Government of Canada / Gouvernement du Canada

# Risk Management Approach

# for

# Phenol, 5-chloro-2-(2,4-dichlorophenoxy) (Triclosan)

## Chemical Abstracts Service Registry Number: 3380-34-5

Environment and Climate Change Canada
Health Canada
NOVEMBER 2016

Canada

# Summary of Proposed Risk Management

This document outlines the proposed risk management action for triclosan. In particular, the Government of Canada is considering implementing a notice requiring the preparation and implementation of Pollution Prevention Plans under Section 56 of the *Canadian Environmental Protection Act, 1999* (CEPA) with the objective of reducing the quantity of triclosan released to the aquatic environment as a result of the use by consumers of triclosan-containing products imported into and formulated in Canada.

Interested stakeholders are invited to provide information regarding any alternatives to triclosan, as well as information about the benefits and impacts associated with the risk management action presented herein. This information should be provided on or before January 25, 2017 to the contact details identified in section 8 of this document.

**Note:** The above summary is a short description of the action proposed to manage triclosan and of information sought to inform the risk management decision-making process. Refer to Section 3 of this document for more complete details in this regard. It should be noted that the identified risk management action may evolve through consideration of additional information obtained from the public comment period, from other sources, and from the information presented in this document.

# Table of Contents

# 1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic[1] to the environment and/or harmful to human health[2] as set out in section 64 of CEPA, and if so to manage the associated risks.

The substance phenol, 5-chloro-2-(2,4-dichlorophenoxy), Chemical Abstracts Service Registry Number (CAS RN) 3380-34-5, referred to throughout this document as "triclosan", was identified as a priority for assessment under CEPA since it met the categorization criteria set out in the Act.

Triclosan was also scheduled as a pest control product for re-evaluation under Health Canada's Pest Management Regulatory Agency (PMRA) pesticide re-evaluation program to determine whether it meets modern human health and environmental standards as required by the *Pest Control Products Act* (PCPA) (Canada 2002a). 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. Consequently, as of December 31, 2014, triclosan is no longer registered in Canada for use as a pest control product.

[1] Section 64 [of CEPA]: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- *(b) constitute or may constitute a danger to the environment on which life depends; or*
- *(c) constitute or may constitute a danger in Canada to human life or health.*

[2] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of products by consumers. A conclusion under CEPA on the substances in the Chemicals Management Plan is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS (Workplace Hazardous Materials Information System) that are specified in the *Hazardous Products Regulations* and the *Controlled Products Regulations* for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

# 2. Issue

## 2.1 Assessment Conclusion

Health Canada and Environment Canada conducted a joint scientific assessment of triclosan (ECCC and HC 2016). A notice summarizing the scientific considerations of the assessment report for this substance was published in the *Canada Gazette*, Part I, on November 26, 2016 (Canada 2016).

**Conclusion under CEPA**

Based on the information available, the assessment concluded that triclosan meets the criteria under paragraph 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. However, it is concluded that triclosan does not meet the criteria under paragraph 64(*b*) of CEPA 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.

It is also concluded that triclosan does not meet the criteria under paragraph 64(*c*) of CEPA as 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.

Even though it is continuously present in the environment, triclosan has been determined not to meet the persistence criterion as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000) of CEPA. Similarly, while triclosan accumulates in organisms to levels that can cause adverse effects, it does not meet the bioaccumulation criterion as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

Further information on the conclusion for triclosan can be found in the assessment report (ECCC and HC 2016) available at http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/triclosan-eng.php.

**Status under PCPA**

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. Consequently, triclosan is no longer registered in Canada as a pest control product as of December 31, 2014.

## 2.2 Recommendation under CEPA

When a substance is found to meet one or more of the criteria under section 64 of CEPA, the Ministers can (1) take no further action with respect to the substance, (2) recommend the addition of the substance to the Priority Substances List for further assessment, or (3) recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

Based on the findings of the assessment for triclosan conducted under CEPA, the Ministers recommend adding triclosan to the List of Toxic Substances in Schedule 1 of the Act.

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the preliminary assessment (EC and HC 2012) and Risk Management Scope document (EC 2012a). As the Ministers finalize the recommendation to add triclosan to Schedule 1 of CEPA, a risk management instrument must be proposed and finalized within a set period of time, as outlined in sections 91 and 92 of CEPA (refer to section 8.2 of this document for targeted publication timelines applicable to this substance).

