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SEX, GENDER AND CHEMICALS

FACTORING WOMEN INTO CANADA'S CHEMICALS MANAGEMENT PLAN

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SETTING THE STAGE

SEX, GENDER AND THE ENVIRONMENT

Chemical substances are found everywhere in our environment. Whether it be at home, outdoors, or in the workplace, we are continuously coming into contact with various chemicals through our air, water, food, cosmetics, clothes, personal care products and everyday household items (Cooper & Vanderlinden, 2009; Program on Reproductive Health and the Environment, 2008). As our detection methods improve, we are forced to confront the evidence of these exposures: biomonitoring studies now show that nearly everyone has measurable amounts of almost all known toxic chemicals stored somewhere in their bodies (Centers for Disease Control and Prevention (CDC), 2009; Environmental Defence, 2009; Statistics Canada, 2010).

At the same time, we are witnessing a rise in incidence of a number of diseases and disorders in men, women and children. These include some cancers, irreversible developmental and neurodevelopmental syndromes, reproductive disorders, and a number of autoimmune diseases . Many scientists, environmental groups and health practitioners suggest that the environment significantly contributes to many of these conditions (Brouwer et al., 1999; Butter, 2006; Cooper & Vanderlinden, 2009; de Leon et al., 2010; Genuis, 2010; Grandjean & Landrigan, 2006; Gray et al., 2010; Program on Reproductive Health and the Environment, 2008; The Collaborative on Health and the Environment (CHE), 2011). Research has demonstrated that even low levels of exposure to certain chemicals, at certain key times, can have dramatic effects on bodily systems and processes, leading to various adverse health conditions. For example, many of the chemicals that get into our bodies are structurally similar to hormones and are thought to be capable of triggering changes in how cells and organs function, having an impact on a diverse array of metabolic, growth and reproductive processes in the body (Europa, 2008; Schwartz & Korach, 2007; The Endocrine Disruption Exchange (TEDX), 2011; United States Environmental Protection Agency (US EPA), 2011; United States Food and Drug Administration (US FDA), 2010). In recent years, evidence has emerged from animal research and some epidemiological studies that is giving rise to significant worry about the impact endocrine disruption is having on the health of Canadians. This knowledge has challenged traditional tenets of toxicology that maintain conservative ideas of linear dose-response curves for toxic exposures, threshold levels for chemical safety, and specific modes of toxic action (Hanahan & Weinberg, 2000; Thornton, 2000; vom Saal & Sheehan, 1998).

There is also growing evidence that these exposures affect different bodies in different ways, due to the fact that people's lives and health are influenced by both biological (sex-related) and social (gender-related) factors. Not only do women, men, boys and girls possess different vulnerabilities to exposure based on biology; they also face different health risks based on gendered practices, socioeconomic and cultural circumstances, structural disparities in access to basic resources, varied health-seeking behaviours, and different responses from health systems leading to diverse health outcomes (Clow et al., 2009).

The Canadian Government has a clear primary responsibility and role in ensuring a safe environment and healthy population. An analysis of chemical exposures, their biological and social impacts, and the implications for the evaluation and management of toxic substances is therefore undertaken with sex and gender considerations in mind. The objective of our analysis is to evaluate the current regulatory regime for chemicals released into our everyday environments so as to create inclusive and comprehensive regulatory processes that ensure the health and safety of ***everyone.***

CANADA'S COMMITMENTS TO SEX- AND GENDER-BASED ANALYSIS (SGBA)

The Federal Government has made strides over the years to acknowledge and address considerations of sex and gender in various policies and programs.

This recognition began in 1974 with the *Lalonde Report* and in 1986, a report entitled *Achieving Health for All: A Framework for Health Promotion*, introduced discussions of equity into health policy debates and drew particular attention to differences in health outcomes related to income, for both women and men. Canada also signed a United Nations agreement called the *Convention on the Elimination of all Forms of Discrimination Against Women* (CEDAW) as well as the *Beijing Declaration and Platform for Action* developed at the Fourth World Conference on Women. These commitments spurred the development in Canada of a federal women's health program, supported by the Women's Health Bureau in Health Canada (now the Gender and Health Unit) as well as a *Women's Health Strategy* committed to understanding how both "sex" and "gender" are related to health outcomes (Clow et al., 2009).

Most importantly, the Government undertook formal commitments to conduct Sex- and Gender-Based

Analysis (SGBA) with the establishment of *The Federal Plan for Gender Equality* in 1995, which called for the implementation of SGBA throughout federal departments and agencies. The basis of this plan is that all Federal Government departments are responsible for analyzing proposed policies, conducting SGBA and including gender considerations in policy development (Office of the Auditor General of Canada, 2009). See a complete description of SGBA in Box A.

BOX A: SEX-AND GENDER-BASED ANALYSIS

Sex- and gender based analysis (SGBA) is a method for integrating sex and gender considerations into health research, policy and practice (Clow et al., 2009). It seeks to understand how specific policies and programs might affect women differently than men. SGBA can help to promote sex and gender sensitive research, policies and programs that expand the understanding of health determinants in both sexes, provide knowledge that may result in improvements in health and health care, and ultimately help in achieving gender equality (Office of the Auditor General of Canada, 2009).

In conducting such an analysis, it is important to avoid the generalization of men or women as homogeneous groups. Rather, each is made up of a diverse range of individuals with unique experiences, understandings and needs based on other social factors where disparities may exist. These other variables or determinants of health include socioeconomic status, race and ethnicity, age, education, culture, sexual orientation, religion, geography, working conditions, and access to social support networks and health care services, and can all act and interact to affect the health and care for an individual (Clow et al., 2009; Gupta & Ross, 2007; Public Health Agency of Canada, 2010). In carrying out SGBA, it is therefore necessary to look not only at the similarities and differences between women and men, but also at the differences among groups of women and men.

A CALL TO ACTION: THE AUDITOR GENERAL'S REPORT ON SGBA IN GOVERNMENT PRACTICES

In her Spring 2009 Report, the Auditor General of Canada evaluated the success of the Government in fulfilling its SGBA obligations and the state of SGBA integration into all department programs and policy work. The report found that despite a stated commitment, there is no government-wide policy requiring departments or agencies to perform SGBA, and that the frameworks in use in each department vary considerably. Those departments that do perform SGBA cannot provide evidence demonstrating that sex and gender-based analyses are used in designing policy (Office of the Auditor General of Canada, 2009).

In particular, an examination of Health Canada activities revealed that although the department had adopted a Women's Health Strategy in 1999 to enact an SGBA strategy, there is a lack of full-time appointed staff, training, evaluation, and effective implementation of SGBA into health programs and policies. Where SGBA has been performed in the department, there has been no integration of the analysis into policy development (Office of the Auditor General of Canada, 2009).

The SGBA process is vital to planning appropriate health programs and services, developing inclusive health policies and conducting research. It is effective because it requires policy-makers, scientists and researchers to think about who they are trying to serve and whose needs they are trying to meet. Growing attention to discussions of equity and health has increased the need and obligation to understand the fundamentals of SGBA in order to respond to gender related health inequities on a local and global scale. Not only would an adequate integration of SGBA in health-related programs help the Government to meet its legal obligations of gender equality under Canadian law, including those set out in the *Canadian Charter of Rights and Freedoms* and the *Canadian Human Rights Act*; it would also help the Government come into line with recent international developments, such as the World Health Organization's Commission on the Social Determinants of Health (Clow et al., 2009; Office of the Auditor General of Canada, 2009). Simply put, integration of a sex- and gender-based analysis makes for better science and more inclusive policies.

CHEMICALS MANAGEMENT IN CANADA

There are several federal and provincial regulatory frameworks for chemicals management in Canada, including the *Canadian Environmental Protection Act*, 1999 (CEPA), the *Food and Drugs Act,* the *Fisheries Act* and the *Pest Control Products Act* . Part 5 of CEPA is the primary legislative tool for the management of toxic chemicals (Environment Canada, 2011). See Box B for a more in-depth description of provisions under CEPA.

BOX B: THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

The Canadian Environmental Protection Act, 1999 (CEPA), administered by the Minister of the Environment, is the primary element of the federal legislative framework for protecting

the Canadian environment and human health (Environment Canada, 2011). The prevention and management of risks posed by toxic substances is a key feature of the Act, and includes specific requirements for the assessment and management of approximately 23,000 substances currently existing in commerce or being released to the environment in Canada in a significant quantity. These substances are listed in an inventory called the *Domestic Substances List* (DSL), and are jointly assessed by The Minister of the Environment and the Minister of Health to determine if they meet the definition of "toxic" under CEPA ("CEPA-toxic"). The Act called for three different types of activities: 1) Categorization of the DSL (under section 73 of the Act), which took place between 1999 and 2006 and involved the identification of low, medium and high priority substances based on whether they were persistent, bioaccumulative and inherently toxic (PBiT), or presented significant potential for human exposure; 2) Assessment of substances on the *Priority Substances List* (PSL), a process used to investigate priority chemicals that require a more comprehensive scientific assessment to determine if they are toxic or capable of becoming toxic; and 3) Review of other jurisdictions' decisions (Environment Canada, 2011). The Government completed the process of categorization within the legislated time period, and introduced the Chemicals Management Plan in December 2006 (Environment Canada, 2011; Government of Canada, 2007).

About 4,300 substances screened by Environment Canada and Health Canada were identified as requiring further assessment, and have thus been subject to attention under the Chemicals Management Plan, with a particular focus on 500 high priority substances (Government of Canada, 2007).

THE CHEMICALS MANAGEMENT PLAN

The Chemicals Management Plan (CMP) was announced by the Federal Government on December 8, 2006 as a joint initiative of Health Canada and Environment Canada aimed at improving the degree of protection against hazardous chemicals in Canada and ensuring their proper management through a number of proactive measures (Government of Canada, 2010a). The launch of the program coincided with heightened concern among Canadians about chemical substances in the marketplace and the expectation that the Federal Government would provide oversight to reduce the risks to human health and the environment. The CMP focuses on chemicals flagged as potentially harmful in the categorization of existing substances on the *Domestic Substances List* (DSL). These substances include those that were put into commercial use before 1987 without ever being subjected to a health and environmental assessment. The stated intention of the CMP is to provide a basis for sound and effective public and environmental health policies, interventions and control measures through substance identification, tracking of exposures, monitoring and surveillance.The Plan mandates the evaluation of low, medium and high priority substances chemicals by sector (such as existing substances under the DSL, new substances, Pilot Project chemicals, Petroleum Sector Stream chemicalsiii, and substances within the Pest Control Products Act) in order to determine whether they meet the three criteria of toxicity under section 64 of CEPA (see Box C) and should be added to the List of Toxic Substances in Schedule 1 of the Act (Schedule 1) (Environment Canada, 2011; Government of Canada, 2010a;).

BOX C: SECTION 64 OF CEPA

A substance is found toxic under Section 64 of CEPA if it is entering or may enter the environment in a quantity or concentration or under conditions that:

(a) Have or may have an immediate or long term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) Constitute or may constitute a danger in Canada to human life or health.

The decision to add a substance to the List of Toxic Substances in Schedule 1 is based on (1) whether the substance meets the ecological criteria of persistence, potential for bioaccumulation, and inherent toxicity (PBiT), or presents the greatest potential for exposure, and (2) is identified as posing high hazard to human health based on available evidence on carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity (Environment Canada, 2011; Government of Canada, 2010a).

Adding a chemical to Schedule 1 gives the Federal Government the authority under CEPA to place restrictions — known as "risk management measures" — on the substance. Measures can include: regulations limiting substance-related activities or substance concentrations in the environment; pollution prevention plans that outline actions to prevent or minimize the creation or release of pollutants; environmental emergency plans; guidelines to recommend a concentration for toxic substances; and voluntary codes of practice, among others. Substances may also be added to the Virtual Elimination List, which allows for actions that reduce releases of a substance to the point of 'virtual elimination' (Environment Canada, 2011; Government of Canada, 2007). However, it is important to note that adding a chemical to Schedule 1 does not necessarily require further action on the part of the Government in terms of restricting or managing that substance.

