To whom it may concern;

Re: Proposed Risk Management Approach for Triclosan

Below are comments from Ecojustice, Environmental Defence, the Canadian Association of Physicians for the Environment (“CAPE”), Équiterre, and the David Suzuki Foundation (“DSF”) in response to the Government of Canada’s Proposed Risk Management Approach for Triclosan published November 26, 2016. We applaud the government’s decision to add triclosan to Schedule 1 under the Canadian Environmental Protection Act, 1999 (“CEPA”). Nonetheless, we are concerned that the government has failed to adopt a science-based, precautionary approach to the regulation of triclosan in Canada. The Proposed Risk Management Approach will not protect the health of Canadians and the environment.

Our three overarching concerns are as follows:

1. In its assessment of triclosan and proposed risk management approach, the Government of Canada failed to consider that triclosan-containing washes and sanitizers offer no advantages beyond regular soap and water. These products are unnecessary and do not benefit Canadians.

2. Health Canada’s determination that triclosan does not constitute, or potentially constitute, a danger in Canada to human health for the purposes of subsection 64(2) reflects a failure to apply the precautionary principle.

3. The Government of Canada’s proposed risk management approach will leave Canadians – including children in particular – as well as the aquatic environment exposed to serious and unnecessary risks associated with the continued use of triclosan in this country. Canada should ban triclosan-containing washes and sanitizers as other countries around the world have done.
I. Introduction

Leading the legal effort for a brighter future, Ecojustice is Canada’s only national environmental law charity. Ecojustice has a staff of lawyers and scientists who use the power of the law to defend nature, slow climate change, and stand up for the health of our communities.

Environmental Defence is a national charity that challenges and inspires change in government, businesses and people to ensure a greener, healthier and prosperous life for all. Environmental Defence has a staff of policy experts supported by scientists, business leaders, lawyers, and community members working hard to protect Canada’s environment and human health.

CAPE is a non-profit organization established and run by physicians who have a deep concern about the adverse impacts that a degraded environment can have on human health.

DSF collaborates with Canadians from all walks of life to conserve our environment and find solutions that will create a sustainable Canada through science-based research, education and policy work.

Équiterre (legal name ASEED) has worked with citizens, farmers, organizations, think tanks, businesses, municipalities and governments of all stripes to influence environment and climate change policies and related practices in Quebec and Canada.

II. Prohibiting Triclosan Would Promote CEPA’s Sustainable Development Objectives

We support the Ministers’ decision to add triclosan to Schedule 1 of CEPA and to implement risk management strategies authorized by CEPA to reduce concentrations of triclosan in the environment. The assessment of triclosan identified use of consumer products containing triclosan – including personal care, non-prescription drug, natural health, and cleaning products – as the main source of triclosan in the Canadian environment. Although some of these products are regulated under the Food and Drug Act, that statute does not address releases or risks to the environment. We therefore agree that additional risk management under CEPA is appropriate and necessary.

However, we have serious concerns about the adequacy of the Ministers’ Proposed Risk Management Approach to protect the aquatic environment and human health. The Proposed Risk Management Approach focuses on the release of triclosan to surface water via wastewater treatment plants rather than on reducing risks to children and other members of Canadian society who are exposed to triclosan through consumer products. As set out in further detail below, the Proposed Risk Management Approach falls far short of the measures taken in other countries such as the United States (“US”), Australia, Japan, and the European Union (“EU”), and will expose Canadians – including children in particular – to serious and unnecessary health risks.

The primary purpose of CEPA is to contribute to sustainable development through pollution prevention. Sustainable development is “development that meets the needs of the present without compromising the ability of future generations to meet their own needs.” In the context of assessing substances under Part 5 of the Act, this means that in addition to considering the risks
posed by a given substance, a key consideration is whether and to what extent its use is necessary to meet the needs of present Canadians. Where a substance poses risks to human health or the environment and it has little to no utility, prohibition or significant restrictions on the use of that substance will advance CEPA’s objective of sustainable development.

Consideration of the benefits of a given substance is also necessary to ensure decision-making applies the precautionary principle as mandated by sections 2(1)(a) and 76.1 of CEPA. Where a substance poses little to no benefit but poses serious risks to the environment and human health, the range of cost-effective measures to prevent environmental degradation will be broad and will often include prohibition of the substance for those uses which provide no benefit.

