February 27, 2018

The Honourable Catherine McKenna
Minister of Environment and Climate Change Canada
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Dear Minister McKenna and Minister Petitpas Taylor:

Re: Response to Proposed Pollution Prevention Planning Notice Requirements for Triclosan

The undersigned non-governmental organizations (NGOs) submitted comments and met with government officials on a number of occasions regarding the risk assessment and management options on triclosan (Phenol, 5-chloro-2-(2,4-dichlorophenoxy)(CAS RN 3380-34-5) since 2012. Most recently, NGOs engaged in several face to face and teleconference meetings with Environment and Climate Change Canada and Health Canada staff in June 2017 and in January 2018, to discuss ongoing concerns that the growing body of evidence of health impacts associated with exposure to triclosan has not been yet fully reviewed and considered by Health Canada. We also participated in the workshop held on January 19, 2018 to discuss the government's preferred management approach to triclosan as outlined in the following Proposed Pollution Prevention Planning Notice for Triclosan (Consultation Document) released on December 13, 2017 (Proposed P2 Plan).[1]

[1] Environment and Climate Change Canada and Health Canada. Proposed Pollution Prevention Planning Notice for Triclosan: Consultation Document. December 13, 2017. Access at https://www.canada.ca/content/dam/eccc/documents/pdf/p2/20171208-01-en.pdf on February 16, 2018.

The government's process to assess triclosan began in 2011. The draft risk assessment was released in 2012 with the final assessment released in 2016. Given the considerable time required to complete the assessment, our organizations wish to reiterate our disappointment with the government's final conclusions regarding the human health toxicity of triclosan under CEPA. We are concerned that the government is missing a significant opportunity to address the impact of triclosan on human health, its contribution to antibiotic-resistance, and its toxic break-down products to the environment, by proposing P2 plans for manufacturers and users of triclosan rather than choosing to apply regulatory measures on triclosan in personal care products in support of a more precautionary approach. This was surprising in light of the fact that the consultation document recognizes that the main source of release of triclosan to the Canadian environment is through the use of triclosan in personal care products, and the strong regulatory actions by the US Food and Drug Administration and several US states to prohibit the use of triclosan and 17 other anti-bacterial chemicals in key consumer and personal care products.

We provide the following brief comments to highlight our ongoing concerns with the CEPA conclusions on toxicity to human health and the proposed P2 plan requirements. The recommendations and commentaries submitted by our organizations on triclosan between 2012-2017 continue to be relevant and we urge you reconsider them.[2] Our recommendations below focus on the need for the government to commit to a systematic scientific review of health and environmental impacts from triclosan and publish an updated State of Science Report. Further, we reaffirm our recommendation to prohibit the use of triclosan in personal and consumer products in Canada.

Limitations of Canada's Approach for Strong Environmental and Health Protection

Canada's approach to chemicals risk assessment has failed in this case to ensure strong environmental and health protections. Here are a few noteworthy observations.

Require review of recent studies on human health impacts from triclosan

In many of our submissions since 2012, we have highlighted the lack of analysis or review of the growing evidence demonstrating human health effects associated with triclosan exposure. In our submission of January 2017, our organizations provided a list of over 20 studies that were not considered in the final risk assessment and management decision.

The lack of substantial review of these studies and potentially more recent studies continues to be a gap in Canada's assessment of triclosan. In fact, it was noted by the proposed risk management reports that the risk management instrument selection was based on evidence available as of September 2016.

We were informed that new studies would be eventually reviewed but no explicit commitment was made on the timing of the review of new data. It was disappointing to hear during our face

[2] See: Various NGO submissions on triclosan are posted to www.cela.ca.

to face meeting, that the list of studies which was submitted by NGOs in its January 2017 submission did not appear to warrant further investigation. Since some of these studies were epidemiological studies – the gold standard of toxicity information, we are not confident that Health Canada will undertake a systematic review of any recent studies to assess new potential human health implications from exposure to triclosan – regardless of exposure levels.

Disproportionate focus on exposure over hazard data and inherent hazardous properties, undermining protection from toxic chemicals such as triclosan

We have continually expressed our concerns that Canada's risk based framework to assess chemicals weakens the type of management required to protect the environment or human health. The current approach permits continued use of a specific chemical until a sufficiently high exposure level has escalated to cause unacceptable toxic impacts. The Margin of Exposure (MOE) approach relies heavily on establishing MOE with less emphasis on establishing a RfD from published studies showing toxic impacts. As well, a cumulative risk assessment for triclosan and triclocarban would probably change the result as was shown for brominated diphenyl ethers congeners.

