January 25, 2017

The Honorable Catherine McKenna
Minister of the Environment

The Honourable Jane Philpott
Minister of Health

Transmission by email: *ec.ministre-minister.ec@canada.ca; Hon.Jane.Philpott@Canada.ca*

RE: Submission in Response to Canada Gazette publications on the final decision for phenol, 5-chloro-2-(2,4-dichlorophenoxy) [triclosan] (CAS RN 3380-34-5), Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999 and proposed Management Strategy

Dear Minister McKenna and Minister Philpott:

The Canadian Environmental Law Association (CELA), Chemical Sensitivities Manitoba, Ontario Rivers Alliance, Ottawa Riverkeeper, Prevent Cancer Now and Citizens Network on Waste Management are submitting the following comments in response to the *Canada Gazette* publications (Vol. 150, No. 48 — November 26, 2016) for the Publication of final decision after assessment of a substance — phenol, 5-chloro-2-(2,4-dichlorophenoxy) [triclosan], CAS RN (3380-34-5) and *Canada Gazette* (Vol. 150, No. 50 — December 10, 2016) for Order Adding a Toxic Substance to Schedule 1 to the *Canadian Environmental*

Protection Act, 1999 (CEPA 1999).[1] In addition, we are also offering comments on the proposed Management Strategy for triclosan.[2]

SUMMARY

Section A of our submission highlights our concerns with the final assessment decisions on triclosan, including bioaccumulation and persistence. We also highlight key studies and reports which have not been included or given adequate consideration in the human health assessment of triclosan.

In Section B, we express our support for the proposal to add triclosan to the List of Toxic Substances in Schedule 1 of CEPA 1999.

Section C of our submission highlights our concerns with the proposed risk management strategy for triclosan to implement the use of Pollution Prevention Plan (P2 Plans) Notices and urge the government to develop regulatory measures that aim to prohibit the use of triclosan in consumer products.

Introduction

We welcome the release of the final decision on triclosan, despite a long delay from the release of the draft risk assessment in March 2012. Since the publication of the screening assessment of triclosan in the *Canada Gazette* on March 31, 2012, many public interest organizations, including some of our organizations, have forwarded recommendations to the government to uphold its decision on the toxicity of triclosan under CEPA 1999. In our letters, we recommended that the government "take necessary measures to ensure a phase out of this chemical in all products to address the ongoing presence of triclosan in the environment". Such correspondence include letters dated November 27, 2014 and July 27, 2015.[3,4] The NGO statement on triclosan dated November 27, 2014, signed by 50 organizations, has been attached to this submission for your consideration. CELA also sponsored a GreenScreen

[1] See: Environment and Climate Change Canada and Health Canada. November 2016. Assessment Report Triclosan Chemical Abstracts Service Registry Number 3380-34-5. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=65584A12-1

[2] Environment and Climate Change Canada and Health Canada. Risk Management Approach for Phenol, 5-chloro-2-(2,4-dichlorophenoxy) - Triclosan November 2016. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=371A2F3C-1

[3] Various signatories. Environment and Health Groups' Statement on Triclosan: Call on Canadian Government to Prohibit Triclosan in All Products dated November 27, 2014. Accessed at http://www.cela.ca/sites/cela.ca/files/triclosan_statement.pdf

[4] Letter to The Honourable Leona Aglukkaq, Minister of the Environment, and The Honourable Rona Ambrose, Minister of Health dated July 27, 2015. Accessed at http://www.cela.ca/sites/cela.ca/files/Triclosan-NGO-letter-July-2015.pdf

Assessment on triclosan and and coauthored a report (2014) titled, *Chemicals in Consumer Products are Draining Trouble into the Great Lakes Ecosystem*.[5,6]

Based on the final risk assessment, the government concluded that triclosan "meets the criteria under paragraph 64(*a*) of CEPA 1999 as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity".

Section A: Comments on Final Decision on Triclosan

As in other substance assessments conducted under CEPA 1999, the assessments are completed with information and opinions that have been included from various scientific papers, documents, and communication between the government and other interested stakeholders (including industry stakeholders). In any substance assessment, it is essential to promote openness and transparency about the information presented, and even more crucially, clear identification of the selection methods for the scientific papers and documents that have been identified for evidence. Information from Table 4-14 of the assessment on triclosan under the heading "Uncertainty characterization and analysis of the weight of evidence in the risk assessment of triclosan" is useful qualitatively. However, justification for inclusion of data for the assessment should be required from a quantitative point of view. For example, additional commentary should be included on the following:

- The extent of the literature search conducted.
- The systematic review of the literature.
- The decision making process used to determine the lines of evidence including read-across data and analogues.
- The parameters applied to determine the weight of evidence to draw conclusions.
- The development of the level of confidence in the data set (high, medium, low).

The data used in an assessment should contribute to a more robust and transparent assessment, with an aim to potentially reduce bias.

We welcome the government's final conclusion of toxicity under CEPA 1999. However, we are highlighting a few of our significant concerns with the final assessment results. They are listed below.

