Environment and Climate Change Canada / Environnement et Changement climatique Canada

Canadian Environmental Protection Act, 1999

Draft Federal Environmental Quality Guidelines

Triclosan

Environment and Climate Change Canada

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Introduction

Federal Environmental Quality Guidelines (FEQGs) provide benchmarks for the quality of the ambient environment. They are based solely on the toxicological effects or hazard of specific substances or groups of substances. FEQGs serve three functions: first they can be an aid to prevent pollution by providing targets for acceptable environmental quality; second they can assist in evaluating the significance of concentrations of chemical substances currently found in the environment (monitoring of water, sediment and biological tissue); and third, they can serve as performance measures of the success of risk management activities. The use of FEQGs is voluntary unless prescribed in permits or other regulatory tools. Thus FEQGs, which apply to the ambient environment are not effluent limits or "never-to-be-exceeded" values but may be used to derive effluent limits. The development of FEQGs is the responsibility of the Federal Minister of Environment under the *Canadian Environmental Protection Act, 1999* (CEPA) (Government of Canada (GC) 1999). The intent is to develop FEQGs as an adjunct to risk assessment/risk management of priority chemicals identified in the Chemicals Management Plan (CMP) or other federal initiatives. This factsheet describes the Federal Water Quality Guideline (FWQG) for the protection of aquatic life from adverse effects of triclosan (Table 1). This fact sheet is based largely on the assessment report published under Canada's Chemicals Management Plan, and using information identified up to April 2015 (Environment and Climate Change Canada, Health Canada (ECCC, HC) 2016). No FEQGs have been developed for the sediment and biological tissue compartments at this time.

FEQGs are similar to Canadian Council of Ministers of the Environment (CCME) guidelines in that they are benchmarks for the quality of the ambient environment and are based solely on toxicological effects data. Where data permit, FEQGs are derived following CCME methods. FEQGs are developed where there is a federal need for a guideline (e.g. to support federal risk management or monitoring activities) but where the CCME guidelines for the substance have not yet been developed or are not reasonably expected to be updated in the near future.

Table 1. Federal Water Quality Guideline for triclosan.

Aquatic Life	Guideline Value (μg/L)
Freshwater	0.38

Substance Identity

Triclosan ($C_{12}H_7Cl_3O_2$; CAS Registry Number 3380-34-5) is a chlorinated aromatic compound with phenol and ether functional groups. There are no known natural sources of triclosan and its presence in the environment is exclusively due to anthropogenic activity. Triclosan can be released to the environment as a result of its use in many products used by consumers, or as a result of the industrial manufacture or formulation of products containing triclosan. Triclosan released into municipal wastewater reaches wastewater treatment plants (WWTPs) where it is partly removed from the wastewater, depending on the type of treatment, and then released into surface water as part of WWTP effluents (ECCC, HC 2016).

Government of Canada (ECCC, HC 2016) concluded, based on the considerations of the potency of triclosan and the current exposure levels observed in the Canadian environment, that potential for harm exists from exposure to triclosan in aquatic ecosystems. It was concluded that triclosan meets the criteria under section 64(a) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Triclosan did not meet the criteria under sections 64(b) and 64(c), as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends, and it 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.

Uses

Triclosan is used in cosmetics, drugs and natural health products (ECCC, HC 2016). There were 482 cosmetic products containing triclosan notified to Health Canada, including skin cleansers (body, face and hands), moisturizers, face and eye makeup, deodorant sticks/sprays, fragrances, tanning products, shaving preparations, bath products, exfoliants, massage products, styling products and shampoos (ECCC, HC 2016). Approximately 130 drug products containing triclosan with an assigned drug identification number were listed on Health Canada's Drug Product Database (DPD 2015). There are 14 licensed natural health products (e.g., toothpaste, foot gel, acne treatment, body spray, skin cleanser and lotion) that contain triclosan as a non-medicinal ingredient (NHPID 2015).

A survey conducted in 2013 on the manufacture, import, use and release of triclosan for the year 2011 indicated that triclosan was not manufactured in Canada and that between 10 000 and 100 000 kg of triclosan was imported by twenty-nine companies in Canada in 2011 as either the pure substance or in product and five companies exported 100 to 1000 kg of triclosan in manufactured products (EC 2013). Twenty companies reported using triclosan to manufacture formulated products. The formulated products containing triclosan included over-the-counter drugs, cosmetic and cleaning products such as antibacterial soap, skin cleansers, toothpastes, make-up, deodorants, skin creams, fragrances, general all-purpose cleaners and general purpose detergents. Of the total quantity of triclosan used in Canada, 88% was used in antibacterial soaps, skin cleansers and toothpaste (registered as drugs, cosmetics or natural health products); 6% used for other reported product types; and for the remaining 6% the end uses were not identified (EC 2013).