The CMP also coordinates new investments in research and monitoring to learn more about the effects of chemical exposure and provides a means for measuring the success of actions to control or reduce risk. Supplemental to the CMP process is the Canadian Health Measures Survey (CHMS), launched in 2007 by Statistics Canada, which involves the collection of key information relevant to the health of Canadians by means of direct physical measurements such as blood pressure, height, weight and physical fitness. Measurements are also taken in the form of critical biomonitoring data indicating the levels of 91 key chemicals that have known or suspected health effects, are of public concern and show evidence of exposure in the Canadian population. These chemicals include metals (e.g., mercury, lead, cadmium), organochlorines (e.g., aldrin, chlordane, DDT, hexachlorobenzene), polychlorinated biphenyls (PCBs), polybrominated flame retardants (PBDEs), perfluorinated compounds (PFCs) (e.g., PFOS, PFOA, PFHxS), phthalates, chlorophenols, and pesticides (Statistics Canada, 2010). The goal of this exercise is the development of national baseline data on major health concerns and exposures to environmental contaminants, thereby enabling the Government over time to determine connections between chemical exposures and health status, and informing policy and regulatory development. While this represents a start in the collection of data on Canadian contaminant exposures, it leaves us far behind the long-term biomonitoring studies that have been taking place in Europe and the US over many years (CDC, 2009; Cooper & Vanderlinden, 2009) .

THE CHALLENGE

One of the most contentious elements of the CMP has been the Ministerial Challenge program ("The Challenge"), which calls on chemical manufacturers, importers, and industrial users to provide new information about the properties, uses, releases and management of 200 high priority chemical substances which are PBiT and present a high likelihood of exposure (Government of Canada, 2010a). Through the application of a "weight-of-evidence" approach and the precautionary principle, regulators indicated that they would find substances CEPA-toxic under The Challenge unless industry submitted evidence convincing them otherwise.

The chemicals included in The Challenge have been undergoing assessment in 12 batches over a three-year timeframe, with 15-20 chemicals having been released to industry and stakeholder groups every three months for a six-month comment period. Manufacturers, importers and industrial users of high-priority substances have been asked to provide Environment Canada and Health Canada with information through a voluntary questionnaire, technical substance profiles, and mandatory surveys issued under Section 71 of CEPA. This information is used to draft a screening assessment for each chemical, based on release data, exposure data, and toxicity data (Government of Canada, 2010a). See Box D for an overview of risk assessments under the CMP. As of the release of this report, over 90% of substances under The Challenge have undergone draft and final screening assessments (Government of Canada, 2010a; Tilman & Ford, 2010). If substances are found to be CEPA-toxic, a document outlining proposed risk management measures must also be prepared.

BOX D: RISK ASSESSMENTS UNDER THE CMP

Screening assessments, prepared by staff in the Existing Substances Programs at Health Canada and Environment Canada, are scientific evaluations of chemical substances identified as a priority under The Challenge.

These risk assessments examine scientific information on the potential exposure and harm of a given substance to human health and the environment, and develop conclusions about the toxicity of that substance. Based on these evaluations, the Government decides whether or not to list the substance on Schedule 1. It is important to note that even where the Government declares a substance to be "toxic" under this process, they may decide not to take any further steps to restrict exposures to the chemical for Canadians. Alternatively, they may decide to conduct further in-depth assessment, much like the approach used for chemicals under the PSL, or ideally, to apply risk management conditions that would restrict the use of the substance in the Canadian market and its release into the Canadian environment (Environment Canada, 2011; Government of Canada, 2011a).

Each assessment includes consideration of information acquired from mandatory surveys sent to industry to collect information on the extent and nature of manufacture, import, export and use of a substance; a voluntary questionnaire inviting interested stakeholders to submit additional information relating to the extent and nature of chemical manufacture, import, export and use by industry; technical substance profiles, as well as data from original literature, assessment documents, stakeholder research reports, recent literature searches of studies from around the world, and computer modeling records (Environment Canada, 2010a; Government of Canada, 2011a). Evaluation of risk to human health is determined through a comparison of known and estimated chemical exposure and effect (see Figure 1 on pg. 22), as well as an assessment of how confident the government is that this data set is complete (Government of Canada, 2011a; Health Canada, 2008).

The Government has established processes by which both stakeholders and independent experts may offer advice and input on the implementation of the CMP and The Challenge, and foster dialogue on important issues surrounding the chemical assessment and management process (Government of Canada, 2010a). The Stakeholder Advisory Council includes members from Aboriginal bodies, consumer groups, environment and health non-governmental organizations (NGOs), industry associations, producers, users, and labour. In contrast, the Challenge Advisory Panel is comprised of a panel of twelve experts specializing in the precautionary principle, chemical policy, chemical production and economics, environmental and health risks, environmental and biological sciences, environmental health social movements, health and Aboriginal communities, chemicals and health and safety, and health care planning and delivery (Government of Canada, 2010a).

CRITIQUE OF THE CMP AND THE CHALLENGE

The Canadian Environmental Network (CEN) , with the help of Environmental Defence, oversees the CMP Capacity Building Project ("the Project"), a process that coordinates and engages civil society in The Challenge by facilitating and supporting stakeholder input toward CMP decision-making. The pace of activity around the assessment of chemicals is extremely challenging to civil society, as there are tight timelines for providing relevant input. As a result, the intention of the Project is "to enhance civil society capacity to participate in the CMP process and to better respond to the Government's work through increased accessibility, evidence-based platform submissions and opportunities for stakeholder collaboration", in the hopes of generating broad and long-term improvements in the capacity of NGOs to access and respond to the management of chemicals (CEN, 2010). The Challenge has been criticized by a number of independent bodies and non-governmental organizations participating in the Project (Tilman et al., 2010). They argue that the CMP, and specifically The Challenge, is a weak and insufficient process for adequately evaluating chemicals and applying proper precaution in assessments and management proposals. A number of the NGOs have referred to the limited number of substances that have been found CEPA-toxic thus far, despite the fact that they were originally categorized as high-priority on the DSL, and question the CMP's ability to adequately protect public health (Canadian Environmental Law Association and Chemical Sensitivities Manitoba (CELA/CSM), 2010c; Inuit Tapiriit Kanatami (ITK), 2010b; Tilman, 2009; Tilman et al., 2010). It has been noted that there are no mandatory evidence-gathering provisions, and there is no obligation on the part of industry to conduct toxicity testing (Scott, 2009). Additionally, as the analysis in this report reveals, there has been no concerted effort to apply SGBA to chemicals regulation.

In the end, despite the Government's intention to designate substances as CEPA-toxic (unless evidence was provided to the contrary), only a minority of substances assessed in The Challenge were listed as such. Further, corresponding risk management measures have been inadequate and slow in coming. The result is that the ultimate goal of the CMP — reductions in exposures to harmful substances for everyone — is not likely to be met in the near future.

ADDRESSING THE SEX AND GENDER GAP IN CANADIAN CHEMICALS MANAGEMENT

Despite the many research gaps that remain, the rapidly growing body of scientific evidence about risks and harms to unique groups of the population demonstrates the limitations and failings of the present day chemical regulatory system, challenging our thinking about how much information is sufficient to warrant action, how much risk is acceptable, and to whom (Cooper & Vanderlinden, 2009).

In this report, we seek to demonstrate that integration of SGBA into the CMP process would improve chemical assessments and resulting regulatory decisions by illuminating critical shortcomings with the risk assessment tools, meaningfully shaping research and responses, and ensuring that women's voices and concerns are adequately represented in future policy decisions. Accordingly, we have highlighted particular chemical risk assessments that illustrate critical points in our analysis of chemicals management and its relation to women's health.

Understanding the limitations and deficiencies in the CMP process for addressing sex and gender, as well as the shortcomings and gaps that exist in the governing legislation, is critical. We also offer recommendations as to where the process could be improved to accommodate sex and gender determinants, so that we can improve decision-making, policy development, public participation and pollution prevention around chemical substances. Ultimately SGBA can provide justification for the adoption of regulatory measures that reduce hazards and exposures and move towards more inclusive and precautionary regulatory schemes (Chakravartty, 2010).

HOW THE CMP IS FAILING CANADIAN WOMEN

Sex and gender are important considerations in the assessment and regulation of toxic substances, as male and female bodies respond to harmful chemicals in different ways, and men and women tend to have distinct patterns of use and exposures to chemicals based on their particular social location. For example, subtle sex-specific differences in biochemical pathways, hormones, metabolism, body fat composition, blood chemistry and the size of body tissues between females and males can lead to susceptibilities to exposure that impact women's health and reproduction in unique ways (Arbuckle, 2006; Buckingham & Kulcur, 2009; Clow et al., 2009; Public Health Agency of Canada, 2009). These exposures are often found alongside higher rates of disease and other health conditions. Similarly, social factors contributing to women's increased vulnerability to chemical exposures include their disproportionate share of unregulated, paid and unpaid caretaking roles and domestic duties, the nature of paid employment in the service sector, socioeconomic status and financial security, a lack of access to resources and services, limited engagement in political and decision-making processes, and a greater use of personal care products (Chakravartty, 2010; MacGregor, 2010).

The CMP is failing Canadian women because it does not acknowledge their unique vulnerabilities to chemical exposures and ultimately encourages the burden of risk management to fall disproportionately onto their shoulders. As a result, the differential impacts women experience from chemical exposures are overlooked in assessments, and final decisions about chemical use in Canada do not take into account possible long-term health implications for women. It is important that the CMP undertake an analysis that recognizes women as a vulnerable group and the reasons why chemical evaluation cannot be a 'one-size-fits-all' practice.

CRITICAL WINDOWS OF VULNERABILITY

A chemical's effect on the body is determined not only by the dose, but also the timing of exposure. Emerging epidemiological evidence shows that everyone is more biologically vulnerable to certain exposures to toxic chemicals in the environment during key developmental and reproductive life stages, known as *critical windows of vulnerability* (Batt, 2009; Canadian Partnership for Children's Health and Environment, 2007; Cooper & Vanderlinden, 2009; Eyles et al., 2011; Gray et al., 2010). These windows of vulnerability, which include the prenatal period, early life, and puberty, represent times of development or hormonal activity that differentially affect women, men, girls and boys in their sensitivity and susceptibility to chemical exposures, and their ability to adapt to these exposures. Additionally, while traditional toxicology has been based on the understanding that the greater the dose to a toxic substance, the greater the harm, new research points to low doses of some chemicals having more severe effects than high doses, especially during these time periods (Brophy et al. 2011; McClenaghan et al., 2003).

Exposures during these critical windows can have unique impacts on women, especially during pregnancy, lactation, menstruation and menopause. Interruptions in hormonal processes can lead to chronic disease, disorders, and developmental or reproductive problems that affect not just a woman, but also her fetus, child, and subsequent generations (Butter, 2006; Gray et al., 2010; McClenaghan et al., 2003; Program on Reproductive Health and the Environment, 2008; Reuben, 2009). Women also experience differences in chemical exposure based on their social location and environmental interactions, which can further increase their vulnerability. It is imperative that chemical regulation pay particular attention to how biology and critical windows of vulnerability influence men's and women's responses to chemical exposures in different ways.

SOCIAL DETERMINANTS OF HEALTH

Exposure to contaminants at various developmental stages is strongly influenced by social, economic, and cultural factors. A woman's vulnerability to exposure depends on her social location, which is characterized by what the experts call the "social determinants of health." These include socioeconomic or occupational status, race or ethnicity, sexual orientation, education, age, language, living conditions or geography, nutrition, and access to safe drinking water, among others (Cooper & Vanderlinden, 2009; Gupta & Ross, 2007; Hamm, 2009; Public Health Agency of Canada, 2009; Scott & Stiver, 2009). Intersections of identity can result in greater risk of illness, reduced access to health care, and an increase in vulnerability to chemical exposures (McClenaghan et al., 2003). For example, women's work in the domestic sphere, a space that is largely unsupervised and unregulated, often brings women into direct contact with chemicals. In this case, avoiding or minimizing exposures requires navigation among the needs and health of the family, economics, time and environmental considerations (Buckingham & Kulcur, 2009). Women also constitute a large percentage of the country's poor. Poverty and low social status make women more vulnerable to environmental contaminants and less likely to be involved in decision-making about environmental health issues. These factors are often shaped by gender norms framed by social institutions such as the media, academia, and health care systems that define, reproduce, and often justify different

expectations and opportunities for women, men, girls and boys (Clow et al., 2009; MacGregor, 2010).

