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February 17, 2021

**Re: Technical Consultation:**

**Proposed Subgrouping of Bisphenol A (BPA) Structural Analogues and Functional Alternatives**

The following is the response of *Prevent Cancer Now* and Dorothy Wigmore to the Technical consultation on bisphenol-A (BPA) structural analogues and functional alternatives.

An addendum summarizes approaches and considerations principally regarding “Next Steps.” This was prepared at the request of the Canadian Network for Human Health and the Environment (CNHHE).

We are pleased to see that Health Canada is recognizing BPA as an endocrine disrupting chemical (EDC), and venturing into examination of EDCs, because they are important, and poorly assessed and regulated contributors to today’s epidemic of chronic diseases and cancers. The current approach must be considerably improved, however, to achieve the primary objective of the *Canadian Environmental Protection Act*, pollution prevention. This subgrouping exercise illustrates how the necessary screening of all options, with a potentially hazardous structure such as bisphenol, can become intractable and make identification and implementation of inherently safest options the only feasible approach.

This and other approaches are being advanced in the European Union’s Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment.<sup>1</sup>

**Summary of Comments**

- 1. PROBLEM FORMULATION:** Problem formulation and approaches are usually very first steps in assessments like this; however, here but the Technical Consultation lists problem formulation among “next steps.” Thus the current work lacks strategic underpinning. That said, scoping the current BPA analogues and alternatives would appear to be a preliminary step to rein in adverse effects of high volume, hazardous bisphenols. Unfortunately, the working definition of “functional alternatives” apparently does not include non-bisphenol-like chemicals – this is one example of how the current work falls short. More efficient and effective approaches are being developed and used internationally, and should have been central features in this work. Thus the current work is using an out-dated approach, postponing a modern framework to the third consideration in future problem formulation. For example, the European Union is proceeding with “safe by design” and least-toxic

alternatives. Alternatives may belong to very different chemical groups, but provide necessary functions using green chemistry.<sup>1</sup>

2. **SCOPE:** We agree that a large number of structural analogues should be considered in such an exercise, and scoping from knowledge of chemicals in commerce seems reasonable. We note that 2020 references are absent, so this document may already be dated. With an extensive range of potential substances in the chemicals universe, it is not possible to assess whether substances “in the pipe” were identified, or how quickly this work may become dated as additional bisphenol-like, potentially endocrine-active substances are proposed and brought on the market. Halogenated substances bear special attention, because these are expected to exhibit greater persistence, bioaccumulation and biological activity, including endocrine disruption. Halogenated chemicals are listed (e.g., commonly used BPF). New novel bisphenol-like alternatives may include more halogenated chemicals, as these may be proposed after current substances are addressed. This is but one reason not to scope “functional substitutes” narrowly; indeed, it is important to include other types of chemicals, methods and processes.
3. **OUTCOMES CONSIDERED:** Comparisons among similar chemicals are apparently being proposed on the basis of estrogenic activity, but estrogen is only one of many related hormones. Just as steroid hormones are chemically very similar but have different interactions with the family of receptors, bisphenol analogues may interact with receptors other than estrogen receptors. Thus, this information is insufficient to rank potential hazards among these chemicals. The potential for the substitute chemicals to mimic testosterone and other hormones must also be considered, as is being done internationally.
4. **METABOLITES:** Large molecules are listed, and chemicals with large side-chains (that would cause steric hindrance or “get in the way” of receptor binding) may appear safer according to assays. Importantly, the side-chains may be quickly lost as the chemical breaks down, and the resulting bisphenol analogue could then bind to hormone receptors. Metabolites are always important, and particularly so when chemicals are metabolized to active forms in the environment or *in vivo*.
5. **FUNCTIONAL ALTERNATIVES:** This consultation document discusses only bisphenol analogues and related chemicals. The safest *functional* alternatives may not be bisphenols at all; rather, they would emerge from green chemistry.<sup>2</sup> Such alternatives are already on the market (e.g., France’s bisphenols substitution initiative<sup>3</sup>), so the present consultation does not achieve the ultimate goals of informed substitution and safe chemicals policies, to identify the safest alternatives.

