The US & Canadian models for controlling chemicals in products and articles

Technical Report 2

Diàlogos Setoriais
União Europeia – Brasil
MMAA0007

November 2015

milieu
Law & Policy Consulting

This Report has been prepared by Milieu Ltd for the Ministry of Environment, Brazil, under contract to CESO CI Internacional S.A. The author was Gretta Goldenman.

The report was generated within the context of the Sectoral Dialogue on the control and regulation of chemicals between Brazil and EU, funded by the EU under the Sectoral Dialogue Programme. Further details are available at: http://www.dialogossetoriais.org/. It is in response to the 8th call for participation – Control and regulation of hazardous chemicals in articles and products – MMAA0007.

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The US & Canadian models for controlling chemicals in products and articles

TABLE OF CONTENTS

ABBREVIATIONS USED

BPA	Bisphenol-A
CAP	Chemical Action Plan (USA)
CCPSA	Canadian Consumer Product Safety Act
CCCR	Consumer Chemicals and Containers Regulation (Canada)
CEPA	Canadian Environmental Protection Act
CFR	Code of Federal Regulations (USA)
CMP	Chemical Management Plan (Canada)
CPSA	Consumer Product Safety Act (USA)
CPSC	Consumer Product Safety Commission (USA)
CPSIA	Consumer Product Safety Improvement Act (USA)
DSL	Domestic Substances List (Canada)
EU	European Union
FDA	Food and Drug Administration (USA)
FDCA	Food, Drug and Cosmetics Act (USA)
FHSA	Federal Hazardous Substances Act (USA)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (USA)
FPLA	Fair Packaging and Labelling Law (USA)
FR	Flame retardant
GHS	Globally Harmonised System of classification and labelling of chemicals
HPA	Hazardous Product Act (Canada)
OTC	Over the counter
PBDE	Penta, octa, and decabromodiphenyl ethers
PBT	Persistent bioaccumulative and toxic
PCB	Polychlorinated biphenol
PCPA	Pest Control Products Act (Canada
PMN	Pre-manufacturing notification (TSCA)
PMRA	Pest Management Regulatory Agency (Canada)
POP	Persistent Organic Pollutant
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SNUN	Significant new use notification (TSCA)
SNUR	Significant new use rule (TSCA)
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act (USA)
USC	United States Code

US EPA	United States Environmental Protection Agency
VOC	Volatile organic compound
VCRP	Voluntary Cosmetic Registration Program (USA)

1 INTRODUCTION

This Report has been prepared by Milieu Ltd for the Brazilian Ministry of Environment, in order to provide an overview of the models used by the USA and Canada for controlling chemicals in products and articles. The report provides detailed descriptions of each country's legislation relevant to this topic. It also reviews the institutional arrangements and jurisdiction for enforcement, as well as public policies, programs and instruments for supporting the reduction of hazardous chemicals in articles. Finally, it looks at the advantages and disadvantages of each system as they are implemented and as they operate in practice.

The main legislative framework in the USA for managing risks from chemicals, including in products and articles, is the 1976 Toxic Substances Control Act (TSCA), administered by the US Environmental Protection Agency. The TSCA is acknowledged to be out of date and ineffective by almost all stakeholders. In the vacuum left by TSCA, a large number of states, including California and Massachusetts, have supplemented the federal framework with more stringent state-level legislation.

Efforts to update the TSCA regime have been unsuccessful over the years, though a draft bill currently in the USA legislative process is seen as having the best chance in many years of being adopted.

In addition to the TSCA framework, the USA has a regulatory framework specific to product safety, based on the Consumer Product Safety Act. This includes the Federal Hazardous Substances Act, which provides authority to regulate products determined to be hazardous under the criteria set forth in the act. In addition, a number of individual acts regulate specific products that pose particular risks to human or animal health and the environment. For example, cosmetics are covered by the Federal Food, Drug and Cosmetics Act.

With the 1999 Canadian Environmental Protection Act, Canada set in place a quite ambitious regime for controlling chemicals. The 1999 CEPA addresses directly the problem of the many thousands of chemical substances already on the market in the early 1980s, which were never adequately assessed for hazard. The section in 1999 CEPA on chemicals is jointly administered by Environment Canada and by Health Canada.

Canada's system for controlling chemicals in products is largely governed by the Canadian Consumer Product Safety Act, which sets general rules covering those products manufactured, imported or sold in Canada and which is administered by Health Canada. Under the CCPSA are a number of other acts

and regulations relevant for controlling chemicals in products, including the Hazardous Products Act. Specific regulations relevant for controlling chemicals in products cover jewellery for children, glazed ceramics, infant feeding bottle nipples, asbestos products, and toys.

2 THE USA MODEL FOR REGULATING HAZARDOUS CHEMICALS IN PRODUCTS

2.1 BASIC POLICIES AND RULES

The USA legislative framework for managing risks from chemicals, including in products and articles, consists mainly of the following laws and regulations:

- 1976 Toxic Substances Control Act (TSCA)
- Consumer Product Safety Act (CSPA)
- Federal Hazardous Substances Act (FHSA)
- Federal Food, Drug and Cosmetics Act (FFDCA)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

These are described below.

2.1.1 The Toxic Substances Control Act

The 1976 **Toxic Substances Control Act** (**TSCA**) [1] is the main law regulating chemicals on the US market today. It is administered by the US Environmental Protection Agency. Its main policy objectives are:

(a) to develop adequate data with respect to the effect of chemical substances and mixtures on health and the environment (with responsibility for developing such data to rest with the manufacturers and processors of the substances and mixtures),
(b) to regulate chemical substances and mixtures that pose an "unreasonable risk of injury to health or the environment" and
(c) to exercise regulatory authority over chemicals "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation" while assuring that innovation and commerce in chemicals would not present unreasonable risk of injury to health or the environment.[2]

TSCA defines the term ''chemical substance'' as meaning "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical. The definition specifically excludes any mixtures; pesticides (as defined under the Federal Insecticide, Fungicide, and Rodenticide Act); tobacco products; radioactive materials (regulated under

[1] 15 U.S.C. §2601 et seq (1976. Available at: http://www.epw.senate.gov/tsca.pdf.
[2] TSCA, Sec.2(b) POLICY.

the Nuclear Regulatory Commission); firearms and their cartridges; and any food, food additive, drug, cosmetic, or device (as regulated under the Federal Food, Drug, and Cosmetic Act). The term ‘‘mixture’’ is defined separately to mean “any combination of two or more chemical substances if the combination does not occur in nature….”

TSCA distinguishes between “new chemical substance” and existing chemicals. Chemicals already on the market in 1976, when TSCA was put into place, were deemed statutorily to not constitute an “unreasonable risk”. They were assumed to be safe for use (unless evidence emerged to the contrary) and allowed to remain in commerce.

TSCA section 8(b) provided for the US EPA to compile an inventory of all chemical substances manufactured or imported into the United States prior to December 1979.[3] The 62,000 chemicals on the TSCA Inventory are the so-called “existing chemicals”. They include some 8,800 chemicals imported or produced at quantities above 10,000 pounds, most of which have never been adequately tested for hazardous properties.

New chemicals are defined as "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA] section 8(b)." Before manufacturing (or importing) new chemicals for commercial purposes, manufacturers must submit pre-manufacturing notification (“PMN”) to the US EPA.

Note that TSCA Section 5 does not require toxicity testing before submission of a PMN, nor require the PMN to provide any safety information. Without any information on toxicity or other possible hazards, the US EPA must rely on its own resources, including computer modeling, to determine whether the new chemical "may present an unreasonable risk."

TSCA does provide for the possibility of requiring manufacturers or importers of existing chemicals to generate data on risk, manufacturing and processing, and adverse health effects, including published and unpublished health and safety studies, and to report this data to US EPA. Under Section 4 of TSCA, the US EPA has the authority to require manufacturers to test existing chemicals to ascertain whether any unreasonable risks are presented. However, in each case US EPA must make several formal findings. The initial determination that a chemical “may present an unreasonable risk” is subject to judicial review and the standard imposed by the courts is that there must be “substantial evidence” of this unreasonable risk. This has severely hampered the effectiveness of TSCA, since the US EPA may not be able to make such a case in the absence of the very data that it cannot require

[3] TSCA, Sec.8(b) INVENTORY.

industry to generate without first making the determination.

The US EPA faces the same difficult burden of proof in determining whether to make a "new substance" subject to regulation, whether in the form of limits to uses or production volume or even a ban. When it reviews these new chemicals notifications, it must be able to substantiate a finding that the chemical poses an "unreasonable risk to human health or the environment" before it can act to block the manufacture, import or use of the new chemical.

TSCA Section 5 also requires manufacturers to provide notice to US EPA before using either new or existing chemical substances in new ways that could lead to concerns for health and environment. [4] In determining whether a new use of a chemical substance is a "significant new use," US EPA must consider all relevant factors, including:

- Projected volume of manufacturing and processing of a chemical substance.
- Extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance.
- Extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance.
- Reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once US EPA determines there is a "significant new use" of a chemical, it requires the manufacturer (or importer) to submit a "significant new use notice" (SNUN), which triggers a pre-manufacturing notification (PMN) screening. In theory, this gives US EPA the opportunity to review and if necessary prevent or limit exposure to, or effects from, the new use of the substance via a "significant new use rule", also known as a SNUR.[5] However, the system for screening PMNs is weak.

