Summary of Public Comments received on the Risk Management Approach and Final Assessment Report for Triclosan (CAS RN 3380-34-5)

The substance triclosan (CAS RN 3380-34-5) was assessed by Environment and Climate Change Canada and Health Canada as part of the Chemicals Management Plan. Comments on the risk management approach for triclosan were provided by: Action cancer du sein du Québec / Breast Cancer Action Quebec; Association pour la santé environnementale du Québec / Environmental Health Association of Quebec; Benedictine Sisters; Breast Cancer Action Manitoba; Canadian Cosmetic, Toiletry and Fragrance Association; Canadian Environmental Law Association; Chemical Sensitivities Manitoba; Citizens Environment Alliance of Southwestern Ontario; Citizens Network on Waste Management; City of Toronto; Clean Water Action; Colgate-Palmolive Canada Inc.; Community Health Opposition to Known Emissions Dangers; Crooked Creek Conservancy Society of Athabasca; Dr. Gail Krantzberg, Professor; Ecojustice; EcoSuperior Empire State Consumer Project, Inc.; Environmental Defence; Équiterre; Federation of Ontario Cottagers' Associations; Food and Consumer Products of Canada; Friends of the Earth Canada; Georgian Bay Association; Halifax Project; Health, York University; Lake Ontario Waterkeeper; Learning Disabilities Association of Canada; National Network on Environments and Women's Health; York University; Ontario Ministry of the Environment and Climate Change; Ontario Rivers Alliance; Ottawa Riverkeeper; Oxford Coalition for Social Justice; Pesticide Action Network North America; Petition from Canadian Citizens; Prevent Cancer Now; Quill Plains (Wynyard) Chapter; Council of Canadians; Save The River / Upper St. Lawrence Riverkeeper; Science and Environmental Health Network; Synergie Santé Environnement; The Canadian Association of Physicians for the Environment; The David Suzuki Foundation; Toronto Environmental Alliance; various Canadian Citizens; Wastewater Education; Watershed Sentinel Educational Society; and Women's Healthy Environments Network.

A summary of comments and responses is included below, organized by topic:

Risk Management – Alignment with United States (US) Ban 3
Risk Management – Alignment with Other Jurisdictions 4
Risk Management – Potential Dumping of Products in Canada 4
Risk Management – Selection and Design of Risk Management Instrument 6
Risk Management – Alternatives 6
Risk Management – Recognition of Early Actions 7
Risk Management – Support for proposed approach 7
Risk Assessment – Support for Conclusion 7
Risk Assessment – Disagreement with Conclusion 8
Risk Assessment – Conclusion 8
Risk Assessment – Public Comments 8
Risk Assessment – Human Health Exposure Assessment 8
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 9
Risk Assessment – Human Health Exposure Assessment 10
Risk Assessment – Human Health and Ecological Exposure Assessment 10
Risk Assessment – Human Health and Ecological Exposure Assessment 10
Risk Assessment – Human Health and Ecological Exposure Assessment 10
Risk Assessment – Alignment with US and EU 10

Risk Assessment – Uses and Releases 11
Risk Assessment – Uses and Releases 11

Topic	Rolled up comment	Response
Risk Management – Alignment with United States (US) Ban	Several stakeholders were of the view that triclosan should be banned.	Canada undertook a rigorous scientific assessment and found that triclosan can be toxic to the environment above certain levels. The assessment establishes a predicted no-effect concentration (PNEC), which represents the concentration of triclosan in the environment at and below which harm is not expected to occur in the aquatic environment. At the time of the assessment, the levels in the aquatic environment were above this level of concern at a limited number of sites. To address this ecological risk, the Government has proposed the use of a Pollution Prevention Planning Notice (P2 Notice) to reduce the amount of triclosan from products that are imported into and formulated in Canada by 30% from 2011 levels. A P2 Notice is a regulatory and enforceable tool that would require companies to create and implement a pollution prevention plan. Many companies have committed to move or have already moved away from triclosan. This tool could recognize those companies that have already taken action, while encouraging further reductions from others. In addition, Canada already restricts the amount of triclosan that can be used in cosmetics, non-prescription drugs and natural health products. Since 2014, triclosan has not been registered for use in plastics, polymers and textiles in Canada. Considering all the factors mentioned above, a ban was not selected as the proposed risk management instrument.

