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INTERNATIONAL MANAGEMENT OF CHEMICALS

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INTERNATIONAL MANAGEMENT OF CHEMICALS

INTRODUCTION

Governments worldwide are examining new approaches to chemicals management in order to improve environmental and public safety and health, while encouraging a competitive chemicals industry. The *Canadian Environmental Protection Act 1999* (CEPA 1999) is Canada's attempt at a new generation of chemicals legislation and it contains some aspects that are internationally groundbreaking. To put CEPA 1999 into international context, this paper provides an overview of principal chemicals legislation in the United States and Australia and the new legislation proposed in the European Union (EU). CEPA 1999 is currently under statutory parliamentary review, and a section of this document briefly discusses these international efforts with respect to some of the issues identified to date in the review.

UNITED STATES

The *Toxic Substances Control Act* (TSCA) of 1976 is the main legislation dealing with the manufacture, import, use and distribution of chemical substances in the United States (U.S.). Other statutes relating to chemicals management are the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), *Federal Food, Drug and Cosmetic Act* (FFDCA) and the *Occupational Safety and Health Act* (OSH Act).(1)

The TSCA authorizes the Environmental Protection Agency (EPA) to review and manage chemical substances before and after they enter the market. Industry is required to notify the EPA a minimum of 90 days in advance of the production or import of a new

(1) Commission for Environmental Cooperation (CEC), "Summary of Environmental Law in the United States: Chemical Substances and Products," *Summary of Environmental Law in North America database*, September 2003, http://www.cec.org/pubs_info_resources/law_treat_agree/summary_enviro_law/publication/usdoc.cfm?varlan=english&topic=11 (accessed 1 June 2006).

substance, and to provide various types of information that the EPA can use to determine risk. Any data suggesting that a chemical poses a substantial risk must be reported.(2) The EPA may review chemicals to determine whether they pose an "unreasonable risk," in which case various actions are available to the Agency to ban, restrict, or otherwise manage them. In the case of existing substances, the EPA must find that "a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk to human health or the environment" and choose the "least burdensome" regulation that adequately addresses the risk. The EPA must also consider the costs and benefits of the proposed regulation.(3)

The TSCA allows for individual states to regulate chemicals not already controlled under federal regulations. Accordingly, some states have passed legislation to restrict specific brominated flame retardants and other states, such as Maine and California, are developing their own chemicals policies.(4)

In 1994 and most recently in 2005, reviews by the U.S. General Accounting Office (GAO; renamed "Government Accountability Office" in 2004) found that a combination of legal, procedural and financial constraints had seriously limited the EPA in exercising its authorities under the TSCA, particularly with respect to controlling existing substances. It found that the EPA was often unable to access adequate data sets, had regulated few chemicals and had not fully assessed risks.(5) One of the main problems the GAO identified was that the burden of acquiring data with respect to the toxicity of chemicals rested with the EPA and that "EPA officials say the act's legal standards are so high that they have generally discouraged [the] EPA from using its authorities to ban or restrict the manufacture or use of chemicals."(6)

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(2) U.S. General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, Report to Congressional Requesters, Washington, DC, September 1994, http://archive.gao.gov/t2pbat2/152799.pdf (accessed 1 June 2006).

(3) U.S. Government Accountability Office, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, GAO-06-217R, Washington DC, 4 November 2005.

(4) D. Ditz, *Cloudy Skies, Chance of Sun: A Forecast for U.S. Reform of Chemicals Policy*, Center for International Environmental Law, 9 May 2006, www.ciel.org/Publications/Cloudy_Skies_9May06.pdf (accessed 29 May 2006).

(5) GAO (1994), pp. 3-5; U.S. Government Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, Washington DC, June 2005.