A main shortcoming of the Government of Canada’s proposed approach to assessing triclosan and to developing a Risk Management Approach for the substance is its failure to consider the benefits (or lack thereof) that the substance offers. Such considerations were key to the recent decision of the US Food and Drug Administration (“FDA”) to ban triclosan and other active ingredients in over-the-counter consumer antiseptic wash products. Companies were unable to demonstrate to the FDA that triclosan and other ingredients are safe for long-term daily use and are more effective than plain soap and water in preventing illness and the spread of certain infections. There is no evidence to suggest that the risks and benefits of triclosan are any different in Canada than they are in the US, yet the government’s Proposed Risk Management Approach fails to protect the environment and human health to the same extent as the FDA’s ban. Canada’s failure to take precautionary, science-based action puts us behind not only the US but also the EU, Australia, and Japan.

Given the serious risks posed by triclosan (explained below) and its lack of sanitary benefits, strong, effective measures are needed to reduce exposure in Canada. However, the Proposed Risk Management Approach for Triclosan relies upon pollution prevention planning – a weak form of risk management that does not ensure emission reductions and has in the past proven to be ineffective.

Part 4 of CEPA provides for the development of pollution prevention plans for substances that are designated as toxic under Part 5 of the Act, that contribute to air and water pollution in another country, or that violate international agreements binding on Canada. With respect to triclosan, the Government of Canada has identified the following proposed risk management objective: “reducing the quantity of triclosan released to the aquatic environment as a result of the use by consumers of triclosan-containing products imported into and formulated in Canada”.

To achieve the proposed risk management objective and work towards achieving the proposed environmental objective of reducing concentrations of triclosan in the aquatic environment to levels below 376 ng/L, the Government of Canada proposes to develop a notice requiring the preparation and implementation of pollution prevention plans under section 56 of CEPA. The Notice would apply to formulators and importers of products containing triclosan.

Historically, pollution prevention plans have been successfully implemented in some cases, but have underperformed in many others. CEPA does not allow the government to establish minimum reduction requirements – enforcement is limited to the development and implementation of the pollution prevention plan, and not the results it achieves. In order for pollution prevention planning to be effective, the Minister should be empowered (and required) to prescribe emission reduction targets, rather than simply monitor whether a plan has been
developed and implemented. Ultimately, introduction of a more effective and prescriptive pollution prevention plan framework requires amendment of CEPA by Parliament.

Furthermore, the main source of triclosan pollution in the environment is consumer use of products containing triclosan, not emissions or releases from formulators or importers. However, the government’s proposal is for pollution prevention planning to be undertaken by formulators and importers of products containing triclosan. The Proposed Risk Management Approach does not address this disconnect and offers no analysis of the potential for pollution prevention planning to achieve the proposed environmental objective of reducing concentrations of triclosan in the aquatic environment to levels below the predicted no-effect concentration (“PNEC”). We conclude that this approach will be inadequate when it comes to protecting the environment.

In light of the limited utility of the existing pollution prevention plan framework, and in order to achieve the government’s stated environmental and risk management objectives in relation to triclosan, the Ministers should use the more effective tools contained in CEPA, including in particular issuing a ban on triclosan in consumer hand washes and sanitizers. This approach is set out in more detail below.

III. The Ministers Failed to Act Expeditiously

Our concerns about the Government of Canada’s regulation of triclosan are compounded by the inordinate delay in publishing the assessment of triclosan and the Proposed Risk Management Approach for Triclosan. Public comments were invited over a 60-day period commencing March 31, 2012. Following the “scientific consultation” envisioned in subsection 77(5) of CEPA, the Ministers are to consider comments received “in an expeditious manner” and publish in the Canada Gazette a summary of the summary of the screening assessment and a statement indicating the measure that the Ministers propose to take. Despite this legal requirement to act expeditiously, the Ministers took approximately 4.5 years to publish their assessment of triclosan and the Proposed Risk Management Approach. Despite this significant delay, the public was not given an opportunity to comment on the assessment and provide more recent scientific information relevant to the Ministers, even though scientific evidence of the health and environmental risks posed by triclosan has continued to grow over the 4.5 years since the public was invited to comment.¹

Our review of the assessment of triclosan has found several weaknesses which we discuss further below. Given the long delay since the initial assessment was published, it is our position that the Ministers have a duty to consider these comments and recommendations, and to revise the assessment as appropriate.

IV. Triclosan Should be Prohibited in Hand Washes in Canada

Triclosan is a preservative and anti-bacterial agent used in 1,600 cosmetics and personal care products in Canada. This includes products such as anti-bacterial soaps, hand washes, toothpaste, and deodorants. The US FDA recently made the decision to ban triclosan in soaps and hand washes because manufacturers were unable to demonstrate it is both safe for long-term daily use and more effective than plain soap and water in achieving the objectives of illness prevention and stopping the spread of certain infections. The FDA’s ban is similar to that passed by the EU one year ago, and Australia and Japan have set limits on triclosan in hand washes that are far below the levels permitted in Canada.

