, 68 REGULATORY TOXICOLOGY & PHARMACOLOGY 212 (2014).
capabilities and resources of European Authorities. Thus, on the whole, it is not apparent which system, CEPA or REACH, will earn more public confidence in the long run.

With respect to TSCA reform, it is encouraging that EPA has already developed a scoring system for chemical priority setting that has been published and subjected to public comment.\textsuperscript{211} It is also beginning to be used in priority-setting applications.\textsuperscript{212} The EPA system has subtle differences from the Canadian and European approaches that need to be examined carefully before it is mandated in a legislative context. For example, EPA’s system places relatively greater weight on toxicity than persistence and bioaccumulation compared to the EU’s and Canada’s use of the PBT concept. Like Canada and Europe, EPA sees a role in priority setting for information on both hazard and exposure. Thus, there is some reason for optimism that the US can devise a credible priority-setting system for application to existing chemicals.

We conclude with a cautionary remark: the Canadian regulatory culture is more cooperative and less adversarial than that in the US. TSCA reformers who seek to replicate the Canadian priority setting process in the US may need to reconsider some of the legalistic aspects of the current TSCA regime (e.g., hybrid rulemaking and the substantial evidence test of judicial review).\textsuperscript{213} If TSCA reform cannot achieve a somewhat more cooperative regulatory culture between EPA, industry, and environmental groups, then a fragile priority setting process based on limited data, modeling, and professional judgment may not survive the brutal forces of administrative litigation in the US.

3. Ample Opportunity to Review/Appeal Initial Listing Decisions is Important

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{211} ABELKOP ET AL., supra note 24, at 54–57.
  \item \textsuperscript{212} OPPT, supra note 194.
  \item \textsuperscript{213} 15 USC §§ 2605(c), 2618(c)(1)(B)(i).
\end{itemize}
\end{footnotesize}
A heavy reliance on screening data necessitates the incorporation of institutions for adaptive management and flexibility into chemicals governance.\textsuperscript{214} That is, once a decision is made based on evidence that is inherently imperfect and incomplete, stakeholders should be given opportunities to provide additional information as it becomes available, especially through advancements in the science of risk assessment. A difficulty is balancing the need to move forward with the desire of certain stakeholders to circle back. For example, how much data is sufficient to warrant an appeal? To the extent possible, a regulatory system should encourage stakeholder input into the assessment process at an early stage so as to avoid unnecessary appeals. However, the generation of hard data and precaution-based regulation do not necessarily move at the same speed. Appeals or look-backs at previous decisions may be necessary. Such processes should be incorporated into the assessment processes prior to management decisions as well as into priority-setting decisions.

Once a chemical is officially listed by the government as a priority chemical for risk assessment and regulation, the chemical may become stigmatized in the marketplace. Lists of chemicals for management (e.g., the REACH Candidate List) are likely to have more of a stigmatizing effect than priority lists of substances for assessment. Chemical users in the chrome plating and industrial tooling sectors, for example, have already been impacted by de-selection pressures under REACH.\textsuperscript{215} In the United States, stigma may cause market deselection of the


\textsuperscript{215} Rowan Technology Group, REACH, www.rowantecnology.com/US-and-European-rules/european-regulations/reach (arguing the listings under REACH can lead to product deselection; such pressures are already impacting sectors such as chrome plating and industrial tooling; there are replacement chemicals for the substances listed under REACH but companies fear that the replacement chemicals may also be listed as SVHC; the chemicals, such as chromic acid and cobalt salts, serve as coatings and are used for corrosion control on aircraft); Peter de la Cruz, \textit{I. EPA Approaches, in Dialogue, Toxic Substances Chemical Act Reform: Chemical Prioritization}, 42 \textit{Environmental Law Reporter} 10313, 10316 (2013).
chemical,\textsuperscript{216} may prompt state and local regulation of the substance,\textsuperscript{217} and may elicit product liability claims related to the chemical’s alleged hazards.\textsuperscript{218} Previous literature on technological stigma suggests that once a technology is stigmatized, it is difficult for the stigma to be removed based on additional evidence or a revised governmental determination.\textsuperscript{219} Thus, it is important that the initial listing determinations by agencies be subject to appeals that can detect and reverse erroneous false-positive listings.

The design of REACH was somewhat sensitive to this concern. Before a substance is placed on the Candidate List, there is a comment period under Article 59(4) that allows any stakeholder to make a case in favor or in opposition to the listing.\textsuperscript{220} This is a consultation process rather than an appeal mechanism. A candidate listing can also be appealed to the European Court of Justice.

REACH does not contain a mechanism whereby stakeholders can obtain an independent, transparent scientific review of a listing decision. The regulatory personnel who propose a chemical for listing under REACH are the same personnel who evaluate any comments that are received from stakeholders during consultation. Appeals to the European Court of Justice are

\textsuperscript{216} Retailers such as Wal-Mart are inclined to use official lists of chemicals of concern when pressuring their suppliers for greener products. See Melody M. Bomgardner, \textit{Wal-Mart Details Chemicals Policy}, CHEMICAL \& ENGINEERING NEWS, March 10, 2014, at 18.


\textsuperscript{220} REACH, art. 59(4).
legalistic in nature, and the European Authorities are accorded significant discretion by the Court.\textsuperscript{221}

CEPA, on the other hand, has a scientific appeal procedure: CEPA authorizes the Minister of the Environment to establish a Board of Review made up of expert scientists to revisit decisions on whether substances are CEPA-toxic or not, for example, when new information becomes available. The most notable example to date is Siloxane D5, which EC and HC determined to be CEPA-toxic, thereby authorizing risk management.\textsuperscript{222} In 2009, industry stakeholders requested the establishment of a Board of Review to revisit the determination on Siloxane D5. The Minister agreed to establish a board to review the determination, and industry submitted additional data that was not previously available to the government. Reviewing the new data, the board suggested that the government reverse its determination that Siloxane D5 is CEPA-toxic, and the government accepted the recommendation and reversed its determination. Although this particular case involved industry submission of new data, the appeal procedure is also available in Canada when the interpretation of existing data is the sole point of controversy. The appeal procedure in Canada may garner more widespread political support if it is also available for use by the NGO community to reverse a questionable decision that a chemical is not CEPA toxic.

The absence of an appeal procedure (other than judicial review) for decisions to identify substances as SVHCs and to place them on the Candidate List and Authorization List is a salient issue. Even without a substance evaluation, Member States can propose a substance for restriction or nominate a substance for inclusion on the Candidate List. Member States, through

\textsuperscript{221} REACH, art. 94; Treaty on the Functioning of the European Union, art. 263, https://www.ecb.europa.eu/ecb/legal/pdf/c_326201212026en.pdf. REACH art. 91 lists certain decision that are subject to appeal, but the scope of the art. 91 is quite limited.

REACH’s substance evaluation process, also have the authority to influence SVHC listing
decisions, and such decisions do not have to rely on—or be consistent with—the scientific data
and determinations made by industry scientists in the registration dossier.223

On the other hand, the information in the registration dossiers may be used by industry to
persuade ECHA, the Commission, and other Member States that a provocative Annex XV
dossier prepared by one Member State should not be accepted. Although the time and resources
invested in registration dossiers are substantial, the presence of the registration dossier under
REACH may provide a valuable tool for industry that is not available in the CEPA process
(where registration dossiers are not submitted at the outset). The advantage that industry gains
through registration may be heightened if the quality of the dossier (i.e., the reliability and
completeness of the information on hazard, uses, exposure pathways, and risk management
measures) is strong.

Finally, the formal incorporation of external expert peer review of draft risk assessments
should be considered.224 Peer review of risk assessments need not take a substantial amount of
time—a few weeks to a few months—and could greatly reduce the risk of false positive and false
negative outcomes. Peer review may be especially warranted when there is either a high chance
of a decisionmaking error or when the impact of an error would be particularly troublesome in
terms of human and ecological health on the one hand and economic impacts on the other.

For TSCA reformers, a challenge might be to design a scientific appeal procedure that
would not unduly delay or chill the priority-setting process but would offer industry and NGOs a
viable mechanism to override—or compel reconsideration of—decisions that lack adequate

223 Herbatschek et al., supra note 128, at 131 (Substance evaluation may proceed based on information in the
registration or dossier or “any other appropriate source”).
224 NRC 1983, supra note 21, at 144.
Abelkop & Graham

scientific support. To a great extent, the notice and comment requirements for informal rulemaking (and threat of judicial review) may accomplish this task without the need for an additional appeal procedure. Stakeholders may generate and submit additional data in response to a rulemaking notice from EPA. EPA would then have to consider the data prior to its final decision, lest the agency risk its decision being overruled under judicial review as arbitrary and capricious. In the alternative, if a review mechanism is built into the risk assessment and management processes, judicial review may not be necessary at all or Congress may prescribe a particularly deferential standard of review.