(6) United States Government Accountability Office, *Testimony Before the Committee on Environment and Public Works, U.S. Senate: Statement of John B. Stephenson, Director, Natural Resources and Environment*, GAO-06-1032T, 2 August 2006, http://www.gao.gov/new.items/d061032t.pdf#search=%22GAO-06-1032T%20%22 (accessed 14 August 2006)

A number of Acts aimed at improving chemicals management have been introduced in Congress, including the "Child, Worker and Consumer-Safe Chemicals Act," presented in the Senate in July 2005. The authors of this bill contend that the changes would address concerns outlined in the GAO's June 2005 report, although the proposal has been criticized by industry.(7) This bill has thus far not been given a committee hearing or preliminary vote.(8) Legislation is currently pending (House Resolution 4591) which would enable U.S. ratification of a number of international chemicals management agreements it has signed, through modifications to the TSCA. Several groups, including some state attorneys general and environmental organizations, oppose the legislation as written as they feel it may prevent states from implementing stricter restrictions on persistent organic pollutants covered by international agreements than those put in place by the EPA.(9)

EUROPEAN UNION

In 2003, the European Commission adopted a proposal for a new, integrated chemicals management policy entitled "Registration, Evaluation and Authorisation of Chemicals" (REACH). In addition to replacing more than 40 current directives and regulations, the regulations would introduce some significant shifts in chemicals management, notably reversing the burden of proof so that it rests with producers and importers rather than regulatory bodies, as well as systematically eliminating the distinction between existing and new substances through a phased registration process.

The implications of the proposed regulations will be felt within and outside of the EU's borders; accordingly, the process has been watched closely and has faced substantial opposition from industry groups and other countries.(10) In 2001, Canada submitted its position,

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(7) P. Phibbs, "Report Lists Actions Congress Could Take To Improve EPA Assessments Under TSCA," *Chemical Regulation Reporter*, Bureau of National Affairs, Vol. 29, No. 9, 18 July 2005, http://ehscenter.bna.com/pic2/ehs.nsf/id/BNAP-6EEFVN?OpenDocument (accessed 5 June 2006).

(8) Ditz (2006).

(9) New Jersey Department of Law and Public Safety, *Attorneys General Advise Against Bill That Would Limit States' Ability to Protect Against Dangerous Toxic Chemicals*, http://www.nj.gov/oag/newsreleases06/pr20060228a.html.

(10) See, for instance, *A Special Interest Case Study: The Chemical Industry, The Bush Administration, and European Efforts to Regulate Chemicals*, prepared for Rep. Henry A. Waxman, United States House of Representatives, Committee on Government Reform – Minority Staff, Special Investigations Division, 1 April 2004, http://www.democrats.reform.house.gov/story.asp?ID=427&Issue=Chemical+Regula.

in which it stated its belief in increasing international cooperation particularly through information-sharing as well as its concerns for the costs of REACH to small and medium-sized enterprises.(11) A significantly revised version of REACH passed first reading in the European Parliament in November 2005, and the Council of Ministers of the EU came to a political agreement on a revised text in December 2005. The final legislation is expected to be adopted later in 2006 and come into force in 2007.(12) A coalition of concerned trading countries led by the United States (Canada was not part of the coalition) released a joint press statement outlining its concerns with "REACH's workability, its potential effects on international trade, and the opacity of the regulatory process and implementation preparations."(13)

REACH will introduce a phased timeline (3, 6 or 11 years) for the registration of all chemicals produced in, or imported to, the EU in quantities greater than one metric tonne. For substances produced or imported in quantities greater than 10 tonnes, a chemical safety report will also be required that includes exposure and risk evaluations and information for downstream users.(14)

An EU Chemicals Agency will evaluate submissions on a priority basis and require authorization or restriction procedures where warranted. Those chemicals identified as substances of very high concern (SVHC)(15) will require authorization in order to be used or placed on the market. The aim of authorization is to establish proper control of risks and eventual replacement of the substance and the process applies to specified uses declared in the

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(11) *Comments on the European Regulation Concerning the Registration, Evaluation and Authorization of Chemical (REACH) by the Government of Canada*, submitted to the European Commission's Internet Public Consultation, 2003, http://ec.europa.eu/enterprise/reach/docs/consultation/public/canada_gvnt_public.pdf (accessed 14 June 2006).

(12) For a predicted timetable, see http://www.defra.gov.uk/environment/chemicals/reach/pdf/reach-timetable.pdf (accessed 8 June 2006).

(13) The United States Mission to the European Union, "REACH Requires Further Improvements, According to EU Trading Partners," 8 June 2006, http://useu.usmission.gov/Dossiers/Chemicals/Jun0806_REACH_Statement.asp.

(14) Lowell Center for Sustainable Production, University of Massachusetts Lowell, *REACH – The new E.U. chemicals strategy: a new approach to chemicals management*, www.chemicalspolicy.org/reach.shtml (accessed 7 June 2006).