## CHARGE QUESTIONS

1. Is the substance identification and grouping approach described for BPA analogues and functional alternatives adequate?

- *Substance identification is probably out-dated, given that the references are over a year old. Canada should enforce requirements for disclosure with of novel chemicals in commerce.*
  - *The most important function alternatives, that are not bisphenol-like, were not addressed.*
  - *More rigorous systematic search and review methodologies will be needed going forward. A validated search filter for the identification of endocrine disruptors in systematic reviews, based on ECHA/EFSA guidance, could be utilised in future work.<sup>4</sup>*
- i. What are the strengths of the approach?
    - *Structures with more than two aromatic groups are included.*
  - ii. Are there limitations to the approach, and if so, how do you recommend addressing them?
    - *Yes. Functional alternatives were not addressed to identify the safest possibilities, as is done internationally. Other limitations arise from Canada's lack of comprehensive, systematic disclosure and cataloguing of chemicals, and potentially out-dated literature search. Going forward, systematic methodologies will be required for many tasks. One example of a relevant and comprehensive framework is the systematic review and integrated assessment (SYRINA) of endocrine disrupting chemicals.<sup>5</sup> Another is the COSTER proposal about how to do toxicology and environmental health systemic reviews, with its recommendations for problem formulation.<sup>6</sup> Health Canada may wish to strengthen methodological expertise.*

## **DISCUSSION**

### **Broader consideration of endocrine related outcomes**

Sex hormones including estradiol, testosterone and androgens are very similar to one another, as seen in Figure 1 (reproduced from “Chemistry and Structural Biology of Androgen Receptor”<sup>7</sup>), and yet exert very different effects. A complex interplay of hormones – both estrogens and androgens – orchestrates distinctive development and functions in females and males.<sup>8</sup> Similarly, differences among bisphenol analogues that are evident among structures tabulated in tables 3-3 and 3-4 in the consultation document, that are associated with lower estrogenic behaviour, may shift the analogue to have another effect, rather than no effect. These may extend to effects on thyroid<sup>9</sup> or other outcomes.



## **Pragmatic action on high volume EDCs**

Bisphenols are widely used chemicals that came to public attention when the high-volume chemical bisphenol-A (BPA), the principal component of polycarbonate plastic, was found to mimic the action of estrogen. It was found at concerning levels in Canadians, and was restricted from use in items for infants and young children including baby bottles and toys.<sup>16</sup> A 2012 study co-authored by Health Canada researcher Tye Arbuckle, found BPA in 75% of breast milk samples from 27 women and 93% of urine from 31 infants.<sup>17</sup> Multiple bisphenol chemicals are now identified as EDCs, so alternatives should have a safer chemistry. The same has been observed with per- and polyfluorinated chemicals (as was summarized in a recent submission regarding Canada's Plastics Consultation).

## **Workers**

Workers' potentially much higher exposures (e.g. BPA released in canning operations, potentially affecting men who want to have children, pregnant women and the milk of lactating women) have not featured in assessments, largely because workers' exposures have been considered a provincial jurisdiction and are not assessed under the Chemicals Management Plan policies. Dr. Christine Norman described efforts to address this crucial gap to the Stakeholder Advisory Council for the Chemicals Management Plan, and we look forward to consideration of workers in chemicals management.

## **Chemicals governance**

Risk governance encompasses early choices (proposed registration for use), screening the anticipated hazards and exposures, and then hazard and risk (hazard+exposure) assessment and decision-making typically on the basis of risk. The act of registration of a new chemical amounts to posing the hypothesis that no human or environmental harm will ensue. This ethical obligation requires surveillance and analyses to validate (or not) assumptions of exposure and harms.

The European Environment Agency concluded that risk assessment cannot keep up with increasing diversity of chemicals, or disentangle harms from exceedingly complex and interacting mixtures,<sup>18</sup> and that only feasible approach to transition to a sustainable system is to adopt a "safe by design" approach. This involves a much smaller inventory of inherently-safer substances *and approaches* to meet needs or "essentiality."<sup>2,19</sup> Frameworks and datasets have been developed by several programs such as GreenScreen<sup>20</sup> and the International Chemicals Secretariat (ChemSec) Substitute It Now.<sup>21</sup>

This BPA technical review is a logical first step to wrestle with the conundrum of a myriad of bisphenols, and one angle on potentially regrettable substitute chemicals; certainly there are important lessons to be learned. This subgrouping exercise illustrates how the necessary screening of all options, with a potentially hazardous structure such as bisphenol, can become intractable and make identification and implementation of inherently safest options the only feasible approach.

