Summary of Public Comments received on Preliminary Assessment and Risk Management Scope 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 Chemical Management Plan. Comments on the preliminary assessment and risk management scope for triclosan were provided by: the American Cleaning Institute, Canadian Consumer Specialty Products Association, Canadian Cosmetic, Toiletry and Fragrance Association, Canadian Environmental Law Association, Canadian Medical Association, Chemical Sensitivities Manitoba, Colgate-Palmolive Canada Inc., Ecojustice Canada, Learning Disabilities Association of Canada, Thomson Research Associates, Wilfrid Laurier University and various Canadian citizens.

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

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Uses and Releases	The overall use and number of products containing triclosan is likely to be far less than 1600.	Based on information from a section 71 survey and Health Canada's Cosmetic Notification process, the assessment was updated to reflect the current use patterns and number of products containing triclosan in Canada. At the time of the assessment, there were 322 cosmetic products, 16 authorized natural health products, and approximately 118 drug products with an assigned Drug Identification Number that contain triclosan.
Human Health Exposure Assessment	We are concerned that exposure to chloroform may have increased as a result of increased use of triclosan, and we question whether the conclusions made in the 2001 chloroform assessment are still valid.	The Canadian Drinking Water Quality Guideline for trihalomethanes recommends the formation of chloroform from all possible sources should be monitored by all drinking water facilities. This is done to help ensure that these substances (including chloroform) do not exceed the maximum acceptable levels described in the Canadian Drinking Water Quality Guidelines. Based on current levels and trends of exposure to triclosan, increased exposure of the general public to chloroform is not expected.
	It is unclear how the government intends to be informed about the potential effects of triclosan to human health at low levels of exposure.	Human biomonitoring data (urine and breast milk) accounts for all exposures, and is compared to potential human health effects in the assessment. Recently evaluated biomonitoring data on pregnant women is also incorporated into the assessment. Biomonitoring data provides an actual measure of internal exposure rather than assessing exposures based on individual uses of each consumer product. Attempting to evaluate exposures to triclosan based on use results in various uncertainties because use patterns and methods of use vary from person to person.
	The margin of exposure (MOE) calculation is not regarded as a margin of safety that can be used to set limits on exposure or to decide risk management actions.	The MOE is a measure of risk, and the target MOE of 300 for this assessment was determined by taking into account the standard uncertainty factors (10-fold for intra-species variations and 10-fold for inter-species extrapolation) and an additional 3-fold uncertainty factor to account for database deficiencies. The calculated MOEs for the Canadian population were concluded to be acceptable as they were above the target MOE. Therefore, triclosan does not pose a health risk to Canadians at current levels of exposure and no risk management actions are required to address health concerns.
Bioaccumulation	It is disagreed that triclosan is bioaccumulative under the *Persistence and Bioaccumulation Regulations*. The	Following the publication of the preliminary assessment, additional information on the bioaccumulation of triclosan was made available to Environment and Climate Change Canada relevant to studies

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	Government of Canada should consider a re-evaluation of the bioaccumulation assessment as the bioaccumulation assessment appears to be biased toward a single study (Schettgen et al., 1999) – when there is another study (Orvos et al., 2002) that should also be considered. A comparison of these two studies suggests triclosan may not meet the referenced criteria for bioaccumulation or—at a minimum—that there is sufficient uncertainty in available data to warrant further investigation.	conducted by Schettgen et al. (1999) and by Orvos et al. (2002); other studies were also submitted. This new information was analyzed and incorporated in the assessment in order to update the bioaccumulation assessment and its relevancy to the ecotoxicity of triclosan. The available data indicate that triclosan accumulates in organisms to levels that can cause adverse effects. However, this substance does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPAthe Canadian Environmental Protection Act, 1999 (CEPA).
	Bioconcentration factors (BCFs) ranging from 1526 to 3589 L/kg can be calculated for various pHs using a simple linear regression model of the BCF-pH relationship from Schettgen et al. (1999) to re-scale the data from Orvos et al. (2002).	The pH does have an effect on the bioconcentration of triclosan in fish. The BCF values calculated takes this factor into account and indicates that triclosan bioconcentrates in fish to a certain level.
Fate	Photodegradation is an additional degradation pathway for triclosan, as there is evidence that triclosan in the aquatic environment photodegrades to less toxic degradation products.	Photodegradation of triclosan in water is discussed in detail in the assessment report.
Toxicity	Triclosan should be banned in all products because of evidence indicating that it contributes to antimicrobial resistance.	The assessment included further details on the potential for 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.
	Given evidence that triclosan affects immune systems, the Government of Canada should prohibit the use of triclosan from all sources.	The Government of Canada considered all evidence regarding immune function, including data available on laboratory animals and humans. Based on a lack of significant immune response in subchronic and chronic animal studies, triclosan-induced immunotoxicity was not identified as a health effect of concern.
	Triclosan is toxic to the environment, even at low levels.	The Government of Canada concluded that triclosan is harmful to the environment according to section 64 (a) of CEPA.
	It is unclear why only the acute toxicity of methyl-triclosan is mentioned in the assessment when the continuous release of	Chronic exposure to methyl-triclosan is expected to occur for aquatic organisms. The only toxicity data available for methyl-triclosan were for acute exposure. An assessment factor was

