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RISK MANAGEMENT SCOPE

For

Triclosan

Chemical Abstracts Service Registry Number (CAS RN):
3380-34-5

Environment Canada
Health Canada

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Canada

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SUMMARY OF RISK MANAGEMENT AND INFORMATION GATHERING

1. The Government of Canada will consult with stakeholders on the potential for voluntary reduction in the use of triclosan in products.
2. The current registrant of technical grade triclosan has chosen not to maintain their Canadian registration for pesticidal uses. Discontinued pest control products and associated treated products are subject to enforcement action under the Pest Control Products Act and can be incorporated into compliance strategies under the Government of Canada's Food and Consumer Safety Action Plan.
3. The Government of Canada proposes to use both Section 71 of CEPA 1999 and voluntary information gathering to collect current information on the manufacture, import and use of triclosan in Canada.
4. Pending the results of voluntary action and the analysis of updated use pattern information, risk management measures to reduce releases of triclosan from products and/or industrial effluents may be proposed, as appropriate.

Note: This summary is an abridged list of the instruments and tools proposed to risk-manage this substance. Please see section 8 of this document for a complete explanation of risk management.

1. ISSUE

Health Canada and Environment Canada conducted a joint scientific assessment of available information relevant to the evaluation of triclosan in Canada. The joint report brings together a draft risk assessment under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) and a re-evaluation under the *Pest Control Products Act* (PCPA) (Canada 2002).

Preliminary Assessment Conclusion under CEPA

A Notice summarizing the scientific considerations of the Preliminary Assessment was published for triclosan by Environment Canada and Health Canada in the *Canada Gazette* Part I, on March 31, 2012, under subsection 77(1) of CEPA 1999.

Based on the assessment of human health hazard and exposure, the Preliminary Assessment proposes 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.

Based on the assessment of the ecological hazard and exposure, the Preliminary Assessment proposes that triclosan is entering or may enter the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. The Preliminary Assessment also proposes that triclosan meets the criteria for bioaccumulation (based on bioconcentration data in fish), but does not meet the criteria for persistence, as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999 (Canada 2000).

Preliminary Assessment Conclusions under the PCPA

Based on the Preliminary Assessment, Health Canada's Pest Management Regulatory Agency (PMRA) proposes to conclude that the use of pest control products containing triclosan in Canada does not pose an unacceptable risk to human health. While use of these products may contribute to environmental exposure to triclosan, given the registered uses and the life-cycle of triclosan-treated products (*e.g.* treated plastics, textiles, leather, paper and rubber), pest control products are not expected to contribute significantly to the risks to aquatic organisms identified in the preliminary assessment. Therefore, the PMRA proposes to conclude that the use of pest control products containing triclosan does not pose an unacceptable risk to the environment. No further risk mitigation measures will be required at this time as the current registrant of triclosan has chosen not to maintain their Canadian registration. Should a registrant seek to re-enter the Canadian market, further data may be required to supplement the current risk assessment.

For further information on the proposed Preliminary Assessment conclusions for triclosan, refer to http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/other_chem-autres_sub-eng.php. Please note that, based on comments received during the consultation process, the proposed conclusions described in this document and in the Preliminary Assessment could be subject to change.

2. CURRENT USES AND INDUSTRIAL SECTORS

A survey conducted under section 71 of CEPA 1999 requested information on the manufacture, import, uses and releases of triclosan in a quantity greater than 100 kg and at a concentration of 1% w/w or more for the year 2000 (Environment Canada 2001). Results from this survey indicate that triclosan was not manufactured in Canada at the reporting threshold of 100 kg. Approximately 54 000 kg of the substance was imported to Canada in the year 2000 and incorporated into products such as hand soap, dishwashing/laundry products, institutional fabric softeners, facial cleanser, toilet bowl deodorizer, underarm deodorants, textiles, synthetic innersoles and used as a sanitizing agent in textile mills (Environment Canada 2003).

Triclosan is used as a medicinal ingredient in drugs and as a preservative (non-medicinal ingredient) in drugs, cosmetics and natural health products. Most cosmetics and the large majority of drugs and natural health products that contain triclosan are considered personal care products. Personal care products can be defined as substances or mixtures of substances which are generally recognized by the public for use in daily cleansing or grooming. Personal care products may fall into one of three regulatory categories in Canada: cosmetics, drugs, or natural health products (Health Canada 2008).

