CANADIAN ENVIRONMENTAL LAW ASSOCIATION
L'ASSOCIATION CANADIENNE DU DROIT DE L'ENVIRONNEMENT

May 30, 2012

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Transmission: Original by email (substances@ec.gc.ca)

Re: Triclosan: Response to Government of Canada Preliminary Assessment

Response to: Publication after screening assessment of a substance — Phenol, 5-chloro-2-(2,4-dichlorophenoxy)- (triclosan), CAS No. 3380-34-5 — specified on the Domestic Substances List (subsection 77(1) of the Canadian Environmental Protection Act, 1999) as published in the Canada Gazette, Part 1: Notices and Proposed Regulations dated March 31, 2012.[1]

About CELA

The Canadian Environmental Law Association (CELA) is a public interest organization founded in 1970 for the purposes of using and improving laws to protect public health and the environment. CELA is also a legal aid clinic and represents individuals and citizens' groups otherwise unable to afford legal assistance in the courts and before tribunals on a wide variety of environmental matters. Our public interest and poverty law mandate extends to diverse initiatives related to law reform, public education, and community organizing across priority program areas, including environmental health.

CELA has a long history of responding to implementation activities involving Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) with a specific focus on the categorization obligations set out in Section 73 of the Act. Since 2006, CELA has responded to assessments and management proposals on specific substances targeted under Canada Chemicals Management Plan (CMP).

[1] Government of Canada. Publication after screening assessment of a substance — Phenol, 5-chloro-2-(2,4-dichlorophenoxy)- (triclosan), CAS No. 3380-34-5 — specified on the Domestic Substances List (subsection 77(1) of the Canadian Environmental Protection Act, 1999), in the *Canada Gazette*, Part 1: Notices and Proposed Regulations, on Vol. 146, No. 13 — March 31, 2012. See at: http://www.gazette.gc.ca/rp-pr/p1/2012/2012-03-31/html/notice-avis-eng.html#d107

Overall Comments

1) CELA supports the finding that triclosan meets the criteria of section 64 (a) of CEPA and is considered toxic. However, we are concerned that preliminary assessment conducted on triclosan does not conclude that triclosan meets the criteria 64(c) of CEPA. Rather, we do believe that the scientific evidence warrants a finding that triclosan may constitute a danger in Canada to human life or health. We are also extremely disappointed in the proposed management strategy for triclosan.

2) The government has sufficient evidence to seek stronger measures that will prohibit the use of triclosan in consumer and personal care products. The current approach relies on voluntary actions that are primarily negotiated with industry to address triclosan in products and industrial effluent are considered inadequate. CELA urges the federal government to take immediate regulatory measures to prohibit triclosan in consumer products based on the evidence presented, including:

The Preliminary Assessment effectively outlines data that show:

- there are1600 consumer products containing triclosan known to be in the Canadian market,
- triclosan is found extensively in surface water, including the Great Lakes-St. Lawrence River Basin,
- detected in biosolids that may be applied to agricultural fields,
- detected in almost 75% of the humans urine sampled in by US. Centers for Disease Control and Prevention, and
- triclosan is known to be bioaccumulative in the environment and is inherently toxic to aquatic organism.
- that while human health impacts from triclosan remain contentious and there are uncertainties related to these data, evidence as been presented to suggest that triclosan affect thyroid functions and liver functions.

We have the following overall concerns, with details presented below, with the Screening Assessment, including:

1) Insufficient attention to evidence about antimicrobial resistance
2) Evidence of Harm to Humans adequate
3) Persistence value for triclosan means triclosan available continuously
4) Triclosan detected in Wastewater Effluent widespread
5) Triclosan contributes the to formation of toxic transformation products (methyl triclosan, dioxins and Furans and others)
6) Adverse effects observed in aquatic organisms

7) Consideration of the Great Lakes-St. Lawrence Region required

8) Risk Management Strategy inadequate, lacks regulatory measures to prohibit triclosan in products

Insufficient attention to evidence about antimicrobial resistance

The Preliminary Assessment relies on the studies completed by the Australian Department of Health and Aging NICNAS and the studies completed by the European Commission in 2009 and 2010. These documents indicate that insufficient evidence demonstrates that the use of triclosan can lead to an increase in triclosan resistance in bacterial populations. We disagree with these findings in light of concerns raised in the literature and the precautionary response taken by leading medical organizations regarding the use of triclosan in household products.