## 2.3 Public Comment Period on the Risk Management Scope

The Risk Management Scope document for triclosan, which summarized the proposed risk management actions under consideration at that time, was published on March 31, 2012. Industry and other interested stakeholders were invited to submit comments on the Risk Management Scope document during a 60-day comment period. Comments received on the Risk Management Scope document and new information gathered on the use of triclosan were taken into consideration in the development of this document. A summary of responses to the public comments received is available at http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/triclosan-eng.php.

# 3. Proposed Risk Management

The exposure source of concern, identified in the assessment, is the release of triclosan to surface water via wastewater treatment plant effluents from the use of triclosan-containing products by consumers. As such, this document will focus on this exposure source of concern (refer to section 5.2 of this document).

Risk management actions are already in place under the *Food and Drugs Act* (FDA), outlined in section 7 of this document. However, regulations under the FDA do not provide authority to address releases to the environment. Risk management is, therefore, proposed under CEPA.

## 3.1 Proposed Environmental Objective

Proposed environmental objectives are quantitative or qualitative statements of what should be achieved to address environmental concerns.

The proposed environmental objective for triclosan is to reduce concentrations of triclosan in the aquatic environment to levels below the predicted no-effect concentration (PNEC) of 376 ng/L.

## 3.2 Proposed Risk Management Objective and Action

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulation(s), instrument(s) and/or tool(s) for a given substance or substances.

The proposed risk management objective is to reduce the quantity of triclosan released to the aquatic environment as a result of the use by consumers of triclosan-containing products imported into or formulated in Canada.

To achieve the proposed risk management objective and work towards achieving the proposed environmental objective, the Government of Canada plans to develop a notice requiring the preparation and implementation of pollution prevention plans under section 56 of CEPA. The Notice would apply to formulators and importers of products containing triclosan.

A Pollution Prevention (P2) Planning Notice is an instrument under CEPA that requires organizations to develop and implement P2 plans in order to achieve the risk management objective. The P2 Notice outlines factors to consider when developing and implementing the pollution prevention plans. Facilities must implement the actions identified in their plans. These Notices allow organizations to identify options within their plans to eliminate or reduce pollution at the source,

and to evaluate these options and implement them within a specified time frame. In adopting P2 plans, individual organizations have the flexibility to identify the most cost-effective options to achieve the set risk management objectives.

ECCC has found that these plans are an effective means of achieving risk management objectives in different sectors (e.g. textile mills effluents - http://ec.gc.ca/planp2-p2plan/default.asp?lang=En&n=389059A9-1 ). They have also been effective when reducing levels of a substance in manufactured items (e.g. manufacturing of soap and cleaning products containing nonylphenol and its ethoxylates - http://ec.gc.ca/planp2-p2plan/default.asp?lang=En&n=B2D19B6D-1).

Data on levels of triclosan in the environment is collected as part of Environment Canada's Monitoring and Surveillance Program under the CMP. This information may be used in the future to verify if the environmental objective is being met.

## 3.3 Risk Management Information Gaps

Information on the following items would help inform the development of the proposed risk management instrument.

1. Information about potential alternative substances to triclosan;
2. Identification of any products that contain triclosan for which no viable alternatives exist (along with an explanation);
3. Information on impacts and benefits of the proposed risk management instrument (for industries, consumers, the environment, etc.); and
4. Information on changes in use patterns following the 2011 data received from the section 71 Notice under CEPA.

This type of information should be provided on or before January 25, 2017 to the contact identified in section 8 of this document.

# 4. Background

Triclosan is used as a preservative and as an antimicrobial agent in a wide range of products used by consumers including personal care, non-prescription drug, natural health, and cleaning products. As noted in section 2.1 of this document, triclosan was also registered in Canada, prior to December 31, 2014, as a pest control product for use in textiles, leather, paper, plastic and rubber to stop the growth of bacteria, fungus, mildew, and to prevent odours.

## 4.1 Current Uses and Identified Sectors

A survey conducted under section 71 of CEPA requested information on the manufacture, import, use and release of triclosan in a quantity greater than 10 kg and at a concentration of 0.001% w/w or more for the year 2011 (Environment Canada 2013).

Results from this survey indicated that triclosan was not manufactured in Canada. The total quantity of triclosan imported into Canada ranged from 10 000 to 100 000 kg, either as a pure substance to manufacture formulated products or as an ingredient in formulated products. Formulated products containing triclosan include non-prescription drugs, natural health, personal care and cleaning products such as antibacterial soaps, skin cleansers, toothpastes, make-up, deodorants, skin creams, fragrances, general purpose cleaners, and detergents.

# 5. Exposure Sources and Identified Risks

## 5.1 Sources and Releases to the Canadian Environment

There are no known natural sources of triclosan; its presence in the environment is solely a result of human activity.