Topic	Rolled up comment	Response
Risk Management – Alignment with Other Jurisdictions	Canada's risk management approach is not aligned with that of the United States (US), Japan, Europe or Australia.	Existing controls in Canada and other jurisdictions, including the United States (US), Europe, Japan and Australia, were noted in the published Risk Management Approach document. Slight variations between jurisdictions often occur due to differences in regulatory regimes. However, in general, limits in Canada are similar to those found in Japan, Europe and Australia. Canada has limits for triclosan of 0.03% in mouthwash, 0.3% in cosmetics and natural health products, and 1% in non-prescription drugs. Australia allows levels higher than 0.3% in cosmetics, but only with labelling. Japan allows less triclosan in cosmetics with a limit of 0.1%. Europe allows the same level as Canada (i.e., 0.3%) but only for certain types of cosmetics, including toothpastes, hand soaps, body soap / shower gels and deodorants (non-spray), face powders and blemish concealers, and nail products where the intended use is to clean the fingernails and toenails before the application of artificial nail systems. Europe allows a higher level of triclosan in mouthwashes compared to Canada (i.e., 0.2% vs. 0.03%). More significant differences exist between Canada and the US. For example, the US does not have any limits on the levels of triclosan allowed in cosmetics. However, the United States Food and Drugs Administration (US FDA) has published a final rule entitled the Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use, which after September 6, 2017, in effect bans triclosan in a specific product type (antibacterial hand and body washes), as manufacturers did not submit information to demonstrate that triclosan was both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections.
Risk Management – Potential Dumping of Products in Canada	Several stakeholders expressed concerns about the potential for the United States Food and Drug Administration (US FDA) ban to result in an increase in the availability of triclosan hand washes and soaps in Canada, and a correlating increase in their use and exposure to triclosan.	The Government of Canada currently restricts the amount of triclosan in products under the *Food and Drugs Act*: • 0.03% in mouthwashes • 1.0% in non-prescription drugs • 0.3% in cosmetics and natural health products

Topic	Rolled up comment	Response
		In addition, in 2014, under the *Pest Control Products Act*, Canadian registrants voluntarily discontinued the sale of pest control products containing triclosan for use as a material preservative in textiles, leather, paper, plastic and rubber materials. The number of cosmetic products containing triclosan has decreased in Canada, based on cosmetic notifications to Health Canada (i.e., from 1,600 at the time of the preliminary assessment down to 322 at the time of the final assessment), which suggests that the use of triclosan is decreasing. In addition, many companies have committed to move or have already moved away from triclosan. A P2 Notice is a regulatory and enforceable tool that would require companies to create and implement a pollution prevention plan. The proposed objective of the P2 Notice is to reduce the amount of triclosan from products that are imported into and formulated in Canada by 30% from 2011 levels. Considering the existing restrictions in Canada, the proposed P2 Notice, the length of time that the US FDA is providing to US companies to inform their business decisions, and the nature of the North American market for these products, it is unlikely that sales of US products would increase in Canada. Results from the Triclosan P2 Notice will be evaluated and levels of triclosan in the Canadian environment will continue to be measured under the Chemicals Management Plan monitoring and surveillance program to make sure that levels stay below the point where there could be a concern. If levels are found to remain above the target level, the government could take further action on triclosan.

Topic	Rolled up comment	Response
Risk Management – Selection and Design of Risk Management Instrument	Several stakeholders submitted comments expressing concern that the use of a P2 Planning Notice may not address the source of concern, which is, releases resulting from the consumer use of products containing triclosan. Some did not view the P2 Planning Notice as adequate to protect human health and the environment. Some were concerned that the benefit of the substance (or lack thereof) was not taken into consideration in selecting the risk management instrument. Some were also concerned that the risk management instrument would not address growth in imports or products containing triclosan.	A P2 Notice is an enforceable instrument under the *Canadian Environmental Protection Act, 1999* (CEPA). Therefore, those who are subject to it will have enforceable requirements, including reporting on anticipated and actual results toward meeting the objective. The proposed objective of the P2 Notice is to reduce the amount of triclosan in products that are imported into and formulated in Canada by 30% from 2011 levels. This target was selected to achieve Canada's environmental objective. Results from the proposed Triclosan P2 Notice will be evaluated and levels of triclosan in the Canadian environment will continue to be measured to make sure that levels stay below the point where there could be a concern. If levels are found to be above the target level, the government could take further action on triclosan. When P2 Notices have been used in the past for products, they have been highly successful in achieving their objectives and have been shown to be an effective tool in helping protect the environment and human health. For example, the P2 Notice on nonylphenol and its ethoxylates contained in products was successful and the quantities of these substances used to make products in Canada and in imported products were reduced by 96%.
Risk Management – Alternatives	Several stakeholders expressed concern that the substitution of triclosan may result in its replacement with alternative substances that may cause more environmental harm. Some asked that companies be required to seek	The proposed P2 Notice would require those subject to the Notice to consider all the factors outlined in the Notice when preparing their Plan. The triclosan P2 Notice could require those subject to the Notice to consider using alternative substances to triclosan that reduce or minimize harmful effects to the environment or to health, while complying with all other relevant existing legislation. In

