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ARTICLE

Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union*

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Industrial chemicals are ubiquitous. There are approximately 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 (U.S.), of the 84,000 chemicals listed on the federal government's inventory, approximately 8,000 (non-polymeric) chemicals are produced in

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1. Derek C.G. Muir & Philip H. Howard, *Are There Other Persistent Organic Pollutants? A Challenge for Environmental Chemists*, 40 ENVTL. SCI. & TECH. 7157, 7158 (2006).

2. *Id.*

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 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

3. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-249, TOXIC SUBSTANCES: EPA HAS INCREASED EFFORTS TO ASSESS AND CONTROL CHEMICALS BUT COULD STRENGTHEN ITS APPROACH 10 n.12 (2013) [hereinafter GAO TOXIC SUBSTANCES].

4. *See id.* at 12–17; JOHN S. APPLEGATE & KATHERINE BAER, STRATEGIES FOR CLOSING THE CHEMICAL DATA GAP 1 (2006), *available at* http://www.progressivereform.org/articles/Closing_Data_Gaps_602.pdf; CHEM. MFRS. ASS'N, PUBLIC AVAILABILITY OF SIDS-RELATED TESTING DATA FOR U.S. HIGH PRODUCTION VOLUME CHEMICALS (1998); ENVTL. DEF. FUND, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES (1997), *available at* http://www.edf.org/sites/default/files/243_toxicignorance_0.pdf; NAT'L RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 19 (1984); John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365, 1380–83 (2008).

5. *See* Michael Gilek et al., *Introduction to* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES 1, 3 (Johan Eriksson et al. eds., 2010).

6. Gunnar Bengtsson, *Global Trends in Chemicals Management*, *in* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES 192, 199–202 (Johan Eriksson et al. eds., 2010); HENRIK SELIN, GLOBAL GOVERNANCE OF HAZARDOUS CHEMICALS: CHALLENGES OF MULTILEVEL MANAGEMENT 1–7 (2010).

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[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.[9] That year, the Canadian government launched its Chemicals Management Plan (CMP) to meet the WSSD goal.[10]

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 the environment, and to enhance the sustainability and competitiveness of the European chemical industry.[11]

Japan enacted revisions to its chemicals law in 2003 and 2009, along with South Korea in 2008 and 2013, and China in

7. The World Summit on Sustainable Development, Johannesburg, S. Afr., Aug. 26–Sept. 4, 2002, *Report of the World Summit on Sustainable Development*, U.N. Doc. A/CONF.199/20. *See also* United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3–14, 1992, *Preliminary Report of the United Nations Conference on Environment and Development*, U.N. Doc. A/CONF.151/26 (Vol. II), Annex II (Aug. 13, 1992).

8. *See* Canadian Environmental Protection Act, S.C. 1999, c. 33, *available at* 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.

9. CEPA § 73(1). *Categorization of Existing Substances*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=1695F8D0-5CC4-EDA1-AF63-6F23A94064DD (last modified July 9, 2013).

10. Press Release, Prime Minister of Canada, Canada's New Government Improves Protection against Hazardous Chemicals (Dec. 8, 2006), *available at* http://www.pm.gc.ca/eng/media.asp?category=1&id=1450.

11. Lucas Bergkamp & Mike Penman, *Introduction to* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 3–4 (Lucas Bergkamp ed., 2013); Veerle Heyvaert, *Regulating Chemical Risk: REACH in a Global Governance Perspective*, *in* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES 219–21 (Johan Eriksson et al. eds., 2010).

2010 and 2013, to name only a few.[12] Additionally, U.S. states, prominently California, have enacted new programs aimed at assessing and reducing the potential for adverse effects from chemical exposures.[13]

Meanwhile, the U.S. 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.[14] 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.[15] The House of Representatives has recently held hearings on TSCA reform, and a draft reform bill has been circulated for comment.[16] Although it is far from clear that Congress will pass TSCA reform in the near future, there is more legislative momentum for reform than there

12. Jean-François Tremblay, *China Steps Up Toxin Controls*, 91 CHEMICAL & ENGINGEERING NEWS 10 (Mar. 4, 2013); *Korea Toxic Chemicals Control Act (TCCA)*, CHEM. INSPECTION & REGULATION SERV., http://www.cirs-reach.com/KoreaTCCA/Korea_Toxic_Chemicals_Control_Act_TCCA.html (last visited Nov. 5, 2014); *Speech by MEP Minister Zhou Shengxian at 2013 National Work Meeting on Environmental Protection*, MINISTRY OF ENVTL. PROT. – CHINA (Feb. 4, 2013), http://english.mep.gov.cn/Ministers/Speeches/201303/t20130320_249648.htm; *The Amended Japanese Chemical Substances Control Law*, REACH24H CONSULTING GRP. (Mar. 17, 2011), http://www.reach24h.com/en-us/cscl.html.

13. *See*, *e.g.*, CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, SAFER CONSUMER PRODUCTS, PROPOSED REGULATIONS, R-2011-02: ATTACHMENTS (2013), *available at* http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/2-SCP-REVISED-Proposed-Regulations_APA-MARKUP-April-2013.pdf.

14. *See, e.g.*, *Revisiting the Toxic Substances Control Act of 1976*: *Hearing Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce*, 111th Cong. 1 (2009) [hereinafter House, *Revisiting TSCA*], *available at* http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67095/pdf/CHRG-111hhrg67095.pdf; MITCHELL P. SMITH, ENVIRONMENTAL AND HEALTH REGULATION IN THE UNITED STATES AND THE EUROPEAN UNION 26-27 (2012).

15. Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013), *available at* http://cen.acs.org/content/dam/cen/91/web/S-1009-113th-Congress.pdf.

16. STAFF OF H.R. ENERGY & COMMERCE COMM., 113TH CONG., DISCUSSION DRAFT ON CHEMICALS IN COMMERCE ACT (Comm. Print 2014), *available at* http://docs.house.gov/meetings/IF/IF18/20140429/102160/BILLS-113pih-TheChemicalsinCommerceAct.pdf.

has been since 1976 as evidenced by the serious bipartisan negotiations under way in both chambers of the U.S. Congress.[17]

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. United States 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.[18] 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

17. *See* Press Release, Senate Comm. on Env't & Pub. Works, Vitter Announces Growing Support for Bipartisan TSCA Reform Bill (Apr. 15, 2014), *available at* http://www.epw.senate.gov/public/index.cfm?FuseAction=PressRoom.PressReleases&ContentRecord_id=f88d6771-eafb-65e1-85bc-86dca0416958.

18. *See generally* ANNE-MARIE SLAUGHTER, A NEW WORLD ORDER (2004); David Lazer, *Global and Domestic Governance: Modes of Interdependence in Regulatory Policymaking*, 12 EUR. L.J. 455, 455 (2006). On environmental law, see Francesca Bignami & Steve Charnovitz, *Transatlantic Civil Society Dialogues*, *in* TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 270 (Mark A. Pollack & Gregory C. Shaffer eds., 2001); Gabrielle Bouleau & Matt Kondolf, *Rivers of Diversity: Water Regulation in California and the EU*, *in* TRANSATLANTIC REGULATORY COOPERATION: THE SHIFTING ROLES OF THE EU, U.S., AND CALIFORNIA 84 (David Vogel & Johan F.M. Swinnen eds., 2011); Mauro Pettricione, *Reconciling Transatlantic Regulatory Imperatives with Bilateral Trade*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (George A. Bermann et al. eds., 2001); Per-Olof Busch & Helge Jörgens, *The International Sources of **Policy** Convergence: Explaining the Spread of Environmental **Policy** Innovation*s, 12 J. EUR. PUB. **POL'Y** 860 (2005); Veerle Heyvaert, *Globalizing Regulation: Reaching Beyond the Borders of Chemical Safety*, 36 J.L. & SOC'Y 110 (2009); Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817 (2009); Joanne Scott, *From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction*, 57 AM. J. COMP. L. 897 (2009); Tseming Yang & Robert V. Percival, *The Emergence of Global Environmental Law*, 36 ECOLOGY L.Q. 615 (2009).

insights to draw some lessons that may be of interest to U.S. policy makers engaged in TSCA reform. CEPA and REACH are seen by stakeholders as state of the art in chemicals assessment and management, and thus the U.S. 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.[19] 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 U.S. 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.[20] Such information facilitates

19. Alex Scott, *Global Approach to Chemical Regulations: A Worthy, But Difficult Goal*, CHEMICAL & ENGINEERING NEWS, June 11, 2012, at 26.

20. *See generally Material Safety Data Sheets (MSDSs) - General*, CANADIAN CTR. FOR OCCUPATIONAL HEALTH & SAFETY, http://www.ccohs.ca/oshanswers/legisl/msdss.html (last visited Nov. 1 2014).

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.[21]

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, as well as the management of those releases, exposures, and risks.[22] 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.[23] 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.[24] We offer some depth in the review of the four

21. Bengt Bucht, *Capacity Building for Chemicals Control: Legislation, Institutions, Public-Private Relationships*, *in* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES 283, 285 (Johan Eriksson et al. eds., 2010).

22. Andreas Klinke & Ortwin Renn, *Risk Governance: Contemporary and Future Challenges*, *in* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES 9, 13–22 (Johan Eriksson et al. eds., 2010).

23. *See* Ragnar Löfstedt, *The Substitution Principle in Chemical Regulation: A Constructive Critique*, 17 J. RISK RES. 543 (2014).

24. *See, e.g.*, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 3 (1983) [hereinafter NRC 1983]. JOHN S. APPLEGATE ET AL., THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES: CASES AND MATERIALS 3–4 (Robert C. Clark et al. eds., 2d ed. 2011); *see also* C.J. van Leeuwen, *General Introduction*, *in* RISK ASSESSMENT OF CHEMICALS: AN INTRODUCTION 2–6 (C.J. van Leeuwen & T.G. Vermeire eds., 2d ed. 2007); Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA:*

components because it is critical 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,[25] 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.[26] 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).[27] Greater priority for environmental wellbeing is also given to chemicals that may persist (P) in the environment rather than break down, that may bioaccumulate (B) in organisms, and that may be toxic (T). Chemicals that have all three properties are called PBTs.[28] Chemicals that are very persistent and very

Guidelines for Responsible Risk Regulation, 23 HARV. ENVTL. L. REV. 93, 95–98 (1999).

25. *See, e.g.*, RICHARD WILSON & EDMUND A.C. CROUCH, RISK-BENEFIT ANALYSIS 113–21 (2001); HUMAN AND ECOLOGICAL RISK ASSESSMENT: THEORY AND PRACTICE (Dennis J. Paustenbach ed., 2d ed. 2009).

26. NRC 1983, *supra* note 24, at 19–23.

27. *See generally* Laura N. Vandenberg et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 ENDOCRINE REV. 378 (2012), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3365860/.

28. *See generally* ADAM D.K. ABELKOP, TODD V. ROYER & JOHN D. GRAHAM, PERSISTENT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS: TECHNICAL ASPECTS, POLICIES, AND PRACTICES (forthcoming 2015); JOHN WARGO, GREEN INTELLIGENCE: CREATING ENVIRONMENTS THAT PROTECT HUMAN HEALTH 284–87 (2009).

bioaccumulative are sometimes referred to as vPvBs and may also be regulated as a special class.[29]

The Fifteenth Century German scientist Paracelsus (credited for founding the discipline of toxicology) explained that "the dose makes the poison."[30] Alcohol can kill people if ingested in excessive amounts, but alcohol can also improve health if consumed in moderation.[31] 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.[32] 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.[33]

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).[34] 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 the dosage to an organism increases, and other factors are held constant, the probability and/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

29. REACH, art. 14(3)(d); ABELKOP, ROYER & GRAHAM , *supra* note 28.

30. APPLEGATE ET AL., *supra* note 24, at 4.

31. *See, e.g.*, *Alcohol Use: If You Drink, Keep it Moderate*, MAYO CLINIC (Feb. 11, 2014), http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/in-depth/alcohol/art-20044551.

32. *See* TED SCHETTLER ET AL., GENERATIONS AT RISK: REPRODUCTIVE HEALTH AND THE ENVIRONMENT 63 (MIT Press Paperback ed. 2000). *See generally* Vandenberg et al., *supra* note 27.

33. On the importance of exposure in risk 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).

34. NRC 1983, *supra* note 24, at 19, 21, 23–27.

number of adverse health outcomes in the population can be substantial.[35]

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.[36]

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.[37] 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.[38] In practice, sensitivity to chemical exposure is usually analyzed for groups of people rather than on an individual-by-individual basis. The "safe"[39] dose of a

35. The low-dose effects of bisphenol-A, the primary component of many plastics, are a matter of intense scientific and public debate. *See* SARAH A. VOGEL, IS IT SAFE? BPA AND THE STRUGGLE TO DEFINE THE SAFETY OF CHEMICALS (2013); WARGO, *supra* note 28, at 272–76.

36. *See* David L. Eaton & Steven G. Gilbert, *Principles of Toxicology*, *in* CASARETT & DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 17, 19 (Curtis D. Klaassen & John B. Watkins eds., 7th ed. 2008).

37. *Id.* at 23, 23–24 (A threshold occurs when there is "some dose below which the probability of the individual responding is zero."); NRC 1983, *supra* note 24, at 25 ("[B]elow a particular dose (the "threshold" dose of a given carcinogen) there is no adverse effect.").

38. On the distinction between the individual and population dose-response function, see NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 141–43 (2009) [hereinafter NRC 2009].

39. 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 ten percent 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*

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).[40] Historically, 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.[41]

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.[42] 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.[43] 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.[44] 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.

Laboratory Animal Carcinogenicity Data in Occupational Risk Assessment, *in* CHEMICAL RISK ASSESSMENT AND OCCUPATIONAL HEALTH: CURRENT APPLICATIONS, LIMITATIONS, AND FUTURE PROSPECTS 105, 105–11 (C. Mark Smith et al. eds., 1994). For a basic statistical treatment of the issues, see CHARLES D. HOLLAND & ROBERT L. SIELKEN, QUANTITATIVE CANCER MODELING AND RISK ASSESSMENT (1993).

40. For a classic introduction to the determination of "safe" doses, see JOSEPH V. RODRICKS, CALCULATED RISKS: THE TOXICITY AND HUMAN HEALTH RISKS OF CHEMICALS IN OUR ENVIRONMENT (2d ed. 2006).

41. NRC 2009, *supra* note 38, at 177.

42. CULLEN & FREY, *supra* note 33, at 2.

43. *See id.*

44. *Id.*

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.[45]

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.[46] 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.[47] 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.[48]

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.[49] 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 also 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

45. *See* Deborah H. Bennett et al., *Defining Intake Fraction*, 36 ENVTL. SCI. & TECH. 3A, 5A (2002), *available at* http://ehs.sph.berkeley.edu/krsmith/publications/02_bennett_1.pdf.

46. *Id.* at 4A.

47. Campbell-Mohn & Applegate, *supra* note 24, at 96–97.

48. *See id.*

49. On the complexities in exposure assessment, see CULLEN & CHRISTOPHER FREY, *supra* note 33.

risk assessment procedures.[50] 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.[51]

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 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.[52]

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.[53] 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.[54] It is not always easy to

50. *See* EUROPEAN COMM'N, ADDRESSING THE NEW CHALLENGES FOR RISK ASSESSMENT (2012), *available at* http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_037.pdf.

51. *Id.*

52. *See, e.g.*, M.E. Meek et al., *Risk assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS Framework*, 60 REG. TOXICOLOGY & PHARMACOLOGY S1, S1 (2011); Pamela R. D. Williams et al., *Cumulative Risk Assessment (CRA): Transforming the way we Assess Health Risks*, 46 ENVTL. SCI. & TECH. 10868, 10868 (2012).

53. *See* Rall, *supra* note 39, at 107–08.

54. *See id.* at 108.

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.[55] There are a surprisingly large number of methodological choices (approximately fifty)[56] in chemical risk assessment that can drastically affect the outcomes of the assessment,[57] and those choices are associated with greater uncertainty for some 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).[58]

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

55. Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 91–92 (1988).

56. For a tabular presentation of over fifty analytic choices in chemical risk assessment, see U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-01-810, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES' PROCEDURES, ASSUMPTIONS, AND POLICIES, 120–50 (2001).

57. *See* NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 106 (1994) [hereinafter NRC 1994]; Campbell-Mohn & Applegate, *supra* note 24, at 100–1; Oliver A. Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 17 TUL. ENVTL. L.J. 163, 167–68 (2003); Latin, *supra* note 55, at 92–94; Howard Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and 'Fine-Tuning' Regulatory Reforms*, 37 STAN. L. REV. 1267, 1267–71 (1985); Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 413–14 (1995).

58. *See* NRC 1994, *supra* note 57, at 7.

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.[59] Professional judgments about risk tradeoffs also play an important role in the process of chemical substitution.

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;[60] in other cases, the new information is reassuring because it suggests less risk than previously predicted.[61] 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.[62] Although such adaptive

59. *See* George M. Gray & John D. Graham, *Regulating Pesticides*, *in* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT 173–92 (John D. Graham & Jonathan B. Wiener eds., 1995); *see generally* Löfstedt, *supra* note 23.