The main source of release of triclosan to the Canadian environment is through the use of triclosan-containing products by consumers, which are typically released down the drain to wastewater.

The industrial manufacture of products containing triclosan is also a source of release of this substance to wastewater. However, based on monitoring and surveillance data collected on triclosan for some locations over a number of years, these facilities are not likely a significant contributor of triclosan in the environment.

Triclosan released into wastewater reaches wastewater treatment plants (WWTPs). WWTPs with secondary wastewater treatment are efficient in

removing triclosan from wastewater compared to other forms of treatment. However, secondary treatment may create methyl-triclosan, which is a potentially more persistent and more bioaccumulative substance than triclosan as indicated in the assessment report. Triclosan is released to aquatic ecosystems via WWTP effluents.

Triclosan is also released to terrestrial ecosystems via the spreading of biosolids from WWTPs. Levels of triclosan in soils were estimated based on the measured concentrations of triclosan in biosolids in Canada, and using parameters such as triclosan half-lives in soil and regulated application rates for biosolids. The risk characterization considered these estimated levels of triclosan in soils as well as its high toxicity to certain soil organisms and indicated that triclosan is not likely to cause harmful effects on these organisms given the low estimated triclosan levels in soil.

Based on information presented in the assessment, landfills are not a likely source of triclosan to the environment (Canada 2016a).

### 5.2 Exposure of Concern in Canada

The main exposure of concern for triclosan is in aquatic ecosystems. Measured concentrations of triclosan in surface water are available for numerous water bodies in both densely and lightly populated areas of Canada from 2002 to 2014 (see Tables 4-3 A to L of the assessment). Even though the majority of measured triclosan concentrations in surface water are below the level determined to be protective of toxic effects (or the PNEC), there are a few instances where this level was exceeded.

Assuming that the data available for concentrations in surface water are representative of those for the entire country, for locations where triclosan is prevalent, i.e., near populated areas across Canada, concentrations are expected to exceed the PNEC for triclosan. This indicates that triclosan can reach levels where there is a potential for harmful effects in aquatic ecosystems.

## 6. Risk Management Considerations

### 6.1 Alternatives

There are many classes of preservatives that may be used for product preservation, including organic acids and their salts, paraben esters, quaternary ammonium compounds, formaldehyde donors, alcohols, and other miscellaneous chemicals.

Commonly used preservatives, other than triclosan, that are allowed in cosmetic products in Canada and the United States include benzoic acid, sodium benzoate, sorbic acid, potassium sorbate, parabens, dehydroacetic acid and salts, imidazolidinyl urea, diazolidinyl urea, DMDM hydantoin, methylchloroisothiazolinone (MCI) and methylisothiazolinone (MI) mixture, MI alone, chlorphenesin, benzyl alcohol, caprylyl glycol, and iodopropynyl buylcarbamate (Steinberg 2010).

Several antiseptic categories also exist. Health Canada's Drug Product Database (DPD) contains product-specific information on drugs approved for use in Canada. The database includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products. Most of the products containing triclosan as an active ingredient outlined in the DPD are antibacterial and antimicrobial soap/skin cleansers and toothpastes. A search of the database indicates that active ingredients, other than triclosan, reported for antibacterial and antimicrobial soap/skin cleansers in the DPD include benzalkonium chloride, chloroxylenol, bronopol, and chlorhexidine gluconate (Health Canada 2014a).

While some of the substances discussed above may have a use function similar to triclosan in certain applications, it is important to note that most have not been assessed under CEPA. For more information on substances assessed under this Act as part of the CMP, please refer to the Chemical Substances website at: http://www.chemicalsubstanceschimiques.gc.ca/.

## 6.2 Socio-economic and Technical Considerations

Socio-economic factors have been considered in the selection process for the instrument respecting preventive or control actions, and in the development of the risk management objective. Socio-economic factors will be considered in the development of the instrument as identified in the *Cabinet Directive on Regulatory Management* (TBS 2012) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

Approximately 94% of the soap, cleaning and toilet preparation manufacturing establishments in Canada are either micro (less than 5 employees) or small (5 to 99 employees). The total number of employees in that sector was 11 236 in 2012. Net revenues in the Soap, Cleaning Compound and Toilet Preparation Manufacturing industry group decreased from $312.3 million in 2004 to $211.4 million in 2012 or by 4.8% per year on average. In the latest year, net revenues increased by 27.0% (Industry Canada 2015a).