Approximately 1600 cosmetics and natural health products containing triclosan were reported to be in commerce in 2011 (CNS 2011, LNHPD 2011). Cosmetics and natural health products identified to contain triclosan include skin cleanser, lotion, make-up, deodorant, fragrance, shaving preparation, shampoo, toothpaste, foot gel, acne treatment and body spray (CNS 2011, LNHPD 2011). The presence of triclosan in these products acts as a non-medicinal material preservative to prevent the growth of bacteria within the product (LNHPD 2011).

In addition, approximately 130 personal care products regulated as drug products, including toothpaste, skin cleansers and moisturizers, were notified to Health Canada. In these products,

triclosan is an active medicinal ingredient, intended to control microorganisms bucally (for the prevention of gingivitis) and dermally (to help prevent the spread of certain bacteria) (DPD 2012).

Triclosan is registered in Canada under the PCPA as an active ingredient in six pest control products, for use in textiles, plastic, paper, leather and rubber materials. The triclosan products used in manufacturing are formulated as emulsifiable concentrates and are applied as material preservatives during the manufacturing process to textiles (including leather) and paper at a maximum rate of 0.375% active ingredient (a.i.) by weight of the final product. According to the current Canadian end-use product label, triclosan can be applied to textiles by padding or spray (in the picker) at a rate of 0.056% a.i. by weight of final product, and to plastic, rubber material, textiles, leather, and paper by spraying a 0.7% a.i. solution until thoroughly wet. The current registrant of technical grade triclosan has chosen not to maintain its Canadian registration (Canada 2012).

3. SUMMARY OF HUMAN HEALTH ASSESSMENT

The potential sources of exposure to triclosan for Canadians include products treated with or containing triclosan (including but not limited to cosmetic products, treated textiles, and food contact materials such as cutting boards and counter tops), ingestion of drinking water contaminated with triclosan, exposure from breast milk and from contaminated household dust.

Exposure of the Canadian population to triclosan was assessed using the available biomonitoring data for triclosan from the US National Health and Nutrition Examination Survey (NHANES). The biomonitoring data for the US population provide actual measures of exposure resulting from all potential sources and routes. Thus these data are considered the most accurate estimates of total exposure of the general population in Canada to triclosan, given the similarities in registered uses and availability of consumer products (including imported treated articles) on the US and Canadian markets. Additional Canadian biomonitoring data were used to characterize exposure of children under the age of 6 years old to triclosan.

Risk to human health from exposure to triclosan was estimated by comparing mean and upper-bounding exposure estimates in humans to the most critical effect levels in health effects studies conducted in laboratory animals in order to calculate a margin of exposure. For the general population, comparison of the estimated mean and upper bound daily dose to critical effect levels in mice (based on liver effects) resulted in margins of exposure between 700 and 13,000. Children under the age of 6 years old were not included in the NHANES study; therefore, exposure for this subpopulation was derived separately and included potential exposures via breast milk, household dust, and mouthing of triclosan-treated plastic products. Comparison of exposure estimates to the critical effect levels resulted in margins of exposure greater than 988. These margins of exposure were considered adequate to address uncertainties in the health effects and exposure database for triclosan (Canada 2012).

4. SUMMARY OF ECOLOGICAL ASSESSMENT

4.1 Release to the Environment

Triclosan does not occur naturally in the environment. Based on its use pattern and on its physical and chemical properties (e.g., low volatility), triclosan is not expected to be released or to partition to air. Release of triclosan to wastewater systems occurs directly through the use of rinse-off personal care products and indirectly via human waste discharges. In addition, releases from products treated with triclosan (textiles, plastics) may occur due to leaching of triclosan during washing (Canada 2012).

There are no available measurements of triclosan in manufacturing or recycling facility wastewater effluents. Triclosan was not detected above 20 µg/L in leachate from 10 landfills under the Chemicals Management Plan Monitoring and Surveillance program in sampling conducted in 2010/11 (Canada 2012).