Some studies suggest that triclosan loses its effectiveness as in fighting certain bacteria. For example, a presentation by Stuart B. Levy noted specific experiments that have been conducted that focused on assessing the effectiveness of antibacterial products in fighting specific bacteria.[2] Levy noted that the use of triclosan may cause changes in the environmental flora where bacteria that are resistant to triclosan that may result in growth of those bacteria while others that are susceptible are suppressed. The use of triclosan in household products may be contributing to the resistence of bacteria to antibiotics. Levy noted that "no current data demonstrate any health benefits from having antibacterial-containing cleansers in a health household. However, the use of these products may change the environmental microbial flora."[3]

For example, the Canadian Medical Association raised serious concerns about use of antibacterials in household products and in a2009 resolution stated that:

The Canadian Medical Association calls upon the federal government to ban the sale of household antibacterial products due to the risk of bacterial resistance and to recognize that soap and alcohol-based solutions are as effective in preventing household infection.[4]

Likewise in 2000, the American Medical Association stated:

> *The use of common antimicrobials for which acquired resistance has been demonstrated in bacteria as ingredients in consumer products should be discontinued, unless data emerge to conclusively show that such resistance has no impact on public health and that such products are effective at preventing infection.*[5]

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[2] Levy, Stuart B. Conference Presentations: Antibacterial Household Products: Cause of Concern, in E*merging Infectious Diseases*, Vol. 7, No. 3 (Supplement), June 2001.

[3] Ibid. p. 514.

[4] Canadian Medical Association. 2009. *Public Health Issue Briefing: Antimicrobial / Antibacterial Products*. See at http://www.cma.ca/multimedia/CMA/Content_Images/Inside_cma/Office_Public_Health/HealthPromotion/Antimicrobial-IssueBriefing_en.pdf.

The U.S. Food and Drug Agency states that the "FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water. Consumers concerned about using hand and body soaps with triclosan should wash with regular soap and water."[6] The FDA is expected to release its assessment on triclosan in 2012.

Additional studies that investigate bacterial resistance to triclosan that are not noted in the Screening Assessment include:

1) Braoudaki, Maria; Hilton, AC. 2004. Low level of cross-resistance between triclosan and antibiotics in Escherichia coli K-12 and E. coli O55 compared to E. coli O157. In **FEMS Microbiology Letters:** 235(2), pages 305–309.
2) Aiello, AE; Larson, EL; and Levy, SB. 2007. Consumer Antibacterial Soaps: Effective or Just Risky? **Clinical Infectious Diseases:** 2007; 45:S137–47.
3) Yazdankhah SP, et al. Triclosan and antimicrobial resistance in bacteria: an overview. ***Microbial Drug Resistance***, 2006; 12(2): 83-90. See at: http://jmm.sgmjournals.org/content/58/4/436.long
4) Ledder RG, et al. Effects of chronic triclosan exposure upon the antimicrobial susceptibility of 40 ex-situ environmental and human isolates. 2006. ***Journal of Applied Microbiology***. May; 100(5): 1132-40. See at: http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2672.2006.02811.x/pdf

The Screening Assessment section 3.6 on Antibacterial Resistance appears to have inadequately addressed the range of available data and professional medical opinion on this matter.

Evidence of Harm to Humans adequate

The Preliminary Assessment on triclosan relied on data gathered from other jurisdictions including the United States, Australia and European Union to complete its assessment on toxicity under CEPA, 1999. An example includes Canada's review of the biomonitoring results collected by the US Center for Disease Control through its *National Health and Nutrition Examination Survey* (NHANES) to determine the level of triclosan measured in the human populations. As stated in the Preliminary Assessment, the US results would be relevant for the Canadian context.

Based on the US biomonitoring data, it showed that significant portion (nearing 75%) of the population tested has detectable levels of triclosan. This demonstrates that triclosan is pervasive in society and, although linkages to human health effects may not be well established, this data is a cause for concern. The science to determine the impacts of triclosan on human may not be identified at the same pace as the studies focused on assessing the extent of impact from triclosan observed in the environment and some animal species. The biomonitoring studies along with

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[5] American Medical Association. 2000. *2000 Annual Meeting of the American Medical Association*. Reports of the Council on Scientific Affairs. See at: http://www.ama-assn.org/resources/doc/csaph/csaa-00.pdf.