Additionally, the distinction between prioritization decisions as opposed to assessment and management decisions is crucial. Prioritization decisions should not be considered final agency actions that are subject to judicial review unless stakeholders can demonstrate the priority-setting determination per se triggers significant real-world impacts. Thus, here again, reformers must keep in mind that EPA’s regulatory culture is much more influenced by litigation risk than either the Canadian or European regulatory cultures.

4. Discretionary Risk Management Accelerates Priority Setting

Once a priority-setting process has determined that a chemical is of concern and requires further scrutiny, the system can be designed to have either automatic (mandatory) or discretionary risk management outcomes. One can certainly argue on policy grounds that risk management discretion is appropriate because a variety of measures are available, and a measure that is appropriate (i.e., effective and cost-effective) for one use may not be for another. Here we

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225 In the United States, TSCA reformers have decades of experience with independent review bodies such as the EPA Science Advisory Board, the National Research Council of the National Academy of Sciences and the Health Effects Institute. For a description of the origins and early work of these groups in chemical risk assessment, see HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION (John D. Graham ed., 1991); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICY MAKERS (1998).
make a second argument for risk-management discretion based on the fact that priority setting appears to progress rapidly when it is known that regulators have some discretion in risk management at the conclusion of a priority-setting process.

Canada’s prioritization scheme is designed to separate the risk assessment and management processes. Recall that under CEPA, the government conducts SLRAs to inform a determination as to whether or not a substance is CEPA-toxic. The determination that a substance is CEPA-toxic provides EC and HC with the legal basis for adding the substance to the Toxic Substances List, and the addition of the substance to the TSL in turn provides EC and HC with the legal authority and obligation to recommend and enact risk management. The determination that a substance is CEPA-toxic, though, does not automatically lead to any particular management measure.

The legislative choice to separate assessment and management decisions in Canada has allowed the Canadian chemical categorization and CMP to work as quickly as they have. A similar outcome may be desired by TSCA reformers. Indeed, the speed with which EC and HC are completing the assessments under the CMP is a large part of what makes the Canadian approach attractive as a potential model for TSCA reform. Attaching mandatory management measures, especially highly stringent ones, to the outcomes of risk assessments might have been problematic because it would have elevated the weight of prioritization and assessment decisions, resulting in more contention and lobbying about the information and analysis supporting those decisions.\(^{226}\) Since the CMP process is separated from risk management decisionmaking, it may not have withstood the intense stakeholder scrutiny that would have resulted from mandatory risk-management measures such as phase-outs and substitution.

On the other hand, the initial reluctance of the European Commission to list a large number of SVHCs may have been due to a fear that a literal, legalistic reading of REACH calls for automatic phase-out of all chemicals designated as a SVHC. The EU’s approach in the SVHC Roadmap provides an indication that the EU will build more flexibility into both the listing and risk management phases. Also, the pace of SVHC listings under REACH accelerated only after the RMO approach in the SVHC Roadmap was formulated and proposed. However, the pace of SVHC listings might have accelerated only temporarily to meet short-term political commitments rather than as a response to additional clarity provided by the SVHC Roadmap.

An alternative approach that was rejected would have ensured that all potential SVHCs are added to the Candidate List, and all chemicals on the Candidate List are added to the Authorization List, even though the risk management ramifications would have been dramatic. The SVHC Roadmap and Implementation Plan seem to envision consideration of risk management options prior to considering substances for inclusion on the Candidate List. The lack of legislative clarity on this question creates confusion as to the precise roles of prioritization and assessments under REACH. Indeed, litigation may be required to fully resolve this question. In general, the extreme complexity of REACH may place unnecessary burdens on both government and stakeholders.

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227 A similar behavioral pattern was observed in the US under the Clean Air Act. When the Congress mandates a highly stringent risk-management approach for a listed chemical, regulators are unlikely to list chemicals under the provision. Such behavior was observed under § 112 of the Clean Air Act, which regulates toxic air pollution. John D. Graham, *The Failure of Agency Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act*, 34 Duke Law Journal 100 (1985). See generally John Mendeloff, *The Dilemma of Toxic Substance Regulation: How Overregulation Causes Underregulation* (1988).

228 On ECHA’s most recent additions to the Authorization List, see *ECHA Proposes Five Substances for Authorisation*, CHEMICAL WATCH, Feb. 10, 2014; Herbatschek et al., *supra* note 128, at 135.

229 REACH, preamble (77), art. 58.


232 Abelkop et al., *supra* note 60.
Overall, the experiences of Canada and the EU suggest that for prioritization and assessment to move quickly, the choice of risk management measures should be preserved as a separate question. For TSCA reformers, preserving a range of options for risk management of different uses (as a part of legislative design) may help accelerate the priority setting and risk assessment processes.

Decoupling risk management from risk assessment necessitates deadlines for both processes. Both CEPA and REACH incorporate strict deadlines into their assessment and management processes. Experience with CEPA in particular demonstrates the importance of strict deadlines for categorization and for screening assessment. Risk management instruments must also be introduced according to specified time periods as prescribed in CEPA §§ 91 and 92: following a decision to recommend a substance for inclusion on the TSL, the ministries have two years to propose a risk management instrument and another eighteen months to finalize it. Thus, TSCA reform legislation may benefit from the inclusion of mandatory deadlines for prioritization and assessment of priority chemicals and associated management decisions. The harder challenge for TSCA reformers is to design deadlines that are practically enforceable, since the agency and stakeholders bypass many deadlines in US regulatory systems when there is no penalty on anyone for missing the deadlines.

Additionally, we noted above that prioritization decisions should not be considered final agency actions that are subject to judicial review, at least if there are no demonstrated real-world impacts of the priority-setting determination. If assessment and management decisions are separated, the drafters of TSCA reform legislation should give careful thought to legislating burdens of proof for assessment and management decisions that do not impair EPA’s ability to reach scientifically sound decisions within an expeditious timeframe. Given that assessment and

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233 CEPA §§ 91, 92.
management decisions have different implications, burdens of proof for assessment and management decisions should not be the same.

Lastly, the separation of assessment and management decisions should not give license to extra stages of litigation that drain public and private resources and impede expeditious and scientifically sound risk assessment and management decisions. TSCA reformers may consider focusing judicial review at either the assessment or the management stage, but not both unless it can be demonstrated that the priority-setting determination has real-world impacts such as market deselection, tort litigation, and state and local regulatory actions. That is, if assessment decisions analogous to CEPA-toxicity findings are subject to judicial review, then EPA should have permissive authority to apply risk management tools following notice and comment. In the alternative, TSCA reformers may want to provide EPA with permissive authority to determine that risk management of a particular substance or use is warranted, but focus judicial review efforts on EPA’s risk management decisions.

5. Adequate Public Resources are Necessary

Both Canada and the EU have dedicated substantial public funding to their prioritization and assessment processes. In fiscal year 2014, ECHA’s budget was approximately €119 million (~ $160 million US).234 The EU Member States also expend public resources on REACH to oversee ECHA and Commission activities, conduct substance evaluations, and administer other functions. The Netherlands alone spends approximately 4 to 5 million Euros per year, apart from REACH enforcement activities. If the activities of all 28 Member States are counted, the public

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investment in REACH in the Member States may be 10 to 15 times the level of the investment in the Netherlands.\footnote{Dick Sijm, Head, Bureau REACH, Department for Industrial Chemicals, The Netherlands, Personal communication, May 7, 2014.} The Canadian government has allocated about $500 million Canadian (\$450 million US) for each of the first two five-year phases of the CMP\footnote{Health Canada, Backgrounder: Canada’s Chemicals Management Plan, Oct. 2011, http://hc-sc.gc.ca/ahc-asc/media/nr-cp/_2011/2011-128bk-eng.php.}, and accounts from government and stakeholders in Canada report that this level of funding has been necessary for EC and HC to meet legislative goals.

Public resources committed to REACH are larger than those committed to the CMP. Perhaps that is to be expected since the European economy is many times larger than Canada’s. Chemicals sales in 2012 were €539 billion in the EU and $45 billion (Canadian) in Canada.\footnote{Statistics Canada, Manufacturing Sales, by Subsector, http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/manuf11-eng.htm; European Commission, Chemicals, http://ec.europa.eu/enterprise/sectors/chemicals/index_en.htm.} ECHA experienced early budget shortfalls, though they were largely due to infrastructural and implementation difficulties that have now been mostly addressed.\footnote{See, e.g., Industry bodies surprised by ECHA funding concerns, CHEMICAL WATCH, July 25, 2008, http://chemicalwatch.com/931/industry-bodies-surprised-by-echa-funding-concerns.} Regardless of how they are compared, both Canada and the EU provide substantial public funds to chemicals assessment and regulatory decisionmaking.