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	triclosan and methyl-triclosan into the aquatic environment suggests that chronic exposure would be an important component of toxicity consideration. This information also should be included in the assessment.	applied to these data to provide a conservative estimate of a Predicted No-Effect Concentration (PNEC) for chronic exposure.
	The reliability of the study from which the critical endpoint (growth in cucumber) was selected is questionable, as is the relevance of the test species (given that it does not reflect Canadian circumstances and corresponding agricultural practices). Furthermore, toxicity to earthworms can be used as worst-case because these organisms live in soil, and most of their diet consists of soil.	The study from which the critical endpoint (NOEC of 65 µg/kg for growth in cucumber) was originally selected was conducted in quartz sand, which does not represent types of agricultural soils where biosolids containing triclosan would be applied. Based on studies conducted with soils similar to those in natural settings (i.e. containing organic matter), reproduction in earthworms (the most sensitive endpoint) is used as the critical endpoint in the assessment.
Ecological Exposure Assessment	Research indicates the difficulty of translating the results of myriad soil/biosolids application studies to plant toxicity data. Since plant roots are likely taking up chemicals in soil through the soil pore-water, it is more appropriate to determine the soil pore-water concentration of the chemical and to compare it against effects studies in pure systems.	It is recognized that plant roots take up chemicals in soil through the soil pore-water, but organisms such as earthworms that feed on soils are exposed to both pore-water and soil particles. The critical endpoint is now based on an earthworm species, therefore total concentration of triclosan in soil as an indicator of exposure is considered to be appropriate.
	The preliminary assessment does not demonstrate that triclosan is removed efficiently by wastewater treatment plants (WWTPs). As such, wastewater treatment technology should not be considered an adequate means of controlling and preventing the release of triclosan to the environment.	Monitoring data indicates that triclosan is removed efficiently by WWTPs that have a secondary treatment process or a lagoon treatment process (the average removal rate for these processes is greater than 90%). However, WWTPs that only have a primary treatment process or no treatment at all have low removal rates. It also is recognized that even when the removal rate is high, triclosan can still reach the environment, either through WWTP effluent or the application of biosolids to soil. A risk of harm to aquatic organisms, but not to terrestrial organisms, was identified in the triclosan assessment. The proposed risk management instrument for triclosan that aims to control the releases of triclosan into the aquatic environment is outlined in the Proposed Risk Management Approach (available online at www.chemicalsubstanceschimiques.gc.ca).

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	The value of 46.4 µg/g for concentration of triclosan in biosolids that was used to derive a PEC for soil is an outlier. A more appropriate worst-case value would be one closer to the 95th percentile, somewhere on the order of 28–30 µg/g.	It is agreed that the value of 46 µg/g is an outlier. The 95th percentile of the concentration of triclosan in sludge and biosolids was used and, although lower than the original value, is still considered to be a conservative estimate.
	Based on information from a study by Gottshall et al. (2012), it is possible to conclude that when triclosan is applied to soils as part of biosolids, it is less bioavailable to soil organisms.	It is agreed that some studies suggest triclosan to be less bioavailable to soil organisms when applied to soils as part of biosolids. However, ingestion of soil particles by certain organisms could represent an uptake route.
Risk Management	Additional surveillance programs are needed to evaluate the ability of a biocide to induce/select for antibiotic resistance. It is unclear how the government intends to build upon any risk management initiatives in order to deal with issues related to the use of antimicrobials such as triclosan.	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 (http://www.phac-aspc.gc.ca/cipars-picra/index-eng.php). All substances that have undergone assessment remain subject to future evaluation if new substantive information is identified that indicates further consideration is warranted. This could result in the drafting of new risk management initiatives, as necessary.
	The Government of Canada should develop a management approach for endocrine disruptors.	In the case of endocrine active substances, risk assessments for existing substances under CEPA consider information on potential endocrine-related effects and other information when determining the potential hazard and risk of a substance. The Government's proposed risk management activities focus on minimizing identified risks based on available information. If an assessment concludes that a substance meets one or more section 64 criteria of CEPA, a risk management approach document is developed and published. The Government of Canada's response to a petition (310) on the health and environmental impact of