(15) SVHCs are those that meet the following criteria: persistent, bioaccumulative and toxic (PBTs); carcinogenic, mutagenic, or toxic to reproduction (CMRs) category 1 and 2; very persistent and very bioaccumulative (vPvB); and those for which there is an equivalent level of concern to those already mentioned, based on scientific evidence of probable serious effects to human health or environment (to be identified case-by-case).

application for authorization. For substances that are not classified as SVHC but nonetheless are found to pose an unacceptable risk, the regulations allow for restrictions or a ban on the substance or particular uses.(16)

For chemicals in products, REACH would require registration of substances intended to be released from articles. It also requires notification for articles containing SVHC above a certain concentration and total quantity; however, this notification is exempted if exposure to humans can be avoided under reasonably foreseeable conditions; for example, by providing instructions for its proper use and disposal.(17)

The new regulations also stipulate the types of information that will or could be made publicly available by the Agency, except for information for which valid claims of commercial confidentiality are made. REACH aims to make information available so that the public can make informed choices about chemicals to which it is exposed.

AUSTRALIA

In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) came into effect in 1990, under the *Industrial Chemicals Notification and Assessment Act 1989*.

All chemicals available for use in Australia, more than 38,000 in total, are listed in the Australian Inventory of Chemical Substances, which comprises existing substances (those in use between January 1977 and February 1990) as well as assessed new substances.(18) All manufacturers and importers must also be registered with NICNAS, and provide secondary notification when there are changes in circumstances.

NICNAS assesses all new industrial chemicals and assesses existing chemicals on a priority basis where specific concerns are raised regarding human health and environmental effects. In the case of existing chemicals, if a substance is declared a priority existing chemical (PEC), all manufacturers and importers must apply for assessment to continue using the substance. Recommendations can be made by the regulatory authority regarding control and risk reduction for declared uses of the chemical.

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(16) European Commission, *Flowchart of the Commission Proposal*, 2006, http://ec.europa.eu/environment/chemicals/background/flowchart_reach.pdf (accessed 27 July 2006).

(17) European Commission, *Questions and Answers on REACH*, 23 March 2006, http://ec.europa.eu/environment/chemicals/pdf/qa.pdf.

(18) The AICS lists chemical identity data, but no toxicity information or identities of manufacturers or importers.

Industry has the option of submitting an assessment performed under an approved foreign scheme, with acceptance subject to approval by the Director. Assessments submitted in Canada and European Union countries are preferred. NICNAS also specifically accepts as equivalent assessments of Low Concern Polymers made under CEPA 1999.(19) Canada and Australia signed a bilateral agreement in 2002 to facilitate cooperation and information exchange as envisaged in Organisation for Economic Co-operation and Development (OECD) initiatives, including the sharing of reports.

The Department of Health and Ageing is currently conducting a review of the "existing chemicals" regime, especially in light of changes to overseas programs including REACH and CEPA 1999.(20) This review is looking particularly at determining national priorities for assessment, improved use of overseas testing and assessment program outputs, and community access to information on chemical hazards and risks.(21)

DISCUSSION OF KEY ISSUES

A. Precautionary Principle

Under CEPA 1999, the precautionary principle is defined as follows: "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." CEPA 1999 includes the precautionary principle in both the preamble and the operational parts of the Act. The Act states that the government is obliged to apply this principle in the administration of the Act and the National Action Committee must use it when giving advice and recommendations. Moreover, the principle must be applied when conducting and assessing the results of screening assessments and other reviews. Because the precautionary principle is largely open to interpretation, in 2003 the government released a guidance document

(19) Australian Government, Department of Health and Ageing, *NICNAS Handbook for Notifiers*, 2004, http://www.nicnas.gov.au/Publications/NICNAS_Handbook/Handbook_For_Notifiers_PDF.pdf (accessed 28 July 2006).

(20) Australian Government, Department of Health and Ageing, *Review of the Existing Chemicals Program*, http://www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program.asp (accessed 14 June 2006).

(21) NICNAS, *Review of the Existing Chemicals Program: Background Paper*, June 2003 http://www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program/FinalBackgroundpaperforfocusconsultation.pdf (accessed 13 June 2006).

entitled *A Framework for the Application of Precaution in Science-based Decision Making about Risk*.