A. Triclosan is toxic to the aquatic environment

We are pleased that the Ministers recognize that triclosan has or may have an immediate or long-term harmful effect on the environment or its biological diversity and therefore meets the definition of “toxic” set out in section 64(a) of CEPA. This is because triclosan is known to be toxic to aquatic plants and animals even at low concentrations – causing reduction in growth and reproduction, and impacting survival. It bioaccumulates in fish and has been detected in numerous waterbodies across Canada because it is continually released when products containing triclosan are washed down the drain. Triclosan can transform into dioxins, a highly toxic group of chemicals, when it degrades in surface water while exposed to sunlight. Alarmingly, it also has the potential to react with chlorine in drinking water to form the carcinogen chloroform.

The species sensitivity distribution in the government’s preliminary assessment for aquatic organisms proposed a PNEC of 115 ng/L for triclosan. The 2016 assessment does not explain why the final PNEC of 376 ng/L is more than three times higher than the PNEC proposed in March 2012. The Danish EPA risk assessment yielded a PNEC of 50 ng/L based on an algae study. We recommend that Environment Canada review the final PNEC to ensure it is protective of all aquatic species including the most sensitive species to the harmful effects of triclosan.

Recommendation 1

Environment Canada should review the predicted no-effect concentration (“PNEC”) for triclosan to ensure it is protective of all aquatic species, including those most sensitive to the harmful effects of triclosan.

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**B. Triclosan is toxic to humans**

We are disappointed that, based on its assessment of human health risk, Health Canada has maintained its position that triclosan does not meet the standard for human health toxicity for the purposes of subsection 64(c) of CEPA.

The assessment of threshold substances requires determining the dose-response relationship, with the aim of identifying the highest dose of the substance that does not reveal any adverse effects. This dose is defined as the No-Observed-Adverse-Effect-Level (“NOAEL”). NOAEL is established by reviewing toxicological and epidemiological studies. The NOAEL is converted to an Acceptable Daily Intake (“ADI”) over a lifetime with the application of uncertainty factors and compared to estimates of exposures. Selection of the NOAEL forms the basis of a risk assessment.

This approach is outdated because many substances, including in particular endocrine-disrupting chemicals such as triclosan,⁶ challenge traditional concepts in toxicology, in particular the dogma of “the dose makes the poison”. This is because endocrine-disrupting chemicals can have effects at low doses that are not predictable by knowing the effects at higher doses. We provide the following comments on the assessment, but fundamentally the assessment should recognize that triclosan is an endocrine-disrupting chemical that is capable of adverse effects even at extremely low levels of exposure.

**Recommendation 2**

The government’s assessment of triclosan should recognize triclosan as an endocrine-disrupting chemical that is capable of adverse effects even at extremely low levels of exposure.

1. **The selected NOAEL is not protective of health**

A NOAEL of 25 mg/kg bw per day of triclosan was selected by Health Canada from a 90-day oral toxicity study in mice resulting in an ADI of 0.08 mg/kg bw per day. This choice of NOAEL is not precautionary based on the studies reviewed in the assessment and the NOAEL used by other jurisdictions.

Several studies referenced in the government’s assessment indicate adverse effects may occur at or below the chosen NOAEL of 25 mg/kg bw per day. For instance, a 90-day study on mice reported “[a] decrease in cholesterol levels”, “a slight increase in liver/gallbladder weights in

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females “and “[a] slight increase in the number of animals with liver lesions” at a dose of 25 mg/kg bw per day.7

A 91-day study on beagle dogs revealed “a number of “abnormal” values in individual animals at 25 mg/kg bw per day and above suggestive of liver dysfunction, as were urinalysis findings of bile salts and polymorphonuclear leukocytes in the urine at all doses”. This study also observed “unusual Kupffer cell activation, bile retention and/or necrosis were seen in the liver of one female, two males and two animals of each sex at 25, 100 and 200 mg/kg bw per day, respectively” and “[s]evere liver damage was associated with bone marrow hyperplasia and was seen in one female at 25 mg/kg bw per day” that were not present in control animals. This study found “clinical signs of toxicity, liver damage and enhanced hematopoietic activity were observed at the lowest dose tested” and set the LOAEL of 24 mg/kg bw per day.8

In a 90-day oral toxicity study on Beagle dogs, body weight gain in females at 12.5 mg/kg bw per day was significantly lower in relation to untreated controls. This study found a NOEL of 12.5 mg/kg bw per day based on liver morphology.9

A 60-day study on male Wistar rats found that triclosan caused “a significant decrease in the weight of testis and sex accessory tissues (SATs) at 10 and 20 mg/kg bw per day.” Several other statistically significant effects were noted in this study, including a “decrease in daily sperm count at 20 mg/kg bw per day as compared to the control.”10 This study appears to have been dismissed by Health Canada because of unverified concerns about contamination of the triclosan with dioxin. This is contrary to the precautionary principle, given that where there are threats of serious damage, lack of full scientific certainty is not to be used as a reason to postpone cost-effective measures to prevent environmental degradation.