In practice the US EPA has only 90 days from receipt of a PMN to act before the new chemical may be legally marketed and included in products or the new use of an existing chemical may occur. It is estimated that only 40 percent of the chemicals on the market have been tested for acute toxicity and mutagenicity, let alone for long-term effects or specific endpoints (including neurotoxicological, developmental, reproductive, and chronic) or for toxicity to aquatic organisms.

TSCA Section 5(b)(4) authorizes US EPA to compile and keep a list of those chemical substances that it has found may present an unreasonable risk of injury to health or the environment. Before making a

[4] TSCA, Sec.5.8(b) MANUFACTURING AND PROCESSING NOTICES.
[5] http://www2.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-actions-reduce-risk-new#SNUR.

finding with respect to a particular chemical, the US EPA must consider all relevant factors, including the effects of the chemical substance on health and the environment, and the magnitude of human and environmental exposure to the substance.

In theory, if a chemical or mixture is found to present an unreasonable risk to human health or to the environment, the US EPA has the power to impose regulatory controls. Under TSCA Sec. 6 (Regulation of hazardous chemical substances and mixtures) if the US EPA finds "a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture … presents, or will present an unreasonable risk of injury to health or the environment," it has authority to impose requirements "to the extent necessary to protect" against such risk. The rules imposed must be the "least burdensome requirements".

TSCA Sec. 6 gives the US EPA a wide range of possible controls. They could consist of one or more of the following:

(1) prohibiting or limiting the manufacturing, processing, or distribution in commerce of such substance or mixture;

(2) prohibiting or limiting a particular use of a substance or mixture;

(3) requiring a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions;

(4) requiring that manufacturers and processors of such substance or mixture make and retain records of the processes used, and monitor or conduct tests which are "reasonable and necessary";

(5) prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture;

(6) prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture;

(7) requiring manufacturers or processors to give notice of such unreasonable risk of injury to distributors in commerce and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, and so on.

However, the burden of proof that the EPA must meet in order to impose such requirements has proven almost impossible to meet. For example, in 1989 the US EPA issued a final rule under TSCA Section 6 to ban the manufacturing, importing, and processing of nearly all asbestos-containing products in the USA – a ban that was subsequently overturned by the courts in 1991.

As a consequence, the EPA has had only limited success in using the regulatory authority granted

under TSCA section 6 to control chemicals tested and deemed dangerous to public health.

It is noteworthy that the Section 5(b)(4) power under TSCA to name chemicals that present an unreasonable risk to human health and the environment to a list of "chemicals of concern" has never been used in the years since TSCA came into force. Through April 2010, US EPA released action plans on five chemicals or chemical groups—phthalates; long chain perfluorinated chemicals; penta-, octa-, and decabromo diphenyl ethers (PBDEs) in products; shortchain chlorinated paraffins; and bisphenol A (BPA). For three of the action plans (phthalates, PBDEs, and BPA), US EPA announced that it intended to add the chemicals to a ''chemicals of concern'' list using its authority under TSCA Section 5(b)(4)(A)(i). However, as of November 2015, this action has not yet been taken.

In fact, in the now 39-year history of TSCA, the US EPA has succeeded in restricting only five chemicals (PCBs, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium). TSCA directly regulates polychlorinated biphenyl (PCB) products.[6] It provides that after January 1, 1978, "no person may manufacture, process or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner." Acting under the TSCA and other laws, the EPA has published regulations for PCB disposal and set limits for PCB contamination of the environment, and has negotiated with firms for remediation of sites contaminated with PCBs.

TSCA was amended in 1986 and 1990 to authorize US EPA to require asbestos abatement in schools and accreditation for those who inspect for asbestos-containing materials. Another amendment in 1988 on "Indoor Radon Abatement" requires the EPA to publish a guide about radon health risks and to perform studies of radon levels in schools and federal buildings.[7] Finally, a 1992 amendment on "Lead Exposure Reduction" requires the EPA to identify sources of lead contamination in the environment to regulate amounts of lead allowed in products, including paint and toys, and to establish state programs that monitor and reduce lead exposures.

In addition, the use of chlorofluorocarbons in manufacturing is now strictly prohibited in all manufacturing processes in the United States, even if no chlorofluorocarbons are released into the atmosphere as a result.

The US EPA has issued specific regulations under TSCA with respect to "consumer products" as covered under the TSCA Significant New Use Rules (SNURs).[8] For the purpose of SNURS, consumer product is defined as ". . . a chemical substance that is directly, or as part of a mixture, sold

[6] 15 USC 2605(e).
[7] 40 CFR 195.
[8] http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-regulations-issued-under-toxic-substances

or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation."[9] A chemical substance which is a consumer product can also be a commercial product. The consumer product definition is not based on exposure, but rather location and to whom the chemical substance/mixture is made available for use.

While the US EPA has only weak regulatory powers under TSCA, it nonetheless continues to pursue a number of activities aimed at better control of chemicals, including chemicals in products.[10] As mentioned earlier, in 2010, as part of its efforts to enhance its chemical management program under TSCA, US EPA released a series of "chemical action plans", or "CAPs". These summarize the hazard and exposure information available for the particular chemical, outline potential risks believed to be presented by the chemical, and identify the steps US EPA proposes to take to address the concerns raised.

As of April 2011, CAPs had been issued for the following substances:[11]

- bisphenol A (BPA)
- dyes derived from benzidine and its congeners
- hexabromocyclododecase (HBCD)
- long chain perfluorinated chemicals (PFCs)
- methylene diphenyl diisocyanate (MDI) and related compounds
- nonylphenol (NP) and nonylphenol ethoxylates (NPEs)
- phthalates (including eight phthalates)
- polybrominated diphenyl ethers (including penta, octa, and decabromodiphenyl ethers) (PBDEs)
- short chain chlorinated paraffins (SCCPs) and other chlorinated paraffins
- toluene diisocyanate (TDI) and related compounds

The types of actions proposed ranged from initiating various rulemaking procedures pursuant to TSCA, including

- Significant New Use Rules (TSCA section 5)
- Consent Orders (TSCA section 5)
- Limitations of Manufacturing, Processing & Use (TSCA section 6)

[9] 40 CFR 721.3.
[10] http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-reduction-activities.
[11] A brief guide to the status of each CAP can be found at http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/summary-all-chemical-action-plans-issued-epa.

The USPA also works directly with industry on various voluntary stewardship efforts, and encourages industry to reduce risk by moving to safer alternatives by conducting assessments of alternatives to chemicals of concern.

The US EPA ChemView database

The US EPA ChemView database[12] is intended as a one-stop source for all health and safety data submitted to EPA, and any regulatory actions taken on specific chemicals. It currently contains information on 12,000 chemicals and provides links to useful chemical information from other federal agencies and programs.

Information available in the US EPA ChemView database

Data Submitted to EPA

- Test rule and voluntary data for 178 chemicals
- TSCA §8(e) substantial risk notices for 2,400 chemicals, which include 600 submissions with fully templated data details
- TSCA §8(d) health and safety studies submitted under TSCA for 140 chemicals
- High Production Volume Information System voluntary submissions for 1,513 chemicals

US EPA Assessments

- Hazard Characterizations for 1,018 chemicals
- Design for the Environment Alternatives Assessments for 48 Chemicals
- Integrated Risk Information System (IRIS) Assessments for 546 chemicals
- Design for the Environment List of Safer Chemical Ingredients for 659 chemicals

US EPA Actions

- Significant New Use Rules for over 1,900 chemicals, representing actions on new chemicals and existing chemicals from 2000-present.
- Consent Orders for 245 chemicals. (Consent Orders represent the outcome of EPA's review of a premanufacture notice (PMN) for a new chemical substance where an order under TSCA §5(e) is issued

Manufacturing, Processing, Use, and Release Data

- Chemical Data Reporting for 7,235 chemicals is presented in a more user-friendly format for ChemView
- Toxics Release Inventory data for 609 chemicals
- Pollution Prevention (P2) information for 347 TRI chemicals

[12] http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview

State regulation of toxic substances and chemicals

In the absence of an effective federal regime for controlling toxic chemicals, a number of state governments have enacted their own chemicals regulatory programs. At least 38 states have passed over 250 chemical-related laws, resulting in a patchwork of state policies.[13] For example, Massachusetts adopted the Toxics Use Reduction Act in 1989,[14] which requires Massachusetts companies using large quantities of specific toxic chemicals to evaluate and plan for pollution prevention opportunities, implement them if practical, and annually measure and report the results.

California's Proposition 65 was enacted as a ballot initiative in November 1986.[15] It was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. It requires the state to maintain and update a list of chemicals known to cause cancer or reproductive toxicity, a list that now numbers some 700 chemicals.

TSCA Reform Efforts

TSCA is almost universally viewed as a failure today. Environmentalists, public health advocates and chemical companies all agree that TSCA has failed to effectively regulate the tens of thousands of chemicals in use today. Since its adoption in 1976 and particularly since the EU's enactment of REACH in 2006, there have been many efforts to reform the TSCA regime, only to flounder because of disagreement on the form the new legislation should take.