REACH is explicitly underpinned by the precautionary principle and also contains specific directives within the legislation as to how this should be employed. For example, where there is uncertainty regarding the scientific evidence, the safety assessment should be based on evidence giving rise to the highest concern. On the other hand, the U.S. does not consider the precautionary principle to be a basis for policy.

It must be noted however that, whether or not there is specific reference to the precautionary principle in a law, its operational aspects will define whether or not it is precautionary in practice. Considerable attention has been given to the fact that the United States does not make reference to this principle in its laws while Europe frequently does. It has been noted, however, that the relative levels of precaution in practice vary on a case-by-case basis.(22) In the case of the management of toxic chemicals, the problems pointed out by the General Accounting Office would suggest that in practice the implementation of the TSCA in the U.S. is less precautionary than that of the proposed REACH system.

B. Voluntary vs. Mandatory Approaches

The EU and U.S. approaches to chemicals management also represent markedly different views on the virtues of voluntary and mandatory policy tools. The U.S. generally opposes regulations that could increase costs for industry without clear evidence of targeted benefits, instead favouring an open regulatory environment that they consider to be more conducive to innovation and investment. The American system often relies on voluntary and incentive programs to compel actions in the public interest,(23) including the High Production Volume (HPV) Challenge Program, the Voluntary Children's Chemical Evaluation Program (VCCEP), Persistent, Bioaccumulative and Toxic (PBT) Chemical Program, Sustainable Futures Voluntary Pilot Project, and various programs that generate and make available certain

(22) Jonathan B. Wiener and Michael D. Rogers, "Comparing precaution in the United States and Europe," *Journal of Risk Research*, Vol. 5, No. 4, 2002, pp. 317-349.

(23) For further details regarding U.S. chemicals policy tools, see *Overview: Office of Pollution Prevention and Toxics Programs*, prepared by Battelle for the U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, 24 December 2003, http://www.chemicalspolicy.org/downloads/TSCA10112-24-03.pdf (accessed 14 June 2006).

information on risk, exposure and potential effects of toxic substances.(24) Of note, the U.S. Centers for Disease Control and Prevention maintain an extensive biomonitoring program that published its third biennial report in 2005.(25)

In contrast, the EU takes the position that voluntary measures on chemicals management are insufficient and that clear requirements will foster greater innovation and competitiveness. In particular, REACH is intended to promote the development of less hazardous substances that can replace existing substances. Furthermore, the EU has evaluated the costs and benefits of the proposed legislation, concluding that estimated costs to the economy (and particularly the chemicals industry) are considered manageable and strike an appropriate balance relative to projected benefits to human health and the environment.(26) Other analysis paints a dramatic picture of the possible negative impacts of REACH.(27)

C. Burden of Proof

The EU clearly places the burden of proof on industry: "responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances."(28) Therefore, REACH will require industry to submit specific types of information, as outlined in the legislation, on existing substances produced in quantities above a certain threshold. It is currently proposed that substances produced in quantities over 1 tonne annually will require basic physical chemical data to be submitted, while those substances with production of over 10 tonnes annually would

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(24) Australian Government, Department of Health and Ageing, *Existing Chemicals Review: Overview of overseas existing chemicals programs*, National Industrial Chemicals Notification and Assessment Scheme, 2003, http://www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program/EC_reviewInternationalPrograms.pdf.

(25) Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals*, National Center for Environmental Health, NCEH Pub. No. 05-0570, July 2005, www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf (accessed 2 June 2006).

(26) European Commission, Environment, *Impact Assessments*, 6 July 2006, http://ec.europa.eu/environment/chemicals/background/impact_assessment_intro.htm (accessed 16 August 2006).

(27) Angela Logomasini, "Europe's Global REACH: Costly for the World; Suicidal for Europe," produced for the Hayek Institute (Brussels) by Angela Logomasini, who is director of Risk and Environmental Policy at the Competitive Enterprise Institute, http://www.fahayek.org/gazette/imagesup/Reach_EN.pdf.

