



THE DANGERS OF PHTHALATES.

**HOW THE COMMONLY USED CHEMICAL IS
POORLY AFFECTING OUR CANADIAN
CITIZENS**

BRIEFING NOTE FOR RECOMMENDATION

SHANIA BHOPA - SENIOR POLICY ADVISOR

**CANADIAN WOMEN'S FOUNDATION
BRIEFING NOTE FOR RECOMMENDATION
POLICY RECOMMENDATION - PHTHALATE BAN**

Date: Dec. 3. 2019

**PREPARED FOR: Vito Buonsante, Deputy Minister - Ministry of Health
BRIEFING NOTE FOR RECOMMENDATION, POLICY OPTIONS**

**PREPARED BY: Shania Bhopa, - Canadian Women's Foundation
Senior Policy Advisor, President**

Re: Proposal to ban Phthalates in Canadian Products

Executive Summary

This proposal describes the current crisis affecting millions of women in Canada. The usage of common household items containing phthalates are negatively affecting women. Our research findings were gathered from worldwide human and animal studies to understand the negative effects of phthalates. Phthalates do not form covalent bonds with the products in which they are used (Pecht, n.d.). This leaves the serious potential for the chemical to leach, resulting in them to be easily absorbed through the skin or inhaled (Pecht, n.d.). This chemical absorption has led to the potential of various negative health outcomes on pregnant women and their offspring, including pregnancy loss, anatomical changes in infant boys and the increased risk of a child being born with Attention Deficit Hyperactivity Disorder. Currently Canada has no restrictions or legislation to protect consumers from phthalates. This proposal considers the European Union as a model to understand the way they have taken action towards protecting their citizens. In hopes of implementing change, two recommendations are provided in this proposal to help guide the necessary steps to move forward. The recommended awareness campaign will act in educating the population at risk. This recommendation will complement the solution to use alternative chemicals such as bio-based, or benzoic acid-based plasticizers. The Ministry of Health has a vital role in the Canadian Environmental Protection Agreement (CEPA). My goal is that the Ministry of Health will take the considerations of this proposal to implement the proposed ban on phthalates.

Issue

The Canadian population is negatively affected by their commonly used household items that contain phthalates. Research states that the endocrine-disrupting chemical is linked to pregnancy

loss among women undergoing medically assisted reproduction (Messerlian et al., 2016). Evidence suggests the possibility of anatomical changes in infant boys, from phthalates that may affect their ability to reproduce later in life (Staff, 2019). A significant number of human studies have linked prenatal exposure to DEHP phthalates with altered neurodevelopment in children such as Attention Deficit Hyperactivity Disorder (Phthalates, 2018). The negative impact that phthalates have, are detrimental to the future of humankind. It is essential that we act upon this issue, and work together in efforts to establish a ban on the phthalate chemical.

Background

Phthalates are the most commonly used man-made plasticizer and are popular due to their relatively low cost, low volatility, and ability to create very elastic materials (Pecht, n.d.). Phthalates are used in soft polyvinyl chloride (PVC) material present in many common household items (State, 2016). Phthalates do not form covalent bonds with the products that they are used in (Pecht, n.d.). This leaves the serious potential to leach, resulting in them to be easily absorbed through the skin or inhaled (Pecht, n.d.). Aside from using phthalates in plastics, manufacturers use phthalates in beauty products (State, 2016). Phthalates are used because they cling to the skin and nails to give perfumes, hair gels, and nail polishes more staying power (Center, 2013).

Phthalates are commonly known as endocrine-disrupting chemicals, having the ability to produce adverse developmental, reproductive, neurological, and immune effects (Endocrine, 2019). Research shows that endocrine disruptors pose a great risk, specifically during prenatal and early postnatal development (Endocrine, 2019). Endocrine disruptors can mimic naturally occurring hormones in the body such as estrogen, androgens, and thyroid hormones, potentially producing overstimulation (Endocrine, 2019).

Male Reproduction

There are 28 strains of Phthalate chemicals (Phthalates and Cumulative, 2008). Most of the studies on the effects of phthalates and male reproduction have been conducted in rodents, primarily rats (Phthalates and Cumulative, 2008). The reproductive developmental process in rodents is found to be analog to those in humans (Phthalates and Cumulative, 2008). Human males have been found to have a high incidence of reproductive disorders such as Cryptorchidism and hypospadias (Phthalates and Cumulative, 2008). The actions of phthalates on the developing reproductive tract exhibit concordance with the human male population that make up the testicular dysgenesis syndrome (Phthalates and Cumulative, 2008). It was found that Phthalates with chain lengths of four to six carbons (dibutyl, butylbenzyl, dipentyl, and

diethylhexyl) reduce fetal testicular testosterone and impair male reproductive development (Phthalates and Cumulative, 2008).