[6] U.S. Food and Drug Administration. Triclosan: What Consumers Should Know. Prepared by the U.S. Department of Health and Human Services. See at: http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm.

available ecological evidence of harm from triclosan should be given appropriate weighting to determine potential level of risk to human health. Assessment of these substances would be more protective of human health and the environment if there was a paradigm shift towards a hazard based assessment approach, where the inherent properties of a substance would be greater consideration for determining management measures.

Available data presented in the Preliminary Assessment outline that there is a wide range of potential health impacts associated with triclosan that include liver impairments and thyroid function that was seen in a variety of animal studies. These animal studies formed the basis for establishing NOAELs, LOAELs, and LOELs that are applied in the human health exposure assessments. CELA is not in a position to evaluate or challenge whether these values are adequately stringent for each health endpoint. However, it is worth re-iteriating that the impacts seen in animals are not only affected by the concentration levels of exposure but the route of exposure (oral, dermal and inhalation routes) which may exhibit different effects in animal species; or the duration of exposure, formulation, and applied dose in the product. Formulating human health exposure scenarios using these values, therefore, raises concern that the risk level estimated may not consider closely the importance of each of the contributing factors adequately and may be lost in making a determination for the general population. It is of particular concern as the use of triclosan in products appears to be expanding not reducing. CELA would suggest that the approach to rely on conducting human health exposure assessment may be inadequate to address the cumulative and synergistic impacts experienced by the general population. A greater reliance to review inherent hazards of substances may be more appropriate to inform the level of management required for many of these substances.

Below, we list gaps or weaknesses observed with the human health assessment on triclosan:

1) *Lack of rationale for decisions*. Although other agencies determined a NOAEL (for dermal toxicity) of 80 mg/kg bw per day for triclosan, Health Canada accepts the NOAEL levels determined by the US EPA for dermal toxicity to triclosan at 40 mg./kg bw per day without provided adequate rationale for supporting these levels.[7] This is one example to demonstrate that government has taken a specific approach in their decision making process but has not provided the scientific or policy rationale to support the approach.

2) *Applying safety factors.* The absence of developmental neurotoxicity studies was noted by Health Canada and the application of an additional 3-fold uncertainty factor was proposed for exposure scenarios.[8] Rather than apply additional safety factors as data gaps are identified, the government could use its full authority under the CEPA 1999 to address missing data by applying section 71(1)(c) of CEPA 1999.

3) *Evidence of thyroid effects*. The studies examining impacts to thyroid effects from exposure to triclosan demonstrated that triclosan indeed causes alternations to the thyroid, although the range of concentration for observed effects is wide and differs for each animal species. The statement presented in the Preliminary Assessment that "A number of uncertainties remain as to whether the magnitude of the observed thyroid homome alternation is sufficient to affect brain

[7] Health Canada and Environment Canada. Preliminary Assessment: Triclosan Chemical Abstracts Service Registry Number 3380-34-5. March 2012. See at: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=6EF68BEC-1. p. 21.

[8] Ibid. p. 33.

development in rats." The information gap on potential effects from triclosan again are identified with reference to the lack of developmental neurotoxicity study.[9] Identifying these data gaps should justify applying the precautionary principle in making a determination on toxicity of triclosan to human health as well as using provisions in CEPA to address the data gap. The government's assessment has not applied the necessary precaution in the human health assessment results for triclosan.

4) *Lack of focus on potential endocrine disruption and chronic low dose exposur*e. While the assessment provided a focus on thyroid effects, the assessment lacks a focus on potential for endocrine disruption in humans or effects from chronic low dose exposure.

5) *Interpretation of adverse effects from triclosan exposure is narrow*. In the Preliminary Assessment, the following statement was made:

> *adverse outcome pathway identifies key events for triclosan-induced hypothyroxinemia, a number of uncertainties remain as to whether the magnitude of the observed thyroid hormone alteration is sufficient to affect brain development in rats. In the existing animal database for triclosan, no neurodevelopmental effects were reported following triclosan exposure*[10]

Despite evidence that triclosan exposure affects liver function, it is concerning that this observation would not be considered an adverse effect in an animal. Only if there is a result impact on the development, reproduction or survival of the organism, does it seem to warrant further attention. This approach to assessing impact to animals or human from triclosan is too narrow.