TSCA reformers need to find creative ways to generate additional revenue for EPA to implement TSCA reform. Taking a cue from ECHA, which collects registration fees, EPA could partially fund risk assessment with fee-generated revenue. Reliance on general federal revenue is probably the least attractive approach, since there are so many competing claims for those dollars. Fees on companies that manufacture, process, and/or use high-priority chemicals would
be a sensible “user-fee” approach.\textsuperscript{239} Although the amount of public sector resources that are required will vary by system design, any credible system aimed at addressing the large volume of existing chemicals will require significant public sector resources.

III. BURDEN OF DATA GENERATION AND SAFETY DETERMINATION

Any plausible reform of TSCA needs to address two fundamental questions: Where should the burdens of generating data and of making safety determinations be placed?\textsuperscript{240} At a high level of abstraction, TSCA, CEPA, and REACH all call on government and stakeholders to identify chemicals of concern, prioritize them for assessment and management decisions, conduct risk assessments, and make risk management decisions. Thus, in this part we compare the Canadian and European burdens as we draw insights about how TSCA reform legislation might structure the legal obligations and related formal relationships between government and industry. Given the way that TSCA has been interpreted in previous litigation, some legal commentators believe that one or more of the burdens of proof under TSCA need to be reconsidered through reform.\textsuperscript{241}

Legislation can place the burden of data production for assessment wholly on the government, wholly on industry, or some hybrid combination. In theory, legislation could require the government to generate much of the toxicity data or predictions on its own. The government could also utilize public funds to estimate releases and exposures for specific uses by


\textsuperscript{240} In the legal community, these burdens are known as “the burden of going forward” and the “risk of non-persuasion.” Fleming James, Jr., \textit{Burdens of Proof}, 47 VA. L. REV. 51 (1961). The burden of going forward places the obligation on a certain party to produce evidence. Here, we refer to this burden as the burden of data generation. The risk of non-persuasion indicates which party loses if the evidence does not meet the relevant standard of proof. We refer to this as the burden of making safety determinations.

\textsuperscript{241} Applegate, \textit{Synthesizing}, supra note 56, at 737.
undertaking inspection and monitoring programs throughout the supply chain from chemical production to use and disposal. In today’s world of severe constraints on public sector resources and expertise, neither TSCA, CEPA, nor REACH have put the data burden primarily on government. In one way or another, all three regimes envision industry as the data generator.

Placement of the burden of proof of safety is also a fundamental feature of chemicals regulation that can affect the design and function of the entire regulatory program:

The allocation of burden of proof is more than just a means to a regulatory end; it is also a normative position. Burden of proof expresses a fundamental public policy by placing responsibility for determining a chemical’s safety either with the manufacturer or with the government, making it either an essentially private or essentially public decision, respectively. The normative burden of proof also gives direction to regulators in their substantive evaluation of a chemical, telling them how selective to be, how doubts are to be resolved, and how judgment is to be exercised.²⁴²

Indeed, who holds the burden of making safety determinations is a central issue that must be resolved in TSCA reform: Do companies in the industry have any legal obligation to make an affirmative technical case that their uses of existing chemicals satisfy the prevailing safety standard in legislation? Under the laws of the fifty states that govern products liability, companies already have some safety obligations, but here we refer to an additional legal obligation that would arise from a safety standard in TSCA reform legislation.

With regard to proving the safety of existing chemicals, REACH is often seen as accomplishing a reversal of the burden of proof from government to industry whereas the Canadian approach leaves much of the burden of making safety determinations in the hands of government. As clear as the legal theory may be, the realities of both CEPA and REACH are more complex than the previous sentence suggests. If our research has revealed anything, it is a confirmation of what risk managers have known for decades—that successful chemicals risk

²⁴² Id. at 745.
management requires an enormous amount of cooperation between government and stakeholders in industry and public interest organizations. Thus, while CEPA and REACH do have quite different allocations of legal responsibility, implementation of both legislative designs has been a cooperative effort. At a practical level, both CEPA and REACH share burdens among government and stakeholders, shifting them back and forth, depending on the nature and stage of the regulatory process.

Since there are interesting interconnections between the burden of data generation and the burden of proving safety under a legislated safety standard, we discuss the two burdens together. If manufacturers or downstream users must affirmatively show that the ways in which they use chemicals meet a legislated safety standard, then they have an added incentive to generate additional information beyond that provided by marketplace competition and duties of care under tort law. If the burdens of producing data and proving unacceptable risk rest with the government, then manufacturers and downstream users may be inclined to refrain from making scientific investments in data generation until they are compelled to do so. Given this conceptual background, we turn to a look at how Canada and the EU have resolved these difficult issues.

A. CEPA 1999 and the CMP

CEPA primarily places the burden of data production on industry but maintains the burden of proof of risk (that a substance or use is unsafe) on the government. The burdens are structured to facilitate cost-effective decision making and flexibility in the application of risk management. Since data generation and analysis are expensive, CEPA is designed to produce only the amount of data and analysis that are necessary to reach a management decision. In this respect, the CEPA approach reduces the risk of information overload on government at the same

\[243\] Id.
time that it places the burden of making safety determinations on government. Moreover, the spirit of the CMP is that of a cooperative endeavor between stakeholders and government in identifying and managing risks. Although this may seem idealistic, CEPA and the CMP have operated effectively through iterative processes of interaction and feedback between government and stakeholders.

CEPA § 71 authorizes EC to require the submission of data from any person who “may reasonably be expected to have access” to it for the purpose of determining “whether a substance is . . . or is capable of becoming” CEPA-toxic, “or for the purpose of determining whether to control, or the manner in which to control, a substance.”\(^\text{244}\) Recall that a substance is CEPA-toxic “if it is entering or may enter the environment in a quantity or concentration under conditions that” may result in harm to human health or the environment.\(^\text{245}\) A finding that a substance is CEPA-toxic constitutes the government’s burden of demonstrating that a risk exists. The statute, therefore, directly links the burdens of data production and proof of (un)safety.

Under CEPA §§ 71 and 72, authorities can require the submission of existing and new data through surveys (mandatory data submissions) of companies.\(^\text{246}\) There is no substantial burden of proof or procedural hurdle that EC must surpass to issue a data submission survey under § 71 other than that the purpose must be to inform risk assessment or management decision making. EC publishes a notice of the data submission requirement in the Canada Gazette, similar to the US Federal Register.

The notice describes the parameters of the survey, including what substances the survey applies to, who must respond (e.g., those who imported or used a quantity of the substance in a

\(^{244}\) CEPA § 71.

\(^{245}\) CEPA § 64.

\(^{246}\) CEPA § 72 conditions authority to require generation of new information under CEPA § 71(c) on authorities having a reason to suspect that a substance could be CEPA-toxic. Therefore, the government cannot require the generation of new information for a priori information gathering.
calendar year greater than 100 kilograms at a concentration of 0.001 % by weight in a product or mixture intended for residential use), the total quantity imported or used, the Function Code and the Consumer and Commercial Code (as used in the US by EPA), a description of the generic name of the substance, a description of the mixture or product containing the substance, studies on hazard characteristics (e.g., as persistence, bioaccumulation, and toxicity), confidentiality requests, and the date by which the information must be submitted to the government.  

For the Challenge, the notices applied to batches of fifteen to thirty substances and addressed substances alone and in products or mixtures. Other surveys can also be mandated, for example, a “one-off” update on quantities manufactured, imported, and exported for a large number of substances, referred to as an “Inventory Update.”

Some stakeholders have reported difficulty due to lack of clarity in requests (e.g., regarding the level of detail required) or limitations they face on access to certain data (e.g., uses throughout the supply chain). EC, however, has been diligent in gathering feedback on data submission challenges and has included stakeholders in the design of § 71 notices. EC has encouraged companies to cooperate in submitting data on their own and/or through industry organizations.

Interestingly, information collected under REACH is finding its way into Canada, though not directly through government-to-government exchange. The Canadian government has in certain instances entered into agreements with groups of REACH registrants (called consortia) to

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251 Id. at 7, 12.
collect data from REACH registration dossiers from the registrants themselves rather than from ECHA because the registrants own the data.