(28) Council of the European Union, *Common Position 7524/06*, 12 June 2006, http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf (accessed 16 August 2006).

require a full chemical safety report. Furthermore, if a substance is identified as a SVHC it will not be authorized unless industry justifies its use by showing that risks can be adequately controlled(29) or that the socio-economic benefits outweigh the risks and no suitable alternatives or technologies exist. By the EU's reasoning, "[i]f a company is producing a substance in such volumes that it has to be registered, we believe that they should have the resources available to demonstrate its safe use. If these resources are not available one would question whether they should be producing the substance."(30)

With respect to existing substances, U.S. legislation is quite the opposite of what is proposed for REACH. As described previously, the burden lies entirely with the EPA to prove that "a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk to human health or the environment" and to choose the "least burdensome" regulation that adequately addresses the risk, which must include consideration of the costs and benefits of the proposed regulation. Past experience with trying to control asbestos in the United States attests to the arduous task these requirements place on the EPA in order to restrict existing substances.(31) The process is more effective in dealing with new substances, as a review takes place prior to the commencement of manufacturing, and the threshold for action by the EPA is much lower. In addition, various EPA policies give signals to manufacturers regarding chemicals that may be of concern, and various methods are employed to encourage development of safer products and production systems.(32) However, companies are only required to submit whatever information they possess at the time of notification; they are not obligated to generate a specific set of data. The EPA is then charged with evaluating the material and ordering further testing as they see fit.

In Canada the *New Substances Notification Regulations* under CEPA 1999 outline the information requirements for particular types of substances that industry is required to submit; the government then assesses the data to evaluate the risk and needs for management.

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(29) The current proposal specifies that adequate control cannot apply to PBTs, vPvBs and non-threshold CMRs as a threshold cannot be established for these substances, based on criteria in the proposal.

(30) European Commission, *Questions and Answers on REACH*, 23 March 2006, http://ec.europa.eu/environment/chemicals/pdf/qa.pdf.

(31) U.S. Government Accountability Office, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, Washington DC, June 2005.

(32) Lowell Center for Sustainable Production, University of Massachusetts, Lowell, *The Promise and Limits of the United States Toxic Substances Control Act*, 10 October 2003, www.chemicalspolicy.org.

D. Assessment of Existing Substances

Existing substances in Canada are currently being categorized for their level of risk but it is uncertain how those substances deemed to be a risk will be managed. In REACH, a clear process has been proposed. Where a substance poses unacceptable risks, the commission decides on risk management, prohibition of certain uses or a ban of the substance. If a substance has very hazardous properties, producers or importers are charged with proving that they can adequately control use of the substance in order to receive authorization for its use. If its use cannot be adequately controlled, a substance may still receive authorization if it is shown that the socio-economic benefits outweigh the risks and that suitable substitutes are not available. However, the legislation stipulates that, by definition, CMRs and substances with effects of equivalent concern for which there is no threshold of effect, as well as PBTs and vPvBs, cannot be adequately controlled.(33) There is an emphasis on promoting substitution and the development of less hazardous substances.

In the absence of a comprehensive screening process to classify existing substances in the U.S., voluntary programs such as the High Production Volume (HPV) Challenge have been implemented to compel industry to provide more toxicity data on existing substances produced in quantities of over 1 million pounds (approximately 450,000 kg) a year. While these programs are producing results, the EPA has not yet adopted a methodology for prioritizing the chemicals or for determining those that require additional information.(34)

E. Timelines

REACH aims to have all chemicals produced in quantities over 1 tonne annually registered within 11 years of its coming into force. Registration is prioritized based on hazard and exposure risk. Those chemicals that have been defined as posing the greatest potential risks will have to be registered in the first 3 years, while other categories of substances will have either 6 or 11 years to be registered. Subsequent phases (evaluation, authorization) have timelines attached, and substances will be submitted to these processes on a priority basis, as resources permit. Once a substance is recommended for authorization, there are defined time periods for

(33) European Commission, *Flowchart of the Commission Proposal*, http://ec.europa.eu/environment/chemicals/background/flowchart_reach.pdf (accessed 16 August 2006).