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		endocrine disrupting chemicals used in cosmetics can be found on the website of the Office of the Auditor General of Canada (http://www.oag-bvg.gc.ca/internet/English/pet_310_e_35780.html).
	The long-term effects of triclosan are unknown, so the Government of Canada should prohibit the use of triclosan from all sources.	The assessment considered long-term ecological effects of triclosan by characterizing risks to aquatic and terrestrial organisms and concluded that triclosan is harmful to the environment according to section 64 (a) of CEPA. As such, a Risk Management Approach document was developed that outlines the proposed risk management action being considered for triclosan (available at www.chemicalsubstanceschimiques.gc.ca). The assessment considered short- to long-term human-health effects of triclosan by characterizing risks to the general population by comparing exposure estimates in humans with critical levels in health effects reported in animal studies. Based on the results of the assessment, it was concluded that triclosan does not pose a health risk to Canadians at current levels of exposure.
	Due to environmental and human health concerns, triclosan should be managed further in non-medical, consumer products.	Based on the results of the assessment, it was concluded that current levels of exposure to triclosan do not pose a risk to human health. The assessment also concluded that triclosan may be harmful to the environment. As a result, a risk management action is being proposed by Environment and Climate Change Canada and this action is described in the Risk Management Approach document (available at www.chemicalsubstanceschimiques.gc.ca).
	The use of triclosan in all non-prescription products should be discontinued because there is clear evidence that humans are contaminated with triclosan and that the	Based on a complete review of the human health effects and exposure data—as well as a comparison between potential health effects and current exposure levels in humans in Canada—it has been concluded that triclosan does not pose a health risk to

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	substance can cause harm. Furthermore, there is no evidence of benefits derived from its use in non-prescription products.	Canadians at current levels of exposure.
	A call for voluntary reduction of triclosan is premature considering that the assessment has not been finalized.	As a result of the conclusion of the assessment, a Risk Management Approach document was developed that outlines the proposed risk management action being considered for triclosan (www.chemicalsubstanceschimiques.gc.ca).
	Mandatory collection of data for risk management is premature considering that the risk assessment has not been finalized. Instead, we suggest data gathering to further inform risk assessment and management activities.	In order to help identify potential sources and quantities of releases of triclosan to the environment, a mandatory survey was published in February 2013 to gather data needed to provide an update on quantities, use patterns, product details and industrial processes involving the substance. This information was considered in the assessment.
	Relying on existing WWTPs to control the release of triclosan to the environment is not effective because the water treatment process contributes to the formation of other hazardous substances. This formation—along with the number of toxic transformation products that have been identified—only adds to concerns about extensive use of triclosan.	Methyl-triclosan is a transformation product formed from triclosan in wastewater systems. The risk quotient analysis presented in the assessment suggested that methyl-triclosan alone in aquatic ecosystems does not reach levels that would be harmful to aquatic organisms. However, given likely co-exposure with triclosan, there could be a risk of harmful effects overall. As a result of the conclusion of the assessment, a Risk Management Approach document was developed that outlines the proposed risk management action being considered for triclosan. It is available online at www.chemicalsubstanceschimiques.gc.ca.
	Although the Government of Canada legislates soaps and disinfectants, it does not regulate other products containing triclosan (including deodorants, drugs and natural health products), nor does it regulate its presence in various types of textiles (including clothing, bedding, plastic and rubber materials). Discontinued pest control products and articles treated with pesticides should be subject to the Government of Canada Food and Consumer Safety Action Plan.	Products containing triclosan are regulated under the *Food and Drugs Act* and the *Pest Control Products Act* (PCPA). For any product containing triclosan as a medicinal ingredient, concentration limits are 1.0% triclosan for antiseptic skin cleansers and 0.3% for toothpaste. Cosmetic products containing triclosan must meet the conditions specified on Health Canada's Cosmetic Ingredient Hotlist. Triclosan is permitted in cosmetic products at concentrations equal to or less than 0.3% in all cosmetics (i.e. deodorants, creams, face washes, etc.) or 0.03% in mouthwashes. All oral cosmetic products containing triclosan must also carry cautionary statements and meet the quality requirements for impurity levels. Products that do not meet the Hotlist conditions may contravene the *Food and Drugs* or the C*osmetic Regulations*.
	Anyone seeking the registration of triclosan	

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	as a pest control product in Canada should supply updated technical data on the substance.	Triclosan is listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role for use as antimicrobial preservative in natural health products. Similar to the Hotlist, the NHPID lists concentrations of triclosan of less than or equal to 0.03% in mouthwashes and 0.3% in topical products and dentifrices as restrictions associated with the use of triclosan in natural health products. The import, packaging, manufacture, distribution, labeling, sale and use of products that control pests are regulated in Canada under the *Pest Control Product Act* (PCPA) and Regulations. Compliance issues related to pest control products are managed consistent with the Health Canada's Pesticide Management Regulatory Agency (PMRA) Compliance Policy. Compliance issues related to antimicrobial treated articles are also managed consistent with the Compliance and Enforcement Strategy developed as part of the Government of Canada's Food and Consumer Safety Action Plan. Data required to support an application to register a pest control products in Canada depends on the nature of the product and the purpose of the submission. Detailed information on the type of data required is available on Health Canada's PMRA website [http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/pmra-arla/index-eng.php].
	Personal care wash products that make antibacterial, antimicrobial and antiseptic claims are therapeutic products and would not be allowed if they were not effective, yet the reference to the Public Health Agency of Canada (PHAC) publication *Get the Dirt on Clean Hands! Your Top Questions Answered* suggests that they are not effective. We recommend this reference be removed from the risk management scope document, the public summary and the Q&As.	The content being referred to in this comment was removed from the PHAC website and is no longer available.
	Strategies for managing dioxins and furans should undergo a federal review to ensure	Polychlorinated para-dibenzodioxins (PCDD) and polychlorinated dibenzofurans (PCDF) were assessed and found to be a concern in