Under the CMP, EC and HC use the information gathered in § 71 surveys to conduct SLRAs to determine whether or not substances are CEPA-toxic. In addition, some data are generated directly through contracts with the government or by the government itself (e.g., biomonitoring studies, mining of existing data, and development of predictive tools). Although industry has expressed some difficulty in gathering and submitting data in response to requests from the Canadian government, the data submissions required under CEPA § 71 do not rise to the level of detail or comprehensiveness of REACH registration dossiers. The requests for data in Canada are far more limited and targeted to exactly what Canadian regulators think they need.

As noted above, the standard for authorizing risk management is whether or not a substance is CEPA-toxic. The placement of the burden of proof is squarely on the government. EC and HC must find that a substance is CEPA-toxic in order to apply risk management. The assessment process, which entails a screening level risk assessment, is explicitly structured to answer this question: whether a substance “is entering or may enter the environment in a quantity or concentration under conditions that” may cause harm to human health or the environment. This is a risk-based standard, though it is certainly vague compared to what a risk assessor would demand for practical implementation. It does require the consideration of both hazard and exposure. Regulators do not need to find that the use or disposal of a substance actually presents a risk or likely presents a risk, but rather that it may present a risk. Though there are regulations that specify methods for determining persistence and bioaccumulation, no guidance has been released that specifies the ministries’ burden of proof in determining whether or not a substance

\[252\] CEPA §§ 64; 65(3); 77(4) (emphasis added).
\[253\] Persistence and Bioaccumulation Regulations, supra note 85.
may enter the environment or may cause harm. In other words, if use or disposal of a substance raises the plausible possibility of a risk to human health or the environment, then authorities are empowered to determine that the substance is CEPA-toxic and initiate the risk management process.

Further, under certain evidentiary circumstances, CEPA compels authorities to add a substance to the Toxic Substances List. For example, if a SLRA indicates that a substance is CEPA-toxic, persistent, bioaccumulative, and its presence in the environment “results primarily from human activity,” it must be recommended for addition to the TSL and is automatically considered for “Virtual Elimination”—prohibition on the release of a substance beyond a certain threshold under which the substance cannot be accurately measured in emissions and effluents. On the other hand, a determination that a substance is CEPA-toxic, by itself does not automatically trigger the application of any particular risk management instrument. Further risk-management considerations are necessary to make sure an appropriate response is made.

Recall that there are three potential outcomes if a SLRA leads authorities to determine that a substance is CEPA-toxic. Authorities may opt to take no further action if, for example, they determine that voluntary measures by industry, market de-selection, or another action is appropriate to control the risks. They may add the substance to the Priority Substances List, though this path has been all but abandoned as a risk assessment provision. Finally, the ministries may recommend that a substance be added to the TSL, which is a formal step toward risk management measures.

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256 CEPA, § 77(2).
257 Substances that would have been determined to be CEPA-toxic, but the demonstrated absence of exposure in the Canadian context prevented that conclusion, are controlled by the government’s policy of issuing a SNAc, which
CEPA provides EC and HC with a wide variety of risk management options to control exposure to CEPA-toxic substances at any point in the chemical’s lifecycle. Once a substance is recommended for addition to the TSL, the ministries have two years to propose and issue a “regulation or instrument respecting preventive or control actions in relation to a substance.”

As of July 2014, there are 132 substances or types of substances on the TSL.

CEPA provides authority for EC and HC to adopt any of about thirty different policy tools, including restrictions on the quantity of manufacture, sale, import, or export; amount, location, and conditions of releases; labeling, handling, and storage; and the generation and submission of information. The agencies may also issue guidelines, standards, or codes of practice or facilitate voluntary risk management efforts. For example, authorities have issued regulations that pertain to specific TSL substances (e.g., polybrominated diphenyl ethers and PCBs), certain sources of TSL substances (e.g., pulp and paper mill effluent containing chlorinated dioxins and furans), certain uses and products that contain TSL substances (e.g.,

effectively means the substance will need to be assessed as a new substance should a manufacturer or importer wish to use it. SNAc Approach, supra note 94.

258 CEPA, § 91.
260 CEPA, § 93.
261 CEPA, § 93 (risk management tools), § 95 (requirement to report releases), § 98 (liability for remedial efforts after a release), § 100 (export controls). See also Meek & Armstrong, supra note 72, at 598; United Nations, Department of Economic and Social Affairs, Division for Sustainable Development, Canada National Reporting to CSD-18/19, Thematic Profile on Chemicals, at 8, http://sustainabledevelopment.un.org/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf.
concentration limits for 2-butoxyethanol in products for indoor use), and more general risk management tools.

One such tool is the Prohibition of Certain Toxic Substances (PCTS) regulations. Authorities developed the PCTS regulations because “it was suggested that it would be simpler and more effective administratively to develop a generic banned-substances regulation to which substances would be scheduled rather than having separate regulations . . . .” The PCTS regulations include several sub-lists, also called schedules. At present, the twelve substances listed on Schedule 1 are prohibited from manufacture, import, sale, and use.

PCTS Schedule 2 functions somewhat like REACH authorization: listed substances are prohibited from manufacture, import, and sale, unless exemptions are provided under limited authority. However, Canada’s exemption mechanism may be more flexible. The Minister of the Environment must issue a permit if “there is no technically or economically feasible alternative,” “the applicant has taken the necessary measures to minimize or eliminate any harmful effect of the toxic substance on the environment and human health,” and the applicant has prepared a plan to phase out the use of the substance within three years after the permit is issued. Schedule 2 lists five substances with permanent permitted uses, one substance with a temporary permitted use, two with permitted concentration limits, and two with reporting thresholds. Thus, although the CEPA-toxicity standard does not necessarily mandate the consideration of socio-economic data, consideration of substitutes, or differentiation in uses, such factors are built into the risk

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267 PCTS Regulations, supra note 265.
268 Id. § 10.
management decision-making process that follows a finding that a substance is CEPA-toxic and the addition of the substance to the TSL.

   Under an alternative tool, the agency may require industry to develop Pollution Prevention (P2) Plans, programs to minimize the release of substances listed on the TSL.\textsuperscript{269} Through P2 plans, EC develops a risk management objective for a particular substance and compels businesses to develop their own management strategies for preventing releases of the substance.\textsuperscript{270} EC has used P2 plans as precursors to or in lieu of other risk management strategies, especially those where information asymmetries make it difficult for the agency to determine what the most effective or efficient management option might be.

   Another risk management instrument that is gaining momentum is the use of a Significant New Activity (SNAc) requirement, which is very similar in concept to the TSCA Significant New Use Rules, for substances whose current use(s) is either extremely limited and well-controlled, or if quantities in current Canadian commerce are zero or very low.\textsuperscript{271} The SNAc is applied to enforce notification of new or increased use (with an associated requirement to provide risk-related information as per a New Substance Notification), which allows the regulator to conduct an updated risk assessment.

   Some criticize the Canadian approach for not fully reversing the burden of proof of safety on to industry.\textsuperscript{272} The legislation does not require industry to make a safety determination, but CEPA does authorize EC and HC to compel industry to provide data in specific cases\textsuperscript{273} and, in

\textsuperscript{271} SNAc Approach, supra note 94.
\textsuperscript{273} CEPA § 71.
fact, this is an integral first step to the assessments done under the CMP. Moreover, the SLRAs utilize a tiered approach starting with upper-bound exposure estimates and refining those estimates, as necessary and where possible, depending on the level of information available.\textsuperscript{274} P2 plans also reverse the burden of proof of safety onto industry by establishing a risk management objective that industry is responsible for meeting.

The spirit of the CMP is that it is a cooperative endeavor between government, industry, and NGO stakeholders. To be sure, praise of CEPA and the CMP is certainly not universal, as many specific decisions have raised controversy. Nonetheless, many stakeholders, including both industry and NGOs, seem to be pleased with the degree of activity under CEPA and the CMP, especially as compared to the level of activity prior to the enactment of CEPA 1999.\textsuperscript{275} As of 2013, none of the stakeholders are seeking to overhaul the system to the degree they are currently in the United States.\textsuperscript{276}

\textbf{B. REACH}

REACH places the data-generation and risk-assessment burdens primarily on industry. The obligations vary depending on the quantity of the substance to be imported or manufactured, the potential for the substance to cause harm to persons or the natural environment (toxicity), and whether the substance is an existing substance or a new substance. Recall that greater amounts of information are required for chemicals that are manufactured or imported in higher volume. Once the 10-tonne threshold is reached for a registrant, a Chemical Safety Report for the

\textsuperscript{274}This is a technical process that is motivated by value-of-information thinking. See NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 110–11 (1995).
\textsuperscript{275}ENVIRONMENTAL DEFENCE, supra note 92; Goodhand et al., supra note 196.
\textsuperscript{276}Cheryl Hogue, Support Grows for Chemical Law Reform, 91 CHEMICAL & ENGINEERING NEWS 22, June 10, 2013, at 22–23.
substance must be added to the registration dossier. The CSR must include a chemical safety assessment, including information on hazards to human health and the environment, physiochemical hazards, and an assessment on whether the substance qualifies as PBT or vPvB. If the safety assessment reveals that the substance is hazardous or qualifies as a PBT or vPvB, then additional information is required, including exposure scenarios and risk characterization. Information on substances makes its way through the supply chain via documents called Safety Data Sheets.