6) *Cumulative Effects* – The Preliminary Assessment gives consideration to aggregate exposures to triclosan, including estimations for babies in this regard. However, cumulative effects should be expanded beyond aggregate exposures of triclosan alone and should include consideration of identified transformation products (such as dioxins and furans) that may have the potential to contaminate drinking water or affect agriculture lands where biosolids containing triclosan has been applied. Dioxins and Furans as a class are known persistent, bioaccumulative toxic substances and warrant additional consideration in these assessments.

Issues related to Ecological Assessment

a) Persistence of Triclosan

The Preliminary Assessment notes that triclosan does not meet the criteria established for persistence in the Persistence and Bioaccumulation Regulations, 2000 (PB Regulations) under CEPA 1999. However, given the extent of detection of triclosan in various environmental media, particularly water, the interpretation of persistence under the regulation for this scenario may be

[9] Ibid, p. 30.

[10] Ibid.

too narrow. The continuous presence of triclosan appears to have the same impact in the environment as if it were persistent in nature. In fact, the transformation of triclosan to toxic by-products such as dioxins is a direct result of the triclosan released into the water and its contributions to dioxins levels in such waters may have detrimental effects for aquatic species as well as terrestrial and benthic species due the hazardous properties and the environmental fate of dioxins. For the purposes of this assessment, triclosan should be considered persistent. Given that this substance also meets the bioaccumulation criteria under the PB Regulations, the risk management proposal for triclosan should consider virtual elimination.

b) Triclosan detected in Wastewater Effluent widespread

The evidence that demonstrate the presence of triclosan in surface water is substantial. So is the evidence that wastewater treatment plants have been able to remove triclosan during the treatment process but substantial amounts of triclosan continue to be released in the wastewater effluent. The data provided in section 4.1.2.3 of the Preliminary Assessment confirms that the range of triclosan discharged in wastewater effluent across Canada is large. This can be attributed to various factors including the type of wastewater treatment facility as well as seasonal changes will have a significant influence on the efficient removal of triclosan. According to the Preliminary Assessment, "triclosan is removed efficiently by WWTPs." CELA does not agree with this statement based on the data presented in Table 14 of the assessment. The table show significant decrease in concentration of triclosan but effluent concentrations remain relevant based on its bioaccumulative. Although data show that removal rate for triclosan from WWTP was measured upto 96% , a significan portion of triclosan eventually ended up in WWTP sludge. Furthermore, these rates would be reflective of those plants which have secondary treatments in place. Not all jurisdictions in Canada employ such treatment, and there are still a few regions where there are not treatment available. Therefore, we would not consider giving WWTP technology consideration as an appropriate control measure for triclosan.

Finally, triclosan removed from the wastewater effluent may continue to pose problems if it ends up in biosolids produced from wastewater treatment sludge. The information gathered in the Preliminary Assessment indicated that 97% of the samples of biosolids tested for triclosan.[11] The range of concentration of triclosan in wastewater sludge was considerable in Canada as it was in other jurisdiction. The discovery that anaerobic digestion did not effectively contribute to the removal of triclosan provides further evidence that wastewater treatment technology should not be considered an adequate means to control and prevent the release of triclosan into the environment.

c) Triclosan contributes the to formation of toxic transformation products (methyl triclosan, dioxins and Furans and others

The Preliminary Assessment notes various types of products that are produced in the presence of triclosan. Evidence shows that triclosan is methylated during the wastewater treatment process to create methyl triclosan or that chloramines that are used as an alternative disinfectant for drinking water treatment may react with triclosan to form 2,4-DCP and 2,4,6-trichlorophenol. The formation of these substances should be a cause for great concern.

[11] Ibid. p. 60.