Approximately 82% of pharmaceutical and medicine manufacturing establishments are either micro or small. The total number of employees in that sector was 31 802 in 2012. Net revenues in the Pharmaceutical and Medicine

Manufacturing industry group decreased from $1.5 billion in 2004 to $1.1 billion in 2012 or by 4.0% per year on average. In the latest year, net revenues increased by 5.4%. For these two categories of establishments, about 72% of the employers are located in Ontario and Quebec (Industry Canada 2015b).

Approximately 94% of Pharmaceuticals, Toiletries, Cosmetics and Sundries Merchant Wholesalers are also either micro or small and 72.5% of the employers are located in Ontario and Quebec. In 2012, the Pharmaceuticals, Toiletries, Cosmetics and Sundries Merchant Wholesalers industry group generated $2.6 billion in profits, up from $1.6 billion in 2003. This represented an average annual increase of 5.5%, with a 0.1% decrease observed between 2011 and 2012 (Industry Canada 2015c).

As identified in section 3.3 of this document, there are some data gaps related to socio-economic factors. However, public information was considered in the selection process of the proposed risk management instrument, including the announcement made by some companies regarding the phasing out of triclosan in all or in some products they manufacture (e.g., Loblaw Companies Limited[3], Johnson & Johnson[4], Proctor & Gamble[5], Colgate-Palmolive[6] and Avon[7]) or from their store shelves (e.g., Walmart[8]).

# 7. Overview of Existing Risk Management

## 7.1 Related Canadian Risk Management Context

*Food and Drugs Act*

Triclosan is listed as a restricted ingredient on Health Canada's List of Prohibited and Restricted Ingredients in cosmetics (more commonly referred to as the Cosmetic Ingredient Hotlist), which is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain ingredients may contravene the general prohibition found in section 16 of the *Food and Drugs Act* (FDA), or may contravene one or more provisions of the Cosmetic Regulations. Section 16 of the FDA states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user". The restriction sets a maximum concentration of 0.03% of triclosan in cosmetic

[3] http://media.loblaw.ca/default.aspx?SectionId=5cc5ecae-6c48-4521-a1ad-480e593e4835&LanguageId=1&PressReleaseId=47fe7eec-e638-46a9-878f-0a5d038cb011

[4] http://www.safetyandcarecommitment.com/ingredient-info/other/triclosan

[5] http://www.pg.com/en_US/sustainability/safety/ingredients/triclosan.shtml

[6] http://www.colgate.com/app/Colgate/US/Corp/LivingOurValues/Sustainability/Ingredients.cvsp

[7] http://www.avoncompany.com/corporate-responsibility/about-cr/positions-policies/triclosan/

[8] http://www.usatoday.com/story/news/nation/2013/09/12/walmart-disclose-phase-out-toxic-chemicals-products-cosmetics/2805567/

mouthwashes and 0.3% in other cosmetic products (Canada 2007, Health Canada 2014b).

Drugs are subject to the requirements of the *Food and Drugs Act* (Canada 1985a) and the *Food and Drug Regulations* made under that Act, which takes into account safety and efficacy considerations (Canada 1978). Health Canada's Antiseptic Skin Cleanser monograph states that the permitted concentration of triclosan as an active ingredient can range from 0.1% to 1.0% (Health Canada 2006). Higher levels may be permitted but companies are required to submit safety and efficacy data to Health Canada for evaluation.

Natural health products are regulated as per the requirements of the *Food and Drugs Act* and the *Natural Health Products Regulations* made under that Act, which provide for the licensing of products that meet appropriate safety, efficacy, and quality requirements (Canada 2006). Triclosan is listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role for use in natural health products as an antimicrobial preservative at concentrations of equal to or less than 0.03% in buccal products (e.g., mouthwashes), at concentrations of equal to or less than 0.3% in topical products (e.g., foot gels, acne treatments, body sprays, skin cleansers and lotions) and at concentrations of equal to or less than 0.3% in dental products (e.g., toothpastes), provided that triclosan does not contribute to the claim of the product. According to the Licensed Natural Health Products Database (LNHPD), triclosan is currently used as a non-medicinal ingredient in licensed natural health products in Canada (Health Canada 2015).

*Pest Control Products Act* (PCPA)

In Canada, the import, packaging, manufacture, distribution, labeling, sale and use of pest control products are regulated under the PCPA (Canada 2002a) and Regulations. Compliance issues related to pest control products are managed consistent with Health Canada's PMRA Compliance Policy.

The 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. Consequently, as of December 31st, 2014, triclosan is no longer registered in Canada as a pest control product.