One of the common misconceptions about REACH is that it compels numerous new toxicity tests on thousands of chemicals that have been marketed for years without any toxicity information. REACH does contain basic information requirements regarding hazards, but REACH is designed to minimize the number of new animal toxicity tests. ECHA and the Member States have issued detailed guidance on the numerous avenues that registrants can pursue to avoid the time and expense of animal toxicity testing. They can report previously conducted tests (if they are applicable and sufficient), they can make inferences based on structurally similar chemicals, they can allow a test of one chemical to serve for an entire category of chemicals, and they can perform modeling exercises to predict acute and chronic ecotoxicity. The registrants bear the full responsibility for justifying these “adaptations,” and the process of obtaining ECHA approval for adaptations is burdensome for industry, since it

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277 REACH, art. 10(1)(b); 14(1).
278 REACH, art. 14(3).
279 REACH, art. 14(4).
280 REACH, art. 31, 32.
281 See, e.g., WARGO, supra note 23, at 287 (describing the “REACH testing program” as “an important step” because it “will require toxicity testing by manufacturers of more than 30,000 compounds”)
282 REACH, Annex VII–X.
284 For example, Quantitative Structure-Activity Relationships. Herbatschek et al., supra note 128.
involves preparation of detailed justification documents and a laborious process of answering questions from ECHA. In some cases, registrants decide it is less onerous to perform tests—even if they are expensive—than to seek ECHA acceptance of adaptations.\textsuperscript{285}

One indication of the limited amount of animal testing induced by REACH is the proportion of requests for approval of animal tests in relation to the number of registration dossiers submitted to ECHA. By May 2013, ECHA had received 33,656 registration dossiers on 8,469 substances.\textsuperscript{286} The number of dossiers including a proposal for animal testing was modest: about 800 tests were proposed (by 2012), 62 percent for a single toxicity endpoint (reproductive effects, either developmental or two-generation studies).\textsuperscript{287} Additionally, some of these tests are not expected to be conducted because ECHA approval of some tests will render other proposed tests unnecessary, since registrants will be able to use “read across” techniques to allow a test of one substance in a category to satisfy the data requirement for other chemicals in that category.\textsuperscript{288}

One of the innovative features of REACH is the requirement that multiple manufacturers of the same chemical join together and submit a single dossier (“one substance, one registration”). Companies form Substance Information Exchange Forums (SIEFs) and contractual organizations called consortia to facilitate information sharing, which means that test data in the possession of one company can be used to meet the obligations of all companies in the group. A lead registrant may bear the brunt of the work but may also collect some fees from other companies in the group to defray some of the costs of being a lead registrant. One company

\textsuperscript{287} \textit{Id.}
\textsuperscript{288} \textit{Id.} at 376–77, 380, 387.
in a SIEF must sell its data to others, a pattern that has led to some interesting negotiations since there is no obvious way to set a price for data from an older toxicity study. Elsewhere, we have written about some of the complex financial and legal issues that arose during the initial formation and operation of SIEFs and consortia under REACH. The transaction costs were substantial (and arguably greater than they needed to be), but there is no question that the collaboration between manufacturers (and users) of chemicals has reduced the amount of new toxicity tests and other data gathering that might otherwise have been necessary. Equally, the requirement has forced a significant workload on industry.

Starting with the 2010 registration deadline and now with the recent passage of the 2013 registration deadline, REACH has stimulated the assembly of a massive electronic database of chemical properties, uses, exposure pathways, and risk management measures. The huge inventory is housed at ECHA. Thus, some of the data gaps on chemicals in commerce have been filled, and more data gaps on lower-volume chemicals will be filled by the next registration deadline in 2018.

There is some evidence that the actual act of gathering and submitting the data has produced some positive benefits. Registration has not only facilitated communication among risk managers and other professionals within different branches of large companies, but it has also facilitated communication between different companies throughout the supply chain of chemical products. Stakeholders have indicated that this communication has allowed them to achieve some efficiencies in operations, data gathering, and decision making on chemical uses.

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289 Abelkop et al., supra note 60, at 11025–29.
290 Mike Penman & Martin Richards, REACH Consortia, in THE EUROPEAN UNION REACH REGULATION: LAW AND PRACTICE 185–86 (Lucas Bergkamp ed., 2013) (if each stakeholder had to submit their own hazard data, a large amount of unnecessary animal testing could occur; Hungary and the UK succeeded with an amendment to REACH calling for “one substance, one registration”)  
291 Abelkop et al., supra note 60.
and product design. In addition, a large portion of registration information is now publicly available on the Internet, through ECHA’s website, for examination by governments around the world, public interest organizations, consumers, processors, retailers, and companies throughout the chemical industry.\textsuperscript{292}

A challenge for the EU is to ensure that the information is put to good use in risk management. European Authorities indicate that registration dossiers require registrants to make affirmative safety determinations that risks of chemicals are “adequately controlled.”\textsuperscript{293} Thus, REACH is said to reverse the burden of proof of safety onto industry.

In our view, the ideal of reversing the burden of proof is commendable. It should be the responsibility of companies to ensure the safety of the products that they place on the market. In practice, however, the implementation of the reversed burden of proof has presented challenges. EU Authorities indicate that a finding of “adequate control” is a central part of some registration dossiers, but stakeholders seem to be less certain of this obligation, perceiving registration as more of a data collection process than a risk management process. Part of the difficulty might be traced to some ambiguity as to the meaning of “adequate control,”\textsuperscript{294} but the bigger issue may be a perception that EU Authorities must ultimately take action under the authorization or restriction processes to ensure adequate control of exposures (e.g., ECHA cannot pull a registration because it believes risk management measures are inadequate).\textsuperscript{295}

Moreover, the safety determinations made by registrants within registration dossiers might not always be the same determinations that a regulator would make. As an example, the ECHA PBT Expert Group concluded that Siloxane-D5 is a vPvB and should therefore be classified as a SVHC and slated for authorization. However, the registrants have concluded in their dossier that it is not a vPvB. Substances that are vPvB (along with PBTs and CMR substances) are considered “non-threshold” substances under the statute. That is, they are substances for which, under REACH, it is assumed that there is no safe level of exposure, and hence the risks cannot be adequately controlled. For substances that REACH presumes do not have a safe level of exposure, it is a mystery how a registration dossier could demonstrate adequate control of exposure (unless exposures are eliminated). Yet, the registrants have determined that risks are, in fact, adequately controlled. This apparent inconsistency might not have any practical impact; it is entirely plausible that risks are adequately controlled (after all, the Canadian Board of Review determined that Siloxane-D5, as it is used in Canada, is not CEPA-toxic). However, this case raises broader questions about the clarity of regulatory mandates under REACH and the potential for contradictory outcomes under different parts of the regulation (i.e. registration versus authorization).

Additionally, the concept of “safety” is a social construct and different sectors of society have different views about what is “safe.” Although the concept of placing the burden of proof on industry may be superficially attractive to some, the risk outcome is based largely on

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298 Elsewhere we have argued that the REACH’s safety standard under authorization is not consistent with the standard under registration because registration process does not permit the registrant to consider benefits (under the “adequate control” standard) whereas the authorization process permits consideration of benefits during socio-economic analysis of specific uses. See Abelkop et al., supra note 60, at 11062–64; Abelkop et al., supra note 293, at 390–93.
companies’ determinations of what constitutes “safety.” Chemical manufacturers have the most
direct control over internal safety in handling and less control over safety of how chemicals are
used downstream. More importantly, industry can make a safety determination, but cannot
decide on societal acceptance of its position on risk. Acceptable levels of risk may turn on
whether emphasis in a risk assessment is placed on hazard or exposure data; this has historically
been a point of contention between industrial interests and consumer health and environmental
advocates.

What’s more, the Siloxane-D5 case raises questions about the trustworthiness of safety
determinations in registration dossiers: if Annex XV dossiers rely primarily on data from
registration dossiers to identify SVHCs, then companies have a strong incentive to find that their
substances do not have vPvB, PBT, CMR, or endocrine disrupting properties. The same can be
said of the data submitted under CEPA (and indeed any regulatory program). The difference is
that the volume of data that the government must inspect under CEPA is much more
manageable, and government is not relying on industry to self-regulate. REACH does not rely
wholly on industry to regulate itself through registration; ECHA conducts audits of the
registration dossiers, often requesting or compelling clarifications or additional data/analysis.