In the last couple of years, however, in a rare display of bipartisanship, Congressional leaders have appeared to be ready to move forward. In 2013, the late Senator Frank Lautenberg, a New Jersey Democrat, teamed up with a Republican colleague from Louisiana to put forward a draft bill that would update TSCA.

The draft bill, which was written with extensive input from the chemical industry, required additional disclosure from chemical companies and strengthened EPA testing requirements. However, it drew the opposition of hundreds of environmental and public health organizations – mainly because the draft bill contained provisions specifying that federal rules would supersede any state-level chemical regulations, such as those in place in California and Massachusetts. Indeed, strong opposition has been voiced by several state attorneys general because of the fear that more stringent state controls of toxic chemicals would be preempted by an updated TSCA.

[13] http://www.foreffectivegov.org/reducing-chemical-exposure
[14] http://www.mass.gov/eea/agencies/massdep/toxics/tur/ .
[15] http://oehha.ca.gov/prop65.html

Opposition to the draft law, now named the Frank R. Lautenberg Chemical Safety for the 21st Century Act, is now less strident after several major changes were negotiated that bolstered the role of state governments, while strengthening chemical regulatory requirements and oversight of industry. It is supported by a wide range of stakeholders, including the American Chemistry Council (an industry trade association) and the Environmental Defense Fund, and in both the U.S. Senate and House of Representatives its supporters are almost equally divided among Republicans and Democrats If it is adopted in the next few months, it will be the biggest update to US environmental law in 25 years.

2.1.2 The Consumer Product Safety Act

The *Consumer Product Safety Act* (CSPA)[16] was enacted in 1972 as an umbrella law. According to section 2 of the CSPA, its purposes are:

> (1) to protect the public against unreasonable risks of injury associated with consumer products;
>
> (2) to assist consumers in evaluating the comparative safety of consumer products;
>
> (3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and
>
> (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

The CSPA established the US Consumer Product Safety Commission (CPSC) and defined its basic authority. It authorizes the CSPC to develop safety standards and pursue recalls for products that present unreasonable or substantial risks of injury or death to consumers. It also allows CPSC to ban a product if there is no feasible alternative. The CPSC has jurisdiction over more than 15,000 different products, except for those products that are expressly within another federal agency's jurisdiction, such as food, drugs, cosmetics, medical devices, tobacco products, firearms and ammunition, motor vehicles, pesticides, aircraft, and boats.

The CSPA's regime was augmented in 2008 with the passage of the *Consumer Product Safety Improvement Act* (CPSIA). The CPSIA imposed new testing and documentation requirements. It set new acceptable levels for several substances, including lead, particularly for products intended for use by children. "Children's products" are defined as any consumer product designed or intended primarily for children 12 years of age or younger.

[16] http://www.cpsc.gov//PageFiles/105435/cpsa.pdf . The CPSA is codified at 15 U.S.C. §§ 2051–2084.

The following factors are considered in determining if a product is intended for a child 12 years of age or younger:

1. A statement by the manufacturer about the intended use of the product, including a label on the product, if such statement is reasonable.
2. Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.
3. Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger.
4. The *Age Determination Guidelines Relating Children's Ages to Toy Characteristics and Play Behavior*[17] issued by the Commission staff in September 2002, and any successor to such guidelines.

The lead standards for children's goods also apply to charity shops and second-hand goods stores selling children's products.

A considerable number of federal regulations are associated with the CPSA,[18] including safety standards for various products including cigarette lighters, and a ban on lead in paint. Other statutes administered as part of the CSPA regime include:

- Federal Hazardous Substances Act (FHSA), 15 U.S.C. §§ 1261-1278
- Flammable Fabrics Act (FFA), 15 U.S.C. §§ 1191-1204;
- Poison Prevention Packaging Act (PPPA), 15 U.S.C. §§ 1471-1477;
- Refrigerator Safety Act (RSA), 15 U.S.C. §§ 1211-1214;
- Virginia Graeme Baker Pool and Spa Safety Act (VGBA), 15 U.S.C. §§ 8001-8008; and
- Children's Gasoline Burn Prevention Act (CGBPA), 110 P.L. 278.

2.1.3 Federal Hazardous Substances Act (FHSA)

The Federal Hazardous Substances Act (FHSA)[19] requires hazardous household products ("hazardous substances") to be labelled to warn consumers about the potential hazards that those products present and what they need to do to protect themselves and their children from those hazards. The objective of these labelling requirements is to help consumers store and use those products safely and to inform them about first aid steps to take if an accident happens. The FHSA also authorises the Consumer

[17] http://www.cpsc.gov/PageFiles/113962/adg.pdf .
[18] 16 CFR parts 1101 through 1406.
[19] 15 U.S.C. §1261.

Product Safety Commission to ban certain products if they are so dangerous or if the type of hazard they present is of such a nature that labelling will not provide adequate consumer protection.

Federal Hazardous Substances Act's definition of "hazardous substance"

(A) Any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
(B) Any substance which the Commission by regulation finds… meet the requirements … of the act (restated in (A) above).
(C) Any radioactive substance if, with respect to such substance as used in a particular class of article or as packaged, the Commission determines by regulation that the substance is sufficiently hazardous to require labelling in accordance with the act in order to protect the public health.
(D) Any toy or other article intended for use by children which the Commission by regulation determines, in accordance with section 3(e) of the act, presents an electrical, mechanical, or thermal hazard.

The term "hazardous substance" as used in the FHSA does not apply to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act. It also does not apply to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house. In addition, the term also does not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The term does however apply to any article which is not itself a pesticide within the meaning of FIFRA but which is a hazardous substance by reason of bearing or containing such a pesticide.

Whether a product must be labeled depends on its contents as well as whether consumers are likely to be exposed to any hazards the product presents. The FHSA only covers products where it could be reasonably foreseen that during purchase, storage, or use they might be brought into or around a place where people live. This includes products used or stored in a garage, shed, carport, or other building that is part of a consumer household.

Labelling is required

1. if a product is toxic, corrosive, flammable or combustible, an irritant, or a strong sensitizer, or if it will generate pressure through decomposition, heat, or other means; and

2. if the product has the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

Under the FHSA, a product is:

(1) *Toxic* if it has the capacity to produce personal injury or illness to humans when it is inhaled, swallowed, or absorbed through the skin, or if it can cause long term chronic effects like cancer, birth defects, or neurotoxicity.
(2) *Corrosive* if it destroys living tissue such as skin or eyes by chemical action.
(3) *Irritant* if it is not corrosive and causes a substantial injury to the area of the body that it comes in contact with. Irritation can occur after immediate, prolonged, or repeated contact.
(4) A strong *sensitizer* if declared by the Commission by regulation that the substance has a significant potential to cause hypersensitivity. This includes hypersensitivity that does not happen when a person first comes in contact with the product, and only becomes evident after the person has been exposed to the product for a second time.[20]
(5) *Flammable*, depending on the results of testing.[21]
(6) *Generates pressure*, through decomposition, heat, or other means. This includes certain aerosols, fireworks that contain explosive powder, and certain pool chemicals that, when their containers are heated by sunlight may start to react and generate pressure in the containers.

The FHSA requires a hazardous product to be labeled with the following information in English:

(1) The name and business address of the manufacturer, packer, distributor, or seller;

(2) The common or usual or chemical name of each hazardous ingredient;

(3) The signal word "Danger" for products that are corrosive, extremely flammable, or highly toxic;

(4) The signal word "Caution" or "Warning" for all other hazardous products;

(5) A statement of the principal hazard or hazards that the product presents, for example, "Flammable", "Harmful if Swallowed", "Causes Burns", "Vapor Harmful", etc.;

(6) Precautionary statements telling users what they must do or what actions they must avoid to protect themselves;

(7) Where appropriate, the first aid treatment to perform if the product injures someone;

(8) The word "Poison" for a product that is highly toxic, in addition to the signal word "Danger";

[20] 16 CFR 1500.13 lists the products that the Commission has classified as strong sensitizers.
[21] 16 CFR 1500.3(c)(6) defines the terms "extremely flammable", "flammable", and "combustible" as they apply to liquids, solids, and the contents of self-pressurized containers like aerosol cans.

(9) Instructions for consumers to follow if a product requires special care in handling or storage; and

(10) The statement "Keep out of the reach of children".

The label must be on the immediate package of the hazardous product, and on any outer wrapping or container that might cover up the label. If a hazardous product such as a plant does not have a package, it still must have a hang tag that contains the required precautionary information. This information must also be in any literature that accompanies the product and that contains instructions for use.

As noted earlier, the FHSA authorises the Consumer Product Safety Commission to ban a hazardous product if it determines that the product is so hazardous that cautionary labeling is not sufficient to protect the public. Accordingly, the following products have been banned by the Commission:[22]

(1) Extremely flammable water repellents for use on masonry walls and floors inside homes;

(2) Carbon tetrachloride and mixtures containing it;

(3) a. Aerial fireworks devices that create an audible effect through a charge of more than 2 grains of pyrotechnic material;

b. firecrackers that produce an audible effect through a charge or more than 50 mg. (.772 grains) of pyrotechnic material; and

c. other fireworks devices that do not meet the general performance requirements of 16 C.F.R. 1507. Kits and components used to produce the banned fireworks are also included in the ban. Pest control devices are not.

