European and Canadian Environmental Law:

Best Practices and Opportunities for Co-operation

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This support has provided a timely opportunity for CELA to analyze the differences and similarities in Canadian and European law and policy, and to introduce an informed public interest perspective to the governmental, legal and diplomatic engagements seeking to reconcile our differing approaches.

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~ INTRODUCTION ~

European and Canadian Environmental Law:
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The Canadian Environmental Law Association (CELA) has conducted a comparative study of European and Canadian policy, law and regulation, including the consideration of relevant American law where applicable, in four areas that are critical to the protection of human health and the environment.

Purpose

The purpose of this report is to identify similarities, divergences and best practices in legislation and public policy related to chemicals, product stewardship, the sustainable use of natural resources and food biotechnology. This analysis is intended to enable governments to evaluate their current policies and legislation, and make revisions to provide the optimal protection of human health and the environment. It is our view that a deepened understanding of European approaches and advances over the last decade in environmental regulation can play an important role in improving public protections both in Canada and Europe.

Objectives

The objectives are:

- To conduct a comparative study of European and Canadian regulation and policy, with consideration of relevant American law, to identify similarities, differences and best practices to provide optimal protection of human health in four areas – chemicals law and policy, product stewardship, the sustainable use of natural resources and food biotechnology.
- To develop recommendations on regulatory best practices and opportunities for Canada-European Union co-operation that would play a role in improving law and public policy.
- To introduce these recommendations for consideration in Canada during the review of the *Canadian Environmental Protection Act*, the development of the proposed *Canadian Health Protection Act*, the implementation of the "Smart Regulation" initiative, the discussions on Canada-US Regulatory Co-operation, and the development of product stewardship programs in Canada at the federal and provincial levels.
- To disseminate information regarding European Union regulatory approaches widely in Canada and the United States through electronic publication and public events involving government decision-makers, academics, business representatives and civil society.
- To influence Canadian parliamentarians and decision-makers through targeted briefing sessions.
- To establish links between Canadians and Europeans in civil society working in these areas.

Methodology

The research methodology consisted of first, a review of the relevant legislation and published academic studies, particularly those that compared Canadian, European and American law in the four subject areas, and extensive Internet searches of government documents, public policy and legal analyses by academics, governments and non-governmental organizations. Second, interviews were conducted with key informants, including academics, public officials and representatives of non-governmental organizations.

Background

The original impetus for this work changed to some extent when trade discussions between Canada and the European Union were suspended in early 2006. One of the initial objectives was to produce a comparative review of legislation that could be considered during the negotiation of the Canada-European Union (EU) Trade and Investment Enhancement Agreement (TIEA) and during the discussions between Canada and the United States with respect to regulatory co-operation.

The negotiation of the TIEA, launched in May 2005, focused attention on regulatory trends and differences on the two continents. At the World Trade Organization (WTO), disputes between Canada and the EU showed that three of the major cases - beef hormones, asbestos, and biotechnology measures - all involved differences in regulatory approaches. As the EU carried out implementation of the End-of-Life Vehicles Directive and developed the REACH proposal on chemicals, Canada raised concerns about the impacts on Canadian commodity exports. These conflicts highlighted the need for better understanding of the regulatory approaches in Canada and Europe and the ways in which these differences might be reconciled, possibly resulting in better policies and regulation world-wide.

Although the suspension of the TIEA negotiations altered the context for this research, other significant opportunities became available to present our work comparing Canadian and European approaches and promoting best practices identified in each jurisdiction. The analysis of chemical law and policy has been used to inform the Parliamentary review of the *Canadian Environmental Protection Act* and the National Policy Consultation sponsored by the Canadian Partnership for Children's Health and the Environment. Second, the Extended Producer Responsibility research has been presented to the Extended Producer Responsibility (EPR) Committee of the Canadian Council of Ministers of the Environment (CCME). It also supports a collaborative effort with the Canadian Autoworkers (CAW) and their campaign for EPR for End-of-Life vehicles. Third, the research on food biotechnology will be used as part of CELA's ongoing input into Canada's Biotechnology Strategy and a possible review being called for by the Canadian Biotechnology Advisory Committee.

Trade Practices and Environmental Policies

In North America, environmental regulation expanded rapidly in the 1980's but largely ground to a halt in the 1990's. As the improvement of environmental regulation stalled, governments

were aggressively pursuing trade liberalization, corporate deregulation and voluntary approaches advocated under free trade agreements.

At the same time, in Europe the late 1990s saw a revival of environmental commitment that propelled the European Union into the forefront of environmental and public health initiatives internationally. These initiatives included the updating of existing legislative programs such as the chemicals review that led to the REACH Regulation, the enactment of a comprehensive legislative framework governing genetically modified feed and foods, and the establishment of producer responsibility legislation that required industry to take responsibility for major items such as cars and electronic equipment after their use.

This wave of environmental regulation has challenged both Canada and the United States (U.S.) to consider their own regulatory frameworks, the impact of European initiatives on their ability to export goods to Europe and the implications for international trade.

Currently, Canada's economy has become one of the most trade-dependent in the world, relying primarily on the United States and Europe for both exports and imports. In Canada, exports represent 38.1% of economic activity and imports 33.7%. Both exports and imports are highly concentrated on only two markets: 81.6% of exports go to the U.S. and 6% to the EU. With respect to imports, 68.9% came from the U.S. and 10% from the EU in 2005.[1]

Although Canada's trade with the United States is greater, the European Union is a significant part of Canada's economy. Canada's Ambassador to the EU, Jeremy Kinsman, points out that Canada is now part of a "wider North Atlantic Economy". [2] Taken together the NAFTA-EU market represents 83% of Canada's global activity. He also makes the point that while the US will always be Canada's "number one target of opportunity and preoccupation", the EU is very significant for Canada with recent trade in goods plus services plus affiliate sales equal to $217 billion in Canadian dollars, compared to U.S. totals of almost $1.3 billion. Kinsman calls the Canadian stake in the EU "vital to Canadian business, finances and our success in the world".[3]

The Canadian government has noted that:

> Most EU-Canada trade and investment disputes/irritants are regulatory in nature and our attempt to address these irritants, for example through Mutual Recognition Agreements (MRA) and the European Union-Canada Trade Initiative (ECTI) [1998], have had mixed results. A review of the effectiveness of these approaches would be timely.[4]

One of Canada's first attempts to resolve trade differences, including differences in environmental regulation, began in 1999 with the formation of the Canada – Europe Roundtable

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[1] Department of Foreign Affairs and International Trade, *Sixth Annual Report on Canada's State of Trade: Trade Update April 2005,* online: Trade and Investment Reports http://www.dfait-maeci.gc.ca/eet/trade/state-of-trade-en.asp>.

[2] Kinsman, Jeremy "State of the European Union", Panel Session at the Canadian Institute of International Affairs, Toronto, April 26, 2006 [unpublished]

[3] Ibid.

[4] Joint [EU-Canada] Action Plan for Regulatory Co-operation, Section IV, Para. iii, Accessible at: Canada Europa <http://www.dfait-maeci.gc.ca/canada-europa/mundi/summit-athens2003-regulatorydialogue-en.asp>.

(CERT). Senior business leaders[5] from both sides of the Atlantic formed the Roundtable as a permanent association for "dialogue on major trade and investment matters between business leaders and governments".[6]

The Canada-Europe Roundtable worked hard to influence governments on issues such as better integration of transatlantic capital markets, more predictable rules for mergers and acquisitions, preventing the rise of non-tariff barriers to trade and investment flows, and the design of a complementary regulatory cooperation framework between Canada and the EU.[7]

In March 2004 at a meeting held just before the formal launch of the TIEA negotiations, Pascal Lamy, then EU Trade Commissioner and now Director-General of the World Trade Organization, highlighted his view that "the real obstacles to trade and investment (between Canada and the EU) are differences in regulation. This is a message that started with CERT."

However, the negotiations lost momentum after just three rounds and were suspended even before all of the topics identified had been introduced into the negotiations. In a presentation to the Canadian Institute for International Affairs in April 2006, Ambassador Otto Ditz, the Austrian Ambassador to Canada, said that the real negotiations should be a triangular affair between Canada, the European Union and the United States. He said that to get the interest of the business community it was necessary to have a NAFTA – EU conversation.

The Canadian Environmental Law Association set out in November 2005 to look at Canadian and EU regulatory differences in four major areas – chemicals, extended producer responsibility, sustainable use of natural resources and food biotechnology. Our aim was to act on the Canadian government's assertion that the "review of the effectiveness of these approaches would be timely".[8] This report is intended to characterize the differences in transatlantic approaches to environmental issues.

One of the first considerations in comparing European legislation with equivalent Canadian and U.S. legislation is the adoption in Europe of the "precautionary principle". In a 2003 paper, "Comparing Environmental Governance: Risk regulation in the EU and the US", David Vogel suggests that "the substantive differences between European and US regulatory policies do not stem from the fact that the EU and several Member States have formally adopted the precautionary principle, while the US has not. … It is rather because political support for more stringent health, safety and environmental regulations is now greater in Europe than in the United States that a number of regulations enacted by the EU are now more risk averse or "precautionary" than in the US."[9]

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[5] CERT membership at the time included: Alcan, Interbrew, Bombardier, GPC International, Tractebel (Suez) TSX Group, Novartis, MDS, NOVA Chemicals, CGI, Blake, Cassels & Graydon LLP, SNC Lavalin, Canadian Manufacturers & Exporters, Monsanto, Forest Products of Canada, Spirits Canada, Canadian Chamber of Commerce, EU Chamber of Commerce in Toronto and the American European Community Association.

[6] CERT High Level Meeting with Canadian Trade Minister and European Trade Commissioner on Canada-EU Trade and Investment Enhancement Agreement, Press Release, 18 March 2004, online: Canada Europa <www.canada-europe.org>.

[7] Ibid.

[8] DFAIT, *Supra* Note 4.

[9] Vogel, David, "Comparing Environmental Governance: Risk Regulation in the EU and the US" (September 1, 2003). *Center for Responsible Business. Working Paper Series.* Paper 2. 25, 26. online: e-Scholarship Repository, University of California <http://repositories.cdlib.org/crb/wps/2>.

Vogel highlights how recent European policies have been introduced following a "series of regulatory failures" such as mad-cow disease which have undermined public confidence in the regulatory process and the capacity of science to identify harm. A recent collection of essays sponsored by the European Environment Agency reviewed twelve examples of "regulatory failures" in both Europe and the US.[10] In every case, these failures were due to the fact that policy-makers had been insufficiently proactive. The Agency was unable to come up with a single example of public welfare being undermined by too stringent regulations.[11]

The political support for more stringent health, safety and environmental regulation in Europe has been at the root of new policies for chemicals, food biotechnology and products that have generated significant conflicts with the less risk-averse character of current regulatory policy in North America.

Another important area of difference between Europe and North America lies within differences in corporate culture regarding environmental issues.

These differences were highlighted in the findings of a year long study that assessed the international state-of-the-art in Environmentally Benign Manufacturing (EBM), conducted by an interdisciplinary panel sponsored by the United States National Science Foundation. During the course of its study, the panel visited 50 sites in Japan, Europe and the United States. In the introduction, they state: "US manufacturing might be characterized as the most wasteful industrial activity in the most wasteful nation."[12] Although the panel did not directly address Canada, Canada's environmental record and manufacturing orientation can be considered similar to the United States.

The panel concluded that:

> Each region that we visited, the US, Europe and Japan, has different approaches to developing an environmentally benign manufacturing strategy. Each region has different drivers. In the US, the drivers are the correlation between cost-savings and the environmental benefit. In Europe, the high-population density, a recycle mindset, and the take-back provisions drive environmental policy. In Japan, the drivers are the export economy, high population density and ISO 14000. For American firms *[and by extension Canadian ones]* with a majority of sales abroad, responding to the US drivers alone is not sufficient.[13]

The cultural and social differences between Europe and North America are significant, and they have generated different regulatory responses to the current environmental challenges. This report investigates European and Canadian approaches and draws out ideas and recommendations that can be used to improve public protections in each of the four areas.

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[10] European Environment Agency, "Late Lessons from Early Warnings: The precautionary principle 1896-2000" (2001). *Environmental Issue Report No. 22.* online: European Environment Agency <http://reports.eea.europa.eu/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf>.
[11] Ibid. p. 23.
[12] Bras, Bert et al. "Environmentally Benign Manufacturing: Trends in Europe, Japan, and the USA" (2002) 124 Transactions of the American Society of Mechanical Engineers 908.
[13] Ibid., p. 920.

1. Chemicals Policy in Canada, the European Union and the United States

By Anne Wordsworth

1.1 *The Chemical Information Deficit*

For most people in the developed world, daily life without industrial chemicals would be unimaginable. Yet, after decades of everyday use, unexpected toxic effects are regularly reported in scientific journals and in the media.

For example, testing of indoor air and household dust in typical homes has demonstrated the presence of endocrine disrupting chemicals from consumer products such as nonylphenols, brominated flame retardants and pesticides.[1] Biomonitoring of human urine samples has revealed high levels of phthalates in American children and women of child-bearing age[2], with personal care products and soft plastic toys being investigated as possible sources.

These scientific revelations and the public concern surrounding them have become a significant influence in the reconsideration of chemicals legislation and policy in Europe and in North America. Because of a historic failure to investigate the consequences of chemicals and their effects on public health and the environment before manufacture and widespread use, huge gaps in our knowledge of chemicals exist.

An analysis by the Environmental Protection Agency in 1998 found that, of the 3,000 chemicals that are used in the highest volumes in the United States,[3] forty-three per cent had no testing data at all that would establish their basic toxicity. Only 7 per cent had a full set of safety tests.[4] For chemicals used in lower volumes, even less information was available.[5]

Similarly, the European Chemicals Bureau, in their subsequent 1999 analysis, found that only 14 per cent of the high production volume chemicals on the European market had a basic set of safety testing data publicly available. Sixty-five per cent had some data but less than the basic set, and 21 per cent had no data.[6] The European Commission commented that the information was "sketchy for around 99 per cent" of the chemicals in use.[7]

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[1] Rudel, Ruthann A. et al, "Phthalates, Alkylphenols, Pesticides, Polybrominated Diphenyl Ethers, and Other Endocrine-Disrupting Compounds in Indoor Air and Dust" in *Environ. Sci. Technol.*, 37 (20), Sept. 2003, 4543-4553.

[2] Blount, BC et al. (2000) "Levels of seven urinary phthalate metabolites in a Human Reference Population", in Environmental Health Perspectives 103: 979-82; Brock, JW et al. (2002) "Phthalate Monoester Levels in the urine of Young Children" in *Bulletin of Environmental Contamination and Toxicology* 68: 309-14.

[3] High volume chemicals are defined in the United States as chemicals manufactured or imported at more than 1 million pounds a year or approximately 500 metric tonnes. The European Union and the OECD define high volume chemicals as over 1000 tonnes or 2.2 million pounds per year.

[4] Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Chemical Hazard Data Availability Study, April 1998.

[5] Goldman, Lynn R. (1998) "Chemicals and Children's Environment: What We Don't Know About Risks" in Environmental Health Perspectives 106, Supplement 3.

[6] Allanou, Remi, Bjorn G. Hansen & Yvonne Van der Bilt, Public Availability of Data on EU High Production Volume Chemicals, Part 2, European Chemicals Bureau, Chimica Oggi, July/August 2003.

[7] Euractiv, "Ministers soft on substitution rules for dangerous chemicals", December 13, 2005.

More recently, in September 2006 the Canadian government concluded one of the most extensive reviews of substances ever undertaken. The government identified more than 4,000 suspect chemicals in Canada with the potential to be persistent, bioaccumulative and "inherently toxic".[8]

Since these findings were released, countries have made progress in addressing the lack of information, particularly with respect to high volume chemicals. However, these studies demonstrate that most chemicals on the market today in Canada, the United States and Europe, came into commerce without the critical data that would assist governments in evaluating their safety, and many of these substances have the potential to damage human health and the environment.

To address this imperfect state of knowledge about chemical safety, governments have been responding with different legislative and policy scenarios. Sometimes legislative initiatives are focused on a single chemical or a class of chemicals when new information emerges and attracts headlines; sometimes legislative regimes are drastically overhauled, and one government is more ambitious in addressing chemical threats than others.

With respect to this kind of movement, it is widely acknowledged that the European Union's new regulation, the Registration, Evaluation and Authorisation of Chemicals, known as REACH, will change the culture of chemical control in many ways, and bring it more into line with the urgent needs of the twenty-first century. It has been described as "setting the stage for a new global standard" and as "the most important initiative with respect to chemicals".[9]

Canada is also responding to the changing landscape of chemical policy by re-examining the *Canadian Environmental Protection Act* with a view to improving its effectiveness. Only the United States has downgraded legislative tools as a means of addressing the information gap, preferring to rely on voluntary programs and the cooperation of the chemical industry.

In this chapter, we examine the current and proposed legislation governing chemicals in Canada, Europe and, to a more limited extent, the United States. Drawing on a comparison of these legislative and policy scenarios, we offer our analysis of the most promising way forward in controlling the chemical hazards that confront us.

1.2 *Origins of Chemicals Legislation in Canada, Europe and the United States*

The original chemical laws in Canada, Europe and the United States were passed to establish control over toxic substances. Governments, in response to public concern over the health and environmental impacts of chemicals such as polychlorinated biphenyls, vinyl chloride and

[8] "Inherent toxicity" is not defined under CEPA, but Environment Canada uses inherent toxicity for the hazard that a substance presents to an organism (DSL Categorization criteria).

[9] Wilson, Michael P. with Daniel Chia & Bryan Ehlers, Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation, prepared for the California Senate Environmental Quality Committee, California Policy Research Center, University of California, 2006, p.61, describes the importance of REACH, and Mark Shapiro, New Power for "Old Europe", *International Journal of Health Services*, 35:3, 2005, p.551, finds that the European Union's new standards are forcing American companies to reconsider longstanding production practices.

fluorocarbons, developed legislation directed at industrial chemicals that would give governments a role in production and use decisions.

As a result, the structures of laws governing chemicals in all jurisdictions have many similarities. At the same time, the different history and political culture of each jurisdiction has affected the development of the legislation and led to significant differences. These differences have become more pronounced as countries have gained experience with their legislation and made important changes.

The process of refining chemicals legislation continues today. Both Canada and the European Union are revising their chemicals legislation. They are aiming to construct an orderly process under which they will examine more chemicals in order to identify those that pose a risk to human health and the environment and put in place measures for eliminating or managing these chemicals. The U.S. is not currently revising its legislation, but has developed alternative programs to accomplish similar objectives.

1.2.1 Canada and the Canadian Environmental Protection Act

The *Canadian Environmental Protection Act*, *1999* (CEPA), is the principal law governing the control and management of chemicals in Canada. It replaced an earlier version of CEPA, which was developed in the mid-1980s in response to public concern over toxic chemicals leaking into the Niagara River from the notorious Hooker Chemical landfills near Niagara Falls, New York, and the appearance of a toxic "blob" in the St. Clair River near Windsor, Ontario.[10]

The primary purpose of CEPA is "to contribute to sustainable development through pollution prevention".[11] One of CEPA's goals is to achieve sustainable development while acknowledging the need to integrate environmental, economic and social factors in all decisions by government.

Because CEPA replaced many outdated environmental statutes, various parts address diverse issues -- from the control of toxic substances to public participation, vehicle emissions and biotechnology. The primary focus of this report will be Part 5, Controlling Toxic Substances. Although Environment Canada is responsible overall for administering CEPA, Part 5 is the joint responsibility of Environment Canada and Health Canada. CEPA does not cover substances that are regulated under other statutes such as pesticides, cosmetics, food and drugs, except where these substances have an industrial application that result in environmental impacts.

Part 5 mandates the Ministers of Health and Environment to assess chemicals to determine whether they are potentially toxic, and to manage them in order to prevent pollution that may harm the environment or human health. Chemicals which are determined to be "toxic" may be added to the Toxic Substances List. A substance would be defined as toxic if it enters the

[10] Government of Canada, "Bill C-32: The *Canadian Environmental Protection Act*, 1999", Background. Accessible at <http://www.parl.gc.ca>. See also Paul Muldoon, "An Environmental Perspective on CEPA: Some Observations on How the Law was Developed and On-Going Issues for Implementation, Canadian Environmental Law Association, November 23, 1999.

[11] CEPA, Declaration in the Preamble.

environment in amounts that have or may have an immediate or long-term effect on the environment or human health. The government then proposes a plan for managing these substances. There are two tracks set out under the 1995 federal Toxics Substances Management Strategy – virtual elimination and life-cycle management.

CEPA provides for a parliamentary review of the Act and its administration every 5 years. A review that began in the fall of 2005 is currently underway. This review is viewed by environmental groups involved in the process as "an opportunity to create the legislative and administrative conditions that will result in healthier lives and a sustainable economy for all Canadians". [12] They have recommended that the government study programs in other countries for controlling toxic substances, such as REACH.

1.2.2 The European Union and its Chemicals Policy

The European Union has been in the process of developing a new regulatory regime for the control and management of chemicals since 1999. One of its main objectives is to remedy the lack of knowledge about the toxicity of existing chemicals and the slow pace of filling in the data gaps. It is also intended to give industry responsibility for ensuring the safe use of chemicals.

Under the current European chemicals program, industry is required to submit available information on high volume chemicals. Government agencies of Member States, referred to as public authorities, are then responsible for deciding which chemicals need to be examined and assessing them. These procedures have been viewed as cumbersome and time consuming. Only 141 high volume chemicals have been identified as candidates for risk assessment, and risk management measures have been developed for a very limited number of these. In addition, it was decided that public authorities were disproportionately burdened with the responsibility for establishing the safety of chemicals. These problems have prompted the development of a new approach.[13]

A White Paper, called "Strategy for a Future Chemicals Policy", was released by the European Commission in February 2001. One of the driving forces behind the reform of chemicals policy was Sweden's desire to improve the management of chemicals within the European Union. [14] In 1999, the government of Sweden had adopted a national objective of a non-toxic environment, embracing the idea that "the environment must be free from man-made substances and metals that represent a threat to health or biological diversity".[15] Because most of the country's environmental problems originate from outside its borders, Sweden became active in promoting better chemicals policy internationally as one way of accomplishing its own goals.

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[12] Canadian Environmental Network Toxics Caucus, "The ENGO Agenda for the Review of the *Canadian Environmental Protection Act* (1999)", submitted to Environment and Health Canada, March 2005, p. 8.
[13] European Commission, Q & A on the new Chemicals policy REACH, Brussels, October 29, 2003.
[14] Lofstedt, Ragnar E. (2003) "Swedish Chemical Regulation: An Overview and Analysis", in *Risk Analysis*, Vol. 23, no. 2, p. 411-421.
[15] Swedish Government, 1997 Environmental Quality Objectives, Objective Number 12.

In October 2003, a draft regulation known as REACH – the Registration, Evaluation and Authorisation of Chemicals – was made public. The REACH regulation was intended to put in place a comprehensive program of chemicals management, and replace three current European Directives and one Regulation with a single regulatory framework. REACH will replace the Dangerous Substances Directive (67/548/EEC), the Dangerous Preparations Directive (88/379/EEC), the Existing Substances Regulation (EEC 793/93) and the Limitations Directive (76/769/EEC).[16]

The stated purpose of REACH is "to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation" of the European chemicals industry.[17] Article 1(3) adds that the Regulation is based on the principle that manufacturers, importers and downstream users must ensure that the substances they use do not adversely affect human health or the environment. Furthermore, the provisions of REACH "are underpinned by the precautionary principle".[18]

The main elements of REACH are the registration process for all chemicals manufactured or imported into Europe above a certain threshold, the evaluation of selected registered chemicals to determine whether they pose a risk to human health or the environment, and the requirement for an authorization or approval by government authorities for the use of chemicals that are defined as chemicals of very high concern. A new European Chemicals Agency will be established in Helsinki, Finland.

Exemptions from REACH include radioactive substances, substances subject to customs supervision, non-isolated intermediates, wastes and, if Member States choose, substances used for defense purposes. Registration is not required for substances such as food additives and flavourings, and medicinal products regulated under other directives.

Because of the changes that were proposed in the new regulation, the debate around REACH has been extremely intense. It has been characterized as "one of the fiercest political battlegrounds in the history of policy definition in the European Union".[19]

A compromise on REACH negotiated with the Council of the European Union was adopted by the European Parliament on December 13, 2006.[20] As a result, REACH is due to enter into force progressively from June 1, 2007.[21] For the purposes of this report, we have discussed the REACH regulation as it was proposed in the Common Position adopted by the Environment Council on June 27, 2006, updated to take into account the changes which appear in the final

[16] Under European legislation, regulations apply directly to all Member States while directives are adopted by Member States as national laws.
[17] REACH, Article 1(1).
[18] Ibid., Article 1(3).
[19] Euractiv, Chemicals Policy Review (REACH), August 17, 2004.
[20] European Parliament Media Release, "Parliament adopts REACH – new EU chemicals legislation and new chemicals agency", December 13, 2006.
[21] The European Parliament, made up of Members of Parliament elected from all EU Member States, and the Council of Ministers, composed of Ministers from the governments of Member States, are both responsible for the development and passage of legislation. The European Commission is the administrative decision-making body of the European Union that drafts legislation and administers decisions.

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of December 18, 2006.[22]

REACH is one of several legislative initiatives introduced in Europe that are redefining chemical and materials policy throughout the world. The other legislation that has had an impact not only on European activities, but also on Canadian and American companies, are the Waste Electrical and Electronic Equipment (WEEE), the Restriction of Hazardous Substances in Electrical and Electronic Equipment (ROHS) and the End of Life Vehicles Directives, also discussed in this report. As a result of these new European directives, many North American companies are eliminating toxic substances such as lead or mercury from their electric and electronic products in order to be eligible for sales to the European market.[23]

1.2.3 The United States and the Toxic Substances Control Act

In 1970, when the American public and legislators supported a flurry of new environmental legislation, the President's Council on Environmental Quality developed a legislative proposal intended to address the increasing problems of toxic substances.[24] After six years of public hearings and debate, the United States passed the *Toxic Substances Control Act* (TSCA) in 1976 conferring on the Environmental Protection Agency (EPA) broad powers of authority to regulate toxic substances.

The Act was intended to implement a chemicals policy that would make industry responsible for developing adequate data on the effects of substances on human health and the environment, and to give the government authority to regulate those chemicals that present an unreasonable risk.[25] Like CEPA, TSCA does not cover chemical substances regulated under other statutes, such as pesticides, food, food additives, drugs, or cosmetics.

Under TSCA, the EPA has the ability to collect or to require the generation of information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them. This allows the EPA to assess whether chemicals pose unreasonable risks and provides EPA with tools for appropriate control actions. However, the EPA is only authorized to take action on substances where there are findings of risk or high exposure potential.

In spite of TSCA's broad potential powers, the effectiveness of TSCA in the management of chemicals has been questioned throughout the thirty years of its existence by the U.S. Government Accountability Office, formerly the General Accounting Office, in a number of reports.[26] These reports make it clear that TSCA has been a weak legislative vehicle compared to other U.S. environmental statutes. The EPA has placed restrictions on only 5 existing

[22] The final text of the Regulation was published on December 30, 2006 in the Official Journal of the European Union.
[23] Inform, "The WEEE and ROHS Directives: Highlights and Analysis", July 2003.
Accessible at: <http:// www.informinc.org>.
[24] Battelle, "Overview: Office of Pollution Prevention and Toxics Programs", prepared for the U.S. Environmental Protection Agency, Dec. 24, 2003.
[25] TSCA, Section 2.
[26] General Accounting Office, "*Toxic Substances Control Act*: EPA's Limited Progress in Regulating Toxic Chemicals", May 17, 1994.

chemicals under Section 6 of TSCA and 4 new chemicals under Section 5(f).[27] In addition, because of the problems inherent in the legislation, the EPA failed in 1990 to convince the courts that restrictions on asbestos were justified, and this failure has resulted in a reluctance to take further regulatory action for chemical control.

1.3 *Approaches to Chemical Management: Chemical Inventories*

The enormity of the task of improving our knowledge about the chemicals in use today can only be understood in the context of historical precedent. At the time each country enacted legislation to manage toxic chemicals, they grandfathered all chemicals in use when the legislation was passed. This has resulted in two classes of chemicals with distinctly different regulatory approaches – first, existing chemicals or those that were already in use at the time the legislation was passed, and secondly, new chemicals which would be introduced into commerce after the passage of the legislation.

The number of chemicals that are considered to be "existing" chemicals manufactured or used in Canada, the United States and Europe is estimated in different ways over different time periods. As countries introduced legislation which would require notification or screening of new substances, they attempted to identify the chemicals which were already in commercial use in their countries. These inventories are not directly comparable. Nevertheless, they form the basis of each country's approach to managing chemicals.

In Canada, the government has developed a list of 23,000 chemicals, which is referred to as the Domestic Substances List. The Domestic Substances List represents those chemicals which were in commercial use between January 1, 1984 and December 31, 1986 in quantities of 100 kilograms or more manufactured or imported in any calendar year during that period. In addition, the Domestic Substances List includes new chemicals introduced onto the market since that time where the government has been notified of their introduction and the chemicals have been assessed in accordance with CEPA regulations governing new substances.

In the United States, the original TSCA chemical substance inventory included 62,000 existing chemicals. This list was based on information reported to the EPA by manufacturers and importers between 1975 and 1978. The inventory describes organic, inorganic, polymers and unknown substances produced, processed or imported into the United States that were not exempted under TSCA or regulated under other U.S. laws. Since the organization of the TSCA inventory in 1978, another 20,000 chemicals have entered the market and been added to the list, bringing the total TSCA inventory to approximately 82,000 chemicals. The chemicals on the original TSCA inventory list represent 99 per cent of the chemicals by volume currently on the U.S. market.[28]

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[27] U.S. Government Accountability Office (GAO), "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program", GAO-05-458, June 2005, p.58. As of June 2005, EPA had placed restrictions on five existing substances -- PCBs, fully halogenated chlorofluoroalkanes, dioxin, asbestos and hexavalent chromium, and 4 new chemicals, all of which are used in metal working fluids.

[28] Lowell Center for Sustainable Production, "The Promise and Limits of the United States Toxic Substances Act", October 10, 2003. Accessible at <www.chemicalspolicy.org/usfederal.shtml>.

The European Union has identified 100,106 chemicals in commercial use throughout Europe as of September 18, 1981.[29] This list is the European Inventory of Existing Chemical Substances (EINECS). About 80,000 of these are believed to be in commerce.[30] Since 1981, about 3,800 additional substances have entered the market.[31] Unlike the U.S. and Canada, however, these are not added to the lists of existing chemicals but are listed in a separate inventory of new chemicals.

1.3.1 Discussion

These lists are a snapshot in time, and cannot be relied upon as an accurate representation of the total number of chemicals in use in each jurisdiction today. They were originally compiled in the mid-seventies and eighties. However, the last twenty to thirty years have seen a remarkable acceleration and change in chemical production and use -- many chemicals that were used in small quantities at that time have now become high volume chemicals, and some chemicals that were in commerce then are no longer manufactured and used.

Canada has no updated list that would reflect the volumes of chemicals in use at the present time. There are no legal provisions for removing chemicals from the Domestic Substances List and no requirements for updating the volumes initially reported. For new chemicals approved by the government and added to the Domestic Substances List, estimates of production volumes are collected at the time of their approval. However, there are no requirements to amend the estimates of "new" chemicals even if the production volumes of these chemicals increase significantly, except when a trigger threshold is about to be reached.[32]

The United States does require periodic updating of its chemical inventory which is limited to those chemicals produced or imported in high volumes. An Inventory Update Reporting rule under TSCA, promulgated in 1986, required reporting of chemicals on the TSCA inventory that are produced or imported above 10,000 pounds per year per producer every 4 years. In 2002, 8,300 chemicals were reported on the public (non-confidential) version of the inventory update.[33]

This rule has been recently amended so that, beginning in 2006, the reporting threshold is 25,000 pounds per year (approximately 11 tonnes) and the reporting periods extended to every 5 years.[34] These diminished reporting requirements will reduce the amount of information available to the EPA and the public about which chemicals are in commerce and in what quantities. No information is required on lower amounts.

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[29]Commission of the European Communities, "White Paper: Strategy for a future Chemicals Policy", Brussels, February 27, 2001, p. 6.

[30] Brown, Valerie J., "Spheres of Influence: REACHing for Chemical Safety", in *Environmental Health Perspectives* 11: 14, Nov. 2003, p. A767-9.

[31] European Commission,, "REACH in Brief", September 2006, p. 3.

[32] GAO, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program", June 2005, p. 44.

[33] Environmental Defense, "Environmental Defense's Responses to the American Chemistry Council's 'TSCA Myth vs. Fact'", prepared August 3, 2006.

[34] Environmental Protection Agency, "Inventory Update Reporting, Basic Information". Accessible at <www.epa.gov/oppt/iur/pubs/guidance/basic-information.htm>.

However, not all changes to the rule will result in reducing the information available. For the first time, processing and use information will be reported. In addition, information on inorganics which were previously exempt will be reported.

The United States has also found that their previous estimates for the number of high volume chemicals did not accurately reflect current use. More than 500 chemicals that were manufactured or imported in small quantities in 1990 had risen to levels greater than 1 million pounds per year just a decade later, a level that qualifies them as high volume chemicals.[35]

The fact that these estimates are outdated is significant because they affect governments' prioritization of chemicals for assessment. Volume is used as a measure of exposure in calculating risk. Accordingly, governments may be unaware of the greater exposures, and, therefore, underestimate the degree of risk for those chemicals previously reported as used in small quantities.

The European inventory, EINECS, does not make the information on volumes of listed chemicals publicly available.[36] However, REACH will introduce a system of registration that will require European companies to identify chemicals manufactured and imported at or above 1 tonne. Companies must also identify quantities based on graduated volume thresholds, and make it known if they significantly increase the quantities and reach a higher tier of production, or if they cease manufacturing or importing.[37] Although there are no annual reporting requirements, registration of chemicals will give the European Union volume information on which to judge the potential exposure hazards of chemicals. This will be a major factor in determining which chemicals will be subject to an evaluation.

1.4 *Screening New Chemicals*

In order to ensure that governments are informed about new chemicals coming onto the market, Canada, Europe and the United States have legislated notification requirements. New chemicals are defined as those chemicals not already listed on each country's "existing chemicals" inventory.

Notification requirements are intended to allow for the early assessment of health and environmental risks of chemicals before they become widely used. Although all countries require notification for new chemicals manufactured and imported into their jurisdictions, the timing and requirements vary significantly.

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[35] In the United States, a voluntary initiative known as the High Production Volume Challenge (described in Section 5: Filling in the Data Gap on Existing Chemicals) was launched in 1998. Since that time, 574 chemicals increased in volume to become high production volume chemicals, in addition to the 2,800 originally identified. Accessible at the American Chemistry Council website at <http://www.americanchemistry.com/s_acc/sec_policyissues.asp?CID=432&DID=1493>.

[36] Interorganization Programme for the Sound Management of Chemicals, "Chemical Inventories", produced by UNITAR and UNEP, May 1999.

[37] REACH, Article 22(1).

Both Canada and the European Union require that, along with notification, companies submit testing data for new chemicals. While the United States requires companies to submit a pre-manufacture notice for new chemicals, it encourages, but does not require, the submission of test data.[38]

1.4.1 Canada and the New Substances Notification Regulations

Under the *Canadian Environmental Protection Act*, there are two points of entry for new chemicals. The main entry point is through the *New Substances Notification Regulations*. New substances are defined as those substances not on the Domestic Substances List.

The *New Substances Notification Regulations* establish the essential rules for the introduction of new chemicals into Canada. They include the notification of the Environment Minister of the proposed introduction of a new chemical, the submission of information needed for the government to do an assessment, the appropriate fee, and a defined period of assessment.[39] According to the government, the regulations were "created to ensure that no new substances are introduced into the market before an assessment of their potential toxicity has been done".[40]

As part of the notification for introducing a new substance onto the Canadian market, the regulations have different information requirements based on volume, as well as on the type of substance – whether it is a new chemical, polymer or biotechnology product. Different assessment periods are also allocated depending on the quantity and the type of substance.

For chemicals imported or manufactured between 100 kilograms and 1,000 kilograms (one metric tonne) in one calendar year, little information other than the name, the CAS number and the material safety data sheet are required. Data requirements are only triggered for chemicals when the quantity exceeds 1,000 kilograms, and increase when they pass 10,000 kilograms.

Above 1,000 kilograms or one tonne in a calendar year, a company provides a New Substances Notification package at least 60 days before manufacturing or importing a new substance. At this volume of manufacture or import, basic data on toxicity and health effects, as well as exposure information including whether the chemical will be used in products for children, are part of the notification package submitted to the government.[41] The package must include physical and chemical data, acute toxicity and mutagenicity testing. Above 10,000 kilograms per year, additional data are required, including skin irritation and skin sensitization testing, repeated dose toxicity and additional mutagenicity testing. The regulations also require companies to submit "all other information and test data" that are in their possession relevant to identifying environmental and human health hazards.

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[38] Government Accountability Office, Letter to Senators James Jeffords, Frank R. Lautenberg and Patrick Leahy, "Chemical Regulation: Approaches in the United States, Canada, and the European Union", November 4, 2005.
[39] Environment Canada, "A Guide to the new *Canadian Environmental Protection Act*". Accessible at: <http://www.ec.gc.ca>.
[40] Environment Canada, Assessment and Management of New Substances in Canada, New Substances Program. Accessible at <http://www.ec.gc.ca/substances/nsb>.
[41] New Substances Notification Regulations, Schedule V.

Another list, known as the Non-Domestic Substances List, is a second entry point for new substances into Canada. The Non-Domestic Substances List is comprised of those substances that are not on the Domestic Substances List, but are in use internationally. This list is based on the United States *Toxic Substances Control Act* inventory, and is estimated to include about 56,000 substances. CEPA requires that this list be updated periodically, but in practice it is updated annually or semi-annually taking into account substances that are added to the TSCA list.

Although substances on the Non-Domestic Substances List are subject to the *New Substances Notification Regulations*, the testing required to gain approval for these substances is less onerous. The same testing requirements apply to higher volume thresholds of substances on the Non-Domestic Substances List and to lower volumes of substances that have not been used before in another jurisdiction. For instance, the data requirements and the time frames for assessment are the same for chemicals on the Non-Domestic Substances List above 10,000 kilograms and for new chemicals above 1,000 kilograms. This means that companies introducing chemicals into Canada that are already in commerce in the United States or other jurisdictions do not have to provide the same level of data that must be provided for chemicals in first-time use.

In addition, an agreement formalized in 1998 between the Canadian and the U.S. governments, known as the Four Corners Agreement, allows substances to be accepted into Canada at higher volumes with less data. Under this agreement, substances can be added to the Non-Domestic Substances List without waiting for the 5 year period mandated by the Act. These privileges are granted to companies manufacturing or processing chemicals in the United States because it is assumed that these chemicals have already been reviewed by the EPA. However, under TSCA, data on new substances are not required as part of the notification to the EPA.

The New Substances Notification Regulations set out specific time frames for each government review. When the government receives the new substances notification package, the period of assessment begins. This takes approximately 60 days, although the legislated time frames vary between 5 and 75 days depending on the volume and the type of substance.[42] During this time, Health Canada evaluates the new chemical based on human health risk, and Environment Canada the environmental risk, to determine if the chemical is toxic or capable of becoming toxic.

If the time legally allocated for the review period has expired, the government must allow the manufacturer or importer to bring it onto the market even if the review is not complete. This provision creates an avenue through which substances may come onto the Canadian market without being properly evaluated.

However, if the government decides that more information is needed, it may request data from the company that has submitted the notification. This stops the assessment clock until the data are submitted. If the government does not request additional information, when the time

[42] Ibid.

period is over the assessment is deemed to be finished. An estimated 300 new substances are approved in Canada every year out of approximately 850 applications.[43]

In addition, significant new activity provisions exist in CEPA. The government may determine that a new substance poses no risk for a particular use but may have the potential to be toxic if it is used in a significant new activity. In these cases, the government may issue a "significant new use activity" flag to the company which wishes to introduce it, and also list it on the DSL with a flag. These provisions are meant to prevent risks from the new use of a substance.[44] However, the Minister has the discretion of waiving the information requirements if the substance can be controlled, if it's not practical to get the test data, or if the information is not needed.

A major disparity in the Canadian government's approach to new substances, in contrast to the assessment procedures for existing substances, is the lack of transparency in the process. Unlike the assessments of existing chemicals which are made publicly available, assessments of new substances are not made public.[45] In contrast, risk assessments of new chemicals being introduced into Europe are made public, and comment is invited before they are finalized.

Only if a determination of toxicity is made under CEPA and a prohibition or restriction is placed on the substance is the information published. To date, the government has designated just 5 new substances as CEPA-toxic and placed them on the List of Toxic Substances. These include one pesticide and 4 new fluorotelomers. Restrictions have been proposed in Canada for the fluorotelemers, which would be used as water and oil repellants. Other new substances, once they are assessed or the time limit has expired, are added to the Domestic Substances List.

1.4.2 The United States and Pre-Manufacture Notice

The United States has different requirements for the introduction of new chemicals. It requires companies to give notice earlier in the process than Canada or Europe, but does not require companies to submit data with their notifications.

For chemicals not listed on the TSCA inventory, the Act requires that companies notify the Environmental Protection Agency (EPA) at least 90 days before introducing a new chemical onto the market by means of a "pre-manufacture" notice. The "pre-manufacture" notice signals the intent to manufacture or import a new chemical. In contrast, both Canada and Europe require notification when a substance is introduced at specific quantity thresholds.

The pre-manufacture notice includes the identity of the chemical, the use, anticipated production volume, potential exposure levels and release information. It must be provided to the EPA before production or manufacturing is scheduled to begin in order to allow the Agency time to review the notice and decide whether any action to limit the chemical is necessary. If the EPA does not take any action or does not request an extension of the assessment period,

[43] Canadian Environmental Network Toxics Caucus, "The ENGO Agenda for the Review of the *Canadian Environmental Protection Act* (1999)", submitted to Environment and Health Canada, March 2005, p. 17.
[44] CEPA, Sections 80 and 104.
[45] ENGO Agenda. p. 17.

the chemical is considered to be approved after the 90 day review period has expired. Notice is also required for chemicals when the EPA issues a Significant New Use Rule. After production begins, companies must file a notice of commencement within 30 days, and the substance is then added to the TSCA inventory.

At the time a pre-manufacture notice is submitted, companies are asked to submit any data that they have on the properties of the chemical. In practice, however, the companies generally do not have data at the time of the pre-manufacture notice and do not submit anything.

According to a 2005 report by the Government Accountability Office (GAO),

> *TSCA* does not require chemical companies to test new chemicals for toxicity and to gauge exposure levels before they are submitted for EPA's review and, according to EPA officials, chemical companies typically do not voluntarily perform such testing.[46]

It was estimated by the EPA that 85 per cent of pre-manufacture notices do not include any health test data.[47] That TSCA does not require companies to submit data as part of the notification package is the major divergence from Canadian and European laws governing new chemicals.

Under Section 4, the EPA is authorized to issue a test rule that requires companies to conduct tests and submit data. However, it must show that current data are insufficient, that testing is necessary and that the substance either may present an unreasonable risk or may result in significant exposure.[48] Consequently, test rules are rarely issued. Approximately 2,000 new chemicals are approved each year by the EPA, about half of which proceed to production and are then placed on the TSCA Inventory.

Consequently, the burden falls on the EPA to estimate hazard and exposure data on new chemicals and to determine their safety. The EPA relies on mathematical estimation models to decide whether or not to take action to restrict or control a new chemical. These models compare new chemicals with chemicals of similar molecular structures that have previously been tested. They are considered by the EPA to be reliable screening tools. However, the GAO found that the use of these models is not equivalent to a full assessment because they are not always accurate in predicting chemical properties and toxicity, especially with respect to general health effects.[49] As of June 2005, the EPA had taken some action to reduce the risks for 3,500 of the 32,000 new chemicals submitted by companies for review.[50]

This has implications for Canada's new chemicals program. The lack of requirements for testing data in the United States reinforces the data gap in Canada. Because substances on the TSCA list have been incorporated into the Non-Domestic Substances List in Canada or under the Four

[46] U.S. Government Accountability Office, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program", June 2005.
[47] Ibid., p. 11.
[48] Ibid., p. 13.
[49] Ibid., "Highlights, What GAO Found".
[50] Ibid., p.16.

Corners Agreement, they are allowed onto the Canadian market without having to submit as much data at the same volume thresholds established for new chemicals.

1.4.3 Europe and the New Substances Program

Under amendments to the Dangerous Substances Directive (67/548/EEC) which came into force in 1981, a notification system for new substances became mandatory in all countries of the European Union.[51] A separate inventory of new substances, known as the European List of Notified Chemical Substances (ELINCS), includes chemicals introduced into the market after the development of the EINECS list of existing chemicals. New chemicals become eligible for ELINCS after a company has notified the member state 30 to 60 days in advance of the substance coming on the market depending on the tonnage, and the member state has checked the information dossier for completeness. Unlike the Canadian regulations, listing a chemical on ELINCS is not an indication of the government's approval.

The European requirements for new chemicals, which will be replaced by REACH, have been more rigorous than either Canada or the United States.

First, a manufacturer or importer has to notify the government agency of the member state in which they are doing business when they intend to introduce chemicals in volumes higher than 10 kg per year. This notification threshold is lower than the threshold established in Canada. However, under REACH the threshold for notification will be raised to 1 tonne or 1,000 kg per year.

Secondly, for all new substances, they are required to submit a technical dossier that provides the identity of the substance, exposure estimates based on production, proposed uses, information on physical and chemical properties, acute toxicity testing, as well as safety precautions.[52] For all substances at or above one tonne per year, more physical and chemical data must be provided and test reports from toxicological and ecological assays, including mutagenicity, reproductive toxicity and repeat dose toxicity. More extensive data are required if a new chemical is introduced in volumes at or above 100 or 1,000 tonnes per year per manufacturer.