[5] ToxServices LLC . May 2014. Triclosan (CAS# 3380-34-5) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment. Prepared for the Canadian Environmental Law Association. Accessed at http://www.cela.ca/sites/cela.ca/files/3380-34-5-TriclosanGreenScreen.pdf

[6] Canadian Environmental Law Association. July 2014. Chemicals in Consumer Products are Draining Trouble into the Great Lakes Ecosystem : GreenScreen® Assessment Shows Triclosan and Triclocarban Should Be Avoided. Accessed at http://www.cela.ca/sites/cela.ca/files/TC-TCC-CELA-997_0.pdf

Environment

1) **Decision on bioaccumulation of triclosan warrants additional review** – The final assessment concluded that triclosan does not meet the criteria for bioaccumulation as set out in the Persistence and Bioaccumulation Regulation. Several studies focusing on the bioaccumulation of triclosan were submitted for further consideration but they were not available to the public.

   The vast majority of studies considered in the final assessment report were the same as in the draft assessment – excepting two unpublished reports, Arnot (2015) and Arnot (2016), which were submitted directly to Environment and Climate Change Canada. The final assessment report cited the same values for bioconcentration (BCF) and bioaccumulation (BAF) in aquatic species (Table 4-10), and noted that "there is evidence of bioaccumulation in algae and aquatic invertebrates." However, an additional passage (4.3.1.2 Molecular size and bioconcentration) included in the final assessment stated that:

   Sakuratani et al. (2008) also investigated the effect of cross-sectional diameter on passive diffusion in a BCF test set of about 1200 new and existing chemicals. They observed that substances that do not have a very high bioconcentration potential (BCF < 5000 L/kg ww) often have a maximum diameter of greater than 2.0 nm and an effective diameter of greater than 1.1 nm. For triclosan, the maximum diameter of 1.3 nm and effective diameter of 0.81 nm were determined, and suggest that triclosan will be passively diffused without restriction through the lipid bilayer.[7]

   > *Since Sakuratani et al.'s 2008 review of BCF data and molecular size parameters, other studies such as Arnot et al. (2009) have explored this relationship and concluded that "Reduced bioaccumulation that is often associated with larger molecular size can be explained by factors other than molecular size, and there is evidence of absorption of molecules exceeding the proposed cutoff criteria. The available data do not support strict cutoff criteria, indicating that the proposed values are incorrect.*[8]

[7] Environment and Climate Change Canada and Health Canada. November 2016. Assessment Report Triclosan Chemical Abstracts Service Registry Number 3380-34-5. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=65584A12-1

[8] Jon A. Arnot, Michelle I. Arnot, Don Mackay, Yves Couillard, Drew MacDonald, Mark Bonnell, and Pat Doyle. "Molecular size cutoff criteria for screening bioaccumulation potential: fact or fiction?" Integrated Environmental Assessment and Management 6, no. 2 (2010): 210-224

The conclusion that triclosan does not meet the criteria for bioaccumulation is in contrast to the findings by the European Union[9] where the Biocidal Products Committee (BPC)'s opinion concluded that triclosan is very bioaccumulative (vB) and that its transformation product, methyl triclosan, is "probably also vB."[10] This opinion was adopted by the BPC on June 25, 2015, confirming that "Triclosan is a candidate for substitution by being toxic and very bioaccumulative."[11]

Further investigation on the bioaccumulation of triclosan should be considered as it may have a significant impact on the risk management options under consideration for triclosan.

2) Address continuous presence of triclosan – Based on the final assessment, triclosan does not meet the criteria for persistence as outlined in the Persistence and Bioaccumulation Regulation. However, the extensive use of triclosan in various applications including natural health products, consumer and personal products, creates a situation where there is the continuous presence of triclosan in the environment, particularly in the proximity of wastewater effluents. Currently, there are no policies or regulations under Canada's chemicals management program that are well positioned to address this situation. The absence of adequate regulations or policies may lead to an inaccurate reflection of the toxicity associated with triclosan and severely undermine the management approach to address this and similar chemicals.

The proposed assessment finding for the bioaccumulation of triclosan presents a good example for Canada to review and strengthen the Persistence and Bioaccumulation Regulations under CEPA 1999, and more appropriately, align with other major jurisdictions that apply more stringent and protective criteria.

3) Minimal consideration to by-products of triclosan – There are a number of known by-products of triclosan resulting from triclosan going through a waste water treatment process. These include methyl-triclosan, chloroform, and dioxins and furans, which are estimated to be present in waste water effluent in lower concentration levels than triclosan. From data included in the final assessment and the risk management approach documents, it has been suggested that the removal rates of triclosan can range from 49 – 98% from secondary treatment plants in Canada. However, a minimal explanation was provided in the final assessment as to why the toxicity and risks associated with these by-products were not further explored. For example, the reliance

[9] European Chemicals Agency (ECHA). 2015. Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Triclosan. Accessed at https://echa.europa.eu/documents/10162/efc985e4-8802-4ebb-8245-29708747a358

[10] Ibid.