The presence of methyl triclosan in wastewater effluent has been documented in the Preliminary Assessment report. However, the following comment requires further explanation on the methylated process:

> *Methyl-triclosan should not be considered a degradation product of triclosan, since it is the result of an addition of a methyl group to the triclosan parent molecule, and no degradation takes place.*[12]

Nevertheless, methyl triclosan is considered a transformation product and deserves to be a focus of concern. In particular, the Preliminary Assessment notes that "While there is limited monitoring information for methyl-triclosan in the environment and there is uncertainty regarding the observed half-lives and bioaccumulation estimates for this compound, the available laboratory and aquatic field evidence indicates that methyl-triclosan is likely to be both more persistent and more bioaccumulative than triclosan." We are pleased to see section 4.8, in which there is a focus on evaluating the methyl triclosan under the TSMP framework and the following conclusions are made:

> *There is evidence of the bioaccumulation of methyl-triclosan in aquatic organisms. A field monitoring study in fish showed residues 90 times higher than those for triclosan. A second field monitoring study reported fish BAFs greater than 5000.*
>
> *Methyl-triclosan is considered inherently toxic to the environment…*[13]

The presence of these substances should influence the type of management measures required for triclosan.

Triclosan can also undergo transformation in the presence of sunlight which produce substances such as 2,4-dichlorophenol (2,4-DCP) as well as lower chlorinated dioxins 2,7/2,8-DCDD.[14] These transformation products are of significant concern from a health and environmental perspective. These products have been detected extensively in the surface water at concentration levels that be influenced by the pH level of the water body.

The Preliminary Assessment indicated that lower chlorinated dioxins as detected would be less harmful to the environment, as stated below:

> *Data available on the degradation of 2,7/2,8-DCDD and the aquatic toxicity of 2,8-DCDD indicate that these compounds should be less harmful to the environment than other dioxins, such as their tetrachlorinated congeners (e.g., 2,3,7,8-TCDD). 2,7/2,8-DCDD are not*

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[12] Ibid.

[13] Ibid. p. 109.

[14] Environment Canada and Health Canada. Preliminary Screening Assessment for Triclosan (CAS RN: 3380-34-5). March 31, 2012. Pages 52-53. See website: http://www.ec.gc.ca/ese-ees/6EF68BEC-5620-4435-8729-9B91C57A9FD2/Triclosan_EN.pdf.

> *on the list of 17 dioxins and furans that are of the greatest concern based on international toxicity equivalency factors.*[15]

These dioxins forms should not be dismissed so forthright since there are information gaps associated with these substance including the knowledge that, "the toxicity of 2,7-DCDD is unknown."[16]

Overall, the class dioxins and furans should be given greater attention in this assessment and the risk management strategies for consideration for triclosan reflect the concerns associated with dioxins and furans. Consider that:

> *The Ministers of the Environment and of Health Canada have concluded that polychlorinated dibenzodioxins and polychlorinated dibenzofurans may enter the environment in quantities which have immediate and long-term harmful effects on the environment, and which constitute a danger in Canada to human health. These substances are therefore considered "toxic" as defined under Sections 11(a) and 11(c) of the Canadian Environmental Protection Act, 1988.*[17]

In Canada, dioxins and furans have been targeted for virtual elimination under the Federal Toxic Management Plan, listed to Schedule 1 Toxic Substances List under CEPA 1999 [18]and meet the criteria for persistence and bioaccumulation under the Persistence and Bioaccumulation Regulations under CEPA 1999. Because of their impacts to the environment and health, dioxins and furans are the subject of global measures for elimination through the Stockholm Convention.

Therefore, CELA rejects the following statements noted in the Preliminary Assessment, which states that "The relative importance of triclosan as an environmental source of PCDDs is expected to be low compared to with other sources on a national scale."[19] And the statement made in section 4.8, that these dioxins "…are not likely to be of environmental concern, since they are transient (not persistent) and are less harmful to the environment than other dioxins, such as the tetrachlorinated congeners (e.g., 2,3,7,8-TCDD).

Since there is adequate evidence showing the impacts of dioxins and furans to the environment and human health and the understanding that impacts can occur at very low concentration, it is premature to disregard sources of dioxin and furans produced from triclosan. The assessment has not fully considered the cumulative or additive impacts of dioxins and furans. Furthermore, there is no recent dioxin inventory for Canada that documents all sources of dioxins. The

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[15] Ibid.

[16] Ibid.

[17] Government of Canada. CEPA Registry. Dibenzo-para-dioxin. See at: http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=57DDE940-4A96-48CA-BB47-24DDC98CC16C.