Available Canadian data on triclosan concentration in influents to wastewater treatment systems range from 102 to 3 640 ng/L. Measured wastewater treatment systems effluent concentrations range from 30 to 4 160 ng/L. Secondary and lagoon wastewater treatment processes are most effective at removing triclosan with measured removal rates as high as 98% and 99%, respectively. Other treatment types are much less efficient at removing triclosan with removal rates of 0% (assumed) for no or preliminary treatment and 10% (measured at one system) for primary treatment. During the wastewater treatment process, a portion of triclosan partitions to biosolids (wastewater treatment sludge) which may be used to amend agricultural soil. This application releases triclosan to the terrestrial environment. (Canada 2012).

4.2 Exposures of Concern

A Species Sensitivity Distribution was generated in the Preliminary Assessment for aquatic organisms based on many available toxicity studies and a Predicted No-Effect Concentration (PNEC) of 115 ng/L was obtained based on this distribution.

The Preliminary Assessment indicates that triclosan concentrations of concern can be found in surface water that receives inputs from wastewater systems. These concentrations exceed levels below which no adverse effects are observed in aquatic organisms. Overall, studies do not demonstrate a consistent effect of triclosan on thyroid-mediated amphibian metamorphosis. However, one study demonstrated effects, including developmental stage and TRβ mRNA induction. Based on bioconcentration data in fish, triclosan is bioaccumulative and it is proposed that it meets the criteria for bioaccumulation under the *Persistence and Bioaccumulation Regulations*. There is also evidence of accumulation in algae, macrophytes, and invertebrates. Triclosan does not meet any of the criteria for persistence under the *Persistence and Bioaccumulation Regulations*; however, continual input to surface water via wastewater system effluents is likely to result in continuous presence in receiving aquatic ecosystems.

The Preliminary Assessment also concludes that triclosan could adversely affect terrestrial organisms exposed through the spreading of municipal sewage sludge to agricultural soils and identifies the potential for agricultural runoff to contain triclosan in concentrations above the estimated PNEC in streams with low dilution capacity.

4.3 Impurities, Transformation and Degradation Products

Chlorinated Impurities and Degradation/Reaction Products

Chlorinated impurities in triclosan (such as polychlorinated dibenzodioxins and dibenzofurans) and chlorinated degradation/reaction products (such as 2,4-dichlorophenol and various polychlorinated dioxins) may be present in the environment due to release of triclosan. The relative importance of triclosan as an environmental source of polychlorinated dibenzodioxins and dibenzofurans is expected to be less than other sources on a national scale. Additionally, those polychlorinated dioxins associated with triclosan are not on the list of 17 dioxins and furans that are of the greatest concern based on International Toxicity Equivalency Factors (Canada 2012).

Methyl-triclosan

Methyl-triclosan is a transformation product formed from the methylation of triclosan in wastewater systems and the ambient environment (surface water and soil). Measured concentrations of methyl-triclosan in wastewater systems in the US ranged from 2 to 50 ng/L. While this substance is likely not persistent under aerobic conditions, it is still present in surface waters over wide areas associated with triclosan and is bioaccumulative in aquatic organisms. Available data suggest that methyl-triclosan is less toxic to aquatic organisms than triclosan, but is nonetheless of high inherent toxicity. However, the risk quotient analysis presented in the Preliminary Assessment suggests that methyl-triclosan in aquatic ecosystems does not reach levels that would be harmful to aquatic organisms on an acute basis (Canada 2012).

5. KEY CONSIDERATIONS FOR ENVIRONMENTAL RISK MANAGEMENT

5.1 Existing Canadian Risk Management Measures

Different aspects of the use of triclosan are currently regulated under several pieces of Canadian legislation including the *Food and Drugs Act*, the *Pest Control Products Act* and the *Transportation of Dangerous Goods Act*. Existing requirements related to the content of triclosan in certain products, requirements for the registration of pest control products containing triclosan and transport of the substance are in place for the protection of both human health and the environment. Details of these existing Canadian risk management measures are listed in Annex 1.

5.2 International Environmental Risk Management

Existing international risk management measures currently in place for protection of human health and the environment are listed in Annex 2. In general, Canadian risk management of triclosan in cosmetics and personal care products for human health concerns is well aligned with the concentration limits set in these products in other countries.