*Transportation of Dangerous Goods Act and Regulations* (TDGR)

Triclosan is classified as Class 9 dangerous goods, UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Not Otherwise Specified) under the *Transportation of Dangerous Goods Regulations* (TDGR) pursuant to the *Transportation of Dangerous Goods Act*. The TDGR set out specific requirements governing the handling and transport of dangerous goods (Canada 2011).

Of note, under CEPA, the transboundary movements of substances classified under Class 9 of the TDGR, that are intended to be disposed of or recycled, are subject to the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (Canada 2005) or the *Interprovincial Movement of Hazardous Waste Regulations* (Canada 2002b).

Wastewater Releases

There are no existing Canadian risk management measures identified specific to controlling the releases of triclosan to the environment.

However, while not specific to releases of triclosan to the environment, it should be noted that the management of wastewater systems, including biosolids, is subject to various federal, provincial, territorial and municipal legislation in Canada. The Government of Canada put in place the *Wastewater Systems Effluent Regulations* (WSER) (Canada 2012), made under the *Fisheries Act* (Canada 1985b),which require wastewater systems to achieve and maintain at least a level of secondary wastewater treatment. Triclosan is not explicitly regulated in the WSER, but studies suggest removal rates of 49-98% of triclosan from secondary treatment plants in Canada. However, secondary treatment may create methyl-triclosan, which is a potentially more persistent and more bioaccumulative substance than triclosan as indicated in the assessment report.

Furthermore, the Canadian Food Inspection Agency regulates biosolids intended for use as a fertilizer or supplement under the *Fertilizers Act* (Canada 1985c) and *Fertilizers Regulations* (Canada 2009). Provinces and territories manage the maintenance and operation of wastewater systems and/or composting facilities as well as the processing, use and disposal of biosolids and other nutrient sources, including land application, through a variety of acts, regulations, best management practices and guidelines. In order to obtain approvals, permits or licenses, various standards and information requirements must be met. Municipalities typically have sewer use by-laws. In addition, other organizations, such as the Canadian Council of Ministers of the Environment (CCME) and the Bureau de normalisation du Québec[9], have standards and guidelines in place that jurisdictions can use when developing policy or reviewing requirements related to wastewater systems and biosolids (CCME 2009, 2010).

## 7.2 Pertinent International Risk Management Context

### 7.2.1 United States

*Federal Food, Drug and Cosmetic Act*

[9] CCME and BNQ publications are available at: http://www.ccme.ca/ and http://www.bnq.qc.ca/

On September 6, 2016,the United States Food and Drug Administration published the final rule regarding over-the-counter (OTC) antiseptic wash products (US FDA 2016). The rule requires that OTC consumer antiseptic wash products containing certain active ingredients can no longer be marketed. Companies will no longer be able to market in the United States antibacterial washes containing these ingredients, because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections. Some manufacturers have already started manufacturing their products without these ingredients. This rule is effective September 6, 2017.

This rule applies to consumer antiseptic wash products containing one or more of 19 specific active ingredients, including ingredients – triclosan and triclocarban. These products are intended for use with water, and are rinsed off after use. This rule does not affect consumer hand not-rinsed "sanitizers" or wipes, or antibacterial products used in health care settings or by the food industry.

The *Federal Food, Drugs and Cosmetic Act* requires that companies comply with quality standards set by the United States Pharmacopeia for prescription and OTC drugs (Legal Recognition of USP Standards 2015).

*Endangered Species Act* (ESA)

On May 13, 2015, the United States Environmental Protection Agency (US EPA) responded to the Citizen Petition for a Ban on Triclosan filed by Food & Water Watch and Beyond Pesticides. The US EPA granted one request in the petition to evaluate and conduct a biological assessment of potential effects on species listed under the ESA (US EPA 2015).

*Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)

Under FIFRA, the US EPA regulates antimicrobial uses of triclosan in a wide variety of consumer, commercial, institutional, and industrial use products, when used as a material preservative.

Minnesota

On May 16, 2014, Minnesota passed a bill[10] banning the use of triclosan in some consumer products sold in the state. The ban is effective January 1, 2017, and states that *"No person shall offer for retail sale in Minnesota any cleaning product that contains triclosan and is used by consumers for sanitizing or hand and body*

[10] Entire bill title reads: A bill for an act relating to environment; prohibiting and regulating certain lead and mercury products; modifying ban on formaldehyde in children's products; prohibiting certain cleaning products containing triclosan; amending Minnesota Statutes 2012, sections 115A.932, subdivision 1; 116.92, subdivisions 4, 5, 6, 8j, by adding a subdivision; Minnesota Statutes 2013 Supplement, sections 325F.176; 325F.177; proposing coding for new law in Minnesota Statutes, chapters 116; 145.