VULNERABLE POPULATIONS, WOMEN, AND THE CMP

Health Canada describes Vulnerable Populations within the CMP as "people who are more at risk from harmful substances than others" as a result of physical differences, behaviours, location and/or control over their environment (Government of Canada, 2010a). It has been recognized in recent policy debates that children are a vulnerable group that require special protections that demand improvements to standard-setting processes (CELA & Environmental Defence, 2006; Cooper & Vanderlinden, 2009). Still, the risk assessment and management approach of the CMP makes only passing reference to vulnerable populations, does not consistently apply ideas of vulnerability to all substances under the Plan, and limits consideration of vulnerable groups to children in Section 5.3 of the voluntary questionnaire (CELA/CSM, 2009; Environment Canada, 2010a). Additionally, there has been little consideration of how differences in male and female biology and development might affect vulnerability to chemical exposures, or how social location might factor into gendered exposures and risks of harm (de Leon et al., 2010). Box E offers examples of two chemicals for which risk assessments failed to fully integrate sex and gender considerations. Only by applying a sex-and gender-based analysis can the Government begin to acknowledge the various risk factors that differentially expose women to harm from chemical exposures and to integrate these understandings into chemicals management and regulation.

BOX E: ARE SEX AND GENDER BEING INTEGRATED INTO RISK ASSESSMENTS UNDER THE CMP?

BHA (common additive, CAS RN No. 25013-16-5)

1,1-dimethylethyl-4-methoxy-Phenol, also known as BHA, is an industrial chemical used as a food additive in Canada to delay deterioration of flavours and odours, and to increase shelf life. It is also an antioxidant and antimicrobial preservative used in personal care, pharmaceutical, natural health and veterinary products, and a formulant used as a stabilizer or fragrance in pesticide products (Environment Canada & Health Canada, 2010c). Exposure is primarily through permitted use as an antioxidant in some foods and through its use in personal care products such as shampoos and skin moisturizers.

Despite the ubiquitous presence of BHA in many products used by every population group, both the draft screening assessment and the final assessment of BHA in The Challenge concluded that the chemical does not have the potential to harm human health or the environment, and the Government has therefore proposed no further action on the substance (Environment Canada & Health Canada, 2010c).

This is despite animal studies and some epidemiological studies that have shown BHA to be a carcinogen and a suspected endocrine disruptor (Kang et al., 2005; Zhu et al., 1997), which could adversely affect a female's health during windows of vulnerability related to reproduction and development. The final assessment stated that the two critical effects identified for characterization of risk to human health were carcinogenicity and changes in endocrine measures (effects on the thyroid gland, altered sex hormones and adrenal gland), and that the 'confidence in the toxicity database for BHA' was only moderate, with limited information available to estimate dermal absorption of BHA in humans (Environment Canada & Health Canada, 2010c). Additionally, even though the assessment provides gender-disaggregated data, the final decision was based on a mean all-person calculation of estimated exposure, thereby ignoring key facts: that women have increased intakes of BHA from dermal exposure, that women on average use more personal care products than men, and that women would therefore be expected to experience higher exposure levels (Environment Canada & Health Canada, 2010c). In making this decision, Health Canada and Environment Canada neglected to consider the specific effects such a chemical could have on women's health (Tilman, 2010a).

Table 8. Excerpt from the risk assessment developed by Environment Canada and Health Canada in relation to intakes of BHA from dermal exposure to frequently used personal care products *(Environment Canada & Health Canada, 2010c, p. 19)*

Product	Intake (mg/kg-bw per day)[1]	
	Average	Maximum
Men		
Shaving cream	0.000141	0.000141 (all shaving preparations are in 0–0.1% range)
Aftershave	0.000 846	0.000 846 (all shaving preparations are in 0–0.1% range)
Hair gel	0.000 207	0.002 07
Deodorant spray	0.003 66	0.003 66 (all deodorants are in 0–0.1% range)
Shampoo	0.001	0.004 32 (using 0.43% BHA, 95th percentile)

Total	0.006	0.01
Women[3]		
Deodorant spray	0.003 66	0.00 366 (all deodorants are in 0–0.1% range)
Facial makeup	0.0005 64	0.005 64
Eau de toilette	0.001 28	28 (no fragrances in this range; used value for 0–0.1% range)
Hairspray	0.000 507	0.005 07
Face cleanser	0.000 352	0.003 52
Face cream, applied twice daily	0.001 13	0.003 72 (using 0.33% BHA, 95th percentile)
Body lotion, applied twice daily	0.0113	0.0372 (using 0.33% BHA, 95th percentile)
Shampoo	0.001	0.004 32 (using 0.43% BHA, 95th percentile)
Total	0.02	0.06

[1] Average intake assumes that the BHA content is 0.1%. The majority of products were in this category. Maximum intake assumes that the BHA content is 1%, unless otherwise specified. Dermal absorption is 5% (Schumann 1991).

[2] Shampoo assumed to be used on alternate days.

[3] Other products used on a daily basis include eye shadow, mascara and eyeliner. Their contribution to total intake is negligible. Oral exposure from lipstick is negligible in comparison with exposure from food (Appendix 1).

HBCD (flame retardant, CAS RN No. 3194-55-6)

Cyclododecane, 1,2,5,6,9,10-hexabromo-, also known as hexabromocyclododecane or HBCD, is the third most commonly-used brominated flame retardant globally. It is found in polystyrene foam insulation used in building materials, textiles such as upholstered furniture, upholstery seating in transportation, wall coverings and draperies, and other products such as some glues, paints, adhesives, plastics and electronic goods (Environment Canada & Health Canada, 2010d). HBCD was identified in the CMP Screening Assessment Pilot Project initiated in 2001 to address 123 high priority chemicals suspected to meet categorization criteria of toxicity and targeted for screening level risk assessment before categorization results were finalized (Government of Canada, 2010b). In the CMP draft screening assessment, the Government recommended that the chemical be added to Schedule 1 because it is entering the environment in a quantity or under conditions that constitute a danger to the environment, but is not harmful to the health of the general population at current levels of exposure (the final screening assessment is not yet available) (Environment Canada & Health Canada, 2010d). As a result of this decision, even though HBCD will be listed as toxic under CEPA, the risk management measures that come into place for the chemical will not have to include mandatory management for effects related to human health.

This is despite animal and wildlife studies that have shown reproductive, developmental and behavioural effects, some of which are transgenerational in nature, including endocrine disruption, interferences to the pituitary and thyroid glands, and decreased fertility. Further, many of these effects are noted to be restricted to females (Chengelis, 2001; Ema et al., 2008; Van der Ven et al., 2006). Additionally, HBCD is being reviewed by the Persistent Organic Pollutants Review Committee established under the Stockholm Convention on Persistent Organic Pollutants (POPs) , and may be added to the Convention as early as 2013 at the Sixth Conference of the Parties (Stockholm Convention on POPs, 2008).

The Government decision on HBCD is especially troubling as the assessment neglects to consider the full range of vulnerable populations, other than infants, who are unintentionally and unknowingly exposed to HBCD as a result of its persistence in air, water and soil. Even though it is known to be a long-range transport chemical with a strong potential to bioaccumulate and biomagnify up the food chain, the assessment did not look at how this transport might affect northern communities and Aboriginal women who are exposed to the chemical through traditional food sources (Environment Canada & Health Canada, 2010d; ITK, 2010a). Estimates of intake of HBCD from food are based on concentrations identified in a market-based survey of U.S. food commodities and reflect common food consumption in North America (Schecter et al., 2009). Fish was singled out as a food of particular concern, with a value based on levels of HBCD in lake trout from Lake Ontario (Alaee et al., 2004). These estimates neither account for the amount of fish eaten by women as a traditional food source in northern communities, nor the higher concentrations of HBCD that would bioaccumulate in fish in these northern environments. Furthermore, the assessment of HBCD asserted that the most highly exposed subpopulation of the general population of Canada was breast-fed infants of 0-6 months of age (Environment Canada & Health Canada, 2010d). The assessment fails to address the burden women in northern communities must carry in the transfer of elevated amounts of HBCD through their breast milk (Environment Canada & Health Canada, 2010d).

BURDENS OF MANAGING RISK FALL ON WOMEN

To date, the CMP process has fallen short in its mandate to reduce and ultimately eliminate toxic chemical exposures, with a number of harmful chemicals still on the market as ingredients in a range of products (Tilman & Ford, 2010). Reducing exposures has instead become the duty of individual Canadians, with the burden often placed on women to navigate product safety and to limit chemical exposures to themselves and their families.

LABELING AND PRECAUTIONARY CONSUMPTION

Calls for effective "labeling" of consumer products containing toxic substances has become a common demand of groups seeking policy change around toxics (Boyd, 2010; David Suzuki Foundation, 2010; Deacon, 2011; Smith & Lourie, 2009). These demands are usually voiced in the language of the consumer's "right-to-know" about the contents of the products they use, so that the public may make informed decisions about their purchases. The calls for labeling, however, serve short-term needs and ultimately encourage practices of *precautionary consumption*, where, instead of ensuring that chemicals are eliminated from various consumer products based on their risk of exposure and harm to individuals, the responsibility is instead placed on the consumer to make decisions on products based on what they believe is healthy and safe (Altman et al., 2008; MacKendrick, 2011). Because women are often the primary caregivers within the home and family, and usually control household consumption, the burden of this individualized regulatory regime, and the duty to make informed choices, often falls on women. This practice reinforces women's socially prescribed roles as providers for the household, adding to their 'care burden' from both a physical and emotional perspective, and contributing to the gendered divisions of labour and exploitation of women's unpaid work in the home (Buckingham & Kulcur, 2009; MacGregor, 2010; Picchio, 1992; The Source Women's Health Data Directory (The Source), 2011b).

Further, practices of precautionary consumption cannot guarantee reduced exposures or fewer adverse health outcomes. Exposures to a certain chemical could theoretically be avoided by staying away from certain types of products once labeled, but exposures to the same chemical might occur as additives or residues in other consumer products that are unlabeled. The stakes for women are high, as personal care and cleaning products are heavily marketed towards, and used by, women, thereby increasing women's exposure to harmful chemicals (MacKendrick, 2011). See Box F for an example. Exposure can also come about through general environmental contamination, which appears in low levels in food and dust and are not accounted for through labeling practices (CDC, 2009; Environmental Defence, 2009; McClenaghan et al., 2003)

Precautionary consumption also raises equity concerns, as we know that women will vary in their capacities to engage in informed decision making around product purchases based on levels of education, income, language proficiency, scientific literacy, time and geography. As a result, precautionary consumption is more likely to happen within groups with higher socioeconomic and education status who are able to obtain alternatives that are not affordable to all Canadians - a particular concern for women who make up the majority of Canada's poor (Chakravartty, 2010; MacKendrick, 2011). Labeling is also a policy response that fails to address the production of chemicals, and their use in manufacturing processes, that may have impacts on workers or on communities in which those facilities are located.

An effective policy of applying SGBA would take into account intersecting identities of both men and women and be more sensitive to how burdens of exposure might be placed on women as a result of their societal roles and responsibilities. This type of social analysis is regrettably missing from assessments of chemicals within the CMP, ultimately encouraging the burden of risk management to fall disproportionately onto women. Regulatory frameworks, as well as the campaigns of environmental non-governmental organizations (ENGOs), need to shift from those of individual action to ideas of collectivized care that emphasize public decision-making and government policy and work to support and protect all women (MacGregor, 2010).

BOX F: WHERE PRECAUTIONARY CONSUMPTION FALLS SHORT

1,4-Dioxane (solvent and unintentional ingredient, CAS RN No. 123-91-1)

1,4-dioxane is a synthetic substance which is used intentionally as a solvent in the production of pharmaceuticals, fats, waxes, varnishes, cleaning and detergent preparations, adhesives, and cosmetics. It is also found as an unintentional ingredient in many products: residual 1,4-dioxane is formed during the production of ethoxylated substances used in a variety of applications including cosmetics, shampoos, moisturizers, lotions, detergents, food packaging, agricultural products and industrial processes. It has been classified by a number of international bodies as a probable human carcinogen, due to animal study evidence suggesting

effects on the liver, breast, nasal cavity and lungs. Reproductive and immunological effects have also been observed in studies with mice (Environment Canada & Health Canada, 2010a; International Agency for Research on Cancer (IARC), 1999; US EPA, 1990).