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	they both meet Toxic Substance Management Policy goals and address newly identified sources.	1990 under CEPA, and a number of risk management measures were subsequently put into place. Since then, progress on these measures has been reviewed. For example, a national inventory of sources indicates that dioxin and furan releases to the atmosphere have declined by more than 80 percent since 1990 (Commission for Environmental Cooperation 2011). Ultimately, 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. Some uncertainty remains with respect to their potential impacts on the environment, however, and these transformation products could be subject to further study.
	Please clarify why the limits for polychlorinated dioxins are only for oral cosmetics, not for other cosmetic products containing triclosan.	Commercial preparations of triclosan may contain PCDD and PCDF impurities. Due to the potential gastro-intestinal absorption of PCDD and PCDF in the mouth, their concentrations should not exceed the concentration levels listed in Health Canada's Cosmetic Ingredient Hotlist. In general, absorption is greater when dioxins and furans are ingested than when applied to the skin (Environment and Climate Change Canada, Health Canada 1990).
	There is adequate information indicating that triclosan is present in the Great Lakes waters. This is sufficient justification for the government to consider specific measures to reduce use of triclosan to protect the Great Lakes basin, including the monitoring of triclosan and its transformation products (including dioxins) in that area, as well as areas that are known to have triclosan-containing effluent to surface waters of the lakes. This, in turn, should inform future risk management.	The assessment concluded that triclosan is harmful to the environment. As a result, a risk management action is being proposed by Environment and Climate Change Canada and this action is described in the RMA document (available at www.chemicalsubstanceschimiques.gc.ca). In addition, further monitoring and surveillance will be undertaken to verify trends in concentrations of triclosan in the environment. If results of monitoring show increase in concentrations of triclosan in the environment, Environment and Climate Change Canada may consider further risk management.
Information and Data Gaps	The preliminary assessment does not address the cumulative effects of exposure to triclosan and substances that share a similar mechanism of toxicity such as endocrine	The assessment considered all relevant scientific studies on potential effects of triclosan on endocrine systems, in particular to thyroid function, including data available in laboratory animals and humans. This ranged from short-term studies to more chronic

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	disruption. It may be more appropriate to review inherent hazards of substances to inform the level of management required for many of these substances. It also does not consider the cumulative effects of exposure (particularly resulting from exposure to different consumer products) to triclosan and substances that produce the same toxic metabolites.	scenarios. However, these effects were not considered to be critical in the characterization of risk in humans. 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 was used to characterize both mean and upper-bound exposure estimates for the Canadian general population. This data takes 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. Health Canada's Science Policy Notice SPN2001-01, entitled "Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment" (PMRA 2001), describes the steps for identifying mechanisms of toxicity of pesticides that cause a common toxic effect, the types of data needed and their sources, how these data are to be used in reaching conclusions regarding commonality of mechanisms of toxicity, and the criteria Health Canada applies for categorizing pesticides for the purpose of cumulative risk assessments. No relevant evidence indicating that triclosan shares a common mechanism of toxicity with other pesticides or shares a toxic metabolite produced by other pesticides has been identified. The available information did not support a cumulative risk assessment for triclosan.
	The available information on the pervasiveness of triclosan in humans and the ecological evidence of harm should be given appropriate weight when determining the potential risk to human health.	All available information on potential hazards of triclosan was considered in the assessment, including information on humans and other mammals. A conservative database NOAEL 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.