*cleansing. This shall not apply to individual products for which specific US FDA approval for consumer use has been secured"* (Minnesota 2014).

### 7.2.2 European Union

*Cosmetic Products Regulations*

Annex V of the European Regulation (EC) No. 1223/2009 on Cosmetic Products provides a list of preservatives allowed in cosmetic products and their maximum concentrations in ready-for-use preparations.

Commission Regulation (EU) No. 358/2014 of 9 April 2014 amended Regulation (EC) No. 1223/2009 to allow a maximum concentration of 0.3% only in: toothpastes, hand soaps, body soaps/shower gels and deodorants (non-spray), face powders and blemish concealers, nail products where the intended use is to clean the fingernails and toenails before the application of artificial nail systems; and a maximum concentration of 0.2% for mouthwashes (European Commission 2014a). The regulation previously allowed the use of triclosan in cosmetics as a preservative at concentrations up to 0.3% (European Union 2009).

*Biocidal Products Regulations*

The *Biocidal Products Regulations*, concerning introduction in the market and use of biocidal products (European Union 2012), which are used to protect humans, animals, materials or articles against harmful organisms, entered into force on September 1, 2013. This regulation repealed the *Biocidal Products Directive* (Directive 98/8/EC) (ECHA 2015).

In the European Union, triclosan as a biocidal active substance is not approved for use as a film preservative; as a fibre, leather, polymerised material preservative; or in disinfectants and algaecides other than those intended for direct application to human or animal (European Commission 2014b).

In January 2016, a final decision by the European Commission was published to not approve triclosan as an active substance for use in human hygiene biocidal products. The scenarios evaluated in the environmental risk assessment identified unacceptable risks (European Commission 2016). The Biocidal Active Substances List has been updated to reflect this recent decision.

*Classification, Labelling and Packaging Regulations*

Under Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (European Union 2008), products containing triclosan are classified as both an irritant to eye and skin and as dangerous for the environment (for both acute and chronic aquatic exposure). Labelling

requirements include phrases identifying both of these hazards. Cosmetic products are exempt from the requirements of this regulation.

### 7.2.3 Australia

Triclosan is listed on Schedule 6 of the Poisons Standards 2014. Schedule 6 listing reduces the extent of harm through the use of distinctive packaging with strong warnings and safety directions on the label. For triclosan, this requirement applies when used in cosmetic preparations for human use containing more than 0.3% (Australian Government 2014).

### 7.2.4 Japan

Triclosan is included in the Standards for Cosmetics, which sets a maximum allowable concentration of 0.1% in cosmetic products (Japan Ministry of Health and Welfare 2000).

# 8. Next Steps

## 8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in section 3.3 of this document) prior to January 25, 2017.

Comments on the Risk management Approach document and additional information should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819- 938-3232
Fax: 819-938-3231
Email: ec.substances.ec@canada.ca

Interested parties who have a business interest in triclosan are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding triclosan and may be contacted for further information.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the proposed Pollution Prevention Planning Notice instrument. Comments received

on the Risk Management Approach document will be taken into consideration in the development of the instrument. Consultation will also take place as the instrument is developed.

## 8.2 Timing of Actions

Publication of responses to public comments on the Risk Management Approach document: no later than November 2018.

Publication of the proposed instrument, if required: no later than November 2018.

Consultation on the proposed instrument, if required: 60-day public comment period starting upon publication of the proposed instrument.

Publication of the final instrument, if required: no later than May 2020.

# 9. References


Australian Government. 2014. *Poisons Standard 2014.* Available from: http://www.comlaw.gov.au/Details/F2014L01343

Canada. 1985a. *Food and Drugs Act* (R.S.C., 1985, c.F-27). Available from: http://laws-lois.justice.gc.ca/eng/acts/f-27/

Canada. 1985b. *Fisheries Act (*R.S.C., 1985, c. F-14)*.* Available from: http://laws.justice.gc.ca/en/F-14/

Canada. 1995. Environment Canada. Toxic Substances Management Policy. Reprint of original 1995 Edition. ISBN 0-662-61860-2. Available from: http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=2A55771E-1

Canada. 1999. *Canadian Environmental Protection Act, 1999* (S.C. 1999, c. 33). *Canada Gazette* Part III, vol. 22, no. 3. Available from: http://laws-lois.justice.gc.ca/eng/acts/C-15.31/

Canada. 2000. *Persistence and Bioaccumulation Regulations*. P.C. 2000-348, 23 March 2000, SOR/2000-107, *Canada Gazette* Part II, vol. 134, no. 7, p. 607-612. Available from: http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-107/page-1.html