In addition, under another amendment to the Dangerous Substances Directive which took effect in November 1993, Member States must do risk assessments of new chemicals.[53] These risk assessments are generally started after the notification has been accepted, although they are not completed within the 30 to 60 day notification period.[54] After an assessment is completed, Member States may classify new chemicals according to 4 categories: 1) of no immediate concern, 2) of concern and further information for revision of the assessment is required, but

[51] European Chemicals Bureau, New Chemicals: Overview. Accessible at: <http://ecb.jrc.it/new-chemicals/content1.php>.
[52] United Kingdom, Notification of New Substances, Testing Requirements. Accessible at: <www.hse.gov.uk/nons>.
[53] European Union, Directive 92/32/EEC, amending for the seventh time Directive 67/548/EEC, Article 16 (1).
[54] Dr. Birgit Sokull-Klüttgen, Assessment of Chemicals - New Substances, European Commission – DG Joint Research Centre, Toxicology & Chemical Substances, Personal Communication, October, 2006.

deferred until the chemical reaches the next trigger volume, 3) of concern and information is required immediately, or 4) a chemical is recommended for risk reduction measures.

Since 1993, more than 1000 notifications have been submitted to the European Chemicals Bureau by the Member States, of which about 52 per cent indicated the substances were of no immediate concern. About 11 per cent were of concern, and for these, the Member States recommended that risk reduction measures be immediately implemented. Some of these substances were voluntarily withdrawn by the company that submitted the notification, and, for others, restrictions on their use were recommended.

The European experience screening new chemicals shows that roughly half of the new substances have been found to pose a threat of harm to the environment, and about 10 per cent could be a serious danger. These statistics suggest the possible scope of the environmental problems that would emerge if existing chemicals underwent the same level of review.

However, with the introduction of REACH, Europe will depart from the regulatory practice of differing requirements for new and existing substances. This distinction will be eliminated, and all new and all existing substances will have to be registered if they are manufactured or imported in quantities at or above 1 tonne per year. Unlike the current new chemicals program in Europe, no registration or data will be required for new substances that are introduced on to the market in quantities less than one tonne per year. New chemicals which have already been assessed and approved under the Dangerous Substances Directive will be automatically listed as registered chemicals when REACH comes into force.

It is also important to note that new chemicals introduced when REACH comes into effect will require registration, but will no longer be subject to a mandatory government review. Furthermore, if these chemicals are introduced at high volumes, only testing proposals for acquiring data, and not the data itself, will be submitted as part of the registration package.

1.4.4 Discussion

Testing and assessing new chemicals before they become widely used are critical to protecting health and the environment. The nature of the data that is included in new chemical notification packages and the time frames must be sufficient to allow governments to identify chemicals that may be problematic and to make competent decisions about their future use.

The United States is the only one of the three jurisdictions that does not require actual test data as part of its new chemical notification procedures. Although companies are asked to submit data on hand at the time of the pre-manufacture notice, they generally do not have the data. Consequently, new chemicals are reviewed in the United States with very little data from the companies that intend to introduce them.

This affects the introduction of new chemicals into Canada through the Non-Domestic Substances List, which facilitates the entry into Canada of chemicals in use in the United States. These chemicals are assumed to have been adequately reviewed by U.S. authorities although

there is little evidence to support this assumption. This is a major weakness of the Canadian notification system.

In contrast to the United States, legislation in both Canada and Europe requires testing data at various volume thresholds of use. In both jurisdictions, the requirements are structured so that more test data must be provided for chemicals used in greater quantities.[55] Canada, unlike the United States or Europe, requires a re-review of new chemicals when a company using the chemical increases the volume of production or import, and reaches a new tier in the hierarchy of testing requirements.

Currently, requirements for new substances introduced into the European Union are the most rigorous, requiring companies not only to provide data on all substances introduced in quantities greater than 10 kilograms, but also ensuring that extensive data are collected for higher volume chemicals and that the risks are assessed.

However, the current European new chemicals program will be eliminated under REACH, and all chemicals, new and existing, will be subject to the same requirements. With respect to new chemicals, REACH will ease the notification threshold from 10 kilograms to 1 tonne per year under the framework of the registration process. Although Canada has notification requirements for new chemicals above 100 kilograms, no testing data are required until a chemical is manufactured or used in quantities of more than one tonne per year. This means that for chemicals introduced into Canada and Europe in quantities of less than one tonne per year, companies will not have to submit any testing data. Under REACH, the information for new chemicals required under the current program at levels between one tonne and 10 tonnes per year will be reduced.

Even with reduced requirements under REACH, however, the information required for substances manufactured or imported at or above one tonne per year in Europe will be more rigorous than the information required by Canada. Canada's regulations for new substances, for example, do not require skin sensitization or skin irritation tests for substances below 10 tonnes while REACH will require these tests for all substances over one tonne. In Europe, companies that manufacture or import chemicals at higher volumes will be required to provide information or make proposals for testing reproductive toxicity, but reproductive toxicity testing is not required under CEPA.

Although Europe requires more testing or proposals for testing than Canada and the United States, no jurisdiction has data requirements that ensure a complete knowledge of potential effects on the environment and human health, particularly for chemicals manufactured or imported in low volumes. In Canada and Europe, testing data for specific hazardous end-points such as endocrine disruption are not required as part of the notification process for any substance in any quantity. REACH has also been described as "incomplete" for not taking neurodevelopmental disorders into account.[56] Neither REACH, nor any other jurisdiction,

[55] GAO, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program", June 2005, p. 14.

[56] Euractiv, "Medics Storm into EU Chemicals Debate" quotes Dr. Philippe Grandjean, University of Southern Denmark, as saying "REACH is incomplete because it does not take neurodevelopmental disorders into account". In a study published in Lancet online "Developmental neurotoxicity of industrial chemicals", November 8, 2006, Dr. Grandjean and Dr. Philip Landrigan argue that testing chemicals for their effects on brains would prevent the impairment of brain development, and should be included in REACH.

emphasizes testing for developmental neurotoxicity as a primary objective, even though these tests are considered by many experts to be critical for protecting children.[57]

In addition, time frames which limit a government's discretion and ability to fully assess a new chemical may create an avoidable risk for the public and the environment. The relatively short timelines -- 5 days to 75 days in Canada and 90 days in the United States -- are notable in contrast to the long, legally intricate processes by which chemicals are evaluated as toxic. Full risk assessments generally take about 5 years in comparison with the average 60 day review allocated for new chemicals in Canada. In Europe, under either current legislation or under REACH, government reviews and approvals are not tied to the notification or registration process, but are conducted independently. The European Union's practice of doing risk assessments has set the highest standard for ensuring the safety of new chemicals coming on the market.

There is also a lack of transparency in Canada's New Substances program, in comparison with Europe and with Canada's own existing substances program. In Canada, there is no public access to assessments of new chemicals or peer review of the information on which government approvals are based. Nor are there any mechanisms to inform the public when new substances are being reviewed or approved. Although this is partly due to the confidential nature of business decisions with respect to new chemicals, it makes it difficult for the public to know how effectively the government conducts reviews of new chemicals. Under REACH, non-confidential information in registration packages will be made available to the public.[58]

It has been argued that the European Union's strict testing requirements for new chemicals have stifled innovation because companies find it easier to continue using "existing" chemicals that are untested and possibly hazardous, rather than developing new chemicals. However, since the introduction in Europe of the assessment program for new chemicals, Member States have recommended controls for almost half of the new chemicals proposed for introduction and concluded that about 10 per cent of them were hazardous. This experience presents a compelling argument for maintaining, and even strengthening, rigorous pre-market testing for new chemicals.

1.5 *Filling in the Data Gap on Existing Chemicals*

The importance of filling in the data gap on existing chemicals is recognized as an international problem. In 1987, the Organization for Economic Co-operation and Development (OECD) recommended to all member countries in a binding Decision-Agreement that they strengthen their national programs to "systematically investigate existing chemicals in order to identify those which need to be managed and/or controlled".[59] In a subsequent 1990 Council Act, the OECD established a program to investigate the risks of existing chemicals through the

[57] Lanphear, Bruce, Charles V. Vorhees & David C. Bellinger (March 2005), Protecting Children from Environmental Toxins: Toxicity testing of pesticides and industrial chemicals is a crucial step. Public Library of Science PLOS Medicine, Vol. 2, No. 3.
[58] European Commission, Reach in Brief, Access to Information, p. 14.
[59] Organisation for Economic Co-operation and Development (OECD), Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals, C(87) 90 (Final), 1987.

coordinated and shared efforts among OECD countries, including Canada, the United States and the European Member States. However, progress has been extremely slow.

In order to establish benchmarks for the generation of data, the OECD developed the Screening Information Data Set (SIDS). This data set represents the minimum amount of testing required to make an initial hazard assessment of the health and environmental effects of high volume chemicals. The basic tests required by SIDS include about 20 tests that determine acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxicity and environmental fate. The basic set of tests is estimated to cost about $200,000 per chemical.[60]

The focus of initial efforts has been the development of data for high volume chemicals. These are the chemicals that are thought to pose the greatest potential for exposure, and Canada, the United States and the European Union have all adopted this as one of their criteria for evaluating chemicals. The OECD developed a list of 5,235 chemicals used in volumes of over 1,000 tonnes in at least one OECD country or the European Union.

While cooperating with the OECD, the governments of Canada, the United States and the countries of the European Union are pursuing their own programs. All countries are taking steps to review existing chemicals, to collect available information and to give priority to those chemicals that need more intensive evaluation.

However, each country has taken a distinctly different approach. In Canada, the government has started down this path through the review and categorization of existing chemicals, as well as the assessment of chemicals on its priority list. The European Union and its Member States have been collecting available data on single chemicals and doing risk assessments. In the United States, the EPA has been performing individual risk assessments, but because of the slow pace of this process, it has launched a broader initiative to generate basic data on chemicals through a voluntary sponsorship program by industry.

The information collected by these initiatives will enable authorities to set priorities, assess the risks of chemicals more expeditiously, make more informed decisions about the management and control of chemicals, and give better direction to industry on how to manage or control risks. Although their collective efforts should eventually result in a basic set of screening-level data for high volume existing chemicals, the individual approaches taken by each country have not yet coalesced into the coordinated and shared efforts to gather information encouraged by the OECD.

1.5.1 Canada and the Categorization Program

In her 2002 report on the toxic substances program of the Canadian government, the Commissioner of the Environment and Sustainable Development expressed concern about the incomplete knowledge base in Canada. She pointed out that there is good information on only a few substances. For many others currently in use, “there are few data about toxicity,

[60] U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, Chemical Hazard Data Availability Study, April 1998, p. 10.

persistence, exposure and effects. The risks may be insignificant – or they may be significant".[61]

In Canada, the government has chosen as one of the first steps in the review of existing chemicals to use available information to categorize them according to their potential effects. The *Canadian Environmental Protection Act* mandated a review of existing chemicals, known as the Domestic Substances List (DSL), within 7 years of the Act's passage in 1999.[62] This work has been carried out by the departments of Health and the Environment.

The Minister of Environment was responsible for identifying and categorizing substances on the DSL according to whether they are persistent, or bioaccumulative and "inherently toxic" to non-human organisms. The Minister of Health was responsible for identifying and categorizing those substances with the greatest potential for exposure to the general population, as well as those which are considered "inherently toxic" to humans and which were found by Environment Canada to be persistent or bioaccumulative.

Using the Domestic Substances List, Health Canada and Environment Canada have reviewed and categorized all 23,000 substances. The deadline was September 13, 2006, and the results of the process are gradually being made public. About 4,000 substances have been identified as meeting the categorization criteria. Of these 4,000, 396 are expected to meet all of the criteria – persistent, bioaccumulative and inherently toxic, and deemed to be high priority.[63] For those substances meeting these criteria, further screening is required.

To identify the manufacturers and their uses of selected substances identified through categorization, Environment Canada published a survey notice in the Canada Gazette, under Section 71 of CEPA on March 4, 2006, requiring information. The purpose of the notice is to help focus further government efforts in prioritizing chemicals for screening by identifying substances that are no longer in use, and by collecting information on how companies are using these chemicals. Also included in the Notice were certain Health Canada priority substances such as polymers, which are deemed to have great potential for exposure, in addition to other substances that may present a high hazard to human health.

On December 8, 2006, the government of Canada announced its "Chemicals Management Plan" which outlines some of the steps that it will take to address the results of the categorization exercise.[64] The most significant actions under the plan include:

- Uses of five categories of substances, including brominated flame retardants and perfluorinated compounds, will be restricted by regulation;
- Industry will be asked to provide information on 200 high priority substances to enable completion of screening assessments within three years and risk management strategies within another three years. These substances will be published in batches of 15-30 in the Canada Gazette every 3 months beginning February 2007;

[61] Commissioner of the Environment and Sustainable Development, 2002 Report to the House of Commons, Background and Other Observations, Section 1.26.
[62] CEPA, Section 73.
[63] Canadian Environmental Law Association, "Time to Push Federal government to get rid of most dangerous chemicals", Backgrounder, August 17, 2006. Accessible at www.cela.ca.
[64] Government of Canada, "Chemicals Management Plan", released December 8, 2006. Accessible at: <www.chemicalsubstances.gc.ca>.

- Significant new activity provisions will be applied to 150 highly hazardous substances not in use in Canada in order to ensure that information is provided and reviewed before they can be used in Canada. The same provisions will be applied to 150 other hazardous substances that are already in use in order to ensure that new or increased use of these substances is not done without assessment and controls; and
- Low risk chemical substances that were identified by categorization will be screened quickly in order to determine whether further assessment is necessary.

The categorization exercise is an unprecedented initiative for identifying existing chemicals of concern. Canada has already done considerable work, and can be said to be ahead of both Europe and the United States in establishing those chemicals which need further assessment. However, there are several weaknesses in the categorization procedures that may lead to the exclusion of chemicals that may in fact be chemicals of concern.

For example, categorization has been done based on the Domestic Substances List. However, because the Domestic Substances List is now twenty years old, estimates of exposure based on chemical use in 1986 does not accurately reflect the exposures of today. The use of some substances may have significantly increased, and therefore represent a greater potential hazard. A 2001 study, conducted by Health Canada to determine the accuracy of the DSL, showed that of a sample of 110 substances, 7 had changed by more than one order of magnitude since the collection of data in 1986. [65]

Another weakness is the categorization of substances based only on available data. No new toxicity data have been collected or generated that would have assisted in categorization decisions. As a result, about 1500 substances are considered by the government to be "uncertain" because they have no data or have conflicting data. Where there is an absence of information available on a substance, it would be considered as not having met the categorization criteria. Decisions to exclude these chemicals mean that some of these chemicals may be toxic, but without evidence that they are, they are eliminated from being reviewed in the next stage of the process.[66]

In addition, there is no definition of inherent toxicity in CEPA. Although inherently toxic "refers to the hazard a substance presents to the environment or human health", Environment Canada has made categorization decisions using the results of aquatic toxicity tests to represent "inherent toxicity" to non-human organisms.[67] Although Environment Canada and Health Canada considered properties such as carcinogenicity or mutagenicity for chemicals that were persistent or bioaccumulative, chemicals with these properties may have been eliminated from being categorized "in" because they were not first found to be persistent or bioaccumulative.

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[65] Health Canada, A Study to Determine Currency of DSL Quantity Data for Use in Categorization of DSL Substances, August 2001. Accessible at: <http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/currency-donnees/conclusions_e.html>.

[66] Environmental groups have recommended that surveys be used to fill information gaps for "uncertain chemicals" categorized out under the categorization process. See Canadian Environmental Law Association & World Wildlife Fund Canada, "Non-Governmental Organizations' Preliminary Comments on Path Forward Activities for Existing Substances", January 17, 2006.

[67] Environment Canada, "Frequently Asked Questions and Descriptions of Colour Codes", Existing Substances Evaluation: Categorization of the Domestic Substances List (DSL). Accessible at: <www.ec.gc.ca/substances/ese/eng/dsl/cat_faq.cfm>.

The European Union, by contrast, identifies carcinogens and mutagens in several different legislative vehicles, including REACH, as substances of very high concern.

As a result of these weaknesses in the process, the government is likely to be prematurely ruling out potential chemicals of concern where data are not adequate or where toxic properties may not have been given sufficient weight.

1.5.2 Europe: the Existing Substances Program and Registration

The European Union has been reviewing existing chemicals in a coordinated fashion since 1993. Its efforts to fill in existing data gaps are more directly tailored to the objectives of the OECD. The current "existing" EU chemicals program was established by the adoption of the Existing Substances Regulation (EEC 793/93) and based on substances identified from the EINECS list. The Regulation set up a four step program of data collection, priority setting, risk assessment and risk reduction.[68]

The Regulation required some manufacturers and importers to submit available data on existing chemicals. This was initially focused on high production volume chemicals – those chemicals that are imported or produced in quantities above 1000 tonnes per year. Information for these chemicals was to be submitted by 1994.[69] By 1998 information on lower volume substances (greater than 10 but less than 1,000 tonnes per year) was to be submitted.[70]

After collecting data, the Commission, in consultation with Member States, would identify priority substances that required immediate attention. Risk assessments would be done by Member States on the priority chemicals, along with analyses of costs and benefits, and risk reduction strategies would be developed for substances that required further control measures.

However, within several years, the pace at which chemicals could be assessed was judged to be too slow and the process too cumbersome. Member States were not able to obtain enough information on chemicals to develop priorities and conduct risk assessments. It was estimated that "testing would take hundreds, if not thousands of years".[71]

A renewed effort to create a process for identifying and controlling chemical risks that would be more efficient and effective was initiated. A White Paper that outlined a strategy for a future chemicals policy was released in 2001, a proposed REACH regulation was published in October 2003 and finalized in December 2006. The European Union, under the REACH regulation which will take effect in June 2007, has dramatically revised its approach.

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[68] Existing Substances Regulation 793/93, Part 1, Article 3. See also European Chemicals Bureau, Existing Chemicals Program. Accessible at: <http://ecb.jrc.it/exting-cehmicals/content1.php>.
[69] Ibid., Article 4.
[70] European Chemicals Bureau, Existing Chemicals, "Overview", Step 1: Data Collection. Accessible at: <http://ecb.jrc.it/existing-chemicals>.
[71] Ackerman, Frank & Rachel Massey, "The True Costs of REACH", a study performed for the Nordic Council of Ministers, 2004.

In order to relieve public authorities of the burden of establishing chemical safety, REACH will transfer the onus of generating information about chemicals and their hazards from public authorities to the manufacturers and importers, and make industry primarily responsible for the safe use of chemicals. This is consistent with recent European directives, which place responsibility on the producers for the safety of their products such as the Restriction of Hazardous Substances in Electrical and Electronic Equipment (ROHS) Directive. These Directives recognize that government authorities do not have sufficient resources for the task at hand.

The first major departure of REACH from previous chemical legislation is the establishment of a system of registration for all chemicals manufactured or imported into the European Union. Under Article 6, REACH will require all manufacturers and importers of chemicals over 1 metric tonne per year to register these chemicals. Without registration, substances cannot be manufactured or placed on the market of the European community. No registration is required for substances produced or imported in quantities of less than one tonne, or for substances used in research for a period of five years. Registration is estimated to apply in total to about 30,000 chemicals – 20,000 chemicals between 1 and 10 tonnes per year, and 10,000 chemicals over 10 tonnes per year.[72]

Registration dossiers will include the identity of the substance and the manufacturer or importer, information on the manufacture and uses, hazard classification and labelling requirements, as well as guidance on safe use.[73] As well, summaries of information and proposals for testing as required by the relevant annexes will be part of the registration dossiers. The requirements for data will increase in relation to the volume of chemicals manufactured or imported.

In addition, manufacturers and importers of substances in quantities of 10 tonnes per year or more are required to prepare a chemical safety report.[74] Chemical safety reports are based on a new process called chemical safety assessment, a type of risk assessment described in Annex I of REACH.

The chemical safety assessment is to consider the hazards of the substance, the exposure arising from the manufacture or import, the identified uses, the operational conditions and risk management measures applied or recommended to downstream users.[75] It must also include an assessment of human health hazards, physicochemical properties, environmental hazards and the chemical's persistent, bioaccumulative or toxic properties, or the chemical's potential to be very toxic and very bioaccumulative.[76] If the manufacturer or importer concludes that the substance is dangerous or is assessed as having persistent, bioaccumulative or toxic characteristics, an exposure assessment and risk characterization must also be done.

Unlike a traditional risk assessment which aims to predict the degree of risk, a chemical safety assessment aims for risk control.[77] REACH requires companies to "identify and apply the

[72] White paper, p.4.
[73] REACH, Article 10.
[74] Ibid., Articles 10(b) and 14.
[75] Ibid., Annex I (0.5)
[76] Ibid., Annex I (0.6).
[77] Warhurst, Michael (2005) "REACH, A New Approach to Chemicals Regulation in Europe: A Brief History, Key Features and Expected Outcomes", in *Journal of European Environmental Policy,* 31, 164-172.

appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets".[78]

There will be four tiers of data required for registration dossiers, as described in the Annexes to the Regulation. Registration requirements are graduated, but they must include everything applicable to lesser volumes plus the information required by the relevant Annexes for those tonnages.

The first tier applies to chemicals manufactured or imported in quantities from 1 to 10 metric tonnes per year. The required data include information on basic physicochemical properties, such as boiling point, flammability and explosive properties. Some toxicological data will be required for the registration of chemicals from 1 to 10 metric tones per year that meet certain criteria such as carcinogens or mutagens. These include skin irritation testing, eye irritation, skin sensitization, mutagenicity, and acute toxicity, as well as ecotoxicological information on aquatic toxicity and degradation.[79] It is expected that the majority of the 20,000 chemicals produced at this level will not meet the criteria and will not have to submit this data. This toxicological information, however, will be required for chemicals imported or manufactured at levels above 10 tonnes per year. Also, information such as the main use of the chemical and routes of exposure will be required.

The second tier of the data required for registration dossiers applies to chemicals manufactured or imported in volumes from 10 to 100 tonnes per year.[80] In addition to the basic tier one data, more toxicological and ecotoxicological data must be submitted for substances at or above 10 tonnes per year. The data include further skin irritation testing, eye irritation, mutagenicity, acute toxicity, reproductive/development toxicity screening, toxicokinetics, as well as ecotoxicological data including short-term toxicity testing on fish, degradation, and fate and behaviour in the environment.

The third tier of data requirements apply to chemicals manufactured or imported in volumes from 100 to 1,000 tonnes per year.[81] For these chemicals, although testing requirements are higher, it is not required that data from any of these tests be submitted with the registration dossiers. Registrants are only required to submit testing proposals and time schedules for fulfilling the information requirements, the need for which will be established through dossier evaluation.[82] Decisions on which tests will be done will be decided, at least in part, by animal welfare concerns. In these quantities, manufacturers and importers must provide additional information on physicochemical properties of chemicals, such as viscosity. Toxicological requirements are greater, and include testing for repeated dose toxicity, second generation reproductive toxicity, bioaccumulative tests in aquatic species, and more extensive data on degradation, and fate and behaviour of the chemical in the environment.

Finally, the most extensive data are required for chemicals manufactured or imported in quantities of 1000 tonnes per year or more.[83] Like tier three, registrants are not required to

[78] REACH, Article 13(6).
[79] Ibid., Annex VII.
[80] Ibid., Annex VIII.
[81] Ibid., Annex IX.
[82] Lowell Center for Sustainable Production, "A Brief introduction to the European Commission's regulatory proposal on Registration, Authorisation and Evaluation of Chemicals (REACH)", April 2006.
[83] REACH, Annex X.

submit any of this information with the registration package. Rather, they are only required to submit testing proposals and time schedules. Reproductive toxicity testing and carcinogenicity testing may be proposed at this level or may be required by the Agency.[84]

However, in preparing the data required for all of the tiers, manufacturers and importers have a considerable number of options or conditions that they may apply to the testing, including for higher-tier substances opportunities to waive certain tests.[85]

In order to reduce the amount of testing that would be done under REACH, it was originally proposed that companies share the responsibility for testing and registering substances. This idea was known as "one substance, one registration". Because of the strong industry opposition to this proposal, it has been made more flexible for companies with an option to register on their own.[86] This will allow industry to safeguard confidential information, where necessary.

The registration dossiers will be sent to a newly-created European Chemicals Agency. The Agency will be responsible for a completeness check but will not review them for quality or adequacy of data. The data will only be checked when substances are selected for evaluation.

REACH also provides for companies that purchase chemicals from major manufacturers and importers, called "downstream users" to be provided with better information on the chemicals that they use and their properties. Manufacturers and importers that submit registration dossiers containing chemical safety reports must outline exposure scenarios that describe the uses of chemicals and appropriate management measures and give this information to the companies they supply as an addition to the safety data sheets.[87] This provision has been described as a "key element of REACH that creates producer responsibility on the substance producer or importer".[88]

In addition, downstream users will have to submit information to suppliers on the ways in which they use chemicals and the potential exposure scenarios if they differ from the exposure scenarios described by the manufacturer or importer. These uses must also be covered in the chemical safety reports submitted by the manufacturer.[89] If a downstream user wishes to protect the information on how they use a particular chemical, they must prepare their own chemical safety report.

REACH contains legislated deadlines for registration. Depending on the tonnage of use, companies have 3, 6 or 11 years within which to register and submit the required data.[90] Priority chemicals for registration are those that are the highest concern, such as carcinogens or persistent substances, and those manufactured or imported in the highest volumes. These

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[84] Ibid.

[85] REACH, Article 13(1) allows companies to generate information by the use of models rather than tests. It also allows testing to be omitted where "justified by information on exposure and implemented risk management measures as specified in Annex XI, Section 3".

[86] REACH, Article 11(3).

[87] Ibid., Article 31(2).

[88] Warhurst, Michael, History, Key Features and Expect Outcomes of REACH, Journal of European Environmental Policy, Vol. 3, 2005, p. 169.

[89] European Commission, Questions and answers on REACH, December 2006.

[90] REACH, Article 23.

chemicals must be registered within 3 1/2 years of REACH coming into force in June 2007. It is anticipated that at the end of 11 years, all chemicals in use at one tonne or more per year in Europe will be registered, and basic safety data available.

1.5.3 The United States and the High Production Volume Challenge Program

The United States government has also recognized the lack of data on chemicals used by their industries. However, they have chosen a different approach – one which puts the onus on industry to develop the data but imposes few regulatory requirements.

In 1998, in a joint effort with Environmental Defense, a major environmental organization, and the Chemical Manufacturers Association (now the American Chemistry Council), the EPA launched the High Production Volume Challenge Program in order to systematically obtain testing information on those chemicals used in the highest volumes. The objective of this program is to gather information and a minimum set of basic safety data, like SIDS, on approximately 2200 high-production volume chemicals (defined in the United States as those chemicals produced at one million pounds or more per year).

Chemical companies are asked to make a voluntary commitment to adopt or sponsor chemicals. As a first step, the companies provide the EPA with data summaries of existing information. Along with the data summaries, industries submit a "test plan" that outlines how they propose to fill in data gaps for specific chemicals or classes of chemicals.

Since the Program's inception in 1998, industry chemical manufacturers and importers have participated in the Program by sponsoring over 2,200 chemicals. About 600 chemicals were removed from the program either because they were no longer produced in high volumes, there was no need to test them, or they were exempted by the EPA.[91] About 300 were not sponsored, and are considered "orphans".

The intention of the EPA is to make the results of these testing programs public when they were completed. When all of the results are published, the data collected under this program will provide both the EPA and the public with basic information about the chemicals that are produced and used in the largest quantities in the U.S.[92]

A status report by Environmental Defense, published in 2003, "Facing the Challenge" expressed optimism and concern over the progress of the program.[93] The report indicated that many companies were not meeting their commitments to previously agreed upon time limits, and concluded that "efforts will need to be redoubled if the program's objective of having all data on HPV chemicals publicly available in 2005 is to be met".[94]

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[91] Environmental Defense, HPV Chemical Tracker. Accessible at: <www.environmentaldefense.org/go/hpvtracker>.
[92] Environmental Protection Agency, High Production Volume (HPV) Challenge Program. Accessible at: <http://www.epa.gov/chemrtk>.
[93] Denison, Richard A. & Karen Florini, Facing the Challenge: A Status Report on the U.S. HPV Challenge Program, Environmental Defense, 2003.
[94] Ibid., p. xi, Executive Summary.

As of December 2006, industry sponsors had submitted about 740 final data sets to the Environmental Protection Agency. However, the EPA has not yet reviewed them for quality or completeness.[95] For 660 more chemicals, summaries of existing data and test plans to develop the data have been submitted, but not final data sets.

For 414 chemicals, industry sponsors have not yet submitted initial test plans, and 277 chemicals under the High Production Volume Challenge Program remain unsponsored "orphans".[96] Basic information on these chemicals will be lacking, unless companies step forward to test them. The EPA had stated that they would do test rules that would require industries to provide information on those chemicals which remained unsponsored. However, test rules have been issued for only 17 of these chemicals.

In addition, since the introduction of the program in 1998 another 574 chemicals have reached levels that qualify them as high volume chemicals.[97] So far, however, only 232 -- less than half of these -- have found industry sponsors. Such fluctuations in production levels as have become evident through the High Volume Chemical Challenge Program demonstrate that any country's chemical inventory may become out of date over a relatively short period of time.

The delay in generating more results from this program has been due in part to the time taken by the EPA to review test plans while sponsors waited for approval, and in part to the shifting of some industries' commitment away from the EPA program to the OECD program which is on a slower time frame.[98]

1.5.4 Discussion

Registration is the centrepiece of the European Union's new approach to chemical management. Neither Canada nor the United States have developed any equivalent process that would identify all existing chemicals in use above 1 tonne per year, and require basic information on production and use.

The registration process in Europe will have the result of improving our knowledge about chemicals. For governments, it will strengthen the capacity to assess risk and to identify more effectively the substances that require further controls. For manufacturers and importers, it will lead to a better understanding of the toxicity of the chemicals that they produce and use, and this in itself will lead to improvements in health and safety. In Europe, information will be passed down the supply chain through enhanced safety data sheets. This means that many companies that buy chemicals from a manufacturer or importer will have access to the hazard information and exposure scenarios generated by registration and that knowledge will enable them to handle hazardous chemicals more safely.

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[95] Environmental Defense, TSCA Myth vs. Fact, Environmental Defense's Responses to the American Chemistry Council's "Facts", August 3, 2006.
[96] Environmental Defense, HPV Chemical Tracker. Accessible at <www.environmentaldefense.org/go/hpvtracker>
[97] American Chemistry Council, High Volume Chemical Challenge Program. Accessible at: <http://www.americanchemistrycouncil.com>.
[98] Richard Denison, Senior Scientist, Environmental Defense, Personal Communication, September 2005.

It is also likely to lead to the replacement of hazardous substances with safer substitutes. This benefit was demonstrated in the United States when safety data sheets were initially introduced into the workplace. A survey conducted in 1992 by the U.S. General Accounting Office found that 30 per cent of the employers had replaced hazardous chemicals in their workplaces with less hazardous ones because of the information they received from the material safety data sheets.[99] By providing enhanced safety data sheets, registration will help further REACH's goal of reducing chemical risks through substitution.

In producing basic screening level data, the U.S. High Volume Chemical Challenge Program will also benefit governments by generating safety information that will be made publicly available. The development of categorization information in Canada is likewise an important contribution to evaluating and controlling chemicals. The identification of the most hazardous chemicals on the Domestic Substances List provides a road map that can be used not only in Canada but by many countries to begin the task of assessing and managing these chemicals. It is the first time that any government has attempted to classify and understand the properties of all chemicals in use in their jurisdiction.

CEPA, however, does not lay out any strategy for generating and collecting new data on these chemicals. Furthermore, the government's authority for gathering data is legislatively and politically limited.[100] Under Section 71, it may send a written notice to manufacturers or importers requiring toxicological or other testing, but only if there is "reason to suspect that the substance is toxic or capable of becoming toxic".[101] This suggests that some assessment of toxicity would have to be done in order to develop reasons that would legally justify requiring testing. With respect to the categorization process which narrows the field of chemicals down to those that may be toxic, Canada needs to apply the information-gathering provisions of CEPA to collect key missing data from industry that would facilitate the next phase of screening level assessments. Canada has taken a step in this direction with its December 2006 announcement that 200 substances will be listed in the Canada Gazette in batches of 15 to 30 starting February 2007, and industry will be asked to provide information in order to facilitate screening level risk assessments of these substances. A significant concern remains, however -- that potentially hazardous chemicals may have been eliminated by the categorization exercise from further review because of a lack of data.

One of the major differences in the approach taken to existing chemicals in both Europe and the United States compared to the approach taken in Canada is the transfer of responsibility from government authorities to industry. In the United States, companies have been asked to generate data that would assist the government in understanding the properties of high volume chemicals, and in Europe, industries will be required to assess the hazardous properties of their chemicals and assess the risks.

This transfer of responsibility resulted from the recognition that governments did not have sufficient data for prioritizing chemicals and conducting safety assessments. Nor could they do these assessments within a reasonable period of time. In contrast, the Canadian Departments of Health and the Environment have assumed the responsibility and the burden of categorizing

[99] General Accounting Office, "Occupational Health and Safety, Employers' Experiences in Complying with the Hazard Communication Standard", Accessible at: <http://archive.gao.gov/d32t10/146524.pdf>.
[100] CEPA, Sections 68, 70 and 71.
[101] TSCA, Section 4.

existing chemicals so that the most toxic may be given priority for assessment and management strategies developed. Although there is considerable value in having the government, rather than industry itself, responsible for reviewing the potential toxicity of existing chemicals, Canada faces a challenge in proceeding with the next stage of the assessment work in an efficient and effective way.

There are also questions about how effective REACH will be in providing information. The original vision for REACH anticipated that the information gaps would be filled within 11 years. However, arguing for more workable provisions, the chemical industry has been successful in persuading the European Council and Parliament to reduce the information requirements.

Moreover, several new provisions have been added to REACH at higher tiers of registration that give companies discretion in omitting testing information or finding alternative ways of providing it. These conditions create an element of uncertainty over the amount of information that will ultimately be available. There are also concerns that inadequate or inaccurate information may be submitted in the registration dossiers that will not be reviewed by any independent government agency unless the particular substance is selected for evaluation.

To summarize, REACH has set up a regulatory framework which promises to deliver useful information on chemicals and their potential hazards in a standardized way. The U.S. and Canadian programs will also contribute essential information. The most optimistic scenario would be that all three approaches generate information that is shared among the countries involved, and that decisions on which chemicals need to be restricted or eliminated could be consistent across jurisdictions. Additionally, the information should be collected and funnelled into an international body such as the OECD. However, it will take several years before the programs are completed, and the effectiveness of these different efforts becomes evident.

1.6 *Assessing Chemicals that May Pose a Hazard*

After information on existing substances has been collected, the next challenge is to identify those chemicals most likely to pose a hazard and assess the degree of risk. Although governments have traditionally relied on risk assessment to accomplish this, risk assessments has its limitations. A report from the U.S. Government Accountability Office found that:

The lack of precise knowledge about the type, likelihood, and extent of adverse effects from exposure to a contaminant results in uncertainty in risk assessment that can be reduced only by advances in scientific understanding or better collection of data.[102]

The experience of Canada, the United States and Europe has demonstrated that the selection of priority chemicals and their subsequent risk assessment is a long, complex and resource-intensive process. Consequently, relative to the number of chemicals in use, very few substances have been fully assessed. The problem has been not only due to the lack of basic data on chemicals as discussed earlier, but also to the “burdensome regulatory processes”, as

[102] US Government Accountability Office, Human Health Risk Assessment, GAO-06-595, May 2006, p. 2.

they were described by the Canadian Commissioner of the Environment and Sustainable Development.

1.6.1 Canada and the Assessment of Existing Substances

In Canada, there are seven tracks by which substances may become candidates for full risk assessment.[103]

The categorization process is the most ambitious track by which the government will identify existing chemicals that need further assessment. In Canada, once a substance on the Domestic Substances List has met the criteria for categorization and is deemed to have the potential for toxicity, the next stage will be the selection of chemicals for a screening level risk assessment. Screening level risk assessment is an intermediate stage for deciding which chemicals require a full assessment.

However, the requirements for which substances meeting the categorization criteria will undergo a screening level risk assessment are not clear. The government has indicated that priority may be given to substances based on the level of concern, the availability of data, the potential for co-ordination with international activities and a regard for the efficient use of resources. No plan of action has as yet been presented. Only two classes of substances have undergone a screening level risk assessment – polybrominated diphenyl ethers (PBDEs) used as flame retardants, and perfluorooctane chemicals (PFOS) which are used as stain repellants. Screening level risk assessment is also being applied to 123 other substances under a pilot project.

Unlike the categorization process which had a legislated deadline, the government has not established timelines for the screening level risk assessments and for the subsequent full risk assessments. The federal Commissioner of the Environment and Sustainable Development in her audit of the federal government's categorization program said that "this process may take up to a few decades to complete".[104]

A second track by which substances may be designated as "toxic" is the Priority Substances List. This list, developed in Canada through stakeholder consultations, identifies substances that need to be assessed on a priority basis within five years.[105] The public may also request that a substance be added to the Priority Substances List.[106] Responsibility for these assessments is shared by Environment Canada and Health Canada. An initial list of 44 priority substances, selected in 1989, has been assessed and 25 of them designated as "toxic". A second list of 25 substances was created in 1995, of which 18 were designated as "toxic". In total, 69 substances have been assessed under this program.

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[103] Environment Canada, Identifying Candidate Substances for Risk Assessment. Accessible at: <www.ec.gc.ca/substances/ese/eng/sect75_identification.cfm>.
[104] Report of the Commissioner of Environment and Sustainable Development. Background and Other Observations, 2002, Section 1.8.
[105] CEPA, Section 76.
[106] Ibid., Section 76 (3).

A third track is the review of decisions of provinces or other OECD countries. Under the provisions of CEPA, Canada is obliged to review the decisions of other OECD countries to ban or severely restrict substances. If a government review indicates that the substance is of concern but there is not enough information to determine its toxicity, it may also be placed on the Priority Substances List. As Europe proceeds with its regulatory process, there is the possibility that more substances will be assessed or even possibly restricted in Canada based on decisions made in the European Union. Theoretically, decisions to authorize or restrict chemicals in Europe under REACH would influence similar considerations in Canada.

There are four other possible routes by which a substance may also become a candidate for risk assessment -- by information supplied by industry, through the assessment of "new" substances, through emerging science and monitoring, and through international assessment or data collection.

A full risk assessment may take up to 5 years to complete. By 2002, the Commissioner of the Environment and Sustainable Development's audit found that at that time several substances on the Priority Substances Lists were still without a final published decision although the government had had 13 years for the first list and 7 years for the second in which to do the work. She attributed the delays in completing risk assessments for priority substances to the lack of sufficient information on toxicity, the complexity of the decision-making and administrative processes, and the limits on the departments' resources.[107]

When the risk assessment is completed, it is published in the Canada Gazette as a draft assessment subject to a 60 day comment period. A full risk assessment may lead to a conclusion that no further action is needed, that the substance should be added to the Priority Substance List for further assessment, or that a substance is toxic.

In Canada, the identification of "toxic" substances, or substances that may be hazardous, is one of the main thrusts of CEPA. Under Section 64, a substance is defined as "toxic" if it enters or may enter the environment in amounts or under conditions that may pose a risk to human health, the environment or its biological diversity or to the environment that supports life. It then becomes a candidate for the List of Toxic Substances.

1.6.2 Europe and Evaluation

Priorities for risk assessment under the current European legislation are very similar to Canada's. Priorities are established by a Committee made up of representatives of Member States and the European Commission. Four lists of priority chemicals have been created since the legislation was passed in 1994. Once chemicals are on the priority lists, member countries are responsible for conducting risk assessments. After an assessment is drafted by a member state, it is submitted to the Committee, which decides whether risk reduction measures are required or whether more information is needed before making a final decision.

[107] Report of the Commissioner of Environment and Sustainable Development. Background and Other Observations, 2002, Section 1.43.

By 2004, only 141 substances had been identified by Member States as priorities for comprehensive risk assessments, and only 70 risk assessments had been finished.[108] Of those 70, 57 required risk reduction measures and further information was needed to conclude the assessments for 2 other substances. For 11, the risk assessment concluded that no new information or testing was required and that the risk reduction measures in place were sufficient.

In the White Paper, the risk assessment process was described as "slow and resource-intensive and does not allow the system to work efficiently and effectively."[109] The White Paper found other major problems in the system. It found that information on the uses of substances and exposures were difficult to obtain. It found that decisions on further testing of substances could only be taken via a lengthy committee procedure, and that testing information could only be requested from industry if authorities had shown that a substance posed a serious risk. This resulted in a "catch" in the system where authorities had to prove that a substance could pose a serious risk before test results could be requested, but without test results, it was "almost impossible to provide such proof".

The information in registration dossiers submitted under REACH is intended to address these problems, and provide information that will allow authorities to more readily identify those chemicals for which further assessment is desirable. Some evaluation of the risks of substances will be done by the companies themselves in the preparation of their chemical safety assessments. In addition, the testing proposals that must be provided in the dossiers of those chemicals which are hazardous and those used in high volumes will allow authorities to obtain the tests that are needed. REACH also provides for Member States undertaking evaluations to request any information needed for the assessment. These provisions will eliminate the need for authorities to prove a chemical poses a serious risk before asking for test data.

Following from registration, REACH will establish a process for evaluation. Evaluations will draw on the information provided in the registration dossiers to select chemicals for further assessment.

Two types of evaluations will be conducted. Under the first evaluation process, at least 5 per cent of registration dossiers in each tonnage band will be subject to a quality check by the European Chemicals Agency to ensure that key elements such as chemical safety assessments and reports meet the requirements of the regulation. The Agency will also check all dossiers above 100 tonnes per year to ensure that no unnecessary animal testing is being proposed.[110]

Another type of evaluation, which is more comparable to a risk assessment, is the substance evaluation.[111] The Agency will develop criteria for identifying the chemicals which are the highest priority for evaluation based on the hazards, the exposure and the tonnage of particular substances. Chemicals meeting the criteria will become the priority chemicals for assessment under REACH. This is described as a "risk-based approach".

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[108] European Chemicals Bureau Newsletter, "Existing Substances", Issue No. 4, December 23, 2004.
[109] Commission of the European Communities, White Paper: Strategy for a Future Chemicals Policy, Brussels, February 27, 2001.
[110] REACH, Article 40.
[111] Ibid., Article 44.

In order to coordinate the evaluations, the Agency, together with the Member States, will develop a three year rolling action plan which identifies the substances that will be evaluated each year. The plan will include suspect substances where there are grounds "for considering…that a given substance constitutes a risk to human health or the environment".[112] If a member state has concerns about a substance, it may propose that it be evaluated. Member States will carry out the evaluations and may choose substances from the action plan that they wish to evaluate, but the Agency is responsible for coordinating the work plan and ensuring that all evaluations are done.

Progress reports will be published each year on the Agency's website.[113] Member States may ask for further information from companies, even if the information is not a part of the proposed testing in the registration package. However, evaluations must be done within 12 months from the time the evaluation begins or from the time the information is submitted. After 12 months, the evaluation is deemed to be finished.[114]

Once evaluations have been completed, the member state will consider how the risks of a chemical should be managed, and make recommendations to the Agency. Evaluations may lead to a decision that a chemical should not be used unless it is authorized or approved by the European Union, or that a chemical should be restricted.

1.6.3 United States and Existing Substances Risk Assessments

Under TSCA, unlike Canada and Europe, there is no requirement for the Environmental Protection Agency to identify priority chemicals and determine their risk. EPA relies upon advice from advisory groups and information from voluntary testing programs to determine which chemicals should be considered the highest priorities for assessment.

By 2005, under its existing substances program, the EPA had only completed internal reviews of the risks for 2 per cent of the chemicals listed in the TSCA inventory since they began their reviews in 1979.[115] In 1994, the EPA estimated that it could review only 20 to 30 chemicals per year, given its available resources. The collection of information on chemicals' effects and exposures was described as "time-consuming and resource intensive".[116]

As with new chemicals, the EPA must issue a test rule if it wishes to obtain additional information from industry. A test rule can take up to 30 months to finalize, and the testing itself may take between a few months and a few years. Test rules are also very difficult to issue because in order to require further information, the EPA must already possess information that suggests the chemical may present problems. This is the same problem identified in the

[112] REACH, Article 44(2).
[113] Ibid., Article 54.
[114] Ibid., Article 46(4).
[115] U.S. Government Accountability Office, Chemical Regulation, p.18. Uwe Lahl & Joel Tickner, "Deficits in US and European chemicals legislation – reform efforts and the transatlantic openness for dialogue", Lowell Center for Sustainable Production, p. 5, estimate that 1,200 substances of the original 62,000 on the TSCA list had been reviewed by 2003.
[116] General Accounting Office, EPA's Limited Progress, p. 12.

White Paper's critique of the challenges faced by Member States of the European Union in collecting information. As a result, the EPA has issued very few test rules.

The U.S. EPA is now in the process of collecting information through the High Production Volume Challenge Program. This allows the EPA to accomplish its goal of obtaining information more efficiently, and to avoid the time-consuming process of issuing rules to gather data for every chemical. However, the data sets developed under the HPV program are limited to screening level data, which are not sufficient for full risk assessments.

An advisory committee to the EPA has made recommendations on how the data could be used to prioritize chemicals for further assessments.[117]

1.6.4 Discussion

Audits or reviews of all countries' programs have come to similar conclusions – that the prioritization of chemicals and the subsequent risk assessments suffer from poor data and slow, resource-intensive procedures. As a result, only a very small percentage of existing chemicals have been assessed in any country. For example, Canada has completed 69 and the European Union 70 under their priority substance assessment programs. The lack of information and the delays which characterize all three approaches have been key factors in influencing the decision in the European Union to introduce a new regulation.

As far as the initial job of prioritizing chemicals for further evaluation goes, Canada may be considered to be farther ahead than other jurisdictions with the categorization initiative. In particular, the United States lacks a formal mechanism for choosing which chemicals should undergo assessment. However, the work required to screen 4,000 substances in Canada promises to make it a long process. Even when screening level risk assessments have been completed, the substantial work involved in doing full risk assessments for an unknown number of chemicals will be outstanding. This process may take decades, if the critique of the Commissioner of the Environment and Sustainable Development is accurate. She has expressed concern at the government's delay which allows potentially toxic chemicals to continue damaging human health and the environment.

The expectation is that REACH will generate data that can identify priorities more quickly, and lead to more efficient and effective assessments. REACH has laid the groundwork for better chemicals assessment -- through the registration requirements for data on existing substances, through the chemical safety assessments and through the proposals for testing in the dossiers of high volume chemicals and chemicals with hazardous properties. This should lead to a more methodical evaluation process conducted by Member States and coordinated by the European Chemicals Agency.