[11] European Chemicals Agency (ECHA). 2015. The Biocidal Products Committee adopts 11 opinions. Accessed at https://echa.europa.eu/documents/10162/22699796/Annex_BPC_11.pdf/2c1bc66b-476d-46b5-823e-8e501b982612

on secondary treatment technology results in the formation of methyl-triclosan which has the potential to be more persistent and bioaccummulative as compared to its parent compound, triclosan. Although the amount of methyl-triclosan is significantly less than that of triclosan, the government's decision fails to give sufficient consideration to the impact of methyl triclosan formation in its final decision; nor has it given any indication it will address the toxic by-products of triclosan released from waste water treatment plants.

Human Health

The comments below, although relevant to triclosan, encompass a broader perspective that reflects concerns about Canada's risk-based approach for substance assessment. CEPA 1999 states that "…the primary purpose of this Act is to contribute to sustainable development through pollution prevention". Canada's Chemicals Management Plan (CMP) was developed with the aim of reducing the risks posed by chemicals to Canadians and their environment.[12] Canada's implementation efforts on these objectives rely on conducting hazards and exposure assessment for specific substances to identify and manage risks. The risk-based approach tends to emphasize the need to manage risks. We offer that the most effective, efficient, pragmatic approach to achieve these objectives is to shift the approach from a risk-based approach to one that is hazard based. This approach would address the hazards associated with a substance and would rely on identifying the inherently safest, least-toxic, most and sustainable means to achieve an end.[13]

1) **Hazard assessment conducted by US and EU on triclosan results –** Several jurisdictions including the US and European Union (EU) have applied a hazard-based approach to triclosan. For example, the US Food and Drug Act (FDA) recent final rule on the Safety and Effectiveness of Consumer Antiseptics released on September 6, 2016[14], resulted in prohibiting the use of 19 substances, including triclosan, in targeted consumer antiseptic wash products. These products are rinsed off after use and this does not affect consumer hand not-rinsed "sanitizers" or wipes, or antibacterial products used in health care settings or by the food industry. The FDA requires data from affected industry stakeholders to demonstrate the safety and efficacy of the use of triclosan in their products.

[12] Government of Canada. Chemicals Management Plan. Accessed at http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php

[13] Prevent Cancer Now. December 2016. Canadian Environmental Protection Act (CEPA) Review Controlling Toxic Substances

[14] US Food and Drug Administration. Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use. A Rule by the Food and Drug Administration on 09/06/2016. In the *Federal Register*. Accessed at https://www.federalregister.gov/documents/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for

In the EU, a hazard assessment by the EU Scientific Committee on Consumer Safety concluded on the safety of triclosan in specific products. A review by Johnson et al. in 2016[15] highlighted that the EU Scientific Committee on Consumer Safety's opinion on triclosan (SCCP/1192/08) was adopted in January 21, 2009 and stated that:

> *Taking into account the provided toxicological data, the SCCP considers that the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.*
>
> Further noting that:
>
> *However, its use at a maximum concentration of 0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks ("common-use products" as defined by the applicant) are considered safe. Any additional use of triclosan in face powders and blemish concealers at this concentration is also considered safe but the use of triclosan in other leave-on products (e.g. body lotions) and in mouthwashes is not considered safe for the consumer due to the resulting high exposures.*[16]

2) **Justification to Omit Key Information in Use Patterns and Exposure Section** – The final assessment on triclosan has removed key US information in the section "Use Patterns and Exposure Assessment" that is relevant to complete the exposure assessment on triclosan. This omission is significant as the missing data draws from the US Food and Drug Administration's work requiring submission of evidence to demonstrate the safety of triclosan for a specific range of antiseptic products. Such a gap could have significant implications for the decision making process on triclosan.

3) **Key health studies contain potential bias** – The human health assessment may include studies that contain potential bias associated with funding sources. Such bias may lead to greater uncertainty with the results of the studies. We highlight **two** such studies relied upon in the human health assessment.
    a. Cullinan et al., 2012;

[15] Paula I. Johnson, , Erica Koustas, Hanna M. Vesterinen, Patrice Sutton, Dylan S. Atchley, Allegra N. Kim, Marlissa Campbell, James M. Donald, Saunak Sen, Lisa Bero, Lauren Zeise, Tracey J. Woodruff. "Application of the Navigation Guide systematic review methodology to the evidence for developmental and reproductive toxicity of triclosan." In *Environment International*, 92–93 (2016): 716–728

[16] ibid

b. Witorsch, 2014

Both studies were industry funded. This knowledge may raise questions related to the potential gains by the company to demonstrate the efficacy of triclosan in products. The Witorsch 2014 study specifically raised such concerns. Johnson et al. conducted a systematic review of the literature to determine the developmental and reproductive toxicity of triclosan. In this review, Johnson et al., made the following statements that question the reliability of the Witorsch review of endocrine disrupting toxicity from triclosan:

> *The…review of endocrine disrupting activity of triclosan by Witorsch concluded that personal care products containing triclosan do not pose a risk of adverse effects from endocrine disruption (Witorsch, 2014). While both the present review and the Witorsch review found insufficient evidence in humans and evidence of a dose-dependent decrease in thyroxine in rats, our conclusions about the available evidence differed from Witorsch for several reasons. First, our criteria for reaching a decision about a chemical's toxicity were defined and stated before our review was undertaken. In our review we had consensus on the final overall strength of the rodent evidence (sufficient), based on consistency in the findings of the studies and the meta-analysis estimate of reduced thyroxine concentrations in relation to postnatal triclosan exposure (Tables 4 and S4). In contrast, the Witorsch narrative review had no predefined criteria for reaching its conclusion and ultimately discounted the rat findings on thyroxine… In short, having consistent disruption of all thyroid system endpoints, in human studies (implicit if rats are to be discounted), and a documented mode of action sets a very high bar for demonstrating a chemical's toxicity. In addition, it is not consistent with the broad range of evidence evaluations by authoritative bodies such as U.S. EPA and IARC and is not necessary to make determinations about hazard (e.g., the mechanism of smoking is not known, but it is a carcinogen).*
>
> *A second possible reason for the difference between our conclusion that triclosan is "possibly toxic" versus Witorsch's "TCS does not present a risk of endocrine disruptive health effects through exposure to personal care products" is that our review focuses on the potential hazard of triclosan and does not estimate exposure or conduct a risk assessment.*[17]

[17] Ibid.

4) **Additional studies that warrant consideration in support of health impacts associated with triclosan** – The assessment completed by Environment and Climate Change Canada and Health Canada was substantial. It is noted, however, that there have been a number of studies that were released recently or not considered in the final assessment on triclosan that merit consideration for assessing the human health impacts of triclosan. We note that several studies including Cherednichenko et al., 2012; Gee, R. H. et al., 2008; Jacobs et al., 2005 are all relevant to the recent US FDA final rule released in September 2016, while another study by Fang et al., 2016, was also referenced in the US FDA final rule but released more recently. These and other studies are itemized in Table 1 below:

We ask you to consider these studies for human health effects associated with triclosan.

Table 1: Potential references not considered or new on human health effects from triclosan

Author /Title of Article	Description	Affiliations	Cited By
Ajao et al., 2015 "Mitochondrial toxicity of triclosan on mammalian cells."	Human PBMC and keratinocytes	University of Helsinki, Finland; Institute of Theoretical and Experimental Biophsyics (Russia); University of Pannonia, Hungary	Olaniyan et al., 2016
Braun, JM. 2016 "Early-life exposure to EDCs: role in childhood obesity and neurodevelopment"	"Ultimately, improved estimates of the causal effects of EDC exposures on child health could help identify susceptible subpopulations and lead to public health interventions to reduce these exposures" Triclosan as an endocrine disrupting chemical, was included in this study.	Brown University, Providence, Rhode Island, USA	New study
Cherednichenko et al., 2012 ''Triclosan Impairs Excitation-Contraction Coupling and Ca^{2+} Dynamics in Striated Muscle."	Physiological effects on muscle function in mice and fish	University of California; University of Colorado	U.S. FDA Proposed Rule 2013

Fang et al., 2016 "Absorption and Metabolism of Triclosan After Application to the Skin of B6C3F1 Mice."	Absorption, Distribution, Metabolism and Excretion (ADME) Data (mice)	U.S. National Center for Toxicology Research	U.S. FDA Final Rule 2016
Feng et al., 2016 "Endocrine Disrupting Effects of Triclosan on the Placenta in Pregnant Rats."	"Taken together, these data demonstrated that the placenta was a target tissue of TCS and that TCS induced inhibition of circulating steroid hormone production might be related to the altered expression of hormone metabolism enzyme genes in the placenta. This hormone disruption might subsequently affect fetal development and growth."	Beijing Center for Disease Control and Prevention; Beijing Advanced Innovation Center for Food Nutrition and Human Health; etc.	N/A (New Study)
Fernando D.M. et al., 2017 "Multi-omics approach to study global changes in a triclosan-resistant mutant strain of Acinetobacter baumannii ATCC 17978."	Resistance to triclosan	Winnipeg, University of Manitoba and the Public Health Agency of Canada	
Gee, R. H. et al., 2008 ''Oestrogenic and Androgenic Activity of Triclosan in Breast Cancer Cells."	FDA: "new data suggesting that triclosan… can cause alterations in thyroid, reproductive, growth, and developmental systems of neonatal and adolescent animals" (US FDA, 2013) "Triclosan possesses intrinsic oestrogenic and androgenic activity" (Gee et al., 2008)	University of Reading, UK	U.S. FDA Proposed Rule 2013
Henry and Fair, 2013 "Comparison of in vitro cytotoxicity, estrogenicity and anti-estrogenicity of triclosan, perfluorooctane sulfonate and perfluorooctanoic acid."	Effect on human breast cancer cells "The overall results demonstrated that triclosan, PFOS and PFOA have estrogenic activities and that co-exposure to contaminants	National Oceanic and Atmospheric Administration	Olaniyan et al., 2016