5.3 Alternative Ingredients and Products

Alternative antimicrobial medicinal ingredients in skin cleansers containing triclosan as an antibacterial medicinal ingredient are identified in Health Canada's Antiseptic Skin Cleanser Monograph as: benzalkonium chloride, benzethonium chloride, chlorhexidine gluconate, chloroxylenol, methylbenzethonium chloride and triclocarban (Health Canada 2006). Of these chemicals, only two met the Government of Canada's categorization criteria

(methylbenzethonium chloride and triclocarban) indicating that there may be available substitutes with more favorable profiles for environmental risk. Further information on the technical and economical aspects of substitutes will be sought from industry stakeholders.

Additionally, the Public Health Agency of Canada and the US Food and Drug Administration (US FDA) have indicated that soaps with added antibacterial ingredients, such as triclosan, are no more effective than the mechanical action of washing with plain soap and water to remove bacteria from hands (PHAC 2011, US FDA 2010). Alcohol based hand sanitizers (for use without water) that do not contain triclosan are also available. This indicates that, for at least some categories of personal care products, there are available and acceptable alternatives to products containing triclosan as an antibacterial ingredient.

6. EXISTING DATA NEEDS

6.1 Updated Use Pattern Information

Data needs exist concerning the quantity of triclosan currently in use in Canada. Available data is from a section 71 survey for the year 2000 and uses and quantities are anticipated to have changed significantly since that time. Data is needed to provide current information on which products or industrial processes are major sources of triclosan in the environment, an important consideration in developing future risk management actions. Risk assessment conclusions are based on measured levels of triclosan in receiving waters which are reflective of overall risk, but do not provide an indication of which products or processes are the major sources.

In addition, industry and other interested stakeholders are invited to submit comments on the content of this risk management scope or other information that would help to inform decision making. All submitted information will be considered; however, the specific information described below would help to address uncertainties and inform decision making:

Use of triclosan

- Expected future trends in triclosan import/manufacture/use quantities and use patterns;
- Potential alternatives for triclosan in various products; and
- Description of issues associated with potential alternatives.

Industrial releases of triclosan

- Transportation and handling practices (e.g., types of containers used, in which form (powder, liquid), how it is transferred, what is done with empty containers, etc.);
- Details of the product formulation process (e.g., when the substance is added to the process and the way it is introduced); and
- Existing practices for managing industrial releases at manufacturing facilities.

The Government of Canada will consult with industry on the use of both Section 71 of CEPA 1999 and voluntary information gathering to collect up-to-date information on the manufacture, import and use of triclosan in Canada.

6.2 Monitoring in Canadians and the Environment

Triclosan has been added to the Chemicals Management Plan Monitoring and Surveillance program where data on levels in wastewater, landfill leachate and surface water are being collected. Data collected through this work will be used to inform future risk management development and provide a baseline against which progress can be measured.

Data on levels of triclosan in Canadians is collected through the Canadian Health Measures Survey.

7. ENVIRONMENTAL AND RISK MANAGEMENT OBJECTIVES

All risk management actions for triclosan will have the same environmental objective, or long term goal, which is to achieve ambient concentrations in the Canadian environment that are protective of the environment and its biological diversity.

In accordance with the Toxic Substances Management Policy, Environment Canada intends to use the life cycle management concept to prevent or minimize the release of triclosan into the environment. Triclosan primarily enters the Canadian environment via discharge of wastewater system effluents and application of biosolids to agricultural fields. Therefore, the overall risk management strategy for triclosan will focus on reducing levels of triclosan in wastewater systems by reducing inputs from products and/or industrial effluents.

Risk management objectives will be set following the collection of further data on the quantities of triclosan used in Canada and on technical and economic information concerning available substitutes. The eventual reduction target will reflect the best available techniques economically achievable (BATEA) in order to reduce the environmental risks associated with those products that contain triclosan.

8. PROPOSED PATH FORWARD FOR ENVIRONMENTAL RISK MANAGEMENT

Triclosan has explicit health benefits in some types of products. Thus, in developing an approach for risk management, the objective will be to mitigate risks to the environment, while maintaining the use of triclosan where necessary for health protection.

8.1 Voluntary Action on Products

The potential for voluntary action to reduce or eliminate the use of triclosan will be explored for those products where there are limited health benefits and appropriate substitutes exist. The Government of Canada will consult with stakeholders in the coming months to discuss the potential for voluntary reduction in the use of triclosan in products.