Attention Deficit Hyperactivity Disorder

It is found that there is an association between phthalate concentration and the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) (Park et., 2014). In a study of 180 children from a child Psychiatric Clinic in South Korea, the urine phthalate metabolite of (DEHP, DBP, and DBDS) concentrations between clinic-referred boys with and without ADHD. The comparison occurred between the brain CT and phthalate metabolite concentrations, multiple regression analyses were performed (Park et., 2014). DEHP was positively correlated with commission error scores, that are indicators of a deficit in response inhibition, which is considered to be a core deficit in ADHD (Park et., 2014). Similar findings were proven in a case-control study of the Norwegian Mother and Child Cohort. Findings suggest that children of mothers in the highest quintile of DEHP had almost three times the odds of an ADHD diagnosis as those in the lowest (Engel, 2018). Maternal urinary concentrations of DEHP were monotonically associated with an increased risk of ADHD (Engel, 2018).

Fertility

Recurrent pregnancy loss is the termination of pregnancies before 20 weeks of gestation. The principal component analysis revealed three primary components of phthalate exposure: DEP, DEHP, and DBP (Liao et al., 2018). It was found that the urinary level of DBP was significantly associated with elevated risk for recurrent pregnancy loss (Liao et al., 2018). Results from a study in the Department of Occupational Medicine at the Aarhus University Hospital found that the exposure to MEHP phthalate in the period around conception and pregnancy loss; was associated with a higher occurrence of pregnancy loss (Toft et al., 2012). In a US study, it was found in 215 females seeking fertility treatment that higher urinary concentrations of di(2-Ethylhexyl) phthalate (DEHP) metabolites were associated with a significant decrease in antral follicle count among women seeking infertility care (Messerlian et al., 2015).

Considerations

It is important to incorporate the phthalate ban in Canada, as we have seen the negative side effects associated. Currently, the Canadian Environmental Protection Act, 1999 (CEPA) has the sole purpose to protect the environment and the health and well-being of Canadians (Climate, 2018). CEPA has a “risk-based” method of making decisions, looking at the harmful properties of the chemical substance and how much exposure there is for people or the surrounding environment (Climate, 2018). Canada's assessment recognizes that many phthalates are hazardous; however, claiming that exposure to the general population is low (Canada Misses,

2018). Within the CEPA under section 55, The Ministry of Health must preserve and improve public health under this act (Climate, 2018). The Ministry of Health should issue objectives, guidelines, and codes of practice concerning the elements of the environment that may affect the life and health of the people of Canada (Climate, 2018). Essentially the Canadian government deems it unnecessary to ban phthalates because the majority of evidence surrounding its harm, is based on animal trials. While there are many human studies, the issue is the lack of concrete evidence. Moving forward to implement this ban it is essential to consider the funding available to conduct human studies. The Federal government must fix the Canadian Environmental Protection Act (CEPA) by introducing amendments in 2020. It is essential to the public that all toxicological data and safety information must be accessible to consumers and regulators to assure safe use and public trust (acs).

On June 29, 2018, the government outlined their commitments to continue to strengthen the protection of the environment and health of Canadians through policy and program improvements, future law reform and engagements on key issues (Canada, 2017). The Chemical Management Plan (CMP) offers to strengthen the integration of across the government of Canada's chemical management programs, to address approximately 4,300 priority chemicals by 2020 ((Phthalates Factsheet, 2017). CEPA 1999 is the primary legislation, that the CMP operates under (Phthalates Factsheet, 2017).

When considering options to implement the ban of Phthalates in Canada, we must understand the global concern of the harmful effects of phthalates (Canada Misses, 2018) Canada decided against following the U.S and the EU to restrict the use of chemicals, Canada decides not to protect its citizens from Phthalate exposure (Canada Misses, 2018). When the CEPA was published in 1999 there was no concrete evidence available to understand the need to ban Phthalates. However, through the years there has been an increase in the availability of information. It is necessary to look to the global concerns for phthalates and understand the way other countries have acted upon protecting their citizens, we can look towards the European Union as a model. While Canada is not banning the 28 phthalates, the European Union listed seven of these under "Substances of Very High Concern" (Canada Misses, 2018). The European union has listed The EU has banned six phthalates in consumer products (Erickson, 2017). The four phthalates are di-isononyl phthalate (DINP), di-n-octyl phthalate (DNOP), butylbenzyl phthalate (BBP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP) (SGS). The proposed restrictions eliminate continued use authorizations for consumer products that contain the phthalates at levels greater than 0.1% by weight (Erickson, 2017).

The U.S Consumer Product Safety Commission has banned two of these phthalates from children's toys and articles, while Canada's assessment does not label them as toxic (Canada Misses, 2018). The CEPA has the responsibility for managing risks of chemicals, it is negligent to refrain from implementing a ban or further restrictions on phthalates.