The information provisions that allow Member States to obtain information for evaluations should ensure that the European Union acquires from industry the data needed for

[117] National Pollution Prevention and Toxics Advisory Committee, Letter to Stephen L. Johnson, Acting Administrator, U.S. Environmental Protection Agency, February 18, 2005.

assessments. Both the European Union and the United States have found it difficult to obtain information or testing data because of legislation under which they must demonstrate the potential toxicity of a chemical before they could require companies to produce this information.

Canadian legislation is also limited by the need to show that there is reason to suspect that a substance is toxic or capable of becoming toxic, under Section 71. Consequently, the government has been reluctant to use these provisions. In several instances during the assessment of priority substances, Canada has had to update assessments based on new information and science for at least 13 chemicals.[118] It is possible that Canada's screening and risk assessments could be concluded more quickly and reliably if the government is more aggressive in using its legal authority to seek out information on suspect chemicals from industry.

The European Union has taken the procedures of existing regulatory frameworks, and tried to address some of the deficiencies that have hampered previous attempts to assess chemicals. Although this appears to be an improvement on previous regulatory frameworks, the effectiveness of the REACH process and its ability to prioritize and assess chemicals through registration and evaluation procedures are speculative until there has been experience with the actual legislation.

1.7 *Strategies for Control or Risk Reduction*

Once it has been determined that the risks of a chemical warrant further controls, Canada, the United States and Europe have a choice of management tools, structured to different levels of control. These range from voluntary agreements on reductions to legislated bans and restrictions.

As all countries move ahead on identifying substances of concern, the strength of a country's management tools will be a critical factor in determining the effectiveness of controls on hazardous substances and the degree of risk reduction to human health and the environment.

1.7.1 Canada and CEPA-Toxic Substances

In Canada, a management program is mandatory once substances are placed on the List of Toxic Substances. However, the administrative and decision-making processes that lead to a substance being declared toxic are complex, as the Commissioner of Environment and Sustainable Development has pointed out. Even after an assessment finds that a substance is "toxic", there are several stages before a final decision is made and controls put in place.

First, the Ministers of Health and Environment must recommend to Cabinet that the substance be added to the List of Toxic Substances. If Cabinet accepts this recommendation, the proposal

[118] 2002 Report of the Commissioner of the Environment and Sustainable Development, Section 1.39.

is published in the Canada Gazette. A 60 day public comment period ensues. At this time, it may also be proposed for virtual elimination.

After the public consultation has been completed, the Ministers must publish a final decision, and recommend to the Governor in Council whether or not the substance should be added to the List of Toxic Substances. Management controls for a substance can only be put in place once the Governor in Council has agreed.

If the substance is finally added to the Toxic Substances List, the government must develop and propose a management strategy within two years. After a draft strategy has been proposed, the Minister has a further 18 months to finalize it. This means a possible interim period of 3 ½ years from the time a substance is added to the List until a strategy is in place. At the present time, there are 79 substances on the Toxic Substances List.

If a substance is declared toxic, there are two possible management tracks established by the government's 1995 *Toxic Substances Management Policy* which are applied to "CEPA-toxic" substances. Track 1 is targeted at the virtual elimination of a substance. Track 2 is the management and control of a chemical's risks throughout its life cycle. Most substances on the List are Track 2. Track 2 chemicals are allowed for use, but their releases to the environment are controlled.

Virtual elimination was intended to be the most restrictive category under the *Canadian Environmental Protection Act*. It was meant to control those substances whose release, even in very small amounts, could cause problems. To qualify for virtual elimination, in theory toxic substances must result primarily from human activity, be persistent and bioaccumulative. The examples given by the government of substances for which virtual elimination is desirable are DDT and PCBs.

However, very few substances have been identified as Track 1. Of 79 listed substances, only six substances or classes of substances are Track 1. Most of the substances identified as Track 1 are banned in Canada or in other developed countries.

Although virtual elimination would appear to be the most restrictive category available to control hazardous substances, it has not been a useful tool for chemical management. The goal of virtual elimination is the reduction of emissions below the "level of quantification", defined under CEPA as the "lowest concentration of a substance that can be accurately measured using sensitive but routinely available measurement technology".

In practice, the level of quantification has been a controversial concept that has been difficult to apply. Although the Ministers of Health and Environment are required to establish a Virtual Elimination List, the List has only one substance, hexachlorobutadiene, announced in the Canada Gazette December 13, 2006. Because of the difficulties in developing levels of quantification, Environment Canada and Health Canada have designated several substances as Track 1 for virtual elimination, but have not proposed regulations that would add them to the Virtual Elimination List.

There is one other provision in the legislation that allows the Canadian government to act quickly to restrict a substance, if it poses an extreme hazard. The government under Section

94 of CEPA may issue a legally binding "interim" order requiring control action. This may occur under two circumstances – where a substance is deemed to be extremely hazardous but it is included in the List of Toxic Substances, or if a listed substance is not being adequately regulated.

Most substances on the List of Toxic Substances are subject to Track 2 management plans based on the life-cycle of the chemical. A range of options exist. These include options such as regulations that may impose bans or restrictions, pollution prevention plans, codes of practice, as well as non-regulatory instruments such as environmental performance agreements, guidelines, memoranda of understanding and voluntary agreements. For many listed toxic substances, the government uses several management strategies.

Regulations, as provided for in Section 93 of the Act, have been more effective in controlling or restricting substances than the virtual elimination procedures.

For example, the government has used the Prohibition of Certain Toxic Substances Regulations, 2005, to ban or restrict several toxic substances. The Regulations prohibit the manufacture, use, sale, offer for sale and import of the toxic substances listed in Schedules 1 and 2 to the Regulations. There are 9 substances subject to a total ban under Schedule 1 including substances such as Mirex and DDT.

Under Schedule 2 of the regulations, 2 other substances – hexachlorobenzene and benzidine – are also prohibited except for some very specific applications identified in the Act. In Canada, then, a total of 11 substances are prohibited or restricted.

Sector-specific regulations also have the potential to control or manage toxic substances. They are legally binding, transparent and have clearly articulated targets for reduction. For example, the 2003 Solvent Degreasing Regulations for trichloroethylene and tetrachloroethylene have clear targets. The regulations impose a three-year freeze in consumption on companies using more than 1,000 kilograms per year, followed by a 65 per cent reduction in the following years.

The regulations are expected to drive most industry users to find substitutes. According to Environment Canada, companies prefer to find alternatives to regulated chemicals rather than be subject to the monitoring and reporting regimes required by the regulations.[119] Environment Canada published a list of alternatives to solvent degreasers on its Pollution Prevention website. This is one of the few instances in which safer substitutes have been actively promoted by the government.

Pollution prevention plans are another management option for listed toxic substances. Under Part 4 of CEPA, Pollution Prevention, the government is authorized to require companies to prepare and implement pollution prevention plans for a specific substance within a certain time frame.[120] This is done through a notice in the Canada Gazette. Companies must respond by notifying the Minister when the plan has been prepared and declare that it is being implemented. They must also notify the Minister within 90 days of a plan being fully implemented.

[119] Rick Loughlin, Solvent Degreasing Coordinator, Environment Canada, Personal Communication, June 2004.
[120] CEPA, Section 56(1).

However, there is no posting of pollution prevention plans themselves. Only the declarations that plans are underway and interim progress reports are posted. The Minister may require a company to submit its pollution prevention plan, but only after a notice is published in the Canada Gazette.[121] Plans have been used as a strategy for only about 7 different substances or classes of substances, even though pollution prevention is one of the main goals of CEPA.

Some aspects of Canada's pollution prevention planning program are similar to the successful program implemented under the Massachusetts Toxics Use Reduction Act (TURA). TURA also requires companies to prepare pollution prevention plans. However, these pollution prevention plans apply to the whole facility and require an analysis of materials flow from chemicals received at the plant through to the waste stream. Summaries of these plans and material accounting data are publicly available.

In contrast, the preparation of plans in Canada is directed at individual CEPA-toxic substances. These may lead to reductions in emissions of specific substances, or to substitutions for the designated substance. However, since there is no public scrutiny of the content of the pollution prevention plans or their implementation, it is impossible to judge the effectiveness of this program as a way of controlling toxic substances. There is also no apparent government process for measuring the reductions of substances and their risks by the use of pollution prevention plans.

For many toxic substances, the government has chosen non-regulatory options to reduce the risk. The government's formal policy, as outlined in the Treasury Board documents, is to use non-regulatory means or instruments to address issues, and to use regulations only when non-regulatory options are not better suited to address the issue.[122] This has led the government to propose many non-regulatory management strategies. For example, Environment Canada has established guidelines for the levels of volatile organic compounds in consumer products. These guidelines are not legally binding, and there is no information to indicate whether affected companies are complying with the guidelines. Indeed, the Commissioner of the Environment and Sustainable Development found that neither the voluntary initiatives, nor the process for determining whether or not to use them, were "robust".[123]

1.7.2 Europe: Restrictions and Authorizations

Like Canada, the European Union uses risk assessments to determine how a substance should be managed. After a member state has drafted a risk assessment, the Member States, mediated by the Commission, decide whether a "substance of concern" requires further risk reduction measures. If it does, a control strategy is developed, including possible restrictions.

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[121] CEPA, Section 60(1).

[122] Treasury Board Secretariat, A Guide to the Regulatory Process for TBS Program Analysts, says "Departments must review their regulatory proposals to ensure that they are necessary and that non-regulatory means or instruments are not better suited to address the issue identified." Accessible at: <http://www.tbs-sct.gc.ca/ri-qr/processguideprocessus_e.asp>.

[123] 2002 Report of the Commissioner of the Environment and Sustainable Development, Section 1.46 refers back to the conclusions of the 1999 audit of voluntary initiatives.

Currently, under the 1976 marketing and use directive, also known as the Limitations Directive (76/769/EEC), the European Union may place restrictions on the manufacture, use or placing on the market of a substance. This Directive is similar to CEPA's Regulations for Prohibition of Certain Toxic Substances.

In recent years, the European Union has used its legal frameworks to restrict more chemicals than either the United States or Canada. Decisions to place restrictions on substances are taken for several reasons: where Member States are taking different approaches to managing a chemical; when these decisions offer the most effective way of eliminating the risk; and, where urgency is needed and there are no other community laws that deal with the risk.[124] The ability to impose restrictions offers Member States and the European Commission an opportunity to act quickly to limit the use of a chemical that appears to be a severe hazard or risk.

Under REACH, Europe will not only maintain and streamline its authority to restrict chemicals, but it will also introduce a new mechanism for managing chemicals under REACH, known as authorization. The legal framework for authorization presents an opportunity to control the most hazardous substances, and, it is hoped, to promote substitution. Restrictions and authorizations will give the European Union two different management options for controlling substances of concern.

Restrictions have been described as the "safety net" within REACH for those chemicals which pose "unacceptable risks" to human health and the environment on a Europe-wide basis.[125] Restrictions can apply to all chemicals, including those that are not part of the registration process, those chemicals that are not yet registered but will be phased in, or to any chemicals when immediate action is needed. The initial list of restricted substances will be carried over from the Limitations directive, and will include restrictions such as the ban on asbestos and restrictions on certain azo-dyes.[126] An inventory of restrictions will be published by the Commission by June 1, 2009.[127]

If Member States wish to propose restrictions on a substance after an evaluation has been done, they must prepare a formal dossier within twelve months. This dossier must show that the chemical poses a risk to human health or the environment, and propose the most appropriate risk reduction measures. Restrictions may also be proposed by the European Chemicals Agency on behalf of the European Commission. These dossiers will be made available on the Agency's website, and public comment will be invited.

At the same time that the proposed restrictions are published, the dossier will be submitted to the Committee for Risk Assessment for its opinion as to whether the restrictions are appropriate for reducing the risk to human health and/or the environment. The Committee has nine months to consider the dossier and give its opinion. The dossier is also submitted to the Committee for Socio-economic Analysis for an opinion on the socio-economic impact. This Committee has 12 months in which to publish its conclusions. Upon receiving these opinions from the Agency, the European Commission will make a decision and impose restrictions, as it

[124] European Commission, DG Health and Consumer Protection, "Unsafe Products: An Overview". Accessible at: <http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/index_en.htm>.
[125] European Commission, REACH in brief, September 2006.
[126] REACH, Article 68. Restrictions will be listed in Annex XVII.
[127] Ibid., Article 67(3).

judges necessary. Decisions must take into account not only the socio-economic impact of the restriction but also the availability of alternatives. [128]

The Commission itself may also propose restrictions on substances, which are classified as carcinogenic, mutagenic or reproductive toxins, on their own, in preparations or in products where these substances can be used by consumers, by going directly to a committee of Member States.

REACH will also introduce another management tool, authorization, which will be used to ensure that the most hazardous chemicals are controlled. The aim of authorization is:

> the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.[129]

Under REACH, at the conclusion of an evaluation, Member States may choose to recommend that a chemical be authorized. A chemical which is designated as "authorised" may only be used or placed on the market with an approval. In order to use these chemicals, companies must apply to the government for an approval in the form of an "authorisation". Authorizations will be applied to substances of very high concern where the effects on humans and the environment are very serious and normally irreversible.

When REACH comes into force, the European Chemicals Agency will produce a candidate list of chemicals for authorization, based on certain hazardous properties.[130] Decisions on which substances will be subject to authorization will be taken through a Committee procedure. About 1400 chemicals of very high concern will likely be on the list of authorized chemicals.

The substances that will be candidates for authorization are:

- carcinogens, mutagens and substances classified as toxic for reproduction (categories 1 and 2 in accordance with Directive 67/548/EEC);
- substances that are persistent, bioaccumulative and toxic, based on scientific criteria;[131]
- substances that are very persistent and very bioaccumulative, based on scientific criteria; and
- substances that give rise to an "equivalent level of concern" to those above where there is scientific evidence of probable serious effects to humans or the environment such as substances with endocrine disrupting properties, as identified on a case-by-case basis.[132]

To use a substance that is on the authorized list, companies will have to apply for an authorization for each use of the substance. They must include in their submission an analysis of possible alternatives, specifying their risks and the technical and economic feasibility of

[128] REACH, Article 68(1).
[129] Ibid,, Article 55.
[130] European Commission, Questions and Answers on REACH, December 2006, p.5.
[131] These criteria are set out in Annex XIII of REACH.
[132] REACH, Article 57 (a) to (f). These substances will be specified in Annex IV of REACH.

substituting them.[133] If suitable alternatives are available, a substitution plan including a timetable for proposed action must be submitted by the company. If alternatives do not exist, the companies must submit information on their research and development activities into alternatives.

Industry has argued against being required to apply for authorizations for substances of very high concern if they can control the risks. This has led to a provision in REACH that companies may be authorized to use a chemical if the risks to human health and the environment can be "adequately controlled".[134] Adequate control may be demonstrated in the chemical safety assessment.

However, after a special session of Council called to clarify "adequate control", a statement from the United Kingdom Presidency said

> authorisations should not be granted on the grounds of adequate control in the case of substances that are persistent, bioaccumulative and toxic or very persistent, very bioaccumulative. For substances where it is not possible to determine safe thresholds with current methods, the proposal provides for a review within 12 months after entry into force of the regulation...in addition, it was agreed that applications for authorizations should always include an analysis of possible alternatives by the registrant.[135]

Substances deemed not to have safe levels of exposure include non-threshold carcinogens, mutagens and reproductive toxins.

If the risks cannot be adequately controlled, an authorization may still be granted if it can be shown that socio-economic benefits outweigh the risk to human health or the environment and if there are no suitable alternative substances or technology.[136] Before an authorization is approved, opinions are given by the Committees for Risk Assessment and Socio-economic Analysis. The European Chemicals Agency must also make the authorization applications available on their website, and interested parties can make contributions on the alternative substances or technologies.[137]

Authorizations would be subject to a time-limited review, with the time being determined on a case-by-case basis. The time limits have also been another focus of intense debate. The European Parliament voted for a mandatory 5 year time limit at first reading of REACH, as a way of discouraging the use of the authorized chemical and encouraging substitution.

Authorization, like registration, is another innovative approach developed under REACH. It puts the onus on industry to justify the continued use of a hazardous substance, rather than making

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[133] REACH, Article 62 (4) (e) and (f). A decision was also made in the final discussions on REACH that the Commission will decide after 6 years if endocrine disrupting substances should be included in a list of substances that can only be authorized in light of their socio-economic costs and benefits, according to the Press Release issued December 13 by the European Parliament.
[134] REACH, Article 60(2).
[135] Press Release, Council of the European Union, Extraordinary Council Meeting, Competitiveness (Internal Market, Industry and Research), Brussels, December 13, 2005.
[136] REACH, Article 60(4).
[137] Ibid., Article 64(2).

governments impose restrictions. It also ensures that governments know when certain chemicals are being used and under what circumstances.

Although authorized substances will be based on the risks of a chemical, authorization shifts the emphasis away from managing chemicals based solely on risk assessment towards a management strategy that gives greater weight to the hazardous properties of a chemical. Irreversible hazardous properties such as persistence or bioaccumulation are considered to be so important that chemicals with these properties must be regulated in a way that takes into account whether their continued use is justified, given the risk.

1.7.3 The United States and Restrictions

Under U.S. chemicals legislation, there are almost no mechanisms by which even the most hazardous chemicals can be successfully restricted. Section 6 of TSCA authorizes the Environmental Protection Agency to issue regulations to reduce the risks of chemicals if "there is a reasonable basis to conclude…that a chemical substance or mixture…presents or will present an unreasonable risk of injury to health or the environment".

There are several conditions in the Act, however, that make it difficult for the EPA to enact rules that restrict the use and manufacture of chemicals. For example, under Section 6, the EPA is required to "use the least burdensome requirements" to protect against unreasonable risks. EPA believes that it must have substantial evidence that the health benefits of restricting the chemical outweigh the costs to industry in order to take action to control a chemical. The General Accounting Office in 1994 commented that "this standard is especially difficult for major controls or restrictions on widely used chemicals because the costs can be extensive and the full range of benefits may be difficult to document".[138] It has been described by other commentators as "setting the bar too high".[139]

This conclusion was demonstrated by the EPA's failure to convince the courts of its authority to regulate asbestos in 1990.[140] The EPA issued a final rule under Section 6 of TSCA in 1989 that prohibited the manufacture, importation, processing and distribution of asbestos in most products. When the asbestos industry challenged the ban (Corrosion Proof Fittings v. EPA), the court decided that the EPA did not have sufficient evidence to enact a ban.

The court found that EPA had not used the least burdensome regulation to achieve its goal of minimizing risk, had not demonstrated a reasonable basis for the regulatory action, and had not adequately balanced the benefits of the restriction against the costs of industry. In Canada the costs and benefits of control actions are taken into account but they do not restrict the government's ability to take action to control toxic chemicals.

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[138] General Accounting Office, *Toxic Substances Control Act*: EPA's Limited Progress in Regulating Toxic Chemicals, Testimony before the Subcommittee on Toxic Substances, Research And Development, Committee, U.S. Senate, May 17, 1994.

[139] Goldman, L. (2002) Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development, Environmental Law Reporter 32, pp. 11018-41.

[140] Lowell Center for Sustainable Production, The Promise and Limits of the United States *Toxic Substances Control Act*, October 10, 2003.

In spite of its regulatory inability to control even the most well-established carcinogens such as asbestos, the EPA has been forward-thinking in its promotion and sponsorship of green chemistry research. Although it has not legislated substitution, in 1991 it developed Design for Environment that includes a green chemistry program to "promotes the research, development, and implementation of innovative chemical technologies that prevent pollution in both a scientifically sound and cost-effective manner".[141] Since then, the EPA has influenced the development of greener chemicals and processes through grants, partnerships with industry and its Presidential Green Chemistry Challenge Awards.

1.7.4 Discussion

Under CEPA, the decision-making process under which a chemical is designated as toxic in Canada is complex. One a chemical is declared toxic, it may take as long as 3 ½ years to develop a management strategy. Furthermore, the criteria and the rationale for when tools, such as pollution prevention plans, are applied to the management of toxic chemicals in Canada are not clear. In most cases, other than the audit of the Commissioner of the Environment and Sustainable Development, there is no evaluation of the effectiveness of control measures. Even when toxic chemicals are known carcinogens, there is no consistent management strategy that would control their emissions or use.

In contrast, the "authorisation" process under REACH will introduce an important new concept into modern chemicals policy. It offers the idea that chemicals with extremely hazardous properties, such as carcinogens or reproductive toxins, should be used only under special circumstances, or not at all. It challenges the traditional regulatory view that chemicals are assessed for risk and then managed based on the degree of acceptable risk. Because the effects of some chemicals are serious and usually irreversible, hazardous properties will be important under REACH in determining whether chemicals will be authorized for use or not. Authorization has the advantage of providing the government or relevant authority with the discretion to limit the release of particularly hazardous chemicals, as well as keeping governments informed about the volume and the circumstances under which hazardous chemicals are being used.

However, the inclusion of "adequate control" as a condition of obtaining authorization has been described as creating "wide discretion" for the authorities.[142] This newly-added provision could emerge as a significant loophole in the strict management of chemicals that was originally envisioned under REACH, depending on how it is interpreted and applied in the authorization process.

An important objective of REACH is the substitution of the most hazardous substances with less hazardous or non-hazardous ones. The authorization procedures are one of the mechanisms within REACH for promoting substitution. In the final version of REACH, an analysis of

[141] U.S. Environmental Protection Agency, Design for Environment, Partnerships for a Cleaner Future. Accessible at: <http://www.epa.gov/dfe>.
[142] Koch, Lars & Nicholas A. Ashford (2006) "Rethinking the role of information in chemicals policy: implications of TSCA and REACH", *Journal of Cleaner Production* 14, p. 34-46.

substitutes is required when companies apply for authorization. Although most REACH stakeholders generally agree with the goal of substitution, the way in which substitution could be accomplished through the authorization process has been a key focus of discussion.

The European Parliament, in its first reading of REACH in November 2005, had stipulated that authorizations could only be granted if there were no suitable alternatives or technologies. This condition is widely supported by non-governmental organizations monitoring the development of REACH. Including this condition in REACH would have created a strong mechanism for substitution. Nevertheless, even with the weaker conditions placed on the consideration of appropriate substitutes in the final regulation, it is assumed that the burden of applying for authorizations will promote the adoption of less hazardous substitutes and safer processes.

CEPA itself has no direct mechanism for promoting substitution. Although regulatory controls for a substance may encourage substitution, the emphasis in CEPA is on pollution control or prevention, rather than on substitution. Similarly, the United States does not have federal legislation that promotes substitution. It has, however, created programs based on grants and incentives that have contributed to research and development of safer chemicals and processes.

It has been suggested by researchers that there are other more efficient mechanisms for finding safer substitutes.[143] They propose several options using information as a tool, rather than relying on the complex process of risk assessment. For example, governments could publish databases of preferred and disfavoured technologies; they could require labelling that would identify safe or hazardous products; or, they could publish lists of substances for which safer substitutes should be found.

Denmark and Sweden have both developed lists of undesirable substances as a way to discourage the use of certain hazardous chemicals and to provide an early warning to users that these chemicals may in the future be subject to restrictions. REACH's list of "authorized" chemicals, CEPA's List of Toxic Substances or Canada's categorized lists of substances of concern could be used intentionally to identify chemicals for which safer substitutes are desirable.

For the most hazardous substances where the level of risk is unacceptable, bans or restrictions are an effective way to prevent environmental and health damage. The restrictions under the Limitations Directive have allowed the European Union to act quickly to manage emerging threats. The new restrictions provisions under REACH will offer the European Union the same flexibility and provide a safety net with which to manage chemicals that are exempted from registration, are not yet registered or need immediate action.

In contrast, Canada's virtual elimination provisions do not allow a quick response. Although chemicals meeting the criteria of persistence and bioaccumulation should be controlled because of their irreversible effects, very few of the chemicals known to have these properties are slated for virtual elimination. There has been only one substance approved for the Virtual Elimination List under CEPA because of the difficulty of deciding a "level of quantification."

[143] Ibid.

Sector-specific regulations and the Prohibition of Certain Toxic Substances Regulations have been the most useful tools in Canada for banning or restricting substances. They offer the government a direct way to impose restrictions on the manufacture, use or offering for sale in products of toxic substances. However, only 11 chemicals have been banned or restricted under the Prohibition of Certain Toxic Substances Regulations. In contrast, the European Union has restricted the marketing and use of about 100 substances under the Limitations Directive.[144] For example, the Limitations Directive has been used to restrict nonylphenol and its ethoxylates to 1 per cent by volume in cleaning products, where Canada has used pollution prevention plans to reduce their use. In addition, the EU has restricted the marketing of about 900 substances classified as carcinogenic, mutagenic or toxic to reproduction.

1.8 *Consumer Products*

One way in which human health may be affected by toxic chemicals is through their intentional and unintentional release from consumer products. This is a particularly important consideration with respect to children's health. Consumer products are being increasingly recognized as a significant source of exposure to toxic chemicals for children and pregnant women. For example, common household products like toilet bowl or diaper pail disinfectants, that generally use 1,4-dichlorobenzene, can be a cancer risk. In June 2006, a study in *Environmental Health Perspectives* which assessed the homes of Los Angeles and New York teenagers for exposures to carcinogens in their daily lives found 1,4-dichlorobenzene presented the second highest cancer risk.[145] However, very little government control is exercised with respect to consumer products.

The way in which the European Union, Canada and the United States have responded to public concern and mounting scientific evidence on the potential toxic effects of phthalates, for example, reflects the different approaches and shortcomings of the three jurisdictions. It demonstrates the lack of clear policy or appropriate legislative frameworks for addressing the problems of toxic chemicals in products. However, Europe has shown more willingness than Canada or the United States to respond to scientific findings that implicate toxic products, whether or not they emerge from a systematic or an accidental process. The example of phthalates illustrates the differing responses and reinforces the importance of generating data on existing substances where available data are inadequate for assessing the risk.

[144] European Commission, REACH in Brief, September 2006, p.3.

[145] Sax, Sonja N et al. (online June 15, 2006) A Cancer Risk Assessment of Inner-City Teenagers Living in New York City and Los Angeles, Environmental Health Perspectives.

A Case Study of Phthalates: Same Substances, Different Countries, Different Rules

Phthalate esters are plasticizers, widely used to soften vinyl chloride and make it flexible. They have been on the market for about 50 years and they would be considered "existing substances" in Europe, Canada and the United States. They are found in an array of products ranging from IV drip bags in hospitals, building materials, cosmetics, clothing with plasticized images pressed onto them, soft plastic toys, and printed food packaging. "Rubber boots, swimming pool liners, traffic cones, insulation on electrical wiring – anything you see that's plastic, it's likely that it contains phthalates. They're everywhere," according to Mike Shelby, director of the Center for the Evaluation of Risks to Human Reproduction at the National Institute of Environmental Health Services.

There are a number of different types of phthalate esters, some of them regarded as more toxic than others based on available data. However, for some phthalates, there is very little information. Recent research published in peer-reviewed scientific journals has shown increasing evidence of their various toxic effects. One of the most important studies was done by Dr. Shanna Swan and her colleagues at the University of Rochester in 2005. They found a significant relationship between the phthalate exposure of pregnant women and adverse changes in the genitals of their baby boys.[159] Although previously animal studies had shown that phthalates can cause male infertility and birth defects, this was one of the first studies to suggest reproductive harm to humans. A recent Canadian study, led by Jiping Zhu of Health Canada, showed that breast feeding infants were ingesting significant levels of phthalates in their mother's breast milk.[160]

In response to concern from Member States about the toxicity of phthalates, Europe has been the first jurisdiction to restrict phthalates as the scientific evidence of its toxicity has emerged. In 1990, a temporary ban was placed on phthalates in children's toys. A series of risk assessments were prepared on phthalates under the Existing Substances Regulation. On July 6, 2005, after considering these risk assessments, the European Parliament voted overwhelmingly in favour of a permanent ban on the use of certain phthalates. Three phthalates, DBP, DEHP and BBP classified as toxic to reproduction, were banned from use in all toys and childcare articles. Three other phthalates, DINP, DIDP and DNOP where information was either lacking or conflicting, were banned from toys and childcare articles that could be put in children's mouths.

Continued...

[159] Swan, Shanna H et al. (August 2005) "Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure", in *Environmental Health Perspectives*, Vol. 113, No. 8: 1056-1061.
[160] Zhu, Jiping et al. (online July 2006) "Phthalate Esters in Human Milk: Concentration Variations over a 6-Month Postpartum Time", *Environmental Science & Technology.*

Although there was uncertainty about the toxicity of the last three phthalates, the European Parliament voted for restrictions based on the "precautionary principle" saying that a potential risk to children could not be excluded. These restrictions have been incorporated into the marketing and use directive 76/769/EEC, which will become part of REACH. They come into force in January 2007, and ensure a consistent application of these restrictions in all countries of the European Union.

The first three phthalates that are classified as reproductive toxins are also banned from use in cosmetic products in Europe under the Cosmetics Directive. Canada and the United States, on the other hand, have not placed legally binding restrictions on any phthalates even though assessments have been done that would support taking action. Two phthalates – DEHP and DINP – have been the focus of most concern in Canada and the United States because of their potential to affect children.

Canada has taken very limited actions on DEHP and DINP. Although DEHP has been designated as toxic under CEPA and DINP was assessed as a health concern, Canada has not introduced any regulations that would reduce the risks.

Based on an assessment done by Health Canada and Environment Canada, DEHP (bis (2-ethylehexyl) phthalate) was declared toxic because "it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health". Subsequently, Canada listed it on the List of Toxic Substances. DEHP is the most widely used plasticizer in the world.

As a result of designating DEHP as a "toxic" substance, the government must propose a management strategy. Rather than ban or restrict DEHP, however, Canada has not enacted any regulations, or even taken non-regulatory initiatives. According to the published management strategy, industry has taken some limited actions that would reduce public exposure to DEHP.[161] A Health Canada study, for example, tested food packaging and found that none of the products contained DEHP or DINP. The Vinyl Council of Canada indicated that DEHP had been replaced in children's toys with DINP.

Continued...

[161] Environment Canada, "Strategic Options for the Management of Toxic Substances – Bis (2-ethylhexyl) phthalate" concludes that "Since no readily identifiable link between human exposure and the manufacture and/or use of DEHP-containing plastics has been characterized, it would not be advisable that Environment Canada and Health Canada proceed with further risk management actions at this time. Appropriate risk management actions will be taken under the appropriate legislation following the result of the additional research, if necessary". Accessible at: <http://www.ec.gc.ca/toxics/docs/sor/dehp/en/toc.cfm>.

However, DINP also became suspect for its potential adverse health effects, and in November 1998, Health Canada issued an advisory regarding the use of DINP in soft vinyl teethers and rattles (but not pacifiers and bottle nipples). Like the European Parliament, Health Canada expressed concern that children could be exposed to high levels of phthalates by sucking or chewing on these toys. After a risk assessment showed its potential to damage liver and kidneys based on animal studies, Health Canada requested that manufacturers of small soft vinyl toys replace DINP with a safe substitute. Advisories are one option available to Health Canada under the *Hazardous Products Act*, but they are not legally binding.

The United States has also been reluctant to impose any restrictions on phthalates. Instead, government agencies and advisory groups have debated the toxicity and potential exposure of phthalates, and few controls, if any, have been put in place.

In 1995, the Toy Manufacturers of America (now the Toy Industry Association) entered into a voluntary agreement with the U.S. Consumer Product Safety Commission (CPSC) not to use DEHP in toys for children younger than 3 years of age. This was to include toys such as pacifiers, rattles and teething rings. This action was taken based on the conclusion of a scientific panel of the CPSC that DEHP was a possible carcinogen. DINP was to replace DEHP.

In November 1998, environmental groups petitioned the Consumer Product Safety Commission to remove DINP from toys for children up to age 5. The Toy Industry Association voluntarily agreed to remove DINP from toys intended for the mouth while CPSC studied the risk. In 2003, the U.S. Consumer Product Safety Commission concluded that children's toys, containing DINP, were not a health risk based on the estimated time that children would spend sucking on toys each day.

As a result, DEHP and other phthalates continue to be found in children's toys in North America. In tests done by non-governmental organizations in 2005, Environment California and U.S. PIRG, of 18 children's products tested, 15 contained one or more phthalates. One teething ring contained 410 ppm of DEHP.162 Other toys contained DBP and DNOP.

Continued...

[162] Environment California, "The Right Start: The Need to Eliminate Toxic Chemicals from Baby Products", November 2005.

In addition, the Center for the Evaluation of Risks to Human Reproduction, of the U.S. National Toxicology Program, produced reports in 2000 and 2005 that expressed concern that DEHP exposure can adversely affect reproductive development in infants less than one year old. They concluded that male infants undergoing medical procedures with vinyl equipment could be at considerable risk. In spite of this recommendation, the U.S. Food and Drug Administration continued to allow the use of DEHP in medical equipment. They have only recommended consideration of alternative devices to DEHP-plasticized PVC for high risk procedures on male neonates, pregnant women carrying male fetuses and peripubertal males.[163]

End

1.8.1 Discussion

Toxic substances in products fall between the cracks of various pieces of legislation. Once a substance is found to be a risk, it may be present in a range of products that are subject to different statutes – for instance, laws governing products, cosmetics, drugs, or toxic chemicals.

In Canada, the *Canadian Environmental Protection Act* and the *Hazardous Products Act* both have provisions for regulations that could ban or restrict toxic substances in products. However, there has been a reluctance to use these regulatory powers to control toxic substances in products.

In the United States like Canada, the regulation of toxic substances in products is the responsibility of different agencies, depending on the product. Food, drugs and cosmetics are the responsibility of the Food and Drug Administration, while hazardous products fall under the purview of the Consumer Product Safety Commission. Articles that contain chemical substances are entirely exempt from TSCA.

Similarly, Europe lacks a clear regulatory framework for toxic substances in products. Although Europe has shown a greater willingness to impose restrictions, it has relied primarily on the Limitations Directive to control toxic substances in products on a chemical by chemical and product by product basis.

REACH is unlikely to significantly improve the management and control of toxic chemicals in products. During the stages of its development, substances in consumer products have been a focus of the ongoing controversy. REACH does provide for substances that pose a risk to human health and the environment to be authorized or restricted. However, the major provisions of REACH, like U.S. and Canadian toxics legislation, are directed primarily at the control and management of toxic substances by industry.

[163] U.S. Food and Drug Administration, "FDA Public health Notification: PVC Devices Containing the Plasticizer DEHP", July 12, 2002.

Substances in articles under REACH are generally exempt from registration requirements unless chemicals will be intentionally released from the products at one tonne per year or more. This would mean that substances in manufactured goods such as cars, textiles or electronic chips would not be registered. Notification will be required if the substance in an article is of very high concern (i.e. on the list of candidate substances for authorization), and if it is present in an article in quantities above a concentration limit of 0.1 per cent by weight or above one tonne per year, although this is dependant on the conditions of use.[164] Based on a notification, the European Chemicals Agency has the option to require a full registration. Some information on hazardous chemicals in products will be available to the public on request.[165]

1.9 *Summary of Best Practices*

Canada, the United States and Europe are all taking steps to address the "burden of the past" – the large number of chemicals for which little or no data exist and which may be hazardous. As well, they are subjecting new chemicals to review before they enter the market. Although all the legislative and policy initiatives being undertaken will provide valuable information and set the stage for future controls, REACH has the potential to improve on previous and current attempts to establish a framework for managing chemicals. It is difficult, however, to judge REACH in advance of its implementation. The original goals of REACH may prove elusive if the final regulation is weakened by exemptions and conditions, and if it starts to replicate the cumbersome provisions of the failed chemical frameworks currently in place.

There are several ways in which REACH promises to improve on existing legislation. Many of the concepts embodied in REACH may be considered best practices. Similarly, elements of Canadian and American legislation offer best practices that could contribute to better models of chemicals legislation and policy. These include the following:

1) REACH, along with several European directives, has established the precautionary principle as a guiding principle. Several provisions of REACH, such as authorization or restriction, create the opportunity for acting in a more considered and cautious way with respect to future chemical control. With the restrictions placed on phthalates, for example, the European Union has shown that where potential toxicity of chemicals cannot be ruled out, it will support limits on their use.

   Although CEPA refers to the precautionary principle, the goals and commitments of CEPA emphasize sustainability and pollution prevention. Consequently, CEPA has been applied very conservatively. First, there has been little or no action taken to limit or manage a chemical before a complicated legal and political process confirms its toxicity, and secondly, most management strategies emphasize emission controls or reductions, rather than elimination or substitution.

[164] European Commission, "REACH in Brief", 2.2.2 Substances in Articles, September 2006.
[165] Ibid.

Best practice: Adopting the precautionary principle formally in legislation and putting it into practice with respect to the thorough screening of new chemicals and tighter controls on existing chemicals.

2) In order to understand the potential hazard from exposure to toxic substances, governments need accurate and up-to-date information on chemical use. The United States requires regular reporting every five years of high volume chemicals in use under the Inventory Update Reporting Rule. Although the quantities and the conditions make it a less effective practice than it could ideally be, Canada has no provisions for updating its original list of existing substances. The government has used the Canada Gazette to solicit information for its categorization and screening program. REACH does not explicitly require periodic updates, but it does require notification by companies of different tonnage threshold changes or of their intention to cease manufacture of a chemical.

Best practice: Regular reporting requirements and updates for all chemicals in use that will inform governments when a chemical is no longer manufactured or when a chemical is becoming a high volume chemical, as well as requirements for notification of significant new uses.

3) All governments should apply the strictest standards to new chemicals in order to guarantee future chemical safety. The European Union regime that was established for new chemicals has been the strictest in the world – requiring not only basic data but also risk assessments. It also has tiered data requirements so that the highest volume chemicals are the most carefully described. As a result, a significant number of chemicals proposed for use in Europe have been either withdrawn or restricted. It is hard to estimate how much damage has been averted with this kind of thorough screening, but given the history of chemical problems, every country should consider applying similar requirements for new chemicals.

Best practice: The European Union's pre-REACH requirements for testing and assessment of new chemicals, including adequate time frames for assessment and a transparent process that allows the public to know what chemicals are being reviewed and the results of those assessments.

4) REACH will give the European Union a mandate to obtain all information necessary for assessment when a chemical has been chosen for evaluation – first, through testing requirements and proposals in registration dossiers, and, secondly, upon request of a member state doing the evaluation. Canada's ability to require industry submission of data under *CEPA* is limited by the need to show that a chemical is toxic or capable of becoming toxic.

Best practice: The unfettered legislative authority of governments, as provided for under REACH, to collect sufficient data from industry for all chemicals in order to properly evaluate their potential toxicity.

5) Registration procedures under REACH promise to improve industry accountability by requiring notification about the volume and types of chemicals in use, by requiring the generation and collection of data and by making information on chemicals publicly

available. In addition, the transfer of responsibility from public agencies to the industry that produces and uses these chemicals will reduce the burden on governments to generate data or to solicit information from industry on chemicals and their use.

Best practice: The introduction of a tiered registration process that will give governments notification of all new and existing chemicals, their use, toxicity data and other critical information.

6) The requirement for companies to develop a chemical safety report when they are manufacturing or importing chemicals in quantities of 10 tonnes or more is another important aspect of chemical safety and information sharing for which industry will be responsible. Chemical safety reports will assess risk and exposure, and aim for risk control. By making industry responsible for assessing chemical risks, more information should be available to help downstream users of chemicals manage risks and make informed choices about the chemicals they use.

Best practice: The development of enhanced safety data sheets with exposure scenarios that provide information down the chain of supply – from chemical manufacturers and importers to companies making products and using these chemicals.

7) The Canadian Environmental Protection Act is an important departure from the traditional framework for chemical legislation. Canada has spent 7 years categorizing existing chemicals in order to identify the most potentially toxic ones. The results of this undertaking should be shared with all jurisdictions. There is a significant public interest in ensuring that the identification of priority chemicals be shared with other jurisdictions, so that the massive workload involved in filling the chemical data gap is not borne by any individual jurisdiction. REACH does not require comprehensive toxicological data for most of the 20,000 chemicals manufactured or imported in the range of 1 to 10 metric tones per year. The prioritizing of chemicals under the categorization program could be used by the European Union to require more data or evaluations for chemicals of concern already identified in the Canadian process. Canada's process could significantly influence the collection of data in Europe and the identification of priority chemicals.

Best practice: The creation of effective mechanisms for the identification of priority chemicals for risk assessment and control. Registration, categorization, public nomination and the obligation to review decisions of other jurisdictions are all good practices for prioritizing chemicals, although registration and categorization constitute the more structured and methodical practices.

8) REACH introduces a system of evaluation that targets the chemicals with the highest volume and those with the most hazardous properties. Because evaluation will be initiated based largely on information in registration dossiers submitted by industry, it is essential that government provide effective oversight. Evaluation, depending on how it is applied, should be a credible check on the quality and reliability of industry data and a process for identifying chemicals that need further control. Canada also has the potential for an effective screening process of those categorized chemicals that pose the greatest hazards that will be carried out by government scientists, independent of industry.

Best practice: A systematic review and evaluation of chemicals in commerce or coming onto the market based on the hazardous properties of those chemicals and their potential for exposure.

9) Authorization of chemicals is a promising but untested process. It may be effective, or it may become mired in struggles over the appropriate list of authorized chemicals and over what constitutes "adequate control". In this respect, REACH gives the European Union and Member States such wide discretion that it is impossible to predict the outcome. Nevertheless, it is anticipated that some 1500 chemicals, already identified as being of high concern, will be proposed for authorization. Canada's categorization work could be useful to the European Union in drawing up the candidate list for the most hazardous chemicals.[166]

Best practice: Better control and management of chemicals of very high concern through an authorization process that requires industry to apply for approval to use a chemical rather than putting the onus on government to request industry to control a chemical.

10) Authorized chemicals will be those chemicals that are considered of highest concern. Canada has also identified chemicals of concern and designated them as "toxic". However, Canada does not explicitly consider carcinogens, mutagens or reproductive toxins as properties which qualify them as "toxic".

Best practice: The identification of chemicals that must be eliminated or controlled based on inherently toxic properties that are considered to have irreversible effects.

11) One of the explicit goals of REACH is the substitution of hazardous chemicals with less hazardous ones. The European Union's authorized list of chemicals of very high concern will function as a disincentive for companies to use these chemicals and promote substitution, particularly if authorizations are time-limited and substitution plans have to be developed. Nevertheless, it had been proposed that chemicals for which safer substitutes are available could not be authorized under REACH, although this concept was not incorporated into the final regulation.

This approach to the substitution of less hazardous alternatives could also be done through the development of regulated lists for which safer substitutes must be found. This is the "safer chemical" approach identified by Lowell Center for Sustainable Development. It means assembling a list of chemicals with undesirable hazardous properties or unwanted toxicity, and substance-by-substance subtracting them from the list of commonly used chemicals.[167] The Canadian government's categorized lists of chemicals that present the greatest hazard to human health and the environment could be regulated in such a way.

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[166] Environmental Science and Technology News, "Chemicals Management may be getting tougher", Policy News, November 1, 2006. Rob Donkers, of the European Commission's delegation to the United States, states that "the information from Canada is very important because that will enable us to quickly establish a list in Europe for these 1500-2000 chemicals."

[167] Geiser, Ken, Lowell Center for Sustainable Development, "Making Safer Chemicals", April 2005.

Furthermore, lists of safer substitutes could be developed in order to promote the substitution of safer existing chemicals for more hazardous ones.

Best practice: The promotion of substitution through an authorization process or other regulated chemical list that does not allow the use of a chemical where a suitable less hazardous alternative exists.

12) The European Union under REACH plans to improve transparency and create new opportunities for the public or interested parties to influence decision-making processes around the use and marketing of chemicals. These include: the public availability of non-confidential information on registered chemicals, regular public notification of chemicals under evaluation, and the opportunity for the public to inform government agencies about less hazardous substances or processes during the authorization process. The European Union will also make some information on hazardous substances in products available to the public to allow them to make choices about their personal exposures. While Environment Canada has a relatively transparent process for assessing existing chemicals, there should be more opportunities for public involvement in the decision-making process around new chemicals and in the creation of non-regulatory instruments for controlling toxic substances.

Best practice: The involvement of the public in the review and approval of chemicals before the government makes final decisions around their marketing and use.

13) Both Canada and the European Union have provided for information sharing in their legislation. CEPA allows for the Environment Minister to share confidential business information with other governments or institutions under agreements or arrangements where they undertake to keep the information confidential.[168] A similar provision exists in European legislation that allows the Agency to disclose information to other governments or to international organizations.[169] Only TSCA restrains the U.S. from sharing information through stringent confidentiality provisions.

Best practice: The legislated ability of governments to share information in order to promote the exchange of information, including the expedient identification of priority chemicals, their assessment and their elimination or management.

To further the goal of the protection of health and the environment, all governments should be regularly reviewing and updating their chemicals legislation incorporating international best practices, particularly those under discussion in REACH. Additionally, all governments should investigate and develop new policy approaches that would accelerate a conversion to safer chemicals and processes.

[168] CEPA, Section 316 (1), parts (c) and (d).
[169] REACH, Article 120.

2. Extended Producer Responsibility in Canada, Europe and the United States

By John Jackson

Introduction: The Waste Management Challenge

The rise of consumerism after World War II resulted in a rapid growth in the amount of waste generated in North America and in Europe. This increase in waste was compounded by changes in the nature of products, such as planned obsolescence, single-use products, and throw-away products.[1] By the 1960s municipal waste management issues started to come to the forefront because the ever increasing consumption levels resulted in ever greater generation of garbage. The search for more and larger landfills and more incinerators combined with the environmental and social problems associated with these resulted in considerable political controversy over the siting of disposal facilities. This led to the rise of recycling programs to try to reduce waste disposal.

By the late 1980s, it was becoming clear that recycling programs as currently constituted were not solving the waste crisis. Waste generation was growing so rapidly that it more than balanced out the amounts diverted from disposal by recycling.[2] Much more successful recycling programs were necessary to reduce the need for disposal.