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	The human health and ecological effects of transformation products such as dioxins and furans were not assessed in the preliminary assessment.	The formation of transformation products (such as lower chlorinated dioxins) and impurities (polychlorinated dioxins and furans) has been considered in the assessment, as has their potential human health and ecological effects. The potential risk for the general population resulting from exposure to transformation products of triclosan is expected to be low. Similarly, ecological effects stemming from exposure to the lower-chlorinated dioxins and methyl-triclosan formed from transformation of triclosan are considered in the assessment.
	Insufficient attention was paid to evidence about antimicrobial resistance in the preliminary assessment.	Based on available information, induction of antimicrobial resistance from current levels of triclosan has not been identified as a concern for human health. Given variability in uses and formulations, links between household uses of triclosan and triclosan resistance in clinical settings cannot be made. Selection for triclosan-resistant bacteria that live in natural sediments has been reported, however, a number of studies of natural water have not found triclosan-resistant organisms.
	The lack of a chronic dermal toxicity study is a concern given the presence of triclosan in consumer products destined for a dermal or oral application.	Assessments are science-based assessments of the available data. Although, a long-term dermal toxicity study with triclosan is not available, the available information indicates that triclosan absorption following dermal exposure to products containing triclosan is lower than absorption following an oral exposure. Furthermore, there were no systemic effects seen in the available short-term dermal study that were unique to this route of exposure. Therefore, characterizing the human health risk based on the oral endpoint is not expected to underestimate the risk, and it reflects standard risk assessment methodology.
	Long-term studies indicate that there is no evidence of emergence of microbial resistance from applications of toothpaste containing triclosan.	New information has become available since the publication of the preliminary assessment. This information, which indicates that no health effects were identified at current levels of exposure, was included in the assessment.
	There are data gaps in the potential effects of triclosan following chronic, low dose exposure.	Assessments are based on considerations of available data. For triclosan, that included data available on laboratory animals and humans, ranging from short-term studies and more chronic

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		scenarios. The use of biomonitoring data from humans in the characterization of risk associated with triclosan accounts for exposure to triclosan from multiple routes and multiple sources, including chronic, low level exposure scenarios.
	We have provided a recently published paper on bioconcentration of triclosan and methyl-triclosan in plants and sediments of a constructed wetland.	The paper provided was analyzed but not cited in the assessment report as it did not add significant new information to inform the assessment.
	The underlying data relied upon to select predicted environmental concentrations (PECs) reflected in the characterization of aquatic risk is incomplete or unavailable. As such, the suitability and rigor of these data—as well as the exposure modelling—cannot be assessed.	The data relied upon to select the predicted environmental concentrations (PECs) for aquatic ecosystems consist of measured concentrations of triclosan in the influents and effluents of WWTPs and surface water. In order to keep the assessment concise, only a summary of these data was included in the assessment (but they are available upon request from Environment and Climate Change Canada at eccc.substances.eccc@canada.ca). Due to requests to keep the identity of certain WWTPs confidential, some information is not available to the general public.
	We recommend more consideration be given to scientific papers that indicate that triclosan is a possible endocrine disruptor. This information—along with other indicators—should provide the government with a strong incentive to eliminate triclosan from non-medicinal consumer products.	The Government of Canada considered all relevant scientific studies on potential effects of triclosan on endocrine systems, in particular to thyroid function, including data available in laboratory animals and humans. This 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.
	Information on the manufacture, import and use of triclosan in Canada should be updated using the mandatory survey instead of a voluntary initiative.	The government has consulted with industry using both a section 71 survey and voluntary information gathering initiatives. Information from both sources was considered and incorporated into the assessment.
	Additional use surveys should be considered in order to update the database with available information on current uses of triclosan. This would help to shape future assessment activities/priorities.	Stakeholders not subject to the section 71 Notice (i.e. those whose use of a substance falls below the reporting threshold in the reporting year) are strongly encouraged to inform the Government of Canada of their activities relating to substances. New information is received through several mechanisms, some of which are defined

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		under specific sections of CEPA, and all substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates further consideration is warranted.
Methodology	Data needs for assessment should be clearly identified in consultation with industry, and they should include specific timelines and details on how the data will be used in the assessment.	The Government of Canada supports collaborating with industry and other stakeholders to fill data gaps required for science-based risk assessments. The information gathering process and Chemical Management Plan timelines are outlined on the Chemical Substances website (www.chemicalsubstanceschimiques.gc.ca).
	The preliminary assessment's approach to assessing impact of triclosan on animals and humans was too narrow.	For the assessment of triclosan, a conservative overall database point of departure was used to characterize risk to human health that was protective of treatment-related effects observed in multiple species (e.g., hamsters, rats, dogs, and monkeys) at higher doses. It also considered any uncertainties in the database for potential liver effects that could occur in humans, as well as effects in other organs and systems. Gaps in the database for triclosan regarding neurodevelopmental toxicity were accounted for with the application of an additional 3–fold factor. Exposure levels were examined for a broad range of subpopulations from infants and toddlers, to adolescents and adults (including workers).
	Based on available information, the hamster is the most relevant species for human risk assessment of triclosan.	In the assessment of triclosan, a conservative overall database point of departure was used to characterize risk to human health that was protective of treatment-related effects observed in multiple species at higher doses. It also considered any uncertainties in the database for potential liver effects that could occur in humans, as well as effects in other organs and systems.
	The methodology for reviewing literature data and the decision processes used for including or excluding data from the species sensitivity distribution (SSD) are unclear.	Chronic toxicity studies on triclosan were reviewed. Only data from studies that were robust and that yielded acceptable endpoints were considered for inclusion in the species sensitivity distribution (SSD). The robustness of studies and acceptability of endpoints were assessed using Robust Study Summaries (these summaries are available upon request from Environment and Climate Change Canada at eccc.substances.eccc@canada.ca). The decision process to select endpoints to include in the SSD is recommended by the Canadian Council of Ministers of the Environment (CCME), as
	We disagree with the choice of certain species and endpoints that were included in the SSD.	