Recommendations

1. Educating The Population at Risk

Research from the Endocrine Society states, low levels of exposure to phthalates, are problematic for vulnerable people like children and pregnant women (Canada Misses, 2018). Educating the population at risk will allow for increased awareness. As the implementation of this ban will take time, it is beneficial to the public, to create awareness campaigns during the enactment stage. Educating the population will allow for consumers to be more careful when purchasing products that contain harmful chemicals.

To implement a public awareness campaign, the first step needed to be taken is to choose the modality necessary to disseminate the information, whether that be physical information templates or digital campaigning (Q what, n.d.). Next understanding the supporters, how this issue can be raised locally and globally. The Canadian Women's Foundation would be pleased to engage with the material and raise awareness.

A positive factor with the implementation of an awareness campaign, is that Canadian consumers would be smarter shoppers when understanding the effects of various chemicals that are in everyday household items. A drawback of such a recommendation is the timeliness of the creation process of this campaign. In terms of the communicative material made it is essential to understand if this campaign will be digital or hard-copy. The impact and the level of reach differ, however, this is a goal that can be further executed with the experience of the Department of Communications.

2. Using the recommended chemicals

The three chemicals that can be used as an alternative to phthalates:

1. are thermoplastics such as polycarbonate/acrylonitrile butadiene styrene (PC/ABS)
2. bio-based plasticizer
3. Velsiflex (calce)

PC/ABS has been used in electronic enclosures due to their high modulus ductility, heat resistance, impact strength and is relatively inexpensive (Pecht, n.d.). The second alternative

plasticizer is bio-based plasticizers. Bio-based alternatives are made from corn, soy, rice, wheat and linseed (Pecht, n.d.). Seven out of eleven of the bio-based alternatives are listed as biodegradable and compostable (Pecht, n.d.). A benzoic acid-based plasticizer called velsiflex has been proven to be a more environmentally friendly product versus the traditional chemical phthalate (velsicol). Velsiflex has the solvating power that is optimized for PVC formulation (Velsiflex., n.d.).

Limitations

Political Factors

The difficulty to occur amendment in 2020 will slow down the progression of the phthalate ban. There may be resistance from the Chemicals Management Plan (CMP) that operates under the CEPA to strategically implement objectives to approach the federal government (Phthalates Factsheet, 2017). The Ministry of Health must take action and understand the human concern for the continued use of phthalates in consumers today. If the Ministry of Health is willing to take a step in the right direction, the likelihood of the implementation of this ban will increase.

Economic Factors

The government spending its funding on research for applicable regulations. Additionally, the costs associated with funding educational material are a limitation with implementing the recommendation. It is essential to the childbearing public that they are aware of the harm in using products that contain phthalates. Especially in those seeking pregnancy, or are currently pregnant. The funding for the education material would be classified under health prevention in which the Ministry of Public Health would need to be in association with this project.

Alternatives being more harmful to the environment. While there may be little research on the environmental harm alternative chemicals may have, it is necessary to understand the harm to human health is a priority.

Next step

Conduct a risk assessment, this process will consist of three analytic steps-hazard identification, dose-response assessment, and exposure assessment (Erikson, 2017). When integrating the results of risk assessment with social, economic and political concerns to reach a decision (Erikson, 2017). Together this will allow for the Ministry of Health to evaluate, quantify, and mitigate the impacts of a hazard (Erikson, 2017). This risk assessment must include the analysis of acute short term hazards as well as chronic long term- impacts, converting the entire lifecycle from research and development (Erikson, 2017).

Conclusion

While all of the above suggestions are viable, the first recommendation is most constructive and thus seeks long term benefits for a range of parties including youth, and parents. Furthermore, while this proposal is addressed to the Ministry of Health, the implementation of this ban could be further assisted by the Ministry of Environment. While it may be costly in time, and resources, the long term benefits to the Canadian population, are impactful. With the implementation of this phthalate ban, there will be an overall increase in female fertility and healthy babies. Moving forward, a proposal of this nature would need to undergo approval by Canada's Cabinet and then passed forward to the House of Commons and Senate. It is necessary to address the health impacts on our citizens, and this starts by enforcing a ban on phthalates in consumer products.

