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Informed substitution within Canada's chemicals management plan
Feedback, and recommendations for rapid progress to healthiest alternatives

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Prevent Cancer Now is a national civil society organization focused on primary cancer prevention, by elimination of preventable, potentially carcinogenic exposures. We are concerned citizens, including scientific experts and clinicians.

In our response to this consultation regarding informed substitution within Canada's chemicals programs, we provide context highlighting the urgency, rigor and decision-points necessary for informed substitution of substances in Canada, focus on interpretation of "substitution" and being "informed," and finally within this context address the questions proposed for the consultation.

Introduction and Current Context

Ambitious, rapid "informed substitution" has the potential to provide a mechanism and framework for desirable and necessary changes, in order to prevent detrimental health outcomes. Pragmatic, functional substitution may also result in necessary reductions in resource extraction, and chemical production and use, to reduce adverse human exposures, as well as greenhouse gases.

Chemicals that are permitted in Canada – to produce, use, and dispose of – are contributing directly to chronic disease. Canadian researchers, including Health Canada, have described how chronic diseases – "diseases of aging" – are no longer diseases of the *aged*. Diabetes,[2,3] inflammatory bowel disease,[4] and bowel and hormone-related cancers[5] – metabolic, inflammatory, autoimmune and endocrine-related diseases – are accelerating in younger and younger Canadians. Autism now affects one in sixty-six Canadian children.[6]

The United Nations Environment Programme issued a sobering Global Environment Outlook (GEO-6), discussing a circular economy and measures to meet environmental goals.[1] In March of 2019, tens of thousands of young Canadians are striking, marching to legislatures, and calling for prompt, dramatic and ongoing actions to blunt climate change.

Canada must act nimbly, making hard choices based on different decision points beyond today's toxicology. Using threshold effects for single chemicals, the premise of risk assessment as well as identification of substitute chemicals, do not adequately account for the reality of complex mixtures including substances such as endocrine disrupting chemicals. These have low dose, non-monotonic, cumulative and synergistic effects.

Shifting the goals. Informed substitution involves making knowledgeable choices. Under today's framework, the decision may be made to restrict or not to permit importation, manufacture, export and sales of hazardous substances *that also* pose excessive risk to human or environmental health. This goal should instead be grounded in prevention and precaution to permit only best practices, production and products.

We discuss both the *making of choices* and *knowledge* in chemicals management.

Making choices – substitution

Currently, a multi-tier system is used to assess and regulate the tens of thousands of anthropogenic chemicals in commerce. Under the *Canadian Environmental Protection Act, 1999* (CEPA), Canada permits substances in commerce, unless and until they are *both* proven harmful, *and* measured or expected to be present in the environment at harmful levels. Taking action on the basis of the hazards of a substance would be more straightforward, precautionary and inherently safer.

New chemicals are subject to screening and possible further assessment, only once they reach thresholds of presence in commerce. Prior examination of efficacy and safety apply to pesticides (*Pest Control Products Act* [PCPA]) and to drugs (*Food and Drug Act* [FDA]).

Recognized hazards (apart from pesticides and drugs) are addressed under the *Hazardous Products Act* and the *Canada Consumer Safety Act.* Applying prior screening and assessment for all novel chemicals, as is already done fairly rigorously for the acknowledged bioactive chemicals, would be inherently precautionary and prudent.

Actions to curtail use of toxic chemicals under CEPA occur only after assessments, and assessments only occur once a threshold of use is met, posing a risk from exposure. Thus, assessments are by design after the fact, are typically after establishment of businesses and generation of markets, and under the *Chemicals Management Plan* (CMP) only after harm has already occurred. This is inefficient to protect public and environmental health.

Currently, substitution is driven by restriction of particular substances, that results in replacement with a similar problematic substance. For example:

- bisphenol A (BPA), an endocrine disrupting chemical, is currently regulated in baby bottles, but the allowable substitutions (e.g., BPS) also exhibit endocrine disrupting properties. It should also be noted that BPA is not regulated in other sources of

exposure, including occupational exposures which have been linked to breast cancer, or cash register receipts that are particularly concerning for cashiers.
- successive banning of individual brominated flame retardants, as a series of almost-identical replacements that built up in the environment to harmful levels were banned in series.

The litany of examples of unfortunate substitutes that prolonged pollution with similar toxicants is well recognized, and was shared by Government of Canada staff with the Stakeholder Advisory Committee in fall 2018.