8.2 Proposed Mitigation Measures for Pest Control Products

The current registrant of technical grade triclosan has chosen not to maintain their Canadian registration for pesticidal uses. Registrations of end use pesticide products will expire in Canada in 2014. Should a registrant of technical grade triclosan seek to re-enter the Canadian market,

further data may be required to supplement the current risk assessment. Discontinued pest control products and associated treated products are subject to enforcement action under the PCPA and can be incorporated into compliance strategies under the Government of Canada's Food and Consumer Safety Action Plan.

8.3 Control Measure for Products and/or Industrial Effluents

Pending final assessment conclusions, the results of voluntary action and the analysis of updated use pattern information, risk management measures to reduce releases of triclosan from products and/or industrial effluents may be proposed, as appropriate.

8.4 Work on Antibacterial Resistance

Health Canada will continue to monitor emerging scientific information pertaining to the potential for biocides, including triclosan, to induce and/or maintain antimicrobial resistance. In addition, the Government of Canada will build upon ongoing efforts to deal with issues related to the use of antimicrobials such as triclosan.

9. NEXT STEPS/ PROPOSED TIMELINES

Next steps / Proposed timeline	
Actions	**Date**
Electronic consultation on proposed risk management scope	March 31 to May 30, 2012
Consultation on proposed voluntary early action and information gathering	Spring/Summer 2012
Publication of Section 71 notice (if needed)	Fall 2012
Publication of final risk assessment and risk management approach document	Fall 2013

Industry and other interested stakeholders are invited to submit comments on the content of this risk management scope or other information that would help to inform decision making. All submitted information will be considered. Please submit comments and information prior to May 30, 2012. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister under CEPA 1999 may submit with the information a request that it be treated as confidential. Comments and information submissions on the risk management scope should be submitted to the address provided below:

Program Development and Engagement Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Substances@ec.gc.ca

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ANNEX 1 – EXISTING CANADIAN RISK MANAGEMENT

Food and Drugs Act

Triclosan is used in a number of comparable products (e.g. handsoaps) which fall under different regulatory regimes (cosmetics, drugs and natural health products). Pursuant to the requirements of the *Food and Drugs Act* (F&DA) and its Regulations, drugs and natural health products require pre-market approval before sale in Canada and cosmetic products require post-market notification of sale in Canada.

Cosmetics

In Canada, triclosan is included on Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply the Hotlist) which indicates a concentration level of triclosan in mouthwash (0.03%) and in other cosmetic products (0.3%). The Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances, when present in a cosmetic at a certain concentration level, may contravene the general prohibition found in section 16 of the *Food and Drugs Act* and that other provisions of the *Cosmetic Regulations* may apply to substances on that list. Section 24 of the *Cosmetic Regulations* requires that the label of a cosmetic that presents an avoidable hazard must include directions for safe use. The Hotlist recommends that oral cosmetic products containing triclosan feature a label statement indicating that children under the age of 12 years old should not use the products, and that mouthwashes feature a label statement to the effect of "Avoid swallowing". In addition, concentrations for polychlorinated dibenzo-p-dioxin (PCDD) and polychlorinated dibenzofuran (PCDF) impurities in triclosan are currently listed on the Hotlist. PCDD and PCDF impurities levels are: (a) 0.1 ng/g (0.1 ppb) for 2,3,7,8-tetra-chlorodibenzo-p-dioxin and 2,3,7,8-tetra-chlorodibenzofuran, and (b) 10 mg/g (10 ppm) for total other PCDD/PCDF impurities, with no individual impurity greater than 5 μg/g (5 ppm).

Drugs

Personal care products that contain triclosan as an active ingredient are regulated as a drug. Drugs are subject to the requirements of the *Food and Drugs Act* 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 the permitted concentration of triclosan as an active ingredient can range from 0.1 to 1.0% (Health Canada 2006).

Natural Health Products

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 considerations (Canada 2006). Triclosan is listed in the Licensed Natural Health Products Database (LNHPD) as an acceptable non-medicinal ingredient in a natural health product when it is used as an antimicrobial preservative at concentrations of equal to or less than 0.03% in buccal products (e.g., mouthwash) and at concentrations of equal to or less than 0.3% in topical products (e.g., foot gel,

acne treatment, body spray, skin cleanser and lotion) and toothpastes, provided that in both cases triclosan does not contribute to the claim of the overall product (LNHPD 2011).