(34) Stephenson (2006).

making applications for authorization. After this point, use of the substance will be disallowed if an application has not been made.(35)

In the Australian system, timelines have been set for each step in the process of assessing a potential Priority Existing Chemical (PEC), which are nominated based on specific concerns regarding human health and environmental effects. Once a substance is declared to be a PEC, importers or manufacturers must apply for an assessment(36) within 28 days. If no applications are made within 12 months, the substance will be removed from the Australian Inventory of Chemical Substances and is thus unavailable for use in the country.(37)

F. Information Requirements for Assessments

Only CEPA 1999 and the proposed REACH legislation require the systematic prioritization and assessment of existing chemicals. Moreover, REACH would become the only legislation that requires basic data to be developed on the physical chemical properties of all existing chemicals produced in quantities of over 1 tonne annually, and the basic health and ecological effects of existing substances produced in quantities of over 10 tonnes annually.(38) Under the TSCA, companies are required to provide existing data for new substances, unless a rule is promulgated requiring further testing. Data on some existing substances is supplied under voluntary agreements or where a case can be made to promulgate a rule.(39) The EPA routinely employs Structure-Activity Relationships (a predictive measure of toxicity as evaluated by the chemical's structure and chemical reactivity) in reviewing new chemicals.

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(35) European Commission, *REACH in Brief*, 2004 http://ec.europa.eu/enterprise/reach/docs/reach/reach_in_brief-2004_09_15.pdf (accessed 11 August 2006).

(36) Assessments provide recommendations to reduce the risks associated with the use, manufacture or import of a PEC.

(37) Australian Government, Department of Health and Ageing, *NICNAS Handbook for Notifiers* (2004). http://www.nicnas.gov.au/Publications/NICNAS_Handbook/Handbook_For_Notifiers_PDF.pdf (accessed 28 July 2006).

(38) Note that CEPA 1999 allows for notice to be published requiring submission of data on a given substance in order to perform an assessment.

(39) U.S. Government Accountability Office, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, GAO-06-217R, Washington DC, 4 November 2005.

G. Recognition of International Schemes

Canada continues to engage with the international community, particularly under the auspices of the OECD, the World Health Organization (WHO) and the United Nations (UN), to develop ways to optimize the sharing of information on chemicals management across borders.

One program of note is the OECD system of *Mutual Acceptance of Data*, whereby member countries have agreed to accept chemical safety data from other countries which have been produced in accordance with the OECD's *Test Guidelines* and *Principles of Good Laboratory Practice*. As well, since 1990, the OECD has facilitated a program to investigate High Production Volume (HPV) chemicals. Through this mechanism, member countries claim particular chemicals and assume responsibility for generating harmonized chemical safety data on a proportion of HPV chemicals equal to the proportion produced by their domestic industry.(40)

Another important initiative is the UN's "Globally Harmonized System of Classification and Labelling of Chemicals" (GHS). This is intended to provide the information necessary on physical hazards and toxicity of chemicals through their handling, transport and use, and to form the basis for harmonization of rules and regulations which would also facilitate trade in chemicals.(41) The GHS was adopted by the UN Economic and Social Council (ECOSOC) in 2003, and is ready for implementation by individual nations. Since 2004 Canada has been engaged in technical consultations with respect to implementation of the GHS.(42)

As regards domestic programs, Australia's approach aims to take greatest advantage of information being generated in foreign countries, while ensuring that assessments satisfy specific criteria developed domestically. For example, assessments submitted to a foreign scheme may be accepted, but each case is subject to approval. The Australian government has also recognized that the Canadian assessment requirements for Low Concern Polymers are equivalent to its own, and thus Canadian assessments for this category are accepted. There is a

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(40) Organisation for Economic Co-operation and Development, *Co-operation on the Investigation of Existing Chemicals: description of OECD work on investigation of high production volume chemicals*, http://www.oecd.org/document/21/0,2340,en_2649_34379_1939669_1_1_1_1,00.html (accessed 13 July 2006).

(41) United Nations Economic Commission for Europe (UNECE), "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)," http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html (updated 26 June 2006).

(42) Health Canada, "The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)," http://www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/index_e.html (updated 15 May 2006).

working relationship between Australia and Canada to facilitate such sharing of information and verification of assessments.

Canada also collaborates and shares information with the United States, particularly through the "Four Corners Agreement." In addition, substances are now placed on the Non-Domestic Substances List under CEPA 1999 after one year of listing under TSCA. Substances on this list are subject to less onerous testing and reporting requirements than unlisted substances.