(4) Liquid drain cleaners that contain 10% or more by weight of sodium or potassium hydroxide and that are not packaged in child-resistant packaging. See 16 C.F.R. 1700 for the child-resistant packaging requirements;

(5) Products containing soluble cyanide salts;

(6) General- use garments containing asbestos;

(7) Self-pressurized products that contain vinyl chloride monomer as an ingredient or in the propellant;

(8) Reloadable tube aerial shell fireworks devices that use shells wider than 1.75 inches.

Other regulations covering hazardous chemical products include special labeling requirements for ethylene glycol, diethylene glycol, benzene, toluene, xylene, petroleum distillates, turpentine, methyl alcohol, charcoal, fireworks devices, and art materials that present a risk of chronic toxicity (16 C.F.R. 1500.14).

[22] 16 CFR 1500.17 provides the details of and exceptions to each specific ban.

In addition, under the Consumer Product Safety Act, the Commission has banned:

(1) Certain extremely flammable contact adhesives (16 C.F.R. 1302);
(2) Paint and other surface coatings containing more than .06% lead, and furniture, toys, and other articles intended for use by children that are coated with such paint (16 C.F.R. 1303); and
(3) Consumer patching compounds and artificial ashes and embers used in fireplaces containing free-form asbestos that can be inhaled (16 C.F. R. 1304 and 1305).

The Commission has also issued labeling requirements for aerosol products that contain chlorofluorocarbons warning that the substance may harm health and the environment by reducing the ozone in the upper atmosphere (16 C.F.R. 1401).

2.1.4 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[23] regulates the distribution, sale and use of pesticides in the USA. All pesticides distributed or sold in the USA must be registered (licensed) by the US EPA. Before US EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment."

FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

Applicants for permission to manufacture and distribute pesticides must provide scientific data from some 120 different tests conducted under US EPA guidelines, in order to assess whether the chemical product has any potential adverse short-term and long-term effects. Data must also be submitted to show that the pesticide is effective for its intended use, the appropriate dosage, and the proposed label to inform the final user about how to use the pesticide so as to avoid any negative consequences.

Note that articles treated with pesticides, if not themselves a pesticide within the meaning of FIFRA but which are hazardous substances by reason of bearing or containing such a pesticide are not

[23] 7 USC §136 et seq. (1996).

covered by FIFRA but rather by the Federal Hazardous Substances Act.

2.1.5 Federal Food, Drug, and Cosmetic Act

The cosmetics industry is regulated under the 1938 Federal Food, Drug, and Cosmetic Act (FDCA),[24] which is administered by the US Food and Drug Administration (FDA). The FDCA defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance".[25] This definition includes products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. Soap is not included. Moreover, products intended for a therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, are considered drugs[26] or in some cases as medical devices,[27] even appearance is affected.

The FDCA prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce and requires cosmetics manufacturers to ensure product safety prior to marketing. A cosmetic is considered "adulterated" if

- "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual";
- "it consists in whole or in part of any filthy, putrid, or decomposed substance";
- "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health";
- "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or
- "it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a)" of the FD&C Act.[28]

A cosmetic is considered "misbranded" if:

- "its labeling is false or misleading in any particular";
- its label does not include all required information;

[24] http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/ucm2005640.htm
[25] FDCA, sec. 201(i).
[26] FDCA, sec. 201(g).
[27] FDCA, sec. 201(h).
[28] FDCA, sec. 601.

- the required information is not adequately prominent and conspicuous;
- "its container is so made, formed, or filled as to be misleading";
- it is a color additive, other than a hair dye, that does not conform to applicable regulations …
- "its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970." [29]

Manufacturers are legally responsible for ensuring the safety of their products. They are required to list all ingredients on the product label and to comply with any restrictions that have been established for cosmetic ingredients and products. For example, regulations under the FDCA prohibit or restrict the use of a number of ingredients in cosmetic products, including bithionol, mercury compounds, certain halogenated salicylanilides, chloroform, and methylene chloride.[30] Regulations also set forth requirements for warning statements on the labels of certain types of cosmetics.[31]

The FDCA does not require premarket approval of cosmetic products and ingredients, with the exception of color additives. It also does not require companies who manufacture or market cosmetics to carry out specific tests to demonstrate the safety of individual products or ingredients, though the FDA advises manufacturers to do whatever testing is necessary to ensure the safety of their products and ingredients. According to the FDA: "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information."[32]

The FDCA does not require cosmetic companies to share their safety information with FDA. The FDA can however pursue enforcement action against products on the market if those products are not in compliance with the law, or against firms or individuals who violate the law. The FDCA's Section 704 authorizes FDA to conduct inspections of cosmetic firms without prior notice in order to assure compliance with the applicable laws and regulations, to determine whether cosmetics are safe and properly labeled, and to identify possible health risks and other violations of the law. The inspections must be at reasonable times and in a reasonable manner.

[29] FDCA, sec. 602.
[30] 21 CFR §700.11, §700.13, §700.15, §700.18, §700.19.
[31] 21 CFR §740.10 – 19.
[32] Federal Register, March 3, 1975, page 8916.

The FDCA also does provide the FDA with the authority to order a recall of a cosmetic product even if it presents a hazard or gross deception[33]. Recalls of cosmetics are voluntary actions taken by manufacturers or distributors. However, the FDA can request a product recall and then monitor the progress of the recall. It can also evaluate the health hazard presented by the product under recall, and assign a classification that indicates the degree of hazard posed by the product. The FDA provides information on all recalls that have been assigned a classification in its weekly publication, the *FDA Enforcement Report*[34]. These weekly reports are available free to those who sign up to receive them.

The FDA's Voluntary Cosmetic Registration Program (VCRP) is a reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. The FDA uses the information to evaluate cosmetic products on the market. Because manufacturers, packers, and distributors are not required to file information about their products or their establishments, the voluntary submissions provide FDA with the best information available about cosmetic products and ingredients, their frequency of use, and the businesses engaged in their manufacture and distribution.

Another law important for regulating cosmetics is the Fair Packaging and Labelling Act (FPLA).[35] Its purpose is to provide consumers with accurate product information in order to prevent unfair or deceptive packaging and labeling of consumer products. It does not apply to products intended for institutional or industrial use. The FPLA requires consumer products to be labeled with (a) the identity of the product, (b) net content, and (c) manufacturer or distributor name and place of business. Both the product identity and the net content must appear on the product's Principal Display Panel (PDP), which is defined as "that part of a label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale."

2.2 INSTITUTIONAL ARRANGEMENTS FOR ENFORCEMENT

2.2.1 The U.S. Environmental Protection Agency

The US Environmental Protection Agency was established in 1970 to bring together a number of federal research, monitoring, rule-making and enforcement activities under one umbrella, so as to better work towards a cleaner, healthy environment for US citizens. It administers a wide range of

[33] http://www.fda.gov/Cosmetics/ComplianceEnforcement/RecallsAlerts/ucm173559.htm.
[34] http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm
[35] http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm .

statutes, regulations and policies, including the 1970 National Environmental Policy Act,[36] the 1970/1977 Clean Air Act[37] and the 1990 Clean Air Act amendments, the 1977 Clean Water Act,[38] and the 1974 Safe Drinking Water Act.[39]

The Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are the two acts administered by the US EPA that are most relevant with respect to the control of chemicals in products, including mixtures and articles.

Within the US EPA, the Office of Pollution Prevention and Toxics (OPPT)[40] manages the programs that come under TSCA as well as the Pollution Prevention Act. Its role includes the assessment and management of new and existing substances with respect to their risks and the management of TSCA's requirements with respect to the import and expert of chemicals. It also maintains the TSCA Inventory, and administers US EPA's programs in support of Green Chemistry, Greener Products and Services, and Safer Choice (formerly Design for the Environment).

The Office of Pesticide Programs (OPP)[41] is responsible for regulating the use of all pesticides (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in the United States. It establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply. In addition to the OPP's regulatory functions, it provides information on issues ranging from worker protection to misuse of pesticides. It also participates in a variety of partnerships related to pesticide use, including the Pesticide Environmental Stewardship Program, a voluntary private and public partnership dedicated to reducing pesticide use and risk.

2.2.2 The U.S. Consumer Product Safety Commission

The U.S. Consumer Product Safety Commission (CPSC)[42] was established as an independent federal regulatory agency charged with reducing unreasonable risks of injury and death associated with consumer products. The CPSC achieves that goal through education, safety standards activities, regulation, and enforcement of the statutes and implementing regulations. The CPSC has jurisdiction over thousands of types of consumer products used in the home, in schools, in recreation, or otherwise.

[36] http://www2.epa.gov/nepa
[37] http://www2.epa.gov/aboutepa/epa-history-clean-air-act-19701977
[38] http://www2.epa.gov/aboutepa/epa-history-clean-water-act
[39] http://www2.epa.gov/laws-regulations/summary-safe-drinking-water-act
[40] http://www2.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp#oppt.
[41] http://www2.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp#opp.
[42] http://www.cpsc.gov/en/About-CPSC/

The CPSC administers and enforces several federal laws that authorize the agency to protect the public against unreasonable risks of injuries and deaths associated with consumer products—most notably the Consumer Product Safety Act (CPSA) and the Federal Hazardous Substances Act (FHSA).