Pest Control Products Act

The Pest Management Regulatory Agency (PMRA) is responsible for administering the *Pest Control Products Act* (PCPA) on behalf of the Minister of Health. Under authority of the PCPA, Health Canada conducts science-based evaluations of pesticides to determine whether they pose minimal risk to human health and the environment. In addition, Health Canada's PMRA re-evaluates pesticides currently on the market to determine whether these products continue to meet current scientific standards.

The product label that is approved as part of the registration process contains the conditions of registration which govern the use of the product. Use of a product in a manner that is inconsistent with the directions or limitations on the label is prohibited. Labels for registered pest control products containing triclosan currently include details on the appropriate directions for use, precautions related to safe use, first aid information and instructions on disposal of unused product and empty containers.

Transportation of Dangerous Goods Act

Triclosan is classified as hazard class 9 - ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Not Otherwise Specified) under the *Transportation of Dangerous Goods Act* (Canada 2011). This act sets out specific requirements governing the handling and transport of dangerous goods.

ANNEX 2 – EXISTING INTERNATIONAL RISK MANAGEMENT

United States – Federal Food, Drug and Cosmetic Act (FD&C Act)

Due to the potential for the formation of dioxins and dibenzofurans as unwanted low level trace by-products in triclosan, the United States Pharmacopeia (USP) recommends concentration limits for the following impurities in triclosan:

- less than 10 μg/g for monochlorophenols;
- less than 10 μg/g for 2,4-dichlorophenol;
- less than 0.25 μg/g for 1,3,7-trichlorodibenzo-p-dioxin;
- less than 0.5 μg/g for 2,8-dichlorodibenzo-p-dioxin;
- less than 0.25 μg/g for 2,8- dichlorodibenzofuran;
- less than 0.5 μg/g for 2,4,8-trichlorodibenzofuran;
- less than 1 pg/g for 2,3,7,8-tetrachlorodibenzo-p-dioxin; and
- less than 1 pg/g for 2,3,7,8-tetra chlorodibenzofuran (USP, 2004).

USP recommendations form the basis of enforcement actions by the U.S. Food and Drug Administration.

United States - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

The United States Environmental Protection Agency (US EPA) regulates the antimicrobial uses of triclosan when used as a material preservative in a wide variety of consumer, commercial, institutional and industrial use products.

The US EPA recently re-evaluated triclosan to determine whether it met current scientific and regulatory standards. A risk management decision was published in the 2008 Reregistration Eligibility Decision (RED). Triclosan was found to be eligible for reregistration as a pesticide provided that the recommended mitigation measures were implemented. These mitigation measures included revisions to the registered use pattern to reduce exposure to workers and the addition of environmental hazard statements limiting the conditions under which effluent containing triclosan can be discharged into lakes, streams, ponds, estuaries, oceans, or other waters or into sewer systems. The US EPA is requiring the technical registrants to perform environmental modeling and surface water monitoring to identify the potential for release at manufacturing facilities (US EPA, 2008).

European Union – Cosmetic Products Regulations

European Regulation (EC) No. 1223/2009 on Cosmetic Products allows use of triclosan in cosmetics as a preservative at concentrations up to 0.3% for the protection of human health.

European Union – Biocidal Products Directive

Triclosan has been "notified" under the Biocidal Products Directive (98/8/EC) for use in human hygiene biocidal products, private and public area disinfectants, film preservatives and as a fibre, leather, rubber and polymerised materials preservative. An assessment of potential risks to human health and the environment is currently underway. There are no current restrictions on the use of triclosan in the EU for these applications.

European Union - REACH

Triclosan is registered under REACH with notified activities including manufacturing of the substance, manufacturing of formulants and manufacturing of personal care products. Triclosan has been scheduled for risk assessment in 2012.

European Union – Classification, Labelling and Packaging Regulation

Under Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures, 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.

Australia

Proposed amendments to Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) will set an allowable limit of 0.3% for triclosan in cosmetic preparations for human use to be implemented in May 2012 (TGA 2011).

Japan

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