Based on the Federal Government's categorization process, 1,4-dioxane was determined to be a high priority for assessment with respect to human health. In the draft screening assessment and final screening assessment of the CMP for 1,4-dioxane, assessors noted that because of factors such as frequency of use, women were the most exposed group, and accordingly, only the exposure estimates for women and children were presented in the final screening assessment report. The final report looked at a total of 6 types of products (Environment Canada & Health Canada, 2010a). The assessors noted that there is uncertainty associated with concentration of 1,4-dioxane as a residual chemical in some product types available in Canada, due to the limited information on the presence or concentrations of the substance in consumer products, as well as uncertainties about how it may contribute to general population exposure and possible health effects (Environment Canada & Health Canada, 2010a).

Despite these uncertainties and the greater risk of exposure for women, assessors concluded that 1,4-dioxane does not meet any criteria to be considered toxic under CEPA. This conclusion was made because the margins between upper-bounding estimates of exposure selected by the Government, and lower-bounding estimates of critical effects levels for cancer and non-cancer outcomes, are considered to be adequately protective to account for uncertainties in the human health risk assessment (See Figure 1 on pg. 22) Of course, this result assumes confidence in the completeness of the information collected on both exposure and effects (Environment Canada & Health Canada, 2010a).

In place of being listed as toxic, 1,4-dioxane is listed on the 'Cosmetic Ingredient Hotlist' **(see Box O on pg. 24),** an official list of prohibited and restricted cosmetic ingredients published by Health Canada to assist companies in ensuring the safety of cosmetic products and other personal care products (Health Canada, 2011a). On the list, 1,4-dioxane's intentional use as an ingredient in cosmetics is prohibited, but its presence as an impurity is not. As a result, even though 1,4-dioxane has been detected as a by-product in over 46% of personal care products tested, it is rarely listed as an ingredient. Such a case demonstrates the serious limitations of precautionary consumption, as well as its gendered burden, as most products containing the byproduct are marketed primarily for use by women and 25% of all women report using at least 15 products daily, many of which contain this chemical (ITK, 2010b).

WHY THE CMP IS FAILING CANADIAN WOMEN

There are various elements of the CMP that have demonstrated neglect of sex and gender considerations in the chemicals assessment and management process. The current assessment process under the CMP employs inadequate endpoints, dated assessment methodologies, suffers from several data gaps, and is hindered by a lack of legislative requirements for examining cumulative and delayed chemical effects. Further, fragmentation in the regulatory regime means that occupational exposures are not included in overall exposure estimates. Finally, there are restrictions in public participation, inadequate risk management measures, and a lack of a precautionary approach. As a result of weaknesses in the process, health issues unique to women are not appropriately recognized or researched, women's voices have been left out of important decisions about their health, and Canada is not advancing towards a more inclusive chemicals management regime. Only in acknowledging and properly addressing these gaps in the assessment and management of chemicals will the federal government be able to provide a comprehensive tool that adequately integrates sex and gender concerns.

INADEQUATE ENDPOINTS

The CMP falls short in its inclusion of women in part because of the specific health endpoints the Government has focused on in their chemical assessments. A toxicity hazard endpoint is a biological event used to determine when a change in the normal function of the human body occurs as a result of toxic exposure. Such an event can include the growth of cancerous tumours, or the development of reproductive irregularities (e.g. infertility, miscarriage). Under section 64 of CEPA, the government is required to assess substances for carcinogenicity, mutagenicity, developmental toxicity and reproductive toxicity, "endpoints" for evaluating a chemical's effect on human health (Government of Canada, 2010a). Despite this mandate, critics allege that the Government's assessment and management decisions have been based almost exclusively on carcinogenicity and have neglected endpoints that may have more importance to women's health (McClenaghan et al., 2003; Tilman, 2010a). Box G offers examples of chemicals where specific endpoints were not acknowledged.

BOX G: EXAMPLES OF CHEMICALS WHERE SPECIFIC ENDPOINTS WERE NOT ACKNOWLEDGED

BHA revisited

In The Challenge, the Government concluded that BHA does not harm human health or the environment, and has therefore proposed no further action on the substance (Environment Canada & Health Canada, 2010c). The draft screening and final assessments of BHA mainly focused on carcinogenic effects to human health as the endpoint of concern, thereby failing to place any emphasis on its endocrine disrupting qualities and estrogenic effects related to reproduction and development (Tilman, 2010a). Although limited studies on BHA associated with endocrine disruption and reproductive and developmental effects were included in the assessment, those studies pointed to changes in endocrine measures, effects on the thyroid and adrenal gland, and altered sex hormones following oral dosing (Environment Canada & Health Canada, 2010c).

Formamide (industrial chemical, CAS RN No. 75-12-7)

Formamide, an industrial chemical used in the crystallization of pharmaceuticals, in soil stabilization, as a solvent in inks, as a component of liquid fertilizers, and as a monomer in some personal care products, was not deemed toxic in its final assessment under the CMP (Environment Canada & Health Canada, 2009c). Based principally on the weight-of-evidence approach of international and national agencies, a critical effect for the characterization of risk to human health for formamide is carcinogenicity. Comparison of the lowest effect levels for non-cancer critical effects with the upper-bounding estimate of intake of formamide yields margins of exposure that are considered by Environment Canada and Health Canada to be adequately protective for non-cancer effects of reproductive and developmental toxicity **(See Figure 1 on pg. 22)**. This is despite the fact that the European Union (EU) classified formamide as a reproductive and developmental Category 2 substance which may cause harm to the fetus, and animal studies have shown that exposure to the chemical can lead to reproductive, developmental and haematological toxicity (Fail et al., 1998; National Toxicology Program (NTP, US), 2008). Animal studies have also demonstrated formamide to cause maternal toxicity and harm to the fetus through both oral and dermal exposures (George et al., 2002; Stula & Krauss, 1977; Tilman, 2009). The confidence in the toxicity data for formamide is considered to be only moderate, with limited inhalation exposure studies and no elaboration on modes of action for carcinogenicity (Environment Canada & Health Canada, 2009c). A greater focus on non-cancer effects of formamide, including reproductive and developmental toxicity, is needed in order to create a more comprehensive assessment of the chemical and to address the uncertainty of data gathered.

ENDOCRINE DISRUPTION AND EPIGENETICS

Chemical assessment decisions neglect the bigger pool of toxicological endpoints specific to sex and gender including neurodevelopmental impacts, and hormonal and endocrine disrupting effects. Endocrine disruption potential is not

explicitly requested in mandatory surveys conducted under section 71 for chemicals targeted under The Challenge; nor is it included under the voluntary questionnaire (CELA/CSM, 2010c; Tilman et al., 2010). Detailed knowledge about exposure to endocrine disruption and their potential health effects exists for only a handful of substances under the CMP (e.g. bisphenol A (BPA)) even though endocrine disruptive potential is suspected for many more substances, and few chemicals in use have been thoroughly tested for endocrine disrupting effects due to traditional toxicological testing protocols that are not designed to test for such mechanisms or do not test at ambient or low exposure levels (Cooper & Vanderlinden, 2009; TEDX, 2011).

Beyond physical changes to the body, evidence has demonstrated that endocrine disrupting chemicals can have an impact on the imprinting of genes (known as 'epigenetic changes') (Crews & McLauchlan, 2006; TEDX, 2011). Exposure to endocrine disruptors can alter genome phenotypes and lead to the turning on or off of methyl groups (DNA methylation) and histones controlling gene expression. These changes can lead to detrimental impacts on a person's health and the health of their children, contributing to the development of cancer and other diseases later in life (Crews & McLauchlan, 2006; Eyles et al., 2011; Gray et al., 2010; Kloc, 2011; TEDX, 2011). A growing body of knowledge suggests that epigenetic effects extend to gender differences in brain function and behaviour. Many psychiatric and neurodevelopmental disorders (such as depression and autism) that are controlled by hormones and often manifest after critical windows of vulnerability, show significant gender differences in relative risk level and severity (Crews & McLauchlan, 2006). Box H offers an example of why the Government should consider endocrine disruption as an endpoint in chemical assessments under the CMP.

BOX H: THE NEED FOR NEW GENDER-SENSITIVE ENDPOINTS

The role of endocrine disruption in breast cancer

Overwhelming evidence has accumulated indicating that the presence of low concentrations of certain chemicals during critical windows of development can damage the endocrine system of our bodies by binding hormone transport proteins or other proteins involved in signaling pathways, inhibiting or inducing enzymes, interfering with uptake and export from cells, and modifying gene expression through epigenetic mechanisms. Endocrine disruption can interfere with the network of natural chemical interactions critical to healthy development and normal function, and lead to a number of diseases and disorders such as breast cancer in women (Colborn et al., 1996; Crews & McLachlan, 2006; Gray et al., 2010; TEDX, 2011). This is of key concern in Canada, as we have among the highest breast cancer incidence in the world, with breast cancer being the leading form of cancer diagnosed in women (Canadian Breast Cancer Foundation, 2010; Gaudette et al., 1996; The Source, 2011a).

Through a number of laboratory studies with animal and cell cultures, and with the support of epidemiological data, the exposure of mammary tissue to endocrine disrupting chemicals during critical periods of development has been shown to alter mammary gland development and increase susceptibility to future carcinogen exposure in the breasts. These studies have demonstrated that chemicals contributing to breast cancer risk also shorten human gestation, lower birth weight, increase the risk of obesity and insulin dysregulation, and are associated with earlier sexual maturation in girls. As a result, one of the main endpoints for assessing chemicals relevant to breast cancer is the testing of endocrine-disrupting chemicals for their potential effects on breast tissue during critical periods of development (Gray et al., 2010; Schwarzman & Janssen, 2010). Such an analysis requires the dismissal of linear approaches to toxicological assessment and would instead require the study of effects of low-dose exposures to chemicals throughout all life stages. In order to collect these data, it is also critical that animal studies on carcinogenicity use both male and female subjects.

In considering experimental models for breast cancer, it is important for testing to identify alterations in biological processes relevant to breast cancer, including cell cycle changes, genotoxicity, endocrine disruption (including suppression or activation of gene expression) and altered mammary gland development and maturation, as well as reproductive events that might increase the susceptibility of the mammary gland to cancer. A chemical does not have to test positive in all categories listed above to act as a breast carcinogen, and a null finding from one test should not be interpreted to mean a chemical is safe until it has been evaluated by the other tests (Crews & McLachlan, 2006; Schwarzman & Janssen, 2010).

CONTESTED ILLNESSES

A number of studies have also demonstrated a relationship between early life exposures to endocrine disrupting chemicals and contested diseases and disorders for which incidence has increased dramatically over the last two decades, especially in women (Brown, 2007; Crews & McLachlan, 2006; Gray et al., 2010; Program on Reproductive Health and the Environment, 2008; TEDX, 2011). Breast and thyroid cancer, multiple chemical sensitivity, fibromyalgia, and autoimmune diseases produce

symptoms that are often ignored or poorly understood by traditional medical practitioners, and have delayed diagnoses, which results in women having unequal access to services that include health care and acquiring or qualifying for insurance and disability (Butter, 2006; Genuis, 2010). Some of the reproductive diseases are risk factors for infertility, and complications with pregnancy. See Box I for a description of multiple chemical sensitivity and its connection to chemicals management and women's health.

It is important that additional data be gathered for toxicity hazard endpoints such as endocrine disruption, chronic toxicity, developmental and neurodevelopmental toxicity, and contested illnesses, even if it means conducting new biomonitoring studies and laboratory tests, in order to account for sex- and gender-specific effects of chemical exposure (Crews & McLachlan, 2006; de Leon et al., 2010).