2.2.3 U.S. Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. Its core functions include medical products, tobacco, foods and veterinary medicine, and cosmetics.

The FDA is responsible for protecting the public health by:

- ensuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices.
- safeguarding most of our nation's food supply (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture[2]), including dietary supplements;
- regulating tobacco products;
- protecting the public from electronic product radiation; and
- ensuring that all cosmetics and dietary supplements are safe and properly labelled.

Cosmetic products are regulated by the FDA's Center for Food Safety and Applied Nutrition (CFSAN), which holds responsibility for ensuring that cosmetics are safe and properly labeled. The Though the FDA does not approve cosmetics, it does approve color additives used in cosmetics.

FDA has the legal authority to inspect cosmetic establishments as well as cosmetics offered for import, and to pursue enforce actions if an infraction such as adulteration or misbranding is identified. The FDA determines whether an inspection of a cosmetic establishment is warranted by considering the type of products, the significance of consumer or trade complaints received, the company's compliance history, FDA surveillance and compliance initiatives, and agency resources.

2.3 POLICIES FOR SUPPORTING REDUCTION OF HAZARDOUS CHEMICALS IN PRODUCTS

2.3.1 The US EPA's Safer Chemicals, Products and Practices Program

The US EPA is encouraging a number of measures aimed at providing incentives for manufacturers and distributors to produce goods that have a reduced impact on the environment. Its Safer Chemicals, Products and Practices Program is aimed at providing US consumers with information on safer cleaning and other products via a searchable website. [43]

The US EPA website also summarizes information about how consumers and institutional purchasers can identify greener products and services.[44] Purchase categories include

- Buildings construction, operations, and maintenance
- Carpets
- Cleaning
- Electronics
- Food services
- Insulation
- Landscaping
- Paints and coatings
- Paper
- Wood products

Note that under Presidential Executive Order 13693, federal government purchasers are now required to buy EPA Safer Choice labelled products.

2.3.2 Federal Green Purchasing Requirements

Each year the federal government purchases over 450 billion USD in goods and services, making it the single largest consumer in the world. An array of various laws, Executive Orders and procurement regulations are in place which require federal agencies to purchase environmentally sustainable products, such as energy efficient products and recycled content products, to the maximum extent practicable.

The US General Services Administration (GSA),[45] a centralized procurement agency for the federal government, helps to ensure that federal purchasers receive cost-effective high-quality products and

[43] http://www2.epa.gov/saferchoice/products.
[44] http://www2.epa.gov/greenerproducts/identify-greener-products-and-services
[45] http://www.gsa.gov/portal/category/21354 .

services from commercial venders. Its mission is to deliver the best value in real estate, acquisition and technology services to the government and hence to the American people.

To help federal agency customers to buy green products, services and vehicles, the GSA has put together a guide to assist vendors in selling green products and services to the federal government.[46] Green products available through the GSA include

- Energy Efficient Products
- Recycled Content Products
- Water Efficient Products
- Biobased and BioPreferred Products
- Environmentally Preferable Products
- Non-Ozone Depleting Substances

The GSA's Green Procurement Compilation[47] is a database of federal green purchasing requirements by product and service category. It covers information on products such as appliances, building finishes, building furnishings, cleaning products and office electronics.

In addition to its Safer Choice program, the USEPA supports the green procurement effort with the Environmentally Preferable Purchasing Program (EPP).[48]

2.4 EVALUATION OF THE USA MODEL FOR CONTROLLING CHEMICALS IN PRODUCTS

Under the TSCA regime, the US EPA struggles to gather information about the vast amount of chemicals in commerce. As of 2015, only 250 of the more than 84,000 existing chemicals have been tested by the US EPA.[49] Moreover, some 3000 high production volume chemicals (HPV) are produced or imported into the USA in quantities exceeding one million pounds per year; because of their high volumes and the lack of basic hazard information, the risk of exposure is a concern.

The fact that producers are not required to investigate and disclose sufficient information on the hazard characteristics of the chemicals they market and use has led to a huge data gap. Moreover, the US EPA lacks the legal tools it needs to efficiently identify, prioritize, and take action to mitigate the potential health and environmental effects of hazardous chemicals. The Chemical Action Plans it

[46] http://www.gsa.gov/portal/category/27116 .
[47] https://sftool.gov/greenprocurement
[48] http://www2.epa.gov/greenerproducts/about-environmentally-preferable-purchasing-program
[49] http://www.foreffectivegov.org/reducing-chemical-exposure .

started developing in 2009-2011 are still largely only plans, and actual implementation still seems far in the future.

In the absence of strong regulatory authority, the US EPA has set in place a number of programs aimed at getting voluntary compliance from manufacturers and at informing institutional purchasers, government buyers and consumers about environmentally preferable goods and services.

The vacuum left by an ineffective TSCA has led to many states setting in place their own state-level laws, resulting in a patch-work of requirements that creates difficulties for industry to achieve compliance. It is hoped that the current efforts to reform and update TSCA underway in the US Congress will succeed this time.

In contrast to TSCA, the Consumer Product Safety Act and the Federal Hazardous Products Act provide the Consumer Product Safety Commission with considerable authority to restrict and even ban products that pose unreasonable risks of injury to the public.

3 THE CANADIAN MODEL FOR REGULATING CHEMICALS IN PRODUCTS

In 1999 Canada took a particularly significant step in regards to evaluating and managing chemical substances, with the adoption of the *Canadian Environmental Protection Act* (CEPA).[50] The 1999 CEPA addressed head on the problem of the thousands of chemical substances on the market before comprehensive environmental protection laws were established, and Canada claims that it is the first country in the world with a comprehensive program in this area.

The 1999 CEPA set in motion a process of categorizing all of the 23,000 so-called "existing" substances currently in use in Canada, in order to focus regulatory efforts on those substances considered to pose the most serious risks to people and the environment. After the completion of this categorization process in 2006, it launched the first phase of its *Chemicals Management Plan*, which was followed by a second phase in 2011.

Canada's system for managing chemicals relies on each level of government – the federal government, the provinces and territories, and the municipalities have shared powers to protect the environment. Regulation of chemical substances is a competence shared at federal level between Environment Canada and Health Canada. The provinces and territories may also set in place regulations relevant for control of chemical substances.

3.1 BASIC POLICIES AND RULES

As noted above, the primary legislation for protecting Canada's environment and population from risks posed by harmful chemicals is the 1999 *Canadian Environmental Protection Act* (CEPA). Other federal laws relevant for chemical substances in products include the following:[51]

- Canadian Consumer Product Safety Act
- Hazardous Products Act
- Pest Control Products Act

[50] http://laws-lois.justice.gc.ca/eng/acts/c-15.31/
[51] http://www.chemicalsubstanceschimiques.gc.ca/approach-approche/laws-lois-eng.php

3.1.1 Canadian Environmental Protection Act, 1999

The *Canadian Environmental Protection Act* (CEPA) was first enacted in the late 1980s, and then renewed and strengthened in 1999. It covers a range of activities that can affect human health and the environment, and addresses pollution issues not covered by other federal laws.

A major part of CEPA 1999 concerns the management of chemical substances. It acknowledges the need to virtually eliminate the most persistent toxic substances, as well as bioaccumulative toxic substances that accumulate within living organisms. The act also covers human health and environmental impacts from biotechnology products, emissions from vehicles and engines, fuels, disposal at sea and marine pollution, hazardous wastes, environmental emergencies and other sources of pollution.

The CEPA 1999 requirements for the assessment and management of substances currently existing in commerce or being released to Canada's environment are jointly administered by Environment Canada and Health Canada.

Canadian Environmental Protection Act's definition of "substance"

"substance" means any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes

(*a*) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment,

(*b*) any element or free radical,

(*c*) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction, and

(*d*) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents,

and, except for the purposes of sections 66, 80 to 89 and 104 to 115, includes

(*e*) any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined,

(*f*) any manufactured item that is formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design, and

(*g*) any animate matter that is, or any complex mixtures of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity.

The CEPA 1999 definition of "substance" is very inclusive, and covers "any distinguishable kind of organic or inorganic matter, whether animate or inanimate that is capable of being released as a single substance, an effluent, emission, waste or a mixture into the Canadian environment". It also includes the term "manufactured item", which is equivalent to the definition of "article" under the EU's REACH Regulation.

Like TSCA in the USA, the CEPA differentiates between "existing" substances or "new" substances. "Existing" substances are those on the Domestic Substances List (DSL) – substances that were already in commercial use in Canada between 1984 and 1986 or were manufactured in or imported into Canada in quantities of 100 kg or more in any one calendar year. The original list comprised some 23,000 substances; almost 2000 other substances have been added since then following their assessment as "new" substances (see below).

CEPA 1999 established a deadline of September, 2006 by which time the DSL was to be 'categorized' according to criteria concerning toxicity and potential for human exposure. Categorization was considered a way to set initial priorities for regulatory action. It involved systematically sorting through the 23,000 substances on the Domestic Substances List to determine which ones met the following criteria:

- are inherently toxic to humans or non-human organisms and are either persistent (i.e., take a long time to break down) or bioaccumulative (collect in living organisms and end up in the food chain); or
- may have the greatest potential for subjecting people in Canada to exposure to the substance.