	and E(2) produced anti-estrogenic effects. Each of these compounds could provide a source of xenoestrogens to humans and wildlife in the environment."		
Jacobs et al., 2005 "Lignans, Bacteriocides and Organochlorine Compounds Activate the Human Pregnane X Receptor (PXR)."	"The evidence that organochlorine chemicals, particularly the ubiquitous triclosan, activate hPXR suggests that these environmental chemicals may, in part, exhibit their endocrine disruptor activities by altering PXR-regulated steroid hormone metabolism with potential adverse health effects in exposed individuals."	University of Surrey, UK	U.S. FDA Proposed Rule 2013
Johnson et al., 2016 "Application of the Navigation Guide systematic review methodology to the evidence for developmental and reproductive toxicity of triclosan."	This is the first systematic review of the human and animal evidence linking exposure to triclosan to adverse reproductive or developmental health endpoints.	University of San Francisco; U.S. EPA	N/A (New Study)
Kwon et al., 2013 "Evaluation of comparative cytotoxicity of spray-type chemicals used in household products."	Effect on human lung cells	National institute of Environmental Research, Incheon, Korea	Olaniyan et al., 2016
Lassen T.H. et. al., 2016 "Prenatal Triclosan Exposure and Anthropometric Measures Including Anogenital Distance in Danish Infants"	Found smaller head and abdominal circumference in newborn boys when maternal TCS levels were higher.	Denmark	
Olaniyan et al., 2016	Review of literature on health	University of Fort Hare,	N/A

“Triclosan in water, implications for human and environmental health.”	effects of TCS (e.g. thyroid homeostasis)	South Africa	(New Study)
Pinto et al., 2013 “Triclosan interferes with the thyroid axis in the zebrafish (Danio rerio)”	"First study demonstrating that TCS acts on the fish thyroid axis."	University of Algarve, Portugal	N/A
Tartaglia GM, et al. 2016 “Mouthwashes in the 21st century: a narrative review about active molecules and effectiveness on the periodontal outcomes”	“The literature has not clearly demonstrated which compound is the best for mouthrinses that combine good efficacy and acceptable side effects. Research should focus on substances with progressive antibacterial activity, prompting a gradual change in the composition of oral biofilm and mouthrinses that combine two or more molecules acting synergistically in the mouth” The study included triclosan.	Functional Anatomy Research Center (FARC) , Università degli Studi di Milano , Milano , Italy; Functional Anatomy Research Center (FARC) , Università degli Studi di Milano , Milano , Italy; Menzies Health Institute Queensland and School of Dentistry and Oral Health, Griffith University , Gold Coast , Australia; Department of Regulatory Affairs , Biokosmes srl , Bosisio Parini , Italy; Department of Veterans Affairs Medical Center , San Francisco , CA , USA.	New study
Walter DI, et al, 2017 “Occupational asthma caused by sensitization to a cleaning product containing triclosan.”		Occupational Lung Disease Service, Birmingham Chest Clinic, Birmingham, United Kingdom	New study
Weatherly et al., 2016 “Antimicrobial agent triclosan is a proton ionophore uncoupler of mitochondria in living rat and human mast cells and in primary human keratinocytes.”	Human mast cells “Our data indicate that TCS is a mitochondrial uncoupler, and TCS may affect numerous cell types and functions via this mechanism.”	University of Maine	Olaniyan et al., 2016

Wei, L, et al. 2016 "Triclosan/triclocarban levels in maternal and umbilical blood samples and their association with fetal malformation"	"Observations suggest that maternal blood test could be a useful assay for detecting fetal exposure to TCS and TCC, and high exposure to TCS may be potentially associated with increased risk for fetal malformations". TSC – triclosan TCC - triclocarban	Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing, China; Clinical Center of Reproductive Medicine, Affiliated Hospital of Weifang Medical University, Weifang, China; The Institute of Inspection and Supervision, National Health and Family Planning Commission in Chaoyang District of Beijing, China; Beijing Centre for Disease Control and Prevention, Beijing, China; Capital Medical University, B Beijing Centre for Disease Control and Prevention, Beijing, China.	New study
Winitthana et al., 2014 "Triclosan Potentiates Epithelial-To-Mesenchymal Transition in Anoikis-Resistant Human Lung Cancer Cells"	Effects on human lung cancer cells "In conclusion, we demonstrated for the first time that triclosan may potentiate cancer cells survival in detached condition and motility via the process of EMT. As mentioned capabilities are required for success in metastasis, the present study provides the novel toxicological information and encourages the awareness of triclosan use in cancer patients."	Chulalongkorn University, Bangkok, Thailand	Olaniyan et al., 2016
Yueh et al., 2014 "The commonly used antimicrobial additive triclosan is a liver tumor promoter."	Long term TCS exposure in mice enhances hepatocellular carcinoma (type of liver cancer)	University of California, San Diego School of Medicine	Dhillon et al., 2015

Yueh and Tukey, 2016 "Triclosan: a widespread environmental toxicant with many biological effects."	Review of TCS "Epidemiology studies indicate that significant levels of TCS are detected in body fluids in all human age groups. We document here the emerging evidence—from in vitro and in vivo animal studies and environmental toxicology studies—demonstrating that TCS exerts adverse effects on different biological systems through various modes of action. Considering the fact that humans are simultaneously exposed to TCS and many TCS-like chemicals, we speculate that TCS-induced adverse effects may be relevant to human health."	University of California, San Diego School of Medicine	Yueh et al., 2014

Section B: Proposal to add triclosan to the List of Toxic Substances in Schedule 1 of CEPA

We support the government's proposal to add triclosan to the List of Toxic Substances in Schedule 1 of CEPA 1999, based on the conclusion that triclosan meets the environmental toxicity criteria as defined in paragraph 64(a) of CEPA 1999.