Thank you for this opportunity to comment, and to encourage a broader approach as is being undertaken in the EU, and we hope soon in the USA.

Please do not hesitate to reach out for further information and discussion. We look forward to next steps.

Respectfully submitted,

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**ADDENDUM**  
**Re: Technical Consultation:**  
**Proposed Subgrouping of Bisphenol A (BPA) Structural Analogues and**  
**Functional Alternatives**

The following is an addendum to the response of *Prevent Cancer Now* and Dorothy Wigmore to the Technical consultation on bisphenol-A (BPA) structural analogues and functional alternatives. Like the main document, it was prepared at the request of Canadian Network for Human Health and the Environment (CNHHE).

Other documents and approaches to consider are:

- ❑ A class approach to identifying BPA analogues (e.g., [bisphenols and phthalates](#) are one of the Green Science Policy Institute's six classes).
- ❑ The COSTER proposal about how to do toxicology and environmental health systemic reviews, particularly its recommendations for problem formulation.<sup>1</sup>
- ❑ The comprehensive international study about ED androgen receptors (CoMPARA), led by the US EPA's Endocrine Disruptor Screening Program, which used sources -- including the Canadian DSL -- which found "consensus models were able to identify approximately 10% of the (55,450) screened chemicals as potential binders to the AR or in agonist/antagonist modes."<sup>2</sup> This is orders of magnitude above the 343 found in the CMP "broad pool" that focused solely on estrogenic effects, raising serious questions about the data sources and methods used.
- ❑ A literature review about the hazards of BPA and its analogues to fish, as an example of reviews that should be considered.<sup>3</sup>
  - ❑ The 2021 "targeted review" about bisphenol analogues, reiterating how analogue alternatives (especially BPS, BPAF, and BPF) "pose equal or greater harmful effects to human health". The paper documents many adverse health effects, some of which may be linked to endocrine disruption.<sup>4</sup>

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<sup>1</sup> Whaley, P., et. al. (2020) "Recommendations for the conduct of systematic reviews in toxicology and environmental health research (COSTER)", *Environment International*, 143: 105926

<sup>2</sup> Mansouri, K., et. al. (2020) "CoMPARA: Collaborative Modeling Project for Androgen Receptor Activity", *Environmental Health Perspectives*, 128(2): <https://ehp.niehs.nih.gov/doi/10.1289/EHP5580>

<sup>3</sup> Faheem, M & Bhandari, R.K. (2021) "Detrimental effects of bisphenol compounds on physiology and reproduction in fish: A literature review", *Environmental Toxicology and Pharmacology*, 81: 103497.

<sup>4</sup> Catenza, C.J., et. al. (2021) "A targeted review on fate, occurrence, risk and health implications of bisphenol analogues", *Chemosphere*, 268: 129273.

- ❑ The EPA’s Chemicals Hazard Assessment (CHA) database, which is linked to the agency’s Design for Environment activities, and has parallels with Clean Production Action’s GreenScreen (used in the Pharos database, for example).<sup>5</sup> Informed substitution and alternatives assessments require checking the hazards of substitutes across a range of end points. Databases like this and Pharos provide international assessments with an eye on informed substitution.
- ❑ The SIN List provides information about the hazards of bisphenols and phthalates, along with information less toxic alternatives that are not necessarily analogues (<https://sinlist.chemsec.org/chemical-groups/bisphenols/> and <https://sinlist.chemsec.org/chemical-groups/phthalates/>).
- ❑ The 2017 document, *Selecting safer alternatives to toxic chemicals and ensuring the protection of the most vulnerable: A discussion draft*, prepared by long-time specialists in alternatives assessment and informed substitution. It emphasizes how “vulnerable populations” have been particularly affected by regrettable substitutions (BPS for BPA is one). The three themes from their work are access to information, genuine “stakeholder” engagement and explicit accounting for trade-off decision consequences. Those trade-offs also need to be evaluated by looking at products’ complete life cycles.<sup>6</sup>
- ❑ The use of predictive toxicology tools, as demonstrated in looking for alternatives to children’s products containing bisphenols, phthalates and parabens.<sup>7</sup> This is consistent with the call by Joel Tickner and colleagues (including two authors of the 2017 CHANGE/NRDC report), based on input from 40-plus specialists.<sup>8</sup>
- ❑ Other work by Tickner, Jacobs and/or their colleagues. Looking for reliability, adequacy, transparency, volume, and ease of use in chemical