Topic	Rolled up comment	Response
	approval of alternatives.	addition, those subject to the Notice could also be required to consider that the ecological assessment for triclosan indicates that triclosan's transformation product, methyl triclosan, and similar chemicals such as triclocarban could also contribute to potential harm. Detailed information about the proposed P2 Notice will be available in the consultation document at https://www.canada.ca/en/health-canada/services/chemical-substances/other-chemical-substances-interest/triclosan.html. In addition, the consultation document notes that due to its properties, phenol, 2-phenoxy-, trichloro deriv. (CAS RN 64111-81-5) is subject to a Significant New Activity Notice under CEPA.
Risk Management – Recognition of Early Actions	One industry association requested that the government take into consideration the downward trend of triclosan use in Canada.	The proposed objective of the P2 Notice would be to reduce the amount of triclosan in products that are imported into and formulated in Canada by 30% from 2011 levels. Many companies have committed to move or have already moved away from triclosan. The proposed P2 Notice could recognize those companies that have already taken action, while encouraging further reductions from others.
Risk Management – Support for proposed approach	Some industry stakeholders expressed general support for the RM approach and objective, noting that the instrument is commensurate with the risk management objective.	Noted.
Risk Assessment – Support for Conclusion	Some expressed support for the conclusion with respect to human health and the fact that the data submitted were considered in establishing the ecological predicted no-effect concentration (PNEC).	Noted.

Topic	Rolled up comment	Response
Risk Assessment – Disagreement with Conclusion	Several stakeholders expressed disappointment that triclosan was concluded to not pose a risk to human health. Many felt that a ban should be instituted as they believe that triclosan poses a risk to human health. Others felt that antibacterial hand soaps are not necessary.	Based on the human health assessment—which used recent biomonitoring data and a conservative No Observed Adverse Effect Level (NOAEL) database—the margins of exposure for human health were deemed adequate and, therefore, triclosan does not meet the criteria set out in subsection 64(c) of CEPA.
Risk Assessment – Conclusion	Comments on the ecological component of the assessment focused on triclosan's potential for bioaccumulation, degradation products, cumulative effects and PNEC value. Several comments were supportive of the ecological component of the assessment.	Comments on the ecological component of the triclosan assessment were considered and were used as appropriate to inform the risk management approach for triclosan to mitigate its effects in the Canadian environment.
Risk Assessment – Public Comments	Given the length of time between the draft and final assessments, the Government of Canada should consider comments on the final assessment. Stakeholders that provided information during the assessment process are concerned about these studies being taken under consideration during the assessment process and conclusion.	The Government of Canada considered all available environmental monitoring data and studies, as well as all available and relevant scientific studies on potential effects of triclosan on human health, including data available on laboratory animals and humans, to reach a conclusion on triclosan toxicity under CEPA.
Risk Assessment – Human Health Exposure Assessment	Assessment should have used a lower No Observed Adverse Effect Level (NOAEL).	All available information on potential hazards of triclosan was considered in the assessment, including information on humans and other mammals. A conservative NOAEL database was selected and compared to upper-bound exposure estimates based on recent biomonitoring data. The margins of exposure were deemed adequate, and therefore triclosan is not considered to be harmful to human health at current levels of use.