60. The thresholds for some substances (e.g., lead) have been repeatedly lowered as new scientific information showed adverse effects at lower and lower doses. JOE THORNTON, PANDORA'S POISON: CHLORINE, HEALTH, AND A NEW ENVIRONMENTAL STRATEGY 79 (2001). This phenomenon has been provocatively called "shrinking thresholds." *Id.* at 79–80. *See generally* Janna G. Koppe & Jane Keys, *PCBs and the Precautionary Principle*, *in* THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS 64, 71–74 (Paul Harremoes et al. eds., 2002).

61. For case studies where new information shows less risk than previously predicted, see PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 6 (Kenneth R. Foster et al. eds., 1993); Aaron Wildavsky & Robert Owen Rye, *Detecting Errors in Environmental and Safety Studies*, *in* BUT IS IT TRUE? A CITIZEN'S GUIDE TO ENVIRONMENTAL HEALTH AND SAFETY ISSUES 410, 412–14 (1997).

62. Under TSCA's new chemicals program, EPA has been creative in allowing new chemicals with low releases and low exposures to be marketed with less data than normal, but also with plans for continued monitoring to

approaches to risk assessment and management have appeal, they are not easy to incorporate into the adversarial legal environment that has characterized implementation of TSCA.

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.[63]

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.[64]

ensure safety over time. Ortwin Renn & E. Donald Elliott, *Chemicals*, *in* THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE 223, 231–32 (Jonathan B. Wiener et al. eds., 2011).

63. 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, Dec. 16, 2013, at 19-20. Alternatives assessment is a close cousin of risk-tradeoff analysis. *See generally* Gray & Graham, *supra* note 59, at 178–89.

64. On the harmful effects of DDT (from its breakdown product DDE), see Jeffrey L. Lincer, *DDE-Induced Eggshell- Thinning in the American Kestrel: A*

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 substantially less than global use of DDT prior to the ban.[65] The argument is that the benefits of DDT use for malaria control justify the environmental risk.[66] 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.[67]

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 U.S. policy makers 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.[68] Open questions remain as

Comparison of the Field Situation and Laboratory Results, 12 J. APPLIED ECOLOGY 781 (1975).

65. Shobha Sadasivaiah, Yeşim Tozan & Joel G. Breman, *Dichlorodiphenyltrichloroethane (DDT) for Indoor Residual Spraying in Africa: How Can It Be Used for Malaria Control?*, 77 AM. J. TROPICAL MED. & HYGIENE 249, 251 (2007).

66. *See* Tina Rosenberg, *What the World Needs Now is DDT*, N.Y. TIMES, Apr. 11, 2004, http://www.nytimes.com/2004/04/11/magazine/what-the-world-needs-now-is-ddt.html; WARGO, *supra* note 28, at 187–88.

67. *See generally* ORG. FOR ECON. COOPERATION & DEV., THE ECONOMIC APPRAISAL OF ENVIRONMENTAL PROJECTS AND POLICIES: A PRACTICAL GUIDE 145–47, 150–51 (1995); MEG POSTLE, COST-BENEFIT ANALYSIS AND CHEMICAL RISK MANAGEMENT (1997).

68. EUROPEAN COMM'N, ROADMAP ON SUBSTANCES OF VERY HIGH CONCERN 2 (2013) [hereinafter SVHC ROADMAP], *available at* http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT; VIRGINIA POTER &

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.[69]

Canada and EU Member States are amongst the U.S.'s largest trading partners, and chemicals management can raise notable trade issues.[70] The U.S. is already working to harmonize regulations with Canada and the EU through the Regulatory Cooperation Council and the Transatlantic Trade and Investment Partnership, respectively.[71] The U.S. also has the 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.[72]

Finally, in congressional hearings on TSCA reform, legislators have shown a keen interest in regulatory activities in

VINCENZA GALATONE, CHEMICALS MANAGEMENT PLAN: MOVING FORWARD IN 2013, ICG CEPA UPDATE CONFERENCE 3 (June 6, 2013).

69. *See* Jonathan B. Wiener & Alberto Alemanno, *Improving International Regulatory Cooperation: TTIP as a Step Toward a Global Policy Laboratory*, 78 LAW & CONTEMPORARY PROBLEMS (forthcoming 2015) (examining regulatory variation as a learning exercise).

70. Lawrence A. Kogan, *REACH and International Trade Law*, *in* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 315-17 (Lucas Bergkamp ed., 2013). *See, e.g.,* Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating whether a Non-Tariff Measure has Matured into an Actionable Non-Tariff Barrier to Trade*, 28 AM. U. INT'L L. REV. 489, 514-24 (2013); SELIN, *supra* note 6, at 97–99.

71. *See generally Hearing on the Regulatory Aspects of Trans-Atlantic Trade and Investment Partnership (TTIP), U.S.-EU Free Trade Agreement*, *Before the Committee on Trade, European Parliament*, (2013) (testimony of John D. Graham, Ph.D., Dean, School of Public and Environmental Affairs, Indiana University, USA), *available at* http://www.europarl.europa.eu/document/activities/cont/201310/20131015ATT72818/20131015ATT72818EN.pdf; UNITED STATES-CANADA REGULATORY COOPERATION COUNCIL, JOINT ACTION PLAN (2011), *available at* http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf.

72. SELIN, *supra* note 6, at 170–71.

both Europe and Canada.[73] 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. Professor John Applegate, for example, employs a Hegelian dialectic method, presenting TSCA as the thesis and REACH as its antithesis (the "anti-TSCA").[74] There are also a few reports that include CEPA in their comparative analyses.[75]

73. *See, e.g.*, *Assessing the Effectiveness of U.S. Chemical Safety Laws*: *Hearing Before the Sub. on Superfund, Toxics, & Envtl. Health of the S. Comm. on Env't & Pub. Works*, 112th Cong. 81 (2011), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-112shrg85224/pdf/CHRG-112shrg85224.pdf; *Prioritizing Chemicals for Safety Determination*: *Hearing Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce*, 111th Cong. 6 (2009) [hereinafter House, *Prioritizing Chemicals*], *available at* http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg74851/pdf/CHRG-111hhrg74851.pdf; House, *Revisiting TSCA*, *supra* note 14, at 130.

74. John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 724 (2008) [hereinafter Applegate, *Synthesizing*]. *See also* Mikael Karlsson, *The Precautionary Principle in EU and US Chemicals Policy: A Comparison of Industrial Chemicals Legislation*, *in* REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES (Johan Eriksson et al. eds. 2010); Ragnar E. Löfstedt & David Vogel, *The Changing Character of Regulation: A Comparison of Europe and the United States*, 21 RISK ANALYSIS 399 (2001) (comparing TSCA to REACH's predecessor); James T.O. Reilly, *What REACH Can Teach Us about TSCA: Retrospectives on America's Failed Toxics Statute*, 1 EUR. J. OF RISK REG. 40 (2010); Renn & Elliott, *supra* note 62, at 223–56; U.S. GOV'T. ACCOUNTABILITY OFFICE, GAO-07-825, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS 4–5 (2007), *available at* http://www.gao.gov/new.items/d07825.pdf.

75. *See* RICHARD DENISON, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION, AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS I-5 (2007), *available at* http://www.edf.org/sites/default/files/6149_NotThatInnocent_Fullreport.pdf [hereinafter DENISON, NOT THAT INNOCENT]; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-217R, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION 6 (2005), *available at* http://www.gao.gov/new.items/d06217r.pdf; ANNE WORDSWORTH, CHEMICALS POLICY IN CANADA, THE EUROPEAN UNION AND THE UNITED STATES 7 (2007), *available at* http://s.cela.ca/files/555_EU.pdf; Richard Denison, *Ten Essential Elements in TSCA Reform*, 39 ENVTL. L. REP. 10020, 10022 (2009) [hereinafter Denison, *Ten Essential*]; Daryl Ditz, Dialogue, *Lessons from Canada and Europe*, *Toxic Substances Chemical Act Reform: Chemical Prioritization* (pt. 2), 42 ENVTL. L. REP. 10316-17 (2013).

Dr. Richard Denison of the Environmental Defense Fund released a noteworthy report in 2007 reviewing the design of REACH, TSCA, and CEPA.[76] 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.[77] 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.

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 twenty-nine 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 Helsinki, and public interest organizations in the U.S. and Europe. These interviews took place between December 2010 and June 2011. In addition to the more structured interviews, we attended the 2011 ECHA Stakeholder Day in Helsinki, Finland and the 2011 Helsinki Chemicals Forum in May of 2011.[78] This initial round of research led to the

76. DENISON, NOT THAT INNOCENT, *supra* note 75, at I-5.

77. *See generally id.*

78. *ECHA Sixth Stakeholders Day*, EUROPEAN CHEMICALS AGENCY, http://echa.europa.eu/web/guest/view-article/-/journal_content/32e60e70-22ed-4092-8b10-9c21f709306b (last visited Nov. 6, 2014). *See Helsinki Chemicals*

publication of an article in 2012 entitled, *Regulating Industrial Chemicals: Lessons for U.S. Lawmakers from the European Union's REACH Program*.[79]

We, along with Professor Todd Royer, Mallory Mueller (both from Indiana University), and an interdisciplinary panel of experts from Europe and the U.S., gathered more recent data through a second round of thirty-eight interviews conducted between November 2012 and June 2013. This project culminated in the publication of a book in 2015 entitled *Persistent, Bioaccumulative, and Toxic (PBT) Chemicals: Technical Aspects, Policies, and Practices*.[80] 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 fifteen 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.[81] The conference featured detailed presentations from representatives of government and industry on the administration of CEPA and the CMP.[82]

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

Forum 2011: Presentations, FINNEXPO, http://finnexpo.multiedition.fi/gallery/main.php?g2_itemId=618 (last updated May 20, 2011).

79. Adam D.K. Abelkop et al., *Regulating Industrial Chemicals: Lessons for U.S. Lawmakers from the European Union's REACH Program*, 42 ENVTL. L. REP. 11042 (2012).

80. ABELKOP, ROYER & GRAHAM, *supra* note 28.

81. INDUS. COORDINATING GRP. FOR CEPA, 2013 CEPA UPDATE CONFERENCE, AGENDA (2013), *available at* http://www.intertek.com/icg-cepa-update-conference-flyer/.

82. *Id.*

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 U.S. commerce each year),[83] 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.[84] REACH and the CMP are designed to address this disparity in assessment. The focus of TSCA reform is also on existing industrial chemicals.[85] 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.

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

83. GAO TOXIC SUBSTANCES, *supra* note 3, at 1.

84. APPLEGATE ET AL., *supra* note 24, at 281; DENISON, NOT THAT INNOCENT, *supra* note 75, at I-1.

85. *See* JERRY H. YEN, CONG. RESEARCH SERV., R43136, PROPOSED REFORM OF THE TOXIC SUBSTANCES CONTROL ACT (TSCA) IN THE 113TH CONGRESS: S. 1009 COMPARED WITH S. 696 AND CURRENT LAW 1 (2013), *available at* http://fas.org/sgp/crs/misc/R43136.pdf.

(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,[86] 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 U.S. policy makers.

Risk assessment requires information on hazards and exposures; 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.[87] Sources of data vary. They may be generated from laboratory tests (e.g., toxicity tests on

86. REACH uses the same processes to govern new and existing chemicals.

87. John S. Applegate, *The Government Role in Scientific Research: Who Should Bridge the Data Gap in Chemical Regulation?*, *in* RESCUING SCIENCE FROM POLITICS 259–60 (Wendy Wagner & Rena Steinzor eds., 2006) [hereinafter Applegate, RESCUING]; *see generally* NRC 1983, *supra* note 24, at 19–20.

animals) or field observations (e.g., biomonitoring in human blood or remote sensing of chemicals in the environment).[88] Data may also be estimated based on complicated computer modeling programs that employ statistical techniques.[89]

The information necessary to support a comprehensive risk assessment can be difficult, time consuming, and expensive to obtain.[90] 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, the Environmental Protection Agency's (EPA) risk assessment process for formaldehyde under TSCA began in the early 1980s.[91] Several draft risk assessments were released for peer review and public comment, including a most recent draft released in 2010.[92] Likewise, the EPA assessment of trichloroethylene (a common groundwater contaminant) began in the 1980s, and while multiple drafts of the risk assessment have been produced, the final draft was issued in 2014.[93] Indeed, both CEPA 1999 and REACH were enacted, in part, because assessment and management decisions under their predecessors

88. *See id.* at 20, 22–23.

89. *See id.* at 24–26.

90. *See, e.g.*, Applegate, RESCUING, *supra* note 87, at 262–63; APPLEGATE ET AL., *supra* note 24, at 8–9; DENISON, NOT THAT INNOCENT, *supra* note 75, at A-15–A-22; Klinke & Renn, *supra* note 22, at 10–13; NRC 1983, *supra* note 24; Campbell-Mohn & Applegate, *supra* note 24, at 99–102; Shere, *supra* note 57, at 440–42.

91. JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 28–34 (1988).

92. *See generally*, NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE R9 (2011), *available at* http://www.nap.edu/openbook.php?record_id=13142; *Integrated Risk Information System: IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010)*, EPA, http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614 (last visited Nov. 4, 2014); Jeremy P. Jacobs, *NAS Reviewers Slam EPA's Formaldehyde Assessment*, N.Y. TIMES (Apr. 8, 2011), http://www.nytimes.com/gwire/2011/04/08/08greenwire-nas-reviewers-slam-epas-formaldehyde-assessmen-83879.html.

93. *See* EPA, NO. 740-R1-4002, TSCA WORKPLAN CHEMICAL RISK ASSESSMENT FOR TRICHLOROETHYLENE: DEGREASER, SPOT CLEANING, AND ARTS & CRAFTS USES (2014), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf.

took too long.[94] TSCA reformers are also looking for a way to accelerate risk assessment and management and reduce the ossification that has 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 a 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.[95] Screening assessments often rely on modeling and estimation techniques.[96] 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 the toxic outcomes."[97]

94. *See* Bjorn Hansen, *Background and Structure of REACH*, *in* THE EUROPEAN REACH REGULATION FOR CHEMICALS 17–18 (Lucas Bergkamp ed., 2013); M.E. Meek & V.C. Armstrong, *The Assessment and Management of Industrial Chemicals in Canada*, *in* RISK ASSESSMENT OF CHEMICALS: AN INTRODUCTION 591, 597 (C.J. van Leeuwen & T.G. Vermeire eds., 2007).

95. NAT'L RESEARCH COUNCIL, APPLICATIONS OF TOXICOGENOMIC TECHNOLOGIES TO PREDICTIVE TOXICOLOGY AND RISK ASSESSMENT 73 (2007) [hereinafter NRC 2007] ("A screening test can be defined as one designed to detect a state or property more quickly and cheaply than more elaborate tests for that state or property. In predictive toxicology, the property being detected by screening tests is generally hazard. Screening tests may not give complete information on toxicity, such as the time course, chronic effects, or dose-response characteristics. Therefore, . . . screening data provide an input to the hazard identification step in risk assessment but do not allow full determination of risk.")

96. *Id*. at 74 ("[T]he current practice of [EPA] under [TSCA], in the absence of more extensive preexisting data, is to screen new chemicals based solely on physicochemical data using quantitative structure-activity relationship models.").

97. *Id.*

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), and a wider variety of data, as well as consideration of 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."[98] 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 chemical's governance regime emphasizes a comprehensive or screening approach to risk assessment, priority setting for assessment and management is essential to maximize 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.[99]

A priority-setting system for risk assessment could start with a focus on chemicals with hazardous properties,[100] or it could

98. NRC 2009, *supra* note 38, at 82. *See generally* ADAM FINKEL, CONFRONTING UNCERTAINTY IN RISK MANAGEMENT: A GUIDE FOR DECISION-MAKERS (1990), *available at* http://digitalcollections.library.cmu.edu/awweb/awarchive?type=file&item=438442; NAT'L RESEARCH COUNCIL, ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 165–71 (2013) (discussing VOI for risk assessment) [hereinafter NRC 2013]; NRC 2009, *supra* note 38, at 82–84.

99. *See generally* Ditz, *supra* note 75.

100. Comments from Ortwin Renn, Professor, University of Stuttgart (Apr. 27, 2014) (on file with author). 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.,

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 must use some rudimentary form of screening based on priority criteria. However, without hard data the 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.[101] There is a temptation to wait for adequate data, since data are needed in order for the 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.[102] 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.[103]

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. *Id.*

101. Ditz, *supra* note 75, at 10317 (indicating that risk-based prioritization is problematic if data on risk are not available).

102. *See id.*

103. *See id.* at 10316.

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."[104] CEPA section 76.1 directs EC and HC to consider the weight of evidence and to apply the precautionary principle in conducting and interpreting risk assessments.[105] REACH is also based on precautionary reasoning.[106] 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. 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 1999.[107] 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.[108] In 2006, the government of Canada launched the Chemicals Management Plan to submit the identified substances warranting

104. Canadian Environmental Protection Act, S.C.1999, c. 33, Preamble (Can.), *available at* http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=24374285-1 [hereinafter CEPA].

105. *The Act Part 5: Controlling Toxic Substances*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=24374285-1&offset=6 (last visited Nov. 4, 2014).

106. Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, art. 1(3), 2006 O.J. (L 396) 1 (EC) [hereinafter REACH].

107. 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.