BOX I: MULTIPLE CHEMICAL SENSITIVITY (MCS) AND UNDERSTUDIED ILLNESSES CONNECTED TO SEX AND GENDER

Multiple chemical sensitivity (MCS), also known as environmental sensitivity/intolerance, describes an acquired environment-linked condition which manifests as a variety of reactions to substances at exposure levels commonly tolerated by many people (Environment and Health Clinic, 2010; Sears, 2007). MCS often stems from an initiating toxic exposure - either developing gradually after chronic exposure to relatively low levels of chemicals, or suddenly after a major exposure to an environmental disaster, a chemical spill in the workplace, or other physiologic trauma (Genuis, 2010; Sears, 2007). This initial exposure leads to a toxicant-induced loss of tolerance (TILT) and hypersensitivity to low levels of diverse and unrelated triggers in the environment, including scented products, cleaning products, laundry detergents, foods, mold, electromagnetic radiation, paints, petrochemicals, cigarette smoke, pesticides, and fuels (Environmental Health Association of Quebec, 2009; Environmental Health Clinic, 2010; Genuis, 2010). The degree of impaired tolerance often parallels the intensity of the total body burden of toxic chemicals that have accumulated in an individual. Symptoms from subsequent triggers can occur throughout the body, may involve various organ systems, and can evoke wide-ranging physical or neuropsychological effects. These responses are highly individual, and depend on both a person's genomic status and how their toxic burden affects their immune response (Environmental Health Association of Quebec, 2009; Genuis, 2010; Phillips, 2010). Approximately 3% of Canadians have been diagnosed with environmental sensitivities, and 15-30% of the population exhibits milder forms of sensitivity. Of those diagnosed, approximately 60-80% are women (Sears, 2007).

Although there is a growing consensus in the medical community and society at large that chemicals in the environment are of concern, and there is emerging evidence related to the mechanisms of MCS, environmental sensitivities are neither universally recognized nor fully understood, and resistance to MCS as a recognized illness is still widespread in medical circles (Genuis, 2010; Sears, 2007). Many see MCS as a psychosomatic disorder, and those who do take the disease seriously tend to be ostracized by the medical community, lose credibility as practitioners, and receive limited financial support because their beliefs challenge traditional frameworks of diagnosis and understandings of how bodies react to the environment (Phillips, 2010). Additionally, many conventional medical doctors have not been trained to recognize or treat environmental sensitivities, often confusing it with other conditions, or managing symptoms through medications that fail to deal with the causes of the problem. Hospitals and other healthcare settings are rarely equipped to accommodate persons with sensitivities.

Even though research has shown that symptoms are linked to chemical exposure, and that the removal of toxic triggers and the elimination of toxic body burdens are not only essential steps to improving health in MCS patients but can in fact reverse the disease, understudied illnesses such as MCS continue to be ignored by the human health assessments under the CMP. In fact, MCS highlights systemic weaknesses in our approach to toxic chemicals regulation overall: it brings into question the assumption that we can identify critical health effect levels that apply across the population.Conditions such as MCS can lead to individuals experiencing lower critical effect levels as a result of their chemical sensitivity **(see Figure 1 on pg. 22).** It is clear that any meaningful consideration of sex and gender considerations in the CMP process would require attention to the influence endocrine disruption might have on the increasing incidence of MCS and other similar disorders (Genuis, 2010).

USE OF DATED ASSESSMENT METHODOLOGIES

New theoretical considerations around toxicology and modes of action of various chemicals challenge pre-existing assessment methodologies presently used under the CMP. Current risk assessments are based on a number of assumptions. Two key assumptions are: (1) the greater the dose of chemical exposure, the greater the harm to human health, and (2) human bodies can safely accommodate some degree of chemical exposure based on the idea of "thresholds." New research now shows that a number of chemicals, including endocrine disruptors, can cause adverse health impacts at low doses, can increase risk at any level of exposure (especially during critical windows of

development), and can have different modes of action (eg. epigenetic effects) that lead to diverse health outcomes (Hanahan & Weinberg, 2000; McClenaghan et al., 2003; Thornton, 2000; vom Saal & Sheehan, 1998). As a result, the accepted assessment approach is inadequate in ensuring the safety of Canadians, and the health of women in particular.

GAPS IN RESEARCH DATA

UNCERTAINTIES AND DEFICIENCIES IN EVALUATION

Inconsistent and insufficient data coupled with methodological and analytical shortcomings of draft and final risk assessment documents contribute to difficulty in ascertaining health outcomes that are sex and gender specific (McClenaghan et al., 2003). Frequent data gaps exist in information collected for high priority chemicals with respect to hazard, exposure scenarios, and use applications. Numerous questions still go unanswered in assessments, including what constitutes a high and low dose, the timing of exposures, the delayed effects of exposure, and confounding variables. Evaluations of adverse effect levels are largely inferred from animal studies, and are very seldom based on human epidemiological data. Some studies have been found to be deficient or of low reliability based on highly uncertain modeling data, or not following scientific protocol, yet they have still been seen as having satisfactory confidence (McClenaghan et al., 2003; Tilman, 2010b; Tilman et al., 2010). In a number of cases, risk assessments have been critiqued for the practice of filling information gaps with informed guesswork, and using discretion where there was limited information - therefore leading to a no-risk conclusion and justifying a refusal to regulate (Cooper & Vanderlinden, 2009; Gray et al., 2010). These weaknesses in data collection and methodology highlight the need for comprehensive monitoring and new research that is both current and addresses sex and gender concerns (Chakravartty, 2010). The absence of such information, however, should not prevent the Government from taking action to protect Canadians more fully from these chemicals through precautionary measures. See Box J for a description of the types of uncertainties found in risk assessments of chemicals under the CMP, and Box K for an example of the data gaps that can exist within an assessment.

BOX J: COMPOUNDED UNCERTAINTIES

Following the characterization of risk of a given chemical to the environment and human health, risk assessment documents often have a section on the uncertainties in evaluation of these risks.

These uncertainties can include:

- The persistence and bioaccumulation of the substance
- The types of products containing the substance
- The types of exposure (oral, dermal, etc.)
- Estimations of exposure and intake of a substance (dose and use level)
- Combinations of exposures from different products/sources/similar chemical compounds
- Overall confidence in toxicity data (limits in research, studies conducted)

A number of assessments conclude that the confidence in toxicity data is moderate or low, and that additional studies to further characterize toxicity would reduce uncertainties in an assessment. Despite these observed gaps in the data and uncertainties around the strength of the research, many of these screening assessments still conclude that the chemical being evaluated does not meet the criteria for declaring a substance toxic under CEPA. The accumulation of uncertainties within each chemical assessment makes the need for a greater adherence to the precautionary principle in the CMP even more critical. Where there is inadequate information or understanding around the characteristics of a certain chemical, its interaction with biological processes, and its use and manufacture within Canada, the Government should be taking precautionary measures to protect the long-term health of all Canadians. As the regulatory process currently stands, it is not clear how the Government makes its conclusions for each assessment once significant uncertainties in evaluation have been identified.

BOX K: DATA GAPS IN RISK ASSESSMENTS

1,4-dioxane revisited

1,4-dioxane offers a case where there were numerous gaps in information needed to properly assess the chemical's risk to human health. Not only are very few personal care products examined for the presence and concentrations of 1,4-dioxane in the draft screening and final assessment, but there is also little consideration of contributions to exposures from other sources, such as food and household products, where exposures to women might also be significant (Environment Canada & Health Canada, 2010a; ITK, 2010b; Richardson & Tilman, 2009)…When evidence in the draft screening assessment was questioned, no obvious efforts were made by assessors to require submission of additional data (through monitoring, submission of experimental data to replace data derived from an analogue, or incorporation of occupational exposure data) from affected industry for the final assessment and risk management measures (CELA/CSM, 2010a).

INSUFFICIENT DATA ON GENDER-SPECIFIC RESPONSES TO EXPOSURE

Studies used by Health Canada to assess chemicals under the CMP rarely focus on gender-specific responses to exposure, and physical effects on women are often only measured in relation to the health of the fetus and newborns. A recent study shows that more than 90 percent of research in the lab is still being done using male rats and mice, even in the study of diseases that disproportionately affect women (Pigg, 2011). This dependency and the lack of critical reflection on research practices in clinical studies may hamper efforts to understand the unique biological effects of chemical exposure on women, and to tackle diseases that affect women more than men through more inclusive science and health policy.

LACK OF SEX- AND GENDER-DISAGGREGATED DATA

Finally, while there are some assessments that separate data on chemical use or exposure based on sex (sex- and gender-'disaggregated' data), such as the screening assessment of BHA, the Government has yet to do anything useful with these results and continues to apply a mean all-person daily intake approach for many substances (Environment Canada & Health Canada, 2010a). There is a critical need for more disaggregated data to be made available, to be incorporated into a greater number of chemical assessments, and to be sufficiently considered in final decisions if a comprehensive SGBA is to be achieved by researchers and assessors (Clow et al., 2009).

NO LEGISLATIVE REQUIREMENTS TO CONSIDER POSSIBLE CUMULATIVE, SYNERGISTIC, OR DELAYED EFFECTS

Research has demonstrated that exposure to a mixture of chemicals can be much more toxic than exposure to chemicals on an individual basis (Eyles et al., 2011; Program on Reproductive Health and the Environment, 2008). With the exception of a limited number of chemical ingredients in pesticides under the Pest Control Products Act, chemicals management policy in Canada remains committed to the unsatisfactory and narrow practice of examining the effects of chemicals one at a time, with a lack of consideration for real-world circumstances of exposure to multiple chemicals and little reflection on long-term studies of health and environmental impacts. Assessments rarely acknowledge that certain chemicals might interact in combination with other chemicals in the environment to produce effects that none could produce on their own, and that cumulative or aggregate impacts are possible in relation to other environmental stressors (McClenaghan et al., 2003). As Colborn et al. (1996) state:

Regulating as if chemicals act only individually is as unrealistic as assuming that a batter in a baseball game can only score a run for his team if he hits a home run. In real life and in baseball, the bases may already be loaded and a single could well be enough (p. 220).

All of this is relevant and important as we characterize actual exposures and assess toxicity (Boyd, 2003; Eyles et al., 2011; Ginsburg & de Leon, 2007; Tilman et al., 2010).

CHEMICALS WITH SIMILAR MODES OF ACTION

In particular, the potential for multiple exposures to chemicals with a common mechanism of toxicity (or "mode of action") calls for attention to the effects of mixtures (Scott, 2008). Some substances that belong to the same chemical class or family may have similar toxicity impacts and use patterns, and additive or cumulative effects for these chemicals need to be included in chemical assessments (CELA/CSM, 2010a). See Box L for an example of how chemicals with the same mode of action might require a more comprehensive risk assessment.

BOX L: THE IMPLICATIONS OF A CHEMICAL-BY-CHEMICAL APPROACH

Dodecamethylcyclohexasiloxane (D6) (volatile organic compound, CAS RN No. 540-97-6)

Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane, (D5) and Dodecamethylcyclohexasiloxane (D6) are volatile organic compounds (VOCs) primarily used to make silicone polymers that form ingredients for personal care products such as deodorants, hair care products, sunscreen, and antiperspirants. Additional uses include plastic products, silicone rubber consumer products such as pacifiers, pharmaceuticals, lubricants, polishes and coatings for textiles, carpeting and paper, sealants and adhesives, architectural coatings, mechanical, heat transfer, and dielectric fluids, surfactants and defoamers. D4 is found in nearly 100 cosmetic products in Canada, D5 in nearly 3,000 and D6 in about 530. In addition, about 6,000 cyclomethicone-containing cosmetics contain these siloxanes (Environment Canada & Health Canada, 2008d; Environment Canada & Health Canada, 2008e; Environment Canada & Health Canada, 2008f).

Assessments for D4 and D5 linked these chemicals to possible reproductive toxicity, as well as found them to be harmful to the environment (Environment Canada & Health Canada, 2008d;

Environment Canada & Health Canada, 2008e). While the final assessment results for D4 and D5 supported the finding that they were toxic under CEPA, the determination of D6 did not, and to date only D4 has been added to Schedule 1 (Environment Canada & Health Canada, 2008d; Environment Canada & Health Canada, 2008f). Even though the liver was identified as a target organ for exposure, the screening assessment for D6 stated that the comparison of the critical effect level for repeated dosage effects via the oral route and the upper-bounding estimates of daily intake of D6 by the general population in Canada results in an adequate margin of exposure (See Figure 1) (Dow Corning, 2006; Environment Canada & Health Canada, 2008e). This is despite the fact that assessors' confidence in the estimate of systemic dosages of D6 through the use of personal care products was low, as all estimates were made by the use of models, and the use pattern data were not from Canadian studies. The confidence in the toxicity database was also low, as there was limited information on acute, short-term, developmental, reproductive and genotoxicity data; a lack of subchronic and chronic toxicity/carcinogenicity data; and no data based on inhalation or dermal exposures (Environment Canada & Health Canada, 2008e). Calculations for D4 showed that the estimated adult female dose was much higher than that for adult males, chiefly because of leave-on skin care products marketed for and used by women.