References

- Accessing the Market: European Union Phthalate Regulations. (2019, April 9). Retrieved December 10, 2019, from <https://www.sgs.com/en/news/2019/04/accessing-the-market-european-union-phthalate-regulations>.
- Canada, H. (2017, April 6). Government of Canada. Retrieved December 10, 2019, from <https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-hemicals/canadian-environmental-protection-act-1999.html>.
- Canada misses the mark (again) in its decision to not ban harmful phthalates. (2018, July 16). Retrieved December 10, 2019, from <https://environmentaldefence.ca/2018/01/16/canada-misses-mark-not-ban-phthalates/>.
- Center for Food Safety and Applied Nutrition. (2013, May 12). Phthalates. Retrieved October 16, 2019, from <https://www.fda.gov/cosmetics/cosmetic-ingredients/phthalates>.
- Climate Change Canada. (2018, August 14). Government of Canada. Retrieved December 10, 2019, from <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-3.html#s55>.
- Endocrine Disruptors. (2019). Retrieved December 10, 2019, from <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm>.
- Engel, S. M., Villanger, G. D., Nethery, R. C., Thomsen, C., Sakhi, A. K., Drover, S. S., ... Aase, H. (2018). Prenatal Phthalates, Maternal Thyroid Function, and Risk of Attention-Deficit

- Hyperactivity Disorder in the Norwegian Mother and Child Cohort. *Environmental Health Perspectives*, 126(5), 057004. doi: 10.1289/ehp2358
- Erickson, B. E. (2017, June 26). European Union further restricts four phthalates. Retrieved December 10, 2019, from <https://cen.acs.org/articles/95/i26/European-Union-further-restricts-four.html>.
- Legislative Services Branch. (2019, November 29). Consolidated federal laws of Canada, Canadian Environmental Protection Act, 1999. Retrieved December 10, 2019, from <https://laws-lois.justice.gc.ca/eng/acts/c-15.31/>.
- Liao, K.-W., Kuo, P.-L., Huang, H.-B., Chang, J.-W., Chiang, H.-C., & Huang, P.-C. (2018). Increased risk of phthalates exposure for recurrent pregnancy loss in reproductive-aged women. *Environmental Pollution*, 241, 969–977. doi: 10.1016/j.envpol.2018.06.022
- Messerlian, C., Souter, I., Gaskins, A. J., Williams, P. L., Ford, J. B., Chiu, Y.-H., ... Hauser, R. (2015). Urinary phthalate metabolites and ovarian reserve among women seeking infertility care. *Human Reproduction*, 31(1), 75–83. doi: 10.1093/humrep/dev292
- (2)Messerlian, C., Wylie, B. J., Mínguez-Alarcón, L., Williams, P. L., Ford, J. B., Souter, I. C., ... Hauser, R. (2016). Urinary Concentrations of Phthalate Metabolites and Pregnancy Loss Among Women Conceiving with Medically Assisted Reproduction. *Epidemiology*, 27(6), 879–888. doi: 10.1097/ede.0000000000000525
- Park, S., Lee, J.-M., Kim, J.-W., Cheong, J. H., Yun, H. J., Hong, Y.-C., ... Kim, B.-N. (2014). Association between phthalates and externalizing behaviors and cortical thickness in children with attention deficit hyperactivity disorder. *Psychological Medicine*, 45(8), 1601–1612. doi: 10.1017/s0033291714002694
- Pecht, M. (n.d.). Phthalate Risks and Alternatives. Retrieved December 10, 2019, from <https://calce.umd.edu/phthalate-risks-and-alternatives>.
- Phthalates Factsheet | National Biomonitoring Program | CDC. (2017, April 7). Retrieved October 16, 2019, from https://www.cdc.gov/biomonitoring/Phthalates_FactSheet.html
- Phthalates. (2018). Retrieved December 10, 2019, from <http://projecttendr.com/chemicals-and-pollutants/phthalates/>.

Phthalates and Cumulative Risk Assessment. (2008). doi: 10.17226/12528

Q. What is a public awareness campaign? (n.d.). Retrieved December 10, 2019, from <http://rasmussen.libanswers.com/academics/faq/248422>.

State of the science of endocrine disrupting chemicals - 2012. (2016, August 4). Retrieved from <https://www.who.int/ceh/publications/endocrine/en/>.

Staff, N. A. H. E. (2019, September 23). Phthalates linked to lower fertility in men and women. Retrieved October 16, 2019, from <https://www.nutritionaction.com/daily/food-safety/phthalates-linked-to-lower-fertility-in-men-and-women/>

Toft, G., Jönsson, B. A., Lindh, C. H., Jensen, T. K., Hjollund, N. H., Vested, A., & Bonde, J. P. (2012). Association between Pregnancy Loss and Urinary Phthalate Levels around the Time of Conception. *Environmental Health Perspectives*, 120(3), 458–463. doi: 10.1289/ehp.1103552

Velsiflex® Plasticizer: Benzoate Based, Non-Phthalate. (n.d.). Retrieved December 10, 2019, From https://www.velsicol.com/products/velsiflex?gclid=EAIaIQobChMIipraxem5glVI4VaBR38aQ3gEAAYASAAEgLpC_D_BwE.