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<sup>5</sup> Vegosen, L. & Martin T.M. (2020) “An automated framework for compiling and integrating chemical hazard data”, *Clean Technologies and Environmental Policy*, 22:441-458. <https://doi.org/10.1007/s10098-019-01795-w>

<sup>6</sup> Californians for a Healthy and Green Economy (CHANGE) & National Resources Defense Council (2017) *Selecting safer alternatives to toxic chemicals and ensuring the protection of the most vulnerable: A discussion draft*. Available at <https://www.nrdc.org/sites/default/files/toxic-chemicals-vulnerable-populations-report.pdf>.

<sup>7</sup> Smith, M. N., Cohen Hubal, E.A. & Faustman, E.M. (2019) “A Case study on the utility of predictive toxicology tools in alternatives assessments for hazardous chemicals in children’s consumer products”, *Journal of Exposure Science & Environmental Epidemiology*, 30:160–170 <https://doi.org/10.1038/s41370-019-0165-y>

<sup>8</sup> Tickner, J, et. al. (2018) “Advancing alternatives assessment for safer chemical substitution: A research and practice agenda”, *Integrated Environmental Assessment and Management*, <https://doi.org/10.1002/ieam.4094>

hazard assessment data sources, and applying multi-criteria decision analysis, He, Malloy and Schoenung concluded:

*multiple data sources are necessary to adequately provide the data needed for a CHA, 2) these data sources should be selected such that they complement each other in their high-performing performance attributes such that all performance attributes are “maximized” by at least 1 data source, and 3) the selection of data sources should be deliberate and explicit, taking into account performance relative to identifiable performance attributes.*<sup>9</sup>

- ❑ New information about absorbing BPA and alternatives in thermal paper (e.g., Reale and colleagues<sup>10</sup>).
- ❑ Follow-up to the proposed framework for systematic assessment of endocrine disruptors<sup>11</sup>, including a presentation by Anna Beronius at the February, 2021 Divergent Science Perspectives Workshop. The authors of the original paper explain how the framework enables “evaluation and synthesis of evidence from multiple evidence streams”, pointing out that “a decision regarding regulatory action is not only dependent on the strength of evidence, but also the consequences of action/inaction, e.g. limited or weak evidence may be sufficient to justify action if consequences are serious or irreversible.”
- ❑ European Union activities, including:
  - Guidance from the European Chemical Agency (ECHA) and European Food Safety Authority (EFSA) about identifying EDs, looking beyond estrogenic effects to include androgen, thyroid and steroidogenesis modalities.<sup>12</sup>
  - The *Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment* and related documents ([https://ec.europa.eu/environment/strategy/chemicals-strategy\\_en](https://ec.europa.eu/environment/strategy/chemicals-strategy_en))

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<sup>10</sup> Reale, E., Vernez, D. & Hopf, N.B. (2020) “Skin absorption of bisphenal A and its alternatives in thermal paper”, *Annals of Work Exposures and Health*, 1–13. [doi: 10.1093/annweh/wxaa095](https://doi.org/10.1093/annweh/wxaa095)

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<sup>12</sup> ECHA/EFSA (2018) *Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009*. EFSA J. 16(6):5311. Available at <https://www.efsa.europa.eu/en/efsajournal/pub/5311>.

- the “Fitness Check” for endocrine disruptors (<https://ec.europa.eu/jrc/en/news/fitness-check-endocrine-disruptors-some-room-improvement>)
- the Council’s 2018 statement, *Towards a comprehensive European Union framework on endocrine disruptors* (<https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF>)

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