The EU may also supplement the safety measures in registration dossiers by managing
risks through the authorization and restriction mechanisms under REACH. Recall that once a
SVHC is placed on the Authorization List, it must be phased out unless the Commission
approves authorization requests for specific uses. As an alternative, the Commission can
establish more targeted restrictions on the manufacture, placement on the market, or use of a
substance that it determines to pose an unacceptable risk to human health or the environment.
Therefore, the notion that REACH fully reverses the burden of proof of safety is a misleading oversimplification. Under authorization and restriction, the burden shifts to the government to identify SVHCs, place chemicals on the Candidate List and then the Authorization List, or apply restrictions. After a chemical is placed on the Authorization List, the burden shifts to industry to apply for use-specific authorizations. Each authorization request must certify either that adequate control of risks for threshold substances has been accomplished or that benefits exceed risks in the case of non-threshold substances (socio-economic analysis). If a company chooses the socio-economic route of justification, it must also demonstrate that no suitable alternatives to the SVHC are available for the specific use.

In December 2013, Rolls-Royce was the first company to gain an opinion from ECHA that the Commission should approve an authorized use of a substance (DEHP) on the Authorization List by making the case that risks are adequately controlled in a specific aerospace application: the seven-year authorization is for the use of DEHP—short for Bis(2-ethylhexyl) phthalate, a reproductive toxin—in the manufacture of aero engine fan blades.299 In 2013, ECHA received a total of eight authorization requests covering two phthalates in seventeen different uses.300 In 2014, ECHA expects about sixteen authorization requests.301 Prior to the first authorization decision, the common perception among industry stakeholders was that the authorization process will be strict, onerous, and unpredictable with regard to outcome.302 Such perceptions are likely to evolve as practical experience with the authorization process is accumulated. There is no precedent yet for an authorization based on socio-economic analysis.

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300 Id.
301 Id.
302 Herbatschek et al., supra note 128, at 134, 139–45.
Overall, the REACH regulation imposes burdens of proof on both industry and government. Those burdens are sometimes independent of each other, but in some cases (e.g., authorization) the sharing of burdens is an iterative process. Both stakeholders and government have experienced “growing pains” in the first years of REACH implementation, but the statute has so far proven to be workable, despite its complexity. In the years ahead, the inspection of a greater volume of registration dossiers, along with more experience with the authorization process, will yield additional insight into the workability of REACH’s approach to chemicals management.

**C. Lessons**

1. Industry should be required to Produce and Supply Safety Data

In addition to accepting some level of responsibility for placing a chemical in the marketplace, manufacturers and processors are likely the least-cost providers of safety information. Many jurisdictions, including the EU, US, and Canada, have pre-manufacturing or pre-marketing notification requirements for new substances. The European and Canadian laws include specific data requirements to accompany the registration package. Hence new substances introduced into commerce may have a more extensive database than many existing (legacy) chemicals. Given this precedent, it is not unreasonable to expect industry to generate and provide similar databases for existing chemicals; and the industry’s response to recent challenges such as the various High Production Volume initiatives tend to confirm that it understands these expectations, although there is still a long way to go before the entire spectrum of legacy

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chemicals has been dealt with. On the other hand, the careful use of limited data and modeling—coupled with safe experience to date—argues against broadly applicable data requirements.

Both CEPA and REACH place the burden of data production primarily on industry.\textsuperscript{305} TSCA § 1 also states, “the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.”\textsuperscript{306} Government as well as stakeholders in industry and public interest organizations engaged in the TSCA reform debate all contend that the placement of the burden of data production should be on industry.

One of the reasons for the broad consensus is straightforward: the chemicals marketplace is characterized by an information asymmetry in favor of industry. Manufacturers, processors, and users are in the best position to obtain data on intrinsic properties, uses, releases, exposure scenarios and pathways, and risk management measures. They can do so at a lower cost than government can because they already have established commercial relationships with each other and because government is in a poor position to appreciate the wide variety of uses throughout industry, the many possible exposure scenarios, the numerous opportunities for chemical releases into the environment, and the wide range of risk management measures that are already employed by companies.\textsuperscript{307}

The approval processes for agricultural chemicals and pharmaceuticals also place the burden of data generation on the private sector, as do various permit processes under the Clean Air Act and Clean Water Act and permit processes for many industrial facilities such as oil and

\begin{footnotes}
\item[305] However, EC and HC have also spent significant resources and time mining existing data and developing predictive tools. See Health Canada, The Health-Related Components of Categorization of the Domestic Substances List (DSL): Approach, Results, and Next Steps, http://www.hc-sc.gc.ca/ewh-semnt/contaminants/existsub/categor/roch-approch-approche-eng.php.
\item[306] TSCA § 1(b)(1).
\item[307] For a discussion of the issues regarding whether data should be generated by industry or government, see Applegate, RESCUING, supra note 67.
\end{footnotes}
gas development, mining operations, and waste disposal (e.g., incinerators and landfills). Thus, there is plenty of regulatory precedent for placing the burden of data generation on industry.

Some scholars have raised issues about the trustworthiness of data generated by industry. After all, companies may perceive that they have little to gain and much to lose by providing regulators with information about the potential risks of using their chemicals. And since only a small percentage of registration dossiers are checked fully by ECHA, registrants may perceive that they can “cut corners” in the registration process.

The use of SIEFs under REACH may create an informal policing of information quality in registration dossiers. If a SIEF’s lead registrant proposes to submit low-quality or misleading information to ECHA, the other registrants in the SIEF who placed their trust in the lead registrant may lose confidence in the lead registrant and seek corrective action. None of the registrants want to be exposed to the risk of potential delays or refusal of registration based on inadequate information or the potential reputation damages from submitting misleading safety information to the government. More generally, it is not difficult to imagine negative consequences that can result for a company that is shown to have submitted incomplete, misleading, or fraudulent data to a regulatory body. Under US tort laws, such behavior could increase the risk of punitive damage awards against a company, assuming that a worker or consumer was ultimately harmed by chemical exposure and a jury is made aware of the company’s misbehavior.

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308 Id. at 273–75; JœE THorNTOn, PANDORA’S PoiSON: CHLORINE, HEALTH, AND A NEw EnViRONmental STRATEGY 98–99 (2000) (arguing that corporate funding of toxicological research has biased thinking in favor of the concept of thresholds); Daniel Uyesato et al., REACH’S IMPACT IN THE REST OF THE WORLD, IN THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 361 (Lucas Bergkamp ed., 2013) (discussing the government of Japan’s preference to not rely on industry-generated data).

309 Under US tort law, a company might face large punitive damages if it intentionally misled the government and resulted in harm to consumers or the environment. Gertz v. Robert Welch, Inc., 418 U. S. 323, 350 (1974) (defining punitive damages); Alexander Volokh, PUNITIVE DAMAGES AND ENVIRONMENTAL LAW: RETHINKING THE ISSUES, Policy Study No. 213 (1996), http://reason.org/files/76a01f43ff7eeec045e97b61c0f23ca5.pdf; RAE ZIMMERMAN,
Procedures for review of regulatory data—sometimes called “regulatory science” due to the applied nature of the information and the possible role of policy drivers or assumptions in the data-generation or data-analysis parameters—should therefore be built into any regulatory system for chemicals.\textsuperscript{310} Both CEPA and REACH have issued guidance concerning the quality of submitted data (e.g., the use of Good Laboratory Practices (GLP) is required by law and emphasized in guidance), have issued test guidelines based on internationally agreed test methods (determined by OECD), and have incorporated detailed procedures to review industry-generated data.\textsuperscript{311} On the other hand, neither CEPA nor REACH precludes consideration and use of non-GLP studies.

Since government scientists and their contractors often have a crucial role to play in the review of industry-generated data and analyses, it is vital that the scientific staff of regulatory agencies receive adequate funding and training to perform their quality-control and data review/interpretation roles. Insofar as data about chemicals are made publicly available (as is increasingly the case in the EU and Canada), public interest groups and interested academics and consultants can also serve as informal critics of quality and relevance. The more that industry data are made available for public scrutiny and are subjected to rigorous review by qualified scientists, the more likely it is that the public will trust the resulting regulatory outcomes.