[18] Listed under CEPA Schedule 1 as: Dibenzo-para-dioxin that has the molecular formula of C12H8O2 and Dibenzofuran that has the molecular formula C12H8O. See at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1&wsdoc=4ABEFFC8-5BEC-B57A-F4BF-11069545E434.

[19] Ibid. p. 11-12.

National Pollutant Release Inventory is Canada's main source of information on dioxins and furan releases but only captures dioxin releases and transfers from industrial sources. This data may not account for the data from all sources of dioxins (e.g. wood burning) or from the photolysis of triclosan since formation of dioxins occurs in the presence of sunlight, which may be completed after wastewater effluents are released from the treatment plant.

The management strategies applied to dioxins and furans should be subject to a federal review. It is unclear if the existing regulatory and non-regulatory tools in place to achieve goals of TSMP for dioxins and furans are being achieved. In addition, current measures may not address sources of dioxins and furans that are now becoming known. If you consider that:

> *The Hotlist recommends that the manufacturers of oral cosmetics products containing triclosan must ensure that polychlorinated dibenzo-p-dioxin (PCDD) and polychlorinated dibenzofuran(PCDF) impurities should not exceed 0.1 ng/g (0.1 parts per billion)[ppb]) for 2,37,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) and 2,3.7,8-tetrachlorodibenzofuran and 10ug/g (10 parts per million[ppm]) for total other PCDD/PCDF impurities, with no individual impurity greater than 5 ug/g 95 ppm).*[20]

It is unclear if these goals and measures would adequately address the dioxins formed and identified as photolysis products from triclosan.

d) Adverse effects observed in aquatic organisms

Extensive evidence to demonstrate adverse effectes on aquatic species was presented in the Preliminary Assessment that included reduction in growth, reproduction and survival rates. The finding, therefore, that triclosan is concerned inherently toxic to aquatic organisms including algae, macrophytes, invertebrates, amphibians and fish is appropriate.

e) Consideration to the Great Lakes-St. Lawrence Region

The triclosan assessment is of significant importance to the Great Lakes-St. Lawrence River ecosystem. Based on the monitoring data presented for wastewater effluent, wastewater sludge, and surface water across Canada, there is adequate information that indicate that the triclosan is detected in the Great Lakes waters. Together, with the conclusions that triclosan meets the criteria outlined in section 64(a) of CEPA, there is sufficient justification for government to consider specific measures to reduce use of triclosan in order to protect Great Lakes basin and the millions of people that live in the region from the impacts of triclosan. The measures should also target dioxins and furans and methyl triclosan, which have been identified as transformation products from triclosan and are found to be harmful to the environment.

The assessment currently does not provide any additional consideration to uniqueness of the Great Lakes-St. Lawrence River ecosystem. The Great Lakes warrant additional consideration during assessment and developing of management measures. The Great Lakes-St. Lawrence River ecosystem is the largest fresh water system in the world, it is home to almost half of

[20] Environment Canada and Health Canada. Preliminary Screening Assessment for Triclosan (CAS RN: 3380-34-5). March 31, 2012.

Canada's population and the waters of the Great Lakes is the primary source of drinking water for over 40 million Canadians and the United States. The protection strategy for this unique ecosystem is needed. The federal government is responsible to protect and restore the Great Lakes as part of its binational commitment, along with the United States under the Great Lakes Water Quality Agreement. The GLWQA will be the principle agreement under the authority of the federal government that will outline how toxic substances, including triclosan, should be managed in the Great Lakes. Based on the proposed measures on triclosan, additional consideration for the Great Lakes region is warranted.

Risk Management Strategy inadequate, lacks regulatory measures to prohibit triclosan in products

Overall, the quality of the proposed risk management strategy could be improved significantly to provide the necessary protection to the environment with respect to the approach and tool applied. The development of measures relies heavily on industry agreements rather than government providing prescriptive action that are necessary to prevent further impacts from the release of triclosan to the aquatic environment.

CELA has the following comments in response to the proposed risk management strategy for triclosan:

Triclosan as an active ingredient under PCPA

- According to the Risk Management Scope Dcoument, "The current registrant of technical grade triclosan has chosen not to maintain its Canadian registration." This intent may not be sufficient to prevent future use of triclosan for use in textiles, plastic, rubber material, leather, and paper. A regulatory measure to prohibit the future use of triclosan as a treatment for textile would be more appropriate.