Aside from the uncertainties about confidence of estimates of exposure to D6, assessment of the chemical failed to consider the possible cumulative and synergistic effects of all three cyclosiloxane chemicals, in light of their similarity in structure and the fact that common toxic effects may be expected. The content of cyclosiloxanes in any individual product may be low, but people can experience higher concentrations of this chemical group in the body due to the number of cyclosiloxane-containing products used daily, and their accumulated exposures over a lifetime. D6 is often detected in the polysiloxane mixtures that include D4 and D5 and assessments have yet to explore the interaction and cumulative impact this may present. The difference in exposure based on gender means that additive effects of polysiloxanes could be particularly problematic for women. There is also the possibility that exposures to D6 might increase as manufacturers make substitutions for the other chemicals in the same class that have now been identified as toxic. A lack of consideration of the cumulative and synergistic impacts of D4, D5 and D6 and other substances that have similar use functions, is therefore a significant gap in the current government risk-based assessment process (CELA/CSM, 2009).

DELAYED EFFECTS OF EXPOSURE

Little research has been done on the long-term effects of chemical exposure on health and the environment. Other than the Maternal-Infant Research on Environmental Chemicals (MIREC) study, a longitudinal investigation following exposures in pregnant women, the government has not demonstrated a commitment to long-term biomonitoring initiatives that could deliver reliable evidence about the effects of prenatal exposures to chemicals in the environment on the health of individuals later in life (Health Canada, 2010). There is a need for more long-term monitoring/biomonitoring studies that show the effects of exposures to specific chemicals at various windows of vulnerability, how those exposures affect gendered development and health later in life, and how a phase-out of a chemical can lead to a weakened association between exposure and negative health impacts (Cooper & Vanderlinden, 2009).

Long-term studies, coupled with new data generated around the cumulative and synergistic effects of chemical mixtures, are necessary in order to develop a better understanding of how such interactions affect sex and gender, and to properly inform chemical assessment and regulation.

LACK OF A REGIME FOR OCCUPATIONAL EXPOSURE

Occupational exposures to chemical substances can play a considerable role in exacerbating health disparities (Gupta & Ross, 2007). Occupational exposure is especially significant for women workers, as gender discrimination in the workplace, as well as gendered divisions in labour, often lead to inequalities in risk (Brophy et al., 2011, Messing et al., 2003). Because women are disproportionately in the low-income bracket, they are more likely to take on precarious employment and are found in greater numbers in hazardous work environments (Gupta & Ross, 2007). Occupations like automotive plastics manufacturing, agriculture, the beauty industry (e.g., nail and hair salons), cleaning and housekeeping services, and health care settings have a disproportionate number of women as employees. Female participation rates in the automotive parts industry in the Essex County area of Ontario ranges from 60-80%, and 9 out of 10 maids and housekeepers are women (Brophy et al., 2011; Gray et al., 2010). All of these workplaces bring women workers into direct contact with a number of harmful carcinogenic and endocrine-disrupting substances, such as additives, solvents, flame retardants, colourants, pesticides and detergents, sometimes at levels above what is considered safe (Brophy et al., 2011). Workers are also often exposed to a mixture of chemicals that may have harmful additive or synergistic effects on health.

WOMEN AND OCCUPATIONAL HEALTH AND SAFETY

Despite evidence that workers are getting sick from exposures and more studies are showing a connection between occupational exposure and disease, governments continue to fail at controlling or eliminating these health risks (Brophy et al., 2011). An exclusion of women from many occupational health studies and a lack of longitudinal studies make it difficult to evaluate relationships between gender-specific disease and occupational exposures, especially during windows of vulnerability (Thompson et al., 2005). Additionally, most occupational research on women reports risk by job type or title, rather than by specific exposures, which makes it difficult to draw direct connections between particular classes of chemicals and health outcomes (Gray et al., 2010).

These types of industrial workplaces also tend to be less regulated and have poor health and safety protections. Health and safety training is often incomplete, existing testing protocols are inadequate, and ventilation of workplaces is problematic or altogether absent. The precarious nature of work in these industries, with part-time and temporary arrangements, low pay and limited access to benefits, can have a chilling effect on efforts to gain occupational health improvements because of the fear of job loss (Brophy et al., 2011). Many of these jobs are held by new immigrants or racialized people who enjoy fewer legal protections, and less access to health care than the general population. These factors limit the ability of many to protect themselves from exposure or to seek medical care in response to chemically induced health problems (Bureau of Labor Statistics (BOLS), 2005; Gray et al., 2010; Jackson, 2004).

In addition to a lack of regulation and other health and safety protections, women tend to experience lower levels of unionization in the workplace. Women in the private services sector in particular tend to be paid less, and enjoy little protection via collective bargaining. Union coverage for women in this sector is almost half that of men, and the union wage premium is also slightly higher for men than women (Jackson, 2004). Low-paid women are less likely to belong to a union. This reflects continued job discrimination and under-valuation of women's work compared to that of men.

ABSENCE OF OCCUPATIONAL EXPOSURES FROM CHEMICAL ASSESSMENT

Currently, occupational exposures are excluded from risk assessments of chemicals under the CMP. Because occupational health and safety regulation falls under provincial jurisdiction, federal chemicals management fails to take occupational exposures into account when creating policy around potentially toxic chemicals, with significant gaps in the data and disjointed chemicals regulation and management. Negligible attention is paid to how the combination of exposures in the workplace, the home and the external environment might increase hazards to workers and elevate harm to human health (Brophy et al., 2011; Gray et al., 2010; McClenaghan et al., 2003). Figure 1 illustrates the ways in which timing of exposure, gendered vulnerabilities of exposure, occupational toxic loads and similar modes of action of various chemicals can culminate in a margin of exposure (MOE) that is much lower than what is often estimated by government risk assessments under the CMP.

In order to adequately address women's elevated vulnerability to toxic exposures in all environments and to allow for better correlations between exposures and health outcomes, it is important that occupational exposures be included in assessments of chemicals under the CMP and their impact on human health incorporated into understandings of risk.

RESTRICTED PUBLIC PARTICIPATION

Among the CMP's objectives is to provide enhanced risk communications to Canadians to ensure consistent, full access to up-to-date information. An opportunity for stakeholder involvement in the CMP is an important avenue for citizen engagement whereby the public can respond to draft risk assessments, final assessments, and risk management approaches released by Government. Current forms of engagement include public comment requirements under CEPA, such as an explicit 60-day comment period when draft risk assessment reports are released, and another 60-day comment period to respond to the draft risk documents or proposed listings of toxic chemicals to Schedule 1 (Government of Canada, 2010a). Unfortunately, as the public survey conducted by the National Network on Environments and Women's Health (NNEWH) in 2009/2010 demonstrates, Canadians still feel that they are not given enough access to information on chemical assessments, the CMP, biomonitoring, and chemical descriptions and uses. Moreover, the survey results illustrate that women's understanding and engagement within the CMP process is particularly limited or lacking, despite the importance of women's health in long-term decision-making under the scheme (Chakravartty, 2010; NNEWH, 2010). The absence of proper participation and public reporting spans a number of sectors of the Plan, including The Challenge, the Petroleum Sector Stream and both the Future Use Notification and the Significant New Activity approaches (Ginsburg & de Leon,

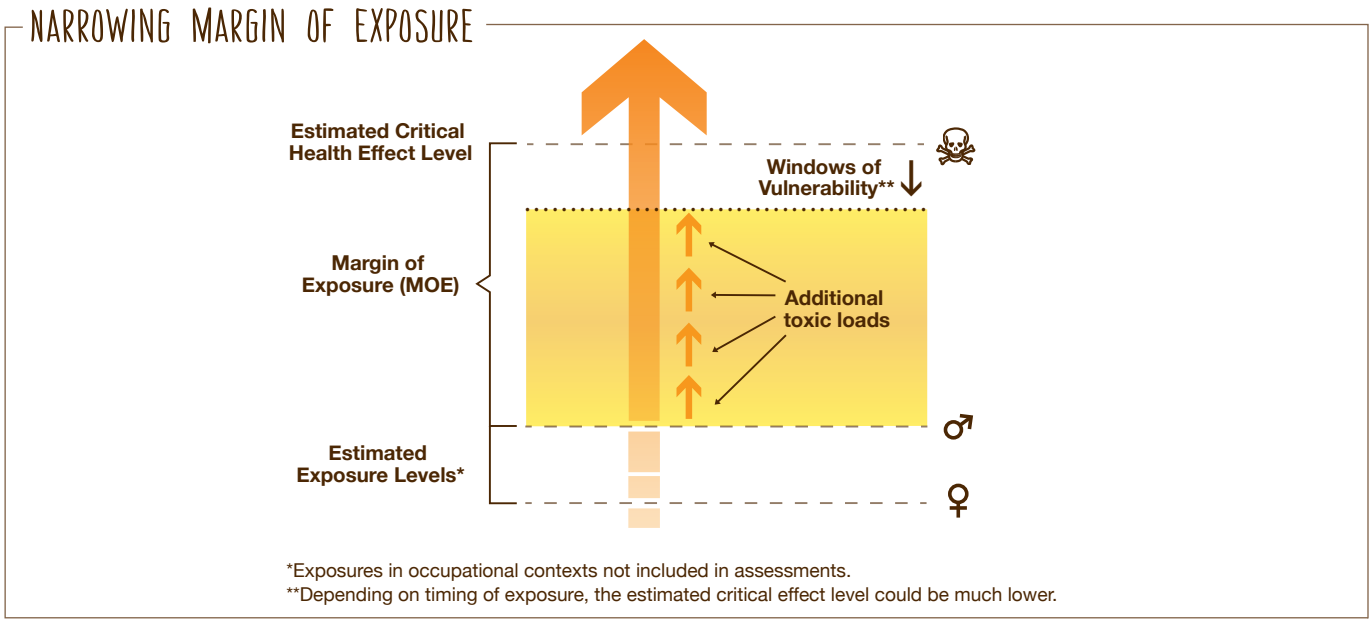

FIGURE 1: NARROWING THE MARGIN OF EXPOSURE

The above diagram illustrates the deficiencies in the margin of exposure (MOE) evaluation approach - a tool used by the Federal Government within a risk assessment to ascertain whether a chemical is CEPA-toxic by calculating the difference between the estimated critical health effect level of the chemical (the threshold at which a chemical is considered harmful to human health or the environment), and its estimated exposure level. This evaluation rarely takes into account the ways in which sex and gender considerations might influence margin values. For example, the estimated critical effect level of a chemical can be much lower for women depending on the timing of exposure, such as whether the exposure occurs during critical windows of vulnerability, or whether a person experiences a particular sensitivity.Moreover, the estimated exposure level can be elevated as a result of a woman's domestic responsibilities and her disproportionate contact with gender-specific products. Exposure levels would be even higher if additional toxic loads, such as occupational exposure, were included in chemical assessments. Finally, the MOE does not take into account chemicals that have similar modes of action. This includes chemicals with similar structures or substances with common mechanisms of toxicity that, when combined in the body, could exacerbate toxic effects. Considering all of these variables, it is likely that in many cases the MOE is vastly over-estimated, especially in relation to women's exposures.

2007). Additionally, with the funding cuts to the RCEN this fall (2011), there will no longer be a coordinated process that allows for public participation through NGO feedback.

A focus on precautionary consumption

The Government's approach, supported by the campaigns of various environmental NGOs, encourages Canadians to make changes to their individual consumption strategies, in accordance with their preferences. This type of practice encourages women to assume that their contribution to, and participation in, the regulation of chemicals is accomplished by "doing good shopping" for safe product choices (Boyd, 2010; David Suzuki Foundation, 2010; Deacon, 2011; Government of Canada, 2011b; Health Canada, 2011b; MacKendrick, 2011; Smith & Lourie, 2009). For example, despite the removal of BPA from baby bottles as a result of assessments deeming the chemical toxic, the Government's management decision does nothing to protect Canadians from exposures to BPA from other sources, including the lining of tin food cans and cash register receipts. The decision respecting the BPA ban further ignores workers' exposures to this chemical in, for example, the manufacturing of plastics (Environment Canada & Health Canada, 2008b). Box M offers more detail on BPA and its assessment under the CMP. In addition, this approach and the corresponding consumer campaigns only serve certain groups of Canadian women who have the financial means, time and education to make these informed decisions.