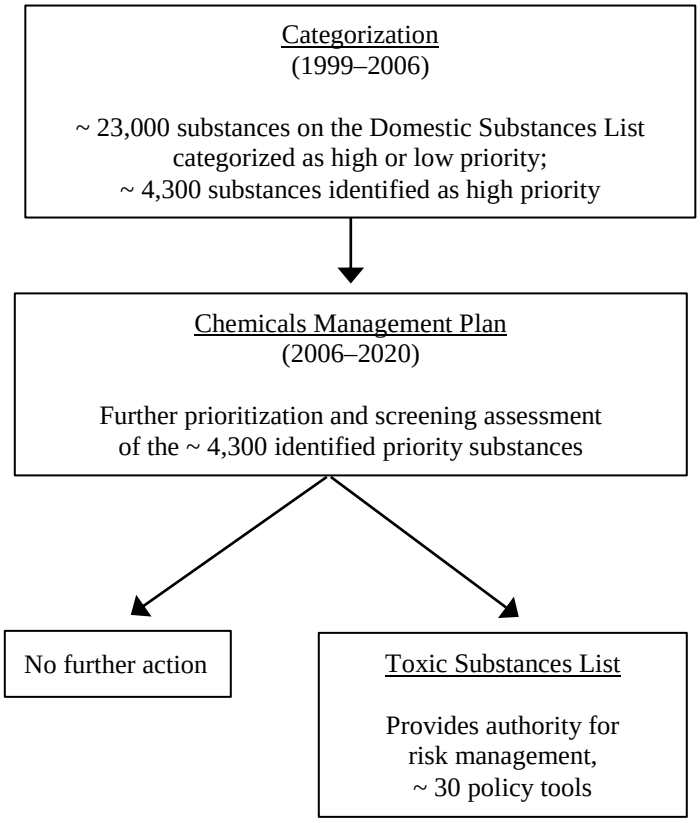
108. CEPA § 73(1).

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.[109] 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.[110] The relationship between categorization and the CMP is depicted in Figure 1.

109. *See Domestic Substances List*, ENV'T CAN., https://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1 (last modified Sept. 17, 2013).

110. *See id.*

Figure 1. Overview of Prioritization and Risk Assessment under CEPA



1. Categorization

CEPA section 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.[111] The CMP also uses these criteria for further prioritization—PBiT as ecological criteria, and GPE and iT as human health criteria.[112]

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.[113] 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.[114] 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.[115] Thus, while inherent toxicity is a hazard-based determination, the formal "toxic" (CEPA-toxic) determination is risk-based, as it

111. CEPA § 73(1)(b). Separate bodies of regulations define persistence and bioaccumulation thresholds more precisely. *See* Persistence and Bioaccumulation Regulations, SOR/2000-107 (Can.), *available at* http://laws-lois.justice.gc.ca/PDF/SOR-2000-107.pdf.

112. *See generally* Christine Norman, Healthy Env'ts & Human Safety Branch, Health Can., Prioritization and Assessment—Experience Under Canada's Chemicals Management Plan at the SVOCs in the Indoor Environment Workshop 5, 6, 8 (Jan. 2011), *available at* http://epa.gov/ncct/expocast/files/SVOC/12_NORMAN%20SVOC.pdf; *Overview of the Existing Substances Program*, ENV'T CAN. (Mar. 21, 2011), http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=EE479482-1&wsdoc=4AB637F0-A096-3237-14BA-E034127B3A9A.

113. *Id.*

114. Meek & Armstrong, *supra* note 94, at 594.

115. CEPA § 64.

incorporates potential for exposure.[116] Inherent 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.[117] 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.

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.[118] In addition, HC determined that another 300–400 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.[119] 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.

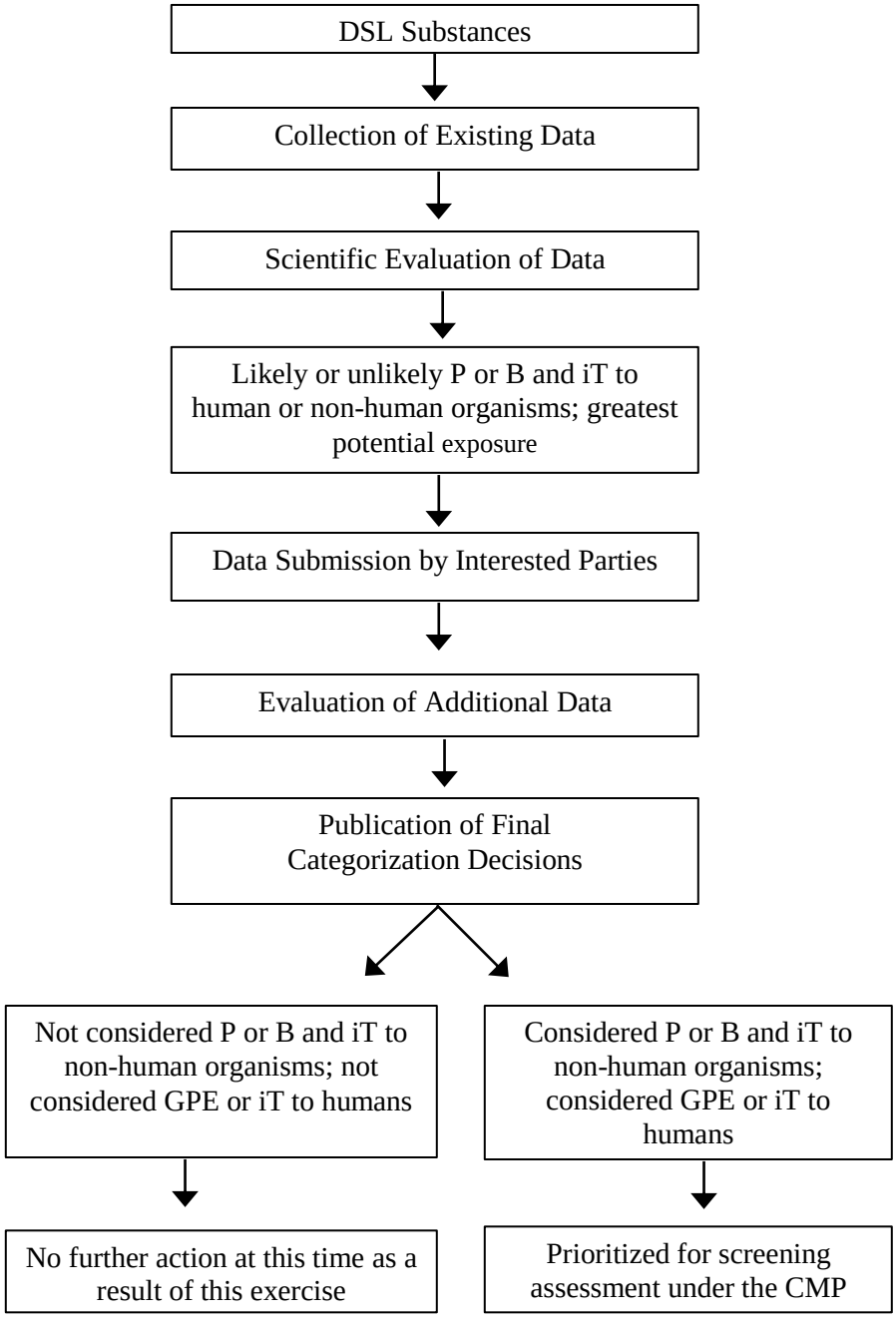
116. G.C. GRANVILLE CONSULTING CORP., REPORT TO THE ICG ON SCREENING ASSESSMENTS UNDER THE CMP 3 (2012).

117. *Categorization of Existing Substances*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=169 5F8D0-5CC4-EDA1-AF63-6F23A94064DD (last modified July 9, 2013).

118. *See generally Search Engine for the Results of DSL Categorization*, ENV'T CAN. (July 9, 2013), http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=D031CB30-B31B-D54C-0E46-37E32D526A1F [hereinafter ENV'T CAN., *Search Engine Results*]. *See also Summary of Government of Canada Categorization for Substances on the DSL*, ENV'T CAN. Sept. 2006 (on file with authors).

119. *See* SUZANNE EASTON, GLBTS SUBSTANCE WORKING GRP., CANADA'S CHEMICALS MANAGEMENT PLAN (CMP) (DRAFT) 6 (2008), *available at* http://www.epa.gov/bns/integration/200804/Easton040808.pdf. For precise results of the DSL categorization, see ENV'T CAN., *Search Engine Results*, *supra* note 118.

Figure 2. DSL Categorization Process for Environment and Health Canada



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.[120] Through this process, EC removed 145 PBiTs that did not meet the criteria from priority consideration. [121] 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.[122]

For the remaining priority substances (more than 4,000), further assessment was warranted. The CEPA section 73 "categorization-level" hazard profiles triggered a Screening Level Risk Assessment (SLRA) under section 74.[123] 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.[124] Recall that the risk-based determination that a substance is CEPA-toxic authorizes the initiation of the risk management process.

120. *See* ENVTL. DEF., CANADA'S CHEMICALS MANAGEMENT PLAN: PROGRESS ANALYSIS 2006–2011, at 12 (2011), *available at* http://environmentaldefence.ca/reports/canadas-chemicals-management-plan.

121. *See* ENV'T CAN., SCREENING ASSESSMENT REPORT 14 (2008), *available at* http://www.ec.gc.ca/lcpe-cepa/documents/substances/pbti-pbit/final_145_PBiT-eng.pdf; Gov't of Can., *Assessment Report on 145 PBiT Substances and Order Amending the Domestic Substances List*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/pbit145-eng.php (last modified May 16, 2014).

122. *See* CEPA § 80; Gov't of Can., *Significant New Activity (SNAc) Approach*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/snac-nac-eng.php [hereinafter *SNAc Approach*] (last modified Sept. 10, 2012).

123. *See* CEPA §§ 73, 74.

124. CEPA § 76.1 (mandating application of the precautionary principle); *see* HEALTH CAN., SCREENING ASSESSMENT OF EXISTING SUBSTANCES UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999, at 1 (2004), *available at* http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/exist_substances-substances_existantes-eng.pdf; Meek & Armstrong, *supra* note 94, at 611 (for descriptions of the SLRA process); Norman, *supra* note 112, at 9.

The CMP constitutes the government of Canada's strategy to further prioritize and assess the priority substances by 2020.[125] 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.[126]

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.[127] 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, though, may require the generation of new data to determine, for

125. VIRGINIA POTER, Industry Coordinating Group CEPA Update Conference: Chemicals Management Plan – Progress Made and Lessons Learned (Oct. 8, 2014) (on file with authors); GOV'T OF CAN., CHEMICALS MANAGEMENT PLAN: PROGRESS REPORT 1 (2013), *available at* http://www.ec.gc.ca/ese-ees/5C49C89D-D6C2-48C2-A256-72870B4044AA/Progress%20Report%20%28December%202013%29_EN.pdf.

126. CEPA § 46(1)(a).

127. *Id.*

example, modes of action and more likely exposure scenarios.[128] 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 forty-four chemicals.[129] The PSL includes a five-year timeline to complete risk assessments.[130] Risk assessments were completed in early 1994, and twenty-five substances were identified as CEPA-toxic.[131] The government published the second PSL in 1995, this time listing twenty-five substances for risk assessment.[132] Authorities found eighteen of them to satisfy the criteria for CEPA-toxicity.[133]

Through the CEPA PSL framework, Canada has addressed a number of substances of notoriety, including dioxins, furans, hexachlorobenzene (HCB), hexachlorobutadiene (HCBD), and chlorinated paraffins, to name a few.[134] Nonetheless, the government, industry, and non-governmental organizations (NGOs) all considered the PSL process to be too slow and, ultimately, impractical.[135] The excessive length of the assessment process was a major driver for the creation of the 1999 update of CEPA, with its requirement for an allowable 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

128. ABELKOP, ROYER & GRAHAM, *supra* note 28.

129. *First Priority Substances List (PSL1)*, ENV'T CAN., http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=95D719C5-1 (last modified June 21, 2013).

130. CEPA § 78.

131. ENV'T CAN., A GUIDE TO UNDERSTANDING THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999, at 9 (2004), *available at* http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04_e.pdf.

132. *Id.*

133. *See id.*; *Second Priority Substances List (PSL2)*, ENV'T CAN., http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=C04CA116-1 (last modified June 21, 2013).

134. *PSL2*, *supra* note 133; *PSL1*, *supra* note 129.

135. Meek & Armstrong, *supra* note 94, at 596–97 (compare our previous comments about the length of time taken for EPA assessments).

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 (CMP) in 2006, following the completion of the DSL categorization.[136] 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.[137] A secondary purpose is to increase public confidence in industry and government chemical management.[138]

Though the CMP is not formally mentioned in legislation, CEPA provides the primary legal authority for actions under the CMP.[139] The CMP is designed to facilitate coordination between CEPA and other laws, including those that govern food and drugs, cosmetics, and pesticides.[140] 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,[141] thus far, government, industry, and some NGO stakeholders seem to be pleased with the design and progression of the CMP.[142] As such, the CMP has all but displaced the PSL as a prioritization mechanism for the assessment of chemicals in Canada.

136. Press Release, Prime Minister of Canada, *supra* note 10.

137. *See* U.N., DEP'T OF ECON. & SOCIAL AFFAIRS, DIVISION FOR SUSTAINABLE DEVELOPMENT, CANADA NATIONAL REPORTING TO CSD-18/19, THEMATIC PROFILE ON CHEMICALS 1 (2011), *available at* http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf.

138. *Canadian Government Takes Action on Harmful Chemicals*, NEWSLETTER (ECHA, Helsinki, Fin.), Oct. 16, 2014, at 23, *available at* http://newsletter.echa.europa.eu/documents/6362380/21743968/newsletter_2014_issue_5_october_en.pdf.

139. *See id.*

140. U.N., DEP'T OF ECON. & SOCIAL AFFAIRS, *supra* note 137, at 1–2.

141. *See generally* Dayna Nadine Scott, *Beyond BPA: We need to Get Tough on Toxics*, GLOBE & MAIL, Jan. 4, 2012, http://www.theglobeandmail.com/globe-debate/beyond-bpa-we-need-to-get-tough-on-toxics/article4085163/.

142. *See* ENVTL. DEF., *supra* note 120, at 15.

Authorities are scheduled to work through the CMP in phases from 2006 to 2020.[143] 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."[144] It targeted nearly 200 of the substances identified in the categorization as highest priority.[145] EC and HC first divided the challenge substances into twelve "batches" to be addressed sequentially.[146] CEPA section 71 provides the government with the authority to compel businesses to provide information about the substances that they manufacture, import, and use.[147] EC and HC published a list of each batch in the *Canada Gazette* approximately every three months beginning in February 2007, using authority under section 71 to challenge industry to provide data on the chemicals in the batch within six months of the publication.[148] 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.[149] In some cases, however, additional data were supplied. After receiving the data, EC and HC conducted SLRAs, which they released for public comment.[150]

143. POTER, *supra* note 125.

144. Gov't of Can., *The Government of Canada "Challenge" for Chemical Substances That Are a High Priority for Action*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php (last modified July 28, 2011).

145. *See, e.g.*, *Proposed Risk Management Approach for Benzenamine, N-phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene (BNST)*, ENV'T CAN. (Aug. 2009), http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=136D3FBF-1.

146. *See* Gov't of Can., *supra* note 144.

147. CEPA § 71.

148. *See, e.g.*, Canadian Environmental Protection Act, 1999, C. Gaz. 141(5) 162–77, *available at* http://publications.gc.ca/gazette/archives/p1/2007/2007-02-03/pdf/g1-14105.pdf; Canadian Environmental Protection Act, 1999, C. Gaz. 141(19) 1178–1201, *available at* http://publications.gc.ca/gazette/archives/p1/2007/2007-05-12/pdf/g1-14119.pdf.

149. Dayna Nadine Scott, *Testing Toxicity: Proof and Precaution in Canada's Chemicals Management Plan*, 18 REV. EUR. COMMUNITY & INT'L ENVTL. L. 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. *Id.*

150. *See id.* at 164.

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.[151] 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.[152] 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, HC then applied a rapid screening framework from a human health perspective.[153] Through this process, EC and HC determined that 472 potential substances required further assessment, 533 required no further action because their estimated exposures were not of concern, and sixty-one needed to be withdrawn from rapid screening either because they were 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.[154]

The third initiative of CMP Phase I, which now extends into Phase II, is the Petroleum Sector Stream Approach.[155] EC and HC divided 164 high priority petroleum substances into five

151. *See id.* at 164–65.

152. ENV'T CAN. & HEALTH CAN., RAPID SCREENING OF SUBSTANCES OF LOWER CONCERN: RESULTS OF THE SCREENING ASSESSMENT, at ii. (2013), *available at* http://www.ec.gc.ca/ese-ees/2A7095CD-A88C-4E7EB089486086C4CBC4/RSI%20Final%20-%20EN.pdf.

153. *See id.*

154. *Id.* at ii–iii.

155. *See* Gov't of Can., *The Petroleum Sector Stream Approach*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/petrole/index-eng.php (last modified Sept. 5, 2014).