In both North America and Europe, governments started applying pollution prevention approaches to industrial facilities in the 1980s. These requirements for industry to act resulted in substantial reductions in emissions from these facilities. However, at the same time as pollution from factories was decreasing, the quantities of waste resulting from the end-of-life phase of products continued to escalate and recycling programs were proving limited in their ability to avoid waste disposal. This led some European countries, led by Sweden and Germany, to decide that the industries that made and sold products instead of municipalities and consumers should take responsibility for the waste stage. Thus the emphasis in these countries now shifted from a focus on facilities to a focus on products.[3]

This shift to a focus on products as the problem led to the introduction of extended producer responsibility (EPR) in Europe. Through EPR, governments shift responsibility for wastes from municipalities to those industries that make or sell the products that become waste and require them to achieve certain diversion targets. Although the concept and term were first introduced only sixteen years ago in 1990,[4] EPR programs spread from Europe throughout the 1990s to many countries around the world. These programs continue to spread today.

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[1] For a detailed description of these changes in the nature of products, see Giles Slade, *Made to Break: Technology and Obsolescence in America*, 2006.

[2] Gary Gardner & Payal Sampat, Mind over Matter: Recasting the Role of Materials in Our Lives, 1998, p. 14. See also, John E. Young & Aaron Sachs, The Next Efficiency Revolution: Creating a Sustainable Materials Economy, 1994.

[3] Thomas Lindhqvist, Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems, Lund University, 2000, pp. 19-24.

[4] Thomas Lindhqvist of the International Institute for Industrial Environmental Economics at Lund University in Sweden is usually given the credit for having introduced this concept.

EPR has become increasingly popular as a reaction to the many products that are "produced annually with shorter product life-cycles," which leads to "a huge number of obsolete products entering the waste stream".[5] Electronics are the prime example of this type of product.

In this chapter, we assess the state of EPR programs in Canada and Europe and compare the two. The chapter also includes a brief comparison with the status of EPR in the United States and draws conclusions about the reasons for the successes and failures of EPR programs.

2.1 *What is Extended Producer Responsibility?*

Sometimes the term EPR is used to mean different things or completely different terms are used to describe a similar concept. It is essential, therefore, that we begin by defining how the term will be used throughout this chapter. The choice of the meaning of the term affects how we make judgments about the various programs considered in this chapter.

2.1.1 The OECD Definition

The Organization for Economic Co-operation and Development (OECD) defines EPR in the following way:

> OECD defines EPR as an environmental policy approach in which a producer's responsibility, physical and/or financial, for a product is extended to the post-consumer stage of a product's life cycle. There are two related features of EPR policy: (1) the shifting of responsibility (physically and/or economically; fully or partially) upstream to the producer and away from municipalities, and (2) to provide incentives to producers to incorporate environmental considerations in the design of their products.[6]

Many industries have long held that the responsibility for their products and the environmental problems associated with them end when consumers buy them from the store shelves. The responsibility for waste management then is upon the user and the municipal governments. The OECD EPR definition switches this responsibility to the industry that made and sold the products. One commentator has described this shift in the following way: "Products would never become 'municipal' waste at all, but would be bought back by their producers ... and returned to the industrial system as 'technical nutrients'".[7]

Since Canada, the European countries, and the U.S. are all members of the OECD and all participated in the development of this guidance manual, this is the definition of EPR that will be used throughout this chapter. However, to aid in this discussion it is important to recognize

[5] Guide, V. Daniel R. Jr, David W. Pentico & Vaidy Jayaraman (2001) "A Framework for Hierarchical Planning and Control for Remanufacturing," in *Greener Manufacturing and Operations: From Design to Delivery and Back*, e. Joseph Sarkis, p. 277.
[6] OECD, EPR Guidance Manual for Governments, 2003.
[7] Spiegelman, Helen. Transitioning to Zero Waste – What can local governments do NOW?, Product Policy Institute, 2006.

that there are differing definitions and also different terms that are sometimes used when discussing EPR.

2.1.2 A Broader EPR Definition

Some EPR proponents believe that EPR should be defined much more broadly than the OECD definition, which focuses on the post-consumer use or waste stage of a product. For example, Gary Davis of the Center for Clean Products and Clean Technologies in Tennessee defined EPR as follows:

> Extended Producer Responsibility is the concept that manufacturers and importers of products bear a degree of responsibility for the environmental impacts of their products throughout the products' life-cycles, including upstream impacts inherent in the selection of materials for the products, impacts from manufacturers' production process itself, and downstream impacts from the use and disposal of the products. Producers accept their responsibility when they design their products to minimize the life-cycle environmental impacts and when they accept legal, physical or economic responsibility for the environmental impacts that cannot be eliminated by design.[8]

In contrast with the OECD definition, in this definition, EPR applies to all stages of the lifecycle of the product – not just the after-use stage. Usually when people use the EPR term, however, they are referring to the more limited aspect as defined by the OECD.

2.1.3 Extended Producer Responsibility or Extended Product Responsibility?

EPR is not always the acronym for the same words. In some cases the "P" stands for "producer"; in others, it stands for "product." Sometimes the terms "product stewardship" or "shared stewardship" are used synonymously with extended product responsibility.

Extended Product Responsibility is the term most frequently used in the U.S. The U.S. Environmental Protection Agency explains the significance this way:

> Product stewardship is a different "take" on the manufacturer-centered extended producer responsibility laws we often hear about abroad. Product stewardship recognizes that product manufacturers can and must take on new responsibilities to reduce the environmental footprint of their products. Without serious producer commitment, we as a country cannot make significant progress toward improved resource conservation and a sustainable economy. However, real change cannot always be achieved by producers acting alone: retailers, consumers, and the existing waste management infrastructure may have to pitch in for the most workable and cost-effective

[8] Davis, Gary, "Extended Producer Responsibility: A New Principle for a New Generation of Pollution Prevention," in *Extended Producer Responsibility: A New Principle for a New Generation of Pollution Prevention*, University of Tennessee, 1994, p. 1.

> solution. The solutions and the actors will vary from one product system to another.[9]

The main difference between product stewardship and Extended Producer Responsibility is the emphasis on all being responsible; in extended producer responsibility the prime responsibility is placed on the manufacturer or seller of the product.

Another example of this approach is the principles developed by Canada's National Task Force on Packaging:

> In keeping with a mutual goal to reduce packaging waste, consumers, industry and governments share responsibility for the environmental impacts of packaging waste and for making packaging stewardship programs viable in Canada.[10]

This understanding is often associated with a non-regulated approach to EPR. For example, the Council of Great Lakes Industries has said:

> Industry believes that it is important that these actions remain voluntary because industry, working with other affected stakeholders, will produce better solutions more quickly, at less cost than those mandated by regulations.[11]

This approach to EPR has been criticized as leading to confusion about exactly who is responsible for what and as resulting in voluntary and incomplete programs.[12]

When EPR is used throughout the rest of this report, it means the OECD definition of Extended Producer Responsibility because this is the term and definition that is recognized by governments in both Canada and Europe. However, as we will see later in this chapter, EPR is not consistently applied among the jurisdictions in Canada, Europe and the U.S. In sections 4 through 6 of this chapter, we describe the programs in Canada, Europe and the U.S. Section 7 compares the three jurisdictional areas and describes reasons for these differences.

2.2 *The Goals of Extended Producer Responsibility*

Governments have several goals for developing EPR programs.[13] The main ones are the following:

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[9] "Product Stewardship," Accessible at: <http:// www.epa.gov/epr/about/index.htm>; The Product Stewardship Institute in the U.S. has a similar statement as their description of responsibility. See <http:// www.productstewardship.us>.

[10] Canadian Council of Ministers of the Environment, *Guiding Principles for Packaging Stewardship*, May 1996, p. 2.

[11] Accessible at: www.cgli.org/positions/prodrespon.html.

[12] See for example, Clean Production Action, Extended Producer Responsibility: A waste management strategy that cuts waste, creates a cleaner environment and saves taxpayers money, p. 21.

[13] The goals listed in this section are derived from the following documents: OECD, Analytic Framework for Evaluating the Costs and Benefits of Extended Producer Responsibility Programmes, 2005; Environment Canada, Assessing When to Implement Extended Producer Responsibility: A Workbook, Accessible at: <www.ec.gc.ca/epr/en/documents.cfm?d=1>; Thomas Lindhqvist, Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems, Lund University, 2000.

- Reduce the costs to government for waste management.
- Achieve cost internalization by transferring waste related costs to producers and consumers of products.
- Reduce environmental impacts of waste management by decreasing amounts of waste going to disposal. The objective here is to increase diversion of waste by reuse and recycling.
- Reduce resource and energy use by decreasing waste generation.
- Encourage or require design for the environment. The objective here is to get the producers of products to redesign products so there are less harmful materials in the products, to make products last longer and be reusable, recyclable and easily dismantled.

Programs vary as to their motivations and, as a result, place differing emphases on each of these goals. This helps explain why EPR programs vary.

In part 9 of this chapter, we assess the extent to which current EPR programs are successful at achieving each of these goals.

2.3 *The Legislative and Policy Applications of Extended Producer Responsibility in Canada*

2.3.1 Canada and EPR at the Federal Level

Under the Canadian constitution the federal government does not have the responsibility or power to act on most waste management issues. This power lies with the provincial and territorial governments. As a result, the federal government is not the legislator or implementer of EPR programs.

This does not mean, however, that the federal government is not involved in EPR. Environment Canada plays a primarily information role in EPR. For example, Environment Canada maintains a website that describes EPR programs in Canada.[14] It also keeps itself informed of EPR programs in other countries so as to be able to bring information on those programs to the Canadian provinces and territories. Much of its work to encourage EPR in Canada is through its participation in the Canadian Council of Ministers of the Environment (CCME).

Environment Canada is currently exploring the possibility of using its powers under the Canadian Environmental Protection Act (CEPA) to require some national EPR programs. Under CEPA, Environment Canada has the power to regulate substances that have been designated as "toxic" under CEPA. Therefore, the federal government could require that industry take responsibility for retrieving and properly handling products that contain a substance that has such a designation and for not including those substances in new products.[15]

Two examples of substances that have been declared toxic under CEPA are PCBs and mercury. Both of these are present in consumer products, which frequently end up in waste disposal

[14] Accessible at: <http:www.ec.gc.ca/epr/inventory>.
[15] Communications with Duncan Bury, Head, Product Policy, Environment Canada, September 27, 2006, and October 2, 2006.

facilities and cause resultant environmental pollution. Although new production of PCBs is banned, PCBs are still commonly found in household products such as upholstery, padding and insulation material in white goods (appliances) and cars.[16] Products in common use that contain mercury include thermometers, thermostats, fluorescent lamps, blood pressure cuffs, nickel-cadmium rechargeable batteries, small transformers within lamp ballasts, old refrigerators and other older household appliances.[17] A recent report on Lake Superior, the largest and most pristine of the Great Lakes, estimated that 72 kilograms of mercury in consumer products were deposited into landfills around that lake in 2005. This was determined to be approximately 5 percent of all the sources of mercury to the Lake Superior basin.[18]

Despite consideration, thus far, Environment Canada has not used its powers under CEPA to require an EPR program for products containing toxic substances.

2.3.2 EPR and the Canadian Council of Ministers of the Environment (CCME)

The CCME is comprised of the ministers of the environment from the federal, provincial and territorial governments. Its purpose is to coordinate their approaches to solving environmental problems by developing consistent guidelines, codes and standards, harmonizing policies and approaches, and sharing information and research.

Thus far, CCME activities have focused on a stewardship or shared responsibility approach instead of a true EPR approach. These activities have been in two areas: packaging and electronics.

CCME and Packaging: In 1989, CCME created the National Packaging Task Force, which was made up of representatives from the provinces, municipalities, industry, and environmental groups. They developed the National Packaging Protocol (NAPP), which was endorsed by CCME in 1990. The target of this protocol was:

> By December 31, 2000: Packaging sent for disposal shall be no more than fifty (50) percent of the amount sent in 1988. Fifty (50) percent of these diversions shall be achieved through new source reduction and new reuse initiatives. Recycling programs shall make up the remainder of these diversions.[19]

The Task Force continued its work after the Protocol was signed to advise during the implementation phase. As part of this work it developed Guiding Principles for Packaging Stewardship, which were adopted by CCME in 1996. This document was appropriately called "stewardship" since it took the shared responsibility approach rather than an EPR approach, contrary to the spirit of OECD's intent.

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[16] Panero, Marta, Susan Boehme & Gabriela Munoz, Pollution Prevention and Management Strategies for Polychlorinated Biphenyls in the New York/New Jersey Harbour, New York Academy of Sciences, 2005, p. 72 & 73.
[17] The Harbor Project: Understanding and Preventing Contamination in the NY/NJ Harbor, New York Academy of Sciences, 2005.
[18] Superior Work Group, Chemical Committee, Lake Superior Lakewide Management Plan, 1990-2005, Critical Chemical Reduction Milestone 2006, p. 135.
[19] Canadian Council of Ministers of the Environment, *National Packaging Protocol*, March 20, 1990.

A survey conducted on packaging sent to disposal in 1996 showed that the 50 percent target had already been met.[20] Despite urging from the National Packaging Task Force to continue the work,[21] CCME closed down the NAPP program in 2000 due to budget constraints.[22]

The NAPP final report showed that the primary reductions in packaging occurred in industrial packaging rather than in consumer packaging.[23] This was due to the introduction of returnable and reusable packaging for delivering product to commercial and industrial customers and the use of lighter materials. One commentator explained that this result of the NAPP program was the product of the fact that NAPP was not an EPR program:

> The NaPP data reveals that when producers are directly responsible for waste management costs (i.e., their own internal pallets and packaging), great reduction and efficiency occurs in very little time. But post-consumer packaging waste has seen little change in the same period. It's no coincidence that the handling of this material – also a product of industry – is paid for by taxpayers via municipal programs.[24]

In 2005, CCME decided to again focus on packaging waste. They established an Extended Producer Responsibility Task Group to pursue this. This group of civil servants from each province and territory and the federal government is to provide guidance on the development and implementation of EPR and product stewardship programs and to consider packaging as a first priority.[25] They held a two-day workshop on EPR in September 2006 to explore EPR. The official statement from the meeting of the ministers of the environment two weeks later referred to addressing packaging waste but made no reference to EPR:

> Ministers agreed to continue to explore opportunities to reduce packaging in Canada. The aim is to address packaging content, the reduction of the amount of packaging and the management of waste packaging, including reuse and recycling.[26]

CCME and Electronics Waste: In 2004, CCME developed Canada-Wide Principles for Electronic Product Stewardship to assist the provinces and territories in the development of electronic-waste programs. The objective of these principles was to encourage the development of similar, but not necessarily identical, EPR programs among all the thirteen provinces and territories across Canada.

In the introduction to the principles, CCME endorsed the OECD definition of EPR. Three of the twelve principles in the document point towards the development of true EPR programs:

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[20] National Task Force on Packaging, National Packaging Protocol: 1996 Milestone Report, 1998.
[21] National Task Force on Packaging, National Packaging Protocol: 2000 Final Report, 2000.
[22] Ibid., p. 1.
[23] Ibid., p. 29.
[24] Clarissa Morawski, "Caught NaPPing," *Solid Waste & Recycling*, October/November 1999, p. 13 & 14.
[25] Presentation by CCME Secretariat at the National Extended Producer Responsibility Workshop, September 27-28, 2006.
[26] CCME, "Environment Ministers Take Action on Air, Water and Soil Quality," October 12, 2006.

- Responsibilities associated with management of e-waste are primarily borne by producers of the products, where "producer(s) means the manufacturer, brand-owner or first importer of the product who sells or offers for sale the product in each jurisdiction."
- Costs of program management are not borne by general taxpayers.
- Consumers have reasonable access to collection systems without charge.[27]

CCME developed these principles at this time because several Canadian jurisdictions were then exploring or developing programs to address electronic wastes. The CCME principles do not, however, ensure that electronic programs across Canada will be similar because the CCME cannot enforce its principles.

2.4 *EPR in the Provinces and Territories*[28]

Canada's thirteen provinces and territories have the prime constitutional responsibility for waste management and as a result for EPR programs. No province or territory has an overall policy on, definition of or strategy for EPR. As a result, EPR programs within each province or territory are inconsistent in their application of EPR principles. For example, in Alberta, industry is required to cover the costs of the used oil program, but has no responsibility for the used tires and electronics programs. The differences are just as diverse among the provinces and territories. In British Columbia, for example, in contrast with Alberta, industry is not required to cover the costs of the used oil program. In another example of diversity of programs across the country, Ontario and Quebec are the only provinces that require industry to contribute to the costs of recycling all packaging.

In this section, charts have been used to show how each province and territory has approached EPR for the waste streams for which EPR or stewardship programs have been developed in Canada: beverage containers, tires, oil, electronics, multi-packaging, batteries, and household hazardous waste.

2.4.1 Beverage Container EPR & Stewardship Programs in Canada[29]

All provinces have programs for beverage containers, but in most cases they are not true EPR programs where industry is responsible for managing and paying for the program. Most of them are deposit-refund systems where the consumer pays a deposit when they buy the beverage and gets that deposit back if they return the beverage container to the store or to a return depot.

In Alberta, all beverage containers are covered by a legislated deposit-refund system with the exception of plastic milk jugs, which are recovered through a voluntary system funded by the

[27] CCME, Canada-Wide Principles for Electronics Product Stewardship, June 2004.
[28] Two prime sources of information throughout the following section are <http:// www.ec.gc.ca/epr/inventory>, and Marbek Resource Consultants Ltd., *Extended Producer Responsibility (EPR) in Canada: Presentation to National Extended Producer Responsibility Workshop*, September 27, 2006.
[29] Sources on this section include, CM Consulting, Who Pays What: An Analysis of Beverage Container Recovery and Costs in Canada 2004-2005, 2006; British Columbia Ministry of Water, Land and Air Protection, British Columbia Industry Product Stewardship Business Plan 2002/2003-2004/2005, 2002.

milk industry. The beverage containers are returned to government set-up depots. Similar deposit-refund return-to-depot systems are in place in New Brunswick, Newfoundland, Nova Scotia, and Saskatchewan.

For milk containers, in Nova Scotia milk producers must provide funding to municipalities to recycle milk cartons.

British Columbia operates a similar program except that an industry association runs the depot system.

In Quebec, beverage containers in the deposit-return system are returned to the retailer.

On Prince Edward Island, soft drinks may only be sold in refillable containers. These are returned to the retailer for a full refund.

In Ontario, currently beverage containers, with the exception of beer containers, are managed through the blue box in a multi-material recover system. There is no deposit on these. As of February 2007, liquor and wine containers will be removed from this system and put under a deposit-return system. Manitoba also manages most of its recycling including beverage containers through a multi-material recycling system instead of deposit-refund.

The National Brewers' Association of Canada operates deposit-return systems across Canada, but the details of the programs vary by province because of differing regulations in each province. This has been a model of EPR, where industry takes full responsibility for its packaging, with no government participation or financial contribution. As an example of the success of this program, in the year spreading between 2005 and 2006, The Beer Store in Ontario recovered 92 percent of all beer containers sold in the province.[30]

JURISDICTION	EPR	STEWARDSHIP	LEGISLATED	TARGETS
Alberta		X	Yes	
British Columbia		X	Yes	75% recovery
Manitoba		X	Yes	
New Brunswick		X	Yes	75% recovery
Newfoundland		X	Yes	
North West Territories			Yes	
Nova Scotia		X	Yes	
Nunavut				
Ontario	X		Yes	
Prince Edward Island	X	X	Yes	
Quebec	X	X	Yes	
Saskatchewan		X	Yes	
Yukon			Yes	
National	X		No	

[30] The Beer Store, Responsible Stewardship 2005-2006: Towards Zero Waste, 2006.

JURISDICTION	WHO MANAGES?			WHO PAYS?		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
Alberta	X		X	X		
British Columbia	X				X	
Manitoba			X		X	X
New Brunswick	X				X	
Newfoundland		X			X	
North West Territories						
Nova Scotia		X			X	
Nunavut						
Ontario			X	X		X
Prince Edward Island				X		X
Quebec	X			X	X	
Saskatchewan			X		X	X
Yukon						
National	X			X	X	

2.4.2 Tires EPR & Stewardship Programs in Canada[31]

Alberta, British Columbia and Manitoba operate tire stewardship programs and fund them by charging a provincial levy on the purchaser of each tire. This goes into a designated fund. New Brunswick, Prince Edward Island, Quebec and Saskatchewan have similar programs.

British Columbia has required tire producers to develop an EPR program to replace the current government-managed program by 2007.[32] Manitoba is also currently working on changing its program into an EPR program. They hope to achieve this in 2007.[33]

In Ontario, an industry stewardship organization developed an EPR program for used tires. It was submitted to the Ministry of the Environment for approval in September 2004. In June 2005 the multi-stakeholder board responsible for overseeing these programs was informed that the Minister was not satisfied with the fee levying mechanism in the program. The board awaited further direction from the Minister.[34] In April 2006, the provincial government announced that it was "deferring" the plan.[35]

[31] One source of information for this section in Clarissa Morawski & Daniel Smith, "Where the Rubber Hits the Road," *Solid Waste & Recycling Magazine*, April/May 2001, pp. 6, 7 & 12.
[32] B.C. Ministry of the Environment, *FIRST Tires Program – What's New*.
[33] Manitoba Conservation, Tire Stewardship Regulation to be Reviewed, March 2006.
[34] Waste Diversion Ontario, *2005 Annual Report*, March 2006, p. 9.
[35] Honourable Laurel Broten, Ontario Minister of the Environment, "New directions in waste management in Ontario," April 20, 2006.

JURISDICTION	EPR	STEWARDSHIP	LEGISLATED	TARGETS
Alberta		X	X	
British Columbia		X	X	
Manitoba		X	X	
New Brunswick		X	X	
Newfoundland		X	X	
North West Territories				
Nova Scotia		X	X	
Nunavut				
Ontario				
Prince Edward Island		X	X	
Quebec		X	X	
Saskatchewan		X	X	
Yukon		X	X	
National				

JURISDICTION	WHO MANAGES?			WHO PAYS?		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
Alberta			X		X	
British Columbia		X			X	
Manitoba			X		X	X
New Brunswick			X		X	
Newfoundland		X			X	
North West Territories						
Nova Scotia		X			X	
Nunavut						
Ontario						
Prince Edward Island		X			X	
Quebec		X			X	
Saskatchewan			X		X	
Yukon						
National						

2.4.3 Used Lubricating Oil EPR & Stewardship Programs in Canada

In British Columbia, the brandowners of engine oil, transmission fluid, gear oil and filters and containers are required to provide take back facilities for used residuals of their products at no charge to the consumer. The situation is similar in Nova Scotia and Prince Edward Island.

Alberta, Manitoba and Saskatchewan's programs differ from those in British Columbia, Nova Scotia and Prince Edward Island in terms of who is responsible. In all three cases, fees are charged to distributors who may pass them on to retailers who in turn may pass them on to the consumer through an environmental handling charge. The 80% targets are in policies – not legislation. Quebec has a program similar to that in the Prairie Provinces.

Ontario's Minister of the Environment instructed the stewards of used oil to create a used oil management program plan. In July 2004, the multi-stakeholder board that oversees stewardship programs in Ontario rejected the industry's plan. The board then asked the Minister for instructions on how to proceed.[36] In April 2006, the Minister announced that she would be setting aside the used oil program and would integrate used oil containers and filters into a HHW program.[37]

Jurisdiction	EPR	Stewardship	Legislated	Targets
Alberta	X		X	80% recovery
British Columbia	X		X	75% recovery
Manitoba	X		X	80% recovery
New Brunswick	X		X	
Newfoundland	X			
North West Territories				
Nova Scotia	X		X	
Nunavut				
Ontario				
Prince Edward Island	X			
Quebec	X			
Saskatchewan	X		X	80% recovery
Yukon				

Jurisdiction	Who Manages?			Who Pays?		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
Alberta			X	X	X	
British Columbia	X			X		
Manitoba			X	X	X	
New Brunswick	X			X		
Newfoundland			X	X		
Northwest Territories						

[36] *2005 Annual Report*, op. cit., p. 10.
[37] Minister of Environment Presentation to Annual meeting of Waste Diversion Ontario, "New directions in waste management in Ontario", April 2006.

Nova Scotia	X			X	X	
Nunavut						
Ontario						
Prince Edward Island	X			X	X	
Quebec	X			X	X	
Saskatchewan			X	X	X	
Yukon						
National						

2.4.4 Electronics EPR & Stewardship Programs in Canada

In February 2005, Alberta became the first Canadian jurisdiction to have a program in place for electronic products. Computer monitors, televisions, CPUs and printers are included in the program. Retailers and suppliers charge an environmental fee on the purchaser ranging from $5 to $45. The consumer takes the electronics to municipal collection sites and other depots. There is no fee when the materials are returned. The environmental fee covers the costs of collection, transportation, recycling, public information and awareness, and research into better recycling technologies.[38]

A program for computer monitors, keyboards, mice, cables and desktop printers and televisions is being developed in British Columbia. The regulations supporting this were passed in February 2006 and will go into effect a year and a half later. Saskatchewan has also passed regulations to support electronics stewardship; the program will come into effect in February 2007.[39] These programs are similar to the one in Alberta.

Manitoba is also currently developing an electronics program. Ontario started developing such a program in December 2004.

Jurisdiction	**EPR**	**Stewardship**	**Legislated**	**Targets**
Alberta		X	X	

Jurisdiction	**Who Manages?**			**Who Pays?**		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
Alberta			X		X	

[38] Alberta Recycling Management Authority, Alberta's Electronics Recycling Program: Processor Status Report, November 2005.
[39] Cooper, Rosalind. "Waste Initiatives Across Canada," *Solid Waste Magazine*, June/July 2006, p. 27.

2.4.5 Multi-Packaging EPR & Stewardship Programs in Canada

Ontario has a blue box recycling program for glass, metal, paper, plastic, and textiles.[40] The plan applies only to materials in the recycling program. Brand owners and first importers are supposed to cover half of municipal losses involved in running these recycling programs.

Quebec has just put in place a system similar to that in Ontario. It also provides for payment by industry of 50 percent of municipal losses from recycling programs.

In Manitoba, a two-cent levy is charged to consumers of beverages when they purchase them. This levy is used to fund municipal multi-material recycling programs. This funding cannot exceed 80 percent of municipal costs to operate these recycling programs.

The other provinces and territories do not have EPR or stewardship programs for all packaging.

Jurisdiction	EPR	Stewardship	Legislated	Targets
Manitoba		X	X	
Ontario	X		X	
Quebec	X		X	60%

Jurisdiction	Who Manages?			Who Pays?		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
Manitoba	X			X		X
Ontario	X			X		X
Quebec			X	X		X

2.4.6 Batteries EPR & Stewardship Programs in Canada

British Columbia and Prince Edward Island have programs for returning lead acid batteries. The provincial government manages the program and funds it through a fee on the purchase of each lead acid battery.

The Rechargeable Battery Recycling Corporation (RBRC), an industry organization, provides rechargeable battery and cell phone recycling to consumers by allowing consumers to bring them back for recycling to stores that sell those products. This service is provided without charge to the consumer. Each year RBRC reports on the amounts of materials that they collected. However, there is no reporting on the capture rate for these products. INFORM

[40] *Blue Box Program Plan*, produced by Waste Diversion Ontario in cooperation with Stewardship Ontario, February 2003.

calculated that in the U.S. the capture rate was around 10 percent in 2000.[41] The program is identical in Canada so the capture rate likely is similar.

Jurisdiction	EPR	Stewardship	Legislated	Targets
British Columbia		X	X	
Prince Edward Island		X	X	
National	X			

Jurisdiction	Who Manages?			Who Pays?		
	Industry	Gov't	3rd Party	Industry	Consumer	Taxpayer
British Columbia		X			X	X
Prince Edward Island		X			X	X
National	X			X		

2.4.7 Household Hazardous Waste EPR & Stewardship Programs in Canada[42]

In British Columbia the materials covered in household hazardous waste (HHW) are paint, pesticides, flammable liquids, aerosols and gasoline. In British Columbia, HHW are returned by the user to depots scattered across the province and one-day collection events. There is no charge to the person who returns the used products. Pharmacies are required to take back and properly dispose of medications through the Post-Consumer Pharmaceutical Stewardship Association.[43]

In Nova Scotia and Quebec, paint is the only item in the HHW EPR programs.

The costs of these programs are usually covered by eco-fee levies on brand owners. The retailer often recovers these fees by charging a visible eco-fee to the buyer.

Manitoba had prepared a draft regulation for HHW, but withdrew it in 2001 while an overall review of Manitoba's EPR programs was being carried out.[44]

Ontario's minister of the environment announced in December 2006 that stewards are required to develop a stewardship program for some HHW materials by May 31, 2007.[45] This will be a

[41] Sheehan, Bill & Helen Spiegelman, "Extended producer responsibility policies in the United States and Canada: history and status," *Governance of Integrated Product Policy: In Search of Sustainable Production and Consumption*, 2005, p. 216.
[42] Product Care Association, 2004 Summary Report: Paint, Flammable Liquids, Pesticide and Gasoline Stewardship Programs.
[43] B.C. Ministry of the Environment, *Medications Return Program*.
[44] Green Manitoba Eco Solutions, Discussion Paper: E-Waste Stewardship Program, 2005.
[45] Letter from Laurel Broten, Ontario Minister of the Environment, to Gemma Zecchini, Chair, Waste Diversion Ontario, December 12, 2006.

partial EPR program since industry will only be responsible for costs after municipalities have collected and sorted the materials.

2.5 *Europe and Legislative Initiatives on Extended Producer Responsibility*

In the introduction to this chapter, we described the environmental problems and the new understandings of the causes of those problems that led to EPR. EPR programs began in Europe and developed much more quickly there during the 1990s than they did in Canada and the U.S. for two prime reasons. The first was the much more limited availability of land in Europe on which landfills could be sited than in North America. This meant that Europeans felt the negative consequences of the ever growing waste quantities more quickly than did people in Canada and the U.S. Secondly, there is much more of a tradition of strong government roles in Europe and of industry taking responsibility in Europe.

The strong US traditions of individualism and unfettered capitalism limit the types of government intervention that are acceptable politically. This has certainly been the case when attempts have been made to legislate extended producer responsibility (EPR) at the national level.[46]

2.5.1 EPR at the European Union Level

In Europe, the European Union has played an active role in pushing EPR forward since it was formed in 1993. Directives and regulations related to EPR ensure that the 25 member countries of the European Union, including the ten most recent additions to the EU, will achieve the goals and methods articulated in these regulatory tools. This results in reasonably consistent waste management approaches and actions throughout Europe.

The EU has passed EPR directives, which Member States are required to implement by introducing national legislation, for three waste areas: end-of-life vehicles, waste electrical and electronic equipment, and batteries. A prime goal of this is to harmonize national efforts and to "ensure the smooth operation of the internal market and avoid distortion of competition in the Community".[47] In addition, the EU's directive on packaging, although not strictly EPR in nature, pushed the spread of EPR programs for packaging throughout Europe.

End-of-Life Vehicles (ELV) [Directive 2000/53/EC]: The EU passed this directive in September 2000. The goals of the program are to "aim, as a first priority, at the prevention of waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of-life vehicles and their components so as to reduce the disposal of waste, and at the improvement in the environmental performances of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-of life vehicles".[48]

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[46] Fishbein, Bette K.and John R. Ehrenfeld & John E. Young, Extended Producer Responsibility: A Materials Policy for the 21st Century, p. 56.

[47] See for example the whereas's in the directive on management of end-of-life vehicles.

[48] Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, Article 1.

The Directive has four main types of actions:

1) **Prevention**: This places the responsibility on vehicle manufacturers and material and equipment manufacturers to:

   - limit the use of hazardous materials (vehicles made after July 1, 2003 may not contain lead, mercury, cadmium and hexavalent chromium except for specified uses);
   - design and make vehicles in a way that facilitates dismantling, reuse, recycling and recovery;
   - include increasing quantities of recycled content in vehicles.

2) **Collection**: Economic operators must set up systems to collect all end-of life vehicles and have such collection centres reasonably available to vehicle owners. “Economic operators” are defined as “producers, distributors, collectors, motor vehicle insurance companies, dismantlers, shredders, recoverers, recyclers and other treatment operators of end-of life vehicles, including their components and parts.” EU Member States must set up a deregistration system for vehicles that shows that the vehicle went to an authorized treatment or destruction facility. The last holder or owner of a vehicle must be able to send a vehicle to a collection centre without cost. Producers of vehicles are to “meet all, or a significant part of,” the costs of the collection system.

3) **Treatment**: Member States are required to ensure that:

   - hazardous materials are stripped from vehicles at treatment centres before further treatment so as to prevent contamination of recovered streams;
   - stripping is carried out in a way that will ensure suitability for reuse and recovery, and in particular recycling.

4) **Reuse and Recovery:** Economic operators are required to meet the following targets in each member state:

   - By January 1, 2006, reuse and recovery shall reach a minimum of 85 percent by weight; reuse and recycling shall be a minimum of 80 percent by weight; for vehicles made before 1980 lower targets may be set but they must not be lower than 75 percent for reuse and recovery and 70 percent for reuse and recycling (unlike recovery, recycling does not include energy recovery, e.g., incineration with energy recovery);

   - By January 1, 2015, reuse and recovery shall reach at least 95 percent and reuse and recycling shall reach a minimum of 85 percent.

Waste Electrical and Electronic Equipment (WEEE) [Directives 2002/96/EC and 2002/95/EC]: In January 2003, the EU passed two directives on WEEE: one on recovery of WEEE,[49] the other on restricting the use of hazardous substances in WEEE.[50]

The goals of the program are identical to those just provided for end-of-life vehicles with the substitution of "waste electrical and electronic equipment" for "waste from vehicles". WEE includes large and small household appliances, IT and telecommunications equipment, consumer equipment (e.g., televisions, radios, hi-fi equipment), lighting equipment, electrical and electronic tools, toys, leisure and sports equipment, medical devices, monitoring and control instruments, and automatic dispensers.

The first Directive requires the following actions:

1) **Product design**: The Member States are to:

- "encourage" design and production of equipment in ways that facilitate dismantling and recovery;
- take measures so producers "do not prevent, through specific design features or manufacturing processes, WEEE from being reused, unless such specific design features or manufacturing processes present overriding advantages, for example, with regard to the protection of the environment and/or safety requirements."

2) **Collection**: Member States are to ensure that for private households collection systems are set up that:

- Collect WEEE separately from unsorted municipal waste;
- Waste can be returned free of charge;
- Distributors take back an old product when a similar type of product is being purchased from them;
- Producers may set up their own collection or take-back systems provided they meet the targets in the Directive;
- By December 31, 2006, WEEE is collected from private households at a rate of at least four kilograms on average per inhabitant.

For non-private households, producers of electrical and electronic equipment are responsible for setting up and operating collection systems.

3) **Treatment**: WEEE producers are responsible for setting up treatment systems.

4) **Recovery**: WEEE producers are responsible for recovery. The priority is to be given to the reuse of whole appliances. This form of reuse is not included in the recovery targets. The targets producers must meet by December 31, 2006 are:

[49] Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment.
[50] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

- 80 percent recovery by average weight per appliance and 75 percent reuse and recycling for large household appliances and automatic dispensers;
- 75 percent recovery by average weight per appliance and 65 percent reuse and recycling for IT and telecommunications equipment and consumer equipment;
- 70 percent recovery and 50 percent reuse and recycling for other types of WEEE.

5) **Financing**: Producers of WEEE are responsible for financing the collection, treatment, recovery and disposal of WEEE from private households and promotion costs. They are not allowed to show this cost separately to the purchasers of products, except for a transition period of the first eight to ten years for historical wastes. For new products, the individual producer is required to provide a guarantee that the after use costs will be covered.

   For WEEE from non-households, the government can make the users partially or fully responsible for the costs. Otherwise the producers are fully responsible.

The second directive on WEEE, which is usually referred to as "restriction of the use of certain hazardous substances" (RoHS), requires the following actions:

- From July 1, 2006, new WEEE products may not contain lead, mercury, cadmium, hexavalent chromium, and polybrominated biphenyls (PBB). There is a tolerance level of 0.1 percent for lead, mercury, hexavalent chromium, and PBBs. The tolerance level of cadmium is 0.01 percent. Originally, or polybrominated diphenyl ethers (PBDE) were also subject to this requirement but the provisions were removed in June 2005.
- Some applications are exempted from this requirement, e.g., mercury in fluorescent lamps, lead in glass of cathode ray tubes, cadmium plating).

Waste Batteries and Accumulators [Directive 2006/66/EC]: In September 2006, the EU passed this directive relating to all types and sizes of batteries except that in security or military use or in equipment sent into space.

There are two components to this program: prohibitions on what may be placed on the market, and requirements to recover used batteries.

Batteries may not contain more than 0.0005 percent mercury by weight or more than 0.002 percent cadmium by weight. Button cells may contain up to two percent mercury. Exemptions are also provided for emergency or medical equipment and for cordless power tools.

Requirements around collection of batteries are:

1) **Collection**:

- Separate collection points for batteries that are easily available;
- Requirement that battery distributors take back batteries;
- No charge to end-users;
- Collection targets of:
    - 25 percent of batteries sold by September 2012;
    - Collection of 45 percent by September 2016.

2) **Treatment and Recycling**:

- Producers are responsible for setting up treatment and recycling systems;
- Development of new recycling and treatment technologies will be encouraged;
- Disposal of batteries in landfills or incinerators is banned although the residues of treatment and recycling may be disposed of; and
- By September 2011, 65 percent by average weight of lead-acid batteries, 75 percent by weight of nickel-cadmium batteries, and 50 percent by weight of all other batteries must be recycled.

3) **Financing**: Producers are responsible for any "net costs" from collection, treatment and recycling, and for promotion costs. These costs may not be shown separately to end-users at time of sale.

Belgium, Sweden, Austria, Germany, the Netherlands, and France had battery EPR programs in place before this directive was passed.

Packaging [Directive 94/62/EC amended in 2004 by 2004/12/EC]: The European Union has not passed an EPR directive for packaging but a directive that it passed in 1994[51] has stimulated EPR in EU countries. This directive set targets for the recovery of packaging and packaging waste:

- By June 30, 2001, 50 to 65 percent of packaging waste by weight is to be recovered or incinerated at energy from waste plants;
- By December 31 2008, 60 percent of packaging waste by weight is to be recovered or incinerated at energy from waste plants;
- By June 30, 2001 between 25 and 45 percent by weight of packaging materials are to be recycled (with a minimum of 15 percent by weight for each packaging material);
- By December 31, 2008, between 55 and 80 percent by weight of packaging waste is to be recycled; and
- By December 31, 2008, recycling must reach 60 percent by weight for glass, 60 percent for paper and board, 50 percent for metals, 22.5 percent for plastics, and 15 percent for wood.

The directive did not make producers responsible for packaging wastes. However, the EU Member States found that EPR was the most effective way to achieve these goals and passed EPR laws within their individual countries on packaging. Those in the EU who passed EPR legislation based on the German Green Dot system, which is described in the next section, are Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden.[52] Finland, Italy, and the United Kingdom have non-green dot mandatory EPR systems.

[51] Directive 2004/12/EC of the European Parliament and of the Council of 11 February 2004 amending Directive 94/62/EC on packaging and packaging waste.

[52] See the web site for Packaging Recovery Organization Europe (PRO EUROPE) for details on each of these programs. Accessible at: <http://www.pro-e.org>.

Denmark and the Netherlands have non-mandatory EPR systems based on agreements with the packaging industry.[53]

2.5.2 EPR in EU Member States

Each EU member state passes legislation that implements the EU directives. This does not mean that the EPR legislation passed in each country is identical; they are just required to meet the standards in the directive and to not contradict the requirements in the directive. Rather than describing each state's system in this section, we have chosen to highlight a range of systems that will provide examples of the different types of programs.

Some of the EU Member States passed EPR legislation or regulations prior to the EU directives. Indeed they were the first in the world to pass EPR legislation. As a result, the EU directives are based on the legislation in these Member States. Some of these precedent-setting actions by EU Member States are discussed in this section.

The Swedish Government was the first to approach legislation on EPR.[54] In 1975, they introduced a bill containing the concept although not using the term:

> Before the manufacturing of a product is commenced, it should be known how the waste, which is the result of the production process, should be treated, as well as how the product should be taken care of when discarded.[55]

Sweden was not the first, however, to pass EPR legislation. That country was Germany in 1991.

Packaging:[56] In 1991, Germany passed the Packaging Ordinance. With revisions, this program is still in force. It requires packaging distributors and producers to take back and ensure the recycling of their packaging. As an alternative, companies may create a private system of collection and recycling in collaboration with private and public recovery companies. Because of this choice, it is called the "Duales" system. Industry is required to cover all of the collection, recycling and disposal costs. If the company chooses to use the collaborative approach, it must have a "green dot" on its products. This symbol indicates that the company has paid fees to cover the costs of handling the waste from their products. The collection methods vary by municipality, including depot systems and curb side collection methods. The fees vary according to packaging materials. In 2006, for example, the fees in cents per kilogram ranged from 135 for plastics to 7.6 for glass.[57] The ordinance contains target levels for collection and recycling.

The amounts of materials collected for recycling in Germany increased dramatically after the ordinance was passed. The country was, as a result, confronted by a lack of capacity to actually

[53] See Lisa Quinn & A. John Sinclair, op cit., p. 77.
[54] For a brief history of the development of EPR in Europe, see Thomas Lindhqvist, Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems, pp. 29-49.
[55] Ibid., p. 30.
[56] For an excellent overview of the individual packaging programs, see "European Packaging Directive Transposed into National Legislation All Over Europe," *Resources Report: Newsletter for Sustainable Development*, Issue II, 2000, pp. 2-11.
[57] "Duales System Deutschland GmbH," Accessible at: <http://www.pro-e.org/germany/germany/htm>.

recycle the materials. This meant that in its early days many of the materials collected were shipped to other countries for recycling or dumping. This gave the program a negative reputation, but soon the recycling infrastructure developed to handle the materials and the German packaging ordinance became a great success.[58] The German system became a model for most states within the EU.

France uses a Green Dot system but the responsibility is shared between industry and municipalities. Municipalities continue to be responsible for handling the packaging wastes. The industry organizations Eco Emballages and Adelphe collect fees from individual producers, which they give to municipalities to cover the extra costs involved in selective collection and sorting of packaging wastes.[59]

A few states have used alternative approaches to the Green Dot. For example, the United Kingdom requires companies to meet recovery and recycling obligations; usually they do this through participation in industry organizations. The unusual feature of the U.K. system is that the obligation is divided among four categories: the manufacturers have to pay six percent of industries' costs, the converters nine percent of the costs, the packers and fillers 37 percent, and the sellers of the products have to pay 48 percent of the program costs. Also industry is not obliged to recover all the packaging wastes, only a percentage; the rest remain as a municipal responsibility.[60]

The Netherlands approach to packaging stewardship is based on a covenant or negotiated agreements approach rather than on legislation. It has been pointed out that this voluntary approach has worked in the Netherlands because of "a more or less explicit threat of government intervention."[61] This has become the standard approach for EPR programs in the Netherlands, although it failed to materialize for electrical and electronic equipment. In this case, the government issued a decree to require EPR.

Other Materials: EPR programs are also in place in many EU Member States for tires, automobiles, electronic and electric equipment, and batteries. Because there are EU directives detailing program components for automobiles,[62] electronic and electric equipment, and batteries, the EPR programs for these products are, or will be, much more uniform across Europe than are those for packaging.

Battery recycling is an instructive example of the impact that EU directives will have on bringing similarity among programs. In September 2006, the EU passed its directive on batteries. Prior to this, several countries in Europe had already passed regulations on batteries.[63] In contrast with current requirements in the EU directive, France requires that disposal costs be clearly

[58] Thorpe, Beverley & Iza Kruszewska, Strategies to Promote Clean Production: Extended Producer Responsibility, 1999, section 6.1.
[59] Accessible at: <http://www.pro-e.org/france/france.htm>.
[60] Department for Environment, Food and Rural Affairs, The Scottish Executive, The National Assembly for Wales, *The Producer Responsibility (Packaging Waste) Regulations 1997 (as amended): The User's Guide*, 2nd edition, 2003.
[61] Thomas Lindhqvist, Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems, p. 47.
[62] For description of end-of-life vehicle programs across Europe, see "End of Life Vehicles," *Warmer Bulletin*, May 2001, pp. 22-23.
[63] "Battery Recycling," *Warmer Bulletin*, November 1999, pp. 22-23.

shown to the consumer in the pricing of batteries. France's regulation would have to be changed to mesh with the EU directive, which requires that there not be visible fees.

Member States vary in how completely they implement EU directives. A recent study on the implementation of the WEEE directive is tellingly called Lost in Transposition.[64] They concluded that "most MS [Member States] have clearly not designed their national laws to account for individual financial responsibility for new WEEE, as intended in the legal text and spirit of the WEEE Directive".[65] They also found that EU Member States varied in the responsibilities they gave to municipalities.

2.6 *Product Stewardship in the United States*

EPR is a term that is rarely used in the U.S. Reflecting common usage in the U.S., the U.S. Environmental Protection Agency uses the terms "extended product responsibility" or "product stewardship" instead of "extended producer responsibility." Tellingly, a recent book on the history of garbage and garbage policies in the U.S. doesn't even mention this concept until the last chapter and that is only a brief reference to what is happening in Europe.[66]

In their history of EPR in the U.S., Sheehan and Spiegelman describe how U.S. industry successfully mobilized against EPR between 1988 and 1992.[67] They then describe how the EPR concept was "co-opted" by industry during the 1990's to become programs that were not true EPR.[68] Other commentators point out the irony that "the same companies that run EPR programs in Europe have lobbied heavily against their implementation in the United States."[69] They go on to suggest that the success of industry in the U.S. at preventing EPR is because "political campaigns in the United States are very expensive and industry is a large contributor".[70] Others have hoped that companies having to comply with EPR programs outside of the U.S. will eventually do the same in the U.S., but "the evidence to date provides limited hope for such a development".[71]

Individual companies or industry associations have developed stewardship programs for a wide-range of materials. The prime characteristics of most of these programs are that they are based on:

- shared responsibility among industry, government and consumers;
- voluntary agreements between industry and government;
- lack of uniform availability to consumers;
- lack of targets; and

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[64] van Rossem, Chris, Naoko Tojo & Thomas Lindhqvist, Lost in Transposition: A Study of the Implementation of Individual Producer Responsibility in the WEEE Directive, September 2006.
[65] Ibid., p. 20.
[66] Melosi, Martin V. Garbage in the Cities: Refuse, Reform, and the Environment, 2005.
[67] Bill Sheehan & Helen Spiegelman, pp. 213 & 214.
[68] Ibid., pp. 214-216.
[69] Fishbein, Bette K., John R. Ehrenfeld & John E. Young, Extended Producer Responsibility: A Materials Policy for the 21st Century, p. 56.
[70] Ibid.
[71] Renner, Michael. "Moving Toward a Less Consumptive Economy," in *State of the World 2004*, Worldwatch Institute, 2004, p. 107.