BOX M: PUBLIC PARTICIPATION AS PRECAUTIONARY CONSUMPTION

Bisphenol A (plastics and resin ingredient, CAS RN No. 80-05-7)

Phenol, 4,4' -(1-methylethylidene)bis-, or bisphenol A (BPA), was a substance identified as a high priority for action under The Challenge, since it was considered to pose the greatest potential for exposure to individuals in Canada and also met the ecological categorization criterion for inherent toxicity to aquatic organisms. BPA, an industrial chemical used to make hard, clear plastic such as polycarbonate, is found in many consumer products including reusable water bottles and baby bottles. It is also used in the manufacture of epoxy resins, which act as a protective lining on the inside of metal-based food and beverage cans (Environment Canada & Health Canada, 2008c). Studies have shown that the Canadian population experiences continual and widespread exposure to the chemical, with 91% of Canadians having BPA detected in their urine (Eyles et al., 2011).

The final assessment of BPA under the CMP found the substance to be a reproductive toxicant and concluded that bisphenol A met the criteria as both a human health and ecological priority substance under section 64 of CEPA 1999. BPA was subsequently added to Schedule 1 (Environment Canada & Health Canada, 2008c).

A LACK OF TRANSPARENCY

For women to be truly engaged in the CMP process, transparency in the decision-making practices of government officials around chemicals regulation is paramount. There is a need for a better understanding of what is found in products, the potential risks of chemical exposure in everyday environments, and how regulators have analyzed and compared the costs and benefits of potential risk management actions for each toxic chemical, in order for men and women alike to respond to government decisions on chemical management and regulation (de Leon et al., 2010). For example, the structure of the CMP allows for important decisions about the toxicity of chemicals to be based on confidential information or studies that are not peer-assessed (Scott, 2009; Tilman et al., 2010). Box N provides an example of an assessment that used a confidential study in its final decision. The use of confidential material and the lack of transparency shown, on the part of both industry and Government, is contrary to the basic principles of science and the democratic process, as such information can only be validated and seen as reliable when it is open to independent evaluation. Restricting public access to information impedes others from obtaining adequate information on a substance and assessing the quality of the data provided. This lack of transparency affects the ability to make decisions that adequately address the health and well-being of men and women (Tilman, 2010b).

Meaningful access and engagement of all Canadians in the CMP is crucial to the chemicals regulation process, in order to ensure that women's voices and concerns are adequately represented in future policy decisions, and understandings of sex and gender are appropriately considered in chemical assessments.

BOX N: ASSESSMENT DECISIONS BASED ON CONFIDENTIAL INFORMATION

PADMEC (industrial stabilizer, CAS RN No. 65140-91-2)

Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl] methyl]-, monoethyl ester, calcium salt (2:1), also known as PADMEC, is an industrial chemical used as a stabilizer in plastics, synthetic fibres, elastomers, adhesives, waxes, oils and fats. Prior to its assessment under the CMP, PADMEC was identified as a potential concern to the environment based on information regarding possible persistence, accumulation in organisms and potential to cause harm to organisms (Environment Canada & Health Canada, 2010e). Results of the draft screening assessment indicate that although PADMEC has the potential to remain in the environment for a long time, it is not expected to accumulate in organisms and is therefore not expected to cause harm to human health or ecosystems (Environment Canada & Health Canada, 2010e).

The draft screening assessment report for PADMEC includes a study supplied to the Government by a stakeholder who may import PADMEC into Canada in the future, but whose identity and usage data for the substance remain confidential. The initial assessment for the substance proposed that Significant New Activity Notification (SNAc) provisions be applied to PADMEC — a risk management tool that requires additional information from industry on the re-introduction or new use of existing chemicals under the CMP that might contribute to the amount, exposure level or toxicity of a chemical **(See Box O)** (Environment Canada, 2010b). The new unpublished confidential data, made up of empirical physical and chemical properties, persistence, bioaccumulation and ecotoxicity studies, indicated that PADMEC had a low potential to accumulate and the SNAc provisions were left out of the revised draft assessment. Confidentiality has also been applied to the disclosure of use patterns and potential new uses of PADMEC (Environment Canada & Health Canada, 2010e; Tilman, 2010b). As a result, public access to information is not available and the quality of

this information cannot be independently evaluated to ensure that all aspects of health and exposure, including those related to sex and gender, are considered.

AN EMPHASIS ON RISK MANAGEMENT OVER POLLUTION PREVENTION

The Federal Government made a clear commitment to pollution prevention in its management of toxic chemicals in the 1995 federal Pollution Prevention Strategy and as a cornerstone of CEPA 1999, but true pollution prevention has not featured in the CMP to date, especially in terms of preventing pollution at the source. Few pollution prevention plans have been proposed for high priority substances found to be toxic, with rare exceptions being BPA, toluene diisocyanates (TDIs), isoprene and D4 (Environment Canada & Health Canada, 2008a; Environment Canada & Health Canada, 2008b; Environment Canada & Health Canada, 2009a; Environment Canada & Health Canada, 2009b).

Instead, the Government's approach to risk management so far reveals a preference for non-regulatory mechanisms that have little legal standing, focusing action on end-of-the-pipe solutions, and generally aiming to maintain continuous chemical use with only slight reductions in releases (Chakravartty, 2010; de Leon et al., 2010). Actions such as Significant New Activity Notifications (SNAcs), additions to the Cosmetic Ingredient Hotlist, monitoring and biomonitoring do play some role in reducing exposures, but alone are not adequate in addressing hazards and risks posed by chemicals that have carcinogenic, reproductive, developmental, endocrine disrupting or neurodevelopmental effects, in many cases with disproportionate impacts on women (CELA/CSM, 2009). Box O describes some non-regulatory risk management tools used under the CMP and their limitations in protecting the public from harmful chemicals. These management approaches, as with the assessment process, do not require industry to submit data on vulnerable populations (such as women), chronic toxicity, endocrine disruption potential, neurotoxicity or cumulative/synergistic effects that might differentially affect women's health. Additionally, these mechanisms provide little information on what they involve, have only limited opportunities for the public to engage in subsequent assessments, and can permit the continued usage of a range of toxic chemicals (CELA/CSM, 2010b; de Leon et al., 2010). Finally, non-regulatory, end-of-pipe risk management is inadequate in achieving the overall goal of the CMP to eliminate or reduce toxic chemicals at the source (production, sale and use), identify safe alternatives, or remove inefficiencies in industrial processes (Government of Canada, 2010a).

BOX O: RISK MANAGEMENT TOOLS OFTEN SELECTED OVER POLLUTION PREVENTION APPROACHES

Significant New Activity Notifications (SNAcs)

There has been a trend towards issuing Significant New Activity Notifications (SNAcs) as a risk management tool for a number of chemicals under the CMP that are either designated as PBiT, or are high hazard, low volume substances not currently in commerce in Canada. SNAc provisions, which involve the submission of additional information on industry's use of a chemical, are applied to existing substances when the Government suspects that new activities may contribute to the substance being released in amounts or conditions which would result in the chemical becoming CEPA-toxic (Environment Canada, 2010b).

This approach is inadequate in fully protecting the health of Canadians, with the public and NGOs having little information concerning what they involve, industry not being required to submit data on certain elements of exposure, and with no advancement in the elimination of substances (de Leon et al., 2010; Environment Canada, 2010b). Additionally, data collected from industry in the Challenge survey has a reporting threshold of 100 kg/year, so a number of users of a chemical are not required to report to the Government if their use falls below that threshold. This gap in the government approach does not adequately address aggregate use of these chemicals and applying SNAcs to these substances in this case becomes quite problematic (CELA/CSM, 2010b; Environment Canada, 2010b). Butoximethyl-oxirane (CAS RN No. 2426-08-6), an industrial chemical mainly used in epoxy resin formulations which have applications in coatings, adhesives, binders, sealants, fillers and resins, has been found toxic under CEPA due to evidence that shows it to be a non-threshold carcinogen, a genotoxin and a mutagen. Despite this listing, the Government is proposing SNAc provisions as the risk management approach for the substance (Environment Canada & Health Canada, 2010b; ITK, 2010b). Such a decision neglects the mandate of the Government under CEPA to prevent or eliminate harmful chemicals to the full extent possible.

The Cosmetics Ingredient Hotlist

To assist companies in ensuring the safety of cosmetic products and other personal care products, Health Canada publishes the Cosmetic Ingredient Hotlist, an official list of prohibited and restricted cosmetic ingredients. The Hotlist is based on

Section 2 and 16 of the *Food and Drugs Act* and Section 24 of the Cosmetics Regulations (Health Canada, 2011a). Once a chemical has been placed on the Hotlist, the Government can require a user, importer or manufacturer of the substance to do the following: remove the ingredient from a formulation; reduce the concentration of the ingredient to an acceptable level; provide evidence that the product is safe for its intended use; confirm that the product is labeled as required; or confirm that the product is sold in a child-resistant package. Unless otherwise stated, substances listed on the Cosmetic Ingredient Hotlist are prohibited in cosmetic products. Substances on the list that are assigned specific conditions are only restricted in cosmetic products (Health Canada, 2011a).

While the intention of the Hotlist is to prohibit the current and future use of toxic chemicals in cosmetics, it also permits the continued usage of a range of toxic chemicals with limits, and lacks the necessary regulatory framework to ensure the adequate protection of human health from toxic chemicals on the list (de Leon et al., 2010). 1,4-Dioxane, described earlier, is an example of a chemical that is still in consumer products despite being placed on the Hotlist (Environment Canada & Health Canada, 2010a).

While some cosmetic databases, such as the U.S. Environmental Working Group's *Skin Deep Cosmetic Safety Database*, are very comprehensive and well-publicized, the hotlist remains obscure, and is subject to the same critique as other individual strategies such as 'precautionary consumption' referred to earlier in the report. The effectiveness of the hotlist is therefore limited, as women will vary in their capacities to navigate this type of information and use it effectively (Environmental Working Group, 2011; MacKendrick, 2011).

FAILING TO APPLY PRECAUTION

Critics of risk assessment have pointed out numerous shortcomings in how the CMP decision-making approach confronts the uncertainty, complexity and high stakes risks created by exposures to chemicals (O'Brien, 2000). Since the mid-1990s, repeated calls for a more precautionary approach to policy-making have sprung from evidence about the impacts on development or on health outcomes later in life linked to exposures during vulnerable developmental stages (Cooper & Vanderlinden, 2009).

DISREGARD FOR THE PRECAUTIONARY PRINCIPLE

The precautionary principle asserts that a lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent threats of harm to human health or the environment (Rio Declaration on Environment and Development, 1992). The need to use precaution has been a key feature of CEPA since it was enacted in 1999. While new policies concerning chemical use and exposure, such as Europe's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) program, have been lauded globally for embodying a truly precautionary orientation, critics argue that Canada's regulation of toxic chemicals to date has not meaningfully applied the precautionary principle (Boyd, 2003; Cooper & Vanderlinden, 2009; Health and Safety Executive, n.d.; Scott, 2009). For the most part, assessments and responses to risk continue to be reactive, based on the assumption that risk is unavoidable and that human bodies can accommodate some degree of chemical exposure. As a result, the focus has been placed on risk management over precaution. It is seen as acceptable for there to be delays in responding or refusals to act based on gaps in the research data, and despite the Government's transparency about the many uncertainties regarding chemical exposure and harm in their assessments, it has rarely taken preventive measures in face of these uncertainties and has thereby allowed existing exposures to continue (Cooper & Vanderlinden, 2009).

DEPENDENCE ON POTENTIAL FOR EXPOSURE OVER POTENTIAL FOR HARM

Designations of toxicity under CEPA require both a potential for exposure, and a potential for harm, so that even a substance demonstrating a high probability of harm at any exposure level will not be listed as toxic if estimates of exposure are currently considered low (de Leon et al., 2010; Environment Canada, 2011). Further, even if a substance is listed as toxic, no mandatory risk management measures will flow from this designation. These fundamental weaknesses of CEPA undermine the ability of advocates to demand precautionary action in the face of risks to human health and the environment by toxic exposures, especially when it comes to considerations of sex and gender vulnerabilities. From an SGBA perspective it is important to question whether it is truly possible, with current gaps in data and limited understandings of how chemicals mix and interact within the body, for assessors to establish a threshold of exposure below which we can be confident that there will be no harm.