Canada. 2002a. *Pest Control Products Act (*S.C. 2002, c.28). *Canada Gazette* Part III, vol. 25, no. 3. Available from: http://laws-lois.justice.gc.ca/eng/acts/P-9.01/

Canada. 2002b. *Interprovincial Movement of Hazardous Waste Regulations* (SOR/2002-301). Available from: http://lois-laws.justice.gc.ca/eng/regulations/SOR-2002-301/index.html

Canada. 2005. *Export and Import of Hazardous Waste and Hazardous Recyclable Material*, SOR/2005-149. Available from: http://lois-laws.justice.gc.ca/eng/regulations/SOR-2005-149/index.html

Canada. 2006. *Natural Health Products Regulations (SOR/2003-196). P.C. 2003-847, 5 June 2003, SOR/2003-196.* Available from: http://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/

Canada. 2007. *Cosmetic Regulations*, C.R.C., 869*.* Available from: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._869/FullText.html

Canada. 2009. *Fertilizers Regulations* (C.R.C., c.666). Available from: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._666/FullText.html

Canada. 2011. *Transportation of Dangerous Goods Act: Consolidated Transportation of Dangerous Goods Regulations including Amendment SOR/2011-210 (Amendment 10) and SOR/2011-239 (Amendment 8).* Available at: http://www.tc.gc.ca/eng/tdg/safety-menu.htm

Environment Canada and Health Canada. 1990. Polychlorinated dibenzodioxins and polychlorinated dibenzofurans (Priority substances list assessment report no. 1) [Internet]. Available from: www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/psl1-lsp1/dioxins_furans_dioxines_furannes/dioxins_furans_e.pdf

Environment Canada and Health Canada. 2004. *A Guide to Understanding the* Canadian Environmental Protection Act, 1999. December 10, 2004. Available from: https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E00B5BD8-1

[ECCC and HC] Environment Canada and Health Canada. 2012. Preliminary assessment: triclosan: Chemical Abstracts Service Registry Number 3380-34-5. Ottawa (ON): Environment Canada, Health Canada. .Available at: http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/triclosan-eng.php

Canada. 2012. *Wastewater Systems Effluent Regulations (*SOR/2012-139). Available from: http://laws-lois.justice.gc.ca/eng/regulations/sor-2012-139/index.html

[ECCC and HC] Environment and Climate Change Canada, Health Canada. 2016. Assessment report: triclosan: Chemical Abstracts Service Registry Number 3380-34-5. Ottawa (ON): Environment and Climate Change Canada, Health Canada. Available from: www.ec.gc.ca/ese-ees/default.asp?lang=En&n=65584A12-1

[CCME] Canadian Council of Ministers of the Environment. 2009. Canada-wide Strategy for the Management of Municipal Wastewater Effluent. Available from: http://www.ccme.ca/en/resources/water/municipal_wastewater_effluent.html?

[CCME] Canadian Council of Ministers of the Environment. 2010. *A Review of the Current Canadian Legislative Framework for Wastewater Biosolids.* Available from: http://www.ccme.ca/files/Resources/waste/biosolids/pn_1446_biosolids_leg_review_eng.pdf

[ECHA 2015] European Chemical Agency. 2015. *Understanding BPR*. Retrieved July 2, 2015, from European Chemical Agency, Biocidal Products Regulations: http://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Environment Canada. 2010. Categorization of Existing Substances. Available from: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=1695F8D0-5CC4-EDA1-AF63-6F23A94064DD

Environment Canada. 2012a. Risk Management Scope. Triclosan. Chemical Abstract Service Number 3380-34-5. March 2012. Available at: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=613BAA27-1

Environment Canada. 2012b. Wastewater Program Details. Available from: http://www.ec.gc.ca/eu-ww/default.asp?lang=En&n=BC799641-1

Environment Canada. 2013. *Notice with respect to triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol), Canada Gazette, Part I, February 9, 2013.* Available from: http://www.gazette.gc.ca/rp-pr/p1/2013/2013-02-09/html/notice-avis-eng.html

European Commission. 2014a. *Commission Regulation (EU) No 358/2014 of 9 April 2014 amending Annexes II and V to Regulation (EC) No 1223/2009 of the European Parliament .* Official Journal of the European Union: available from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0358&from=EN

European Commission. 2014b. *Commission Implementing Decision of 24 April 2014 on the non-approval of certain biocidal active substances pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council.* Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014D0227&from=EN

European Commission. 2016. *Commission Implementing Decision (EU) 2016/110 of 27 January 2016 not approving triclosan as an existing active substance for use in biocidal products for product type 1.* Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0110&from=EN