Functional substitution: We agree and support recognition that functional substitution must be a clear end goal of informed substitution.

Substitution must be for *meritorious function*, rather than identification of a similar "drop in" chemical when a particular substance has been determined to be hazardous. For example:

- Plastic electronics cases containing endocrine disrupting phthalates and flame retardants may instead be made of metal. The material is functional, more durable, re-usable and recyclable.
- Sunscreens containing UV filter ingredients such as oxybenzone have been demonstrated to affect development of a variety of organisms including insects,[7] sea urchins,[8] and coral,[9] and even the sex ratio of human newborns,[10] possibly due to progesterone-like effects.[11] Options for substitution include zinc oxide, and titanium dioxide. Zinc oxide is the preferred option because it is an essential nutrient and dissolves in the body, whereas nano-sized titanium dioxide particles are foreign, persistent and migrate through tissues.[12,13]

One powerful approach to substitution includes the **simplification of ingredients lists** (i.e., elimination with no substitution). For example, artificial fragrances and flavours should be proscribed from most consumer products and foods. Fragrances are a powerful marketing tool, but they contribute nothing to the function of many products such as detergents, fabric softeners, personal care products, cleaning products, etc. The thousands of potential fragrance ingredients[14] include common sensitizers that can induce asthma and exacerbations, may be endocrine disrupting chemicals, and are commonly referenced as initiators and triggers of chemical sensitivity reactions.[15] Artificial flavours are unnecessary in healthy foods, and when research is conducted, adverse effects are identified, with the young at particular risk.[16]

Informed Research, Assessment and Public Health

One ultimate bottom line for accountability of chemicals regulation is the actual health of Canadians.

The Commissioner for Sustainability and the Environment has noted that public health is not considered in performance measurement for chemicals management that aims to protect health. Doubtless there is a role for the Canadian Public Health Agency (CPHA) and the Canadian Institute for Health Information (CIHI) to track and report trends of environmentally linked health outcomes with sufficient granularity and detail to be informative to chemicals (including pesticides) management.

Data pertinent to environmental exposures (e.g., levels in the environment, products, foods, water, biological samples), that should be identified and systematically assembled for chemical assessment and regulation, should be transparent, granular, and routinely updated. In short, this information should be assembled and readily available for researchers, and of a quality that epidemiological studies can be carried out. Such studies could potentially link exposures to various toxic substances with health outcomes (e.g., administrative or health records data, as well as research cohorts). Of note, Health Canada has been publishing studies demonstrating harms associated with current exposures to chemicals of concern, particularly in children,[17,18,19,] and yet comprehensive action is still lacking for well known families of endocrine disrupting chemicals such as phthalates, antimicrobials (e.g., triclosan), flame retardants and bisphenols.

"Weight of Evidence"

Assessments commonly state that conclusions represent the "weight of evidence." Hallmarks of weight of evidence approaches, however, are absent. Weight of evidence claims must be backed by systematic reviews. These include transparent, rigorous searching and assembly of all the relevant evidence in public as well as confidential industry studies. Assessors then grade the applicability and reliability of lines of evidence, and finally lines of evidence are transparently weighed, including precautionary approaches to extrapolations and uncertainties, to reach conclusions. Ideally this should be on a common platform that permits seamless use of validated data in downstream syntheses of data.

Systematic review approaches are quintessentially lean, efficient methods. They are highly digitized for efficiencies and accuracy; moreover, the warehouse of data compiled during one assessment can be rapidly updated and analyses re-run, to update assessments as new evidence comes to the fore. For example, a 2018 publication regarding pesticides assessments details electronic infrastructure used for hazard identification.[20]

Weight of evidence is routinely referenced in assessments under the CMP as well as the PCPA, but the methodology and necessary reporting are not yet evident to the public in draft and decision documents. Worryingly, draft assessments typically omit referencing publicly available independent research, and rely upon industry-funded and provided studies. This undermines public confidence in the assessments.

Further information

Prevent Cancer Now and aligned organizations have previously authored several relevant communications, providing further details in support of informed substitution, including:

- Proposed CEPA amendments, for legislation to support informed substitution, to protect vulnerable populations and to improve scientific methods, among other measures;[21]
- Scientific Justification to Address Endocrine Disrupting Chemicals (EDCs): A Roadmap for Action;[22]
- Submission detailing scientific data and data gaps regarding phthalates, in support of broad substitution on the basis of endocrine disruption effects;[23]
- Submission detailing science regarding triclosan, and the need for strong actions to curtail future uses.[24]
- Other submissions regarding chemicals assessment, including of pesticides, are available in the *Prevent Cancer Now* collection: http://www.preventcancernow.ca/main/resources/cancer-prevention-submissions/ as well as on the Canadian Environmental Law Association website.