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		explained in CCME (2007).
	The PNEC of 115 ng/L derived from the SSD is too low and too conservative.	For the assessment of triclosan, a review of the endpoints used in the SSD was conducted. As a result, certain endpoints were modified or removed from the SSD. For instance, endpoints for wetland plants were removed when it was considered that these plants are more closely related to terrestrial plants than to aquatic macrophytes. The SSD was also revised to include data from studies published since the publication of the preliminary assessment in 2012. As a result of the revisions to the SSD, the value of the PNEC has changed to 376 ng/L.
	Monitoring studies should be assessed with respect to quality criteria, such as those used by the Environmental Risk Assessment and Management (ERASM) research partnership.	It is agreed that monitoring studies must be assessed with respect to certain quality criteria (e.g. field sampling method, location and timing, laboratory analytical method, etc.). Environment and Climate Change Canada considers such criteria when using measured environmental concentrations to assess exposure to organisms. When all the information to assess these criteria is not available, the source of the data is considered to assess their reliability (e.g. data from peer-reviewed journals). Unpublished data that are generated by researchers at Environment and Climate Change Canada undergo a quality assurance/quality control check.
	Sound science and transparency are essential to risk assessments that support a regulatory decision under the Chemical Management Plan. The assessment must not be influenced by any pre-conceived biases or misconceptions.	All available information and various external peer reviews were taken into account to ensure that sound science was used to develop the assessment. The publication of the preliminary assessment, followed by the public comment period, ensured that the assessment was transparent.
Risk Characterization	The Government of Canada has not provided scientific or policy rationale to support the approaches used in risk characterization in either the selection of points of departure (such as dermal and inhalation effect levels, or consideration of potential endocrine effects) or in the application of safety factors to account for database deficiencies and to protect infants and children as legislated in	The Government of Canada considers available evidence for laboratory animals and for humans. To characterize risk in humans, the following endpoints are used: · Oral (e.g. nursing) and all other exposure scenarios, where an oral endpoint - NOAEL of 25 mg/kg bw per day from a 90-day toxicity study in mice; · Dermal exposure scenarios, where a dermal endpoint of 40 mg/kg bw per day from a 90-day dermal study in rats; and · Inhalation exposure scenarios, where an inhalation endpoint

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	the *Food Quality Protection Act* (FQPA).	NOAEL of 3.21 mg kg bw per day from a 21-day inhalation study in rats - established by Health Canada, taking into consideration observed minor effects and a shallow dose-response curve for the measured endpoints. · The Government of Canada considered all relevant scientific studies on potential effects of triclosan on endocrine systems, in particular to thyroid function, including data available in laboratory animals and humans. This 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. To ensure a protective margin between levels causing adverse effects in animal studies and potential human exposure, Health Canada applies various factors relevant to the critical effect for toxicity in mammals – while accounting for uncertainties. For triclosan, a protective margin of 300 was established by applying standard uncertainty factors at 10-fold for both interspecies extrapolation and for intraspecies variations. A 3-fold uncertainty factor for database deficiency (i.e. lack of neurodevelopmental studies on triclosan) and a 1-fold PCPA factor (as the application of the 3-fold application for missing studies already accounted for potentially more sensitive populations). The margin of 300 is applied to all routes and durations of exposure. The *United States Food Quality Protection Act* (FQPA) is not applicable to the Canadian situation.
	Methyl-triclosan is not considered to be a major transformation product of triclosan.	Major transformation products are generally defined as compounds reaching at least 10% of the initial applied concentration of the parent compound. In an aerobic soil metabolism study, methyl-triclosan was formed at levels higher than 10% of the applied concentration of triclosan. In an aerobic water-sediment metabolism study, a maximum concentration for methyl-triclosan could not be established, but was reported as >4.8%. Furthermore, under field conditions, methyl-triclosan was reported in fish at levels higher than triclosan.
	There is evidence that triclosan affects	The Government of Canada considered all relevant scientific studies