While the order to add triclosan to Schedule 1 of CEPA 1999 will require the development of risk management tools, the diversity of such tools under consideration may be limited to non-regulatory approaches because of the key changes made from the draft to the final risk assessment on triclosan. The departure from the draft assessment for triclosan includes the decision to conclude that triclosan no longer meets the bioaccumulation criteria set out in the Persistence and Bioaccumulation Regulations, the lack of policy to consider the continuous presence of triclosan in the environment, the omission of data from the US FDA final rule, and the reliance on key studies on the methodology of which has received significant criticism but was not acknowledged in the final assessment.

Section C: Scope of Risk Management Strategy Inadequate: Seek significant revisions to strengthen government direction

Proposed Pollution Prevention Plans Notice - The current scope of the risk management strategy for triclosan proposes to use pollution prevention plans (P2 plans), a non-regulatory tool, to address the environmental toxicity of triclosan. Indeed, the proposed approach represents a change from 2012, when the government proposed to rely on industry voluntary actions. NGO stakeholders submitted extensive comments on the weakness of this approach and urged the government to consider regulatory measures to prohibit triclosan in specific products.

Using P2 Plans as a means to reduce the concentration of triclosan in the aquatic environment is not sufficiently precautionary. The current P2 Plans may offer very little to no change for triclosan-containing products or greater protection for the environment. Rather, the use of triclosan in consumer products may become further entrenched because the presence of triclosan below the predicted no-effect concentration (PNEC) of 376ng/L, would still be allowed in aquatic bodies. While one factor for the affected industry stakeholders to consider is the use of safe alternatives, it is extremely challenging, if not impossible, to require resources to be directed towards the development and adoption of safe alternatives to triclosan.

An effective P2 Plans should produce significant reductions of triclosan use in consumer products as well as its release to the environment. To achieve this, the P2 Plans would require setting reduction targets and timelines. Most P2 Plans Notices to date are not prescriptive in their approach to achieve pollution prevention. However, one example, the Notice requiring the preparation and implementation of pollution prevention plans with respect to effluents from textile mills that use wet processing (TMEs) for nonylphenol (NP) and its ethoxylates (NPEs), set a target of 97% reduction for NP and NPEs within 5 years. The scope and objectives of the P2 Plans for NP and NPEs were successfully achieved.

The absence of targets and timelines would create significant gaps in the approach for triclosan. The current approach to establish environmental objectives using a PNEC level of 376ng/L, may not effectively promote reductions in triclosan use. Even if stringent reduction targets and timelines were to be included, regulatory measures may be necessary to ensure that the government's action will reduce the usage of triclosan in consumer products and its ultimate release into the environment.

Recommendation: We do not support the use of a non-regulatory tool such as Pollution Prevention Plans to address triclosan levels in the environment.

Recommendation: We urge the government to re-consider a regulatory tool that would prohibit the use of triclosan in consumer products.

Types of products - Some companies are voluntarily phasing out triclosan in some or all of the products they manufacture, which will likely result in a reduction in the concentration of triclosan reaching the aquatic environment in Canada. However, there is great uncertainty as to whether or not products like the triclosan-containing hand sanitizers that do not require rinsing off, are also under consideration for chemical removal or concentration reduction. These sanitizers will eventually be washed off the hands still resulting in some triclosan reaching the waste water.

The current emphasis on triclosan-containing consumer products has focused on personal care products, household cleaners, natural health products, mouthwash and toothpaste. Consideration should also be given to other consumer products that may contain triclosan, such as clothing, shopping bags, counter tops, and flooring, as the triclosan from these products can eventually reach aquatic bodies. While the level of triclosan released from these products is not as high as that released from products that are covered under the proposed approach, they do require consideration. The government should require the affected industries to prove the efficacy of triclosan in these products and the use of possible safe alternative chemicals, if warranted.

Consumer Products Containing Triclosan in Canada are Extensive – The survey completed under Section 71 of CEPA 1999 in 2013 provided an updated inventory of products containing triclosan in Canada. The results of the survey indicated a significant decrease in the number of products expected to contain triclosan found on the Canadian market - from over 1600 products (in 2012) to over 300 products (in 2014). Despite the decrease, the number of products containing triclosan remains high.