- lack of detailed reporting on progress.

This makes it inappropriate to call them EPR programs.[72]

Beverage containers are the ones for which the U.S. has the most EPR. Eleven out of fifty states have legislation requiring deposit-return for some beverage containers. In six of these states, the costs of the program for industry are covered through the unredeemed deposits, which they are allowed to keep. The exceptions are California, Hawaii, Maine, Massachusetts, and Michigan.[73]

The area in which there is currently most discussion of true EPR programs in the U.S. is around electronics. Two states have passed legislation requiring producer responsibility. The first was Maine. In 2004, it passed legislation requiring the manufacturers of electronics to be responsible for the costs of handling electronics after they have been collected. Municipalities are still responsible for the collection costs.[74]

In March 2006, Washington State became the second to pass electronics EPR legislation. Manufacturers will be required to pay all the costs of the collection, handling, recycling and disposal of electronics.[75]

The U.S. Government Accountability Office is concerned that

> In the absence of a national framework for dealing with the problem [of waste from electronics], a patchwork of potentially conflicting state requirements appears to be emerging.[76]

EPR has recently focused on electronics in the U.S. as it has elsewhere throughout the world because the projections for the quantities of waste that will be generated by these products is escalating rapidly and because of the toxic materials in these products. It has been described as a "tsunami" of electronic wastes.[77] The successful development of a couple of EPR programs for electronics in the U.S. is also the product of groups such as the Silicon Valley Toxics Coalition and Clean Production Action. They have used the successes in Europe as a powerful support for their lobbying efforts.

Recently a municipality in the U.S. has passed a law requiring EPR. As of December 1, 2006, retailers in New York City are required to take back rechargeable batteries free of charge. The retailers then become responsible for the proper recycling and disposal of the batteries.

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[72] For a listing of criteria for EPR, see Extended Producer Responsibility Working Group, *Extended Producer Responsibility: A Prescription for Clean Production, Pollution Prevention and Zero Waste*, Accessible at: <http://www.eprworkinggroup.org>.
[73] Container Recycling Institute, *Bottle Bill Resource Guide*, Accessible at: <http://www.bottlebill.org>.
[74] Cifrino, Carole. *Maine's E-Waste Law*, 4th National Workshop on Extended Producer Responsibility, Calgary, Alberta, March 2006.
[75] Washington State Department of Ecology, "State moving ahead to carry out free electronics recycling law by Jan. 1, 2009," News Release, November 9, 2006.
[76] United States General Accountability Office, Electronic Waste: Observation on the Role of the Federal Government in Encouraging Recycling and Reuse, July 2005.
[77] Silicon Valley Toxics Coalition, Poison PCs and Toxic TVs: E-waste Tsunami to Roll Across the US: Are We Prepared?, 2004.

2.7 *Comparison of Extended Producer Responsibility in Canada, Europe and the United States*

In contrast with Europe, the programs in Canada are rarely full EPR programs. Significantly one much more frequently sees the term "stewardship" attached to these programs rather than "EPR". The prime motivator for EPR programs in Canada has been to reduce the financial burden on municipalities. After reviewing Canada's packaging programs, two researchers found:

> The conclusions of this paper require policy-makers to appreciate that EPR programs for packaging are much more than a revenue source for Canadian provincial and municipal governments for offsetting the cost of waste diversion and recycling programs. EPR represents a fundamental cultural shift that sees businesses assume new responsibilities for society and the environment.[78]

This fundamental shift has not occurred nearly as much in Canada as in the EU. In contrast with the EU, many EPR programs in Canada are based on direct fees on the consumer instead of on the manufacturer or seller of the product. As the tables for specific used materials show, most of the programs are more appropriately called stewardship programs instead of EPR programs.

The province of Alberta has the most programs among the provinces that could be designated as EPR; nevertheless, consultants for the province concluded that the intentions of their programs are limited.

> A review of current Alberta waste stewardship programs indicated the programs were not designed to promote DfE [design for the environment][79] and are therefore poorly aligned with DfE. Each is strictly a waste management program focused on how to best recover the material stream at end of life.[80]

Thus far EPR programs in Canada have not had legislated targets for recovery, reuse and recycling of materials and products. By contrast, the EU directives contain clear targets. In addition, the EU's end-of-life vehicles and electronics directives include requirements to eliminate or limit the presence of certain toxic substances in products before they are put onto the market. Nothing similar currently exists in Canadian EPR legislation.

There also are differences in the materials covered by EPR programs between Canada and the EU. EPR programs for multi-material packaging recycling programs are covered in only two provinces while they are in place throughout the EU. WEEE programs are common in Europe but only Alberta in Canada has such a program currently, although several others are proposing

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[78] Quinn, Lisa & A. John Sinclair, "Policy challenges to implementing extended producer responsibility for packaging," *Canadian Public Administration*, Vol. 49, No. 1, Spring 2006, pp. 73 & 74.

[79] Design for the environment is defined as follows: "The idea behind DFE is to ensure that all relevant and ascertainable environmental considerations and constraints are integrated into a firm's product realization (design) process. The goal is to achieve environmentally preferable manufacturing processes and products while maintaining desirable product price/performance characteristics." Braden Allenby, quoted in Thomas Lindhqvist, *Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems*, Lund University, 2000, p. 25.

[80] Five Winds International, Design for Environment (DfE) Opportunities within Alberta's Waste Stewardship Programs, Prepared for Alberta Environment, April 2006.

such programs. In Canada, used oil and tires programs are more common than in the EU. There are no programs for automobiles in Canada.

In Canada, the federal role in EPR is minor in contrast with Europe where the EU can direct member countries to implement EPR programs. This means that despite the fact that EPR programs are not identical in EU Member States, they are more similar than in Canada. This diversity means that producers may have to operate very different programs in different provinces or may not even have to operate a program at all in some provinces.

Despite the fact that EPR is not advanced as far in Canada as in the EU, the situation in Canada is much closer to the EU than to the U.S. The term "extended producer responsibility" is rarely heard in the U.S. and when it is raised it causes vociferous debate.

Some reasons for these differences among Canada, Europe and the United States have been presented in the earlier sections where the programs were described.

2.8 *Future Directions for Extended Producer Responsibility in Canada and the European Union*

2.8.1 In Canada

In Canada several jurisdictions are currently reassessing their programs to bring them more fully in line with EPR. For example, New Brunswick is currently proposing to develop a new stewardship board to manage designated materials. This body will ensure that industry carries out the recovery and recycling activities and that industry covers the costs of the programs. The proposed rules would prohibit industry from charging separate fees to consumers for these programs.[81] Alberta and British Columbia have also stated their intention to get closer to true EPR.

Manitoba is currently reviewing its multi-material program for municipal recycling. Ontario will begin a similar review in 2007. Neither province has stated its intention as to what direction it wishes to go in.

The CCME, which is made up of all the provinces and territories and the federal government, is now using the EPR term and developing criteria for EPR, which are much closer to those used in the EU. This point towards the possibility of truer EPR programs in the future in Canada.

The Canadian federal government is considering expanding its role in EPR by using its powers under the Canadian Environmental Protection Act to require EPR for certain products containing toxic substances.

[81] Cooper, Rosalind. "Waste Initiatives Across Canada," *Solid Waste Magazine*, February/March 2006, p. 36.

2.8.2 In the European Union

The EU is currently developing a new thematic strategy on waste. The main thrust here is to see waste "as one side of the resources/product/waste triangle".[82] As a result, the waste strategy is to be meshed with integrated product policy and the strategy on sustainable use of resources.

As part of the strategy on waste, the EU is revising the waste directive. The driving questions that they give as guiding this revised directive are:

> The questions for our times are how do we reduce the amount of waste that our increasing prosperity encourages us to produce, and how do we now need to change our policies so that we deal with waste primarily as a resource from which value can be extracted, rather than as a residue that can only be stored in a landfill.[83]

The thematic strategy and the proposed waste directive do not include expansion of the role of EPR. The thematic strategy explains that new proposals to increase recycling through EU directives are not included because the programs are in their relatively early implementation stage.

If in five years' time it becomes clear that the benefits of recycling are not being adequately delivered by existing measures and the market, then further action will be taken on a material-by-material basis. It is important to note that such action would not necessarily be based on the principle of producer responsibility.[84]

At a March 2006 workshop in Canada, the representative of the EU Commission stated that batteries would be their last planned EPR program, "since the Commission is now working on more horizontal strategies such as on IPP [integrated product policy], sustainable use of resources and waste prevention and recycling".[85]

Environmental groups in Europe disagree with the EU's plans to stop moving forward on EPR:

> We conclude therefore that extended producer responsibility is a policy approach which is politically widely accepted and has a potential to change product design and product related services. It should find imitation for many other product groups which cause waste management problems. We think that packaging, building and construction material, furniture, carpets, lamps (mercury!), vegetable oils and fats (to prevent cross contamination with mineral oils and fats) plastic foils (used in agriculture), and mattresses (where the polyether, latex and iron can be recycled) and paints should

[82] European Commission, EU Waste Policy: The Story Behind the Strategy, 2006, p. 14.
[83] European Parliament, Draft Report on the proposal for a directive of the European Parliament and of the Council on waste, June 20, 2006, p. 26.
[84] Ibid., p. 22.
[85] van der Vlies, Rosalinde. *Europe: Battery Recycling*, 4th National Workshop on Extended Producer Responsibility, Calgary, Alberta, March 2006.

belong to the next generation of product groups where producer responsibility should apply.[86]

The Institute for European Environmental Policy, an independent research institute, determined that integrated product policy would not adequately replace or extend EPR because it is "a policy resting almost entirely on soft instruments".[87] They went on to say that the Eco-design Directive "so far has not established any mandatory requirements for any of the products within its scope, but encourages stakeholders to come forward with self-regulation and standardisation initiatives as an alternative to regulatory eco-design obligations."[88]

By the end of the next five years, EPR programs in Canada and the EU may not be as divergent as they currently are. However, the EU may have explored new approaches to addressing the problems created by products, which Canada will not yet have seriously explored.

2.9 *Impact of Extended Producer Responsibility Programs*

At the beginning of this chapter, we laid out five goals for putting EPR programs in place. These are:

- Reduce the costs to government for waste management.
- Achieve cost internalization by transferring waste related costs to producers and consumers of products.
- Reduce environmental impacts of waste management by decreasing amounts of waste going to disposal. The objective here is to increase diversion of waste by reuse and recycling.
- Reduce resource and energy use by decreasing waste generation.
- Encourage or require design for the environment. The objective here is to get the producers of products to redesign products so there are less harmful materials in the products, to make products last longer and be reusable, recyclable and easily dismantled.

In this section of this chapter, we assess the extent to which EPR programs have been successful at achieving each of these goals and describe the characteristics of the programs that contribute towards achieving those goals. We will also present the best practice for achieving each of the goals.

2.9.1 Reduce the costs to government for waste management

A prime objective in EPR programs in some jurisdictions is to reduce waste management costs for municipal governments and taxpayers. One commentator has described the situation prior

[86] European Environmental Bureau, *Towards a Low Waste Europe – 10 Key Issues*, April 2001, p. 18.
[87] Pallemaerts, M., et al, *Drowning in Process? The Implementation of the EU's 6th Environmental Action Programme* a report for the European Environmental Bureau, 2006, p. 54.
[88] Ibid.

to EPR, where municipalities pay the entire cost of the waste management system as "municipal welfare" for industry.[89]

This is particularly true in Canada in addressing the additional costs involved in recycling instead of disposing of wastes.

The extent to which this has been achieved varies. In packaging, for example, the entire costs of the recovery and recycling of packaging is covered by industry in Austria, Belgium, Finland, France, Germany, Greece, Italy, Luxembourg, Portugal, and Spain.[90]

In others, municipalities still fund some of the costs. In Ireland, for example, municipalities pay 25 percent of the additional costs for separate collection and sorting of packaging for recycling. In the Netherlands, municipalities bear the costs of collecting and sorting packaging; industry pays the costs of transporting them to recovery and recycling plants and of carrying out the recycling and recovery. In Sweden, municipalities sometimes pay part of the additional collection costs. In the U.K., municipalities pay the collection costs.[91]

In Canada, Ontario and Quebec industry must pay municipalities for half of any losses they incur in collecting, sorting, and selling recyclable packaging. In 2004, the losses on recycling programs for "blue box" materials in Ontario were $68.06 million. Industry paid $29.56 million directly to municipalities to help cover these losses; they also put $3.28 million into an effectiveness and efficiency fund directed at research to improve municipal recycling programs, and $1.19 million in in-kind contribution of space by newspapers to advertise municipal recycling programs.[92] This means that municipal taxpayers paid $34.03 million dollars for recycling programs. In 2006, in Quebec industry is required to contribute $29.7 million to cover half of municipal losses.[93]

In Manitoba, taxpayer costs for municipal recycling programs are reduced by a levy on purchasers of beverages, which covers up to 80 percent of municipal costs.

In situations where municipalities operate the programs and collect fees from industry, conflicts arise between municipalities and industrial financial contributors. Industry sometimes accuses municipalities of running programs that in their view are more expensive than need be. In Ontario this led to the Minister of the Environment requiring "cost containment" initiatives to "protect" industry.[94] Others argue about what "efficient" means. For example, some define "efficient" as the program that diverts the most material. Industry does not approach it this way.[95]

In areas with deposit-return systems for beverage containers, government usually ends up with no costs for the system.[96]

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[89] Spiegelman, Helen. "Hope in Wasteland," *Alternatives Journal*, 32:1, 2006, p. 12.
[90] "European Packaging Directive Transposed into National Legislation All Over Europe," op. cit.
[91] Ibid.
[92] Waste Diversion Ontario 2005 Annual Report, p. 32.
[93] CM Consulting, Who Pays What: An Analysis of Beverage Container Recovery and Costs in Canada 2004-2005, 2006, p. 47.
[94] Waste Diversion Ontario 2005 Annual Report, p. 31.
[95] Guy Crittenden, "Toward Best Practices," *Solid Waste Magazine*, October/November 2006, p. 4.
[96] See analysis by CM Consulting, for example, to find how this works out in Canada.

In most instances, for packaging, including beverage containers, industry is only contributing to recycling costs. Municipalities are still left with the disposal costs. The exceptions to this situation are those, such as Germany, where municipalities are no longer responsible for collecting or managing any packaging unless contracted to do so by the responsible industry.

For electronics, EPR programs have usually resulted in all costs being removed from municipalities because municipalities are no longer responsible for playing a management role. In most cases, taxpayer costs are also eliminated in used oil, used tire, and household hazardous waste EPR programs.

EPR and stewardship programs have succeeded in reducing government costs for waste management programs. They have achieved this to varying degrees, however. The limitations in many programs are the result of:

- Not making industry responsible for disposal costs as well as recycling costs,
- Not making industry responsible for 100 percent of the costs.

Best Practice: Require industry to be responsible for operating the programs – not just for making financial contributions to them.

2.9.2 Achieve cost internalization by transferring waste related costs to producers and consumers of products

To the extent that the costs of waste management programs are transferred from government to producers and consumers of products, costs are internalized. The intention behind cost internalization is to ensure that those who make and buy the products will pay the costs associated with the proper handling of them after use. It is hoped that this will motivate them to make and buy products with less negative environmental impacts. Cost internalization also brings more equity in comparison with having these costs taken care of by taxpayers because it is those who make and use the products with negative consequences who have to pay the associated environmental costs. If you don't buy the product, you don't contribute towards the costs for recycling or disposing of it.

In the assessment of "reduce costs to government" the extent of cost internalization has been described. The issue here is one of to what extent are these costs transferred to producers and consumers in comparison with each other.

It is frequently argued that it doesn't matter whether the costs are transferred to the producer or consumer because "In the end, the ultimate consumer pays regardless of where costs are applied".[97] Some economists do not agree with this.[98] They argue that instead of passing costs on by increasing the product price, the producer may cut wages and salaries or reduce profits

[97] Parker, Glenn. "Extended Producer Responsibility: A Practical View," *Warmer Bulletin*, September 1998, p. 17.
[98] See for example, "Appendix 2: Economic Background," *Waste Electronic and Electrical Equipment Study*, prepared for Waste Diversion Ontario by CSR, RIS International Ltd., MacViro Consultants Inc. & Jack Mintz & Associates, Inc, 2005.

accruing to shareholders. They state that the approach taken depends on the competitiveness of the market and the sensitivity of the consumer to prices.[99]

In EPR, the purpose of price internalization is to change behaviour. It is hoped that by internalizing the costs of waste management into the cost of production, i.e., to the producer, that products will be redesigned to make it easier and cheaper to achieve the requirements of the EPR program. This will be discussed later in this section under the design for environment question.

Others argue that it is best to transfer the costs of EPR programs directly to the consumer to encourage the consumer "to make informed purchase and disposal decisions".[100] This will in turn affect industry' decisions:

> At all stages in the production, use and disposal chain, the customer or consumer has an important role to play as an influencer of the producer or supplier through purchase decisions and habit changes. In a pluralist, free market society, this role cannot be over estimated. If the consumer does not buy a product, the contribution of that product to reducing environmental impacts, relative to other products serving the same function, will be lost.[101]

Some argue that the signals sent at the consumer level are less effective than those to the manufacturer. "Because the costs under EPR will be concentrated in the case of the producers (because of the relatively fewer number of actors) and diffuse in the case of the consumer/waste generator, costs under EPR are more likely to stimulate changed behaviour".[102]

If the prime aim is to affect consumer behaviour, visible fees at point of purchase are usually preferred as the mechanism to make the consumer aware of the environmental implications of their purchase and to motivate them to act appropriately.

Deposit-return systems are a common example of direct fees being used as a motivation to use the product properly after use, i.e., to motivate people to return the product for reuse or recycling or proper disposal. The most common use of this is beverage containers. A fee that can be recovered in full or partially clearly correlates with higher recovery rates. In 2004, in Canada, for example, recovery rates for beverage containers in those jurisdictions with a deposit-return system ranged from 87 percent to 66 percent. The rate in Manitoba and Ontario, which do not have extensive deposit-return systems were substantially lower. For example, aluminum cans were recovered at a rate of 54 percent and 46 percent in these two provinces while they were 95 percent to 69 percent in deposit-return provinces.[103]

With rare exceptions deposit-return has not been used for other products in Canada or Europe because retailers usually do not want to be bothered by having products returned to them. In the Netherlands, for example, electronics retailers "faced with storage difficulties and the high

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[99] Ibid., pp. 144-147.
[100] Parker, p. 17.
[101] Ibid., pp. 18 & 19.
[102] Lifset, Reid. "Linking Source Reduction and Extended Producer Responsibility," *Warmer Bulletin*, September 1999, p. 15.
[103] CM Consulting, p. 12.

costs of handling a wide range of used products often offered discounts to customers buying new products if they did not ask to drop off an old one".[104]

For other household wastes, the mechanism most frequently used to motivate proper handling of the material is pay-as-you-throw fees on wastes sent to disposal. This motivates people to maximize recycling because the rate is either zero for recycling or substantially lower than the rate for disposal.[105]

Visible fees that are not returnable, however, have been applied to other products to cover recycling and disposal costs. This is a more common component of EPR programs in Canada than in Europe. This system is used in many programs in Canada, including tires, used oil, household hazardous waste, batteries, and for the only mandated electronics program in Canada (Alberta). Visible fees are much less common in the EU. In fact, the EU directives for electronics, batteries and end-of-life vehicles explicitly prohibit the use of visible fees on the consumer. The reason for this difference is that the EU focus is on placing the costs directly onto the producer with the hope of motivating them to design for the environment.

Conclusion: Recovering the costs for EPR programs through fees on the consumer are not very effective. One factor in this is that the fees are usually the same for all types of the same product so that there is no benefit achieved by buying a product that has been designed for the environment. In fact, often the product that is environmentally preferable is more costly. As a result, the wrong signals are sent to the purchaser.

Cost signals sent to the producer of the product or package are more effective at changing product design.

Best Practice: Require industry to pay the costs for the program, instead of these costs appearing visibly as a charge to consumers.

2.9.3 Reduce environmental impacts of waste management by decreasing amounts of waste going to disposal

The objective here is to increase diversion of waste by reuse and recycling. It is always challenging to measure changes in waste amounts over time and among countries because the measurement methods change over time and differ among countries. Despite this, the best possible use will be made of the admittedly limited data available. It also is impossible to be sure of the extent to which EPR programs were responsible for any changes that occurred.

End-of-life vehicles: A multi-stakeholder group recently assessed progress under the EU directive on end-of-life vehicles.[106] The first target was to collect "all" the end-of-life vehicles in

[104] OECD, EPR Policies and Product Design: Economic Theory and Selected Case Studies, 2006, p. 29.
[105] See Working Group on Waste Prevention and Recycling, OECD, *Impacts of Unit-based Waste Collection Charges*, May 2006; Janet Robins & Maria Kelleher, "The changing face of user-pay programs in Canada: Pay As You Throw," *Solid Waste Magazine*, August/September 2005, pp. 8-13, and David Davies Associates, *High Diversion of Municipal Waste: Is It Achievable?*, Resource Recovery Forum, pp. 8-9.
[106] Stakeholder Consultation on the Review of the 2015 Targets on Reuse, Recovery and Recycling of End of Life Vehicles, November 2005.

certified facilities. A recent assessment concluded that at least 40 percent of end-of-life vehicles are not being captured.[107] This means that

> ... the ambitious target levels set for reuse recycling & recovery by 1/1/2006 will in reality have only half the effect intended if only half the ELVs are captured and in addition the important safe de-pollution procedures prescribed will probably not be undertaken either.[108]

In terms of the reuse and recycling target of 80 percent by 2006, the assessment concluded that this would be close to achievement for the metal waste portion of the wastes, but the non-metallic waste fractions would still be going to disposal at a high rate.[109] The non-metallic parts of vehicles are primarily plastics, fibres and glass. Plastics are becoming an increasing percentage of vehicles, which will exacerbate this problem.

Some countries are, however, on track towards the targets. By 2004, the Netherlands had achieved a reuse and recycling rate of 83.4 percent and reuse and recovery rate of 85.4 percent.[110]

The barriers that they have found to achieving the targets include:

- Lack of adequate infrastructure in some countries to dismantle vehicles;
- Inadequate availability of collection points in some countries; and
- Lack of markets for non-metallic parts of the waste stream.

Some have proposed overcoming these barriers by placing less emphasis on reuse and recycling and allowing more recovery of energy by burning shredded end-of-life vehicles in energy-from-waste incinerators.[111] This is contrary to current EU waste policies.

One of the major environmental benefits already noted as resulting from the end-of-life vehicles directive is higher quality authorized treatment and dismantling facilities, which release less pollutants to the environment.[112]

There are no end-of-life vehicle EPR programs in Canada.

Packaging Waste: The Packaging Directive has had impacts at increasing the recycling rate and reducing the quantities of packaging waste going to disposal. By 1999, Belgium, Denmark, Germany, the Netherlands, Austria, and Sweden had exceeded the 2001 target of 45 percent recycling. A study for the Commission of the European Communities in 2003 concluded:

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[107] Stakeholder Consultation on the Review of the 2015-Targets on Reuse, Recovery and Recycling of End of Life Vehicles, p. 11.
[108] Ibid., p. 8.
[109] Ibid., p. 12.
[110] Ibid., p. 15.
[111] Ibid., p. 31.
[112] GHK in Association with Bio Intelligence Service, A study to examine the benefits of the End of Life Vehicles Directive and the costs and benefits of a revision of the 2015 targets for recycling, re-use and recovery under the ELV Directive, May 2006, p. 69.

> The results shown in this paper make it clear that Directive 94/62/EC has encouraged increases in the recovery and recycling of packaging waste. In addition, although total tonnages of packaging waste continue to increase in most Member States, a decoupling between economic growth and growth of packaging waste has occurred for the EU as a whole and for many individual Member States in the period 1997 to 1999.[113]

Examples of recovery and recycling rates achieved by 2004 under the Green Dot system in Europe include:

- France: 87 percent recovered and 65 percent recycled
- Norway: 94 percent recycling for cardboard, 92 percent for glass, 81 percent for plastics, 61 percent for metals, and 47 percent for beverage cartons.
- Sweden: 96 percent recycling for glass, 85 percent for cardboard, 66 percent for metals, 44 percent for paper and cartons, and 20 percent for plastics.[114]

Between 1990 and 1999, Germany reduced packaging use by 4 percent.[115] Over the same period, the Netherlands, which had a voluntary recycling program, had a rise in packaging volumes by fifteen to twenty percent.[116] In Germany, packaging recovery rates were 37.3 percent in 1991. By 2000, the rate was 76.7 percent. In contrast, the U.S., which did not have such recycling regulations, had a recycling rate for containers and packaging of only 39 percent in 2003.[117]

In Canada, Ontario has the most complete data for packaging materials. The most recent year that data is available for is 2003. That year the recovery rate for packaging materials was 41.8 percent, which is substantially less than in Germany.[118] Ontario's EPR program for these materials did not come into affect until the following year so it is impossible to tell at this point if the program has had an impact on waste recovery.

Other Products: The used oil programs in place in British Columbia, Alberta, Saskatchewan and Manitoba have had steadily increasing recovery rates. In 2004, the percentage of used oil collected across the four provinces was 75 percent. This rate was higher than fourteen other countries with which the rate was compared except the U.K., which had a recovery rate of 76 percent.[119] Thirty percent of the used oil collected in Canada's western provinces was re-refined. By contrast, in the U.K. all the used oil collected was burnt for energy recovery.[120] Re-refinement is an environmentally preferable option.

Conclusion: The EPR programs that have been most effective at reducing the amount of waste being disposed of are those that have precise legislated goals for recovery and recycling.

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[113] Report from the Commission to the Council and the European Parliament on the Implementation of Community Waste Legislation for the Period 1998-2000, 2003, p. 124.
[114] Data at www.pro-e.org.
[115] OECD, EPR Policies and Product Design: Economic Theory and Selected Case Studies, 2005, p. 33.
[116] Ibid.
[117] Ibid., p, 34.
[118] Waste Diversion Ontario, 2005 Annual Report, p. 53.
[119] OECD, EPR Policies and Product Design: Economic Theory and Selected Case Studies, p. 19.
[120] Ibid.

Best Practice: Include precise legislated goals for recovery and recycling.

2.9.4 Reduce resource and energy use by decreasing waste generation

One of the main outcomes of EPR programs is decreased waste disposal and increased recycling . This results in reduced resource and energy use. For example, making an aluminum drink can out of recycled aluminum takes 85 percent less energy than making it from raw materials.[121]

CM Consulting concluded that the reuse and recycling of beverage containers in Canada in 2004 decreased energy use by 15 million gigajoules, which would avoid the need for 2.3 million barrels of crude oil.[122]

Reduced waste generation is even more effective at reducing material and energy use than reuse and recycling. Despite EPR programs, waste generation and as a result material and energy use continue to increase in Canada and the EU. The latest Canada-wide data shows that generation of solid waste increased from 29.3 million tonnes in 2000 to 30.5 million tonnes in 2002.[123] This was an increase of four percent. In Europe, it is estimated that municipal solid waste generation increased by ten percent between 1990 and 1995.[124] It averaged 400 to 450 kg/capita/annum in 2000. This was an increase of thirty percent between 1985 and 2000, an average annual growth rate of two percent.[125]

In order to reduce waste going to disposal, EPR programs have focused on recovery of materials and recycling. These programs have not, however, focused on reduced use of materials and products. For example, the EU packaging directive sets as an overall objective to reduce waste generation, but the only targets in it are for recovery and recycling.[126] A survey of packaging programs across Europe found that waste prevention programs are quite limited.[127]

Indeed, some people believe that EPR programs are designed in ways that may work contrary to reduction, particularly re-manufacturing. Re-manufacturing is …

> The process of returning a used product to at least Original Equipment Manufacturer performance specification and giving the resultant product a warranty that is at least equal to that of a newly manufactured equivalent.[128]

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[121] Sinclair, Rob. Natural Resources Canada, An Analysis of Resource Recovery Opportunities in Canada and the Projection of Greenhouse Gas Emission Implications, 2006, p. 4.
[122] Who Pays What, p. 49.
[123] Statistics Canada, "Solid Waste in Canada," *Human Activity and the Environment*, 2005, p. 1.
[124] Resource Recovery Forum, *Recycling Achievement in Europe*, p. (ii).
[125] Ibid.
[126] European Environment Agency, Effectiveness of packaging waste management systems in selected countries: an EEA pilot study, 2005, p. 5.
[127] European Association of Cities for Recycling, "Packaging waste prevention in Europe," *Warmer Bulletin*, September 2000, p. 11-12.
[128] Resource Recovery Forum, Remanufacturing in the UK: a significant contributor to sustainable development?, 2004, p. 11.

The Society of Motor Manufacturers and Traders fear that the end-of-life vehicle directive will make it harder for automotive parts remanufacturers to obtain essential parts.[129] The refill industry for printer cartridges are concerned that the EU's directive on WEEE doesn't prevent manufacturers from taking actions to prevent reuse of cartridges.[130]

Conclusion: EPR programs have been contributing towards reduced use of resources and energy. The factor that has been most effective at this is the inclusion of specific targets for recycling and reuse in the legislation. This needs to be expanded from the current ways to include specific targets for reduced use of materials and reduced generation of wastes.

Best Practice: Include legislated targets for reduced use of materials and reduced generation of waste.

2.9.5 Encourage or require design for the environment

The person who is generally referred to as the father of EPR, Thomas Lindhqvist, said that "the EPR concept was formulated to promote product and product change in order to reach overall life cycle improvement."[131] The hoped for outcome is often referred to as "design for the environment." It commonly includes designing products so that:

- they have no toxic materials in them,
- they are more durable and are repairable so they last longer,
- they are easily remanufactured or reused for the same purpose,
- they are made of recyclable materials, and
- they are easily dismantled for recycling or reuse.

The objective is to move from a cradle-to-grave cycle for products to a cradle-to-cradle system where products never become waste.[132]

Despite the design for the environment goal, "the focus of most governments … has been on improvement of end-of-life management rather than promotion of design change."[133]

Industry has made substantial changes to products over the fifteen years that EPR programs have been developing. The question, however, is: "To what extent have the changes made been in response to EPR programs?" This is difficult to determine. In a few cases, producers have been surveyed specifically on this question.

A survey in Austria found that the packaging ordinance had been one of the top three factors motivating product changes. In a survey where people could provide more than one answer the packaging ordinance was given as a reason by 55 percent. "Increased environmental awareness" was slightly higher. The main reason, which was given by 65 percent, was

[129] "UK – ELV laws 'could undermine remanufacturing potential'," Resource Recovery Forum, July 2006.
[130] Remanufacturing in the UK: a significant contributor to sustainable development?, 2004, p. 5.
[131] Extended Producer Responsibility in Cleaner Production: Policy Principle to Promote Environmental Improvement of Product Systems, p. 105
[132] McDonough, William & Michael Braungart, Cradle to Cradle: Remaking the Way We Make Things, 2002.
[133] Tojo, Naoko. Extended Producer Responsibility as a Driver for Design Change – Utopia or Reality?, 2004, p. i.

"reduction of packaging costs." The next highest after the packaging ordinance was "retailer demands", which was substantially lower at approximately 30 percent.[134]

In a web-based survey of the electrical and electronics industry in Norway, 68 percent said that the prime motivator for technological changes that they had made were the two EU directives on WEEE.[135] Similar results were derived from a survey in Sweden of automobile manufacturers and of WEEE.[136]

In 2006, a survey was conducted of those industries that are required to pay fees under Ontario's blue box program. Of those companies that had made changes to their packaging, only fourteen percent said the changes were made "in direct response to the Stewardship Ontario program or funding model." In response to the question "How much influence does the Stewardship Ontario funding model have on your company's packaging decisions?", 58 percent said "little or no influence"; 26 percent said "some influence", and five percent said "high level of influence."[137] Respondents to the survey identified cost saving as the main factor in their decisions. They also pointed out that the fact that decisions are often made outside of Canada substantially limits the impact of Ontario's EPR programs on their decisions:

> Global companies establish global packaging standards which incorporate a wide range of criteria, including material and production costs, packaging utility, safety standards, use of recycled content where possible, marketing strategies, customer preferences, and in certain cases, cost of end-of-life recycling.[138]

The difference between European countries and Ontario reflects the fact that the Ontario EPR program does not include legislated targets to stimulate design for the environment.

Examples have been given of changes that have been made to products and packaging as a result of EPR programs. These include:

- Reduction or elimination of the use of certain hazardous substances in automobiles and in electrical and electronic equipment throughout the EU.[139]
- Systematically coding components and materials in vehicles in Europe to make it easier to recycle them.[140]
- In Germany, secondary packaging dropped dramatically.[141] Refill packs and concentrates have replaced large bottles; there are a reduced number of products in blister packages.[142]

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[134] Ibid., p. 111.
[135] Lee, Chin-Yu. Extended Producer Responsibility Stimulating Technological Changes and Innovation: Case Study in the Norwegian Electrical and Electronic Industry, 2004, p. 26.
[136] Tojo, Naoko. Extended Producer Responsibility as a Driver for Design Change – Utopia or Reality?.
[137] Stewardship Ontario, Assessment of Stewards Actions in Response to Stewardship Ontario Fees, 2006, p. 26.
[138] Ibid.
[139] See Extended Producer Responsibility as a Driver for Design Change – Utopia or Reality? and Chris van Rossem, Naoko Tojo, Thomas Lindhqvist, Extended Producer Responsibility: An examination of its impact on innovation and greening products.
[140] A study to examine the benefits of the End of Life Vehicles Directive and the costs and benefits of a revision of the 2015 targets for recycling, re-use and recovery under the ELV Directive, p. 25; Rainer Lucas, End-of-Life vehicle regulation in Germany and Europe – problems and perspectives, 2001, p. 10.
[141] Lifset, Reid. p. 15.

Again the lack of Canadian examples reflects the failure in Canada to design EPR programs specifically with design for the environment in mind. For example, a survey of programs in Alberta concluded that …

> … the programs were not designed to promote DfE and are therefore poorly aligned with DfE. Each is strictly a waste management program focused on how to best recover and recycle the material stream at end of life.[143]

A survey of EPR programs for Environment Canada compared various programs according to their impact on the following factors: reduction in toxicity, increased recycled content, increased recyclability, extended life, and reduction in resources. The Canadian programs consistently scored more poorly than did the European ones.[144]

The design for the environment impacts of EPR programs may well reach beyond the country that the program is in. INFORM has found that the RoHS directive in Europe restricting the use of certain toxic materials in electronic equipment is already having impacts on these same products made and sold in the U.S.145 The requirements to eliminate the presence of certain substances in Europe is resulting in these hazardous materials also being removed from those sold elsewhere if the electronics company sells in both Europe and elsewhere. They do this to achieve production efficiencies.

Best Practices:

Strict prohibitions or bans: This is probably the most effective way to spur substantial product changes. The EU RoHS directive for the WEEE sector is the prime example of this. This works for the EU but would be harder for an individual small country to carry out. However, "it is not easy for individual countries, particularly those with only a small market and a few producers, to set their own product standards".[146]

Bases for differentiation of fees: In most programs, fees are based only on quantity of the product – not the quality of the product. If fees are not less for those who have environmentally preferable products, the motivation to design for the environment will be limited.[147]

Producer or consumer responsible for costs: When the costs for the EPR program are passed on in a fee by the seller of the product to the customer, the signals are not sent to the manufacturer to redesign their product or package. In this situation the producers do not

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[142] Five Winds International, Design for Environment (DfE) Opportunities within Alberta's Waste Stewardship Programs, 2006, p. 7.
[143] Ibid., p. i.
[144] Munroe, Glen. The Relationship between Extended Producer responsibility and Design for Environment, 2002.
[145] INFORM, Impact of the RoHS Directive on Electronic Products Sold in the United States, 2003, and INFORM, The WEEE and RoHS Directives: Highlights and Analysis, 2003.
[146] Lee, Chin-Yu. Extended Producer Responsibility Stimulating Technological Changes and Innovation: Case Study in the Norwegian Electrical and Electronic Industry, p. 34.
[147] See, for example, Chin-Yu Lee, Extended Producer Responsibility Stimulating Technological Changes and Innovation: Case Study in the Norwegian Electrical and Electronic Industry, p. 34.

incorporate the costs into the cost of the product but "treat it as a tax to be passed directly onto the consumer."[148]

Individual producer responsibility for costs: Along with the failure to differentiate fess according to performance goes a grouping of producers together for fee purposes so that the superior producer does not benefit from their actions. This lessens the internalization of costs.[149] As Thomas Lindhqvist says, "Will the individual producer benefit directly from product design improvements?"[150]

Producer physical responsibility for product: Those programs where the producer is not just financially responsible but also physically responsible for the product are most effective. The German packaging experience is a prime example of this.

2.10 *Summary of Best Practices*

EPR can play a major role in protecting the environment both through ensuring better management of products or packages after their use and through redesign of products to reduce their environmental impacts. In Canada, the main focus has been on keeping materials from ending up in landfills and incinerators. Europe has had this focus, but has gone beyond it to also encourage design for the environment measures. Central to the achievement of these goals – especially the design for environment goal – is the placing of full responsibility on the producer rather than the seller of the product or the consumer of the product.

To achieve the potential for EPR programs, the programs need to have the following characteristics:

- Be legislated rather than voluntary;
- Have precise legislated targets with timelines for reduction, reuse, recycling and recovery;
- Have precise legislated guidelines requiring that products not contain designated hazardous materials;
- Ensure that the individual producer benefits directly from any changes they make for design for the environment;
- Make sure costs are not separated as an environmental fee on the consumer when they purchase the product;
- Ensure that the manufacturer actually has physical responsibility for the product.

[148] Quinn, Lisa & A. John Sinclair, p. 70.
[149] European Environmental Bureau, *EU Environmental Policy Handbook*, p. 105.
[150] Lindhqvist, Thomas & Chris van Rossem, *Evaluation Tool for EPR Programs*, p. 4.

3. Toward Materials Efficiency: The Sustainable Use of Natural Resources

By John Jackson

3.1 *Economic Development and the Sustainable Use of Natural Resources*

Over the past few decades, excessive, wasteful energy and materials use have been increasingly recognized as major driving causes of global ecological problems. At times this has risen to the point of raising questions about whether continued growth is acceptable at all. In 1972, *The Limits to Growth*, a study commissioned by a group of businessmen, statesmen and scientists, concluded:

> If the present growth trends in world population, industrialization, pollution, food production, and resource depletion continue unchanged, the limits to growth on this planet will be reached sometime within the next 100 years. The most probable result will be a sudden and uncontrollable decline in both population and industrial capacity.[1]

This study escalated the debate around the appropriateness of current economic growth patterns, resulting in this question being addressed in formal international government forums.

1n 1972, the international government community held its first major conference on the environment in Stockholm. Two of the principles of the resultant *Declaration of the United Nations Conference on the Human Environment* were:

- The capacity of the earth to produce vital renewable resources must be maintained and, wherever practicable, restored or improved.
- The non-renewable resources of the earth must be employed in such a way as to guard against the danger of their future exhaustion and to ensure that benefits from such employment are shared by all mankind.[2]

In 1987, the World Commission on Environment and Development, more commonly known as the Brundtland Commission, released *Our Common Future*, which became a statement of guiding principle for countries throughout the world. It called upon countries "to make development sustainable - to ensure that it meets the needs of the present without compromising the ability of future generations to meet their own needs."[3] The Commission warned: "We are unanimous in our conviction that the security, well-being, and very survival of the planet depend on such changes, now".[4]

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[1] Meadows, Donella H. et al., New York: Universe Books, 1972, p. 24.
[2] Principles 3 and 5.
[3] World Commission on Environment and Development, *Our Common Future*, New York: Oxford University Press, 1987, p. 8.
[4] Ibid. p. 343.

The goal of sustainable development was the guiding principle behind the 1992 Earth Summit in Rio de Janeiro, which was attended by approximately 30,000 people, and the 2002 World Summit on Sustainable Development in Johannesburg.

In 2002, at the Johannesburg World Summit on Sustainable Development (WSSD), Canada and the European Union were among the many countries that agreed to the final "Political Declaration" and the "Plan of Implementation." The plan of implementation included as a prime goal "changing unsustainable patterns of consumption and production".[5]

In this section of our report, we compare the way Canada and the European Union approach the issue of the sustainable use of natural resources. We conclude by assessing whether the current approach to sustainable production and consumption will take us far enough towards solving the problems of over-consumption and offer our recommendations.

Throughout this chapter, it is essential to recognize the dramatic difference that natural resources play in Canada and the European Union. Canada is highly dependent on the export of natural resources for income. By contrast, the European Union is highly dependent on imports for its natural resource needs. Canada exports approximately $150 billion worth of energy, minerals and forest products every year, accounting for almost forty percent of Canadian export earnings.[6] By contrast, the European Union imports more than 95 percent of the metals, 76.8 percent of the oil and 51.3 percent of the gas it uses (2002 figures). It is predicted that this could rise to 90 percent for oil and 80 percent for gas by 2030. The European livestock industry is also partially dependent on imported cattle feed, and much of its seafood is imported.[7] This means that the financial implications of reducing resource use differ dramatically between Canada and the European Union.

Prior to launching into our description of Canada's and the European Union's approaches to sustainable consumption and production, we will define the goals and measurement methods generally used to assess such programs.

[5] Some of the main targets agreed to at the WSSD are: 1) To halve the proportion of people without access to safe drinking water and basic sanitation by 2015; 2) to increase access to modern energy services, improve energy efficiency and the use of renewable energy, and support the target set out in the New Partnership for Africa's Development to ensure energy access for at least 35% of Africans in the next 20 years; 3) to reverse the current trend in natural resource degradation as soon as possible by implementing strategies that include targets to protect ecosystems and achieve integrated management of land, water and living resources, while strengthening regional, national and local capacities; 4) to reduce biodiversity loss significantly by 2010 and halt the decline in fish stocks; 5) to minimise the harmful effects of chemicals, especially by ensuring that, by 2020, chemicals are not used in ways that harm human health and the environment; 6) to develop a ten-year framework of programmes on sustainable consumption and production; and 7) to start implementing sustainable development strategies by 2005 in all countries.

[6] Natural Resources Canada, Sustainable Development Strategy: Moving Forward, 2004, p. 22.

[7] Commission of the European Communities, *Questions and Answers on the Thematic Strategy on the Sustainable Use of Natural Resources*, 2005. Accessible at: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/497&format=HTML&aged=0&language=EN&guiLanguage=en>.

3.2 *Sustainable Consumption Goals*

The most common definition of sustainable development is that from the Brundtland Commission Report, *Our Common Future*: "Development that meets the needs of the present without comprising the ability of future generations to meet their own needs".[8]

The Brundtland Commission asserted that sustainable development must address poverty issues: "...sustainable development requires meeting the basic needs of all and extending to all the opportunity to fulfil their aspirations for a better life. A world in which poverty is endemic will always be prone to ecological and other catastrophes".[9]

The issue becomes one of how to set concrete goals to direct programs and to be able to assess and measure progress. The most commonly defined goals are:

- Ensure development is within the "carrying capacity of the ecosystem":[10] The "ecological footprint" has become a tool commonly used to assess whether countries or the world as a whole are living within the planet's carrying capacity.[11] According to the World Wildlife Fund (WWF), as of 2003, the planet's people were consuming resources at a level 25 percent beyond "the world's ability to regenerate".[12]

- "Delink" or "decouple" economic growth and environmental impacts:[13] This means, for example, that increased production should not result in increased waste generation.

- Increase eco-efficiency by using less resources to make the same amount of product:[14] Under this approach raw materials and energy are saved by being more efficient in their use to create product. It is sometimes referred to as "doing more with less".[15] It is also called "de-materialization." The Wuppertal Institute, a German research group, concluded that "to arrest global environmental degradation, a 50 percent reduction in worldwide materials consumption will be needed – and that to achieve it, industrial countries need to aim for a 90 percent reduction".[16]

- Restore or improve vital renewable resources:[17] It is not enough to prevent a deterioration of natural resources. Efforts must be made to restore the quality and quantity of these resources.

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[8] Our Common Future, p. 8.
[9] Ibid.
[10] Plan of Implementation of the World Summit on Sustainable Development, 2002, Item III, paragraph 15.
[11] This method was developed by Mathis Wackernagel & William Rees, *Our Ecological Footprint: Reducing Human Impact on the Earth*, New Society Publishers, 1996.
[12] World Wildlife Fund, Living Planet Report 2006, p. 1.
[13] Plan of Implementation of the World Summit on Sustainable Development, 2002, Item III, paragraph 15. See also, Science on Sustainability 2006 Summary Report: A view from Japan, Accessible at: <http://www.sos2006.jp>.
[14] Plan of Implementation of the World Summit on Sustainable Development, 2002, Item III, paragraph 15.
[15] William McDonough and Michael Braungart, "The NEXT Industrial Revolution," *The Atlantic Monthly*, October 1998, p. 82.
[16] Young, John. "The New Materialism: A Matter of Policy," *World Watch*, September-October 1994, p. 27.
[17] Declaration of the United Nations Conference on the Human Environment, Principle 3.

- Increase equity in access to resources and provide support for ecologically sound development in countries currently lacking essential services:[18] The WWF report shows that we are already using the Earth's resources beyond its regenerative capacity. What would happen if the rest of the world consumed resources the way that we do in Canada and Europe? The founders of the ecological footprint calculated that it would require two additional planet Earth's to provide the necessary resources, if everyone on the planet had a footprint as large as the average person in Canada and the United States.[19] This means that people in Canada and Europe need to reduce their resource consumption to allow others to consume more and must help people in other counties gain access to more efficient production methods.

  > This means that all countries should have equal access to the world's resources, but also equal responsibility for the management of those resources. This equity principle means a lower resource use per capita than is currently the case in developed countries, and the opportunity for a rise in consumption of resources to a sustainable level for developing countries, to give a balanced pattern by the middle of the 21st century.[20]

These definitions and specific goals provide us with the basis for assessing Canada's and the European Union's programs.