Triclosan was also registered in Canada as an active ingredient in pest control products, for use as material preservative in textiles, plastic, paper, leather and rubber materials. However, as of December 31, 2014, triclosan is no longer registered as a pest control product due to its voluntary withdrawal from the market by the Canadian registrants.

Fate, Behaviour and Partitioning

Triclosan can be released to the environment as a result of consumer use and down-the-drain disposal of products containing triclosan, or as a result of the industrial manufacture of products containing triclosan. The continual nature of triclosan releases results in its ubiquitous presence in the environment. Triclosan is released to aquatic ecosystems as part of waste water treatment plant (WWTP) effluents; however, some triclosan partitions to biosolids during the wastewater treatment process. As a result, triclosan can also reach terrestrial ecosystems by way of biosolids amendment to agricultural land. Triclosan can reach surface water from soil from runoff if there is an immediate rainfall following the application of either liquid or dewatered wastewater biosolids on soil (Topp et al. 2008; Sabourin et al. 2009).

Triclosan is a hydrophobic compound with a high log K_{ow} of 4.8 at pH 6.7 (ECHA 2007-2014) and moderate log K_{oc} (3.34 to 4.67). Triclosan has a pK_a of 8.1; consequently, it will ionize to some extent in most natural water bodies. A low Henry's law constant (5.05×10^{-4} $Pa{\cdot}m^3/mol$) indicates that triclosan does not volatilize from the water surface. Triclosan is susceptible to phototransformation in surface waters (ECCC, HC 2016). Tixier et al. (2002) observed that pH has an impact on its ability to absorb sunlight and that the direct phototransformation rate increases with pH. In aerobic sediments, triclosan is susceptible to rapid oxidation (half-life <21 hr) by manganese oxides (Zhang and Huang 2003). Triclosan is not persistent in soil (half-life 2.9 to 58 days in aerobic soil). Its log K_{oc} value suggests that it is not mobile in soil, especially if the organic carbon content is high, and it is not expected to volatilize from soil (ECCC, HC 2016).

Triclosan is available for uptake by organisms and can also be readily metabolized by organisms. Triclosan is unlikely to biomagnify in aquatic and terrestrial food webs, primarily because it can be metabolised by organisms. Bioconcentration factors (BCFs) for triclosan range from low to high in two fish species (16–19

L/kg for common carp (NITE 2006) and 2018–8700 L/kg for zebrafish (Böttcher 1991; Schettgen et al. 1999; Schettgen 2000; Gonzalo-Lumbreras et al. 2012)), whereas a moderate BCF (1700 L/kg) was reported for mussels (Gatidou et al. 2010). Triclosan bioaccumulation factors (BAFs) reported for snail (500 L/kg) and algae (900-2100 L/kg) were low to moderate (Coogan et al. 2007; Coogan and La Point 2008). It was determined that triclosan has a sufficient bioconcentration potential to result in internal body burdens that exceed narcotic or polar narcotic thresholds of toxicity (ECCC, HC 2016), that is, even low to moderate levels of bioconcentration of triclosan may cause adverse effects in aquatic organisms.

The assessment of triclosan (ECCC, HC 2016) determined that it does not meet the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Government of Canada (GC) 2000), however, it is continuously present in the environment. Similarly, triclosan accumulates in organisms to levels that can cause adverse effects (ECCC, HC 2016), it does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (GC 2000).

Measured Concentrations

The main source of release of triclosan to aquatic ecosystems is via effluents from WWTPs. In Canada, concentrations of triclosan measured in effluents ranged from 12 to 4,160 ng/L between 2002 and 2013 (ECCC, HC 2016). Triclosan concentrations were measured in surface waters of Canada for all provinces and territories, except Prince Edward Island, from 2002 to 2013 and also for certain locations for 2014. Reported concentrations ranged from below the method detection limit of 4-42 ng/L to 874 ng/L and the highest median concentration was 139 ng/L. The available surface sediment monitoring data (2012-2013) from the Pacific and Atlantic regions, Lake Erie and St. Lawrence River ranged from <1 to 47 ng/g (EC unpublished data). No triclosan monitoring data are available for soils in Canada (ECCC, HC 2016). No air monitoring data are available for triclosan and given its short half-life in air (0.66 day), triclosan is not likely to be subject to long-range transport.

Mode of Action

Triclosan inhibits the enzyme enoyl-acyl carrier protein (ACP) reductase involved in type II bacterial fatty acid synthesis (McMurry et al. 1998; Heath et al. 1999; Hoang and Schweizer 1999; Levy et al. 1999). Enoyl-ACP reductase is also shown to be a possible target for triclosan with the brassicacea *Arabidopsis* (rockcress) (Serrano et al. 2007). Activation of peroxisome proliferators-activated receptor alpha (PPARα) is the primary mode of action for triclosan-induced hepatocarcinogenesis in mouse (ECCC, HC 2016). In addition, the molecular structure of triclosan resembles that of several non-steroidal estrogens, such as diethylstilbestrol and bisphenol A, in that it contains two phenol functional groups. Triclosan has been shown to have endocrine disruption effects in amphibians at environmentally-realistic concentrations (Veldhoen et al. 2006). Endocrine disruption effects were also noted in fish and mammals, however these effects occurred at very high concentrations that may not be environmentally relevant.