Efficacy of triclosan in consumer products is an ongoing concern – The final decision on triclosan does not adequately conclude on the efficacy of triclosan in consumer products and its effectiveness as an antimicrobial substance for those uses. The final assessment acknowledges that there is the potential for anti-microbial resistance (AMR) to occur in a clinical setting, however, it did not find evidence to indicate that AMR occurs in a non-clinical setting (the general population). The possibility of AMR to occur in non-clinical setting due to the continued use of triclosan-containing products should be monitored with evidence from all sources of scientific data.

We acknowledge there may be situations, particularly in health care settings, when antimicrobial products containing triclosan may be necessary. When antibacterial function is necessary in a product, an assessment of alternatives should be conducted and clearly

demonstrate that any substitute for triclosan is safe for both human health and the environment.[18]

Imported Products - There is very little confidence that some imported products containing triclosan would be properly labelled to indicate its presence (depending on the country of origin). These products have the potential to contribute to the presence of triclosan in the aquatic environment. The reliance of P2 Plans cannot effectively address the potential growth in imports of products containing triclosan. Furthermore, the regulatory measures to ban triclosan in specific products implemented by US states such as Minnesota,[19] may leave Canada vulnerable to an increase in imported products prohibited in that state. The enforcement mechanism would have to be substantially improved to ensure that imported products comply with the acceptable concentrations of triclosan for the specified product categories. In addition, the consideration of import bans for these products are warranted; this to ensure that Canada does not become a dumping ground for products not allowed in other jurisdictions.

Strengthen Regulatory Measures Rather than Rely on Administrative Tools to Protect the Aquatic environment - Currently, the Cosmetic Ingredient Hotlist under the Cosmetic Regulations of the *Food and Drug Act* permits the use of triclosan by setting maximum concentrations in personal care products.[20] There is a fine balance to be achieved – the government initiating a PNEC for triclosan in aquatic bodies as the maximum allowable limit, the voluntary removal or decrease in the level of triclosan used in products by the major manufacturers of these products, and the specified concentration limits for triclosan as prescribed in the Hotlist. The wide range of options on triclosan use and limits is cumbersome and does not adequately consider the impacts to the environment as a priority. Further consideration on strengthening the approach is necessary in light of the different administrative requirements and non-regulatory tools expected to ensure the protection of the environment.

Alternatives to triclosan in consumer products - The current proposed approach to P2 Plans on triclosan will diminish the importance of seeking safe alternatives to triclosan. It is particularly important to note that there are safe substances currently in use in Canada that can act as preservatives and antiseptics. Some of these substances can be possible alternatives for triclosan in some products. The simple use of soap and warm water in place of triclosan containing products may, in many instances, achieve the desired effect. Further consideration in the Canadian management strategy should be dedicated towards informed

[18] Canadian Environmental Law Assocaition and Clean Production Action. July 2014. Chemicals in Consumer Products are Draining Trouble into the Great Lakes Ecosystem: GreenScreen® Assessment Shows Triclosan and Triclocarban Should Be Avoided. Accessed at http://www.cela.ca/sites/cela.ca/files/TC-TCC-CELA-997_0.pdf

[19] See: http://www.house.leg.state.mn.us/sessiondaily/SDView.aspx?StoryID=5284

[20] Health Canada. Cosmetic Ingredient Hotlist. List of Ingredients that are Restricted for Use in Cosmetic Products. Accessed at http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php#tbl2

substitutions for triclosan. Such consideration would require conducting an evaluation of the hazards of potential alternatives rather than rely on the risk based evaluation undertaken under CEPA 1999.

Currently, many of the potential alternative substances have not been assessed under CEPA 1999. By focusing on a hazard-based assessment to inform safe substitution, a determination can be made to avoid alternatives that have the toxicity impact associated with triclosan and avoid “regrettable substitutions”.

Conclusion

Thank you for your consideration of our comments above. We are available to respond to any questions you may have on our comments.

Yours truly,

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Attachment

Environment and Health Groups' Statement on Triclosan: Call on Canadian Government to Prohibit Triclosan in All Products November 27, 2014

November 27, 2014

Environment and Health Groups' Statement on Triclosan: Call on Canadian Government to Prohibit Triclosan in All Products

We, the undersigned public interest and not-for-profit groups, urge the Government of Canada to take urgent action to officially declare Triclosan (CAS#3380-34-5) to be toxic and add this chemical to the Toxics Substances List (Schedule 1) under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999). Measures must be taken to ensure a phase out of this chemical in all products. As well, mandatory alternatives assessment must occur to ensure informed substitution if chemical biocides can be shown to be necessary in specific applications. Applying alternatives assessment is particularly important to ensure that related antibacterial chemicals such as Triclocarban (CAS#101-20-2) do not become regrettable substitutes for triclosan.

Canadians are exposed to triclosan through a variety of routes including consumer and institutional products, treated textiles and food contact materials, drinking water contaminated with triclosan, breast milk and contaminated household dust.[1] The recent report on human biomonitoring in Canada[2] shows triclosan to be a wide ranging contaminant in the Canadian population. Triclosan is also an endocrine disruptor, with particular impacts on the thyroid. A new study released in August 2014 is the first to report on real-world exposures during pregnancy to triclosan and triclocarban.[3] It found that 50% of babies' cord blood contained triclosan. The presence of these substances pose a direct risk to the delicate balance of thyroid hormone in pregnant women and their infants that is necessary for healthy brain development.