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.[156]

Phase II was announced in 2011 and includes an additional rapid screening effort based on exposure-related information,[157] an approach to address polymers,[158] and the Substance Groupings Initiative (SGI).[159] 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.[160] The rationale for assessing substances in groups is that they may share similar chemical properties or may be used in similar ways.[161] 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.[162] 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 announced on the CMP

156. *Id.*

157. *See* ENV'T CAN., RAPID SCREENING OF SUBSTANCES FROM PHASE ONE OF THE DOMESTIC SUBSTANCES LIST INVENTORY UPDATE: RESULTS OF THE FINAL SCREENING ASSESSMENT 4–5 (2014), *available at* http://www.ec.gc.ca/ese-ees/7340E1B7-1809-4564-8C49-F05875D511CB/FSAR_RSII_EN.pdf. To date, 117 substances have been identified that may not require further risk assessment because of low exposure potential. *Id.* at 5.

158. *See* Gov't of Can., *Polymer Approach*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/polymer-eng.php (last modified Mar. 19, 2012).

159. *See* Vincenza Galatone, ICG CEPA Update Conference: Chemicals Management Plan: Moving Forward in 2013 (June 6, 2013) (conference presentation on file with authors); Gov't of Can., *The Substance Groupings Initiative*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/group/index-eng.php (last modified Aug. 15, 2014) [hereinafter Gov't of Can. SGI].

160. *See id.*

161. *Id.*

162. Steven J. Enoch, *Chemical Category Formation and Read-Across for the Prediction of Toxicity*, *in* 8 RECENT ADVANCES IN QSAR STUDIES 209 (Tomasz Puzyn et al. eds., 2010).

website.[163] However, an aggressive use of this approach might test the limits of the read-across screening technique, which could ultimately undermine confidence in the assessment process.[164]

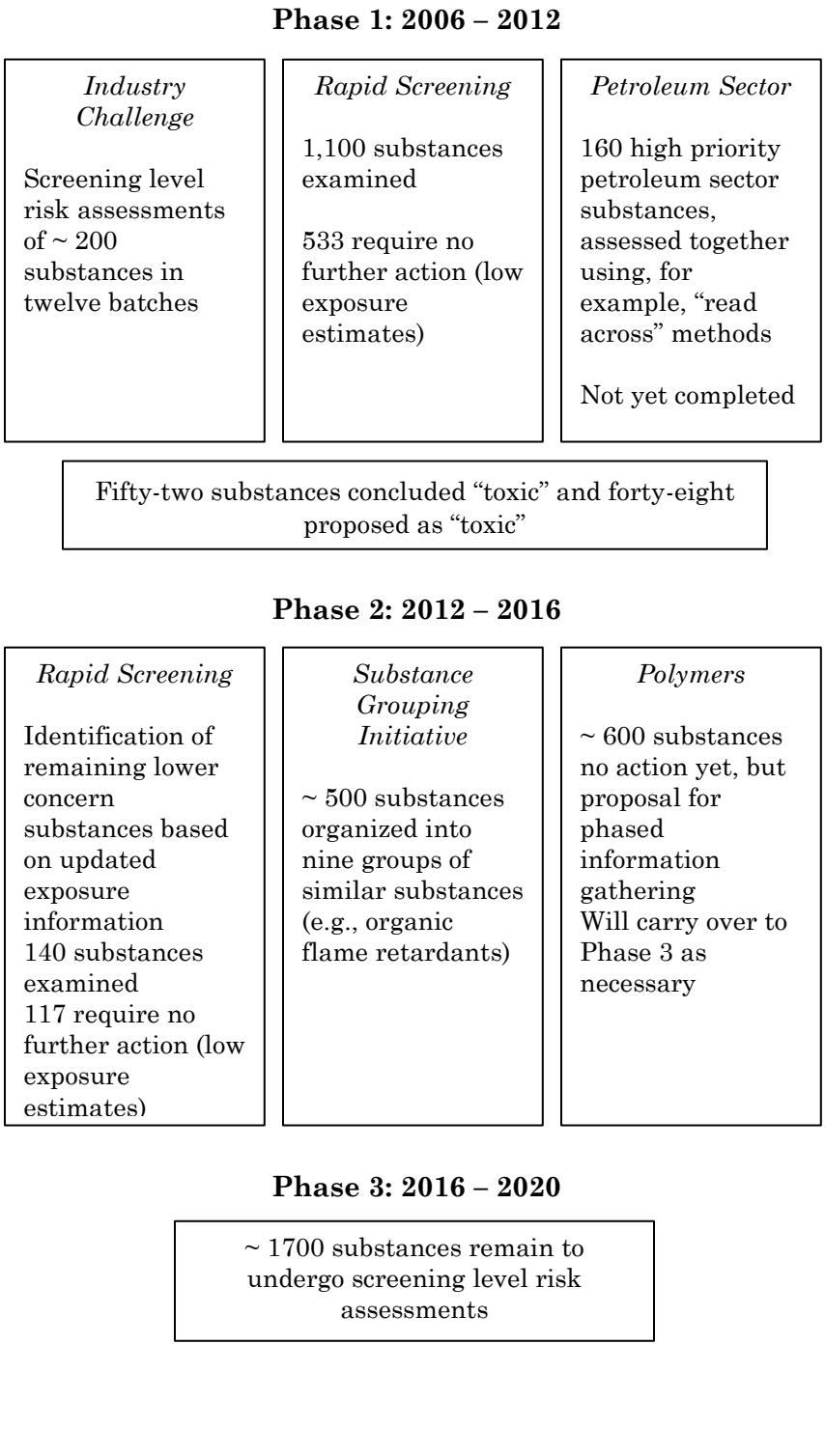
Following the first two phases of the CMP, the Canadian government will still have to conduct SLRAs for about 1,700 priority substances identified in categorization.[165] How the ministries will execute the next phase of the CMP is uncertain, but it seems clear that, regardless of the outcomes of the 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.

163. *See generally* Gov't of Can. SGI, *supra* note 159.

164. *See* CHEM. SENSITIVITIES MANITOBA & CAN. ENVTL. LAW ASS'N, A RESPONSE TO THE PROPOSED RISK MANAGEMENT APPROACH FOR CHEMICALS MANAGEMENT PLAN INDUSTRY CHALLENGE BATCH 3 SUBSTANCES, PUBLISHED IN *CANADA GAZETTE* PART I, VOL. 143, NO. 10 - MARCH 7, 2009 at 3–4, (2009) [hereinafter CSM & CELA], *available at* http://www.cela.ca/sites/cela.ca/files/652%20CMP%20batch%203.pdf (critiquing overreliance on analogue data).

165. Galatone, *supra* note 159, at 4.

Figure 3. Chemicals Management Plan



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.[166] There are three potential outcomes if a SLRA leads authorities to determine that a substance is CEPA-toxic.[167] First, the government may opt to take no further action.[168] 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.[169] 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.[170]

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.[171] 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.[172]

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 "prescrib[ing] the quantity or concentration of the substance that may be released into the environment . . . from any source. . . ."[173] In practice, if a SLRA

166. CEPA § 74.
167. *Id.* § 77(2).
168. *Id.* § 77(2)(a).
169. *Id.* § 77(2)(b).
170. *Id.* § 77(2)(c).
171. *Id.* § 77(3); *Toxic Substances List*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1 (last modified Nov. 6, 2013).
172. CEPA § 77(4).
173. *Id.* § 65(3).

indicates that a substance is CEPA-toxic, it is routinely added to the TSL. As of November 2013, there are 132 substances on the TSL and, as of February 2009, only two substances on the VEL.[174] 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.[175] The European Chemicals Agency (ECHA), in cooperation with Member State governments and the European Commission, administers REACH. Though all 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.[176] 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 single nation. Whereas Canada's DSL lists about 23,000 existing substances, there are about 100,000 substances listed on the EUs various chemicals

174. *Toxic Substances List – Schedule 1*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1&wsdoc=4ABEFFC8-5BEC-B57A-F4BF-11069545E434 (last modified Aug. 4, 2014); *Virtual Elimination List*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=768FCB63-1 (last modified Mar. 7, 2013).

175. REACH, Preamble 3, 4, 7. For a description of the processes under REACH, see generally Nicolas Herbatschek et al., *The REACH Programmes and Procedures*, *in* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 82, 82–170 (Lucas Bergkamp ed., 2013).

176. *See id.*

inventories.[177] REACH is designed to facilitate industry assessment and subsequent voluntary management through registration, to identify Substances of Very High Concern (SVHCs) for authorization, and to identify uses of concern for restriction.[178] 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"[179] —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.[180] 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 one tonne or more per year shall submit a registration to the [European Chemicals] Agency."[181] Downstream users—often small or large companies that make use of a chemical in consumer products or services—may also provide use and safety

177. EUR. CHEM. AGENCY (ECHA), GUIDANCE FOR IDENTIFICATION AND NAMING OF SUBSTANCES UNDER REACH AND CLP 10 (2014), *available at* http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf [hereinafter ECHA, IDENTIFICATION]. About 150,000 substances were pre-registered for the 2008 pre-registration deadline. Press Release, ECHA, List of Pre-Registered Substances Published (Dec. 19, 2008), *available at* http://echa.europa.eu/documents/10162/13585/pr_08_59_publication_pre-registered_substances_list_20081219_en.pdf.

178. *See* Lucas Bergkamp & Dae Young Park, *The Organizational and Administrative Structures*, *in* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 23, 37 (Lucas Bergkamp ed., 2013).

179. REACH, art. 5.

180. *See generally* ECHA, IDENTIFICATION, *supra* note 177, at 10.

181. REACH, art. 6(1).

information on their own or assist in the preparation of registration dossiers through a lead registrant.[182]

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.[183] 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.[184]

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 December 2010 applied to companies that manufactured or imported any substances at volumes of 1,000 tonnes per year or more, substances that are "very toxic" to aquatic organisms at volumes of 100 tonnes per year or more, and CMRs at volumes of one tonne per year or more.[185] In response to this first deadline, ECHA received roughly 25,000 registration dossiers covering about 3,400 substances.[186] The second registration deadline was in June 2013 and applied to companies that manufactured or imported substances at volumes of 100 tonnes per year or more.[187] The third and last registration deadline is June 2018, when all

182. *Id.* art. 37.

183. *See* REACH, art. 10(1)(a).

184. *See generally, e.g.*, Greta Stieger et al., *Assessing the Persistence, Bioaccumulation Potential and Toxicity of Brominated Flame Retardants: Data Availability and Quality for 36 Alternative Brominated Flame Retardants*, 116 CHEMOSPHERE 118 (2014).

185. *See* REACH, art. 23(1).

186. *First REACH registration was a success!*, ECHA NEWSLETTER (ECHA, Helsinki, Finland), Dec. 2010, at 5, *available at* http://echa.europa.eu/documents/10162/13585/echa_newsletter_2010_6_en.pdf.

187. REACH, art. 23(2).

substances manufactured or imported in quantities of one tonne or more are to be registered.[188] As of September 2014, the REACH database contains information on 12,735 substances from 49,100 registration dossiers.[189]

The registration dossier under REACH must contain a minimum set of data, or the substance may not be put on the market in Europe.[190] 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 have more demanding data requirements.[191] For example, once the ten-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.[192] 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.[193]

188. *Id.* art. 23(3).

189. *Registered Substances*, ECHA, http://echa.europa.eu/information-on-chemicals/registered-substances (last updated Sept. 24, 2014).

190. *Id.* art. 5.

191. *See* REACH, art. 12(1), 23.

192. *See id.* arts. 10(a)(x), (b), 14(1)(3).

193. *See id.* art. 14(4); Directive 67/548, of the European Parliament and the Council of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances 67/548/EEC, 1967 O.J. (L 196) 235. The Dangerous Substances Directive will be replaced by the Classification, Labelling and Packing Regulation. *See* Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No 1907/2006, 2008 O.J. (L 353) 1.

2. Evaluation

REACH contains two distinct evaluation processes: dossier and substance evaluation.[194] 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 fulfill all of the registration data requirements.[195] REACH mandates that ECHA must conduct a compliance check on no less "than [five percent] of the total [number of dossiers] received by the Agency for each tonnage band . . . ."[196] REACH does not obligate ECHA to examine the other ninety-five percent of registration dossiers for substantive compliance. From this five percent baseline, ECHA prioritizes its selection of dossiers to examine through random selection (twenty-five percent) as well as a mix of hazard and exposure characteristics and technical concerns (seventy-five percent), including potential PBT, vPvB, or CMR characteristics; wide dispersive use; or excessive confidentiality claims.[197]

The compliance check process is procedurally straightforward but can be scientifically intensive.[198] 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.[199] Experts are responsible for a substantive examination of the portions of the dossier in their area of specialization. The experts determine whether the registrant provided the required and appropriate data. They analyze the quality of the data by evaluating the reliability and validity of the study reports included within the dossier. The

194. *See* Herbatschek et al., *supra* note 175, at 126–33.

195. *See generally* ECHA, DOSSIER EVALUATION, 1-5 (2013), *available at* http://echa.europa.eu/documents/10162/13607/pro_0017_03_dossier_evaluation_en.pdf.

196. REACH, art. 41(5).

197. *Id.*

198. For a detailed description of the steps involved in dossier evaluation, see ECHA, DOSSIER EVALUATION (2014), *available at* http://echa.europa.eu/documents/10162/13607/procedure_dossier_evaluation_en.pdf.

199. *See Evaluation process: Safeguarding the scientific quality of registration information*, ECHA, http://newsletter.echa.europa.eu/home/-/newsletter/entry/6_11-evaluation-process;jsessionid=49BAC7F58F48304C08629EB038A4B67F.live2 (last visited Oct. 28 2014).

team also examines any exposure scenarios, which are required for PBTs, vPvBs, CMRs, and all "classified" (dangerous)[200] substances manufactured or imported at volumes greater than ten 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 achieve "adequate control" of exposures.[201] 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.[202] 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).[203] 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.[204]

Substance evaluation is an altogether different process, carried out by Member States in collaboration with ECHA and the European Commission.[205] It involves evaluation of a specific

200. Directive 67/548, of the European Parliament and the Council of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances 67/548/EEC, 1967 O.J. (L 196) 235.

201. *See* REACH, Annex I, § 5.1.1. *See also* REACH, Annex I § 6.4 (indicating 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).

202. See Target met for 5% compliance checks of the 2010 registration dossiers, ECHA, http://echa.europa.eu/view-article/-/journal_content/title/target-met-for-5-percent-compliance-checks-of-the-2010-registration-dossiers (last visited Oct. 28, 2014).

203. *See* Herbatschek et al., *supra* note 175, at 130.

204. *See generally id.* at 126.

205. *See* ECHA, SUBSTANCE EVALUATION 1 (2013), *available at* http://echa.europa.eu/documents/10162/13607/pro_0023_01_substance_evaluation_en.pdf.

substance rather than a specific dossier.[206] 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.[207] 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.[208] If a registration dossier is missing information on certain hazards (e.g., types of toxicity), the substance evaluation process may be employed to obtain the necessary information from industry, which can then be used for both classification and labeling.[209] 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.[210] 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.[211]

ECHA, through its Member State Committee, determines which substances will undergo substance evaluation, and lists them on the Community Rolling Action Plan.[212] The selection of substances is based on criteria that are related to human health

206. *See generally* Herbatschek et al., *supra* note 175, at 131.

207. *Id.* at 1.

208. *See id.* at 7–8.

209. *See id.*

210. *See id.* at 7.

211. *See* Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No 1907/2006, 2008 O.J. (L 353) 20.

212. REACH, art. 44(2).

and environmental quality, including the chemical's hazardous properties, the potential for exposure, and aggregated tonnage of production (registration data).[213] Political concerns may play a role in a Member State's decision to nominate a chemical or substance for evaluation.[214] 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.[215]

3. Authorization

The authorization process is intended to protect human health and the environment by facilitating the substitution of SVHCs with suitable, safer alternatives.[216] 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.[217] 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

213. *See id.* art. 44(1). *See also* ECHA, SELECTION CRITERIA TO PRIORITISE SUBSTANCES FOR SUBSTANCE EVALUATION 1-2 (2011), *available at* https://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf.

214. *See* Herbatschek et al., *supra* note 175, at 152–55 (indicating that political preferences of Member States influence the prioritization of substances for consideration of inclusion on the Candidate List).

215. *See generally Community Rolling Action Plan*, ECHA, http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan (last visited Nov. 7, 2014)

216. *See* REACH, art. 55, 58(2).

217. *See id.* art. 55, 57, 58(1), (3) (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*, SCI. AM. (Sept. 11, 2011), http://www.scientificamerican.com/article.cfm?id=toxins-all-around-us.

formal Authorization List (REACH Annex XIV).[218] 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.[219]

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.[220] 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.[221] A unanimous decision of the Committee places the substance on the Candidate List, while a split vote turns the listing decision over to the Commission.[222] 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.[223] 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.[224]

218. *See* REACH, art. 59(1).

219. *See id.* art. 55.

220. *See id.* art. 59(2). *See* ECHA, GUIDANCE FOR THE PREPARATION OF AN ANNEX XV DOSSIER FOR THE IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN (2014) [hereinafter ECHA, GUIDANCE], *available at* http://echa.europa.eu/documents/10162/13638/svhc_en.pdf.

221. *See Role of the Member State Committee in the Authorisation Process*, ECHA, http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process (last visited Nov. 7, 2014).

222. Herbatschek et al., *supra* note 175, at 157. To date, all Member State Committee decisions on candidate listing have been unanimous, with contentious negotiation occurring prior to voting. *Id.*

223. *See* ECHA, PRIORITISATION AND ANNEX XIV RECOMMENDATION 1–2, 4 (2013), *available at* http://echa.europa.eu/documents/10162/13607/prioritisation_annex_xiv_recommendation_en.pdf; Herbatschek et al., *supra* note 175, at 135–38.