2. Industry should be required to Analyze Submitted Data and Make Safety Determinations for Envisioned Uses Under the Applicable Standard of Safety


\textsuperscript{311} See, e.g., REACH Art. 13(4) (requiring that ecotoxicological and toxicological tests be carried out under GLP or other international standards); Government of Canada, Information Gathering, supra note 248.
Under US and Canadian law, chemical manufacturers and users are already subject to affirmative duties of care that are expressed in tort laws.\textsuperscript{312} TSCA, however, places the burden of making the safety determination on the government, as does CEPA.

European law relies more heavily on administrative regulation (than tort law) to impose duties of care on industry, and thus it should not be surprising that REACH placed the burden of making a safety determination on industry (e.g., in the registration process and when use-specific authorizations to market a SVHC are requested). REACH also places the safety-determination burden on government under the authorization and restriction procedures. Thus, it is more accurate to describe REACH as a hybrid statute, where some of the safety-determination responsibility is placed on industry and some on government.

As TSCA reformers consider this question, it should be apparent that either arrangement can be workable, as both the Canadian and European safety-determination systems have been operational for almost a decade. The harder question to answer is which safety-determination approach—or what form of hybrid model—is preferable in the US under a reformed TSCA, given the nature of our legal system, the track record of our regulatory authorities in risk assessment and management, the likely constraints on public funding of US regulators, and our political, commercial, and scientific cultures.

Although either burden location in TSCA reform can work, we are inclined to favor a reversal of the burden in the United States as has been implemented in the REACH registration system—companies should be compelled to make a safety determination for specific uses under a statutory standard; determinations should then be reviewed by government regulators.

\textsuperscript{312} Renn & Elliott, \textit{supra} note 44, at 229 (the potential civil liability in the United States from chemical risks is at least as important as the regulatory system).
Elsewhere we have argued that the safety standard in REACH is not clear and consistent, but we do believe that a clear and consistent safety standard should be politically determined. Once the safety standard is established, it should be the responsibility of industry to make the initial showing that they have complied with the standard, and the government should be the final arbiter as to whether industry has complied with the standard. We offer four practical reasons for this policy preference, in addition to our philosophical preference that those who market products have an ethical responsibility to vouch for their safety on the basis of evidence.

First, if the federal government, through EPA risk assessments and management decisions, shoulders the burden of accomplishing chemical safety evaluation, we fear that the risk-assessment work will be performed slowly, and in some cases, it will simply not get done. The result may be insufficient protection of the public and a resulting lack of public trust in the reformed regulatory system. Despite the positive experience in Canada under the CMP as discussed above, our fear is rooted in the well-documented (glacial) pace by which EPA completes hazard assessments under the Integrated Risk Information System and the limited number of risk assessments completed under TSCA. Moreover, EPA has experience in developing a wide variety of risk assessment guidelines that could be applied to industry risk assessments. We have reason to be confident in EPA’s ability to review risk assessments and safety determinations made by industry.

The new role we propose for EPA as reviewer of industry risk assessments approximates the role of US regulators in many other health, safety, and environmental programs ranging from

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313 Abelkop et al., supra note 293.
pharmaceuticals and medical devices to nuclear reactor safety. Indeed, EPA already plays this reviewer role in a variety of its own programs. For example, when agricultural chemical companies make a case for “reduced risk” pesticides under FIFRA (and thus become eligible for accelerated registration decisions), EPA is put in the role of reviewing the risk assessments prepared by industry. 316 Likewise, although EPA does not routinely review industry risk assessments under TSCA’s new chemical program, the agency does have relevant experience reviewing TSCA § 5(h)(4) exemption requests, where it must grant or deny a requested exemption to the requirement that a company prepare a pre-manufacturing notice (PMN) package for a new chemical. EPA in effect must evaluate the company’s claim that there will not be an unreasonable risk with the new chemical without a PMN. To better ensure that safety is provided, EPA may insist that amendments be made to the exemption request, and then those amendments are treated as kind of a binding PMN on the company. More generally, the company’s general obligation to prepare a PMN (an organized package of technical and commercial information) under TSCA has proven to be a very valuable starting point for EPA review rather than being compelled to create a dossier from scratch (as they are currently expected to do for existing chemicals).

Another illustration of EPA acting as a reviewer of industry information occurred in the Organization for Economic Cooperation and Development’s Screening Information Data Set (SIDS) program. 317 Companies prepared an initial package of information—the SIDS Initial Assessment Report—that could be used by EPA in the OECD’s international dialogue. EPA

reviewed the package and, where appropriate, requested revisions, prior to the package being submitted by EPA to the OECD’s international review.\footnote{318}{Robert Diderich, \textit{The OECD Chemicals Programme, in Risk Assessment of Chemicals: An Introduction} 633 (C.J. van Leeuwen & T.G. Vermeire eds., 2007).}

We recognize that EPA has recently pledged\footnote{319}{Cheryl Hogue, \textit{Assessing Chemicals: New EPA Effort Targets Dozens of Substances Already on the Market for In-Depth Scrutiny}, \textit{Chemical & Engineering News}, Apr. 30, 2012, at 28–30.} (and indeed has made some) significant progress in the preparation of risk assessments under the current TSCA regime,\footnote{320}{EPA, Assessments for TSCA Work Plan Chemicals, http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html.} though the scope of the activity is modest compared to what has happened in Canada and Europe since 2006.\footnote{321}{GOVERNMENT ACCOUNTABILITY OFFICE, \textit{Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals But Could Strengthen Its Approach}, GAO-13-249 (Mar. 2013).} At its recent accelerated pace, it would take EPA ten years to complete risk assessments for the 83 chemicals in the current TSCA Work Plan.\footnote{322}{GOVERNMENT ACCOUNTABILITY OFFICE, \textit{Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation}, GAO-13-696T, at 13 (June 2013).} If EPA faces hundreds of priority chemicals under a reformed TSCA, as should be expected given the experiences in Canada and the EU, it is difficult to have confidence in its ability to get the job done.

Second, US policymakers should strongly consider formally incorporating external peer review of risk assessments into TSCA reform. With industry-produced assessments, external peer review overseen by EPA (i.e., EPA would choose the reviewers) could facilitate public confidence in the quality of the assessments.

Third, placing a regulatory obligation on industry to make a finding of safety prior to placing—or continuing to place—a chemical on the marketplace might not be as onerous as some in industry fear, especially since many companies in the industry already have hands-on experience preparing dossiers and making such determinations under REACH. Rather than expect EPA risk assessors to reinvent the wheel based on a similar body of data, it may make sense for companies doing business in the United States to provide what they have done in
Europe for submission to EPA, with appropriate adaptations as determined by EPA. Even if TSCA reform would not grant REACH registration dossiers or responses to CEPA § 71 surveys complete reciprocity, the data burdens on US companies would not be as great as those under REACH and CEPA. Over the last decade, regulatory efforts in Europe, Canada, and elsewhere have facilitated an enormous gain in information on chemical hazards and exposures as well as advancements in risk assessment techniques. To most effectively take advantage of the changing landscape, a reformed TSCA should apply dynamic, adaptive assessment and management decision making processes.

Nonetheless, it may not be wise for US policy makers to apply a formal registration system to as many chemicals as in Europe. There are small and medium-sized businesses in the US that do not do business in Europe, and they would have a steep learning curve under a proposal to transfer a REACH-like registration system to the US. TSCA reform should attempt to minimize rent seeking by multinational firms that have experience under REACH. Even under our modest registration recommendation (focused on high priority chemicals), federal programs of compliance assistance may be necessary for small and medium-sized American companies and their customers.

A registration program under a reformed TSCA does not necessarily need to contain the same data elements that are specified under REACH, but the presumption should be in favor of international harmonization. Careful justification needs to be provided for each departure from the REACH requirements (addition or exclusion). A key question will be what information will be required about production volume, uses, and exposure scenarios, given that EPA already has a Chemical Data Reporting rule that is compelling companies to submit some of this
Registration would be valuable in confirming the quality of the existing information and generating more detailed information from companies (manufacturers, processors, and users) to support exposure and risk assessment on a use-by-use basis. More detailed information on implementation of risk management measures would also be highly desirable compared to the rudimentary information required under REACH. The TSCA registration could call for such information as part of a REACH-like Chemical Safety Report.

There will be a natural tendency for US companies to fear SIEF-like processes that compel collaboration among multiple companies that are usually in the business of competition. However, as we have documented elsewhere, many of the problems with formation of SIEFs in Europe can now be prevented in the US, since we know what caused those problems in Europe and many of the problems were preventable. If Congress tries to engineer a registration process without any SIEF-like entities, the risk of unintended consequences and bureaucratic snafus is greater than if US legislation builds on the experience (“warts and all”) with REACH.