Federal Water Quality Guideline Derivation

Federal Water Quality Guidelines (FWQGs) are preferably developed using CCME (2007) protocols. In the case of triclosan sufficient chronic toxicity data were available to meet the minimum data requirements for a CCME Type A guideline[1]. No CCME water quality guideline for triclosan exists for the protection of

[1] CCME (2007) provides two approaches for developing water quality guidelines, depending on the availability and quality of the available data. The preferred approach is to use the statistical distribution of all acceptable data to develop Type A guidelines. The second approach is based on extrapolation from the lowest acceptable toxicity endpoint to develop Type B guidelines. For further detail on the minimum data requirements for CCME guidelines see CCME (2007).

aquatic life. The FWQG developed here identifies a benchmark for aquatic ecosystems that is intended to protect all forms of freshwater aquatic life for indefinite exposure periods.

An extensive triclosan aquatic toxicity dataset was compiled and evaluated by Environment and Climate Change Canada and is presented in ECCC, HC (2016). In summary, the long-term freshwater toxicity endpoints for three fish, three amphibian, five invertebrate and eight plant species met the CCME (2007) reliability criteria and were used to deriving the FWQG for triclosan (Table 2). In general, plants tended to be more sensitive to triclosan than invertebrates or fish, although both the most sensitive and the least sensitive species in the dataset were algae (Table 2). The Pacific tree frog (*Pseudacris regilla)* was the second most sensitive species in the data set. Among invertebrates, snail (*Physa acuta*) was most sensitive and the least sensitive species was a crustacean, *Daphnia magna*. Of the three reported values for fish, rainbow trout (*Oncorhynchus mykiss*) was the most sensitive whereas the Japanese medaka (*Oryzias latipes*) was the least sensitive fish.

Table 2. Chronic freshwater aquatic toxicity data considered for developing FWQG for triclosan.

Species	Group	Endpoint	Concentration (µg/L)	Reference
Green algae (*Scenedesmus subspicatus*)	▲	72-h EC_{10} (growth)	0.5	Roberts et al. (2014)
Pacific tree frog (*Pseudacris regilla)*	◇	21-d MATC (growth, development)	0.95	Marlatt et al. (2013)
Blue-green algae (*Anabaena flos-aquae*)	▲	96-h EC_{10} (biomass)	0.97	Orvos et al. (2002)
Green algae (*Scenedesmus vacuolatus*)	▲	24-h EC_{10} (growth)	1.09	Franz et al. (2008)
Algae (*Pseudokirchneriella subcapitata*)	▲	96-h EC_{25} (growth)	2.44	Orvos et al. (2002)
Snail (*Physa acuta*)	●	42-d MATC (growth)	3.2	Brown et al. (2012)
Scud (*Hyalella azteca*)	●	10-d LC_{10} (survival)	5	Dussault et al. (2008)
Golden-brown diatom (*Navicula pelliculosa*)	▲	96-h EC_{25} (growth)	10.7	Orvos et al. (2002)
Bullfrog (*Rana catesbeiana)*	◇	18-d NOEC (growth, development)	>11.2	Veldhoen et al. (2006)
Midge (*Chironomus dilutus*)	●	10-d LC_{10} (survival)	20	Dussault et al. (2008)
Duckweed (*Lemna gibba*)	▲	7-d MATC (growth)	22*	Fulton et al. (2009) Study Submission (2013)
African clawed Frog (*Xenopus laevis*)	◇	32-d NOEC (growth, development)	>29.6	Fort et al. (2011)
Water flea (*Ceriodaphnia dubia*)	●	7-d MATC (survival, reproduction)	39*	Orvos et al. (2002) Tatarazako et al. (2004)
Rainbow trout (*Oncorhynchus mykiss*)	■	61-d MATC (fry survival)	49.3	Orvos et al. (2002)
Mosquitofish (*Gambusia affinis*)	■	35-d MATC (sperm count)	76.6	Raut and Angus (2010)
Water flea (*Daphnia magna*)	●	21-d MATC (reproduction)	89	Orvos et al. (2002)
Japanese medaka (*Oryzias latipes*)	■	21-d NOEC (hatchability)	>137	Ishibashi et al. (2004)
Golden-brown diatom (*Nitzschia palea*)	▲	72-h EC_{10} (photosynthesis)	194	Franz et al. (2008)
Algae (*Closterium ehrenbergii)*	▲	96-h MATC (growth)	354	Ciniglia et al. (2005)

Legend: ◇ = Amphibian; ■ = Fish; ● = Invertebrate; ▲ = Plant
*Geomean

Each species for which appropriate toxicity data were available (Table 2) was ranked according to sensitivity and its position on the species sensitivity distribution (SSD) was determined (Figure 1). Several cumulative distribution functions (normal, logistic, extreme value and Gumbel) were fit to the data using regression methods and the model fit was assessed using statistical and graphical techniques. The best model based on goodness of fit was the log normal model; the 5th percentile of the SSD plot is 0.38 µg/L, with lower and upper confidence limits of 0.26 and 0.54 µg/L, respectively.