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	endocrine systems. The Government of Canada should characterize the risk to human health based on endocrine effects of triclosan reported in animal studies.	on potential effects of triclosan on endocrine systems, in particular to thyroid function, including data available in laboratory animals and humans. This 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 characterization of methyl-triclosan as a "major environmental transformation product" in section 4.8 of the preliminary report appears to be overstated. Methyl-triclosan is likely to represent a metabolite of triclosan, but (based on observed relative concentrations) it is unlikely to be considered as a relevant metabolite.	Under laboratory conditions, methyl-triclosan can be formed from triclosan via a major pathway in aerobic soil and water-sediment systems. It is agreed that monitoring data collected shows that methyl-triclosan is found at lower levels than triclosan in water, soil and sediment. Despite lower concentrations in sediment, water and soil, however, the levels of methyl-triclosan reported in biota are significant. As an example, Boehmer et al. (2004) reported methyl-triclosan concentrations in fish (bream muscle) nearly eight times higher than triclosan concentrations. Based on the available monitoring data on methyl-triclosan, this substance is considered to be a relevant metabolite in biota, even though available monitoring data on it is limited.
	In addition, the characterization of methyl-triclosan as "inherently toxic" in section 4.8 of the preliminary report contradicts the preliminary risk characterization analysis of methyl-triclosan that appears in section 4.6.1.1(which concluded that methyl-triclosan is unlikely to represent a risk to aquatic organisms).	Regarding toxicity, a substance may be inherently toxic (i.e. hazardous to organisms) even though it may not pose a risk to organisms or their environment (depending on the levels of chemical in the environment). The definition of toxic under CEPA is based on risk, which takes into account both the inherent toxicity of a substance and its levels of exposure. It is not expected that methyl-triclosan alone would cause adverse effects in organisms based on the current exposure levels in the environment. However, given likely co-exposure with triclosan, there could be a risk of harmful effects overall.
	The Government of Canada should continue to monitor scientific literature regarding antibacterial resistance and the use of biocides.	All substances that have undergone assessment remain subject to future evaluation if new substantive information is identified that indicates further consideration is warranted.
Conclusion	We support the proposed conclusion that triclosan does not meet the criteria for persistence as outlined in the *Persistence and*	Noted.

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	Bioaccumulation Regulations.	
	We strongly support the proposed conclusion that triclosan is "not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health."	
	Scientific evidence indicates triclosan meets the criteria set out in section 64 (c) of CEPA.	Based on the human health assessment—which used recent biomonitoring data and a conservative database NOAEL—the margins of exposure for human health were deemed adequate, and therefore triclosan does not meet the criteria set out in section 64 (*c*) of CEPA.
	There are significant health and environmental concerns with the transformation products that result from the presence of triclosan in the environment, particularly their toxicity, persistence and bioaccumulation properties. More attention should be given to these transformation products in the assessment and resulting risk management strategies.	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 considered to be of concern. Some uncertainty remains with respect to their potential impacts on the environment, however, meaning that these transformation products could be subject to further study.
	The preliminary assessment does not identify any compelling reasons to prevent future registration of triclosan as a pest control product in Canada, provided that the applicant meets the prescribed data requirements for registration under the PCPA.	Potential registrants seeking to enter the Canadian market are encouraged to contact the PMRA for a presubmission consultation meeting to discuss potential data requirements.
	The commenter does not support the preliminary conclusion under section 64a of CEPA. The derived Predicted Environmental Concentrations (PEC) and Predicted No Effect Concentration (PNEC) should be revisited.	The PECs were updated in the assessment with new data available since the publication of the preliminary assessment in 2012. Also, a review of the endpoints used in the species sensitivity distribution (SSD) was conducted. Certain endpoints were added to or removed from the SSD. As a result, the value of the PNEC was revised in the assessment. The conclusion under section 64 (*a*) of CEPA remains the same as that proposed in the preliminary assessment.

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	Given the extent of detection of triclosan in the environment, particularly in water, the interpretation of persistence under the *Persistence and Bioaccumulation Regulations* may be too narrow. The continuous presence of triclosan appears to have the same impact in the environment as if it were persistent in nature. For the purposes of this assessment, triclosan should be considered persistent. Given that this substance also meets the bioaccumulation criteria under Regulations, the risk management proposal for triclosan should consider virtual elimination.	The assessment recognizes that the continual input of triclosan to surface water through WWTP effluents results in its continuous presence in receiving aquatic ecosystems. Hence, chronic exposure of aquatic organisms to triclosan is expected to occur even though this chemical can degrade relatively quickly. Chronic toxicity data were used to determine a PNEC. Even though it is continuously present in the environment, triclosan does not meet the persistence criterion as set out in the *Persistence and Bioaccumulation Regulations* of CEPA. Similarly, while triclosan accumulates in organisms to levels that can cause adverse effects, the assessment report concludes that it does not meet the bioaccumulation criterion as set out in the *Persistence and Bioaccumulation Regulations* of CEPA. The proposed environmental objective for triclosan is to reduce concentrations found in the aquatic environment to levels below the PNEC.
Overarching Comments	The voluntary discontinuation of the use of triclosan as a pest control product should be reflected in the assessment.	The decision taken by the Canadian registrants to discontinue the use of triclosan as a pest control product is noted in the assessment. Voluntary discontinuation of pest control products containing triclosan does not affect the assessment.
	The registration status of triclosan as a pest control product in Canada is not relevant in the context of risk assessment or risk management. The Government of Canada instead should focus on managing illegal uses of triclosan or any other substance imported to Canada.	The use of unregistered pesticides is a violation of the PCPA, as is using a pesticide in a manner other than directed on the product label. The decision taken by the Canadian registrants to discontinue the use of triclosan as a pest control product is noted in the assessment. Voluntary discontinuation of pest control products containing triclosan does not affect the assessment. Health Canada's PMRA is developing a strategy for managing antimicrobial pesticides in articles that were treated prior to importation into Canada. The compliance and enforcement approach for antimicrobial treated articles is risk-based and is currently managed in a manner consistent with the Compliance and Enforcement Strategy of the Government of Canada's Food and Consumer Safety Action Plan.
	We feel the current screening level risk assessment approach does not adequately	The conclusions from the assessments adhere to a precautionary approach using conservative approaches in the event of