European Union. 2008. *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC).* Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20131201

European Union. 2009. *Regulations (EC) No 1223/2009 of the European Parliament and of the Council.* Official Journal of the European Union. Available from: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1223

European Union. 2012. *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.* Official Journal of the European Union: Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2012%3A167%3ATOC

Health Canada. 2005. Dioxins and furans (It's Your Health factsheet). [published 2001 Nov; updated 2005 Sep]. Ottawa (ON): Health Canada. Available from: http://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/environ/dioxin-eng.pdf

Health Canada. 2006. *Antiseptic skin cleansers (Personal Domestic Use) [Internet]. [cited 2016 Feb].* Available from: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=antiseptic_antiseptique

Health Canada. 2014a. Drug Product Database. Retrieved May 2014, from http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php

Health Canada. 2014b. List of Prohibited and Restricted Cosmetic Ingredients ("Hotlist") – June 2010. Ottawa (ON): Health Canada, Consumer Product Safety Directorate [cited December 1, 2014]. Available from: http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/index-eng.phpHealth Canada. 2015. [LNHPD] Health Canada Licensed Natural Health Products Database.

Industry Canada. 2015a. *Soap, Cleaning Compound and Toilet Preparation Manufacturing (NAICS 3256): Definition*. Retrieved March 31, 2015, from Canadian Industry Statistics: https://www.ic.gc.ca/app/scr/sbms/sbb/cis/definition.html?code=3256&lang=eng

Industry Canada. 2015b. *Pharmaceutical and Medicine Manufacturing (NAICS 3254): Definition*. Retrieved March 31, 2015, from Canadian Industry Statistics: https://www.ic.gc.ca/app/scr/sbms/sbb/cis/definition.html?code=3254&lang=eng

Industry Canada. 2015c. *Pharmaceuticals, Toiletries, Cosmetics and Sundries Merchant Wholesalers (NAICS 4145): Definition*. Retrieved March 31, 2015, from Canadian Industry Statistics: https://www.ic.gc.ca/app/scr/sbms/sbb/cis/definition.html?code=4145&lang=eng

Japan Ministry of Health and Welfare. 2000. *Japan Ministry of Health and Welfare Notification No.331 (2000) Standards for Cosmetics.* Available at: www.mhlw.go.jp/english/dl/cosmetics.pdf

Legal Recognition of USP Standards. 2015. Retrieved March 5, 2015, from The United States Pharmacopeial Convention: http://www.usp.org/about-usp/legal-recognition
Minnesota. 2014. *Minnesota Bills SF 2192, 5th Engrossment, 88th legislature (2013-2014).* Available at: https://www.revisor.mn.gov/bills/text.php?number=SF2192&version=5&session=ls88&session_year=2014&session_number=0

[NHPID] Natural Health Products Ingredients Database [database on the Internet]. 2015. Ottawa (ON): Health Canada. [cited 2015]. Available from: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do

[NICNAS] National Industrial Chemicals Notification and Assessment Scheme. 2009. Triclosan (Priority existing chemical assessment report No. 30) [Internet]. Sydney (AU): Australian Government, Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme. Available from: https://www.nicnas.gov.au/chemical-information/pec-assessments

[PMRA] Pest Management Regulatory Agency. 1999. The Pest Management Regulatory Agency's strategy for implementing the Toxic Substances Management Policy. Ottawa (ON): Pest Management Regulatory Agency. Available from: http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir99-03/index-eng.php

Steinberg D.C. (2010). *2010 Frequency of Preservative Use.* Cosmetics & Toiletries. Vol. 125, No.11, p. 46-51.

[TBS] Treasury Board of Canada Secretariat. 2007. *Assessing, selecting, and implementing instruments for government action.* Available from: http://publications.gc.ca/site/fra/456654/publication.html

[TBS] Treasury Board of Canada Secretariat. 2012. Cabinet Directive on Regulatory Management. Available from: http://www.tbs-sct.gc.ca/hgw-cgf/priorities-priorites/rtrap-parfa/guides/cdrm-dcgr-eng.asp

[US EPA]. U.S. Environmental Protection Agency. 2015. *EPA Responds to Citizen Petition for a Ban on Triclosan*. Available at: https://www.epa.gov/pesticides/epa-responds-citizen-petition-ban-triclosan

[

US FDA]. U.S. Food and Drug Administration. 2016. *Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use. Final Rule.* Available at: https://www.federalregister.gov/articles/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for

[USP] United States Pharmacopeia. 2009. USP 32. The National Formulary. NF 27. Official Monographs (Triclosan).