- There is time before the 2014 when the current registration for triclosan to establish a fulsome discussion to identify and assess the safety of safer alternatives that do not possess the same hazardous properties of triclosan. A commitment in this direction will discourage other potential users for triclosan beyond 2014.

Voluntary Action on Products

- The focus on voluntary measures is highly unacceptable. Since the assessment identified that personal care products containing triclosan end up down the drain and eventually releasing triclosan in wastewater effluent, CELA is urging the government to apply regulatory measures to prohibit the use of triclosan in personal care products and consumer products. Municipalities across Canada cannot rely on existing wastewater treatment technology to remove triclosan. With the knowledge that triclosan is released in wastewater, where during the treatment process contributes to the formation of other hazardous substances adds to the concerns related to the extensive use of triclosan.

- In addition, the use of the Cosmetic Ingredient Hotlist to restrict triclosan is not adequate because it seeks a restriction rather than a prohibition. In addition, the Cosmetic Ingredient Hotlist does not have the necessary regulatory trigger needed to ensure accountability by industry to the public on cosmetic ingredients.

- Furthermore, the Preliminary Assessment noted in section 2.3.1 that:

Cosmetic Ingredient Hotlist indicates that oral cosmetic products containing triclosan should include a label statement indicating that children under the age of 12 years should not use the products and that mouthwashes should include a label statement to the effect of "Avoid swallowing" [21]

This form of labelling requirement under the Hotlist will not ensure that vulnerable populations are fully protected from use of products containing triclosan. As such, the consumer bears full responsibility for understanding the impacts of triclosan to health and environment rather than the product manufacturers for the products that are on the market.

Control Measures for Products/or Industrial Effluents

The assessment reviewed evidence that outlined the impacts of triclosan to the aquatic environment and the ability of triclosan to build up in a fish and other aquatic organisms that no concrete proposed measure continues to delay much needed management triclosan in products or releases to the effluent will place the environment and human health at risk. As with the previous proposals to manage triclosan, the current government proposal to wait on final assessment conclusions, results of voluntary action and additional analysis demonstrates that a lack of commitment to prevent the release of triclosan to the environment, particular to surface water. All sources of triclosan should be addressed by developing regulatory measures that would achieve the reduction of use of triclosan. It is also an ineffective approach to rely on existing WWTP plants to control the release of triclosan to the environment, particularly with the number of toxic transformation products that have been identified.

Antibacterial Resistance

The proposal by Health Canada is vague and does not address the issue identified in the assessment. In the absence of data that demonstrate the antibacterial resistance from triclosan, the government has a responsibility to apply the precautionary principle throughout its decision making process, including taking measures to prohibit the use of triclosan in products.

[21] Ibid. p. 13.

Additional Issues Related to CMP Implementation

We are including the following comments related to the progress made on the 2001 Pilot Project and the current approach to screening level risk assessment approach under the CEPA, 1999 since there are reduce opportunities to discuss the quality of assessments and management strategies undertaken under CEPA 1999 and may provide some useful comments for regulators to consider for strengthening approaches for chemicals management in Canada.

Pilot Project for Screening Assessment established in 2001 is a prolonged process

Triclosan (CAS RN: 3380-34-5) was one of 123 substance identified in a Pilot Project launched in 2001 for the purposes of refining Screening Level Risk Assessment (SLRA). The release of assessments completed on the 123 substances targetted in the pilot project has been extremely disappointing. The key objectives for the Pilot Project were to:

- *refine the screening assessment process;*
- *develop and adopt tools and approaches for screening assessments;*
- *develop approaches for setting priorities for screening assessments; and*
- *engage stakeholders on new approaches for screening assessments and priority-setting*.[22]

In the *CEPA Annual Report for Period April 2001 to March 2002*, the Canadian government noted that the "Final results from the pilot project will be used to refine the screening-level risk assessment methodology, the criteria for moving to a more thorough assessment, and the methodology for prioritizing substance assessments."[23] CELA expresses is concern that the federal government has failed to achieve the objectives of the pilot project set out by the government. The results of assessments completed on substances identified in the Pilot Project have been released in an intermittent manner since 2001. It has made it extremely difficult for the public to monitor the pilot project as well as assess how the pilot project has influenced the government's SLRA framework for remaining substances assessed under CEPA 1999.