224. *See generally* Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 Laying Down the Rules and General Principles Concerning Mechanisms for Control by Member States of the Commission's Exercise of Implementing Powers, 2011 O.J. (L 55/13). Under comitology, the Commission drafts an implementing act for submission to a

The authorization process begins with the identification of SVHCs.[225] As of 2014, 175 Annex XV dossiers have been submitted to formally identify substances as SVHCs, 161 substances have been placed on the Candidate List, and thirty-one substances have been placed on the Authorization List.[226] 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.[227] In 2013, the Commission estimated that, at most, 440 substances will need to be assessed for SVHC classification by 2020.[228] Each SVHC may undergo a rudimentary or screening-level assessment prior to a management decision on how to proceed.[229]

To determine which Candidate List substances should be evaluated first to determine if they should be included on the Authorization List, REACH specifies prioritization criteria in Article 58 as PBT and vPvB characteristics, wide dispersive uses, significant market level production and importation volume, and ECHA's capacity to deal with the authorization applications.[230] ECHA has developed a scoring system based on those criteria to

committee of representatives of the Member States referred to as the REACH Comitology Committee (distinct from the ECHA Member State Committee). *See generally id.* The Comitology Committee then decides whether an implementing act should be adopted through a majority vote. *See id.*

225. Herbatschek et al., *supra* note 175, at 152.

226. *Authorisation List*, ECHA, http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list (last visited Nov. 7, 2014); *Candidate List of Substances of Very High Concern for Authorisation*, ECHA, http://echa.europa.eu/candidate-list-table (last updated Dec. 17, 2014); *Submitted SVHC Proposals*, ECHA, http://echa.europa.eu/registry-of-submitted-svhc-intentions (last visited Mar. 16, 2015).

227. Herbatschek et al., *supra* note 175, at 152. *See C&L Inventory*, ECHA, http://echa.europa.eu/regulations/clp/cl-inventory (last visited Jan. 18, 2015) (providing various lists of chemical inventories, including those with hazardous properties).

228. SVHC ROADMAP, *supra* note 68, at 12.

229. *Id.* at 15.

230. *See* REACH, art. 58. *See also* ECHA, PRIORITISATION OF SUBSTANCES OF VERY HIGH CONCERN (SVHCS) FOR INCLUSION IN THE AUTHORISATION LIST (ANNEX XIV) 4 (2014) [hereinafter PRIORITISATION FOR AUTHORISATION], *available at* http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf.

prioritize substances on the Candidate List.[231] However, prior to 2013, no comprehensive, formal procedure had been specified for setting priorities among potential SVHCs to determine which of the ~1,500 should first be evaluated to determine if they actually are SVHCs that require risk management.[232] 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.[233]

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 triggers some unambiguous legal requirements for companies (e.g., notification requirements throughout the supply chain).[234] 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.

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 listed substances, even before they are placed on the Authorization List.[235] To avoid unnecessary de-selection, some suggested that a screening assessment should precede placement of a substance on the Candidate List.[236] 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 are not added to the Authorization List.[237] In other words, once a substance is placed on the Candidate List, the substance cannot be removed until

231. *See* PRIORITISATION FOR AUTHORISATION, *supra* note 230.

232. Herbatschek et al., *supra* note 175, at 152–54.

233. *Id.* at 152. *See generally* REACH, arts. 7, 31, 33.

234. *See Summary of Obligations Resulting from Inclusion in the Candidate List of Substances of Very High Concern for Authorisation*, ECHA, http://echa.europa.eu/candidate-list-obligations (last visited Nov. 7, 2014).

235. Herbatschek et al., *supra* note 175, at 133–34.

236. *See id*. at 135.

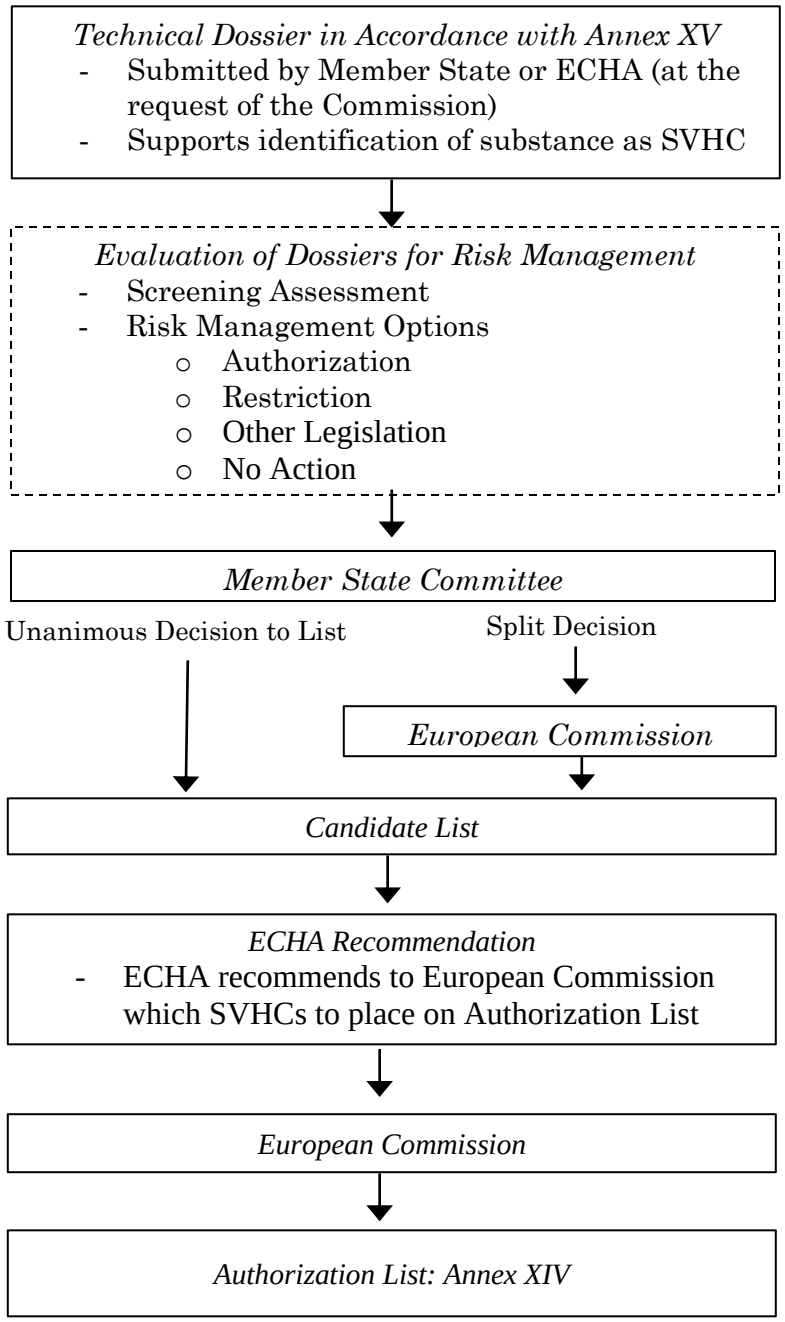
237. *Id.* at 136.

after it is placed on the Authorization List, and a scientific case for removal from the Authorization List has been made.[238] ECHA and the Commission have taken the position that a substance on the Candidate List can be de-listed (using the same criteria for de-listing that applies to substances on the Authorization List), but the legal viability of this position is arguable.[239]

Given the unclear repercussions and potential drawbacks of placing *all* SVHCs on the Candidate List, the Commission introduced the concept of risk management options (RMO) analysis prior to candidate-listing decisions. Figure 4 below depicts the authorization listing process, including where in the process RMO analysis occurs.

238. *Id.* at 139 (see "procedure for de-listing" from the Authorization List).
239. *Id.* at 136.

Figure 4. Process for Inclusion of Substances on the REACH Authorization List



To fulfill the goal of considering all SVHCs for inclusion on the Candidate List by 2020, the Commission released the *Roadmap on Substances of Very High Concern* in February 2013.[240] In December 2013, ECHA released the *SVHC Roadmap to 2020 Implementation Plan* detailing a proposal for prioritizing SVHCs for screening assessment, conducting screening assessments, and considering various risk management options.[241]

The *Roadmap* identifies the Commission's criteria for identifying "relevant SVHCs" for prioritization to undergo RMO analysis.[242] Relevant SVHCs are those that meet the SVHC criteria listed in Article 57 (PBT, vPvB, CMR, or equivalent concern), that are registered for the non-intermediate uses, for which the prima facie case of unacceptable risk (triggering restriction) cannot be currently made, that are not exempt from authorization, and that are not subject to regulation under other EU legislation.[243]

ECHA's *Implementation Plan* outlines a screening process by which substances will be selected for RMO analysis. The registration database will constitute the primary source of information, and chemicals registered for non-intermediate uses will be prioritized for RMO analysis.[244] Authorities will initially identify potential SVHCs by applying an automated program to search the registration database for chemicals that potentially satisfy the Article 57 criteria.[245] Authorities will then apply an automated screening program to the potential SVHCs that are registered for non-intermediate uses to screen for selection criteria, including high volume, highest potential for fulfilling the Article 57 criteria, structural similarity to chemicals on the Candidate List, and additional informational needs.[246] The

240. *See* SVHC ROADMAP, *supra* note 68, at 4.

241. *See* ECHA, SVHC ROADMAP TO 2020 IMPLEMENTATION PLAN 6 (2013) [hereinafter SVHC IMPLEMENTATION PLAN], *available at* http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf.

242. SVHC ROADMAP, *supra* note 68, at 8–10.

243. *Id.*

244. SVHC IMPLEMENTATION PLAN, *supra* note 241, at 12.

245. *Id.* at 12–13.

246. *Id.* at 11–12.

outcome of the screening will yield a pool of "substances of potential concern."[247]

Screened chemicals will be sorted into various hazard groups (e.g., potential PBTs, CMRs, etc.).[248] Expert and coordinating groups within ECHA will assess the chemicals in each group to determine if they satisfy the criteria to be considered SVHCs and/or assist Member States and ECHA.[249] For example, the PBT Expert Group is responsible for determining whether potential PBTs meet the Annex XIII criteria for classification as a PBT, vPvB, or substance of equivalent concern to a PBT/vPvB.[250]

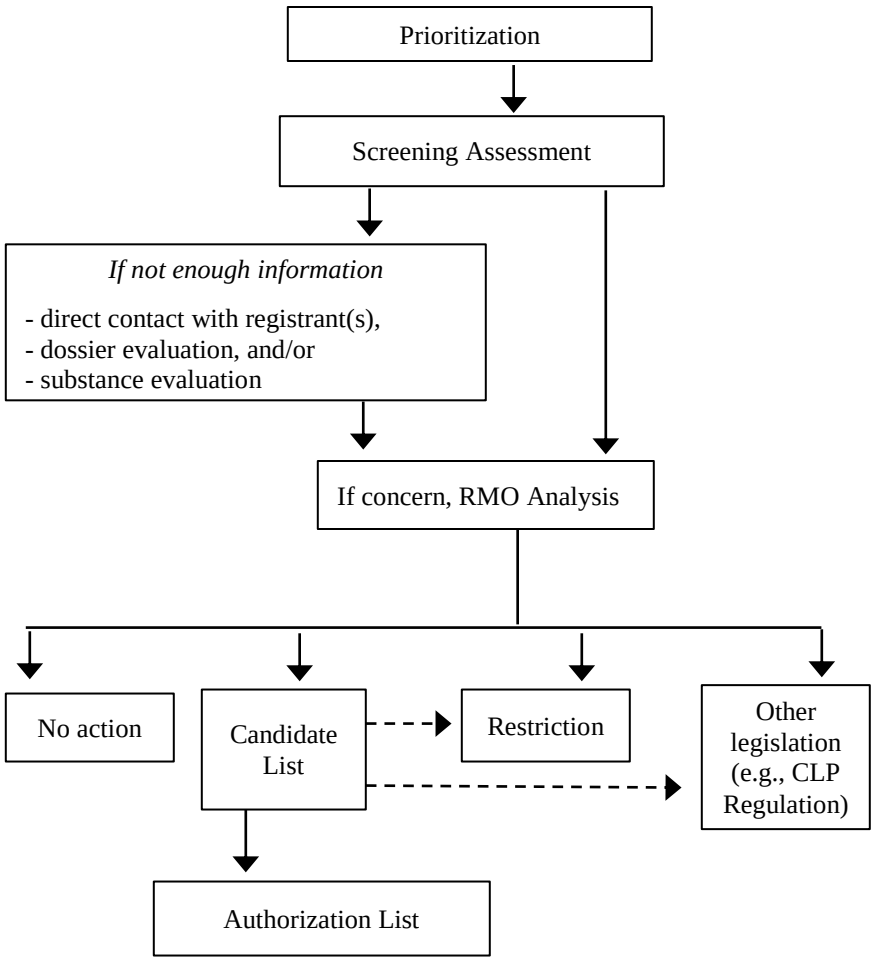
If an expert group determines that a chemical meets the SVHC criteria, the chemical will be added to the pool of chemicals subject to RMO analysis.[251] If the group determines that there is not enough information or that existing information is of too poor of quality to make a determination on the criteria, then the chemical may be subjected to additional information gathering (e.g., substance evaluation) to gain data sufficient to make a determination.[252] The *Implementation Plan* notes that chemicals requiring additional information will be subject to further prioritization. As additional information is added to the registration database, screening will undergo regular reiterations.[253]

The next tier of analysis entails an evaluation of risk management options to determine if risk management is necessary and, if it is, to determine the most appropriate approach to risk management.[254] This process is shown below in Figure 5. The details of RMO analysis are ambiguous, 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

247. *Id*. at 12.
248. *Id*. at 13.
249. *Id.*
250. SVHC IMPLEMENTATION PLAN, *supra* note 241, at 29–30.
251. *See id*. at 23, 26, 29.
252. *Id*. at 29–30.
253. *Id.* at 13.
254. *See* SVHC ROADMAP, *supra* note 68, at 8–10.

as consideration of the restriction process and other regulations that might already apply.[255]

Figure 5. SVHC Identification Roadmap[256]



255. *See generally EU Commission to Propose Five Substance Restrictions Under RoHS2*, CHEM. WATCH (Feb. 7, 2014), http://chemicalwatch.com/18294/eu-commission-to-propose-five-substance-restrictions-under-rohs2 (illustrating EU Authorities exhibiting a preference for restrictions over authorization for some chemicals).

256. Adapted from SVHC IMPLEMENTATION PLAN, *supra* note 241, at 9 (fig.1).

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.[257] ECHA is responsible for drafting a proposed recommendation for additional listings at least once every two years.[258] 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.[259]

The *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.[260] Nonetheless, the European Authorities have a large degree of discretion on how priorities will be set and stakeholders do not have a clear understanding of which substances will undergo screening assessments/RMO analyses first.[261]

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.[262]

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

257. *See* PRIORITISATION FOR AUTHORISATION, *supra* note 230, at 3–4.

258. *See Role of the Member State Committee in the Authorisation Process*, *supra* note 221.

259. *See id.*

260. *See* ECHA, GUIDANCE, *supra* note 220, at 6–7.

261. *See* Herbatschek et al., *supra* note 175, at 152–54.

262. ECHA, GUIDANCE, *supra* note 220, at 10.

the environment.[263] 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 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.[264] 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.[265] 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.

263. REACH, art. 68(1). *See* European Comm'n, *Restrictions*, ENTERPRISE & INDUSTRY, http://ec.europa.eu/enterprise/sectors/chemicals/reach/restrictions/index_en.htm (last updated Aug. 29, 2014).

264. *See* Bergkamp & Penman, *supra* note 11, at 8; Herbatschek et al., *supra* note 175, at 146.

265. Herbatschek et al., *supra* note 175, at 152–54.

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.

Nonetheless, the experiences of both Canada and the EU make abundantly clear the desirability and necessity of prioritization in assessment and management.[266] 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.[267] The European Commission projects a need to make SVHC decisions on as many as 440 substances by 2020.[268]

The approaches to priority setting under CEPA and REACH differ, but both systems recognize 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*.[269]

Once large numbers of registration dossiers were submitted under REACH, EU Authorities realized that they needed

266. *See generally* Ditz, *supra* note 75 (describing that one of the persistent flaws in U.S. regulatory programs is lack of priority setting); CASS SUNSTEIN, THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION 6 (2002).

267. *See infra* Part III.A.1.

268. SVHC ROADMAP, *supra* note 68, at 12.

269. *See id.* at 12–13.

mechanisms to set some priorities to review 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.[270] The priority-setting procedures for authorization, substance evaluation, and restriction under REACH are not yet fully worked out.[271] NGOs have raised concerns that ECHA and the Commission are too slow at formally listing substances as SVHCs.[272] The recent SVHC *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 *Roadmap* and *Implementation Plan*.[273] Priorities for substance evaluation and restrictions under REACH may also be based on exposure as well as hazards, 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 the 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 elements of hazard and exposure. Furthermore, both Canadian and European experiences suggest that the U.S. might do well to either include as much clarity on prioritization criteria and processes as possible in the legislation itself and/or

270. *See* Herbatschek et al., *supra* note 175, at 130.

271. *Id.* at 152.