Topic	Rolled up comment	Response
Risk Assessment – Human Health Exposure Assessment	Assessment should have included risks to First Nations on reserve.	Exposure levels were examined for a broad range of subpopulations, from infants and toddlers to adolescents and adults (including workers), using human biomonitoring data from the Canadian Health Measures Survey (CHMS), the Plastics and Personal-Care Product Use in Pregnancy (P4), and the Maternal-Infant Research on Environmental Chemicals (MIREC). The CHMS is a nationally representative survey which measured spot urine samples from approximately 2,500 individuals aged 3 to 79 years at 18 sites across Canada from 2009 to 2011.
Risk Assessment – Human Health Exposure Assessment	The child/infant exposure assessment should have included hand washes, soaps and toothpastes. The infant exposure assessment should have also included breast milk.	Human biomonitoring data (urine and breast milk) account for all exposures, and are compared to potential human health effects in the assessment.
Risk Assessment – Human Health Exposure Assessment	Triclosan should be considered in the assessment as an endocrine-disrupting chemical capable of adverse effects even at extremely low levels of exposure.	The Government of Canada considered all relevant scientific studies on the potential effects of triclosan on endocrine systems, in particular on thyroid function, including data available for laboratory animals and humans. They ranged from short-term studies to more chronic scenarios. However, these effects were not considered to be critical effects in the characterization of risk in humans.
Risk Assessment – Human Health Exposure Assessment	Stakeholders are concerned that key studies in the human health assessment section could have potential biases because of their source of funding.	A robust process, including a focus on publications in peer-reviewed scientific journals, external peer review and public consultation, is undertaken to ensure use of best available science.
Risk Assessment – Human Health Exposure Assessment	Stakeholders are concerned about human exposure to triclosan contained in consumer products and triclosan's endocrine disruptor characteristic.	The risk to human health resulting from exposure to multiple sources of triclosan (such as consumer products) and routes of exposure was considered through the use of biomonitoring data. Human biomonitoring data were used to characterize both mean and upper-bound exposure estimates for the Canadian general population.
Risk Assessment – Human Health Exposure Assessment	Triclosan is a known endocrine disruptor and it interferes with the human body's natural hormones. Its breakdown products include human carcinogens chloroform and dioxins, one of the most toxic groups of substances known.	The Government of Canada considered all relevant scientific studies on the potential effects of triclosan on endocrine systems, in particular on thyroid function, including data available for laboratory animals and humans. They ranged from short-term studies to more chronic scenarios. However, these effects were not considered to be critical in the characterization of risk in humans. The formation of transformation products was considered in the assessment of triclosan, and based on the available information, the formation of these transformation products was not deemed to be of concern.

Topic	Rolled up comment	Response
Risk Assessment – Human Health Exposure Assessment	Professional groups are concerned that triclosan may contribute to the spread of antibiotic-resistant bacteria.	The assessment included further details on the potential for triclosan-induced antimicrobial resistance. Based on available information, induction of antimicrobial resistance from current levels of triclosan has not been identified as a concern for human health. More information on the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), which monitors trends in antimicrobial use and antimicrobial resistance in selected bacterial organisms from human, animal and food sources across Canada, is available from the Public Health Agency of Canada (https://www.canada.ca/content/canadasite/en/public-health/services/surveillance/canadian-integrated-program-antimicrobial-resistance-surveillance-cipars.html).
Risk Assessment – Human Health and Ecological Exposure Assessment	The assessment does not consider triclosan releases from personal care products that show up in sewage sludge. Antimicrobials in sewage sludge could create a pathway to animal feed and crops intended for human consumption and may contribute to antibiotic resistance.	The risk to human health resulting from exposure from all potential sources of triclosan (such as multiple consumer products) and routes of exposure was considered through the use of biomonitoring data. Human biomonitoring data were used to characterize both mean and upper-bound exposure estimates for the Canadian general population. These data take into account all potential sources and routes of exposure and are considered the most accurate predictors of aggregate exposure because not only do they include specific measurements of the substance, but also because they reflect actual use patterns of various consumer products as they co-occur in practice.
Risk Assessment – Human Health and Ecological Exposure Assessment	Cumulative effects of triclosan exposure with other chemicals should be assessed and required under CEPA.	The available information did not support a cumulative risk assessment for triclosan.
Risk Assessment – Human Health and Ecological Exposure Assessment	Stakeholders urged the government to expedite assessments, including a cumulative assessment of other antimicrobial chemicals (e.g. triclocarban) in consumer products, for environmental and health reasons, as well as curtail developmental of antimicrobial resistance.	Noted.
Risk Assessment – Alignment with US and EU	There is a lack of consideration of the Hazard Assessment on triclosan conducted by the US and EU.	The United States Environmental Protection Agency, Office of Pollution Prevention and Toxics (US EPA OPPT) assessment and the European Union (EU) risk assessment were used to support the selection of critical health endpoints in the human health hazard assessment.

Topic	Rolled up comment	Response
Risk Assessment – Uses and Releases	Many brand owners have removed triclosan in their products, where possible, to help mitigate its presence in aquatic environments. Due to the US FDA ban on triclosan in antibacterial washes in September 2017, Canada could see a decrease in these products on the market as manufacturers change ingredients.	Noted.
Risk Assessment – Uses and Releases	In the section “Use Patterns and Exposure Assessment,” key US information was removed. There was no justification for omitting this key information.	The preliminary assessment for triclosan was based on US biomonitoring data (NHANES), so information on US use patterns was included to support the use of non-Canadian exposure data. The final assessment was updated to include Canadian biomonitoring data.