[22] Government of Canada. Chemicals Management Plan. Screening Assessment Pilot Project. See at: http://www.chemicalsubstanceschimiques.gc.ca/about-apropos/assess-eval/projet-pilot-project/index-eng.php.

[23] Government of Canada. See at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=6DEE3880-1&offset=6&toc=show.

The implementation of the pilot project did not included a public consultation component that provides stakeholders an opportunity to review and comment on the quality or scope of these pilot project screening assessments or determine how the assessments would be used to refine the government's approach to SLRA. The public has relied on the provisions for public comment contained in CEPA 1999 to respond to assessments released on specific substances under the pilot project and updates on the pilot project that have been provided in webinars and information sessions coordinated under the CMP.

It took over 10 years to complete the assessment on triclosan, despite commitment by government to complete the Pilot Project within two years of its release. In our view, the delay in completing the triclosan assessment can be attributed to a number of factors including gaps in scientific data and competing commitments under the CMP, it has nevertheless contributed to the on-going and expansing use of triclosan in a broad array of consumer products, leaving the environment and human health vulnerable to the impacts now associated with triclosan. Since the Pilot Project began in 2001, knowledge that triclosan is used in over 1600 personal care and consumer products in Canada, it is detected extensively in our environment and there is growing number of studies that demonstrate significant health impacts from triclosan. Yet, the government did not take measures to reduce its use in consumer products but is restricted in cosmetic products through the Cosmetic Ingredient Hotlist under the Cosmetic Regulations. Hence, the lack of management measures to address triclosan is unacceptable from an ecological and health perspective.

Current Screening Level Risk Assessment Approach does not adequately support a preventative approach to toxic substances

The preliminary assessment on triclosan demonstrates significant challenges facing the Canadian government regarding the management of existing substances.

1) Under CEPA 1999, the government continues to take significant time to complete assessments on substances, despite shifting from a priority substances risk assessment approach to the current screening level risk assessment framework. While efforts under the CMP have reduced the timeframe for completing assessments on challenging substances, screening assessments for pilot project substances and substances from the petroleum stream have taken longer to complete.

2) Substances meeting one or all criteria set out in section 64 of CEPA 1999 have not automatically been subject to a phase out or prohibition strategy. For triclosan, the proposed management strategies under consideration are not focused on developing and implementing a prevention strategy. Rather, it appears that the government is relying significantly on negotiating voluntary arrangements with affected industry to manage triclosan.

3) The threshold for phase-out of triclosan in consumer products is set too high. Despite the evidence made available in the Preliminary Assessment report, which demonstrate a range of hazards associated with triclosan - including impairments to liver function and thyroid impairments observed in a range of animal studies- the results from the human health exposure assessments, indicate that the present level of exposure not warrant additional measures to

protect human health. Establishing acceptable levels of harm from current exposure conditions continues to create barriers for developing measures that will stop the use of toxic substances.

The benefits for protecting human health from triclosan cannot be realized unless substantial measures are developed to require a phase out of triclosan in all personal care products.

4) The SLRA framework under CEPA remains reactionary in its approach to potential toxic substances. The framework does not implement the precautionary principle effectively throughout the assessment process, particularly in conducting human health exposure assessments, where the inherent hazardous properties associated with specific substances may be diminished in its relevance and where data gaps exists and are addressed by applying additional safety factors. In the exposure assessment, gaps in information may result in revising margins of exposure to compensate for the absence of information, but the results have rarely resulted in a conclusion that toxic substances used extensively in consumer products would be targeted for elimination management strategies.

For regions such as the Great Lakes-St. Lawrence River ecosystem, triclosan has been detected in the waters and sediments of the Great Lakes. The prolonged timeframe in completing the SLRA on triclosan has meant that decision makers have not been able to flag the concerns associated with this extensively used toxic substance and move forward to develop measures that would protect the Great Lakes ecosystem from its impact. The long timeframes associated with these assessments means that it will take upto another 3 years (to 2015) before measures on triclosan can be finalized under CEPA 1999. The quality of the Great Lakes ecosystem will be significantly affected.

Thank you for your consideration to the above issues. Please do not hesitate to contact me, should you have questions.

Yours truly,

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