What is toxic under CEPA 1999?

"A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:
1. have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
2. constitute or may constitute a danger to the environment on which life depends; or
3. constitute or may constitute a danger in Canada to human life or health."
(Section 64)

Substances that are determined to be "toxic" under CEPA 1999 are recommended for addition to the List of Toxic Substances (Schedule 1 of the Act).[52] This triggers consideration of whether preventive or control actions are needed for any part of the substance's life cycle from the research and

[52] http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1&wsdoc=4ABEFFC8-5BEC-B57A-F4BF-11069545E434

development stage through manufacture, use, storage, transport and ultimate disposal or recycling.

Risk management measures available for existing substances under CEPA 1999 include regulations, pollution prevention plans, environmental emergency plans, guidelines, codes of practice and administrative agreements. For regulations or pollution prevention plans, the substance must be on the List of Toxic Substances. In the case of environmental emergency plans, the substance must at least be recommended for addition to the List.

Among the over 50 CEPA regulations[53] currently in force are a number that concern substances in products, including:

- New Substances Fees Regulations
- New Substances Notification Regulations (Chemicals and Polymers)
- New Substances Notification Regulations (Organisms)
- Ozone-depleting Substances Regulations, 1998
- Phosphorus Concentration Regulations
- Polybrominated Diphenyl Ethers Regulations
- Products Containing Mercury Regulations
- Prohibition of Certain Toxic Substances Regulations, 2012
- Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations
- Volatile Organic Compound (VOC) Concentration Limits for Automotive Refinishing Products Regulations

Under Section 65(3) of CEPA1999, substances which are toxic, persistent, bioaccumulative, and anthropogenic (i.e., not naturally occurring radionuclides or inorganic substances) are to be proposed for "virtual elimination". Virtual elimination is the reduction of the quantity or concentration of a toxic substance in releases to the environment to below a "level of quantification"[54] specified by the Ministers. The process starts with adding the substance and its level of quantification to the Virtual Elimination List. The quantity or concentration of the substance that may be released into the environment must then be identified in regulations. There can be one or more such "release limits" in regulations. The Ministers may also require the preparation and submission of a virtual elimination plan that describes the actions that will lead to virtual elimination of the substance and time-frames to complete these actions. As of November 2015, two substances are on the Virtual Elimination List:

[53] http://ec.gc.ca/lcpe-cepa/eng/regulations/default.cfm?n=9E7794D4-1 .
[54] Defined in CEPA 1999 as the lowest concentration of a toxic substance that can be accurately measured using sensitive but routine sampling and analytical methods.

- Hexachlorobutadiene (HCBD)[55]
- Perfluorooctane Sulfonate (PFOS) and its salts[56]

"New" substances – defined as made in Canada or imported from other countries since 1994, i.e., not on the Domestic Substances List -- must be notified to authorities and then evaluated for human health and environmental risks before they can be manufactured or imported into Canada. Responsibility for evaluation is shared between Environment Canada and Health Canada.

A new substance assessment will lead to one of the following results:

- if the substance is not suspected to be toxic, the notifier may import or manufacture the substance after the assessment period has expired;
- if the substance is suspected of being toxic or becoming toxic, the government may take risk management measures;
- if the substance is not suspected of being toxic but a significant new activity could result in the substance becoming toxic, the substance can be subject to re-notification under certain conditions.

For new substances that are toxic or suspected to be toxic, the following risk management measures may be imposed:

- permission for the manufacture or import of the substance subject to specified conditions;
- prohibition of the manufacture or import of the substance for a period not exceeding two years unless replaced by a regulation; or
- prohibition of the manufacture or import of the substance until additional information or test results have been submitted and assessed.[57]

The mandatory information gathering powers granted to the Ministers in charge of Environment Canada and Health Canada under CEPA 1999 also need to be mentioned. Section 71 of CEPA 1999 allows the Minister, for the purpose of assessing whether a substance is toxic or is capable of becoming toxic, or for the purpose of assessing whether to control, or the manner in which to control, a substance, to publish a notice in the *Canada Gazette* requiring any person described in the notice and (a) engaged in any activity involving the substance to notify the Minister that the person is or was during that period engaged in that activity; and (b) to provide the Minister with any information and samples that may be in the person's possession or to which the person may reasonably be expected to have access. The Minister may also send a written notice to any person who is described in the notice

[55] http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=82
[56] http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=164
[57] http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E00B5BD8-1&offset=6&toc=show#s6_2 .

and engaged in any activity involving the importation or manufacturing of the substance or any product containing the substance requiring the person to conduct toxicological and other tests that the Minister may specify in the notice and submit the results of the tests to the Minister.

3.1.2 Canada's Chemicals Management Plan

After sorting through the 23,000 existing substances and categorizing them, the federal government launched the Chemicals Management Plan (CMP) in December, 2006.[58] The CMP is aimed at implementing the 1999 CEPA's sections on toxic substances. The initial 2006 launch was followed by a second phase in 2011.

The Chemicals Management Plan served as a roadmap for assessing and managing the chemical substances already known to have dangerous properties, and for setting research priorities to get the necessary information on other chemicals that may also be hazardous. A major focus of the Plan was to gather information on the properties and uses of the approximately 200 chemical substances identified through the categorization process as high priorities for action. The objective of gathering this information was to decide whether regulatory action is needed to protect Canadians and their environment from any risks these substances might pose.

This initiative, known as the "Challenge", divided the some 200 chemical substances of highest priority into a number of smaller groups of substances and then began publishing official Notices in the *Canada Gazette* under the mandatory information gathering provisions of section 71 of the CEPA 1999 to gather the data information deemed required for improved decision-making. In addition to individual substances, in 2011 the government also launched the *Substance Groupings Initiative*.[59] The groupings covered:

- Aromatic Azo and Benzidine-based Substance Grouping
- Boron-Containing Substances
- Certain Organic Flame Retardants Substance Grouping
- Cobalt-Containing Substance Grouping
- Internationally Classified Substance Grouping
- Methylenediphenyl Diisocyanate and Diamine (MDI/MDA) Substance Grouping
- Phthalate Substance Grouping
- Selenium-containing Substance Grouping
- Substituted Diphenylamines Substance Grouping

[58] http://www.cela.ca/collections/pollution/chemicals-management-canada
[59] http://www.chemicalsubstanceschimiques.gc.ca/group/index-eng.php

The groupings of substances were identified on the basis of structural or functional similarities and grouped in the interest of efficiency gains in assessment and management, including the ability to support informed substitution decisions and stakeholder engagement.

For example the grouping of certain organic flame retardants included ten substances having a similar function, of being applied to materials to prevent the ignition and spread of fire. Criteria for selection included

- Potentially high volume or multiple sources of exposure from persistent, inherently toxic substances. Many FRs were considered of particular interest given their potential (or established) harmful properties and effects to the environment and/or humans.
- Potential to assist with informed substitution. .
- Potential exposure of consumers and children to products treated with FRs.
- Potential risk management efficiencies through for example, the engagement of stakeholders in a discussion on several flame retardants at once. This could result in improved compliance, informed substitution and less duplication of effort.

The Notice in the *Gazette* specified the persons required to provide information as follows:

1. This notice applies to any person who, during the 2011 calendar year, manufactured a total quantity greater than 100 kg of a substance listed in Schedule 1 to this notice, at any concentration.
2. This notice applies to any person who, during the 2011 calendar year, imported a total quantity greater than 100 kg of a substance listed in Schedule 1 to this notice, at any concentration (a) whether alone, in a mixture or in a product; or (b) in a manufactured item that is (i) intended to be used by or for children under the age of six years, (ii) cookware, or a cooking or serving utensil that is intended to come into direct contact with heated food in a residence, unless the component that comes into direct contact with heated food is made of glass, stainless steel or porcelain, (iii) a clothing, a footwear or a sleeping bag, (iv) a bedding intended to be used in a residence, (v) a furniture intended to be used in a residence, (vi) a furnishing intended to be used in a residence, if the substance is contained in a foam or a textile, (vii) a carpet, a vinyl or laminate flooring, or a foam underlay for flooring, intended to be used in a residence, (viii) an electronic, or electrical appliance or equipment, intended to be used in a residence.
3. This notice applies to any person who, during the 2011 calendar year, imported a total quantity greater than 100 kg of 1,3,5-Triazine-2,4,6-triamine (CAS RN 108-78-1), at any concentration, in a food packaging intended to come into direct contact with food.

The notice also invited submission of additional information by interested organizations, including those that manufacture, import, export or use a substance, whether alone, in a mixture, in a product or in a manufactured item. It asked for information on types of uses and quantities manufactured, imported, exported and used, as well as for any unpublished data or studies which could help inform the risk assessment, including information on industrial waste management practices and environmental releases. It noted that the information collected would inform the risk assessment and, if necessary, risk management for these substances.

3.1.3 Canada Consumer Product Safety Act

The *Canada Consumer Product Safety Act* (CCPSA) which came into force in 2011, brought Canada's consumer product safety system into line with the systems of its key trading partners, the USA and the European Union. The law prohibits the manufacture, importation, sale or advertising of consumer products that could pose an unreasonable danger to the health or safety of Canadians. It also prohibits packaging, labelling or advertising a consumer product in a manner that is false, misleading or deceptive in respect of its safety.