Specific international policy developments underscore this assertion. First, the approach taken by the US Food and Drug Administration (FDA) focused on applying a hazard based approach by requiring data from users and manufacturers to demonstrate safety and efficacy for using triclosan in antiseptic products. Since such data was not received, the final decision by FDA resulted in prohibiting the use of triclosan and 18 other antibacterial compounds in key personal care products.

Second, several US states including Minnesota, New York, and New Jersey have policies on triclosan. Minnesota passed a regulation in 2014 to prohibit the use of triclosan in hand and body wash products because of the effects triclosan on the environment. This ban took effect on January 1, 2017.

Third, the release of the 2017 Florence Statement on Triclosan and Triclocarban highlights a consensus by more than 200 scientists and medical professionals across the globe on the hazards of, and lack of demonstrated benefits from the common uses of triclosan and triclocarban in a wide range of consumer products. Based on extensive peer-reviewed research, this statement concludes that triclosan and triclocarban are environmentally persistent endocrine disruptors that are toxic and bioaccumulate in aquatic and other organisms. Evidence of other hazards to humans and ecosystems from triclosan and triclocarban is presented along with recommendations intended to prevent future harm from triclosan, triclocarban, and other antimicrobial substances with similar properties and effects. Since antimicrobials can have unintended adverse health and environmental impacts, they should only be used when they provide an evidence-based health benefit.[3]

In light of these recent developments and management decisions on triclosan, Canada should reconsider its management decision on triclosan. For example, Canada's approach may be vastly improved if it were to include a focus to investigate the merits of using triclosan in

[3] See: https://doi.org/10.1289/EHP1788

consumer products rather than a focus to establish a “safe” level of exposure. Canada’s current approach for triclosan does not lead to a response that is sufficiently protective of health or the environment and does not support a precautionary approach prescribed by the Canadian Environmental Protection Act (CEPA).

Recommendation: Health Canada and Environment and Climate Canada should commit to conducting a systematic scientific review of all recent studies on the impacts to health and environment associated with triclosan and report the results of the review through an updated State of the Science Report on triclosan before the final management approach for triclosan is finalized in the Fall of 2018.

Regulatory measures provide stronger environmental and health protection

We maintain that the best management approach for triclosan is through a regulatory measure to prohibit its use in personal care and consumer products. Prohibiting the use and manufacture of triclosan in products provides certainty that large quantities of triclosan will not be released into the environment. The survey results collected by the government indicated that the number of products containing triclosan has declined significantly since 2011. However, it would be inappropriate to assume that the decline in products containing triclosan would continue with the proposed approach, without a prescriptive and comprehensive compliance and enforcement plan involving monitoring and surveillance of products imported into Canada. The US FDA decision to prohibit the use of triclosan in specific personal products leaves the Canadian market vulnerable to these targeted products.

In addition, the government’s rationale to apply P2 plans for triclosan rather than a regulatory approach was informed through the decision factors contained in the government’s Internal Consideration Document. The factors and reasons used by government to conclude on its preferred management approach are not fully articulated in the Consultation Document and neither have they been provided to stakeholders. The absence of public transparency in this internal approach makes it challenging for public interest stakeholders as well as members of the public to determine that selecting a non-regulatory tool is fully justified.

Recommendation: Reconsider applying a regulatory approach to prohibit the use of triclosan in consumer and personal care products as the preferred management approach for triclosan.

Specific Comments on the Proposed Pollution Prevention Planning Requirements

Our recommended management action for triclosan since 2013 remains to regulate triclosan in a wide range of drug and health products as well as consumer products. As well we have several concerns with the scope and range of the proposed P2 plans notice for triclosan.

Target proposed reduction target of 30% set too low

The government's proposed target to achieve a 30% reduction target for the total mass reduction in triclosan use is set too low to provide adequate triggers to replace triclosan with alternatives that do not exhibit similar toxicity. We are not convinced by the rationale provided by government that the reduction target would ensure that concentrations of triclosan in the environment would remain below the no observed effects level determined in the risk assessment evaluation. In its January 2017 submission in response to the proposed risk management strategy on triclosan, Ecojustice *et. al.* seeked an explanation for the 3 fold increase in the estimated PNEC value obtained in 2012 to the final risk assessment in 2016. Its submission noted:

> The species sensitivity distribution in the government's preliminary assessment for aquatic organisms proposed a PNEC of 115 ng/L for triclosan. The 2016 assessment does not explain why the final PNEC of 376 ng/L is more than three times higher than the PNEC proposed in March 2012. The Danish EPA risk assessment yielded a PNEC of 50 ng/L based on an algae study. We recommend that Environment Canada review the final PNEC to ensure it is protective of all aquatic species including the most sensitive species to the harmful effects of triclosan.[4]

No explanation or supporting documents has been provided by ECCC to explain the 3-fold increase in PNEC value in subsequent meetings with ECCC and Health Canada.