272. *See The EU Regulation of Chemicals*, INT'L CHEM. SECRETARIAT, http://www.chemsec.org/what-we-do/influencing-public-policy/eu-chemicals-regulation/reach (last visited Nov. 7, 2014).

273. *See generally* SVHC IMPLEMENTATION PLAN, *supra* note 241; SVHC ROADMAP, *supra* note 68.

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.[274] Some legislative clarity would reduce the potential for practical implementation problems and uncertainty that Europe is facing. The Canadian experience, though, is not a perfect guide for the U.S., 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,[275] 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 executing their 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.[276] However, the

274. *See* OFFICE OF POLLUTION PREVENTION & TOXICS, EPA, TSCA WORK PLAN CHEMICALS: METHODS DOCUMENT 6 (2012), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf [hereinafter OPPT].

275. *See generally* Ditz, *supra* note 75; ENVTL. DEF., *supra* note 120.

276. *See generally* ENVTL. DEF., *supra* note 120; GRANVILLE, *supra* note 116; Letter from Peter Goodhand, Chief Exec. Officer, Can. Cancer Soc'y, Richard Paton, President & Chief Exec. Officer, Chemistry Indus. Ass'n of Can., Peter Robinson, Chief Exec. Officer, David Suzuki Found., & Rick Smith, Exec. Dir.,

political environment in Canada may not be as receptive to NGO analysis and critique of chemicals management as it is in the U.S. 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 approaches.[277] 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.[278]

Whereas CEPA begins with a prioritization of risk assessment based on limited data, REACH first fills the information gap and *then* employs a prioritization mechanism for

Envtl. Def., to James Flaherty, Minister of Fin., Peter Kent, Minister of Env't, Leona Aglukkaq, Minister of Health, & Stockwell Day, President, Treasury, Bd. & Minister of Asia-Pacific Gateway (Jan. 21, 2011) (on file with author) (supporting funding for CMP Phase 2).

277. *See* ENVTL. DEF., *supra* note 120.

278. *See* PRESIDENTIAL/CONGRESSIONAL COMM'N ON RISK MGMT & RISK ASSESSMENT, FRAMEWORK FOR ENVIRONMENTAL HEALTH RISK MANAGEMENT 26 (1997), *available at* http://www.riskworld.com/nreports/1997/risk-rpt/pdf/epajan.pdf; *see generally* NRC 2013, *supra* note 98, at 7, 138, 224.

risk management that makes use of risk assessments.[279] 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.[280] Because CEPA is based on the 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, compiles a huge volume of information through the registration dossiers, but the database is so large that much of it may never be fully examined.[281] 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.[282] 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

279. Ditz, *supra* note 75, at 10317 (indicating that the purpose of registration is to generate data rather than prioritize chemicals for assessment and management); Renn & Elliott, *supra* note 62, at 242.

280. *See generally* Ditz, *supra* note 75.

281. Abelkop et al., *supra* note 79, at 11056.

282. *See* Herbatschek et al., *supra* note 175, at 90–94.

violations under REACH.[283] Nonetheless, there are already indications that there are significant quality problems with registration dossiers.[284]

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 screening/modeling exercises. Both false-positive and false-negative errors are expected to occur.[285]

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.[286] 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 errors 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.

283. *See generally id.* at 94–95. For a description of how penalties are applied, see MILIEU ENVTL. LAW & POLICY, REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATES 7 (2010), *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/studies/penalties-report_en.pdf.

284. *See, e.g.*, Stieger et al., *supra* note 184.

285. For the classic paper that conceptualized the error problem in chemical priority-setting procedures, see Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L. Q. 207, 219–39 (1978).

286. *See id.* at 220.

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.[287] 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 required.[288] Notably, public interest organizations have raised concerns over false-negative errors 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.[289] On the other hand, HC and EC note that they have made considerable efforts to incorporate the precautionary principle into their assessment processes and to consider endocrine disrupting effects, differential risk to certain groups (including women and children), and cumulative effects of exposure to multiple chemicals when data are available.[290] These critiques do not seem to be inherent to

287. *Id.*

288. *See* Ditz, *supra* note 75, at 10316-17. On why false-negative errors are particularly intolerable for public health, see Mara E. Long, *Predicting Carcinogenicity in Humans: The Need to Supplement Animal-Based Toxicology*, 14 AATEX 553, 553–57 (2007).

289. Dayna Nadine Scott & Sarah Lewis, *Regulating Toxics: Sex and Gender in Canada's Chemicals Management Plan*, *in* OUR CHEMICAL SELVES: GENDER, TOXICS, AND ENVIRONMENTAL HEALTH (Dayna Nadine Scott ed.) (forthcoming Dec. 2014); Scott, *supra* note 149, at 59. *See* CSM & CELA, *supra* note 164, 6, 9.

290. On the consideration of endocrine disrupting effects, *see Federal Research on Hormone Disrupting Substances as Required Under the Canadian Environmental Protection Act, 1999*, OFF. OF THE AUDITOR GEN. OF CAN. (Dec. 14, 2012), http://www.oag-bvg.gc.ca/internet/English/pet_340_e_37607.html. On combined exposures and cumulative effects, refer to the screening assessments for PBDEs and phthalates, *see generally* Gov't of Can., *Phthalate Substance Grouping*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/group/phthalate/index-eng.php (last modified Aug. 15, 2014); Gov't of Can., *Polybrominated Diphenyl Ethers (PBDEs)*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/glance-bref/pbde-eng.php (last modified Feb. 14, 2013). On the precautionary principle, see *Health Canada's Adherence to the Precautionary Principle*, OFF. OF THE AUDITOR

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 with the expectation that reasonable minds will differ on the adequacy of particular methodological approaches to risk assessment.

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.[291] There are ways to combine multiple screening exercises in order to minimize the false-negative error rate.[292] Moreover, for existing chemicals that have been used for decades without any demonstration of adverse effects, there is a practical upper boundary on the possible magnitude of 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.[293] There is a similar body of statistical evidence supporting PBT determinations based on limited data, chemical

GEN. OF CAN. (Mar. 1, 2010), http://www.oag-bvg.gc.ca/internet/English/pet_289_e_33553.html.

291. 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, 8993 (2012). But for a skeptical view of the utility of QSAR approaches, see SCHETTLER ET AL., *supra* note 32, at 242–43. An additional concern is that industry-generated risk assessments might be less conservative than government-generated assessments.

292. Long, *supra* note 288, at 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. *Overview of the Existing Substances Program*, ENV'T CAN., *supra* note 112.

293. For a readable discussion of alternatives to full-scale animal testing that can predict human risk, see *Toxicity Testing Overview*, NON-ANIMAL METHODS FOR TOXICITY TESTING, http://alttox.org/mapp/toxicity-testing-overview/ (last updated Aug. 8, 2014). For a more in-depth discussion, see NAT'L RESEARCH COUNCIL, TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY 1 (2007).

structure, and modeling.[294] 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 the same screening/modeling exercises that were employed in Canada (to reduce the number of animal tests).[295] 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 may be.

It is also useful to compare the Canadian and EU approaches from the perspective of public confidence.[296] 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

294. *See* ABELKOP, ROYER & GRAHAM, *supra* note 28 (estimation methods for measuring persistence, bioaccumulation, and toxicity are described in chapter 2). *See also* HENRIK TYLE ET AL., DANISH EPA, IDENTIFICATION OF POTENTIAL PBTS AND VPVBS BY USE OF QSARS 2 (2002), *available at* http://eng.mst.dk/media/mst/69087/QSAR%20PBT%20final%20clean.pdf.

295. *See* ECHA, GROUPING OF SUBSTANCES AND READ-ACROSS APPROACH - PART I: INTRODUCTORY NOTE 5 (2013), *available at* http://echa.europa.eu/documents/10162/13628/read_across_introductory_note_en.pdf. *See generally* 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 REG. TOXICOLOGY & PHARMACOLOGY 212 (2014); Grace Patlewicz et al., *Use of "Read-Across" for Chemical Safety Assessment Under REACH*, 65 REG. TOXICOLOGY & PHARMACOLOGY 226 (2013); Marta A. Sobanska, *Analysis of the Ecotoxicity Data Submitted Within the Framework of the REACH Regulation*, 470 SCI. OF TOTAL ENV'T 1225 (2014).

296. 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 63, 252 (2012).

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,[297] 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 errors (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 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.[298] It is also beginning to be used in priority-setting applications.[299] The

297. Ball et al., *supra* note 295; Natasha Gilbert, *Data Gaps Threaten Chemical Safety Law*, 475 NATURE 150, 150-51 (2011). *See* Costanza Rovida et al., *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 ENVTL. HEALTH PERSP. 6, 10 (2010); Stieger et al., *supra* note 184; Martin Scheringer, PBT Assessment, Workshop on PBT Science and Policy, December 4, 2013, Brussels, Belgium, at 7.

298. OPPT, *supra* note 274 (describing EPA's prioritization approach to chemical risk assessment); ABELKOP, ROYER & GRAHAM, *supra* note 28 (chapter 5).

299. OPPT, *supra* note 274, at 2.

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.[300] Thus, there is some reason for optimism that the U.S. 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 U.S. TSCA reformers who seek to replicate the Canadian priority setting process in the U.S. 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).[301] 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 U.S.

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

A heavy reliance on screening data necessitates the incorporation of institutions for adaptive management and flexibility into chemicals governance.[302] 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

300. *Id.*; ABELKOP, ROYER & GRAHAM, *supra* note 28 (chapter 5).

301. 15 U.S.C. §§ 2605(c), 2618(c)(1)(B)(i) (2012).

302. On the importance of incorporating institutions for adaptive management into regulatory programs, see Robin Kundis Craig & J.B. Ruhl, *Designing Administrative Law for Adaptive Management*, 67 VAND. L. REV. 1, 15 (2014).

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 reviews of 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.[303] 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.[304] Chemical users in the chrome plating and industrial tooling sectors, for example, have already been impacted by de-selection pressures under REACH.[305] In the United States, stigma may cause market de-selection of the chemical,[306] may prompt state and local regulation of the

303. Herbatschek et al., *supra* note 175, at 134.

304. *See id.*

305. *See* CTR. FOR STRATEGY & EVALUATION SERVS., INTERIM EVALUATION: IMPACT OF THE REACH REGULATION ON THE INNOVATIVENESS OF THE EU CHEMICAL INDUSTRY (2012), *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf; KERSTIN HEITMAN & ANTONIA REIHLEN, TECHNO-ECONOMIC SUPPORT ON REACH: CASE STUDY ON "ANNOUNCEMENT EFFECT" IN THE MARKET RELATED TO THE CANDIDATE LIST OF SUBSTANCES SUBJECT TO AUTHORIZATION (2007), *available at* http://ec.europa.eu/environment/chemicals/reach/pdf/background/report_announcement_effect.pdf; Guido Grunwald & Phillipp Hennig, *Impacts of the REACH Candidate List of Substances Subject to Authorisation: The Reputation Mechanism and Empirical Results on Behavioral Adaptations of German Supply Chain Actors*, 11 J. BUS. CHEMISTRY 53 (2014); *REACH*, ROWAN TECH. GROUP, http://www.rowantechnology.com/US-and-European-rules/european-regulations/reach/ (last visited Nov. 8, 2014) (arguing the listings under REACH can lead to product de-selection; 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).

306. 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, *Wal-Mart Details Chemicals Policy*, CHEMICAL & ENGINEERING

substance,[307] and may elicit product liability claims related to the chemical's alleged hazards.[308] 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.[309] Thus, it is important that the initial listing determinations by agencies are 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.[310] This is a consultation process rather than an appeal mechanism. A candidate listing can also be appealed to the European Court of Justice.[311]

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 legalistic in nature, and the European Authorities are accorded significant discretion by the Court.[312]

NEWS, Mar. 10, 2014, at 19–21, http://cen.acs.org/articles/92/i7/Walmart-Target-Take-Aim-Hazardous.html.

307. On the growing activism among state regulators, see Cheryl Hogue, *State Lawmakers Introducing Bill to Restrict Chemicals*, CHEMICAL & ENGINEERING NEWS, Feb. 18, 2013, at 37, *available at* http://www.environmentalandturf.com/pdf/CEN-Online_State%20Lawmakers%20Introducing%20Bill%20To%20Restrict%20Chemicals_February,%202013.pdf.

308. *See, e.g.*, Roger Meiners & Bruce Yandle, *Common Law and the Conceit of Modern Environmental Policy*, 7 GEO. MASON L. REV. 923, 961–62 (1999); Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 418–19 (1994).

309. Robin Gregory et al., *Technological Stigma*, 83 AM. SCIENTIST 220, 220–23 (1995). *See generally* RISK, MEDIA, AND STIGMA: UNDERSTANDING PUBLIC CHALLENGES TO MODERN SCIENCE AND TECHNOLOGY (James Flynn et al., eds., 2001).

310. REACH, art. 59(4).

311. *Id.* art. 94.

312. *See id.* art. 94; Consolidated Version of the Treaty on the Functioning of the European Union, art. 263, Oct. 26, 2012, 2012 O.J. (C 326) 162, *available at*

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.[313] The most notable example to date is Siloxane D5, which EC and HC determined to be CEPA-toxic, thereby authorizing risk management.[314] In 2009, industry stakeholders requested the establishment of a Board of Review to revisit the determination on Siloxane D5.[315] The Minister agreed to establish a board to review the determination, and industry submitted additional data that was not previously available to the government.[316] 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, an 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 toxic under CEPA.

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 REACH's substance evaluation process, also have the

https://www.ecb.europa.eu/ecb/legal/pdf/c_32620121026en.pdf. REACH art. 91 lists certain decisions that are subject to appeal, but the scope of the art. 91 is quite limited. REACH, art. 91.

313. *See generally* SILOXANE D5 BOARD OF REVIEW, REPORT OF THE BOARD OF REVIEW FOR DECAMETHYLCYCLOPENTASILOXANE (SILOXANE D5) (2011), *available at* http://www.ec.gc.ca/lcpe-cepa/515887B7-AF58-45B7-ADA9-B4ADF8F204DB/CdR-BoR-D5_eng.pdf.

314. SILOXANE D5 BOARD OF REVIEW, REPORT OF THE BOARD OF REVIEW FOR DECAMETHYLCYCLOPENTASILOXANE (SILOXANE D5) 16 (2011), *available at* http://www.ec.gc.ca/lcpe-cepa/515887B7-AF58-45B7-ADA9-B4ADF8F204DB/CdR-BoR-D5_eng.pdf.

315. *Id.*

316. *Id.* at 17.

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.[317]

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 (which does not require industry to submit registration dossiers 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.[318] 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 decision-making 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 scientific support.[319] To a great

317. Herbatschek et al., *supra* note 175, at 131 (Substance evaluation may proceed based on information in the registration or dossier or "any other appropriate source.").

318. NRC 1983, *supra* note 24, at 144.

319. 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 generally HARNESSING SCIENCE FOR

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 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.

ENVIRONMENTAL REGULATION (John D. Graham ed., 1991); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 181 (1998).

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.[320] 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.[321] Since the CMP process is separated from risk management decision-making, 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.[322]

320. CEPA § 74.

321. In the U.S. regulatory system, highly stringent regulatory mandates have induced reluctance among regulators to open rulemakings. *See generally* John D. Graham, *Saving Lives Through Administrative Law and Economics*, 157 U. PA. L. REV. 395, 441 (2008).

322. A similar behavioral pattern was observed in the U.S. under the Clean Air Act. When the U.S. Congress mandates a highly stringent risk-management approach for a listed chemical, regulators are unlikely to list chemicals under

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.[323] 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 were added to the Candidate List, and all chemicals on the Candidate List were added to the Authorization List,[324] 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.[325] The lack of legislative clarity on this question creates confusion as to the precise roles of prioritization and assessments under REACH.[326] Indeed, litigation may be required to fully resolve this question.[327] In general, the extreme complexity of REACH may place unnecessary burdens on both government and stakeholders.[328]

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

the provision. Such behavior was observed under section 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 L.J. 100 (1985). *See generally* JOHN MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION 134–37 (1988).

323. On ECHA's most recent additions to the Authorization List, see Herbatschek et al., *supra* note 175, at 135; *ECHA Proposes Five Substances for Authorisation*, CHEMICAL WATCH (Feb. 10, 2014), http://chemicalwatch.com/18322/echa-proposes-five-substances-for-authorisation.

324. *See* REACH, Preamble (77), art. 58.

325. *See* SVHC IMPLEMENTATION PLAN, *supra* note 241, at 13–14.

326. Herbatschek et al., *supra* note 175, at 152–55.

327. *See generally* EUROPEAN ENVTL. BUREAU & CLIENT EARTH, IDENTIFYING THE BOTTLENECKS IN REACH IMPLEMENTATION: THE ROLE OF ECHA IN REACH'S FAILING IMPLEMENTATION 42–43 (2012), *available at* http://www.eeb.org/EEB/?LinkServID=53B19853-5056-B741-DB6B33B4D1318340.

328. *See* Abelkop et al., *supra* note 79, at 11045.