Other studies have reported health effects at existing levels of exposure. A recent Canadian study found that women with the urine concentrations in the highest 25% (therefore highest exposure) had a longer time to pregnancy even after accounting for maternal and paternal age, smoking, education, body mass index (BMI), and household income.11

In choosing a NOEL to set the ADI, the assessment dismisses the studies on the dogs with limited explanation other than stating “study deficiencies, limited reporting, the age of the studies and the inconsistent results obtained.”

The EU Scientific Committee on Consumer Safety (SCCS) recommended a NOEL of 12 mg/kg bw per day based on haemotoxicity,12 or half that of Canada’s. By choosing a NOEL that is double the limit set by the EU, the Ministers are clearly violating their legal duty to apply the precautionary principle and to protect the health of Canadians.

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8 Ibid at pp 23-24.
9 Ibid at p 24.
10 Ibid at p 27.
11 Ibid at p 29.
Recommendation 3

We recommend that Health Canada lower the NOAEL and the associated ADI for triclosan based on the studies discussed above that have assessed a lower NOAEL, such as that used by the European Union’s Scientific Committee on Consumer Safety.

2. There are serious gaps in the government’s exposure assessment

The potential sources of exposure to triclosan are numerous, including consumer products treated with triclosan such as toys; personal care products containing triclosan, such as soaps, hand washes, and toothpaste; and exposures through breastmilk, drinking water, and household dust caused by the widespread contamination of our environment with triclosan.

To estimate exposure the Government of Canada’s assessment relies on human biomonitoring data, specifically concentrations in urine. The Canada Health Measures Survey (CHMS) found that 72% of the Canadian population are exposed to triclosan based on detections in urine. Some populations such as First Nations on reserves were not included in this study, leaving a gap in knowledge of vulnerable populations that are disproportionately exposed to and impacted by many environmental hazards. It is unclear if the other biomonitoring studies included First Nations. If the risk to First Nations on reserves has not been assessed then that is an unacceptable gap that must be addressed, particularly given other compounding risks faced by First Nations in relation to the social determinants of health.

Recommendation 4

The assessment must consider the health effects of triclosan exposure on vulnerable populations such as First Nations. Many First Nations carry a greater health burden than the average Canadian due to their proximity to industrial pollution sources (e.g. Fort McKay First Nation, Aamjiwnaang First Nation), and historical and ongoing pollution that has contaminated their lands and country foods (e.g. Grassy Narrows First Nation, and many Inuit peoples in Canada’s north).

The Maternal-Infant Research on Environmental Chemicals (MIREC) study examined 200 women in their first trimester of pregnancy and found triclosan in 99% of maternal urine samples. The Health Canada Plastics and Personal-Care Product Use study (P4) detected triclosan in more than 80% of the maternal urine samples. These studies were used to estimate exposure levels for the general population from ages 3 to 79 years.

For children less than 3 years old, there is less urine analysis data available, although what is available shows exposures in the majority of children under 3 years. The assessment attempts to fill this gap in data by examining infants’ and children’s triclosan exposures through nursing, object to mouth behaviours, and dust ingestion and inhalation. It assesses the aggregate exposures of children from 2 to 3 years of age based on dust ingestion, object to mouth, and
nursing combined with the urine data, and in infants under 3 months based only on dust ingestion and object to mouth, combined with the urine data.

The under 3-months infant exposure scenario does not include nursing. The assessment explains that the majority of the babies were breastfed so the urine concentration would be due to breastmilk. This assumption lacks precaution as the triclosan in infants’ urine could also be due to other exposures that are missed in the aggregate assessment.

One such exposure that was excluded from both of these aggregate assessment is that which occurs from the use of triclosan hand washes and soaps. It is not explained why this was omitted from the aggregate assessment as it is a very obvious exposure, and likely would be the highest exposure. Triclosan-containing hand washes and soaps are used in homes and daycares, where children and possibly infants are exposed. Another exposure scenario that is omitted without explanation is through the use of triclosan containing toothpaste. Children as young as 7 months can have teeth and may start to have their teeth brushed, and certainly older children use toothpaste and are more likely to ingest it when they use it than adults.