The 30% reduction target is an extremely low bar for environmental protection as it perpetuates the use of triclosan and provides ongoing benefits to manufacturers and users of triclosan. Significant aquatic ecosystems including the Great Lakes Basin, coastal waterways, Lake Winnipeg and Ottawa River watersheds remain vulnerable to the impacts of triclosan releases to the environment. Establishing high reduction levels substantially elevates environmental protection and establishes triggers for manufacturers and users to review their use of triclosan. The success of P2 plans for other toxic chemicals including nonylphenol and ethoxylates (NPEs) relied on establishing high reduction targets that resulted in a 96% reduction in-use of NPEs.

Recommendation: We do not support a reduction target for triclosan of 30% through a Pollution Prevention Plans. Establish a reduction target of 100% would trigger necessary move from triclosan.

Limitations posed by deregistration of Triclosan under Pest Controls Products Act (PCPA)

The voluntary deregistration of triclosan in effect as of December 31, 2014 is an important preventative approach. This deregistration of triclosan as an active ingredient resulted in the prohibition of use of triclosan in a number of applications including: textiles, leather, paper,

[4] Ecojustice, Environmental Defence, Canadian Association for Physicians for the Environment, Equiterre and David Suzuki Foundation. Undated. Submission to Environment Canada and Climate Change in response to Proposed Risk Management Approach for Triclosan.

plastics or rubber materials manufactured in Canada. It is unclear from the Consultation Document if the voluntary deregistration of triclosan under PCPA has resulted in 100% compliance. It is also unclear how the deregistration of triclosan impacted imports of products not captured in the proposed P2 plans.

An internal Health Canada memo[5] indicated that the department is unable to monitor and track imported products that are treated with pesticides that are not registered in Canada. The memo states that "*compliance and enforcement actions have been taken as appropriate but given the high volume of products being imported into Canada, identification of articles treated with unregistered pesticides is challenging."* The memo further highlights that consumers in most cases are unable to identify products that would contain a chemical such as triclosan given that "*most treated articles do not mention the presence of such a pesticide."*

This raises important questions about Canada's overall approach to address the risks of triclosan and the effectiveness of the proposed P2 plan: what data are collected and released publicly by Pest Management Regulatory Agency (PMRA) to demonstrate compliance with the deregistration of triclosan? Similarly, what data have been collected by PRMA to ensure that products imported into Canada do not contain triclosan? And lastly, how would the government ensure that the imported goods are complying with the proposed P2 rules and objectives?

Recommendation: Require the PRMA to collect and release data, including on imports of products containing triclosan, to demonstrate level of compliance to voluntary deregistration of triclosan under PCPA.

Requirement to consider alternative assessment in P2 Plans remains a non-mandatory requirement under CEPA

The emphasis by government on the role of informed substitution to address triclosan within the scope of P2 Plans is an interesting development. However, there are significant limitations with the P2 planning framework that will undermine the potential effectiveness for informed substitution and conducting alternative assessments. While P2 planning notices has key mandatory requirements outlined under CEPA that include preparing P2 Plans, implementing the Plan, and providing interim reports on the progress to implement the P2 plans, specific section of the P2 planning requirements including "Factors to Consider" lacks appropriate mandatory triggers under CEPA. To elevate the importance of informed substitution of toxic chemicals such as triclosan, it is necessary to include legal obligations outlined in CEPA. Without such legal requirements, a superficial consideration could be undertaken by affected facilities without serious concern for violating CEPA. Dialogue through the legislative review of CEPA and government consultations to plan for chemicals management approach post 2020 including alternatives assessment are currently underway. The government's current efforts to consider the use of alternative assessment and substitution should be informed by these processes. Additional efforts should be taken to review how P2 Planning Requirements under CEPA should be amended to provide appropriate legal obligations to require informed substitution for toxic chemicals. Despite the inclusion of alternatives assessment in the

[5] https://www.documentcloud.org/documents/4329114-Health-Canada-Memo.html

"Factors to Consider" section of P2 plans, the government cannot prevent the possibility of seeing regrettable substitutions to triclosan.