3.3 *Sustainable Use of Natural Resources in Canada*

Canada endorsed the agreements at the Johannesburg World Summit on Sustainable Development. Implementation of these commitments was initially carried out through a secretariat made up of the Department of Foreign Affairs and International Trade, Environment Canada, and the Canadian International Development Agency. This secretariat analysed the Johannesburg World Summit on Sustainable Development and extracted 46 commitments specific to Canada. These were then assigned to the responsible government departments.[21]

Because of its mandate, Natural Resources Canada has the prime responsibility for achieving sustainable use of resources.[22] This Ministry is currently revising its Sustainable Development Strategy for the next three-year period, but the proposed changes in goals and objectives are minor.[23]

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[18] Johannesburg Declaration on Sustainable Development, 2002, paragraph 18.
[19] Op. cit., p. 15.
[20] Carley, Michael & Philippe Spapens, *Sharing the World: Sustainable Living & Global Equity in the 21st Century*, London: Earthscan Publications, 1998, p. 9.
[21] *Sustainable Development Strategies: Evolution of the Federal Approach* Accessible at: <http://www.ec.gc.ca/sd-dd_consult/SDS_federal_approach_e.htm>.
[22] Natural Resources Canada is "mandated with the federal responsibility for ensuring the sustainable development and responsible use of Canada's energy resources, minerals and metals, and forests, and for providing the geographical and geological information base that supports decisions about Canada's land-based and offshore resources." Source: *Sustainable Development Strategy: Moving Forward*, 2004, p. 8.
[23] Sustainable Development Strategy 2006: Discussion Paper for Consultation.

The consultation document identifies four challenges for the coming period:

- Strengthening the foundation for sustainable development;
- Greenhouse gas emissions and energy;
- Positioning Canada as a world leader on sustainable development;
- Demonstrating leadership and commitment to sustainable development in our operations.

These are identical to the "issues" that were identified in its 2004 document called *Moving Forward*.

For the most part, Natural Resources Canada's Sustainable Development Strategy fails to set goals that address the five types of goals outlined in the previous section.

1) **Ensure development is within the "carrying capacity of the ecosystem":**

Natural Resources Canada never raises the question of possible limits on the extent to which natural resources should be used. Indeed, the department takes an approach contrary to this goal. It describes as one of the issues "the need to evaluate exploration incentives to replace declining metal reserves" and sets as a target to develop recommendations on "exploration incentives".[24]

According to the World Wildlife Fund, in 2003, Canada's ecological footprint was 7.6 hectares per capita.[25] This is the second highest ecological footprint in the world – only being less than that in the United States. It is almost three and a half times higher than the world average. However, because of its vast expanse and relatively small population, Canada has a high biocapacity, i.e., "the amount of biologically productive area – cropland, pasture, forest, and fisheries – that is available to meet human needs".[26] As a result, the World Wildlife Fund determined that Canada has an "ecological reserve" of 6.9 hectares for each person.[27] This means that Canada is operating within the carrying capacity of the ecosystem.

This does not mean, however, that Canada's consumption of resources is sustainable. A critical component in all the definitions of sustainability under the United Nations is equity in access to resources. Canada clearly fails in this aspect. This will be discussed further under the equity question.

2) **"Delink" or "decouple" economic growth and environmental impacts:**

Natural Resources Canada's strategy has references to efficient use of resources, environmental responsibility, sustainable management, environmentally benign management, but there is no mention of decoupling level of resource use from economic growth.

[24] Sustainable Development Strategy: Moving Forward, 2004, p. 68.
[25] Living Planet Report 2006, p. 3.
[26] Ibid., p. 2.
[27] Ibid., p. 3.

3) **Increase eco-efficiency by using less resources to make the same amount of product:**

There are references to eco-efficiency in the sustainability documents for the federal government, but concrete targets for eco-efficiency are rare. This goal is addressed in energy use, e.g., "by 2006, improve average energy intensity by 20% in retrofitted commercial and institutional buildings which have received financial benefits".[28] However, no targets are set for increased eco-efficiency in materials use.

Natural Resources Canada's sustainable development strategy says, "Canada has a global responsibility to develop and use its natural resources productively, efficiently and in a socially responsible manner." But there is no reference to a need to reduce the material intensity of production systems. Natural Resources Canada has state of the art information systems on geological information and Canada's mineral resources, but not in such areas as the Total Material Requirements of the Canadian economy.

Natural Resources Canada's second sustainable development strategy *Now and For the Future* identified as a key approach "Promoting technologies and stewardship practices that reduce environmental impacts, conserve biodiversity and increase the efficiency of resource development and use".[29] This objective builds on an earlier policy review published as *The Role of Eco-efficiency: Global Challenges and Opportunities in the 21st Century*,[30] prepared for the interdepartmental Eco-efficiency Working Group as part of the Sustainability Project under the Federal Government's Policy Research Initiative. The definition of eco-efficiency used in the review is that of the World Business Council for Sustainable Development (WBCSD): "the delivery of competitively-priced goods and services that satisfy human needs and bring quality of life, while progressively reducing ecological impacts and resource intensity throughout the life cycle, to a level at least in line with the Earth's estimated carrying capacity".[31]

Eco-efficiency appears in approaches within Environment Canada and Industry Canada, the Canadian Centre for Pollution Prevention and the Policy Research Institute.

Industry Canada identifies environmental technologies as important drivers of innovation and productivity growth, which also contribute to sustainable development, improved competitiveness and better environmental performance. The department maintains a Web site providing information on the benefits of eco-efficiency for Canadian business, including industry practices, case studies, and links to other useful sites and eco-efficiency tools.

Environment Canada's Corporate Environmental Innovation initiative is a partnership-based government initiative designed to help accelerate innovation and to improve the environmental performance of companies. In collaboration with industry, academics, non-governmental

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[28] Natural Resources Canada, Sustainable Development Strategy: Moving Forward, 2004, p. 56.
[29] Natural Resources Canada, *The Path Forward – SDS Now and for the Future*, Accessible at: <http://www.nrcan-rncan.gc.ca/sd-dd/pubs/progfinal1997strat/nrcan_en/conclusion.htm>.
[30] Accessible at: <http://www.nrcan-rncan.gc.ca/sd-dd/pubs/progfinal1997strat/nrcan_en/print3.htm>.
[31] WBCSD's Seven Elements of Ecoefficiency • reduce the material intensity of its goods and services • reduce the energy intensity of its goods and services • reduce the dispersion of any toxic materials • enhance the recyclability of its materials • maximize the sustainable use of renewable resources • extend the durability of its products • increase the service intensity of its goods and services Accessible at: <http://www.wbcsd.ch>.

organizations and other government departments, Corporate Environmental Innovation develops and implements research projects and information initiatives to support Canadian corporate sustainability leaders and to encourage other companies to follow their example. Corporate Environmental Innovation's primary focus is on the link between environmental performance and long-term economic competitiveness.[32]

As has been shown, Canada has programs to encourage eco-efficiency, but these programs fail to set specific targets for improved eco-efficiency in materials use. A prime recurring motivation behind most of Canada's eco-efficiency programs is improved competitiveness in world trading. This appears to be the driving force rather than reduced use of resources because of environmental necessity.

4) **Restore or improve vital renewable resources:**

Natural Resources Canada's sustainable development strategy talks about reducing the negative impacts of activities such as logging and mining. It does not, however, make any references to taking action to restore or improve resources that are in a state of degeneration. In the one instance where they express concern – "base-and precious metal reserves are at historic lows" – their solution is to find new metal reserves to exploit.[33] Experts in the field indicate that there is substantial need for restoration and improvement of natural resources. Thomas Hutton, for example, states that in Canada "we face 'a massive sustainability deficit, i.e., a legacy of costs and resource depletion which must now be seriously addressed, and which includes badly eroded stocks of natural capital, and widespread environmental degradation, as well as major social, economic, and fiscal deficits'".[34]

5) **Increase equity in access to resources and provide support for ecologically sound development in countries currently lacking essential services:**

The strategy sets as a target to "transfer Canadian technologies and know-how".[35] An example of this is Canada's Model Forest Program, which focuses on building grassroots partnerships among environmental organizations, native groups, industry, educational and research institutions, recreationists, landowners, and all levels of government to develop sustainable forest management systems.[36] Canada has been spreading this model through international bodies to encourage its use elsewhere.

For the most part, however, the *Sustainable Development Strategy* puts more emphasis on "international market access issues concerning Canadian natural resource products and producers".[37] No reference is made in the strategy to the first part of this goal – increasing equity in access to resources.

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[32] Corporate Environmental Innovation: a government initiative to support corporate sustainability leadership Andrea Moffat, Adam Auer,Journal of Cleaner Production 14 (2006) 589e600, Accessible at: <http://www.ec.gc.ca/cei-iee/ED714727-D226-45B7-82B5-B5C85969D8F1/CEI-article-Moffat-%26-Auer-ENGLISH-FINAL.pdf>.
[33] Sustainable Development Strategy: Moving Forward, 2004, p. 68.
[34] Quoted in Melody Hessing, Michael Howlett & Tracy Summerville, *Canadian Natural Resource and Environmental Policy: Political Economy and Public Policy*, Vancouver: UBC Press, 2005, p. 13.
[35] Ibid., p. 73
[36] Natural Resources Canada, *Canada's Model Forest Program*, Accessible at: <http:// www.nrcan.gc.ca/cfs-scf/national/what-quoi/modelforest_e_html>.
[37] Ibid., p. 67.

Canada has a major role to play in the redistribution of access to resources because the average Canadian has an ecological footprint that is approximately three and a half times the average in the world. This footprint is second in size only to the United States. Therefore, Canada has a critical role to play in achieving the goals in the international sustainability agreements that it has signed. This can only be achieved by working to reduce Canada's consumption of resources and assisting others to ensure that they have access to the resources they need.

This discussion has focussed on Natural Resources Canada's strategy because it has the prime responsibility for resource use and consumption. The sustainable development strategies for the other departments also do not seriously address these five goals for resource use and consumption. For example, Canada's Department of Foreign Affairs adopted the Brundtland Commission definition of sustainable development. It further elaborated it as "an ethical principle that incorporates a commitment to equity between the current generation and those that will follow; and between the poor and the more affluent".[38] But it has failed to ensure that Canada acts in line with this ethical principle.

Since 1995, each of twenty-nine ministries and agencies[39] are required to every three years prepare a Sustainable Development Strategy, which is tabled in Parliament. The Commissioner of the Environment and Sustainable Development in the Auditor General's office audits progress on these strategies. The Commissioner has repeatedly criticised the Government for failing to follow through on its commitments and has pointed out reasons for this failure.

The report in 2005 summarized the Commissioner's understanding of the reasons why the federal government is failing to adequately implement a sustainable development plan and fulfil its responsibilities under international agreements.[40] These include:

- Lack of government-wide direction: The Commissioner pointed out that the committee of deputy ministers responsible for overseeing the programs has not even been able to agree on priorities and at one point ceased activities for over a year. Also the promised government-wide strategy has never been developed.

- Lack of an action plan on the 2002 World Summit commitments: The Commissioner concluded that Canada "risks not meeting three of the six commitments we examined because progress is slow in some areas and there is no information on progress in others."

- "Government leadership has a tendency to commit without putting in place the structure or resources to deliver on its promises."

- Strategy commitments usually are not "measurable or meaningful."

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[38] Frequently Asked Questions? Accessible at: <http://www.international.gc.ca/trade/sd-dd//faq-en.asp#whatsustain>

[39] See SDInfo for details, Accessible at: <http://www.sdinfo.gc.ca/federal_sd_resources/strategies_e.cfm>.

[40] Office of the Auditor General of Canada, "The Commissioner's Perspective – 2005" and "Chapter 7: Sustainable Development Strategies," *Report of the Commissioner of the Environment and Sustainable Development to the House of Commons*, 2005.

- Leadership from senior management is “often missing.”

- “Performance reporting has been incomplete and inconsistent.”

The Commissioner’s overall conclusion was that:

> ...the government's current promises, if fulfilled, would improve Canada's environmental position. But further new thinking is required to truly achieve sustainable development. ... Achieving sustainability within a generation will require that we Canadians significantly transform our society. The federal government should be leading this sustainability revolution.[41]

Others in government have come to similar conclusions about why Canada is failing to adequately implement sustainable development plans. For example, in 2005 the Canadian Senate's Standing Committee on Energy, the Environment and Natural Resources stated:

> It's time for the Government of Canada to step up to the plate, to show leadership, and to introduce the necessary reforms. This requires greater political will, greater co-ordination and integration within and across federal departments, and perhaps most importantly, a greater recognition that sustainable development is one of the most pressing issues facing the country today. [42]

The Canadian Institute for Environmental Law and Policy, an environmental think-tank, reached similar conclusions in 2005. They cited a need for “strong leadership at all levels, especially from the Prime Minister and Cabinet”.[43]

The Clerk of the Privy Council, Canada’s most senior civil servant, in testimony before the Senate committee in 2005, said:

> We are looking for a true shift to sustainability in how we produce, consume and live our lives. ... we will roll out a much more committed strategy to sustainable development that will really take hold. [44]

The Clerk went on to say that we need "long-term, fundamental, transformative change" in our industrial processes and to "make the culture or paradigm shift" within the public service.

These verbal commitments, if implemented, could produce significant new momentum towards the sustainable use of natural resources in Canada, but, in her 2006 report, the Commissioner

[41] “The Commissioner’s Perspective – 2005,” pp. 12 & 13.
[42] Ibid.
[43] MacDonald, Mary & Susan Holtz, Sustainable Development in Canada: 2005 Update, p. 26.
[44] Ibid.

reported that there had been no government follow through on the commitment by the Clerk of the Privy Council.[45]

3.4 *Sustainable Use of Natural Resources in Europe*

Among other environmental issues, the European Union's Sixth Community Environment Action Programme (Sixth EAP) set out, in 2002, the path to address the sustainable use and management of natural resources:

> Resources are the backbone of every economy. In using resources and transforming them, capital stocks are built up which add to the wealth of present and future generations. However, the dimensions of our current resource use are such that the chances of future generations - and the developing countries - to have access to their fair share of scarce resources are endangered. Moreover, the consequences of our resource use in terms of impacts on the environment may induce serious damages that go beyond the carrying capacity of the environment. These effects risk being aggravated once the developing world has taken up growth and resource use similar to the industrialized countries.[46]

The key aim of the Sixth EAP in the area of sustainable use of natural resources is "to break the linkages between economic growth and resource use and ensure that the consumption of resources and their associated impacts do not exceed the carrying capacity of the environment." Article 8 of the Sixth EAP established the following priority actions on the sustainable use and management of resources:

- an estimate of materials and waste streams in the Community, including imports and exports, for example, by using the instrument of material flow analysis;
- a review of the efficiency of policy measures and the impact of subsidies relating to natural resources and waste;
- establishment of goals and targets for resource efficiency and the diminished use of resources, decoupling the link between economic growth and negative environmental impacts;
- promotion of extraction and production methods and techniques to encourage eco-efficiency and the sustainable use of raw materials, energy, water and other resources;
- development and implementation of a broad range of instruments including research, technology transfer, market-based and economic instruments, programmes of best practice and indicators of resource efficiency.

The *Thematic Strategy on the sustainable use of natural resources* [COM(2005)670] is the prime instrument for defining the path forward to achieve these goals in the Sixth EAP. It was published on December 25, 2005.

[45] Office of the Auditor General of Canada, "The Commissioner's Perspective – 2006," Report of the Commissioner of the Environment and Sustainable Development to the House of Commons, 2006.
[46] Accessible at: <http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0670en01.pdf>.

The Thematic Strategy sets out a 25-year vision to reduce the negative environmental impacts associated with the use of natural resources in a growing economy and to improve resource efficiency. The Commission carried out several background studies[47] using current data and analysis methodologies to assess the impact of European material flows. Over a period of years, it carried out regular stakeholder meetings and internet consultations.

The main actions proposed under the Thematic Strategy at the EU level, and detailed in its Annex (SEC(2005)1684), are:

- Development, by 2008, of a data set and indicators (both resource-specific and overall) to measure progress in efficiency and productivity, and in decoupling resource use from economic growth, and to evaluate negative environmental impacts.
- Establishment of a European Data Centre on natural resources use and their environmental impacts, to be operational twelve months after the Strategy's adoption. This will bring together all the available information in order to monitor and analyse it and to provide policy-relevant information to decision-makers.
- Establishment of a High Level Forum composed of senior officials responsible for the development of natural resource policy in Member States, representatives from the Commission and other stakeholder groups. The role of the Forum is to develop national measures for the implementation of the strategy.
- Establishment of an International Panel on the sustainable use of natural resources in cooperation with the United Nations Environment Programme.

The European Union also identifies specific actions and roles for Member States such as:

- Use of economic instruments;
- Education and training curricula;
- Consumer policies aimed at changing behaviour;
- Development of national measures and programs to achieve the objectives;
- Focus on priority natural resources with the most significant local impacts; and
- Monitoring mechanisms.

The Commission intends to identify successful measures taken at the Member State level that could usefully be implemented European Union wide. It will also consult Member States about possible market-based instruments for managing natural resources.

We will now assess the extent to which the European Union Strategy and associated plans adopt the goals for sustainable resource use that we outlined earlier in this chapter.

1) **Ensure development is within the "carrying capacity of the ecosystem":**

Operating within the carrying capacity of the ecosystem is stated as a prime objective in the European Union policies on sustainable use of resources. Among the European Union Member States, the ecological footprint in 2003 was approximately five hectares per capita in comparison with a worldwide average of 2.2. The biocapacity of the region was 2.64 hectares per capita.[48] This means that Europeans are consuming resources at a rate approximately

[47] Accessible at: <http://europa.eu.int/comm/environment/natres/>.
[48] Living Planet Report 2006, p. 18.

double the carrying capacity of the region that they live in. The implications of this for other countries is discussed under "increase equity in access to resources."

2) "Delink" or "decouple" economic growth and environmental impacts:

Decoupling economic growth and environmental impacts is a prime stated objective of the European Union's policies. The European Union found that in the past twenty years, "overall consumption [of resources] per inhabitant has remained virtually unchanged … and yet the economy has grown by 50% over that period".[49] This indicates that some decoupling has occurred. Nevertheless, the European Environment Agency, a government bureau, points out that this did not "necessarily lead to an absolute decrease in environmental pressures, because absolute resource use has generally remained steady over the past two decades".[50] This indicates that, while "decoupling" is a worthy goal, it is not a sufficient goal on its own to address the problems of unsustainable consumption of resources.

3) Increase eco-efficiency by using less resources to make the same amount of product:

Eco-efficiency is probably the most frequently discussed item in the European Union's goals. However, no measures of the extent to which this has already occurred are provided in the documents and no targets are set.

4) Restore or improve vital renewable resources:

In its Sustainable Development Strategy, the European Union commits to restoring degraded marine ecosystems.[51] Elsewhere in the strategy improvements to renewable resources are not mentioned.

5) Increase equity in access to resources and provide support for ecologically sound development in countries currently lacking essential services:

This is a goal that is highlighted throughout the European Union's documents. It is a goal that has critical importance in Europe because, as was shown by their ecological footprint, they are producing beyond their local resource capacity and, therefore, have dramatic impacts elsewhere and are dependent on wise resource use elsewhere in the world. The introduction to the Thematic Strategy highlights this issue in its introduction:

> The EU is highly dependent on resources coming from outside Europe and the environmental impact of resource use by the EU and other major economies is felt globally. At the same time the growing economies of the developing world such as China, India and Brazil are using natural resources at an accelerating pace. If the world as a whole followed traditional patterns of consumption, it is estimated that global resource use would quadruple within 20 years.[52]

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[49] Thematic Strategy on the sustainable use of natural resources, section 2.
[50] European Environment Agency, Sustainable use and management of natural resources, 2005, p. 5.
[51] Council of the European Union, *Review of the EU Sustainable Development Strategy*, June 2006, p. 13.
[52] Thematic Strategy on the sustainable use of natural resources, section 1.

In the Thematic Strategy, the European Union commits to develop in cooperation with the United Nations Environment Program an international panel to provide advice on achieving sustainability in developing countries.[53] Also, in its *Sustainable Development Strategy* the European Union commits each of its member countries to achieve targets for foreign aid of 0.56 percent of gross national income by 2010 and 0.7 percent by 2015.[54]

Environmental groups such as the European Environmental Bureau, Friends of the Earth, and Greenpeace, as well as research institutes such as the Institute for European Environmental Policy, the Sustainable Europe Research Institute, and the Wuppertal Institute have been heavily involved in consultations around the development of the European Union's *Thematic Strategy on the sustainable use of natural resources*.

These groups are unanimous in their expression of disappointment with the European Union's progress and plans. In his introduction to the recently published *EU Environmental Policy Handbook*,[55] Stephan Scheuer outlines the impressive array of environmental legislation that has been put in place over the last 30 years in Europe, but concludes that "similar or identical concerns remain: environmental progress through technology has been outweighed by growing consumption and natural resource use".[56] Their assessment of the European Union's Thematic Strategy concludes that this will not provide the fundamental needed leap forward. They conclude that "whilst the activities described in the strategy are useful, we are in fact confronted with a postponement of a real strategy for at least five years".[57] The Institute for European Environmental Policy came to a similar conclusion:

> It is unclear whether the initiatives announced in the Thematic Strategy will result in any real changes to how natural resources are used in the EU, and the negative environmental impacts associated with this resource use, at least in the short-medium term.[58]

The main concerns that the environmental groups and research institutes raise include:

- **Lack of precise targets and timetables:** The *Thematic Strategy* has no targets or timetables for achieving critical matters such as resource efficiency improvements or reductions in resource use.[59] They feel that the Commission's plan focuses on data gathering and, as a result, postpones action. These organizations believe that there is enough information currently available to now adopt targets and appropriate indicators to measure progress. Ten of these environmental groups propose that the European Union immediately adopt the following targets:
    - A factor of four increase in resource productivity between 1990 and 2030; and

[53] Ibid., section 5.4.
[54] Review of the EU Sustainable Development Strategy, p. 20.
[55] European Environmental Bureau, EU Environmental Policy Handbook: A Critical Analysis of EU Environmental Legislation, Accessible at: <http:// www.eeb.org>.
[56] EU Environmental Policy Handbook, Chapter 2, page 12.
[57] European Environmental Bureau, *A Targeted Strategy on Resource Use,* July 2006.
[58] Drowning in Process: The Implementation of the EU's 6th Environmental Action Programme, April 2006, p. 36.
[59] Rocholl, Martin, Stefan Giljum et al., Factor X and the EU: How to make Europe the most resource and energy efficient Economy in the World, March/April 2006, p. 24.

- A factor of ten productivity increase by 2050.[60]

- **Member countries not accountable under the Strategy:** Because the Strategy lacks targets, there is nothing that member countries are bound to achieve. Therefore, there is no way to hold them accountable for implementing the Strategy. This contrasts with extended producer legislation at the European Union level, which requires each member country to achieve defined recovery, reuse, and recycling rates.

- **Implementation mechanisms soft in nature:** There is a concern that the tools for implementing the Strategy are "soft".[61] Alternatives to legislation that they raise concerns about are co-regulation, self-regulation, voluntary sectoral agreements, open coordination methods, financial interventions, and information campaigns. They conclude that "the decline in legislative activity in the environmental policy field has become particularly marked since the 6EAP and even more so since the beginning of the current Commission's term of office".[62]

- **Lack of focus on reduction in resource use:** Eco-efficiency as usually defined and as used in the *Thematic Strategy* aims at reducing energy and resource use per capita or per unit of production. This can actually result in increased total use of resources if population or production increases substantially. Environmental groups propose that there be a focus on reduction in total amount of resources used, especially for those resources that have the greatest negative impact on the environment: "We anticipate that for several resources Europe might have to aim for **absolute reductions in resource use of a factor 4 by 2030 and a factor 10 by 2050**, as a result of respecting carrying capacity, a more equitable global access to resources and population growth".[63]

3.5 *Comparison of Sustainable Use of Resources in Canada and the European Union*

The differences in activities on the sustainable use of resources between Canada and the European Union are dramatic.

This issue receives considerable explicit attention in European Union policy development and research, but is largely absent from the discourse in Canada. The *Thematic Strategy on sustainable use of natural resources* in the European Union, the information base on material throughput used to develop the Strategy, the extensive engagement with stakeholders, the discussion about burden shifting to countries outside of the European Union and the debate within the European Council and the European Parliament are all much more extensive than discussions are in Canada on this issue.

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[60] *A programme for the Sustainable Development of the European Union*, March 2006, p. 18. Factor of four and factor of ten means making product with one-quarter and one-tenth the amount of resources and energy as is currently used to make the same amount of product.
[61] Drowning in Process, p. 53.
[62] Ibid., p. 43.
[63] A programme for the Sustainable Development of the European Union, p. 18.

The European Union established an Advisory Forum with representatives of industry, governments, non-government environmental organizations, and academia and set up Working Groups on supply and use of resources to help develop a strategy, each of which prepared a report. The two reports contain 186 recommendations. These recommendations fed into an internet-based stakeholder consultation, the results of which were taken into account in the development of the strategy. [64] No such extensive discussion has occurred in Canada.

The European Union has developed an overall strategy on this topic. Canada has no such government-wide strategy. Natural Resources Canada has developed a strategy on the topic, but it is very weak at addressing, or ignores, issues such as carrying capacity, delinking growth from resource use, country-wide targets for eco-efficiency, and the need to reduce resource consumption in Canada to allow increased equity in access in developing countries. Natural Resources Canada's strategy differs dramatically from the European Union's, which explicitly addresses each of these topics.

The existing policy framework in Canada essentially assumes a throughput materials cycle (extraction-processing-use-disposal as waste) that seeks to maximize access to materials at lowest direct economic costs while managing the environmental and social externalities with end-of-pipe solutions. This means that much less data are gathered in Canada on material flows than in Europe.

Natural Resources Canada's recent completion of *An Analysis of Resource Recovery Opportunities in Canada and the Projection of Greenhouse Gas Emission Implications* is an important exception to this. It quantifies the potential for resource cycling through improved recycling policy and legislation. The report estimates that 23,836,000 tonnes of materials, currently disposed of in Canada, are potentially available for recovery. The recovery of these materials could represent a reduction of green house gases of between 6.5 million to12.6 million tonnes CO2.[65]

By contrast, in Europe extensive work has been carried out using Material Flow Accounting, a methodology that takes all materials into account except water. Overall material consumption in the European Union is currently around 16 tonnes per capita per year.[66] The shares of the various resources are:

- Construction materials (natural stone, sand, gravel, limestone): 40%
- Fossil fuels (oil, gas, coal, lignite): 25%
- Biomass (forestry products, agricultural products): 25%
- Industrial minerals (salt, sand, potash, clay) and metals (iron, zinc, aluminum): 9%.

Despite stable material consumption in Europe over the past twenty years, the environmental impacts of resource use continue to be dramatic. Out of the 16 tonnes per capita resource input every year, ten tonnes stay in the economy as physical stock, e.g., roads, houses and durable

[64] Questions and Answers on the Thematic Strategy on the Sustainable Use of Natural Resources, Accessible at: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/497&format=HTML&aged=0&language=EN&guiLanguage=en#fn5>.
[65] Sinclair, Rob. An Analysis of Resource Recovery Opportunities in Canada and the Projection of Greenhouse Gas Emission Implications, March 2006, Minerals and Metals Sector, NRCan.
[66] Eurostat, Material use in the European Union 1980-2000: indicators and analysis, Working Papers and Studies series, 2002.

goods. The remaining six tonnes leave the economy as waste, CO2 and emissions of other pollutants. This accumulation of material in the economy (physical stock) and in the environment (landfills, CO2, other pollutant emissions) causes environmental impacts to grow.

Many studies conclude that 1) food production, 2) transport and 3) housing contribute, in this order, the lion's share to total environmental impacts of resource use.[67]

Lack of such accounting in Canada makes it impossible to understand resource use and to make judgements about the most appropriate places to focus actions to address problems.

In Canada, the discussion is heavily focused on competitiveness and business opportunities in the resource sector. This helps explain why many of the concepts around sustainable use of resources aren't even discussed in Canada's strategies. In the one case where there is considerable discussion of a core concept in sustainable use of resources – eco-efficiency, the discussion is largely focused on the potential for eco-efficiency within particular firms or as demonstration projects for take up within sectors. The primary motivator here is to increase the individual company's productivity and thus competitiveness – not to reduce resource use for environmental reasons. There are a number of Canadian companies[68] who have successfully taken up the eco-efficiency approach as part of the basic corporate strategy to increase their productivity. This contrasts with Europe where the motivation for eco-efficiency has a major environmental driving force behind it.

Major reasons behind the dramatically different approaches in Canada and the European Union to the sustainable use of resources issue lie in the different resource make-ups of the two areas. The European Union is 90 percent [69] dependent on imports for its natural resource needs, while natural resource exports comprise 40 percent[70] of Canada's exports. This means that Canada sees resources as an economic advantage whereas the European Union sees access to resources as a problem. Also, despite the fact that Canada has an ecological footprint approximately fifty percent higher than the European Union, Canada is currently using only about half of its "carrying capacity." By contrast, consumption in the European Union is twice the "carrying capacity" of that region.[71]

3.6 *Summary of Best Practices*

Canada's and the European Union's high ecological footprints, and the European Union's dramatic overreaching of the carrying capacity of that region, point towards the need for both Canada and Europe to take dramatic action to achieve sustainable use of resources. This

[67] See Policy Review on Decoupling: Development of indicators to assess decoupling of economic development and environmental pressure in the EU-25 and AC-3 countries, Accessible at: <http://www.europa.eu.int/comm/environment/natres/pdf/fin_rep_natres.pdf> and
Environmental Impact of Products (EIPRO). Analysis of the life cycle environmental impacts related to the total final consumption of the EU25, Accessible at:
<http://www.europa.eu.int/comm/environment/ipp/pdf/eipro_draft_report2.pdf>.
[68] Accessible at: <http://www.fivewinds.com/uploadedfiles_shared/Eco-efficiency040127.pdf>.
[69] Op cit at footnote 7.
[70] Op cit at footnote 6.
[71] Living Planet Report 2006, p. 3 &18.

definition of sustainability must be put into world-wide terms – not just of the individual country. This means, for example, that, even though Canada is relatively resource rich, it must still reduce resource consumption for the well-being not only of Canada but the world as a whole.

This chapter has shown that the European Union has gone much further than Canada in taking this issue seriously. Nevertheless, even in Europe it is doubtful that the actions are yet in place to achieve a dramatic change. The main failing is a lack of targets.

To begin the movement forward it is essential that the following goals be specifically addressed:

- Ensure development is within the carrying capacity of the ecosystem;
- Delink or decouple economic growth and environmental impacts;
- Increase eco-efficiency by using less resources to make the same amount of product;
- Restore or improve vital renewable resources; and
- Increase equity in access to resources and provide support for ecologically sound development in countries currently lacking essential services.

In addition, specific targets with timelines should be set for each of the goals.

The main foci in the dialogue on sustainable use of resources currently are on decoupling economic growth from economic impacts, and eco-efficiency. The basic question is whether this emphasis recognizes the fundamental shift in resource use that is needed. Michael Renner has stressed the need:

> But the compulsive worship at the altar of consumption has brought humanity right to the edge of an environmental abyss – depleting resources, spreading dangerous pollutants, undermining ecosystems, and threatening to unhinge the planet's climate balance. Stepping back from this precipice will require a major reduction in human claims on Earth's resources.[72]

William McDonough and Michael Braungart assert that the current focus on eco-efficiency will not result in this fundamental shift:

> Eco-efficiency is an outwardly admirable and certainly well-intended concept, but, unfortunately, it is not a strategy for success over the long term, because it does not reach deep enough. It works within the same system that caused the problem in the first place, slowing it down with moral proscriptions and punitive demands. It presents little more than an illusion of change. Relying on eco-efficiency to save the environment will in fact achieve the opposite – it will let industry finish off everything quietly, persistently, and completely.[73]

McDonough and Braungart call for "the next industrial revolution." Positive signs are present indicating that this next revolution is in its formative stages.

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[72] Renner, Michael. "Moving Towards a Less Consumptive Economy," *State of the World 2004*, Worldwatch Institute, 2004, p. 97.
[73] "The NEXT Industrial Revolution," *The Atlantic Monthly*, October 1998, p. 85.

Karl-Henrik Robert, a Swedish medical doctor and cancer-treatment researcher, has led the development of The Natural Step approach to sustainability, which has been adopted by many industries around the world. The Natural Step is based on the following four conditions for a sustainable society:

1. Nature is not subject to systematically increasing concentrations of substances extracted from the Earth's crust.
2. Nature is not subject to systematically increasing concentrations of substances produced by society.
3. Nature is not subject to systematically increasing degradation by physical means.
4. The ability of humans to meet their needs worldwide is not systematically undermined.[74]

An approach consistent with The Natural Step now being implemented by some industries is the "nutrients" approach described by McDonough and Braungart in *Cradle to Cradle*:

> Products can be composed either of materials that biodegrade and become food for *biological cycles*, or of technical materials that stay in closed-loop *technical cycles*, in which they continually circulate as valuable nutrients for industry.[75]

If products do not meet one or both of these cycles, the authors assert that, for the long-term well-being of the environment, we cannot afford to allow the product to be made.

Based on this next industrial revolution, Ray Anderson, president of Interface Carpets Inc., has developed the following vision for his company:

> We look forward to the day when our factories have no smokestacks and no effluents. If successful, we'll spend the rest of our days harvesting yesteryear's carpets, recycling old petro-chemicals into new materials, and converting sunlight into energy. There will be zero scrap going into landfills and zero emissions into the biosphere. Literally our company will grow by cleaning up the world, not by polluting or degrading it.[76]

The company has turned this vision into concrete zero-based goals. Each year, the company issues a sustainability report in which they assess the extent to which they have moved forward on these goals.

These approaches are a fundamental leap beyond the approach to sustainable materials use that even the European Union is using.

Best Practice:

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[74] Robert, Karl-Henrik. "Integrating sustainability into business strategy and operations: Applying The Natural Step approach and Framework and backcasting from principles of sustainability," in *Ants, Galileo, & Gandhi*, ed. Sissel Waage, Greenleaf Publishing, 2003, p. 67.
[75] McDonough, William & Michael Braungart, *Cradle to Cradle: Remaking the Way We Make Things*, New York: North Point Press, 2002, p. 104.
[76] Anderson, Ray. *Getting There,* Interface, Inc., Accessible at: <http://www.interfaceinc.com/getting_there/Ray.html>.

- **Develop strategies around sustainable materials use that:**
    - **Result in an *absolute* reduction in, or elimination of, use of resources, especially those that are not renewable and not capable of becoming nutrients in the cycle.**
    - **Make choices on materials use on the basis of the extent to which they meet the conditions of The Natural Step or of the nutrients approach.**

This best practice must become our normal practice if our use of materials is to be sustainable over the long-run.

4. The Regulation of Genetically Modified Organisms in Food Production in Canada and the European Union

By Jessica Ginsburg and Anne Wordsworth, with research assistance by Jennifer Agnolin

4.1 *Modern Biotechnology*

Traditional biotechnology, such as the selective breeding of plants, has been used in the food industry for centuries to improve agricultural productivity and create new foods. However, the advent of modern techniques that enable companies to modify the DNA of organisms has resulted in the rapid introduction of new genetically altered seeds and foods. This technology, also called genetic engineering or recombinant DNA, allows the transfer of genes from one organism to another, in some cases into non-related species.

Genetic modification applied to food production has raised issues of environmental protection, food safety and the consumer's right to know. The planting of genetically modified seeds, the use of genetically modified feed for animals and the sales of genetically modified foods or foods containing genetically modified ingredients are all controversial in North America and Europe.

In regulating genetically modified organisms (GMOs), Canada and the United States have taken a substantially different regulatory approach than the European Union.

In Canada, the federal government has adapted existing statutes to accommodate the inclusion of biotechnology, rather than creating a new regulatory regime. This ad hoc approach has been criticized by scientists, environmentalists and health advocates, who have expressed doubts about the ability of Canada's regulatory system to contain the health and environmental risks of genetically modified foods.

To respond to these concerns, the government of Canada requested that the Royal Society of Canada appoint an Expert Panel on the Future of Food Biotechnology.[1] Their 2001 landmark report, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada", contained more than 50 recommendations for improving the regulatory regime in Canada.

The Royal Society acknowledged a long list of problems with the Canadian regulatory regime. First, the federal government is both regulator and promoter of biotechnology, with large research and development subsidies creating a conflict of interest. Also identified were a lack of precaution in the regulation of genetically modified organisms, a lack of adequate testing to establish scientifically-sound safety assessments and a lack of transparency.

In Europe, public concern about the overall safety of the food supply has resulted in a slower, more cautious acceptance of genetically modified foods. Like Canada and the United States, the European Union (EU) was initially enthusiastic about the introduction of biotechnology into

[1] The Royal Society of Canada, *"Elements of Precaution: Recommendations for the Regulation of Food Biotechnolgy in Canada",* An Expert Panel Report on the Future of Food Biotechnology (Ottawa: The Royal Society of Canada, January 2001). In this chapter, the Report of the Expert Panel will be referred to in footnotes as 'The Royal Society of Canada', and page numbers given.

agriculture and food. However, public opinion and political pressure shifted, and in 1998 the European Union was forced to adopt a *de facto* moratorium. Since then, the EU has developed a comprehensive regulatory regime that applies to all facets of food production from the containment of genetically modified crops to consumer labelling and the traceability of genetically modified organisms throughout the food system. The result is a more stringent regulatory framework for genetically modified foods in Europe and a more restricted market than exists in North America.

Canada and the United States, as major world exporters of genetically modified foods, have challenged the EU's policy and regulatory approach to genetically modified organisms at the World Trade Organization (WTO). In 2003, Canada, the U.S. and Argentina brought a case against the EU on the grounds that Europe's regulatory actions have caused "undue delay" in the approvals procedures of genetically modified crops and foods.[2]

Contrasting regulatory regimes have also led to significant differences in the European, Canadian and American positions on the Cartagena Protocol on Biosafety. The Protocol came into force in September 2003 and is the only international agreement that governs GMOs. The purpose of the agreement is to establish common rules for the transboundary movement of GMOs in order to ensure the global protection of biodiversity and human health. The Protocol also requires countries to take a precautionary approach.

While the EU has ratified the Protocol, Canada signed in 2001 but has not ratified. The U.S. has not signed the Convention on Biological Diversity, which is the "parent" agreement to the Protocol, and has challenged the EU's adoption of the precautionary principle with respect to GMOs as part of the WTO dispute.

This chapter discusses the differences in the regulation of food biotechnology in Canada and the EU, with some attention to the U.S. However, since the U.S. and Canada have very similar regulatory approaches to GMOs, the primary focus is on the Canadian and EU regimes.

4.2 *The Legal Framework for Genetically Modified Organisms*

Canada and the European Union have developed very different legislative frameworks for genetically modified organisms. The two different frameworks for foods have been described as "process-based" legislation in the EU, and "product-based" legislation in the U.S. and Canada.[3]

A "product-based" regulatory framework focuses on the products derived from genetic modification, and not on the processes used to create them. In concentrating regulatory attention on the product rather than its development and possible consequences, Canada and the U.S. have made "substantial equivalency" the cornerstone of their regulatory approach.

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[2]World Trade Organization, Dispute Settlement: Dispute DS292, Summary as of October 6, 2006, "European Communities – Measures Affecting the Approval and Marketing of Biotech Products" Accessible at <http://www.wto.org>.

[3] Konig, A. et al (2004) Assessment of the safety of foods derived from genetically modified (GM) crops, *Food and Chemical Toxicology* 42, 1047-1088.

These regulatory differences have also been described as "a fundamental divide" on the regulation of GMOs between "those who seek a strong implementation of the precautionary principle and those who are content with more limited assessments of GMO risks".[4]

4.2.1 Canada and the regulation of genetically modified organisms

The regulation of GMOs is under federal jurisdiction in Canada. The government's dual role of regulator and promoter of biotechnology originated in 1983 when the National Biotechnology Strategy was first announced.

The National Biotechnology Strategy was established both to promote the biotechnology industry and to lay out the principles, including "using existing laws and regulatory departments".[5] As a result, the government established a complex approval system involving several federal departments that play different roles in GMO regulation under the authority of a number of federal Acts.

Also in 1983, a National Biotechnology Advisory Committee was formed to advise the Minister of Industry on the growth and competitiveness of the industry, and the federal government committed itself to significant investments in biotechnology.[6] The government's expenditures on biotechnology research and development were in the range of $400 to $500 million annually.[7]

The two federal agencies with primary responsibility are the Canadian Food Inspection Agency (CFIA) with the responsibility for seeds, most plants, animal fertilizers and feeds, and Health Canada with the responsibility for food. Other departments, including Environment Canada, have some responsibility for assessing the effects of biotechnology on the environment.

Numerous federal Acts play a role in the regulation of agricultural and food biotechnology, including the *Food and Drugs Act*, the *Seeds Act*, the *Feeds Act*, the *Canadian Environmental Protection Act*, the *Health of Animals Act*, the *Pest Control Products Act* and the *Fisheries Act*.

Because of the number of federal Ministries, agencies and committees involved in different aspects of biotechnology, the government also set up a horizontal governance structure intended to co-ordinate the government's approach on strategy and emerging policy issues (see diagram below). However, in 2005 an Auditor General's report on horizontal decision-making criticized this structure, pointing out that the key Ministerial Co-ordinating Committee, composed of the ministers of Agriculture, Environment, Fisheries, Foreign Affairs, Health, Industry and Natural Resources, had met only once in 6 years. The Auditor commented that: "we expected that ministers would receive and consider advice in a timely way, given that rapid

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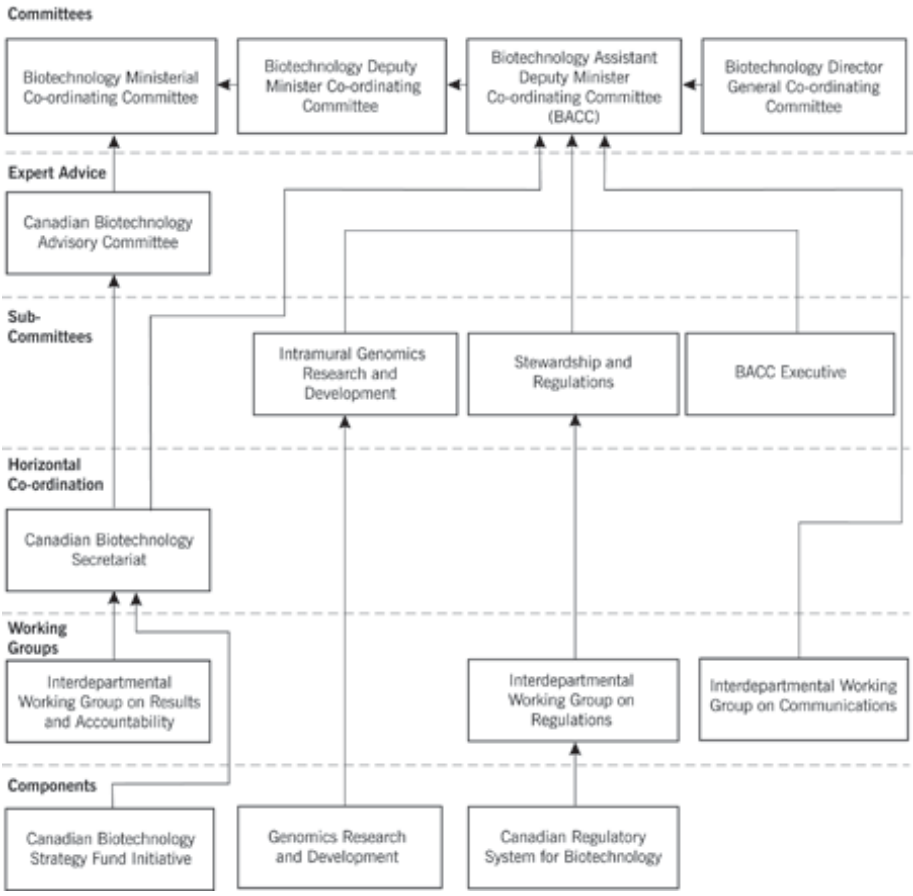
[4] Andree, Peter (June 2006) GM Food Regulation: An analysis of efforts to improve genetically modified food regulation in Canada, *Science and Public Policy* 33:5, p. 11.
[5] CBS Online, "Regulatory System, The Federal Regulatory System, Current Federal Legislative Framework for Biotechnology Products". Accessible at <http://www.biotech.gc.ca>.
[6] Government of Canada, "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process". Accessible at <http://www.biostrategy.gc.ca>.
[7] Office of the Auditor General of Canada, March 2004 Report, Chapter 4, Exhibit 4.1, Examples of federal investment in biotechnology.

changes in biotechnology can affect health, safety, the environment, and the economy". The audit identified a lack of clear direction and leadership at the top level.[8]



Source: Canadian Biotechnology Secretariat

4.2.2 Canadian Food Inspection Agency

The Canadian Food Inspection Agency (CFIA), created in 1997 in order to consolidate services for food, animals and plant health into a single agency, is the lead agency enforcing regulations which apply to agricultural products, including seeds, plants, animal fertilizers and feeds. It assesses new products, including biotechnology products, and monitors and inspects companies and food to ensure that they meet Canada's food safety standards.

The majority of the CFIA's mandate regarding genetically modified crops is derived from the *Seeds Act,* the *Feeds Act,* and their respective regulations. The *Seeds Act* and Seeds Regulations apply to "plants with novel traits" which are intended for release into the

[8] 2005 Report of the Auditor General, Chapter 4, Managing Horizontal Initiatives. Accessible at <http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20051104ce.html>.

environment.[9] The *Feeds Act* and Feeds Regulations govern all livestock feeds manufactured or imported into Canada, including novel feeds.

Federal schemes generally use the term 'novel food' or 'plants with novel traits' as opposed to GMOs. The term 'novel' is defined in the Seeds Regulations to mean a characteristic that has been "intentionally selected, created or introduced…through a specific genetic change" and that "based on a valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health"[10] to any characteristic of an existing approved substance of the same species. The Feeds Regulations definition is extended to include animal health as well as human health.