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 sections 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.[329] 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 U.S. 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 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

329. CEPA §§ 91(1), 92(1).

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 de-selection, tort litigation, or 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 U.S).[330] 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 four to five million Euros per year, apart from REACH enforcement activities. If the activities of all twenty-eight Member States are counted, the public investment in REACH in the Member States may be ten to fifteen times the level of the investment in the Netherlands.[331] The Canadian government has allocated about $500 million Canadian (~ $450 million U.S.) for each of the first two five-year phases of the CMP,[332] and accounts from government and stakeholders in Canada report that this level of

330. ECHA, PRELIMINARY CONCLUSIONS, 32ND MANAGEMENT BOARD MEETING 2 (2013), *available at* http://echa.europa.eu/documents/10162/13608/preliminary_conclusions_mb32_en.pdf; ECHA, WORK PROGRAMME 2014, at 68 (2014), *available at* http://echa.europa.eu/documents/10162/13608/final_mb_39_2013_wp_2014_en.pdf.

331. These numbers reflect personal estimates from peer reviewers.

332. *Backgrounder: Canada's Chemicals Management Plan*, HEALTH CAN. (Oct. 2011), http://hc-sc.gc.ca/ahc-asc/media/nr-cp/_2011/2011-128bk-eng.php.

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 that of Canada. Chemicals sales in 2012 were €539 billion in the EU and $45 billion (Canadian) in Canada.[333] ECHA experienced early budget shortfalls, though they were largely due to infrastructural and implementation difficulties that have now been mostly addressed.[334] Regardless of how they are compared, both Canada and the EU provide substantial public funds to chemicals assessment and regulatory decision-making.

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.[335] 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.

333. *Chemicals*, EUR. COMMISSION, http://ec.europa.eu/enterprise/sectors/chemicals/index_en.htm (last visited Nov. 8, 2014); *Manufacturing Sales, by Subsector*, STATISTICS CAN., http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/manuf11-eng.htm (last modified Oct. 16, 2014).

334. *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.

335. *See* Charles M. Auer, *Periodic Reporting of Hazard Data, Exposure Information on Existing Chemicals*, BNA DAILY ENV'T REP., Apr. 14, 2010, at B-7, *available at* http://www.actagroup.com/uploads/docs/00059082.pdf; Lynn L. Bergeson, *Do It Now, or It May Never Be Done*, ENVTL. F. (Washington, D.C.), May/June 2014, at 446.

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?[336] 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.[337]

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 undertaking inspection and monitoring programs throughout the supply chain of chemical production from use to 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:

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

337. Applegate, *Synthesizing*, supra note 74, at 736–37.

> 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.[338]

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 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

338. *Id.* at 745.

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.[339] 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.[340] 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 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 section 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

339. *Id*.

340. *See* ERICA CRAWFORD & TIM WILLIAMS, PARLIAMENTARY INFORMATION & RES. SERV., LIBRARY OF PARLIAMENT, INTERNATIONAL MANAGEMENT OF CHEMICALS 9 (2006).

assessing whether to control, or the manner in which to control, a substance."[341] Recall that a substance is CEPA-toxic "if it is entering or may enter the environment in a quantity or concentration or under conditions that" may result in harm to human health or the environment.[342] 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 sections 71 and 72, authorities can require the submission of existing and new data through surveys (mandatory data submissions) of companies.[343] There is no substantial burden of proof or procedural hurdle that EC must surpass to issue a data submission survey under section 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 U.S. *Federal Register*.[344]

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 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 U.S. 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

341. CEPA § 71.

342. *Id.* § 64.

343. *Id.* §§ 71, 72. CEPA section 72 conditions authority to require generation of new information under CEPA section 71(c) on authorities having a reason to suspect that a substance could be CEPA-toxic, or if the substance has been determined as a CEPA-toxic or is able to become one. *Id.* § 72. Therefore, the government cannot require the generation of new information for a priori information gathering.

344. *See id.* § 71(1)(a)-(b).

government.[345] For the Challenge, the notices applied to batches of fifteen to thirty substances and addressed substances alone as well as in products or mixtures.[346] 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."[347]

Some stakeholders have reported difficulty due to a lack of clarity in requests (e.g., regarding the level of detail required) or from the limitations they face accessing certain data (e.g., uses throughout the supply chain).[348] EC, however, has been diligent in gathering feedback on data submission challenges and has included stakeholders in the design of section 71 notices.[349] EC has encouraged companies to cooperate in submitting data on their own and/or through industry organizations.[350]

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 collect data from REACH registration dossiers from the registrants themselves rather than from ECHA because the registrants own the data.[351]

Under the CMP, EC and HC use the information gathered in section 71 surveys to conduct SLRAs to determine whether or not substances are CEPA-toxic. In addition, some data are generated

345. *Id.* § 71(2). *See, e.g.*, ENV'T CAN. GUIDANCE FOR RESPONDING TO THE NOTICE WITH RESPECT TO CERTAIN SELENIUM-CONTAINING SUBSTANCES (NOTICE) 5, 17–18, 22 (2013), *available at* https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=ECA8FF32-1.

346. Elpi Karalis & Daren Kelland, Presentation at the Industry Coordinating Group CEPA Update Conference in Mississauga, Ontario: Information Gathering Under the Chemicals Management Plan (CMP) 3 (June 6, 2013) (on file with authors).

347. Gov't of Can., *Domestic Substances List Inventory Update*, CHEMICAL SUBSTANCES, http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche /dsl-lis-eng.php (last modified June 12, 2013).

348. Karalis & Kelland, *supra* note 346, at 4–6.

349. *Id.* at 7, 12.

350. Karalis & Kelland, *supra* note 346, at 15.

351. *Id.* at 16; Daren Kelland & Elpi Karalis, Presentation at the Industry Coordinating Group CEPA Update Conference in Mississauga, Ontario: Information Gathering Under the Chemicals Management Plan (CMP) 6 (Oct. 9, 2014) (on file with authors).

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 section 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 or under conditions that" *may* cause harm to human health or the environment.[352] 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,[353] no guidance has been released that specifies the ministries' burden of proof in determining whether or not a substance *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

352. CEPA § 64. *See id.* §§ 65(3), 77(4) (emphasis added).

353. Persistence and Bioaccumulation Regulations, *supra* note 111, at 1–2.

environment "results primarily from human activity," it *must* be recommended for addition to the TSL and is automatically considered for "Virtual Elimination"[354] —prohibition on the release of a substance beyond a certain threshold under which the substance cannot be accurately measured in emissions and effluents.[355] 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.[356] 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.[357] They may add the substance to the Priority Substances List, though this path has been all but abandoned as a risk assessment provision.[358] Finally, the ministries may recommend that a substance be added to the TSL, which is a formal step toward risk management measures.[359]

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 issue a "proposed regulation or instrument respecting preventive or control actions in relation to a

354. CEPA, § 77(3); *Toxic Substances List*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1 (last modified Nov. 6, 2013).

355. *See generally The Canadian Environmental Protection Act, 1999 and Virtual Elimination*, ENV'T CAN., https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=BB1FDE0A-1 (Mar. 3, 2013).

356. CEPA § 77(2).

357. *See id.* § 77(2)(a).

358. *See id.* § 77(2)(b).

359. *Id.* § 77(2)(c). 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 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 122.

substance."[360] As of November 2013, there are 132 substances or types of substances on the TSL.[361]

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.[362] The agencies may also issue guidelines, standards, or codes of practice or may facilitate voluntary risk management efforts.[363] For example, authorities have issued regulations that pertain to specific TSL substances (e.g., polybrominated diphenyl ethers and PCBs),[364] certain sources of TSL substances (e.g., pulp and paper mill effluent containing chlorinated dioxins and furans),[365] certain uses and products that contain TSL substances (e.g.,

360. CEPA § 91(1).

361. *Toxic Substances List – Schedule 1*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1&wsdoc=4ABEFFC8-5BEC-B57A-F4BF-11069545E434 (last modified Aug. 4, 2014).

362. CEPA § 93.

363. *Id.* § 93 (risk management tools); *id.* § 95 (requirement to report releases); *id.* § 98 (liability for remedial efforts after a release); *id.* § 100 (export controls). *See* Meek & Armstrong, *supra* note 94, at 598; U.N., DEP'T OF ECON. & SOC. AFFAIRS, *supra* note 137, at 8.

364. ENV'T CAN., PROPOSED RISK MANAGEMENT MEASURE FOR POLYBROMINATED DIPHENYL ETHERS (PBDES) (2013), *available at* http://www.ec.gc.ca/ese-ees/92B7DD05-793A-4E4C-9742-3A25EB2529BE/PBDEs_Consultation_EN.pdf; *PCB Regulations (SOR/2008-27)*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=105 (last modified Aug. 26, 2014; *Polybrominated Diphenyl Ethers (PBDEs)*, ENV'T CAN., http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=5046470B-2D3C-48B4-9E46-735B7820A444 (last modified Oct. 3, 2013); *Risk Management of DecaBDE: Commitment to Voluntary Phase-Out Exports to Canada*, ENV'T CAN., http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=en&n=F64D6E3B-1 (last modified July 23, 2013).

365. Polychlorinated dibenzodioxins, ENV'T CAN., http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=1794091E-5FC5-40F9-BB0B-E823BFC418C6 (last modified July 23, 2013); Pulp and Paper Mill Effluent Chlorinated Dioxins and Furans Regulations (SOR/92-267), ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=21 (last modified Aug. 26, 2014).

concentration limits for 2-butoxyethanol in products for indoor use),[366] and more general risk management tools.

One such tool is the Prohibition of Certain Toxic Substances (PCTS) regulations.[367] 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."[368] The PCTS regulations include several sub-lists, also called schedules.[369] At present, the twelve substances listed on Schedule 1 are prohibited from manufacture, import, sale, and use.[370]

PCTS Schedule 2 functions somewhat like REACH authorization: listed substances are prohibited from manufacture, import, and sale, unless exemptions are provided under limited authority.[371] 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.[372] 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

366. *2-Butoxyethanol Regulations (SOR/2006-347)*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=97 (last modified Aug. 26, 2014).

367. Prohibition of Certain Toxic Substances Regulations, SOR/2012-285 (Can.), *available at* http://laws-lois.justice.gc.ca/PDF/SOR-2012-285.pdf [hereinafter PCTS Regulations].

368. *Polybrominated Biphenyls*, ENV'T CAN., http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=7194BA9D-887F-4426-A2BE-E7E20560B67B (last modified Aug. 8, 2013).

369. PCTS Regulations, *supra* note 367, at 3.

370. *Id.* at Schedule 1, Part 1.

371. *Id.* at Schedule 2, Parts 1–3.

372. *Id.* § 10.

management decision-making process that follows a finding that a substance is CEPA-toxic and its addition 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.[373] 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.[374] 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.[375]

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.[376] 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.[377]

Some criticize the Canadian approach for not fully reversing the burden of proof of safety on to industry.[378] The legislation does not require industry to make a safety determination, but CEPA does authorize EC and HC to compel industry to provide

373. *See Pollution Prevent (P2) Plans*, ENV'T CAN., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=BC71EA4E-1 (last modified Sept. 24, 2013).

374. ENV'T CAN., POLLUTION PREVENTION PLANNING PROVISIONS OF PART 4 OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999, FREQUENTLY ASKED QUESTIONS 1-3 (2008), *available at* http://publications.gc.ca/collections/collection_2009/ec/En4-91-2-2008E.pdf [hereinafter ENV'T CAN., POLLUTION PREVENTION].

375. *See generally id.* at 3.

376. *See generally SNAc Approach*, *supra* note 122.

377. *Policy on the Use of Significant New Activity Provisions of the Canadian Environmental Protection Act, 1999*, ENV'T CAN., https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5CA18D66-1 (last modified Dec. 24, 2013).

378. *See, e.g.*, Adam Briand, *Reverse Onus: An Effective and Efficient Risk Management Strategy for Chemical Regulation*, 53 CAN. PUB. ADMIN. 489 (2010).

data in specific cases[379] and, in 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 refine those estimates, as necessary and where possible, depending on the level of information available.[380] P2 plans also reverse the burden of proof of safety onto industry by establishing a risk management objective that industry is responsible for meeting.[381]

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.[382] As of 2013, none of the stakeholders are seeking to overhaul the system to the degree they are currently in the United States.[383]

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 (CSR) for the substance must be added to the registration

379. CEPA § 71(1).

380. This is a technical process that is motivated by value-of-information thinking. *See generally* NAT'LRESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 110–11 (1995).

381. *See* ENV'T CAN., POLLUTION PREVENTION, *supra* note 374, at 2–3.

382. *See* ENVTL. DEF., *supra* note 120, at 15; Goodhand et al., *supra* note 276.

383. Cheryl Hogue, *Support Grows for Chemical Law Reform*, CHEMICAL & ENGINEERING NEWS, June 10, 2013, at 22–23.

dossier.[384] 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.[385] 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.[386] Information on substances makes its way through the supply chain via documents called Safety Data Sheets.[387]

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.[388] REACH does require basic information regarding hazards,[389] 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.[390] 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.[391] 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

384. REACH, arts. 10(b), 14(1).

385. *Id.* art. 14(3).

386. *Id.* art. 14(4).

387. *See id.* arts. 31-32.

388. *See, e.g.*, WARGO, *supra* note 28, at 287 (The "REACH testing program" is "an important step" because it "will require toxicity testing by manufacturers of more than 30,000 compounds.").

389. REACH, Annex VII–X.

390. *See generally* ECHA, GUIDANCE ON INFORMATION REQUIREMENTS AND CHEMICAL SAFETY ASSESSMENT (2012), *available at* http://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf (discussing as an example, aquatic toxicity to sediment organisms). *See also* UK REACH COMPETENT AUTH., MINIMIZATION OF ANIMAL TESTING (2012), *available at* http://www.hse.gov.uk/reach/resources/18animaltesting.pdf.

391. *See generally* Herbatschek et al., *supra* note 175, at 127, 150 (for example, Quantitative Structure-Activity Relationships).

involves preparation of detailed justification documents and a laborious process of answering questions from ECHA.[392] In some cases, registrants decide it is less onerous to perform tests—even if they are expensive—than to seek ECHA acceptance of adaptations.[393]

One indication of the limited quantity of animal testing that is 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.[394] 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).[395] 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.[396]

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").[397] 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

392. ECHA, HOW TO AVOID UNNECESSARY TESTING ON ANIMALS 12 (2010), *available at* http://echa.europa.eu/documents/10162/13655/pg_avoid_animal_testing_en.pdf.

393. Gerwin Schaafsma et al., *REACH, Non-Testing Approaches and the Urgent Need for a Change of Mind Set*, 53 REG. TOXICOLOGY & PHARMACOLOGY 70, 78 (2009).

394. Bjorn Hansen & Mike Penman, *Is REACH Achieving Its Objectives?*, *in* THE EUROPEAN UNION REACH REGULATION: LAW AND PRACTICE 376–77 (Lucas Bergkamp ed., 2013).

395. *Id.* at 387.

396. *Id.*

397. *Registration*, ECHA, http://echa.europa.eu/en/regulations/reach/registration (last visited Nov. 5, 2014).

all companies in the group.[398] 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.[399] One company 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.[400] 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.[401] 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.[402] 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.[403] Registration has not only facilitated communication among risk

398. *See* Adam D.K. Abelkop et al., *How can REACH be Improved?*, *in* THE EUROPEAN UNION REACH REGULATION: LAW AND PRACTICE 390, 393–94 (Lucas Bergkamp ed., 2013).

399. *See* Mike Penman & Martin Richards, *REACH Consortia*, *in* THE EUROPEAN UNION REACH REGULATION: LAW AND PRACTICE 185, 191 (Lucas Bergkamp ed., 2013).

400. Abelkop et al., *supra* note 79, at 11051-53.

401. Mike Penman & Martin Richards, *REACH Consortia*, *in* THE EUROPEAN UNION REACH REGULATION: LAW AND PRACTICE 186 (Lucas Bergkamp ed., 2013). "If each stakeholder had to submit their own intrinsic hazard data, . . . a large amount of unnecessary animal testing [could occur]." *Id.* Hungary and the UK succeeded with an amendment to REACH calling for "one substance, one registration." *Id.*

402. *See Registered Substances*, *supra* note 189.

403. Abelkop et al., *supra* note 79, at 11056.

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 and product design.[404] 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.[405]

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."[406] 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,"[407] 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

404. *See id.* at 11046–47.

405. *Registered Substances, supra* note 189.

406. Abelkop et al., *supra* note 398, at 390–93.

407. *See id.* at 390; David Santillo & Paul Johnston, *Effect Thresholds and 'Adequate Control' of Risks: The Fatal Flaws in the EU Council's Position on Authorisation Within REACH*, 13 ENVTL. SCI. & POLLUTION RESEARCH INT'L 425, 429 (2006). *But see* REACH, Annex I § 6.4 (describing how adequate control is defined and ECHA's guidance on how it is defined in practice); ECHA, GUIDANCE IN A NUTSHELL: CHEMICAL SAFETY ASSESSMENT, 18–19 (2009), *available at* http://echa.europa.eu/documents/10162/13632/nutshell_guidance_csa_en.pdf.

of exposures (e.g., ECHA cannot pull a registration because it believes risk management measures are inadequate).[408]

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.[409] However, the registrants have concluded in their dossier that it is not a vPvB.[410] Substances that are vPvB (along with PBTs and CMR substances) are considered "non-threshold" substances under the statute.[411] 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).[412]

408. *See* MILIEU ENVTL. LAW & POLICY, *supra* note 283, at 7.

409. ECHA, IDENTIFICATION OF PBT AND VPVB SUBSTANCE: RESULTS OF EVALUATION OF PBT / VPVB PROPERTIES 120 (2014), *available at* http://echa.europa.eu/documents/10162/13628/decamethyl_pbtsheet_en.pdf.