A more comprehensive assessment process that puts a greater emphasis on hazard over exposure is needed (Schwarzman & Janssen, 2010). Other precautionary regulatory innovations being considered in other jurisdictions,

such as the EU, include "magnitude analysis" which takes into account the severity of potential effects based on spatial and temporal scales, susceptible sub-populations (such as women), connectivity, and interactions and multi-causality between or among factors under consideration (Gee, 2006).

RECOMMENDATIONS FOR HOW THE CMP COULD WORK FOR WOMEN

There are a number of steps the Government can take to work towards a chemicals assessment and management regime that is more responsive to issues of sex and gender and more inclusive and comprehensive in addressing women's disproportionate risks and burdens. In light of evidence tying chemical exposures to the rising incidence of diseases and disorders, the Federal Government has an obligation to take precautionary action to prevent illness to all Canadians, including those that have a greater impact on women.

INCREASING WOMEN'S PARTICIPATION AT ALL LEVELS OF THE CMP PROCESS

The CMP process needs to encourage increased public engagement by presenting information on chemical substances in a more understandable and accessible format (de Leon et al., 2010). The Government should establish a process to enhance public transparency in any notifications regarding new substances or future use, and create reporting that is targeted to specific communities and subgroups (such as women). It should support women both technically and financially in mobilizing around chemical prevention and management before final decisions are made regarding the use of substances. Additionally, the government should include organizations focused on women's health in advisory and technical groups related to the assessment and management of chemicals in Canada (Altman et al., 2008; de Leon et al., 2010). Such mobilization and dialogue should not only centre on biological or physical impacts of exposure, but should also incorporate a socio-economic analysis of risk management where women can comment on the cost-benefit analyses carried out by assessors on these factors (de Leon et al., 2010).

USING BISPHENOL A AS A MODEL FOR INCLUSION OF VULNERABLE GROUPS

The BPA draft and final screening assessments, as well as some aspects of the risk management report, offer a framework for how to approach chemical toxicity using alternative endpoints that are more tailored to vulnerable populations (e.g., children) and that focus on ideas of endocrine disruption, hormonal processes and reproductive effects (Environment Canada & Health Canada, 2008c). Not only was there a body of scientific evidence related to the health effects of BPA exposures, but this evidence demonstrated that tiny amounts of the chemical can exert significant effects and that health impacts are most notable when exposures occur during critical windows of development (Gray et al., 2010). Additionally, public participation and understanding of the issues about BPA exposure were paramount in applying political pressure on the Government and influencing their decision to prohibit its use in baby bottles. The approach to BPA's assessment can be useful in working to understand how to incorporate sex and gender into the CMP process and create more participatory, inclusive and engaging assessments and decision-making about toxic chemicals.

Although commendable and precedent-setting internationally, these decisions have yet to produce a strong management framework for reductions in exposures to the chemical. The risk management document fails to provide strict pollution prevention guidelines and reduction or elimination strategies, does not address central and compelling scientific evidence that fetal exposure to BPA provides greatest vulnerability to the chemical's toxic effects (i.e., that other exposures are not also important concerns), and has yet to look at the possible endocrine disrupting effects the chemical might have on other vulnerable groups, such as women and workers (Cooper & Vanderlinden, 2009; Department of the Environment, 2010; Environment Canada & Health Canada, 2008b).

EXPANDING THE ENDPOINTS FOR TOXICITY: USING TESTING THAT ADDRESSES ENDPOINTS SPECIFIC TO GENDERED CONCERNS

Understanding the biology behind endpoints in the chemical assessment process can improve our ability to identify toxic effects caused by exposure to chemicals at various life stages. This knowledge can help assessors to better design tools that consider endpoints specific to gendered concerns. Recent environmental health research has produced a new body of information and understanding that has yet to be fully incorporated into the risk assessment process (Program on Reproductive Health and the Environment, 2008).

NEW TOXICITY TESTING METHODS

A transformative paradigm shift is needed in toxicity testing methods for assessments. A recent study in the United States by the National Academy of Sciences (NAS) recommends screening chemicals based on toxicity pathways linked to the development of disease, rather than relying on traditional toxicology or epidemiological studies that focus exclusively on overt disease endpoints (e.g., tumours, birth defects, infertility). These early biological indicators of harm, such as interference with cellular signaling, hormone disruption, or alterations in gene expression, occur "upstream" of disease endpoints and can potentially be evaluated using in vivo and in vitro cell-based tests in place of laboratory animals (NAS/National Research

Council (NRC), 2007; Program on Reproductive Health and the Environment, 2008; Schwarzman & Janssen, 2010). Chemicals that exhibit any of these effects can be recognized as potential contributors to the risk of that illness.

To accurately evaluate the potential of a chemical to raise the risk of a woman-specific illness, toxicity tests should be designed and conducted with the understanding that effects vary depending on timing of exposure and underlying susceptibility factors. Toxicity tests need to: (1) assess the impact of chemical exposure during a variety of life stages, including gestation, puberty, pregnancy, and post-menopause; (2) account for increased susceptibility due to genetic variation, underlying disease, or exposure to other chemicals and environmental stressors; and (3) account for other disparities in the incidence of the disease, such as those that might derive from ethnicity or processes of racialization (Program on Reproductive Health and the Environment, 2008; Schwarzman & Janssen, 2010).

EFFECTIVELY APPLYING THE PRECAUTIONARY PRINCIPLE AND ENGAGING IN POLLUTION PREVENTION

The Federal Government must find ways to meaningfully implement precaution in its regulation of chemicals: this is the only way to fully protect the environment and human health from effects of toxic substances (Cooper & Vanderlinden, 2009; de Leon et al., 2010; McClenaghan et al., 2003). This requires designating chemicals as CEPA-toxic that are not necessarily in use, manufactured or imported into Canada, but which have potentially harmful ecological and health impacts, or may be hazardous to human health (de Leon et al., 2010). We need protective action when there is an indication of harm rather than waiting for absolute proof of harm.

AMENDING CEPA

The 2009 Auditor General's Report highlighted the Government's failure to fulfill their SGBA obligations within each department, and Health and Environment Canada have been unsuccessful to date in adequately addressing sex and gender within their assessments and decisions under the CMP. With this in mind, the most effective way to include sex and gender in the assessment of toxic chemicals, and strengthen precautionary measures, might ultimately involve the redesigning of CEPA legislation.

Lessons from the 2008 periodic review of CEPA

In the last mandatory periodic review of CEPA, many academics and public interest organizations called for a revision of CEPA to include explicit language directing that vulnerable groups, and specifically the vulnerability of children, be recognized in the evaluation and regulation of chemicals, a position supported by the reviewing parliamentary committee (Canada, House of Commons Standing Committee on Environment and Sustainable Development, 2007; CELA & Environmental Defence, 2006; Krewski et al., 2006). Such language would mandate the use of additional safety factors and child-protective measures in order to begin to ensure that risk assessments are protective of the most vulnerable populations. This would include requirements to assess groups of substances with common mechanisms of toxicity, and to aggregate exposure from multiple pathways (Canada, House of Commons Standing Committee on Environment and Sustainable Development, 2007; CELA & Environmental Defence, 2006). Despite recognizing the need to consider vulnerable populations in risk assessments, the Government's interim response to the Standing Committee's recommendation was vague and failed to provide clear insights into how it would adequately address this concern (Canada, Ministry of the Environment, 2007). To date, no further action has been taken on this recommendation.

Amendments to CEPA should be made to expand the definition of vulnerable populations and to specifically address gendered vulnerabilities through (1) the incorporation of mandatory sex- and gender-based analyses into CEPA risk assessments and management processes; (2) broadening the focus of the CMP survey questions to industry to include more mandatory data requirements and a more comprehensive list of vulnerable populations; and (3) expanding the assessment process to take account of unique attributes of these subpopulations (de Leon et al., 2010).

Focus on hazard over exposure

Adjustments should also be made to the Act in order to create a more comprehensive assessment process that puts a greater emphasis on the hazard of a substance rather than its potential exposure. A 'Hazards Identification Approach' would detect a chemical's effect on key events within biological processes known or suspected to raise the risk of development of a specific disease or disorder (Schwarzman & Janssen, 2010). Such methodology could help guide policy makers in making more informed decisions about what chemicals merit regulation. Priority would be given to those chemicals that have preliminary indicators of hazard to the development or progression of a specific disorder or disease. Biological processes that could be identified include cellular and molecular events (such as endocrine disruption; alterations in hormone levels, metabolism or receptors;

changes in gene expression; cell cycle changes; and genotoxicity), tissue changes (such as altered development of tissue), and susceptibility factors (such as early onset of puberty, increased lifetime duration of estrogen exposure, changes in enzyme metabolism, and obesity) (Schwarzman & Janssen, 2010). For each of the biological changes, currently available assays capable of detecting chemicals that can induce those changes, such as computational, in vitro, in vivo, and human epidemiologic methods, would be catalogued. New toxicity testing methods could be developed and validated to detect events in biological processes that are likely to alter risk but for which current test methods are inadequate.

Deletions from the DSL

The Federal Government should seek to amend CEPA to allow substances that are no longer in Canadian commerce to be deleted from the DSL and added to the Prohibition of Certain Toxic Substances Regulations, 2005 (Environment Canada, 2010c). This would designate as CEPA-toxic chemicals that are not in use, manufactured or imported into Canada, but have been found to meet the hazard criteria for designation as toxic.

Pollution prevention at the source

Finally, in conjunction with these amendments, the Federal Government needs to shift its current approach from chemicals management to focus on pollution prevention measures that eliminate or significantly reduce exposures to toxic chemicals over time (McClenaghan et al., 2003). This could include developing federal toxic chemical substitution and toxic use reduction programs, as well as green chemistry strategies linked to the CMP. Other pollution prevention measures, such as more vigorous use of the Prohibition of Certain Toxic Substances Regulations, and other mandatory pollution prevention measures available under CEPA, would have greater impact than any measures taken to date in protecting Canadians (de Leon et al., 2010).

With the appropriate law reform, CEPA could more effectively incorporate sex and gender-based concerns into the CMP process and ultimately provide more universal forms of protection, eliminate some of the burdens of responsibility on women, and prompt more effective engagement of the public in challenging the production of harmful chemicals through a stringent, inclusive and comprehensive regulatory regime.

ENDNOTES

[i] Mutagenic illnesses can include testicular, breast, ovarian and thyroid cancer; developmental and neurodevelopmental syndromes can include early onset of puberty, learning disorders, attention deficit hyperactivity disorder (ADHD), autism, Parkinson's and Alzheimer's diseases; reproductive disorders can include decreased sperm counts, a rise in the number of premature births, infertility and more difficulty in conceiving and maintaining pregnancies, and premature menopause; auto-immune diseases can include multiple chemical sensitivity, endometriosis, multiple sclerosis, and fibromyalgia. Other ailments that have been connected to environmental exposures include diabetes and obesity (Butter, 2006; Cooper & Vanderlinden, 2009; de Leon et al., 2010; Genuis, 2010; Gray et al., 2010; Program on Reproductive Health and the Environment, 2008; CHE, 2011).

[ii] To read more about each of these regulatory structures, view the following websites:

Canadian Environmental Protection Act:
http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=26A03BFA-1.

Food and Drugs Act:
http://laws-lois.justice.gc.ca/eng/acts/F-27/.

Pest Control Products Act:
http://laws-lois.justice.gc.ca/eng/acts/P-9.01/.

Fisheries Act:
http://laws-lois.justice.gc.ca/eng/acts/F-14/.

[iii] The Petroleum Sector Stream Approach (PSSA) consists of the evaluation of approximately 160 substances related to the petroleum sector. To date, two draft screening assessments on a total of 30 chemicals under the PSSA have been released for comment (Government of Canada, 2010a).

[iv] The results report from cycle 1 of the CHMS (2007-2009), released in August 2010, is an important document for informing policy and regulatory development around chemical assessment and management, and can be viewed here: http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/chms-ecms/report-rapport-eng.pdf.

[v] The Canadian Environmental Network (RCEN) is an independent, non-partisan organization that supports networking, communication and coordinating services for environmental NGOs.

View the RCEN website here:
http://www.cen-rce.org/eng/index.html.
NOTE: The CEN was de-funded in October 2011.

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