By using the term 'novel' rather than 'genetically modified', the regulatory framework is meant to have a wider scope of applicability. However, classifying GMOs under the definition of novel has also allowed the federal government to avoid developing a distinct regulatory regime. Organisms that are modified with and without the use of biotechnology are captured by this definition. However, the majority of plants that are now approved every year as plants with novel traits are genetically modified.[11]

The regulations require that no person undertake the release of a novel seed, feed or supplement without prior notification to, and authorization from, the CFIA.[12] Before granting authorization, the CFIA will review the information accompanying the notification which includes:

- identifying information of the notifier;
- the purpose and objectives of the proposed release;
- the plants derived from the unmodified host seed, in the case of the Seeds Regulations;
- any confinement measures intended to mitigate the establishment and spread, in the environment, of the organism ("or of genetic material"—Seeds Regulations) and the interaction of the organism with the environment;
- the monitoring plan and procedures to be followed both during and after the release;
- the method to be used for the safe disposal of the organism ("and all progeny and plant material"—*Seeds Regulations*; "and all livestock products"—Feeds Regulations);
- the contingency plan to be followed to minimize any adverse effect of an accidental release of the organism ("or genetic material"—Seeds Regulations), ("on the environment, including any adverse effect on human or animal health"—Feeds Regulations);
- the identification and characterization of the novel trait and, where the novel trait is introduced from another species, details of the host and donor organism and of the methods of incorporation of the novel trait into the host organism, where applicable;

[9] Included in this legislation are food crops, trees, and horticultural and marine plants. Exclusions include novel plants species with novel traits (covered by the New Substances Notification Regulations under the *Canadian Environmental Protection Act*) and seeds grown in full containment.
[10] Seeds Regulations, C.R.C.,c. 1400 at s. 107; Feeds Regulations, SOR/83-593 at s. 2; Fertilizers Regulation, C.R.C.,c.666 at s. 2.
[11] Health Canada, Approved Products, Genetically Modified Foods and Other Novel Foods. Accessible at: <http:// www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index_e.html>.
[12] Seeds Regulations, at s. 109(1); Feeds Regulations, at s. 4.1.

- the identification and characterization of the novel organism resulting from the introduction of the novel trait, including details relating to expression of the novel trait and the stability of the incorporation of the novel trait into the novel organism, and a comparison of the characteristics of the novel organism with those of the unmodified host organism;
- all other information and test data in respect of the novel organism that are relevant to identifying risks to the environment, including risks to human health (or animal health—Feeds Regulations) and that are in the person's possession or to which the person ought reasonably to have access;
- other government agencies, either Canadian or foreign, that have been provided with information in respect of the novel organism and the purpose for which the information was provided; and
- a description of the analytical methodologies followed in generating any submitted data, including quality control and quality assurance procedures.[13]

For any proposed unconfined release, the Seeds Regulations additionally require data describing the potential interactions of the seed with other life forms and an evaluation of the potential risk of harm posed to the environment and human health as a result of those interactions.[14] All the major GM crops grown in Canada such as canola, corn, flax, potato, soybean, and wheat are assessed by CFIA under the *Seeds Act* and its regulations.

4.2.3 Health Canada

Under the *Food and Drugs Act*, Health Canada is responsible for establishing and enforcing safety and nutritional quality standards for traditional and novel foods sold in Canada. [15] New GMOs are dealt with under the Novel Foods section of the *Food and Drugs Regulations*.[16] Novel food is defined as:

> (a) a substance, including a microorganism, that does not have a history of safe use as a food;
> (b) a food that has been manufactured, prepared, preserved or packaged by a process that
>
> (i) has not been previously applied to that food, and
> (ii) causes the food to undergo a major change; and
>
> (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
>
> (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
> (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
> (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

[13] Seeds Regulations, at 110; Feeds Regulations, at 4.2; Fertilizers Regulations, at 23.2.
[14] Seeds Regulations at 110 (3).
[15] *Food and Drugs Act,* R.S.C, 1985, c. F-27.
[16] Food and Drugs Regulations, C.R.C., c. 870.

Important to note is that food additives are not included in the definition of novel foods. They are subject to a different assessment by Health Canada under Division 16 of the Food and Drug Regulations governing Food Additives. Novel food additives are not distinguished and therefore new GM food additives undergo the same assessment as other new food additives for approval. The decision documents are not published. Instead, approved additives are added to the list of permitted food additives that appears in the *Canada Gazette.*[17]

The Food and Drugs Regulation on Novel Foods establishes a notification process, requiring anyone wishing to sell or advertise a novel food in Canada to first notify Health Canada, and in turn wait for notification that the food is safe for consumption.

As with the CFIA process, certain information must accompany the notification to Health Canada for food products containing GMOs. This includes:

- the common name under which the novel food will be sold;
- a description of the novel food, together with information respecting its development;
- details of the method by which it is manufactured, prepared, preserved, packaged and stored;
- details of the major change, if any;
- information respecting its history of use as a food in a country other than Canada, if applicable, and
- information relied on to establish that the novel food is safe for consumption, and,
- information respecting the estimated levels of consumption by consumers of the novel food;[18]

Within 45 days of receiving a notification, the Director must review the information and notify the food's producer or importer whether the information is sufficient and the food safe, or if more information is required. If more information is required and subsequently supplied, the Director has 90 days to review the additional information from the date of its receipt and inform the applicant through notification of its sufficiency. If the information is deemed insufficient, the novel food cannot be sold or advertised for sale.

While the regulation itself establishes the basic requirements, the more relevant document is the *Guidelines for the Safety Assessment of Novel Foods*, which provides a specific outline of the information that must be included in a safety assessment and the general principles that Health Canada is to apply in assessing novel foods for safety.[19]

These *Guidelines* state that "emphasis of the safety assessment is on the product and not the process used to develop it".[20] They also state that "a guiding principle in the safety assessment will be comparison of molecular, compositional and nutritional data for the modified organism to those of its traditional counterpart, where such exists. Where similarity of degree of equivalence

[17] The Royal Society of Canada, p. 38.
[18] Food and Drugs Regulations at part B, division 28, section B.28.002.
[19] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, vols. 1, 2 June 2006. Accessible at <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices_e.html>.
[20] Ibid., Vol. 2, p. 4.

cannot be established, a more extensive safety assessment may be necessary".[21] The *Guidelines* go on to list the types of information that are recommended to include for the safety assessment of a genetically modified microorganism (GMMO), such as a bacteria or virus, and a GMO.

In its review of Health Canada's *Guidelines for the Safety Assessment of Novel Foods*, the Royal Society found that despite the *Guidelines*, there are no formal criteria or a decision-making framework for safety approvals of GMOs by Health Canada. Their investigation revealed that decisions are made on a case-by-case, ad hoc basis, and that applications are "based loosely on, though not specifically prescribed by, the *Guidelines*".[22]

4.2.4 Environment Canada

Environment Canada derives its primary jurisdiction over GMOs from the *Canadian Environmental Protection Act*[23] (CEPA) and its New Substances Notification Regulations.[24] The primary purpose of CEPA is to "contribute to sustainable development through pollution prevention".[25] Part VI of CEPA specifically addresses animate products of biotechnology, which includes GMOs[26] and requires that all new products of biotechnology be subject to an assessment of their potential toxicity before being manufactured, imported or sold within Canada.

CEPA is described as umbrella legislation and acts a safety net by requiring an assessment of any biotechnology product that is not regulated by another equivalent piece of legislation, as identified under Schedule IV of CEPA.[27] A new substance may be exempt from CEPA if it has already been subject to an assessment under the *Seeds Act*, the *Feeds Act,* the *Fertilizers Act,* the *Health of Animals Act*, the *Pest Control Products Act* or any of the accompanying regulations.[28]

Since the *Food and Drugs Act* is not listed under Schedule IV of CEPA, the assessment scheme under the F&DA is not considered "equivalent" to that under CEPA. Thus, "new substances in products regulated under the F&DA will also be subject to the notification and assessment processes for new substances under CEPA 1999".[29] The federal government is working to develop a consistent approach. In a 2001 Memorandum of Understanding with Environment

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[21] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, Vol. 2, p. 5.
[22] The Royal Society of Canada, p. 37.
[23] R.S.C., 1999, c. 33.
[24] SOR/94-260.
[25] CEPA, at Declaration.
[26] "Biotechnology" is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms." *CEPA*, at ss.3(1).
[27] The Royal Society of Canada, p. 35.
[28] CEPA at s.106(7), Schedule IV.
[29] Guide to New Substances Notification for Products Regulated Under the *Food and Drugs* Act, section 1.1 "Background" Available online at: <http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/guides/notification-declaration/guide_new-nouv_sub_e.html#1_2>; "Products are considered any food, drug, cosmetic or medical device that are subject to notification under the *Food and Drugs Act* (F&DA). A product may consist of one or more substances…Only individual substances are notifiable under the *New Substances Notification Regulations* (NSNRs)."

Canada, Health Canada agreed to assess products under the *F&DA* until appropriate regulations could be developed under CEPA.[30]

4.2.5 The Legal Framework of the European Union

The European Union has had an active legal framework governing GMOs since the early 1990s, when it enacted a directive governing the deliberate release of GMOs into the environment. The original directive has recently been replaced with new directives and regulations that address various aspects of GMO development and market use. The EU is now recognized as having the most comprehensive legal framework in the world governing GMOs.

The EU defines a GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".[31] The stated purpose of regulating GMOs in the EU is to allow for the trade of biotechnology products with minimal risk to human health and the environment.

The main EU legal instruments governing genetically modified organisms are:

- EC Regulation 1829/2003 on the Regulation of Genetically Modified Food and Feed regarding the placing on the market of GMO food and feed, or food and feed products containing or consisting of GMOs;
- Directive 2001/18/EC on the Deliberate Release of GMOs to the Environment and to the Market, which applies to the experimental release of GMOs into the environment and placing GMOs on the market; and,
- Regulation 1830/2003 Concerning the Traceability and Labelling of GMOs, discussed in Section 6 of this report.

Other legislation governing GMOs completes the regulatory framework, including:

- Directive 90/219/EEC, as amended by Directive 98/81/EEC, on the contained use of genetically modified microorganisms; and,
- EC Regulation 1946/2003, regarding the intentional and unintentional movements of GMOs between Member States of the European Union and third countries. This Regulation regulates the transboundary movements of genetically modified organisms and incorporates the provisions of the Cartagena Protocol on Biosafety.

[30] New Substances Program, Environment Canada and Health Canada, "Review of the New Substances Notification Regulations (Organisms): Backgrounder" (22 February 2006) [unpublished, distributed at the multi-stakeholder Workshop on the Research & Development Exemption Provisions Dealing with Organisms Other than Micro-Organisms, in Ottawa, Ontario] at 15.

[31] EC, Council and European Parliament Regulation 1829/2003 *22 September 2003 on genetically modified food and feed* [2003] O.J.L. 268/1, Article 2(2).

4.2.6 EC Regulation 1829/2003 on the Regulation of Genetically Modified Food and Feed

The European Food Safety Authority (EFSA) is responsible for approving GMOs and authorizing their placement on the market.[32] The governing regulation, the Food and Feed Regulation (EC) No 1829/2003, provides a single authorization procedure for all food and feed containing GMOs,[33] referred to as the "one door, one key" approach.[34] This procedure is based on a single scientific evaluation "of the highest possible standard."[35] The regulation aims to protect human health, animal health, the environment and consumer interests, while "ensuring the effective functioning of the internal market".[36]

Regulation (EC) No 1829/2003 requires that any GMO food or feed product obtain authorization before being placed on the market.[37] The authorization process begins with an application being sent to the national competent authority of a Member State; the national authority will then provide the EFSA with the application information. The EFSA is responsible for sharing the information with the other Member States and the European Commission, as well as releasing a summary of the information dossier to the public.[38]

The application must be accompanied by data comparing the GMO food or feed to its conventional counterpart (except where the applicant includes a proposal for labelling).[39] The application must also contain a reasoned statement that the food or feed does not give rise to ethical or religious concerns (except where the applicant includes a proposal for labelling),[40] and a copy of the studies which have been carried out to demonstrate that the food or feed meets the criteria for authorization.[41] Where appropriate, applicants should also include a proposal for post-market monitoring.[42] The Authority may request that the applicant provide additional pieces of information within a specified time period, as appropriate.[43]

In the case of GMOs or food and feed "containing or consisting of GMOs", the applicant is required to supply a complete technical dossier. The dossier includes risk assessment information and monitoring plans as set out under Directive 2001/18/EC, or pre-existing authorization under that same Directive where it exists.[44] Under these circumstances, the portions of Directive 2001/18/ EC dealing with placing GMOs on the market or in products will not apply.[45]

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[32] The Authority is established by EC Regulation (EC) No 178/2002. This lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Reg 1828/2003 Article 9 grants EFSA authorization powers.
[33] EC, Council and European Parliament Regulation 1829/2003 *22 September 2003 on genetically modified food and feed* [2003] O.J.L. 268/1 at Preamble (12)(13).
[34] As stated on the official European Union web site at <http://europa.eu/scadplus/leg/en/lvb/l21154.htm>.
[35] Reg. No 1829/2003 at Preamble (9).
[36] Ibid. at Article 1(1)
[37] Ibid. at Article 4, 2.
[38] Ibid. at Article 5(2).
[39] Ibid. at Article 5(3)(f) and Article 17(3)(f).
[40] Ibid. at Article 5(3)(g) and Article 17(3)(g).
[41] Ibid. at Article 5(3)(e) and Article 17(3)(e).
[42] Ibid. at Article 5(3)(k) and Article 17(3)(k).
[43] Ibid. at Article 6(2) and Article 18(2).
[44] Ibid. at Article 5(5) and Article 17(5).
[45] Ibid. at Articles 13-24.

Once a valid application has been submitted, the EFSA should aim to render its decision within a six month time period. In preparing its decision, it may ask a food assessment body, competent authority, or national competent authority to conduct an assessment, as appropriate. Also, the application information will be sent to the Community reference laboratory for validation of the proposed detection and identification methods.[46]

The environmental safety requirements in Directive 2001/18/EC also apply in order to prevent adverse effects which may result from the deliberate release of GMOs. The EFSA consults with each national competent authority towards this end, and the national competent authority is given three months to comment.[47]

The *applicant* must demonstrate that the GMO for food or feed use will not:

a) have adverse effects on human health, animal health or the environment;
b) mislead the user or consumer;
c) differ from the food or feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.[48]

Additionally, GMO feeds must not "harm or mislead the consumer by impairing the distinctive features of the animal products."[49] Further, the assessment should "be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used".[50] If the application is not granted, the GMO cannot be placed on the market for food or feed use[51] unless it was already placed on the market authorized prior to this Regulation coming into force. In that case, its use is subject to certain notification requirements.[52]

The EFSA's opinion is made public, including particulars such as the proposal for labelling the food or feed, any conditions or restrictions, post-market monitoring requirements, and method for detection.[53] Confidential information will be excluded from the EFSA's opinion where its disclosure might "significantly harm" the competitive position of the applicant. However, confidentiality is not granted for certain types of information, including the composition, physico-chemical and biological characteristics of the GMO, food or feed, as well as its effects on human and animal health and the environment.[54] The public has 30 days in which to submit comments to the European Commission.[55]

The Commission then has three months to submit its draft decision to the Standing Committee on the Food Chain and Animal Health, taking into account the opinion of the EFSA.[56] The

[46] Reg. No 1829/2003 at Article 6(3) and Article 18(3).
[47] Ibid. at Article 6(4) and Article 18(4).
[48] Ibid. at Article 4(1) and Article 16(1).
[49] Ibid. at Article 16(1)(d).
[50] Directive 2001/18/EC at Annex II (A).
[51] Reg. No 1829/2003 at Article 4(2) and Article 16(2).
[52] Ibid. at Article 8 and Article 20.
[53] Ibid. at Article 6(5), (7) and Article 18(5), (7).
[54] Ibid. at Article 30.
[55] Ibid. at Article 6(7) and Article 18(7).
[56] Ibid. at Article 7(1) and Article 19(1).

Committee is composed of Member State representatives, and chaired by a Commission representative.[57] When a final decision has been reached, details of the decision are published in the *Official Journal of the European Union*.[58] Once granted, the authorization may be renewed after 10 years, and is valid throughout European Community.[59] The authorization holder has an obligation to inform the Commission of any new scientific information which may influence the safety evaluation, as well as any prohibition or restriction which may have been imposed by another country.[60]

The regulation applies to foods or feed produced from a GMO and genetically modified organisms to be used as a source material for food or feed. Where a GMO has already received authorization under this regulation, those foods or feeds which are produced from the GMO will not need to be authorized.[61]

4.2.7 Directive 2001/18/EC on the Deliberate Release of GMOs to the Environment and to the Market

Where a food or feed product contains or consists of GMOs, the applicant may choose to either submit the application under Regulation (EC) No 1829/2003 in order to obtain authorisation for deliberate release into the environment, *or* submit the application under both Regulation (EC) No 1829/2003 and Directive 2001/18/EC.[62] In the former option, the application procedure under Regulation (EC) No 1829/2003 is still conducted in accordance with the information and environmental safety requirements set out in Directive 2001/18/EC. These requirements are incorporated by reference into the Regulation.

The Deliberate Release Directive provides the general legal framework for the deliberate release of GMOs into the environment and onto the market.[63] The precautionary principle is adopted as a guiding objective in Article 1. The Directive is horizontal and Member States must implement it by creating their own domestic regulations.

The Directive requires that anyone seeking to deliberately release a GMO or place a GMO on the market must first conduct and submit an environmental risk assessment and obtain approval.

The Directive does allow for simplified and expedited decision-making process where there is existing knowledge about how a GMO behaves in certain ecosystems. The health and environmental impacts of the non-modified organism must be well known and the genetically modified counterpart must "not present additional or increased risks to human health."[64] This

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[57] Council Decision (1999/468/EC) of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, Article 5(1).
[58] Reg. No 1829/2003 at Article 7(4) and Article 19(4).
[59] Ibid., Article 7(5) and Article 19(5).
[60] Ibid., Article 9(3) and Article 21(3).
[61] Ibid., Preamble 11.
[62] "Questions and Answers on the Regulation of GMOs in the European Union" pg 4. Accessible at: <http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf>
[63] EC, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] O.J. L. 106/1.
[64] Directive 2001/18/EC at Annex V(5).

process requires that only a minimal amount of technical information be provided in order to assess foreseeable risks. This 'fast tracking', however, does not apply to GMOs for intended release on the market.[65]

The Directive generally addresses labelling, requiring that all GMOs not covered by other EU member legislation have a label or an accompanying document containing the words: "this product contains genetically modified organisms".[66]

A separate regulation, Regulation 1830/2003 Concerning the Traceability and Labelling of GMOs, has been established that addresses the traceability and labelling of genetically modified foods.

4.2.8 Discussion

In setting up the regulatory framework for genetically modified foods in Canada, the government chose to adapt existing pieces of federal legislation, rather than developing a single new legislative framework. As a result, there are several federal departments, agencies, committees, statutes and regulations that play a role in the development and approval of genetically modified organisms, and a complex approval system.

The Royal Society made 53 recommendations for improving Canada's regulatory framework. Many of these recommendations centred on the need for the federal government to:

- provide comprehensive assessments of the environmental effects of genetically modified plants before their release and to improve the quality of scientific data required for GMO approvals;
- implement peer reviews of experimental protocols and the individual risk assessments on which GMO approvals are based;
- make experimental data and the rationales on which regulatory decisions are based available to the public; and,
- develop standard guidelines for the long-term monitoring of development of insect-resistance to GMOs containing "insecticidal" properties.[67]

The initial regulatory framework set out by the government has not been revised to incorporate these recommendations in any significant way. More than five years after the Royal Society recommended improving the regulation of GMOs in Canada, little has changed.

In contrast, in the same time frame the EU has developed a single unifying legislative framework that applies to genetically modified crops and foods through every stage of development from planting crops to consumer labelling. As Dr. Peter Andree has pointed out, EU regulators have emphasized the novelty of genetically modified foods "as a source of uncertainty, and have thus established more in-depth regulatory processes."[68]

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[65] Directive 2001/18/EC at Article 7(3).
[66] Ibid., Article 26.
[67] Andree, Peter (June 2006) GM Food Regulation: An analysis of efforts to improve genetically modified food regulation in Canada, *Science and Public Policy* 33: 5.
[68] Ibid.

The EU has adopted a process-oriented regulatory approach, emphasizing formal authorization following a case-by-case risk assessment. This is in contrast to the product-oriented system adopted in the United States and Canada where the focus is on the intended use of the end product rather than on the technology used to create it. EU Health and Consumer Protection Commissioner, David Byrne, has stated that "European consumers can now have confidence that any GM food or feed marketed in Europe has been subject to the most rigorous pre-marketing assessment in the world".[69]

The precautionary principle is central to the EU process-oriented approach. European regulations emphasize pre-market safety assessments that take into account "direct or indirect, immediate, delayed or unforeseen effects of GMOs", as well as "potential cumulative long-term effects associated with the interaction with other GMOs and the environment."[70] In contrast to the Canadian system, EU regulations require post-release monitoring and are given on a time-limited basis. They also require labelling and traceability of GMOs. These elements can all be regarded as important components of a comprehensive regulatory regime that are not present in the Canadian framework.

The release of GMOs to the environment has been highlighted by the Auditor General as one of the key areas of weakness in the Canadian regulatory framework.[71] With respect to the Canadian Food Inspection Agency's decisions regarding unconfined releases of GMOs to the environment, the Auditor found "deficiencies in standard operating procedures, a lack of complete documentation in the files and incomplete definition of data quality standards to guide the evaluations." The Auditor went on to say "we found that the Agency did not have complete documentary evidence and, therefore, was not transparent about how it was evaluating the long-term effects on the environment before authorizing unconfined release of plants with novel traits".

The Auditor concluded that, as a result of these weaknesses, "there could be unassessed risks to the environment". The Auditor stressed the need for significant improvements in controls over evaluation procedures for unconfined releases of GMOs, noting a lack of documentation on releases and the need for more assurance of farmers' compliance with the recommended conditions for planting GMO corn. The Auditor recommended "clarifying the regulatory framework for plants with novel traits in order to strengthen its (CFIA's) ability to effectively deliver its regulatory program."

The findings were described by the Auditor as an early warning signal that some important aspects of the CFIA's processes for regulating plants with novel traits need strengthening. Because the next generation of genetically modified plants is expected to pose new and more complex environmental risks, the Auditor felt it was important that the Agency act on the recommendations in order to meet future challenges.

Within the socio-political and cultural context of European society, people are quite sceptical of the benefits of GM food. The public is more aware of the issues related to the introduction of

[69] E. Tsioumani. 2004. Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments. RECIEL 13 (3) 2004.
[70] Ibid.
[71] Office of the Auditor General of Canada, March 2004 Report, Chapter 4: Canadian Food Inspection Agency – Regulation of Plants with Novel Traits. Accessible at: <http:// www.oag-bvg.gc.ca>.

genetically modified foods and there is a general feeling that GMOs pose an unknown risk that do not justify their use. There is an accepted social legitimacy for actions against GMOs that can be seen in court decisions acquitting activists of pulling out genetically modified farm crops in order to prevent the genetic contamination of traditional crops.[72] These attitudes and public perceptions have influenced the regulatory reality.[73] In contrast, with no labelling Canadians know relatively little about the presence of GM foods on the shelves, and as a result, there is less pressure on the federal government to set up a stringent approvals and monitoring regime.

However, the public's concerns in Europe are countered by global trade pressures and international competitiveness. Therefore, regulatory agencies in Europe have attempted to balance trade pressures and public opposition to genetically modified organisms by introducing a strict regulatory framework to replace the *de facto* moratorium. The European Council's conclusions in Barcelona encourage "measures and a timetable which enable community businesses to exploit the potential of biotechnology while taking due account of the precautionary principle and meeting ethical and social concerns".[74]

4.3 *Assessing the Safety of Genetically Modified Foods*

Human health concerns have been raised as to whether genetically modified food creates new food constituents that may be toxic or cause allergies, whether it introduces anti-nutritional factors and whether it contributes to the creation of antibiotic-resistant bacteria.[75] Concerns exist that genetically modified crops may invade wild ecosystems and overtake native species, pass introduced traits on to other plants, or affect non-target beneficial organisms, thus having a potential negative impact on biodiversity.

Many of these scientific questions are not adequately addressed by the Canadian and American regulatory frameworks which have adopted "substantial equivalency" as a determining factor in the assessment process. This concept essentially suggests that when a GMO appears to be similar enough to its traditional counterpart, it may be treated in the same regulatory manner without the need for further assessment.

This concept has been incorporated into Canadian and American legislative regimes in a way that facilitates the entry of genetically modified foods onto the market without solid scientific evidence of their safety. As a result, the Royal Society has called for its re-evaluation.

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[72] In the UK the court accepted 28 Greenpeace activists' contention that a GM field trial was attacked so that its pollen could not genetically pollute other nearby crops as a lawful excuse for damage of property (M. McCarthy, 'Greenpeace GM Crop Attack Declared Legal'. *The Independent* (21 September 2000) available at <http://www.lawteacher.net/Articles/0528a.htm>.

[73] Ibid. at p 280 states that 66% of the European citizens interviewed in a 2000 survey said they would not buy GM fruits if it tasted better, 53% would be ready to pay more for non-GM food and 66% would not be willing to eat the eggs of hens fed on GM maize. Only 11% felt adequately informed about biotechnology and only 30% believed that industry developing new products through the use of biotechnology did good work for society, while 70% believed that consumer organizations do good work for society. Another survey found that 94% of Europeans wanted the right to choose whether to consumer GM food or not, demonstrating the importance to the public of labeling requirements.

[74] Barcelona European Council, *Presidency Conclusions* (SN 100/1/02/REV 1, 15 March 1992). At 20.

[75] Canadian Institute for Environmental Law and Environmental Policy, "A Citizens' Guide to Biotechnology", March 2002.

Europe, on the other hand, in Regulation 1829/2003 has rejected "the simplified notification procedure based on 'substantial equivalence'" that was present in previous European regulations.[76] Instead, its revised legislative framework requires testing and risk assessments of each new genetically modified organism on a case-by-case basis before genetically modified feed or foods are approved and marketed.

4.3.1 Canada and Substantial Equivalence

When a genetically modified agricultural product is submitted to the CFIA for approval according to the *Seeds Regulations*, substantial equivalence can affect several different stages of the approval process.

First, the CFIA must evaluate whether a genetically modified seed possesses a "novel trait". In section 107(1), the *Seeds Regulations* defines a seed with a "novel trait" as one which is *not* substantially equivalent to an existing seed of the same species. If the genetically modified seed is found to be substantially equivalent, and therefore found not to possess a "novel trait", then it will undergo a lesser safety assessment.

The definition of "novel trait" in section 107(1) reflects an inherent incompatibility between the notions of novelty and equivalence. As of 2005, "all plants derived through genetic engineering have been considered novel"[77] on the basis that they were not substantially equivalent to existing counterparts.

There is considerable confusion caused by apparent inconsistencies between this definition of "novel trait" and government's approach evidenced elsewhere. For instance, in its Regulatory Directive 2000-07 "substantial equivalence" is defined as:

> The equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale.[78]

In this definition, the presence of a novel trait is not only an accepted, but an integral part of the concept of substantial equivalence.

Furthermore, Health Canada has adopted its own approach with respect to the assessment of novel foods pursuant to the Food and Drug Regulations under the *F&DA.* As conceded by the Canadian Food Inspection Agency with respect to Food and Drug Regulations assessments:

> Consideration of substantial equivalence helps to direct the actual safety assessment of the novel food. If on the basis of a full and complete safety assessment of a novel food's characteristics, a food is found to be

[76] Andree, Peter (June 2006) GM Food Regulation, *Science and Public Policy* 33:5, p.2.
[77] CFIA, "Long Term Testing/ Substantial Equivalence" last modified 2005/02/03 <http://www.inspection.gc.ca/english/sci/biotech/reg/equive.shtml>.
[78] CFIA, Regulatory Directive 2000-07 "Conducting Confined Research Field Trials Of Plants With Novel Traits In Canada" last modified 2004-11-19, s. 1.7.13, Available online at: <http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml#1.7>.

> substantially equivalent, the food can be treated in the same manner as the traditional food with respect to safety. If, on the other hand, substantial equivalence is more difficult to establish, then the identified differences, or new characteristics, would be the focus of further safety considerations. When there is no basis for comparison, that is, if no similar traditional food exists, then the new food must be evaluated on the basis of its own composition and properties.[79]

Given these differing approaches, the Canadian government's use of substantial equivalence in the context of novel traits remains ambiguous at best, and completely contradictory at worst.

The second place where substantial equivalence can impact the decision-making process is in the list of exemptions at section 108 of the *Seeds Regulations*. A seed will be exempt from assessment if it is found to be "substantially equivalent" to another seed which has already been released into the Canadian environment. This means its traits, effect on environment, use and safety are considered to be equivalent to the existing product.

Third, any novel seed which has not been exempted will be compared with its unmodified counterpart during the course of the assessment "to assess its relative and acceptable risk."[80] Government may consider – "if the species has a history of safe usage in Canada, the new characteristic was derived using a method that has traditionally been considered safe in Canada, and the new trait is similar to those of the already approved product."[81]

Another concern with respect to determinations of substantial equivalence is the adequacy and objectivity of information on which these judgments are based. Government agencies do not perform their own research on the product but rely on companies seeking approval of the product to submit field trial results, test results and possible risk management techniques. There is no peer review or public check on the quality of the information because the Canadian government refuses to publicly release the test data supplied by companies to support their applications for approval of genetically modified foods.[82]

As the Royal Society noted, "no independent testing of the safety of a GM food by a governmental or other, independent, laboratory, is required" by the regulation or elsewhere.[83] Introducing peer review of experimental protocols and safety assessments was a key component of the Royal Society's recommended framework for improving the approval process for genetically modified organisms.

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[79] CFIA, "Long Term Testing/ Substantial Equivalence" last modified 2005/02/03 www.inspection.gc.ca/english/sci/biotech/reg/equive.shtml.
[80] CFIA, Directive 94-08 « Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml. last modified 2005-01-31.
[81] Reimer, Pearl and Bryan Schwartz (2001) "Biotechnology: A Canadian Perspective", Asper Review of International Business and Trade Law 91-110.
[82] Joint Response: Agriculture and Agri-Food Canada, Environment Canada, Fisheries and Oceans Canada, Foreign Affairs and International Trade – Department of [1996-2003], Health Canada, Industry Canada, Justice Canada – Department of (Jus), Natural Resources Canada, Treasury Board Secretariat to Dr. Éric Darier, Greenpeace, November 3, 2005, Answers to Questions 1 & 2, Accessible at: <http://www.oag-bvg.gc.ca/domino/petitions.nsf>.
[83] The Royal Society of Canada, p. 38.

Other commentators have pointed out that "while researchers at Health Canada and the Canadian Food Inspection Agency analyse the information submitted, the possibility for bias definitely exists…This means possible risks might easily be down-played or even ignored, leading to the existence of a public confidence issue with regard to the safety of genetic engineering."[84]

4.3.2 Europe and Safety Assessment

It is important to note that Europe has now moved towards a more scientifically defensible approach to substantial equivalence. The matter is specifically addressed in the introductory text of Regulation (EC) No 1829/2003, which includes a statement that:

> Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.[85]

There are obvious parallels between this assertion and the Royal Society's recommendation that substantial equivalence not form the basis of assessment decisions. The European Regulation also improves upon the Canadian scheme by requiring each application for authorisation to be accompanied by an analysis, *supported by data*, showing that the characteristics of the food or feed are not different from those of its conventional counterpart (except where the applicant includes a proposal for labelling).[86]

However, as in Canada, the European framework also lacks independent test data as a basis for decision-making. The only data that are presented to regulatory bodies doing the safety assessments comes from companies wishing to gain approval for their products.

A critique of the European approvals system identified the lack of independent test data as a significant flaw.[87] M. Aurelien Bernier stated that the EFSA and the Commission de genie biomoleculaire (CGB) in France who are responsible for examining the authorization dossiers of companies wishing to introduce GMOs are entirely dependant on information supplied by the multinational companies who want to commercialize these products. No other independent information is available. As a result, genetically modified organisms are approved for trials or for market based solely on company tests.

4.3.3 Discussion

The use of substantial equivalence in Canada and the United States has been highly problematic. It has been heavily criticized for its ambiguity and lack of scientific rigour.

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[84] Reimer, Pearl and Bryan Schwartz, at 40.
[85] Reg. No 1829/2003 at Recital (6).
[86] Reg. No 1829/2003 at Article 5(3)(f) and Article 17(3)(f).
[87] Bernier, Aurelien, "La poudre aux yeux de l'evaluation des OGM", Le Monde Diplomatique, November 2006, p. 26-8.

Included in the 2001 report by the Royal Society was a conservatively reasoned commentary on the application of the concept of "substantial equivalence" in the Canadian legislative regime.

The Royal Society of Canada's Expert Panel noted that the concept originated in the conventional breeding process. However, in conventional breeding the development of new varieties from varieties with relative genetic uniformity do not typically result in harmful progeny.

Their concern is that substantial equivalence has been used as a method of facilitating approvals rather than as a way to evaluate the safety of genetically modified organisms. The Royal Society rejected "substantial equivalence" as a regulatory tool because it assumes a new product is safe on a "less than fully substantiated basis."[88]

In Canada, when invoked regarding a new GM variety, the concept "essentially pre-empts any requirement…to assess further the new variety for unanticipated characteristics…If a plant or food is judged to be substantially equivalent to one present in the Canadian diet, passage of this step in the decision tree spells success for its approval"[89]. It is "the most critical element in the current approval process".

In order for substantial equivalence to be used in a valid and meaningful manner, equivalence should be based on an in-depth scientific assessment rather than on superficial similarities. The Royal Society emphasized the need to *demonstrate* equivalence through scientific testing, rather than *assume* substantial equivalence without full assessment.[90]

The Royal Society of Canada went on to suggest that the following protocol would be needed in order for "substantial equivalence" to provide a scientifically-valid safety standard:

> …[R]equires a scientific finding that the new food does not differ from its existing counterpart in any way other than the presence of the single new gene and its predicted phenotypic change. In every other way, phenotypically and in terms of its impacts on health and the environment, it will have been *demonstrated* to be identical to the existing food. Once this finding is made, the food can then be considered (i.e. "treated as") safe, in as much as the existing food is already considered safe, with the caveat that the phenotypic expression of the added novel gene(s) must also be *demonstrated* to have no negative health or safety impacts.[91] [Emphasis added]

The report of the Royal Society of Canada concluded that "the obvious approach to analysis of the consequences of the presence of the transgene is to employ direct testing for harmful outcomes."[92] However, when evaluating whether Canadian Food Inspection Agency met this

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[88] The Royal Society of Canada, p. 226.
[89] *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada, (Ottawa: January, 2001), cited in *Principles for the Regulation of the Safety of Foods Derived from Agricultural Biotechnology*, Canadian Institute of Environmental Law and Policy, Submission to The External Advisory Committee on Smart Regulation, (March 2004) Toronto.
[90] The Royal Society of Canada, p. 182.
[91] Ibid.
[92] The Royal Society of Canada, p. 186.

standard, the Royal Society of Canada found that CFIA's decisions are based on "unsubstantiated assumptions about the equivalence of the organisms, by analogy with conventional breeding."[93]

Many of the Royal Society's recommendations for improving the Canadian regulatory framework for biotechnology were incorporated into the European Union's revised regulatory framework, and "parallel the more precautionary approach that was being embedded in EU regulations at the time of its release".[94]

In Europe and Canada, however, a significant outstanding problem with both approvals process is the absence of independent scientific information available to government agencies reviewing applications for genetically modified foods. In addition to the Expert Panel of the Royal Society in Canada, it has been noted by other commentators reviewing the Canadian and European approvals processes. To date, no action has been taken to solicit independent scientific data into the system of approving genetically modified organisms.

4.4 *The Precautionary Principle and Genetically Modified Foods*

The extent to which the precautionary principle should be used in the assessment and approval of genetically modified organisms has been the focus of debate at an international level.

The precautionary principle was established as an international principle in the Rio Declaration on Environment and Development. The Rio Declaration states that: "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."

The principle subsequently gained momentum through its inclusion in other international agreements and European resolutions. It was incorporated into five environmental instruments signed in Rio de Janeiro.[95] The most important of these international agreements was the Convention on Biological Diversity, parent agreement to the subsequently-negotiated Cartagena Protocol on Biosafety which addresses GMOs.

The Protocol was adopted in January 2000 in Montreal, and became legally binding in September 2003. As of January 2007, 138 countries, including the European Community and 21 countries in Europe have signed and ratified it.[96] Canada has signed but not ratified it, and is thus not legally bound by its provisions. The United States is not a party to the parent agreement, the Convention on Biological Diversity.

The Cartagena Protocol references precaution in its Objective, as set out in Article 1:

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[93] The Royal Society of Canada, p. 182.
[94] Andree, Peter (June 2006) GM Food Fegulation, Science and Public Policy 33:5, p. 5.
[95] Benevides, Hugh and McClenaghan, Theresa. "Implementing Precaution" (April, 2002) Canadian Environmental Law Association Report No. 419.
[96] Cartagena Protocol on Bioasafety, Latest News. Accessible at <http://www.biodiv.org/biosafety/default.aspx>.

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[97]

Furthermore, section 8 of Article 11 reads in part:

> Lack of scientific certainty due to insufficient relevant scientific information... shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.[98]

The Cartagena Protocol holds that governments may decide on the basis of precaution not to permit the importation of a particular genetically modified organism. It also gives countries the right to consider socio-economic factors such as the risk that genetically engineered foods could replace traditional crops.[99]

4.4.1 Canadian Use of Precaution

The precautionary principle has not been applied to the Canadian legislative framework governing biotechnology. However, there has been both judicial and legislative recognition of the principle in Canada in recent years.

One of the leading cases from the Supreme Court of Canada is *114957 Canada Ltée (Spraytech, Société d'arrosage)* v. *Hudson (Town)*. Justice L'Heureux-Dubé wrote that "[s]cholars have documented the precautionary principle's inclusion 'in virtually every recently adopted treaty and policy document related to the protection and preservation of the environment.'"[100] The court also cited the statement on precaution contained in the Bergen Ministerial Declaration on Sustainable Development:

> In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.[101]

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[97] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 1 "Objective", Montreal 2000.
[98] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 11 "Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing," #8.
[99] The World Conservation Union (IUCN), An Explanatory Guide to Cartagena Protocol on Biosafety, IUCN Environmental Policy and Law Paper 46, 2003.
[100] [2001] 2 S.C.R. 241 at para 32.
[101] Bergen Ministerial Declaration on Sustainable Development in the ECE Region, UN Doc. A/CONF.151/PC/10 (1990), 1 YB Intl Envtl Law 429, 4312 (1990).

CEPA contains four references to the precautionary principle.[102] In its "Administrative Duties", the government of Canada is to apply the precautionary principle in exercising its powers to protect the environment and human health.[103] The precautionary principle is also included in Part V of the Act, which deals with the control of toxic substances. However, it is worth noting that the federal government chose not to include similar precautionary language in Part VI of the Act which deals with animate products of biotechnology.

There are many different formulations of the precautionary principle, such as the ones adopted in the Rio Declaration and the Bergen Ministerial Declaration. The choice of which elements to include can influence the effectiveness of the approach as a whole. The Royal Society recommended that the Canadian government consider the fundamental tenets of the precautionary principle in the management of risks associated with GM foods.

> The Precautionary Principle, however variously applied, is fundamentally a rule about how technology developers, regulators and users should handle [scientific] uncertainties when assessing and managing the associated risks. ...One simple expression of the Precautionary Principle is that it counsels restraint in proceeding with the deployment of a technology in the "absence of evidence," and requires that the greater the potential risks, the stronger and more reliable be the 'evidence of their absence.[104]

The Royal Society report adopted these elements of the precautionary principle:

- if society's best predictions of the risks (of new technologies) turn out to be wrong, it is better to err on the side of safety;
- in the development of technology, it is necessary to conduct research to identify potential risks, withhold deployment of the technologies until the uncertainties of risk are reduced, and employ designs to minimize health and environmental risks;
- it is appropriate to shift at least part of the burden of proof that the technology is safe to the proponents of the technology and/or accept a lesser level of evidence as demonstration of risk.

The Expert Panel made five recommendations.[105] First, new technologies should not be presumed to be safe unless there is a reliable scientific basis supporting that conclusion. On this basis, the Royal Society report explicitly rejected the use of "substantial equivalence" as a means of exempting new GM products from safety assessments. Second, proponents of food biotechnology products should bear the primary burden of proof to demonstrate reliably, through rigorous testing, that the products do not pose unacceptable risks. Third, products which pose serious risks to human health should not be approved until scientific uncertainty can be reduced to minimum levels. Fourth, "zero risk" or low threshold safety standards should be imposed where there are catastrophic risks.

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[102] CEPA, at Preamble and sections 2(1)(a), 6.(1.1), and 76.1.
[103] CEPA, at s. 2(1)(a).
[104] The Royal Society of Canada, p. 198.
[105] The Royal Society of Canada, p. 206.

The Expert Panel's fifth, and perhaps most important, recommendation reads in full:

> Where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product. In such cases, regulators should impose upon applicants for approval of the technology the obligation to carry out further research which can establish on reasonable weight of evidence that unacceptable levels of risk are not imposed by the technology.[106]

Following the publication of the Royal Society of Canada's report, the Canadian government responded in November 2001 with an Action Plan detailing its implementation of the Society's recommendations.[107] However, the federal government generally, and the CFIA specifically, have since been criticized for the inadequacy of their response, particularly with respect to precaution. In 2003, the government attempted to clarify how precaution should be applied across government as a whole through *The Framework for the Application of Precaution in Science-based Decision Making about Risk*.[108]

In October 2004 Dr. Peter Andrée and Lucy Sharratt produced a report outlining the progress made, or lack thereof, in the regulation of food biotechnology.[109] Their analysis showed that the federal government had failed to address many of the Expert Panel's recommendations concerning the use of precaution. Dr. Andrée and Ms. Sharratt concluded that "there is nothing in the federal Framework that requires a precautionary approach be taken in the assessment of transgenic organisms..."

More specifically, the Framework failed to address situations where assessors lack adequate scientific evidence to reach a conclusion, which is of particular concern given that "reviews of regulatory decisions made in Canada reveal major deficiencies in the data upon which decisions to approve GM crops have been made."

There are many non-precautionary elements of the CFIA's assessment of GM seeds under the *Seeds Act* and Seeds Regulations. For example, in terms of peer review, "there are still no formal mechanisms in place to ensure CFIA regulatory protocols, and decisions made under such protocols, are independently (and anonymously) reviewed by other scientists."

The report also finds a lack of transparency. The public does not have access to the actual research data supporting assessment decisions, and corporations may choose not to have their product information made publicly available.

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[106] The Royal Society of Canada, p. 206.

[107] Government of Canada, Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, Ottawa, Government of Canada, 2001. Accessible at <http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/RSC_response-reponse_SRC_e.html>.

[108] Government of Canada, Privy Council Office (2003). Accessible at <http://www.pco-bcp.gc.ca/default.asp?Language=E&page=publications&doc=precaution/precaution_e.htm>.

[109] Andree, Dr. Peter and Lucy Sharratt, "Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?", Polaris Institute, October 2004. Accessible at <http://cen-rce.org/eng/bulletins/archive/cen_wk_260.htm#announcement.>.

Objectivity is challenged by the "dual role of the Minister of Agriculture as both regulator and promoter," while recognizing that it is this Minister to whom the CFIA must report. [110]

Finally, the application of precaution is undermined by the CFIA's continued reliance on "substantial equivalence" as a decision making threshold, the exemption of seeds grown in containment, and the Minister's limited authority to act after assessment packages have been received.

More recently, Andree points out that "this situation is troubling, given that the kinds of GMOs Canadian departments and agencies will be expected to regulate…will only become more complex in the years to come."[111]

4.4.2 Europe and the Practice of the Precautionary Principle

Use of the precautionary principle has increased rapidly in Europe. The Treaty Establishing the European Community holds that:

> Community policy on the environment…shall be based on the precautionary principle and on the principles that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.[112]

Between 1994 and 1999, "the term precautionary principle was referred to in 27 European Parliament resolutions."[113] Moreover, the use of precaution became a foundational element of the European Union's handling of GMOs.

In 1987, the European Parliament "passed a resolution calling for a ban on the deliberate release of GMOs until binding regulations covering such releases were in place in Europe."[114] Two Directives followed shortly after in 1990 -- the contained use of genetically modified micro-organisms 90/219, and the deliberate release into the environment of genetically modified organisms 90/220.

The preamble of Directive 90/220 lists several goals, and specifies that preventative action should be taken so as to control any risks from the release of GMOs, and that this should be achieved through consistent notification requirements between the Member States. Thus, the burden of proof is placed on the notifier to demonstrate why a release should be authorized.

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[110] Ibid, p. 14.
[111] Andree, Peter (June 2006) GM Food Regulation: An analysis of efforts to improve genetically modified food regulation in Canada, Science and Public Policy 33: 5, p.10.
[112] Treaty Establishing the European Community as Amended by Subsequent Treaties, Rome, 25 March 1957, Part Three "Community Policies", Title XVI "Environment", Article 130r, #2.
[113] Lofstedt, Ragner, "The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis" (2004) 28:3 *The Journal of Risk and Uncertainty* at 246.
[114] Rogers, Michael, "Genetically modified plants and the precautionary principle" (Oct-Dec, 2004) 7 *Journal of Risk Research* (7-8) at 676.

Following the 1990 Directives, there was a lively debate among industry and non-governmental organizations regarding the adequacy of the Directives' precautionary approach. In the mid 1990s, the tide shifted towards a more permissive approach as industry raised fears over its competitive disadvantage and new evidence suggested that GMOs were perhaps not as serious a threat as initially suspected.[115] Thus, the European Commission launched a review of Directive 90/220. However, by the time the amended Directive was passed in 2001, the pendulum had swung back towards greater precaution due to strong public concerns following the crisis of "mad cow disease" in the cattle industry.

The resulting Directive 2001/18 is viewed as being more precautionary than its predecessor.[116] The main elements of this increased precaution are field trials, marketing consents for a fixed period, traceability and long-term mandatory monitoring for any adverse effect on human health or the environment.

Other precautionary elements of Europe's new regulatory framework include:

- explicit incorporation of the Precautionary Principle;
- independent scientific advice on risk assessments;
- the obligation to formally consult a Scientific Committee; and
- increased transparency through publicly available notification packages, assessment reports, and input from Scientific Committees.