The CCPSA is administered by Health Canada. It defines a "consumer product" as a product, including its components, parts or accessories that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes. Thus the law applies to a wide variety of consumer products including children's toys, household products and sporting goods, including their packaging. Products like motor vehicles and their integral parts, food, drugs (including natural health products) and animals are excluded, as these are regulated by other Canadian laws.

Under the CCPSA, all suppliers of consumer products are responsible for ensuring that the products they place on the Canadian market are in compliance with the provisions of the act. They are obliged to provide information to Health Canada (and, if applicable, to the supplier from whom they received the product) concerning any safety "incidents" related to the consumer product or any product defects, including inadequate labelling or instructions, which could reasonably be expected to result in harmful health effects.

CCPSA, Section 14: Definition of "incident"

- (a) An occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;
- (b) A defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;
- (c) Incorrect or insufficient information on a label or in instructions - or the lack of a label or instructions - that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or
- (d) A recall or measure that is initiated for human health or safety reasons by
  - i. A foreign entity,
  - ii. A provincial government,
  - iii. A public body that is established under an Act of the legislature of a province,
  - iv. An aboriginal government as defined in subsection 13(3) of the *Access to Information Act*, or
  - v. An institution of an entity referred to in subparagraphs (ii) to (iv).

The obligation to report also extends to any corrective measures, such as recall orders, undertaken in other jurisdictions for human health or safety reasons.

In deciding whether an event constitutes a reportable incident, industry must determine:

1. if the event relates to a consumer product that was sold, manufactured or imported in Canada for commercial purposes (including its components, parts or accessories or packaging);
2. if the event meets any of the four criteria set forth in section 14;
3. if the event indicates an unreasonable hazard posed by the normal or foreseeable use of the product or the foreseeable misuse of the product.

It is not necessary for an actual death or serious injury to have occurred; it is sufficient for there to have been reasonable potential for death or serious adverse health effects. It may be important to consider whether the consumer product involved in an incident was being used as originally intended or in a manner that was foreseeable but unintended.

The incident must be reported to Health Canada within two (2) days of the company becoming aware of that incident. To facilitate such reporting, Health Canada has developed a web-based incident reporting form[60] for industry to use when submitting incident reports. An on-line reporting form is also available for consumers to use in reporting incidents related to health or safety concerns with a

[60] See www.healthcanada.gc.ca/reportaproduct.

consumer product. Consumers are also encouraged to report incidents directly to the retailer or manufacturer.

In order to enable any unsafe products to be traced back to their source, the CCPSA requires those who manufacture, import, advertise, sell or test consumer products for commercial purposes to keep certain records. For example, retailers are required to document the name and address of the product's supplier, and the location and the period during which they sold the product. These records must be kept for six years after the end of the year to which they relate.

If a consumer product is not in compliance with the requirements of the CCPSA, Health Canada can issue an order for recall or to take other measures, i.e., to stop the manufacture, importation, packaging, storing, advertising, selling, labelling, testing, or transportation of the consumer product, or any other measure considered necessary to remedy the non-compliance. The person subject to an order can request a review, but only on grounds that involve questions of fact, such as if new or additional evidence becomes available that could affect the understanding of the situation that led to the issuing of the order.

An order for recall must be based on a reasonable belief that a consumer product is a danger to human health or safety. The order for recall must be issued in writing and include a statement of the reasons for the recall and the time and manner in which the recall is to be carried out. The Health Canada website emphasizes that it expects that, where necessary, recalls will be carried out on a voluntary basis by industry.

Health Canada can also require manufacturers or importers to provide or obtain safety information - including studies or tests - that indicate whether a consumer product meets the requirements of the CCPSA.

3.1.4 1985 Hazardous Products Act

The 1985 *Hazardous Products Act* (HPA)[61] controls the sale and importation of hazardous products that are intended for use, handling or storage in a work place. It defines "hazardous product" (« *produit dangereux* ») as meaning "any product, mixture, material or substance that is classified in accordance with the regulations made under subsection 15(1) in a category or subcategory of a hazard class listed in Schedule 2."

[61] http://laws-lois.justice.gc.ca/eng/acts/H-3/page-1.html.

Before the CCPSA came into force in 2011, the HPA consisted of three Parts. Part I of the HPA, which dealt with consumer products, has now mostly been incorporated into the CCPSA (see below). The HPA's Part II sets out the supplier label and material safety data sheet requirements for Canada's Workplace Hazardous Materials Information System (WHMIS). Part III deals with administration and enforcement of the HPA. Parts II and III currently remain in force.

3.1.5 Regulations under the CCSPA

As noted above, the 2011 CCSPA took over a number of existing prohibitions and regulations related to consumer products that were previously under the 1985 *Hazardous Products Act* (HPA).[62] The HPA's Part I was linked to the Act's Schedule I, which had two parts. Part I of Schedule I of the HPA itemized prohibited products (either completely prohibited, or prohibited with conditions), while Part II of Schedule 1 itemized products for which there were restrictions (so-called "regulated products"). The HPA required specific authorisation for the import, advertising or sale of a regulated product, but the CCPSA regime no longer requires this. Rather, it imposes specific requirements and prohibitions on certain consumer products.

Among the specific regulations under the CCSPA relevant for controlling chemicals in products include the following:

- Asbestos Products Regulations (SOR/2007-260)
- Children's Jewellery Regulations (SOR/2011-19)
- Children's Sleepwear Regulations (SOR/2011-15)
- Consumer Chemicals and Containers Regulations, 2001 (SOR/2001-269)
- Consumer Products Containing Lead (Contact with Mouth) Regs (SOR/2010-273)
- Glazed Ceramics and Glassware Regulations (SOR/98-176)
- Hazardous Products (Carpet) Regulations (C.R.C., c. 923)
- Hazardous Products (Cellulose Insulation) Regulations (SOR/79-732)
- Hazardous Products (Charcoal) Regulations (C.R.C., c. 924)
- Hazardous Products (Infant Feeding Bottle Nipples) Regulations (SOR/84-271)
- Hazardous Products (Kettles) Regulations (C.R.C., c. 927)
- Hazardous Products (Mattresses) Regulations (SOR/80-810)
- Hazardous Products (Pacifiers) Regulations (C.R.C., c. 930)
- Hazardous Products (Tents) Regulations (SOR/90-245)
- Phthalates Regulations (SOR/2010-298)

[62] http://laws-lois.justice.gc.ca/eng/acts/H-3/page-1.html.

- Playpens Regulations (C.R.C., c. 932)
- Science Education Sets Regulations (C.R.C., c. 934)
- Surface Coating Materials Regulations (SOR/2005-109)
- Textile Flammability Regulations (SOR/2011-22)
- Toys Regulations (SOR/2011-17)

2001 Consumer Chemicals and Containers Regulation

The 2001 *Consumer Chemicals and Containers Regulation* (CCCR*),*[63] originally enacted on the basis of the 1985 *Hazardous Products Act* (HPA), is now incorporated into the CCPSA. It applies to the importation, advertising and sale of chemical products and containers.

The CCCR requires the "person responsible" to determine (a) the hazard categories of the chemical product or container, (b) the type of container required, and (c) the information to be displayed on the container. It sets forth requirements for classification by hazard, including for toxicity, corrosiveness, flammability, explosivity, or for quick skin-bonding properties. A product classified for any of these hazards must be packaged and labelled in accordance with the CCCR requirements.

Containers must pass the prescribed leakage test. Child-resistant containers must meet child test protocol requirements and maintain child-resistant characteristics throughout the useful life of the product. The person responsible must prepare and maintain documents relating to these determinations.

Note that the CCCR prohibits the importation, advertising or sale of a chemical product classified as "very toxic".[64]

2011 Toys Regulations

The *Toys Regulations*, promulgated under the CCPSA, covers all children's toys and related products manufactured, imported or sold in Canada.[65] The *Toys Regulations* defines "toy" as a product that is intended for use by a child in learning or play. Health Canada interprets this as applying to toys for children under 14 years of age, unless a requirement prescribes a younger age.

The *Toys Regulations* addresses a wide range of mechanical, flammability, toxicological, electrical, thermal and other hazards associated with children's toys. Its requirements with respect to toxicological hazards include:

[63] http://laws-lois.justice.gc.ca/eng/regulations/SOR-2001-269/page-1.html .
[64] http://laws-lois.justice.gc.ca/eng/regulations/SOR-2001-269/page-13.html#h-17 .
[65] http://laws-lois.justice.gc.ca/eng/regulations/sor-2011-17/page-1.html .