Key Questions Identified for the Current Consultation

Who are the partners that have a role to play in considering informed substitution, and what role should each of them play?

Partners in informed substitution include all parties participating in this consultation, including industry, health professionals and academia. This also includes affected groups, such as vulnerable populations, environmental and health organizations, patient groups, consumers, etc. Additional groups, in the context of pesticides (noted in consultation materials), include agricultural stakeholders, organizations addressing food safety, security and quality, groups focused on alternatives such as organic agriculture practitioners and advocates, etc.

Various groups have obvious roles according to their interests (e.g., commercial versus public interest), expertise and lived experience. The "playing field" is uneven among participants, as those with commercial interests have much greater financial resources and industry-specific technical expertise (some of which cannot be verified independently because of confidentiality). Participation in the public interest therefore requires financial, logistical and information/data access support.

Are there considerations or information missing from the study?

The Science Committee and the Lowell Center for Sustainable Production have provided extensive discussion of frameworks, methods and tools that have been, and continue to be, developed to support assessments of substances and potential substitutes. Regulators, industry and civil society may all find "living" (continually updated) lists to be valuable

screening tools, such as the Greenscreen groupings, the SIN (substitute it now) list. Many such lists are catalogued in consultation materials. Tools include the rapidly evolving high-throughput methods for single substances and outcomes such as endocrine disruption, international efforts for data development and accessibility, and approaches to challenges regarding mixtures.

Lists and tools are important, but the first question should be, "is this chemical needed, and the best option to achieve an important purpose?" As we have discussed, we believe that there is a place to overlay pragmatic, least-toxic approaches, to "cut to the chase" and to advance least-toxic options.

We support the proposed concept of an independent, academically affiliated Institute for Informed Substitution, (possibly a virtual collaboration, at least to start) to stay up to date, support and further develop these concepts and tools. A serious challenge will be to ensure ongoing, arms length independence. The Institute would require cross-cutting expertise, for example in health, epidemiology, toxicology, chemistry, engineering, and environmental, agricultural and materials sciences.

Are there potential costs, benefits or impacts of informed substitution on the health of Canadians, the environment, companies or others?

Costs. The largest single item in the federal budget is health care, and a preponderance of these costs are related to chronic diseases. Public health practitioners have noted a lack of improvement in population health, even when "healthy" behaviours are taken up by the population (e.g., steep increases in colorectal cancer in younger Canadians, despite improved prevention-oriented behaviours[25]). Rapid increases in metabolic, autoimmune and neurological conditions (e.g., autism and Alzheimer's disease), and some cancers must arise from environmental exposures. Shaving even a few percentage points from health care costs could reap back costs of improved, pragmatic regulation.

Costs to commercial enterprises could include alternatives identification, possible toxicological testing (although safer alternatives may well have pre-existing databases), product redesign, sourcing, retooling, etc. Costs of elimination of unhealthy, unsustainable products (substitution with the null alternative) might accrue.

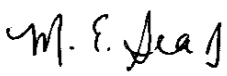
Benefits from healthier use of chemicals and safer goods would accrue to all players, such as concerned citizens and workers, marginalized communities, governments, academia, and to health and environmental sectors. Improved environmental and public health leads to improved productivity and quality of life.

Benefits would include generation of data and knowledge via research, to identify and track determinants of health, and outcomes related to healthier industries and products for daily life. Identification of earlier outcomes to trigger actions could enable more nimble actions for public health. Currently, an entire generation or more can be harmed, while firm "evidence of causality" related to particular exposures is developed via epidemiological and toxicological studies.

Benefits to commercial enterprises could include recognition of environmentally preferable production (and associated markets), improved workplace health and productivity, and social licence. A goal should be to gain identification of Canadian products as being the most sustainable, durable and overall "green" choices.

In conclusion, we thank you for the opportunity to comment regarding informed substitution. We look forward to the necessary nimble reform of regulatory practices and legislation, and for Canadian goods to gain the reputation of being an environmental standard-bearer.

Respectfully submitted,



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