4.4.3 Discussion

On the basis of many European and international legal instruments, it can be concluded that the precautionary principle is emerging or has emerged as part of international law. One optimistic author writes that "the Precautionary Principle may already be so widely adopted that it is ripening into an enforceable norm of customary international law, from which no nation can dissent."[117]

Moreover, the Royal Society report acknowledged that the precautionary principle has become deeply embedded in many international agreements and protocols to which Canada is a party, and called on the Canadian government to respect the precautionary principle in its management of the risks associated with food biotechnology.[118]

Although the government's response to the Royal Society report indicated a willingness to adopt a more precautionary approach, Canada has not made any substantial progress in incorporating the precautionary principle into its regulation of GMOs. Europe, on the other hand, has adopted a regulatory regime that parallels many of the precautionary elements identified in the Royal Society report, including a more transparent approvals process.

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[115] Ibid. at 677.
[116] Ibid. at 683.
[117] Wiener, Johnathan, "Whose Precaution After All? A comment on the comparison and evolution of risk regulatory systems" (Special Issue 2003) 13:207 *Duke Journal of Comparative & International Law.*
[118] The Royal Society of Canada, p. 225.

4.4.4 Availability of Public Information

Transparency and public involvement are essential to building community trust in any regulatory system.[119] Regulatory transparency in the area of food safety is particularly important since international public health issues like mad cow disease and e-coli contamination have undermined confidence in government oversight of the food supply.

The Cartagena Protocol on Biosafety gives prominence to public involvement. It calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs, and calls for the public to be actively consulted on biosafety issues.[120]

Transparency can be considered on two fronts: public involvement in the GMO approval process, and labelling, which is discussed in the next section. Public involvement includes notifying the public when new GMOs are being considered for release prior to approval. Meaningful consultation also requires adequate information so that public comments may be educated and informed.

The EU provides a more open system than Canada. Information must be made available with opportunity for public comment at the beginning of the approvals process. The most significant difference between the two systems is the legal right of citizens in the European Union to have access to the risk assessments on which decisions to approve GMOs are based.

In contrast, neither public access to information nor the opportunity to provide comment are legally required in Canada. Instead, the governing Canadian agencies voluntarily release limited information after a final decision has been made. A pilot project is underway now that releases limited information for public review and comment prior to approval.

4.4.5 Canada and Confidentiality

The Canadian approval process for GMOs has been highly criticized for lacking transparency and providing little, if any, information to the public.[121] The government is not required to:

- Provide notice of when an approval is being considered;
- Allow the public to review the material submitted by an applicant; or,
- Allow for a public comment period on applications.

This is true for approvals under the *Seeds Act*, the *Feeds Act*, the *Fertilizers Act*, and the Novel Foods Regulation of the *Food and Drugs Act*.

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[119] Canadian Biotechnology Advisory Committee, Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada (Ottawa, Report to the Government of Canada Biotechnology Ministerial Coordination Committee, August 2002) at 19, Accessible at: <http://www.cbac-cccb.ca>.

[120] Cartagena Protocol on Biosafety, Article 23(1) and (2). Accessible at <http://www.biodiv.org/biosafety/articles.shtml?a=cpb-23>.

[121] See for example: The Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Technology in Canada (Ottawa, An Expert Panel Report on the Future of Food Biotechnology, 2001), Accessible at <http://www.rsc.ca>; The Sierra Legal Defence Fund, Petition to the Auditor General (9 May 2000) Accessible at: <www.sierralegal.org/m%5archive/2000/pr00_05_09b.htm>; and Royal Society paper, SLDF comment, and The Canadian Biotechnology Advisory Committee Report.

Although not legally required, it has been the general practice of the CFIA and Health Canada to release some information once a decision has been made on an application. These "decision documents" are available online. [122] However, the decision documents for both the CFIA and Health Canada provide limited information, including the product name, name of the proponent, decision date, and brief reasons for the decision. The scientific assessment material upon which a decision is based is not provided.

The Royal Society report has argued that in the interests of transparency, the experimental data and the bases on which decisions are made to approve GMOs should be publicly available. Without independent peer review, the Panel noted that the decision documents lack not only transparency, but credibility as peer review is the basis for scientific evaluation.[123]

Confidentiality and privacy laws currently protect much of the data submitted in applications for approval. In particular, the federal *Access to Information Act* prohibits the disclosure of an applicant's confidential business information that may harm the applicant's commercial interests.[124] A conflict arises between the commercial interests of industry and the environmental, health and safety interests of the public. The decision not to regulate public access to information and the practice of the relevant government agencies not to provide scientific assessment documents for external review creates a default hierarchy where commercial interests take precedence.

In an initiative to improve transparency, Health Canada and the CFIA have launched a pilot project titled the 'Biotechnology Transparency Project'. Under this project, 'notices of submission' posted on the CFIA web site. [125] The notices include information that has been submitted in an application for approval of a new product. A 60 day public comment period allows people to submit their views in an online form to be considered by the CFIA and Health Canada.

The voluntary pilot project does not apply to all products under consideration. Only members of the industry association, CropLife Canada, participate in the project, which represents approximately 85 per cent of industry plant biotechnology developers in Canada. The applicants themselves write the notices that appear online and submit them with their applications for approval.

There is no direction about the information that must be included in a notice, and no indication as to whether they are vetted by the government prior to being posted online. The notices merely list the processes undertaken and the documents submitted in an application. The scientific information itself is not posted. Furthermore, the descriptions of submitted documents are not easily understood by the general public. As a result, the project does not address the recommendations of the Royal Society Expert Panel that:

- Public access be regulated;

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[122] CFIA is accessible at <http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml >; Health Canada, Accessible at <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index_e.html >.
[123] The Royal Society of Canada, p. 36, 214.
[124] R.S.C., 1985, c. A-1 at s. 20.
[125] CFIA, Accessible at: <http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml>.

- All information, particularly scientific information, be available for independent review in order to establish credibility;
- Available information be user friendly.

Because of the lack of information available in Canada on GMOs and their approvals, public interest groups have sought information by petitioning the Auditor General.[126]

The 2005 Greenpeace Canada petition asked the government to improve transparency by providing public access to the full details of studies that are the basis for federal government's GMO decisions. While the federal government asserts that it is committed to regulatory transparency, as stated in the Government of Canada's Action Plan in response to the Royal Society report, public access to documents is nonetheless limited to the government's decision documents on assessments.

4.4.6 European Union and Public Right to Know

The Treaty of Rome requires European Member States to promote the public's right to information in order to protect the health, safety and economic interests of consumers.[127] This guiding principle of the EU is evident in the legal framework governing GMOs.

The two key pieces of legislation that guarantee public access to information regarding GMOs are the Food and Feed Regulation (1829/2003)[128] and the Deliberate Release Directive[129]. They illustrate Europe's radically different approach to the public's right to know.

The Food and Feed Regulation establishes a publicly accessible European Community register of authorized genetically modified food and feed. The application for authorization, supplementary information, opinions from the competent authorities and monitoring reports are all made accessible.[130] An applicant may claim confidentiality over business information but must provide justification for their claim. The European Commission decides whether the claim is valid after discussion with the applicant.[131]

Information prohibited from being treated as confidential includes:

- name and composition of the GMO,
- general description of the GMO and the name and address of the authorisation-holder,
- physico-chemical and biological characteristics of the GMO,

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[126] Office of the Auditor General of Canada, Petition No. 97 - Biotechnology and "Pharming Crops", submitted September 8, 2003 by Greenpeace Canada. Also Petition No. 152 – Full access to information used for decisions on genetically modified organisms, submitted July 8, 2005 by Greenpeace Canada,

[127] *Treaty establishing the European Community*, European Union, 24 December 202, Official Journal C 325, also referred to as the Treaty of Rome, online: <http://eur-lex.europa.eu/en/treaties/index.htm> at Article 153.

[128] *EC, Council and European Parliament Regulation 1829/2003 22 September 2003 on genetically modified food and feed* [2003] O.J.L. 268/1.

[129] *EC, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC* [2001] O.J. L. 106/1.

[130] Reg. No 1829/2003 at Article 29(1).

[131] Ibid. at Article 30.

- effects of the GMO on human and animal health and on the environment,
- effects of the GMO on the characteristics of animal products and its nutritional properties,
- methods for detection, and
- information on waste treatment and emergency response.[132]

Once the EFSA has forwarded its opinion to the Commission, it is required to make its opinion public. The public then has 30 days to submit comments prior to the Commission submitting its draft decision.

The Deliberate Release Directive requires individual Member States to set up a public consultation process, to be held without prejudice to the requirement of a separate public consultation provided by the European Commission. [133] The European Commission must supply the public with the application summaries and public assessment reports and allow for a thirty day comment period prior to market approval.[134] As with the Food and Feed Regulation, the Deliberate Release Directive protects confidential business information, but excludes from this protection the following:

- general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;
- methods and plans for monitoring of the GMO or GMOs and for emergency response;
- environmental risk assessment.[135]

4.4.7 Discussion

The importance of transparency and the questions surrounding the safety of genetically modified foods were illustrated in the case of MON863, a genetically modified corn that has now been approved in both Europe and Canada. MON863, marketed by Monsanto, was developed to express a Bt-toxin intended to protect the corn against corn rootworm. When a French newspaper revealed that the French Commission that evaluates genetically modified food had doubts about its safety, Greenpeace applied to the German agriculture ministry in charge of the initial risk assessment for access to the full documents regarding MON863 in May 2004.[136] The German Ministry decided to give access to the initial rat study which Monsanto classified as "confidential business information."

Monsanto appealed this decision. However, on the basis of Article 25, Directive 2001/83/EEC, which gives the public the right to full access to assessments of GMOs, the German court in 2005 decided the right of society to transparency prevailed over Monsanto's economic interests. The rat study, which became public as a result, showed that significant differences developed between rats fed genetically modified corn and rats fed with conventional corn.

[132] Reg. No 1829/2003 at Article 30.
[133] Directive 2001/18/EC at Article 9.
[134] Ibid. at Article 24.1.
[135] Ibid. at Article 25.4.
[136] Greenpeace, June 2005 – Background briefing: MON863. Accessible at: <http://www.greenpeace.eu.>.

In spite of the concerns raised by this study, MON863 corn was the second GM product approved by the European Food Safety Authority for sale in Europe. It has also been approved by the CFIA and Health Canada. Because of Greenpeace's actions in Europe, however, some of the concerns about MON863 are now publicly known and the rights of the European public to access information about genetically modified foods have been established.

In contrast, the Canadian public has no access to information about the grounds for establishing the safety of genetically modified foods and no legal avenues for acquiring it. Greenpeace Canada has attempted to obtain information on genetically modified farm trials and on the environmental assessments used to determine the safety of genetically modified food by petitioning the Auditor General.[137] The responses of the federal government have made it clear that the government will not release this information to the public.

Although the Canadian government expresses support for public involvement, it has not provided the same opportunities for public input that are legally mandated in Europe. In contrast to Europe, the Canadian public is generally not notified when applications to introduce new GMOs are brought forward. The public has no regulated access to information on which GM approvals are based as the public has in Europe. Furthermore, with the exception of the pilot project where very limited information has been made available, there are no opportunities for public comment before decisions are made approving new GMOs.

4.5 *Labelling and Traceability*

Surveys in North America and Europe show that the public overwhelmingly supports the labelling of genetically modified foods. Actions taken by Canada and Europe in this area illustrate of radically divergent attitudes and approaches towards the interests of consumers.

Despite public support, Canada has developed a voluntary standard which companies may use to identify genetically modified foods or, conversely, foods that contain no genetically modified ingredients. The United States established a similar voluntary guideline in 2001 for genetically modified foods.

In contrast, the EU has put in place the most rigorous labelling regime in the world. Europe also requires the traceability of genetically modified foods. Traceability ensures that governments can track products through the production and distribution chains in order to verify labelling claims; it allows governments to monitor the potential effects of genetically modified organisms; and it enables them to withdraw any products that contain or consist of GMOs where an unforeseen risk to human health or the environment arises.[138]

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[137] Office of the Auditor General of Canada, Petition No. 152 – Full access to information used for decisions on genetically modified organisms, submitted July 8, 2005 by Greenpeace Canada.

[138] European Union, Questions and Answers on the Regulation of GMOs in the European Union, March 2005. Accessible at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en>.

4.5.1 Canada's Voluntary Approach to Labelling

Polling shows that Canadians want labelling to be mandatory. In a Consumers' Association of Canada poll, 91% of those surveyed wanted labels on foods that contain genetically modified ingredients, with 88% saying such labels should be mandatory. [139] The poll confirmed that consumers wanted full disclosure of food ingredients so that "they can make informed decisions."

Despite this public support, there is no requirement in Canada, either at the federal level or any provincial level, that genetically modified foods be identified.

The Expert Panel of the Royal Society considered whether there was a scientific reason to require labels on GM food products when they were not required for novel or exotic foods produced by conventional processes. They concluded that "there was not at this time sufficient scientific justification for a general mandatory labelling requirement".[140] However, this conclusion was based on an expectation that their recommendations regarding regulation of GMOs would be fully implemented.

Since the Royal Society's report, many organizations have called upon the government to implement the recommendations *and* to introduce mandatory labelling. The Agriculture Committee of the Quebec National Assembly has recommended mandatory labelling, and the Quebec government promised in the last election to promote mandatory labelling at a federal level.[141] Other health-focused organizations, such as the Public Health Commissioner of British Columbia[142] and the Ontario Public Health Association, have also called for mandatory labelling of genetically modified foods. The Ontario Public Health Association, for example, has said that "mandatory labelling is necessary for consumer choice".[143]

A federal private members bill that would have legislated mandatory labelling of genetically modified food, Bill C-287, was defeated by the previous government at first reading on October 17, 2001, despite Allan Rock, the Minister of Health at that time, publicly declaring his support for mandatory labelling.[144]

As a result, only the general labelling requirements of The *Food and Drugs Act* and its regulations apply to GMO food and food products. Health Canada and the CFIA share responsibility for labelling. In the absence of any specific legislation requiring labelling of genetically modified food or feeds, the federal government has developed a voluntary national 'standard' that would guide companies wishing to label food as either genetically modified or not-genetically modified.

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[139] Press Release, "Consumers Want Mandatory Labeling of Genetically Modified Foods", Consumers Association of Canada, December 23, 2003. Accessible at <http://www.consumer.ca>.
[140] The Royal Society of Canada, p. 225.
[141] Gruere, Guillaume P. (2006) A Preliminary comparison of the retail level effects of genetically modified food labeling policies in Canada and France, Food Policy 31, p. 148-61.
[142] Public Health Commissioner of British Columbia, 2005 Report.
[143] Ontario Public Health Association, "Protecting Our Food Supply: Public Health Implications of Food Biotechnology", November 2001.
[144] Greenpeace Press Release, *Liberals divided on mandatory labelling of GE food: Greenpeace vows to keep up the fight as Rock disappoints*, October 17, 2001, Available online at: <http://www.biotech-info.net/liberals_divided.html>.

The *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* was adopted on April 15, 2004.[145] If a company chooses to label genetically engineered (GE) food, this document details what must be included and provides examples of what is, and is not, permissible.

The labelling applies to food or food ingredients developed through the use of genetic engineering that are sold to consumers in Canada, whether produced domestically or imported. The term 'genetic engineering' is intentionally used as opposed to genetic modification, which was found to be too broad and inclusive.[146]

Both positive and negative claims are considered acceptable on labels. For example: *this corn is a product of genetic engineering* (positive claim), or *this product contains no genetically engineered material* (negative claim).[147] Further, any claims must be verifiable. Several verification processes are suggested, including audit tracking and chemical analysis.

This voluntary approach to labelling does not carry any legislative or regulatory weight where penalties are provided if advertised claims are false or misleading. Nor are there any enforcement mechanisms.

4.5.2 The European Union Mandatory Labelling

In contrast to the lack of labelling requirements in Canada, amendments to existing EU legislation and new regulations have created the strictest GMO labelling regime in the world.

The EU requires all approved food and feed containing 0.9% or more GMO content to be labelled. Furthermore, the new regulations require the traceability of GMOs through every step of food and feed production.

The EU has required labelling of GMO food and food products since 1990 in Directive 90/220/ECC. In 2001, that Directive was replaced with the Deliberate Release Directive (2001/18/EC).

On April 18, 2004, the Deliberate Release Directive was amended and two new regulations, EC Regulation 1829/2003 on the Regulation of Genetically Modified Food and Feed[148] and Regulation 1830/2003 Concerning the Traceability and Labelling of GMOs[149], were published.

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[145] Government of Canada, Canadian General Standards Board, *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* CAN/CGSB-32.315-2004 (April 15, 2004) available online at: <http://www.pwgsc.gc.ca/cgsb/on_the_net/032_0315/032_0315_1995-e.pdf>.

[146] The Standard defines GE as "techniques by which the genetic material or an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination" Reg, No 1829/2003 at 3.1.

[147] Sample acceptable claims from the *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* CAN/CGSB-32.315-2004 (April 15, 2004), at Appendix B, B2.2.

[148] EC, *Council and European Parliament Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed* [2003] O.J. L. 268/1.

[149] EC, *Council and European Parliament Regulation 1830/2003 of 22 September 2003 concerning the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC* [2003] O.J. L. 268/26.

The Deliberate Release Directive and these two regulations contain provisions that affect the labelling of feed and food products that are genetically modified or contain genetically modified ingredients.

The Deliberate Release Directive, as noted previously, is the general legislation governing the deliberate release of GMOs into the EU environment and into the market. It requires that all GMOs not covered by other EU legislation have a label indicating "this product contains genetically modified organisms".[150] Penalties for breaching the Directive are determined by the individual Member States in their national provisions which adopt the Directive.[151]

The Food and Feed Regulation (1829/2003) is now the key regulation mandating labelling requirements for GMO food and food products containing GMO ingredients. It also extends labelling requirements to animal feed, which was not included in previous EU legislation. Further, products subject to the Food and Feed Regulation do not have to meet the labelling requirements of the Deliberate Release Directive so as to prevent overlap.[152]

The regulation harmonises various laws on GMO labelling by amending or repealing EU legislation previously in force.[153] Food, feed and ingredients need to be labelled if the GMO content exceeds the permissible threshold of 0.9 per cent. This applies to approved GMOs that have undergone a full evaluation procedure under the regulatory system.[154]

Food or feed products containing "adventitious or technically unavoidable" traces of authorized GMOs at a threshold level of 0.9 per cent or less will be exempt from the labelling requirements.[155] Operators must be prepared to supply evidence that they have taken appropriate measures to avoid the presence of GMOs.[156]

Additionally, the Regulation sets an admissible level of 0.5 per cent for "adventitious or technically unavoidable" traces of non-authorized GMOs for a transition period lasting three years from the Regulation's date of application.[157] This transitional threshold of 0.5 per cent is only available to those GMOs which have received a favourable risk evaluation from the European Community Scientific Committee or the EFSA before this Regulation began to apply.

If a product exceeds the 0.9 per cent threshold for approved GMOs or 0.5 per cent for GMOs in transition, the regulation requires that the statement 'produced from genetically modified (ingredient)' or 'genetically modified' appears clearly on the label if there is no ingredient list, and next to the GMO ingredient if an ingredient list is present.[158] These are the only two

[150] Directive 2001/18/EC at Article 26.
[151] Ibid. at Article 33.
[152] Reg. No 1829/2003 at Article 43.
[153] It amends Regulation (EC) No 258/97 and Regulation (EC) No 1139/98 concerning the compulsory indication, in the labeling of certain foodstuffs produced from genetically modified organisms, of information other than provided for in Directive 79/112/EEC. It repeals that Directive and Regulation (EC) No 50/2000. – Described at EU Genetically Modified Food and Feed FAQ, Accessible at: <http://europa.eu/scadplus/leg/en/lvb/l21154.htm>.
[154] Reg. No 1829/2003 at Article 12, 2.
[155] Ibid. at Article 12(2) and 24(2).
[156] Ibid. at Article 12(3).
[157] Ibid. at Article 47.
[158] Ibid. at Article 13(1).

permitted statements. Penalties for breaching the labelling requirements are established by the Member States.[159]

The Traceability and Labelling Regulation (1830/2003) requires that GMO food, feed and products be traceable back to their source materials. At the first stage of production, and all subsequent stages, operators must identify in writing that the product contains GMOs as well as the unique identifiers assigned to those GMOs.[160] Products must be labelled with the words "this product contains genetically modified organisms" or "this product contains genetically modified [name of the organism(s)]".[161]

This regulation incorporates by reference the threshold levels established in the Deliberate Release Directive 2001/18/EC. It also amends the Deliberate Release Directive by adding a threshold level of 0.9% for products intended for direct processing. Accordingly, such products will be exempt from labelling and traceability requirements provided the GMOs have been authorised and such levels are adventitious or technically unavoidable.

Products exempted from the labelling and traceability requirements are those intended for direct use as food, feed or for processing which meet the threshold levels established by the Food and Feed Regulation (EC) No 1829/2003 (see above).[162]

A key feature of this regulation is that it places an onus on operators throughout the food and feed manufacturing process, and not just the final producer, to monitor and label GMOs. The new regime is described as being process-oriented in that "all food products that make direct use of GMOs at any point in their production are subject to labelling requirements, regardless of whether or not GM content is detectable in the end product".[163]

The regulation does not directly apply to food producers outside of the EU. However, such food producers must be aware of these requirements if they are supplying food and food ingredients to the EU market. Operationally, the "first EU recipient of the GMO is required to document the identity of the seller from whom they purchased the material". The first EU recipient is also required to have the supplier provide traceability back to the source of the raw material(s) used in the purchased product, with documentation to support suppliers' claims.[164]

Accordingly, the new regime will entail added responsibilities for non-EU suppliers. This means that external suppliers to the EU market need to put a full traceability program in place for products that they provide to EU food producers, manufacturers, brokers or retailers. The actual fines for compliance violations will be relatively modest, but the cost of recalls and resulting brand damage could be considerable.[165]

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[159] Reg. No 1829/2003 at Article 45.
[160] Ibid. at Article 4(1) and (2).
[161] Ibid. at Article 4(6).
[162] Ibid. at Article 4(8).
[163] GMO Compass, *GMO Labeling Guidelines: New Labeling Laws: What has changed?* (December 15, 2005) Accessible at: <http://www.gmo-compass.org/features/printversion.php?id=93 >.
[164] Cropchoice, *Without a Trace? New GMO Labeling rules in the European Union* (April 16, 2004) Accessible at <http://www.cropchoice.com/leadstry850a.html?recid=2529>.
[165] Ibid.

4.5.3 Discussion

There is little evidence that food companies have used the voluntary standard to label food in Canada as genetically modified or not genetically modified. Consequently, the public in Canada and the United States are generally unaware of the extent of genetically modified foods or genetically modified ingredients in foods.

Studies have shown that people in the United States (and most likely Canada) tend to underestimate the amount of genetically modified food which they are likely to have consumed, with just 26 per cent believing they have eaten genetically modified foods.[166] Many processed foods in the U.S. and Canada contain genetically modified ingredients, such as soybeans. It is estimated that 60 per cent of foods on the market contain genetically engineered substances, since many processed foods contain at least one soybean product. [167]

Furthermore, Greenpeace Canada's surveys have found that since the Canadian government adopted its voluntary policy in 2004, there have been no products labelled as GM products or containing GM ingredients.[168] This lack of interest or action in labelling demonstrates the failure of the voluntary system to help inform consumers and allow them the freedom of choice.

Given broad public support for labelling, the European requirements for mandatory labelling more fully satisfy the public interest in being informed about the nature of their food. The EU asserts that it "recognizes the consumers' right for information and labelling as a tool to make an informed choice." As a result of labelling GM food in Europe, consumer preferences have led many retailers not to carry it. In 1999, the Tesco supermarket chain in Great Britain announced that it would follow the lead of Sainsbury's, Asda, Safeway and Iceland, which banned the use of genetically modified ingredients in their own labelled foods.[169]

Since April 2004 Greenpeace has tracked GM labelled products on supermarket shelves in EU countries.[170] As of November 2004, they had found 77 GM labelled products in 10 of the 25 EU Member States. These products were either GM soya oil or imported products from the United States, Canada, Japan and Korea.

Even the European requirements do not fully satisfy non-governmental organizations. The regulations have been criticized because they do not require labelling for products such as meat, milk or eggs that are obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products.[171] These same products are exempted from traceability requirements. On the other hand, because genetically modified animal feed requires labelling, product producers faced with consumer pressure are able to find out if meat and meat byproducts come from animals fed with genetically modified feed and avoid them if they so choose.

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[166] Food Navigator USA, "Americans Need more info on GM foods, reveals survey", December 12, 2006.
[167] CNN, "U.S., Europe react differently over modified foods", July 8, 1999.
[168] Media Release, "Greenpeace calls for mandatory GE labeling in BC", Greenpeace Canada, October 20, 2006.
[169] BBC, "GM food policy to stay", April 28, 1999.
[170] Greenpeace International, "EU Markets: No Market for GM Labelled Food in Europe", January 2005, p.5.
[171] Friends of the Earth Europe, "Traceability and Labeling of GMOs", November 12, 2005. Accessible at <http://www.foeeuopre.org/GMOs/european_legislation/traceability.htm>.

Another criticism has been that the European regulations allow the presence of up to 0.5 per cent of GM materials in foods and feed that have been scientifically assessed but not formally approved. Friends of the Earth also maintain that the overall 0.9 per cent threshold "undermines consumer choice".[172]

Key aspects of the Canadian and European regimes are markedly different, including threshold levels at which labelling requirements and testing regimes will apply. In addition, the EU has in place traceability requirements which allow governments to monitor health outcomes of consuming genetically modified organisms. In Canada, health or environmental monitoring and surveillance will be "hindered by the Government of Canada's general policy against mandatory labelling."[173] The following chart provides a comparison of the principal elements, and in each category the European labelling practices better serve the public's ability to identify GM food.

CRITERIA	EUROPEAN UNION	CANADA
Level of Government Involvement	▪ Legislated, mandatory	▪ Voluntary standard
Scope	▪ Genetic modification (broad definition)	▪ Genetic engineering (limited)
Threshold	▪ 0.9%	▪ 5%
System of Review	▪ Process-oriented (looks at GE in the process, not the final product)	▪ Novelty based (looks at GMOs present in final product)
Public Review	▪ Public comment period of 30 days before authorisation granted to release GMO	▪ No opportunity for public to get information or provide comment on specific GMO products being labelled
Reliable Information	▪ Legislated, more difficult to change ▪ Positive claims and only two statements are permitted, creating consistency ▪ Member States establish penalty and enforcement regime providing confidence that the system will be followed	▪ Voluntary measure, easily changed ▪ Both positive and negative claims permitted ▪ No specific statements required allowing for inconsistent wording, though samples of acceptable statements are provided ▪ No penalty or enforcement mechanism to ensure compliance

[172] Ibid.
[173] Andreé, Peter (2006) GM food regulation, Science and Public Policy 33:5, p. 10.

ACCURATE AND VERIFIABLE INFORMATION	▪ DETAILED TRACEABILITY REQUIREMENTS IN ADDITION TO DETAILED RISK ASSESSMENT REQUIREMENTS	▪ NO DETAILED VERIFICATION METHOD ESTABLISHED, THOUGH GENERAL ACCEPTABLE METHODS LISTED
Life Cycle Assessment	▪ Traceability and risk assessment that details impacts are required	▪ No requirement

4.6 *World Trade Organization*

On August 7, 2003 the United States, Canada and Argentina launched a case against the European Communities at the World Trade Organization (WTO). The WTO dispute panel completed its interim report on February 8, 2006 and issued its final decision on September 29, 2006, more than three years after the case was launched. The case was prompted by the European Communities' alleged moratorium on new genetically engineered crops during the period from October 1998 to August 2003. The complainants also challenged the national bans which some European Communities' Member States had imposed on GM foods.

The complainants largely succeeded in their arguments, though the European Communities declined to appeal, perhaps due to the fact that the general moratorium had already been lifted by the time the final decision was rendered. Accordingly, the ruling is not expected to significantly impact trade relations, at least in the short term.[174] The panel's ruling did not speak to the scientific safety of the GMOs under dispute or the degree to which GMOs are akin to their conventional counterparts. Additionally, the panel declined to comment upon the European Communities' right to require the approval of GMOs prior to their market placement, or the consistency of the European Communities' approval procedures (e.g. under the Deliberate Release Directive) with WTO agreements.[175]

In light of the WTO decision, the international community has recognised that the ruling opens the door to future challenges, and the U.S. may launch another case challenging the European Communities' requirements around the labelling and traceability of GE crops and foods.[176]

More generally, the ruling undermines the European Communities' regulatory regime and the role of international legal instruments such as the UN Cartagena Protocol on Biosafety. Steve Suppan of the Institute for Agriculture and Trade Policy (IATP) notes that "the EU's unfortunate decision [not to appeal the ruling] could be used to undercut international environmental treaties across the board."[177] The precautionary principle came under particular scrutiny, and

[174] Press release by Institute for Agriculture and Trade Policy, "WTO Biotech Ruling Threatens Precautionary Approach" Sept 29, 2006.
[175] Panel Decision, Part VII Conclusions and Recommendations, para. 8,3.
[176] "EU Bows to White House Pressure to Force Gene-Altered Foods on Europe's Consumers" 11/22/06.
[177] "EU Bows to White House Pressure to Force Gene-Altered Foods on Europe's Consumers" 11/22/06.

as IATP indicates, "the WTO panel ruled that the precautionary principle is too controversial and unsettled in international public law to serve as a basis for panel rulings."[178]

The WTO Panel's findings

The WTO dispute panel presented findings on the European Communities' general moratorium, as well as the Member States' national moratoria. With respect to the former, the panel concluded that a general *de facto* moratorium did exist at the European Communities' level, and that this moratorium resulted in "undue delays" in the approvals of GMOs contrary to Article 8 and Annex C(1)(a) of the WTO Agreement on Sanitary and Phytosanitary Measures (SPS). However, the panel decided that the moratorium was not a "measure" under the SPS Agreement. Rather, they concluded that only the European Communities' approvals procedures, as set out in the Regulations and Directives, constituted "measures", and the moratorium simply impacted "the operation and application of the EC approval procedures".[179] Accordingly and importantly, the European Communities' approval scheme was not found to violate substantive components of the SPS Agreement, merely the procedural components. [180]

The remedy recommended by the panel was that the European Communities' moratorium should be brought into conformity with WTO obligations "if, and to the extent"[181] that the moratorium still existed. This conditional remedy was seen by many as being controversial and inappropriate given the fact that the general moratorium no longer existed at the time of the decision. However, the panel supported its recommendation by suggesting that the moratorium could potentially be re-introduced in the future.

The panel also considered the prohibitions ("safeguard measures") imposed by six individual Member States[182] against specific GMOs. They concluded that the safeguard measures were inconsistent with the European Communities' WTO obligations under Articles 5.1 and 2.2 of the SPS. The European Communities' scientific committees had already assessed and approved each of the GMO products in question, after reviewing the comments of the Member States.

Nonetheless, the European Communities' Regulations and Directives permit individual Member States to prohibit EC-approved GMOs "if these Member States have detailed grounds for considering, based on new or additional information or scientific knowledge, that the particular product poses a risk to human health or the environment".[183] The panel based its ruling on the fact that none of the Member States had conducted their own risk assessments to reasonably support the prohibitions. Accordingly, the panel recommended that the safeguard measures be brought into conformity with the SPS Agreement.

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[178] "WTO Biotech Ruling Threatens Precautionary Approach" Sept 29, 2006, IATP.
[179] Panel Decision, Part VII Conclusions and Recommendations, para. 8.6.
[180] Sungjoon Cho (2006) The WTO Panel on the EC-Biotech Dispute Releases its Final Report" in *The American Society of International Law,* Vol 10, Issue 28.
[181] Panel Decision, Part VII Conclusions and Recommendations, para. 8.16.
[182] The six Member States to allegedly impose prohibitions were Austria, Belgium, France, Germany, Italy, and Luxembourg.
[183] European Communities – Measures Affecting the Approval and Marketing of Biotech Products. Summary of the dispute to date. para. 2.5. Accessible at: <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm>.

It is worth noting that neither the panel nor the Complaining Parties challenged the conditional right of individual Member States to impose measures that are distinct from those of the European Union, as entrenched in the European Communities' approval legislation.[184]

The panel's ruling with respect to the Member States' prohibitions may have broader implications for governments' reliance upon the precautionary principle in the future. The European Community had argued that the prohibitions were defensible according to the precautionary principle, as expressed in the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[185] The Protocol authorizes the precautionary regulation of GMOs in the face of scientific uncertainty. However, the Protocol had not been ratified by any of the complainant countries[186] and it is not a WTO agreement, therefore the panel ruled that it was inapplicable.[187] The panel declined to comment on whether the precautionary principle should be considered to be a general principle of international law. As a result, the ruling is seen to undermine international environmental treaties in general, and threaten the supportability of the precautionary principle more specifically.

4.7 *Summary of Best Practices*

Very different regulatory frameworks governing GMOs in food and feed exist in the EU and Canada. From this review, a number of best practices are apparent, most of them arising from new regulations introduced in Europe and the as yet unimplemented recommendations of the Royal Society of Canada's Expert Panel.

1) Genetically modified organisms differ from other chemicals and agricultural products on scientific and ethical grounds. Thus, GMOs merit a distinct and tailored regulatory regime which adequately captures and addresses such differences. In Canada, the requirements concerning GMOs are fragmented between many different branches of government and existing pieces of legislation. At best, this arrangement causes confusion, and at worse, it creates loopholes and inadequate assessment protocols. The European Union has addressed these problems by developing centralized Regulations and Directives which are solely dedicated to genetically modified foods and feeds.

***Best practice*: The establishment of a single comprehensive regulatory regime governing GMOs.**

2) The assessment of genetically modified organisms should consider not only the end-product, but also the process that was used in its development. Proponents should be required to obtain authorization for every stage of the development of GMOs, beginning with the initial research and development. The assessment should include testing for all harmful effects on health (short and long term toxicity testing, allergenicity, etc.) and on the environment.[188] The information requirements should be developed in conjunction with arms-length scientific experts.

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[184] Panel Decision, Part Vii Conclusions and Recommendations, para. 8.8.
[185] "The WTO Panel on the EC-Biotech Dispute Releases Its Final Report", Oct. 26, 2006, ASIL Vol.10 Issue 28.
[186] "EU Bows to White House Pressure", Accessible at: <http://www.organicconsumers.org/2006/article_3411.cfm>.
[187] "The WTO Panel on the EC-Biotech Dispute Releases Its Final Report", Oct. 26, 2006, ASIL Vol.10 Issue 28.
[188] Royal Society of Canada.

Substantial equivalence should only be used to help evaluate the safety of an organism when equivalence can be *demonstrated* through rigorous scientific testing rather than assumed by government assessors. Assessment regimes should include post-market monitoring and public reporting. Approved products should not be harmful or misleading to the consumer. Authorizations should be renewable after an appropriate period of time, rather than of an indefinite duration, so that new emerging information can be integrated into the assessment and management decisions.

The assessment requirements should be contained within legally binding laws and regulations, rather than delegated to guidelines and directives. Finally, assessments should be carried out in an unbiased manner so that those who assess and regulate the products are at arm's length from those who fund them.

***Best practice*: The elimination of 'substantial equivalence' as the single determining factor in assessments, replaced by the rigorous assessment of the safety of GMOs based on sound science and conducted in full public view.**

3) The precautionary principle should not only be permitted to influence regulatory decision-making, but should be required to so do. In the context of GMOs, precaution dictates, in particular, that substantial equivalence not be used as a decision-making threshold, and "zero risk" safety standards should be required in cases of potentially catastrophic risks.[189]

Countries should also ratify and respect the provisions of the Cartagena Protocol on Biosafety which allows countries to regulate genetically modified organisms on the basis of the precautionary principle.

***Best practice*: The application of the precautionary principle in national and international laws governing genetically modified organisms.**

4) Many commentators, including the Royal Society's Expert Panel, have pointed to the need for the publicly accountable peer review of data and assessments on which government decisions to approve genetically modified foods are based, as well as independent testing of GMOs. Data and risk assessment outcomes should be peer reviewed by a panel of independent experts who report their findings in a public forum.

***Best practice:* Peer review of data submitted by companies in support of their applications for introducing GMOs onto the market and of risk assessments, with findings that are made public.**

5) A transparent approval process is desirable in all areas of public policy, but particularly in decisions with respect to genetically modified organisms where risks to human health and the environment are being assessed and where new and unknown problems may emerge. There should be notification of the public when approvals for GMOs are presented to the government. There should be an opportunity for public comment on proposals before final decisions are made. Furthermore, the science in support of all assessment decisions and research data from

[189] Royal Society of Canada p. 207.

industry experiments should be publicly available. Such transparency has been incorporated into European legislation and has been confirmed by the European courts.

Government assessors should also publish their rationale for all decisions, including decisions to grant waiver requests, within a specified time frame. The rationale should include explanations of how any public comments or objections were addressed.

Companies should always be required to provide evidence substantiating their claims of confidentiality. Information on genetically modified organisms relating to the health and safety of humans and the environment should not be regarded as confidential.

There should be a legal presumption that confidentiality will not be maintained unless stringent conditions are met. Summaries of all notification packages with Confidential Business Information (CBI) claims should be made public prior to the final assessment decisions. The summaries should include a list of the information or studies submitted by industry in support of their applications.

Best practice: **Public access to notifications for new GMOs, public opportunities to comment on proposed new GMOs before final approval decisions are made and public access to data submitted by companies and to risk assessments prepared by government assessors.**

6) The public should have the information on which foods are genetically modified so that they can make informed choices. Canada's decision not to require mandatory labelling makes it impossible for those wishing to avoid genetically modified foods to exercise that preference. The polling is clear that there is strong public support for labelling of genetically modified foods. Because of this, the European labelling regime best meets the public's desire for the opportunity to choose or to avoid genetically modified foods.

Best practice: **Mandatory labelling of genetically modified foods or foods containing genetically modified ingredients that are available in the marketplace.**

7) Without information on which foods are derived from particular GMOs, governments are unable to monitor possible health consequences of consuming genetically modified foods or to detect unforeseen effects. Surveillance studies of populations can only be undertaken where governments are able to distinguish populations that have consumed genetically modified foods from those who have not. In Canada, the ability to do this kind of study is hindered by the lack of labelling.

Best practice: **Traceability legislation that allows governments to track the use of genetically modified foods and monitor potential health and environmental problems.**

Europe has instituted many of the regulatory provisions that have been identified by expert panels in both Canada and Europe as necessary in any legal framework governing genetically modified organisms. Canada, on the other hand, has yet to make significant improvements in spite of the recommendations in the Royal Society of Canada's report. Both jurisdictions,

however, need to ensure that peer review and objective scientific data are incorporated into their evaluations of genetically modified foods and feed.

~ Conclusion ~

Our goal in this report has been to provide a balanced but critical evaluation of Canadian and European environmental legislation and policies in four important subject areas. The scope of our review includes chemicals, extended producer responsibility, the sustainable use of natural resources and genetically modified organisms in food technology. Our decisions on the components of best practices in each area have been drawn from comparing and contrasting approaches and effectiveness of laws and policies in Canada and the European Union.

Although claims have been made that environmental regulation is being used to create barriers to trade or is an obstacle to economic competitiveness, we have chosen to evaluate these laws and other relevant policies strictly on the basis of their contribution to the protection of environment and human health. It would be undesirable to weaken the legislation in a jurisdiction that has enacted strong environmental and health protections in order for a jurisdiction with less protective measures to gain access to their markets. The more desirable choice would be for all jurisdictions to bring their relevant legislation up to the same high standard. It should be noted that in most cases in spite of trade or economic considerations, public opinion strongly supports the more rigorous regulatory frameworks that have been put in place. For example, biotechnology regulations in Europe reflect the public's concerns about the safety of genetically modified food.

In addition, there is little evidence to suggest that tougher standards are creating trade or economic barriers. In fact, the reverse is more likely true – that EU leadership on health and environmental regulations is in fact helping to set an international "standard" that businesses must meet in order to continue to participate in the vital EU economy.

At the end of each chapter, we have identified the best practices in legislation and policy from our review and analysis of the various jurisdictions. Recommendations arising from our analysis of best practices have been made in other forums. For example, the Canadian Environmental Law Association has drawn on the analysis of the regulatory differences in chemicals policy between Europe and Canada to make recommendations to the Parliamentary Committee reviewing the Canadian Environmental Protection Act. CELA has also brought this analysis to the National Policy Consultation sponsored by the Canadian Partnership for Children's Health and Environment. This multi-stakeholder consultation is established to build a dialogue towards developing a national strategy for children's health and environment in Canada and will run throughout 2007.

Rather than make very detailed recommendations to either Canada or the European Union in this report, we have chosen to recommend our best practices as the most desirable way forward for improving legislation and policy in all jurisdictions. Revising legislation to incorporate best practices would in our view provide optimal protection.

In some cases, we are recommending concepts that are desirable but have not yet been adopted by any jurisdiction. For instance, where we identify legislated mandatory substitution for the most hazardous substances as the best practice, this provision of REACH was proposed and discussed, but ultimately not adopted in the final regulation. In another example, we

recommend that governments set absolute reduction targets for the use of certain kinds of resources.

We also strongly urge jurisdictions that already have best practices in place to maintain those practices. It is important that countries that have shown leadership in developing innovative and comprehensive legislation do not weaken their policies and legislation in the face of difficult implementation or opposition to establishing a high international standard. For example, when Germany first introduced extended producer responsibility requirements for packaging, serious problems arose around disposing of the plastics that were collected. As a result, the program was condemned by many people in other jurisdictions. But Germany persisted and this period of growing pains was overcome; the program has become a great success. It is also important that countries resist pressure to dilute environmental and health legislation as a result of challenges before the World Trade Organization or other trade-focused domestic policies.

Best practices are not static. Regular surveys of the effectiveness of legislation and policies are necessary in order to keep improving these frameworks and providing better protection of human health and the environment.

Recommendation One:

Our first and most important recommendation, then, is that all jurisdictions incorporate best practices into their policy and legislative frameworks in each of the four areas we have examined.

As a result of our research into these four areas of legislation and policy, we have identified several recurring themes to which we recommend both Canada and Europe give due consideration.

The first theme is the precautionary principle. Although both jurisdictions have incorporated the precautionary principle into legislative goals, it is important that the precautionary principle become more than simply a guiding principle in legislation and policy. Governments must do more to operationalize the precautionary principle across all four sectors – chemicals, food, waste and the use of resources.

Canada, for example, endorses the precautionary principle, and yet the federal government has not ratified the Cartagena Protocol on Biosafety which allows countries to take action on a precautionary basis. Furthermore, Canada has not incorporated the precautionary principle into its assessment and approval processes for genetically modified seeds or food products, as recommended by the Expert Panel of the Royal Society. Similarly, with respect to chemicals policy, there is some promise but as yet little actual result to demonstrate that Canada is adopting a more precautionary approach.

Recommendation Two:

Our second recommendation is that both Canada and Europe should not only adopt the precautionary principle in all environmental and health-related legislation, but that both countries should ensure that this principle is put into practice, particularly with respect to the approval of new chemicals and new genetically modified organisms, as well as in the assessments of existing chemicals and their approved uses.

Another recommendation that we offer based on our review is that both Europe and Canada review their policy goals and transform targets into legislated limits, so that these policies have the force of law and are respected by the regulated communities. This is particularly true in areas such as extended producer responsibility where legislated targets, such as 60 percent recovery rate for packaging by 2008 in Europe has resulted in these targets actually being exceeded in many of the European countries. This contrasts with the lower recovery rates in Canada, which lacks such legislated targets. Converting policy goals to legislated targets should also be applied in the chemicals policy framework where management strategies for toxic substances that are regulated are more effective and transparent than voluntary strategies.

Recommendation Three:

Third, from our review of the different legislative and policy frameworks, we recommend that governments legislate important environmental goals and targets under programs that currently rely on voluntary commitments.

Another important theme that arises from our research is the need for more transparency in the regulatory process. Although the public is asked to bear the risks of using products containing toxic substances or of eating genetically modified foods, the public's ability to influence decisions about their approvals and introduction onto the market is at best limited and in some areas non-existent. The public is also handicapped in many cases by the ability to identify toxic substances or genetically modified products by the lack of relevant labelling.

In establishing legislative frameworks, governments have in some instances been reluctant to share information with the public and to allow meaningful input into decision-making. As a result, in Canada new chemicals may come onto the market without sufficient information about their potential toxicity. In the case of genetically modified foods, the public has no notification, no information on assessments and no choice in their purchases. The overwhelming public support for labelling has been disregarded by the government. Therefore, we recommend that both the European Union and Canada, but particularly Canada, improve opportunities for public participation in the areas that we have identified in our reviews as lacking transparency.

Recommendation Four:

A fourth and equally important recommendation that arises from our review of legislation in Europe and Canada is the need to improve transparency by expanding the opportunities for the public to understand and influence environmental and health-related decisions that are made in the course of approvals processes. Transparency should also be improved by ensuring that mandatory labelling enables consumers to make informed choices.

The last area that we feel both Canada and the European Union should consider is better sharing of information for the mutual benefit of both jurisdictions and their citizens. Rather than contesting regulatory decisions in other jurisdictions, a more positive course of action would be to ensure productive communication around regulatory actions that protect human health and the environment.

In the area of chemicals policy, for example, both Canada and the European Union have legislated provisions in their chemicals legislation that would allow them to provide information on toxic substances to each other, while allowing for the protection of confidential business information. Canada's work on categorization of substances is an opportunity for Canada to work with the European Union as the REACH regulation comes into effect. Canada could assist Europe in the identification of substances that urgently need assessment, and Europe could eventually help Canada by sharing their evaluations. In addition, the United States will be developing information under the High Production Volume Challenge Program. It is desirable that all these efforts at information-gathering be collected into an "international bank" of information that would contribute to a better understanding world-wide of chemicals.

Recommendation Five:

Our fifth recommendation is that Canada and Europe share the information collected under the legislation discussed in this report in order to further the protection of environment and human health world-wide.

Despite their regulatory and cultural differences, both Canada and the European Union recognize the need and the public desire for improvements in legislative frameworks that protect the environment and human health. Co-operation and a commitment towards evolving and improving best practices would benefit not only both jurisdictions, but would provide the international community with leadership and guidance in these critical areas of public policy.

THE CANADIAN BAR ASSOCIATION

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