- Prohibition against using toxic substances in toys in such a way that they might be a source of exposure, in which case they must be restricted to limited amounts based on known toxicity parameters (Section 25 and Schedule 2)
- Prohibition against using substances that are excessively corrosive, excessively irritant or excessively strong sensitizers in toys if they can come in contact with the skin (Section 26 and Schedule 3)
- Requirement that all finger paints be water-based (Section 39)

The following toys are prohibited under the *Toys Regulations:*

- Toys with a surface coating material to them containing any of the following substances:
    - total lead in excess of 90 mg/kg
    - a compound of antimony, arsenic, cadmium, selenium or barium if more than 0.1% of the compound dissolves in 5% hydrochloric acid after being stirred for 10 minutes at 20°C
    - a compound of mercury.
- Toys containing carbon tetrachloride, methyl alcohol, petroleum distillate, benzene, turpentine, boric acid or ethyl ether (Section 22)
- Balloon blowing kits containing any aromatic, aliphatic or other organic solvent (Section 24)

Note that other CCSPA regulations may also apply to a specific toy, depending on the toy's design, construction, contents and, in some cases, how it is marketed. Relevant regulations include:

- Consumer Products Containing Lead (Contact with Mouth) Regulations
- Glazed Ceramics and Glassware Regulations
- Hazardous Products (Tents) Regulations
- Phthalates Regulations
- Science Education Sets Regulations
- Surface Coating Materials Regulations
- Textile Flammability Regulations

For example, the *Phthalates Regulations* restrict the allowable concentrations of di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP) to not more than 1,000 mg/kg (0.1%) in the soft vinyl of toys and in the soft vinyl of child care articles. A child care article is defined as "a product that is intended to facilitate the relaxation, sleep, hygiene, feeding, sucking or teething of a child under four years of age." It sets similar allowable concentration limits for diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP) in the soft vinyl of toys and in the soft vinyl of child care articles where the soft vinyl can, in a reasonably

foreseeable manner, be placed in the mouth of a child under four years of age. To be considered a part of a toy that can be placed in the mouth of a child under four years of age, one of the dimensions of the toy must be less than 5 cm and the part must be able to be brought to a child's mouth and kept there so that it can be sucked or chewed.

Children's cosmetic items, such as perfume, lipstick, makeup, nail polish, shaving cream, Halloween makeup, face paint and similar items are regulated by Health Canada under the *Cosmetic Regulations*[66] of the *Food and Drugs Act*.

3.1.6 Pest Control Products Act

The 2002 Pest Control Products Act[67] regulates products used for the control of pests. It came into force in 2006, replacing the previous 35-year old regime. The PCPA is administered by Health Canada's Pest Management Regulatory Agency.

The Act requires approval of pesticides before they can be imported into, manufactured, sold or used in Canada. The approval process entails review of all available data, including information on sources of exposure, including food and water.

Even before the 2002 PCPA, Canada started a process of reviewing all pest control products registered prior to 1995 in the light of more recent science, to ensure their continued acceptability for use. Under the new Act, all pest control products must be re-evaluated on a 15-year cycle. If the data required for this re-evaluation is not supplied for a pesticide, it can be removed from the market.

In addition to providing the Pest Management Regulatory Agency with the authority to remove a pesticide from the market if data are not supplied, the PMRA has increased powers of inspection to ensure compliance with the new Act and can also impose higher penalties, up to $1 million for the most serious offences. Finally, the new Act requires registrants of pest control products to report sales data as well as any incidents of potential adverse effects relating to the products they market.

[66] http://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 869/ .
[67] http://laws-lois.justice.gc.ca/eng/acts/P-9.01/page-1.html .

3.2 INSTITUTIONAL ARRANGEMENTS FOR ENFORCEMENT

Canada's federal government shares jurisdiction over environmental matters with the provincial and territorial governments. On the federal level, competence over chemicals in products rests with Environment Canada and with Health Canada.

3.2.1 Environment Canada

Environment Canada (EC) is the federal agency responsible for protecting Canada's environment, including its natural heritage, and for providing weather and meteorological information to the public. Its mandate is to

- preserve and enhance the quality of the natural environment, including water, air, soil, flora and fauna;
- conserve Canada's renewable resources;
- conserve and protect Canada's water resources;
- forecast daily weather conditions and warnings, and provide detailed meteorological information to all of Canada;
- enforce rules relating to boundary waters; and
- coordinate environmental policies and programs for the federal government.

In terms of staff, Environment Canada consists of 6800 employees from a broad range of fields including biology, chemistry, meteorology, climatology, engineering, commerce, communications, engineering, law enforcement, environmental sciences, hydrology, informatics, law, policy, and more. Most of its workforce is outside of Ottawa, spread among 100+ communities across the country.

In the area of chemicals, Environment Canada is responsible for assessing potential risks to the Canadian environment. According to its website,[68] each year Environment Canada assesses the risks of nearly 1000 chemical substances that may be found in Canada's air, water and industrial and consumer products. It also tracks releases, disposals and transfers for recycling of over 300 substances from approximately 8000 facilities in Canada. Environment Canada has enforcement authority over the areas for which it has competence.

[68] http://www.ec.gc.ca/default.asp?lang=En&n=BD3CE17D-1

3.2.2 Health Canada

Health Canada is the federal department responsible for maintaining and improving the health of Canadians. Its remit ranges from overseeing Canada's health care system and services, including drugs and health products, to labelling of food and general product safety.

In the area of chemicals, it is responsible for assessing potential risks to human health posed by existing substances in Canada, and works jointly with Environment Canada, the department responsible for assessing the risks of existing substances to the environment. Within Health Canada, this work is conducted by the Existing Substances Division.

Health Canada also oversees Canada's system for registration and control of pest control products, through its Pest Management Regulatory Agency.

3.3 POLICIES FOR SUPPORTING REDUCTION OF HAZARDOUS CHEMICALS IN PRODUCTS

3.3.1 Green Public Procurement in Canada

The Canadian government supports reduction of hazardous chemicals in products *inter alia* through its *Policy on Green Procurement*, which came into effect in April 2006.[69] The Policy is aimed at enabling government bodies to procure goods and services that have a lesser or reduced effect on human health and the environment than competing goods or services. An environmentally preferred good is one that should have a reduced environmental impact over its entire life cycle.

The objective is to have a positive impact in expanding the market for environmentally sound goods and services, by using the government's significant annual purchasing volumes. Examples of environmental attributes include:

- Reusability -- i.e., contains reusable parts, or has been reused or refurbished;
- Recyclability -- facilities exist capable of recycling the good at the end of its useful life;
- Contains recycled material;
- Produces fewer pollutants, such as greenhouse gas emissions and air contaminants, during manufacture, use or disposal;
- Has a long service life and/or can be economically and effectively repaired or upgraded;

[69] http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/questions-eng.html.

- Reduces waste and makes efficient use of resources, including water and energy;
- Reduced use of toxins and hazardous substances;
- Uses renewable resources; and
- Uses forest goods from sustainably managed forests.

The *Green Procurement Policy* applies to all federal government procurement activities (goods, services and construction) across all stages of the procurement process, from planning and acquisition through use, maintenance and disposal, and to integrate consideration for the environment into the federal government's normal business practices.

3.3.2 Extended Producer Responsibility in Canada

Many products such as electronics, paint and engine oil need proper management at the end of their useful life. Extended Producer Responsibility (EPR) programs aim to make the producer responsibility for collection and recovery or proper disposal of end-of-life products.

In 2009, the Canadian Council of Ministers of Environment[70] issued a *Canada-wide Action Plan for Extended Producer Responsibility*[71] in order to ensure common coordinated policies and commitments for government action and common key elements for building producer responsibility for priority products. A number of Canadian provinces now have extended producer responsibility programs in place, and many more are expected to become operational in the coming years.

Environment Canada maintains an inventory of *Extended Producer Responsibility and Product Stewardship Programs.*[72] The aim is to provide information on the recycling of products, as a service to the Canadian public.

3.4 EVALUATION OF CANADA'S MODEL FOR CONTROLLING CHEMICALS IN PRODUCTS

The ambition of Canada's regime for controlling chemicals in general – to address head-on the problem of the so-called "existing substances" – is commendable. However, progress is slow. It took seven years after the passage of CEPA 1999 to complete the categorisation process, which led to the targeting of some 200 substances considered a high priority for regulatory action.

[70] The CCME is comprised of the 14 environment ministers from the federal, provincial and territorial governments.
[71] http://www.ccme.ca/files/current_priorities/waste/pn_1499_epr_cap_e.pdf.
[72] https://www.ec.gc.ca/gdd-mw/default.asp?lang=En&n=9FB94989-1.

The launch of the Chemicals Management Plan in 2006 generated significant momentum in the assessment of existing substances. The new approach introduced a systematic, outcome-oriented approach to chemicals management in Canada, with substances prioritized for assessment on the basis of risk. In addition, the burden of data gathering shifted from falling solely on government to a shared responsibility with industry. However, substance assessment still rests with Environment Canada and Health Canada, which means that they still shoulder a considerable burden of assessment and monitoring.

Some of the chemicals identified for further assessment are found in products, and any restrictions adopted under CEPA 1999 should mean that the products which used to be manufactured or process using the chemical so regulated will be more protective of human health and the environment.

In line with the USA and the EU, Canada has recently set in place a Consumer Product Safety Act that prohibits the manufacture, import, sale or marketing of products that could pose an unreasonable danger to the health and safety of Canadian consumers. The CCPSA's provision requiring reporting of any safety "incidents" related to the consumer product is especially strong.

Under Canada's regime, most controls over specific substances in products are set via regulations under the CCPSA, such as in the 2011 Toys Regulations and the Phthalates Regulations. The significant number of regulations enacted under the CCPSA is an indication that Canada has set in place a workable system for being able to impose restrictions and prohibitions over hazardous substances to protect the public from the risks to health and environment posed by the presence of such substances in consumer products.