The human and environmental health hazards of triclosan are highlighted in a July 2014 GreenScreen® assessment of triclosan. That report clearly demonstrates that triclosan is a chemical of high concern.[4] Triclosan is highly toxic in the aquatic environment, persistent and bioaccumulative, and is present in wastewater treatment plant effluents as well as in sewage sludge.

Triclosan and triclocarban, a similar antibacterial chemical incorporated into bars of soap and other consumer products, are ranked in the list of top contaminants of concern worldwide. US streams have a 60 – 100% likelihood of containing detectable quantities of both these chemicals. The presence of triclosan and triclocarban is so pervasive globally that they are now detectable in house dust worldwide, in ocean water and locations as remote as the water loop of spacecraft.[5]

In March 2012, two departments of the Canadian Government released their Preliminary Assessment Report for Triclosan. This assessment revealed varying levels of triclosan in wastewater effluent across Quebec, Ontario and British Columbia with data for triclosan concentrations in wastewater sludge across more provinces. Environment Canada concluded that triclosan meets the criterion of 'CEPA toxic' and could be added to the CEPA 1999 List of Toxic Substances for a range of possible risk management measures,[6] though to date, no action has been taken. In contrast, Health Canada stated that triclosan does not constitute a danger in Canada to human life or health. The disparity between the draft conclusions of Health Canada and Environment Canada for triclosan does not provide the necessary regulatory signal to the marketplace that this chemical should be eliminated from commerce.

The two departments failed to take a life cycle perspective to the assessment of triclosan and to take into account that 95% of the human use of this chemical goes down a drain where it further degrades into highly hazardous substances in the receiving waters. Triclosan is not only a direct hazard but undergoes transformation into hazardous methyl-triclosan during wastewater treatment, as well as being photo-transformed into various forms of dioxins including 2,8-DCDD, which the government considers to be of low toxicological concern. However, recent research notes that three other dioxin congeners, which are known photo-transformation products of chlorinated derivatives of triclosan, were also detected.[7] These transformation products are potentially of greater concern than 2,8-DCDD formed directly from triclosan and could be an important, yet unrecognized, source for polychlorinated dioxins in the environment. More dioxin generation will occur when triclosan-containing municipal sludge is incinerated.[8] These transformation products are also of concern in the Great Lakes basin where triclosan has been detected in over 89% of surface water samples.[9] Levels of triclosan and triclocarban in shallow sediments are known to make the survival and activity of many different animal species impossible.[10]

And it is not just our rivers, lakes and oceans that are at risk. Triclosan and triclocarban are contaminating our terrestrial environment, particularly through the application of sewage sludge to land where these chemicals are entering into animal feed and crops destined for human consumption. Researchers also warn that 'accumulation of antimicrobials in worms and plant material and subsequent uptake by higher organisms is a known pathway for ecological risks from exposure of vertebrates, including songbirds.'[11]

Since the draft assessment was released almost two years ago, evidence continues to mount about triclosan's human health impacts – notably a recent study released November 17, 2014 from the US National Academy of Sciences demonstrating that triclosan is a liver tumour promoter.[12]

Triclosan's link to antibiotic resistance is of further high concern. Indeed, the Canadian Medical Association has called upon the federal government to ban the sale of household antibacterial products due to the risk of bacterial resistance.[13] More fundamentally, both the Public Health Agency of Canada and the US Food and Drug Administration have indicated that soaps with added antibacterial ingredients, such as triclosan, are no more effective than the mechanical action of washing with plain soap and water.[14] A GreenScreen assessment of triclocarban[15] reveals this chemical to be an endocrine disruptor, persistent in the environment and highly hazardous in water - underlying the need to prevent the use of triclocarban as a possible substitute for triclosan.

We the undersigned therefore call on the Government of Canada to:

1. ***Officially declare triclosan (CAS RN: 3380-34-5) to be toxic and add triclosan to the Toxic Substances List (Schedule 1) under CEPA, 1999;***
2. ***Implement a phase-out of triclosan in all consumer and institutional products, with priority given to cleaning and personal care products, and require mandatory product labelling during the phase-out period;***
3. ***Adopt a framework of Informed Substitution and ensure that triclocarban is prohibited so that industry does not adopt a regrettable substitution.***
4. ***Require transparent alternatives assessments for safer substitutes if chemical biocides are shown to be necessary in specific cases.***

Furthermore, because the Great Lakes Basin is a binational responsibility, we urge the Government of Canada to liaise with the Government of the United States of America, all provincial and state governments in the Great Lakes Basin, and with the International Joint Commission to prohibit triclosan and ensure transparent alternatives assessments for safer substitutes if chemical biocides are shown to be necessary in specific cases.

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updated December 1, 2014

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ENDNOTES

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