H. Public Access to Information

The U.S., Australia and the REACH proposal all provide for public access to information about chemicals, in forms including reports, fact sheets, assessments, labelling requirements, public inventories and monitoring data. The U.S. directs this through "Right-to-Know" Acts that aim to provide information to the public on chemicals exposure through programs such as the Toxic Releases Inventory, High Production Volume Information System, Voluntary Children's Chemical Evaluation Program, and the *National Report on Human Exposure to Environmental Chemicals*. However, the U.S. GAO has observed that the EPA is limited in its ability to make information obtained under the TSCA publicly available, since the agency is bound to a resource intensive process to dispute confidentiality claims that appear to be unwarranted.(43)

Australia provides public access to certain information, including assessments and an inventory, and is currently addressing the question of community access to information on chemical hazards and risks as part of its review of its existing chemicals regime. REACH focuses on increased transparency as a key objective, and promotes the consumer's right to know in order to make informed choices. It states that specified information will be made available to the public, particularly safety and environmental data, while the right to maintain confidential business information will be respected. Any confidentiality claims outside of regularly recognized confidential business information must be justified by the company and accepted by the Chemicals Agency. Again, and in contrast with the TSCA, the burden of proof is placed on companies, rather than on regulatory authorities.

(43) Stephenson (2006).

I. Consumer Products

The inclusion of "articles" – consumer products – in the proposed REACH legislation has been contentious, and the language has been significantly modified from the original draft. As written currently, producers and importers of articles will be required to notify the Chemicals Agency of the presence of substances of very high concern (SVHC) that are candidates for authorization, above a given quantity and concentration.(44) Guidelines for this are still in development. Substances intended for release from articles may have to be registered.(45)

The United States has objected to including products under REACH, due to concerns about trade restrictiveness. It has also suggested that various elements of REACH may violate World Trade Organization rules, a charge the EU says is false.(46)

The Australian legislation does not specifically target consumer products. However, as in most other countries, releases of a chemical from an article (for example, due to leaching) may need to be included as part of the exposure information used to perform a risk assessment of that chemical.(47)

J. Vulnerable Populations or Ecosystems

Various pieces of legislation in the United States, including the *Clean Air Act*, the *Safe Drinking Water Act* and the *Food Quality Protection Act*, require protection of vulnerable populations; however, the TSCA does not make this explicit.(48) Other American policies and directives exist that do require consideration of health risks to children. In 1997, an Executive Order was issued, stating that:

> to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

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(44) As of 2006, this includes quantities of one tonne or more, and a concentration greater than 0.1% weight by weight. Notification may be exempt if the producer or importer can exclude human and environmental exposure under reasonably foreseeable conditions (EC 2006).

(45) European Commission (2006).

(46) *Ibid*.

(47) Australian Government, Department of Health and Ageing, *NICNAS Guidance Note: Risk Assessment of Chemicals: Assessment of Exposure From All Sources*, http://www.nicnas.gov.au/Publications/Guidance_Notes/Risk_Assessment_PDF.pdf (accessed 15 August 2006).

(48) Lynn R. Goldman, *Testimony before the United States Senate Environment and Public Works Committee*, 31 July 2006, http://epw.senate.gov/109th/Goldman_Testimony.pdf (accessed 14 August 2006).

> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.(49)

Specifically, the EPA's policy requires all EPA standards and regulations to explicitly consider risks to fetuses, infants and children.

The proposed REACH legislation makes reference, in general terms, to consideration of vulnerable subpopulations in the authorization process and in determining the "derived no-effect level" (threshold of effect) as part of the human health hazard assessment, where this assessment is required. As regards vulnerable ecosystems, there is no equivalent reference to this for the environmental hazard assessment, although there is the requirement to use available studies that give rise to the greatest level of concern in coming to a conclusion.(50)

CONCLUSION

International approaches to the management of chemicals vary considerably. Relative reliance on prescriptive and voluntary management regimes is one of the key differences, as is the reliance of the regime on the precautionary principle.

The European model, should REACH come into effect, tends to be more prescriptive and precautionary than the United States model, for instance, which relies more on voluntary programs and is based on risk assessment and cost-benefit analysis. The Canadian regime could be seen as a mix of the two approaches. CEPA 1999 contains the power to be prescriptive, but this power is discretionary.

Just as the degree to which a regime is precautionary should be measured by its implementation as opposed to specific reference to the principle, so too the success of the various approaches should be measured by risk reduction, human and environmental health outcomes and the capacity to sustain a competitive chemical industry.

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(49) W. J. Clinton, *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*, 21 April 1997, http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm (accessed 15 August 2006).

(50) Council of the European Union (2006).

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