It is unclear as to why some exposure scenarios were included and others were omitted from the aggregate assessment. A more precautionary approach would be to include all possible exposure scenarios in the aggregate assessment.

**Recommendation 5**

The children and infants aggregate exposure assessments should be revised to include the use of triclosan containing-hand washes, soaps, and toothpastes. The infant assessment should also include exposure through breastmilk.

The assessment does not consider the impact of the US FDA ban on the availability of triclosan-containing soaps and hand washes in Canada. There is a risk that cheap triclosan products that can no longer be sold in the US will flood into Canada, increasing their presence on store shelves. This could result in an increase in the use of triclosan-containing washes and soaps in Canada.

**Recommendation 6**

The assessment should consider the potential for the US FDA ban to result in an increase in the availability of triclosan hand washes and soaps in Canada, and a correlating increase in use and exposure to triclosan in this country.

Cumulative effects of triclosan exposure with other chemicals was not assessed because it is not required under CEPA. The reality is that no one is exposed to just a single chemical. Indeed, by the time most people are done their morning routine they may have been exposed to over 100 chemicals through personal care products alone. Factors such as income, education level,
occupation, sex, age, and diet leave some populations more exposed than others to harmful chemicals and also more susceptible to the adverse effects that those chemicals can cause.

By way of example, a 2016 study documented cumulative exposures to endocrine disrupting chemicals from baby teether, which leach triclosan, bisphenols, and other endocrine disrupting chemicals. Unfortunately, CEPA still frequently takes a one-by-one approach to assessing chemicals as it does here which is all the more reason to instill greater precaution in the human health assessment.

If the assessment was modified to decrease the NOAEL as recommended above, and all sources of exposure to triclosan were considered, including the potential impacts of the US FDA ban, the estimated Margins of Exposure (MOE) would decrease, showing that Canadians are at a higher health risk from exposure to triclosan than estimated.

3. Triclosan can contribute to the emergence of “superbugs”

In addition to the health effects discussed above, triclosan is also adversely affecting health by contributing to the emergence of antibiotic-resistant germs or “superbugs”, thus decreasing the effectiveness of antibiotics. Citing concerns about bacterial resistance, the Canadian Medical Association has called on the federal government to ban all antibacterial household products.

The assessment cites a study that found “there is the potential for triclosan-resistant bacteria to exist in clinical settings” and although, according to the assessment, it has not been documented outside the clinical setting it will be too late if a superbug does appear as the health impacts would be catastrophic.

4. Conclusions on health toxicity

Given the strong evidence of human health impacts and the risk of bacterial resistance, triclosan constitutes a danger in Canada to human health and meets the definition of “toxic” under section 64(c) of CEPA.

Recommendation 7

The Ministers should find that triclosan constitutes a danger in Canada to human health and meets the definition of “toxic” under subsection 64(c) of CEPA.

15 Supra note 7, The Assessment, at p 73.
**C. Triclosan offers no benefits beyond regular soap and water**

Experts including the FDA, the Canadian Pediatric Society, and the Canadian Medical Association agree there is no evidence that antibacterial soaps containing triclosan are more effective than regular soap and water. The Ministers do not appear to have considered this lack of benefit in their toxicity assessment or Proposed Risk Management Approach. This is a serious and inexplicable oversight.

The only circumstances in which anti-bacterial soaps and washes containing triclosan may be beneficial are in hospital and health care settings, or the homes of persons with serious diseases impacting the immune system, where preventing infectious illness symptoms and reducing bacteria on hands is critical.

In other words, for the vast majority of Canadians triclosan-containing soaps and hand washes should not be used in our homes, offices, daycares, or schools. In those places, they can cause serious harm to people and the environment while offering no benefits. Given the sustainable development and pollution prevention objectives of CEPA, allowing the risks posed by these products cannot be justified.

In the event that the Ministers decide not to adopt a ban on triclosan-containing soaps and handwashes in Canada, then at the very least they should develop risk management measures targeting schools, daycares, and families with young children discouraging the use of these products.

**Recommendation 8**

*Given triclosan-containing soap is no more effective than soap and water, yet poses considerable risks to the environment and human health, it should be banned in soaps and hand washes.*

We would welcome the opportunity to answer any questions with respect to these comments, and remain committed to working with the Government of Canada to ensure the health of Canadians and our environment are protected now and in the future from the unnecessary and serious risks posed by triclosan. Given our organizations’ direct stakeholder interest in the regulation of triclosan in Canada we request to be informed of any future decisions regarding this substance.

Yours truly,

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