410. ECHA, *PBT Assessment: Overall Result*, DECAMETHYLCYCLOPENTASILOXANE, http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d82d68d-a71c-2317-e044-00144f67d249/AGGR-987c9eda-73dc-413e-9d74-c56194ad1383_DISS-9d82d68d-a71c-2317-e044-00144f67d249.html#AGGR-987c9eda-73dc-413e-9d74-c56194ad1383 (last visited Nov. 8, 2014).

411. *See* REACH, art. 60(2)–(3).

412. 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*

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 companies' determinations of what constitutes "safety." Chemical manufacturers have the most direct control over internal safety in handling chemicals and less control over the safety in 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.[413]

The EU may also supplement the safety measures in registration dossiers by managing risks through the authorization and restriction mechanisms under REACH.[414] 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.[415] As an alternative, the

Abelkop et al., *supra* note 398, at 390–93; Abelkop et al., *supra* note 79, at 11062–64.

413. *See* Herbatschek et al., *supra* note 175, at 130.

414. *Id.* at 133–152.

415. *See id.* at 136.

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.[416]

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.[417] 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).[418] 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.[419]

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.[420] In 2013, ECHA received a total of eight authorization requests covering two phthalates in seventeen different uses.[421] In 2014, ECHA received nineteen authorization requests.[422]

416. *See id.* at 145.

417. *See id.* at 139.

418. *Id.* at 140.

419. Herbatschek et al., *supra* note 175, at 140.

420. Press Release, ECHA, Authorisation to Use a Substance of Very High Concern - First Opinions Adopted (Jan. 3, 2014), *available at* http://echa.europa.eu/view-article/-/journal_content/title/authorisation-to-use-a-substance-of-very-high-concern-first-opinions-adopted.

421. *Id.*

422. *Statistics on Received Applications*, ECHA, http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications (last modified Mar. 20, 2015).

Prior to the first authorization decision, the common perception among industry stakeholders was that the authorization process would be strict, onerous, and unpredictable with regard to outcome.[423] 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.

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.[424] Many jurisdictions, including the EU, U.S., 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

423. Herbatschek et al., *supra* note 175, at 134, 139–45.

424. *See* GUIDO CALABRESI, THE COST OF ACCIDENTS 135–97 (1970); Jonathan B. Wiener, *The Real Pattern of Precaution*, *in* THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE 519, 529 (Jonathan B. Wiener et al. eds., 2011).

databases for existing chemicals; and the industry's response to recent challenges such as the various High Production Volume initiatives[425] tend to confirm that it understands these expectations, although there is still a long way to go before the entire spectrum of legacy 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.[426] TSCA section 2 also states, "the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[427] 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.[428] 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

425. *See High Production Volume (HPV) Challenge*, EPA, http://www.epa.gov/hpv/index.htm (last updated Apr. 22, 2013).

426. However, EC and HC have also spent significant resources and time mining existing data and developing predictive tools. *See generally The Health-Related Components of Categorization of the Domestic Substances List (DSL): Approach, Results, and Next Steps*, HEALTH CAN., http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-approche-eng.php (last modified Jan. 31, 2008).

427. 15 U.S.C. § 2601(b)(1) (2012).

428. *See* Applegate, RESCUING, *supra* note 87, 263–65.

the environment, and the wide range of risk management measures that are already employed by companies.[429]

The approval processes for agricultural chemicals and pharmaceuticals also place the burden of data generation on the private sector, as do the various permit processes under the Clean Air Act and Clean Water Act and those applicable to many other industrial facilities such as oil and 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.[430] 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. 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.[431]

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.[432] None of the registrants want to be exposed to the risk of potential delays, a refusal of registration based on inadequate information, or the potential reputation damages caused from submitting misleading

429. For a discussion of the issues regarding whether data should be generated by industry or government, see Applegate, RESCUING, *supra* note 87, at 263–75.

430. *Id*. at 273–75; JOE 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 335, 361 (Lucas Bergkamp ed., 2013) (discussing the government of Japan's preference to not rely on industry-generated data).

431. *See generally Compliance Checks*, ECHA, http://echa.europa.eu/regulations/reach/evaluation/compliance-checks (last visited Nov. 6, 2014).

432. *See generally* Lucas Bergkamp & Mike Penman, *Conclusions*, *in* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 410, 427 (Lucas Bergkamp ed., 2013).

safety information to the government. More generally, it is not difficult to imagine negative consequences that could result for a company that is shown to have submitted incomplete, misleading, or fraudulent data to a regulatory body. Under U.S. 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.[433]

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.[434] 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.[435] On the other hand, neither CEPA nor REACH precludes the 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

433. Under U.S. tort law, a company might face large punitive damages if it intentionally misled the government, and this resulted in harm to consumers or the environment. *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350 (1974) (defining punitive damages); ALEXANDER VOLOKH, REASON FOUND., POLICY STUDY NO. 213: PUNITIVE DAMAGES AND ENVIRONMENTAL LAW: RETHINKING THE ISSUES 10 (1996), *available at* http://reason.org/files/76a01f43ff7eec045e97b61c0f23caf5.pdf; Rae Zimmerman, *Governmental Management of Chemical Risk: Regulatory Processes for Environmental Health* 103–05 (1990) (citing examples of chemical damage claims against Monsanto for $16 million in 1983 and $108 million 1986, the latter including $100 million in punitive damages).

434. Sheila Jasanoff, *Watching the Watchers: Lessons from the Science of Science Advice*, GUARDIAN, Apr. 8, 2013, http.www.theguardian.com/science /political-science/2013/apr/08/lessons-science-advice.

435. *See, e.g.*, REACH, art. 13(4) (requiring that ecotoxicological and toxicological tests be carried out under GLP or other international standards); Karalis & Kelland, *supra* note 346.

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

Under U.S. and Canadian law, chemical manufacturers and users are already subject to affirmative duties of care that are expressed in tort laws.[436] TSCA, however, places the burden of making the safety determination on the government, as does CEPA.[437]

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).[438] 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

436. *See* Renn & Elliott, *supra* note 62, at 228 (stating the potential civil liability in the United States from chemical risks is at least as important as the regulatory system).

437. Denison, *Ten Essential*, *supra* note 75, at 10020.

438. *See* Lucas Bergkamp, *Does REACH Present a Business Opportunity?*, *in* THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE 396, 408 (Lucas Bergkamp ed., 2013).

which safety-determination approach—or what form of hybrid model—is preferable in the U.S. 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 U.S. regulators, and our political, commercial, and scientific cultures.

Although either burden location in TSCA reform could 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. Elsewhere we have argued that the safety standard in REACH is not clear and consistent,[439] 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.[440] Moreover, EPA has experience in developing a wide

439. Abelkop et al., *supra* note 398, at 390.

440. On EPA's slow pace of issuing risk assessment guidelines and performing hazard assessments for specific chemicals, see E. Donald Elliott & Gail Charnley, *Private Product-Risk Assessment and the Role of Government*, 23

variety of risk assessment guidelines that could be applied to industry risk assessments.[441] 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 U.S. regulators in many other health, safety, and environmental programs ranging from 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 the Federal Insecticide, Fungicide, and Rodenticide Act (and thus become eligible for accelerated registration decisions), EPA is put in the role of reviewing the risk assessments prepared by industry.[442] Likewise, although EPA does not routinely review industry risk assessments under TSCA's new chemical program, the agency does have relevant experience reviewing TSCA section 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

JOHN LINER REV. 73, 77 (2009). *See generally* NRC 2009, *supra* note 38, at 45–47, 56–57.

441. *See Guidance & Tools*, EPA, http://www.epa.gov/risk_assessment/guidance.htm (last updated Apr. 28, 2014).

442. *See Conventional Reduced Risk Pesticide Program*, EPA, http://www.epa.gov/opprd001/workplan/reducedrisk.html (last updated Mar. 4, 2014).

Cooperation and Development's Screening Information Data Set (SIDS) program.[443] 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.[444]

We recognize that EPA has recently pledged[445] (and indeed has made some) significant progress in the preparation of risk assessments under the current TSCA regime,[446] though the scope of the activity is modest compared to what has happened in Europe since 2006.[447] 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.[448] 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, U.S. 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.

443. *See OECD SIDS Voluntary Testing Program for International High Production Volume Chemicals,* EPA, http://www.epa.gov/oppt/chemtest/pubs/oecdsids.html (last updated Apr. 27, 2011).

444. *See generally* Robert Diderich, *The OECD Chemicals Programme*, *in* RISK ASSESSMENT OF CHEMICALS: AN INTRODUCTION 623, 633 (C.J. van Leeuwen & T.G. Vermeire eds., 2007).

445. Cheryl Hogue, *Assessing Chemicals: New EPA Effort Targets Dozens of Substances Already on the Market for In-Depth Scrutiny*, CHEMICAL & ENGINEERING NEWS, Apr. 30, 2012, at 28–30.

446. *See Assessments for TSCA Work Plan Chemicals*, EPA, http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html (last updated Oct. 23, 2014).

447. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-249, TOXIC SUBSTANCES: EPA HAS INCREASED EFFORTS TO ASSESS AND CONTROL CHEMICALS BUT COULD STRENGTHEN ITS APPROACH 16 (2013).

448. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-696T, CHEMICAL REGULATION: OBSERVATIONS ON THE TOXIC SUBSTANCES CONTROL ACT AND EPA IMPLEMENTATION 13 (2013).

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 section 71 surveys complete reciprocity, the data burdens on U.S. 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 increase in information on chemical hazards and exposures as well as advancements in risk assessment techniques. To most effectively take advantage of this changing landscape, a reformed TSCA should apply dynamic, adaptive assessment and management decision-making processes.

Nonetheless, it may not be wise for U.S. policy makers to apply a formal registration system to as many chemicals as in Europe. There are small and medium-sized businesses in the U.S. 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 U.S. 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 for 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 information.[449] Registration would be valuable in confirming the quality of the existing information and in 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 U.S. 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 U.S., since we know what caused problems in Europe and many of those issues 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 U.S. legislation builds on the experience ("warts and all") of 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 U.S. 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 a matter of prudent political

449. *See* TSCA Inventory Update Reporting Modifications; Chemical Data Reporting, 76 Fed. Reg. 50, 816 (Aug. 16, 2011) (codified in 40 C.F.R. pts. 704, 710, and 711).

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 U.S. registration system.

IV. 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 to 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 de-selection of the chemicals that present the greatest concern, with encouragement to compete on the basis of green and sustainable chemistry for safer substances.[450] 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.[451]

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 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

450. The burden of producing registration dossiers under REACH has not necessarily spurred innovation in green chemistry. In fact, the early years of REACH implementation have witnessed a shift of highly skilled scientists in the industry from research and development to regulatory compliance. The result may be more data generation and warehousing than innovations in green chemistry. CTR. FOR STRATEGY & EVALUATION SERVS., INTERIM EVALUATION: IMPACT OF REACH REGULATION ON THE INNOVATIVENESS OF THE EU CHEMICAL INDUSTRY, REPORT TO EUROPEAN COMMISSION, ENTERPRISE AND INDUSTRY, at iii (2012), *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf.

451. *See* Melody M. Bomgardner, *Walmart and Target Take Aim at Hazardous Ingredients*, CHEMICAL & ENGINEERING NEWS, Feb. 17, 2014, http://cen.acs.org/articles/92/i7/Walmart-Target-Take-Aim-Hazardous.html; Bomgardner, *supra* note 306.

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.[452] 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 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.

452. S. 1009, 113th Cong. § 6(c)(1), (2), (9) (2013); STAFF OF H.R. ENERGY & COMMERCE COMM., 113TH CONG., DISCUSSION DRAFT ON CHEMICALS IN COMMERCE ACT § 6(b), (c) (Comm. Print 2014), *available at* http://docs.house.gov/meetings/IF/IF18/20140429/102160/BILLS-113pih-TheChemicalsinCommerceAct.pdf.

Appendix A: Names and Affiliations of Interview Subjects, Peer Reviewers, and Commenters

Name	Affiliation	Date of Interview/ Review
John Applegate‡	Indiana University	May 2014
Jon Arnot*	University of Toronto	Feb. 2013
Charlie Auer*†	Charles Auer & Associates, LLC	Nov. 2012
Lynn Bergeson‡	Bergeson & Campbell, PC	May 2014
Lucas Bergkamp‡	Hunton & Williams, LLP	May 2014
Sylvain Bintein*	DG-Environment, European Commission	Apr. 2013
Mark Bonnell*	Environment Canada	Apr. 2013
Vito Buonsante*	ClientEarth	May 2013
Bill Carroll*	Occidental Chemical Corporation	Jan. 2012
Holly Davies*	Department of Ecology, Washington State	Mar. 2013
Dennis Devlin‡	ExxonMobil	May 2014
Bob Diderich*	Organization for Economic Cooperation and Development	Apr. 2013
Peter Dohmen*	BASF	June 2013
Danie Dubé ‡	Environment Canada	May 2014
Steve Dungey*	Environment Agency, United Kingdom	May 2013
E. Donald Elliott†	Covington & Burling, LLP; Yale Law School	May 2014
Cathy Fehrenbacher*	Environmental Protection Agency, USA	Mar. 2013
Christina Franz*	American Chemistry Council	Nov. 2012
Vincenza Galatone*	Environment Canada	Apr. 2013

Mike Gallagher*	Department of Ecology, Washington State	Mar. 2013
Anna Gergely‡	Steptoe & Johnson, LLP	May 2014
John Giesy*	University of Saskatchewan	May 2013
Serena Giordano‡	European Chemicals Agency	May 2014
Geoff Granville*†	GCGranville Consulting Corp.	Feb. 2014
Mark Greenwood*	Greenwood Environmental Council	Dec. 2012
Joshua Grice*	Department of Ecology, Washington State	Mar. 2013
Joseph H. Guth*	University of California, Berkeley	Feb. 2013
Dale Hattis‡	Clark University	May 2014
Veerle Heyvaert†	London School of Economics	May 2014
Ron Hites*	Indiana University	Apr. 2013
Phil Howard*	Syracuse Research Corporation	Jan. 2012
David Kent*	Keller & Heckman	Mar. 2013
Amardeep Khosla*	Industry Coordinating Group for Canadian Environmental Protection Act	Feb. 2013
Masaru Kitano*	Meiji University	Apr. 2013
Joop de Knecht*	Organization for Economic Cooperation and Development	Apr. 2013
Akos Kokai*	University of California, Berkeley	Mar. 2013
Eeva Leinala*‡	Health Canada	Mar. 2013, May 2014
Fe de Leon*	Canadian Environmental Law Association	Feb. 2014
Peter Lepper*	European Chemicals Agency	Mar. 2013
Gordon Lloyd*‡	Chemistry Industry Association of Canada	Mar. 2013, May 2014
Laurence Libelo*	Environmental Protection Agency, USA	Mar. 2013
Jeff Lincer*‡	Researchers Implementing Conservation Action	Sept. 2013, May 2014
Petteri Mäkelä‡	European Chemicals Agency	May 2014
Don Mackay*	Trent University	Feb. 2013

Petteri Mäkelä*	European Chemicals Agency	Mar. 2013
Gary Marchant	Arizona State University	May 2014
Kevin Masterson*	Department of Environmental Quality, Oregon	Mar. 2013
Bette Meek*	University of Ottawa	Apr. 2013
Kai Melzer‡	European Chemicals Agency	May 2014
John Moffett*	Environment Canada	Apr. 2013
David Morin*	Environment Canada	Apr. 2013
D. Warner North†	NorthWorks, Inc.	May 2014
Johanna Peltola-Thies*	European Chemicals Agency	Mar. 2013
Ortwin Renn†	University of Stuttgart	May 2014
Todd Royer‡	Indiana University	Apr. 2014
Christina Rudén	Stockholm University	May 2014
Jake Sanderson*‡	Environment Canada	Apr. 2013
Linda Santry*	NOVA Chemical Corp.	Apr. 2013
Martin Scheringer‡	ETH Zürich	May 2014
Dayna Scott†	Osgoode Hall Law School, York University	May 2014
Jennifer Seed*	Environmental Protection Agency, USA	Mar. 2013
David Shortt*	Dow Chemical Canada ULC	Apr. 2013
Dick Sijm*‡	RIVM	May 2013, May 2014
Georg Streck*	DG-Enterprise, European Commission	Apr. 2013
Anna-Liisa Sundquist*	European Chemicals Agency	Mar. 2013
Jose Tarazona*	European Chemicals Agency	Mar. 2013
Eisaku Toda*	Ministry of the Environment, Japan	May 2013
Henrik Tyle*	Environmental Protection Agency, Denmark	May 2013
Kees van Leeuwen†	Utrecht University	May 2014
Marta Venier‡	Indiana University	May 2014
Rob Visser*	Organization for Economic Cooperation and Development (ret.)	Jan. 2013

Mike Walls*	American Chemistry Council	Nov. 2012
David Widawksy*	Environmental Protection Agency, USA	Mar. 2013
Jonathan Wiener‡	Duke University	Sept. 2014
Dolf van Wijk*	Cefic	Apr. 2013
Graham Willmott*	DG-Enterprise, European Commission	Apr. 2013

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

* Interview Subject

† Compensated Peer Reviewer

‡ Commenter