Fourth, a registration system under a reformed TSCA could apply exclusively to high-priority chemicals—identified through a Canadian-style prioritization process—rather than nearly all chemicals, as is the case in Europe. Under such a system, the sheer number of registration dossiers we have in mind is vastly smaller than the volume that ECHA must process under REACH. If, as we expect, a US registration system for high-priority chemicals proves to be workable for government and the stakeholders, Congress (or EPA) could then decide at a later date whether it is worthwhile to extend the registration system to lower-priority chemicals. Since the last REACH registration deadline is not until 2018 (when many small and medium-sized European companies will be required to register), it certainly makes sense—on the merits, and as

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a matter of prudent political judgment—to wait until after 2018 to decide whether, given the experience of small companies in Europe, low-volume chemicals should be included in a US registration system.

**CONCLUSION**

We conclude by describing a practical approach to TSCA reform that can draw from what we regard as the best of both the Canadian and European experiences. First, Canada has demonstrated that a manageable number of high-priority chemicals can be identified based on limited data and screening/modeling exercises. TSCA reform could pursue promptly in that fashion, without forcing the assembly of thousands of electronic dossiers by industry that have been required under REACH. Indeed, we have already noted that EPA has a well-developed scoring system that could be used to identify a manageable number of existing chemicals for high-priority risk assessment and management.

Second, for the high priority chemicals, TSCA reform could pursue a targeted registration system that places the burden of data generation and safety determination (for specific uses) on industry. This registration system could draw on the key innovations from the European experience: no data, no market; and one substance, one registration. A reformed TSCA should include a clear, consistent, and workable safety standard. The role of EPA would be to review the industry’s safety determinations under that standard on a case-by-case basis, exercising ultimate authority to reject the registration or insist on more information or stronger risk management measures. Industry would have strong incentives to meet registration deadlines, as they have under REACH, because companies would not be permitted to market high-priority chemicals without the registration. Registrants could pay registration fees as well as continual user fees to fund the assessment and management processes.
Third, the burden of making safety determinations could then flip back to EPA. The agency could utilize registration data to determine whether a clear, risk-based safety standard is met, requiring industry to provide additional data if necessary. If EPA finds that the standard is not met, EPA should be given discretion to apply a wide variety of risk management instruments through informal rulemaking. Risk assessment as to whether the standard is met should be separate from a determination of which risk management instrument to apply. EPA’s burdens of proof for finding that the safety standard is not met and for determining which risk management tool(s) to apply should be permissive.

One of the advantages of a focus on high priority chemicals is that it can be aligned with the growing market forces for safety that are already at work in the United States. Chemical manufacturers are facing market deselection of the chemicals that present the greatest concern, with encouragement to compete on the basis of green and sustainable chemistry for safer substances. Already, retailers like Target and Wal-Mart are requesting greater information on chemicals from products manufacturers and restricting sales of products with worrisome chemical inputs.

The TSCA reform approach that we have suggested will accelerate green market forces for chemical uses that cannot be defended through registration while reassuring retailers that some uses of hazardous chemicals do not, due to little or no exposure, pose significant risk and can safely be continued. TSCA reform should support these efforts to increase the amount of

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information available to retailers and consumers, regardless of where the burden of proof is placed.

Because the TSCA reform process is ongoing, we believe that it is most productive to highlight general lessons that policy makers should take away from the Canadian and European experiences rather than comment on a particular draft bill. It is noteworthy, however, that the most recent draft bills that have been presented in committees in the Senate (Chemical Safety Improvement Act) and the House of Representatives (Chemicals In Commerce Act) do in fact include several of the elements that we suggest. Both include prioritization mechanisms as an initial step to identify high priority chemicals, and both separate risk assessment from risk management decisions.326 However, neither includes a registration mechanism. We recognize that the concept of registration may not seem desirable given the complex and burdensome European experience, but we suggest the hybrid approach nonetheless in the spirit of generating some productive dialogue on a new idea in the TSCA reform debate.

Although we have tackled some of the critical issues in the TSCA reform debate by drawing lessons from Canada and Europe, we conclude by acknowledging some key issues that this Article has not addressed. We have not covered how extensive the ecological and human health data requirements for high-priority chemicals should be; what the safety standard under TSCA reform should be; how non-threshold chemicals should be regulated; whether and how state and local regulation of chemicals should by preempted under TSCA reform; whether and how the United States should participate in international chemicals treaties; and how confidential business information and public disclosure of data should be handled in TSCA reform. Though we have commented on judicial review, the particular role that it should play under a reformed TSCA statute is a significant open question as well. We encourage scholars and practitioners

326 Chemical Safety Improvement Act, § 6(c)(1), (2), (9); Chemicals in Commerce Act § 6(b), (c).
interested in TSCA reform, and chemicals regulation in general, to critique our suggested directions and tackle some of the hard issues that we have not addressed.
## Appendix A: Names and Affiliations of Interview Subjects, Peer Reviewers, and Commenters

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>Date of Interview/ Review</th>
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<tbody>
<tr>
<td>John Applegate‡</td>
<td>Indiana University</td>
<td>May 2014</td>
</tr>
<tr>
<td>Jon Arnot*</td>
<td>University of Toronto</td>
<td>Feb. 2013</td>
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<tr>
<td>Lynn Bergeson‡</td>
<td>Bergeson &amp; Campbell, PC</td>
<td>May 2014</td>
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<tr>
<td>Lucas Bergkamp‡</td>
<td>Hunton &amp; Williams, LLP</td>
<td>May 2014</td>
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<td>Sylvain Bintein*</td>
<td>DG-Environment, European Commission</td>
<td>Apr. 2013</td>
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<td>Vito Buomsante*</td>
<td>ClientEarth</td>
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<tr>
<td>Bill Carroll*</td>
<td>Occidental Chemical Corporation</td>
<td>Jan. 2012</td>
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<tr>
<td>Holly Davies*</td>
<td>Department of Ecology, Washington State</td>
<td>Mar. 2013</td>
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<tr>
<td>Dennis Devlin‡</td>
<td>ExxonMobil</td>
<td>May 2014</td>
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<tr>
<td>Bob Diderich*</td>
<td>Organization for Economic Cooperation and Development</td>
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<tr>
<td>Peter Dohmen*</td>
<td>BASF</td>
<td>June 2013</td>
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<tr>
<td>Danie Dube‡</td>
<td>Environment Canada</td>
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<tr>
<td>Steve Dungey*</td>
<td>Environment Agency, United Kingdom</td>
<td>May 2013</td>
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<tr>
<td>E. Donald Elliott†</td>
<td>Covington &amp; Burling, LLP; Yale Law School</td>
<td>May 2014</td>
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<tr>
<td>Cathy Fehrenbacher*</td>
<td>Environmental Protection Agency, USA</td>
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<td>Christina Franz*</td>
<td>American Chemistry Council</td>
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<td>Vincenza Galatone*</td>
<td>Environment Canada</td>
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<td>Mike Gallagher*</td>
<td>Department of Ecology, Washington State</td>
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<td>Anna Gergely‡</td>
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<td>John Giesy*</td>
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<tr>
<td>Serena Giordano‡</td>
<td>European Chemicals Agency</td>
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<tr>
<td>Geoff Granville*†</td>
<td>GCGranville Consulting Corp.</td>
<td>Feb. 2014</td>
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<tr>
<td>Joseph H. Guth*</td>
<td>University of California, Berkeley</td>
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<td>Dale Hattis‡</td>
<td>Clark University</td>
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<td>Veerle Heyvaert†</td>
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<td>Amardeep Khosla*</td>
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<td>Masaru Kitano*</td>
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<td>Joop de Knecht*</td>
<td>Organization for Economic Cooperation and Development</td>
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<td>Akos Kokai*</td>
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<td>Eeva Leinala‡</td>
<td>Health Canada</td>
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<td>Fe de Leon*</td>
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<td>Peter Lepper*</td>
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<td>Laurence Libelo*</td>
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<td>Jeff Lincer*‡</td>
<td>Researchers Implementing Conservation Action</td>
<td>Sept. 2013, May 2014</td>
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<td>Don Mackay*</td>
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<td>Kai Melzer‡</td>
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<td>Ortwin Renn†</td>
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<td>Jake Sanderson*‡</td>
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<td>Jose Tarazona*</td>
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<td>Eisaku Toda*</td>
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<td>Henrik Tyle*</td>
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<td>Rob Visser*</td>
<td>Organization for Economic Cooperation and Development (ret.)</td>
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<td>Graham Willmott*</td>
<td>DG-Enterprise, European Commission</td>
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* Interview Subject
† Compensated Peer Reviewer
‡ Commenter

Note: The interview subjects do not necessarily agree with the methods, findings, or recommendations in this report.