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	support a preventative approach to toxic substances.	uncertainties. In the case of the risk characterization, the conservative nature of the assumptions used in this derivation takes into account uncertainties in effects and exposure databases. Furthermore, the Government of Canada continues to monitor exposure levels through ongoing monitoring and surveillance activities.
	The Chemical Management Plan Pilot Project for Assessment established in 2001 is a prolonged process.	Assessment activities for triclosan took into consideration both the availability of Canadian monitoring data and similar regulatory risk assessment activities from other jurisdictions. This allowed for the inclusion of recent monitoring data (e.g. water and dust), biomonitoring data in Canadians, and current positions on antimicrobial resistance that are held by recognized international bodies. The Government of Canada has produced a number of assessments under the Chemicals Management Plan Pilot project since 2001 (e.g., MBMBP or hexachloroethane). All assessment reports are posted on the Chemical Substances website at www.chemicalsubstanceschimiques.gc.ca.
	The inherent properties of a substance should be given greater consideration when determining management measures.	The inherent properties of triclosan (e.g., bioaccumulation, toxicity) were considered in the assessment. As a result of the conclusions of the assessment report, risk management action is being proposed in the Risk Management Approach document (available at www.chemicalsubstanceschimiques.gc.ca).

References

[CCME] Canadian Council of Ministers of the Environment. 2007. A protocol for the derivation of water quality guidelines for the protection of aquatic life. Winnipeg (MB): CCME.

[CEC] Commission for Environmental Cooperation. 2011. North American strategy for catalyzing cooperation on dioxins and furans, and hexachlorobenzene. Montreal (QC): CEC. Available from: http://www3.cec.org/islandora/en/item/10148-north-american-strategy-catalyzing-cooperation-dioxins-and-furans-and-en.pdf

Environment Canada. 1995. Toxic substances management policy. Ottawa (ON): Environment Canada. Reprinted 2004. Available from: http://www.publications.gc.ca/site/eng/305088/publication.html

Environment Canada, Health Canada. 1990. Canadian Environmental Protection Act: Priority Substances List Assessment Report No.: 1: polychlorinated dibenzodioxins and polychlorinated dibenzofurans. Ottawa (ON): Environment Canada, Health Canada. Available from: http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/dioxins_furans_dioxines_furannes/index-eng.php#a7

Gottschall N, Topp E, Metcalfe C, Edwards M, Payne M, Kleywegt S, Russel P, Lapen DR. 2012. Pharmaceutical and personal care products in groundwater, subsurface drainage, soil, and wheat grain, following a high single application of municipal biosolids to a field. Chemosphere. 87(2):194-203.

Orvos DR, Versteeg DJ, Inauen J, Capdevielle M, Rothenstein A, Cunningham V. 2002. Aquatic toxicity of triclosan. Environ Toxicol Chem. 21(7):1338-1349.

Pannu MW, Toor GS, O'Connor GA, Wilson PC. 2012. Toxicity and bioaccumulation of biosolids-borne triclosan in food crops. Environ Toxicol Chem. 31(9):2130-2137.

[PMRA] Pesticide Management Regulatory Agency. 2001. Guidance for identifying pesticides that have a common mechanism of toxicity for human health risk assessment. Ottawa (ON): PMRA, Submission Management and Information Division. Science Policy Notice SPN2001-01. Available from: http://hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2001-01/index-eng.php.

Reiss RG, Lewis G, Griffin J. 2009. An ecological assessment for triclosan in the terrestrial environment. Environ Toxicol Chem. 28(7):1546-1556.

Schettgen C, Schmidt A, Butte W. 1999. Variation of accumulation and clearance of the predioxin 5-chloro-2-(2,4-dichlorophenoxy)-phenol (Irgasan DP 300, triclosan) with the pH of water. Organohalogen Compd. 43:49-52.