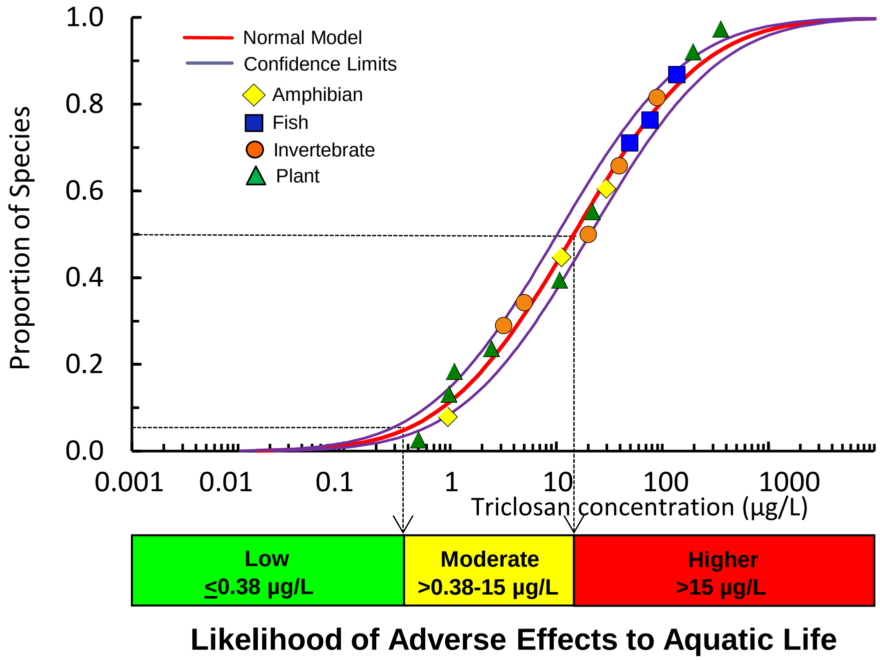

Figure 1. Species sensitivity distribution (SSD) for the chronic toxicity of triclosan and relative likelihood of adverse effects of triclosan to freshwater aquatic life.

The 5th percentile calculated from the SSD (0.38 µg/L) is selected as the PNEC in the ecological risk assessment of triclosan (ECCC, HC 2016) as well as the FWQG. The guideline represents the concentration below which one would expect either no, or only a low likelihood of adverse effects on aquatic life. In addition to this guideline, two other concentration ranges are provided for use in risk management (Figure 1). At concentrations between >5th and 50th percentile of the SSD (>0.38-15 µg/L), there is a moderate likelihood of adverse effects to aquatic life. Concentrations greater than the 50th percentile (>15 µg/L) have a higher likelihood of causing adverse effects. Risk managers may find these additional concentration ranges useful in defining short-term or interim risk management objectives for a phased risk management plans. The moderate to higher concentration ranges may also be used in setting less protective interim targets for waters that are already highly degraded or where there are socio-economic considerations that preclude the ability to meet the FWQG.

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List of Acronyms and Abbreviations

BAF –Bioaccumulation Factor: the ratio of the concentration of a chemical compound in an organism relative to the concentration in the exposure medium, based on uptake from the surrounding medium and food

BCF – Bioconcentration Factor: the ratio of the concentration of a chemical compound in an organism relative to the concentration of the compound in the exposure medium (e.g. soil or water)

CCME – Canadian Council of Ministers of the Environment

CEPA – Canadian Environmental Protection Act

CMP – Chemicals Management Plan

DCDD – Dichlorodibenzodioxin

DPD – Drug Product Database

EC – Effect Concentration
ECHA – European Chemical Agency
FEQG – Federal Environmental Quality Guidelines
FWQG – Federal Water Quality Guideline
LC – Lethal Concentration
MATC – Maximum Acceptable Toxicant Concentration
NITE – National Institute of Technology and Evaluation
NHPID – Natural Health Products Ingredients Database
NOEC – No Observed Effect Concentration
PNEC – Predicted No Effect Concentrations
SSD – Species Sensitivity Distribution
WWTP – Waste Water Treatment Plant