Development of principles, criteria and goals to conduct alternatives assessment will be necessary to achieve an outcome that will avoid regrettable substitution. The proposed approach for considering alternative assessment do not include criteria to conduct such an assessment. One principle that should be integral to an alternative assessment framework is to review the need to use the chemical in the first place, in order to achieve the desired outcome. Triclosan would be one such chemical. It may not be necessary to require alternative assessment to simply find a replacement antimicrobial agent for triclosan.

The Consultation Document lists a number of potential chemicals alternatives to triclosan, some of which remain to be assessed under CEPA. The aim for achieving alternative assessment is to identify which of these potential alternatives do not exhibit inherent hazards to health and environment. The process to conduct alternatives assessment should outline clear obligations regarding timeframe, data collection and assessment framework. Furthermore, such a process should outline explicit emphasis for assessing hazardous properties of potential alternatives.

The consultation document included a list of potential chemical alternatives for triclosan. Methylisothiazolinone (MI), and Methylisothiazolinone/Methylchloroisothiazolinone (in combination) (MCI) were identified as a potential alternatives to triclosan. These chemical/chemical combination have also been proposed for listing to the Cosmetic Ingredient Hotlist. Prevent Cancer Now and Chemical Sensitivities Manitoba submitted their support to prohibit MI use in leave on products but expressed concerns to allow permitted concentrations for the use of MCI for rinse off products.[6]

Triclocarban has also been identified as a potential alternative to triclosan. In 2014, CELA and Clean Production Action released its report, Chemicals in Consumer Products are Draining Trouble into the Great Lakes Ecosystem: GreenScreen® Assessment Shows Triclosan and Triclocarban Should Be Avoided, to highlight the concerns with triclocarban using GreenScreen.[7] The report highlighted the need to prohibit triclosan and triclocarban in personal care and consumer products, particularly due to the inherent toxic properties of triclocarban to avoid regrettable substitutes to triclosan.

Recommendation: Informed substitution through alternative assessment should be initiated through legal requirements that also recognize that in some cases substitutes are unnecessary. Development of an approach should be informed by the CEPA Review process.

[6] Comments regarding the "Consultation to proposed changes to the Cosmetic Ingredient Hotlist: prohibited and restricted substances", issued November 11, 2017. http://www.cela.ca/sites/cela.ca/files/1159%20-%20CosmeticsHotlistSubmission.pdf.
[7] Canadian Environmental Law Association. 2014. Chemicals in Consumer Products are Draining Trouble into the Great Lakes Ecosystem: GreenScreen ® Assessment Shows
Triclosan and Triclocarban Should Be Avoided. Access at http://www.cela.ca/sites/cela.ca/files/TC-TCC-CELA-997_0.pdf

Scope of Persons subject to Proposed P2 Plan Notice

The Consultation Document highlights two categories of persons or class of persons subject to the P2 plan notice. They include:

- manufacturers or importers of cosmetics, natural health products, drugs and cleaning products; and

- anyone who uses, purchases or acquires 100 kg or more of triclosan at any concentration for activities outlined above in any calendar year.

The categories of persons or class of persons subject to the notice raise some concern about the effectiveness of requiring importers to comply with P2 plan requirements and implementation. It may prove challenging for enforcement officers to ensure compliance with P2 plan requirements if importers are based outside of Canada. Canada's survey and claims of non-engagement provides one method of monitoring importers. However, the departments should provide additional information on the compliance and enforcement activities that will be used to focus on importers subject to the P2 Plan Notices.

Two categories of persons or class of person not captured in the notice include retailers and wastewater treatment facilities. The Consultation Documents do not include these categories of persons. Retailers fill an important role in the delivery and offer of products to the Canadian market. The lack of requirements for all retailers to meet the requirements of the notice is considered a significant gap in the management of triclosan. Only retailers that manufacture or import their own label will be subject to the P2 plan notices). Since retailers are in communications with their supplier chains and formulators and have the ability to influence the supply chain, they play a critical role in promoting or identifying alternatives to triclosan. It is unclear how many retailers would not be subject to the notice.

Recommendation: Include a role for all retailers to be subject to address triclosan, including a review of their full supply chain.

Triclosan releases to the environment through wastewater treatment facilities can lead to the formation of a number of byproducts such as dioxins, furans and methyl-triclosan, all considered more toxic than triclosan. Methyl triclosan which may form via wastewater treatment processes is considered potentially more persistent and bioaccumulative than triclosan. Wastewater facilities will continue to be a main source of triclosan releases to the aquatic environment via wastewater effluent but are not targeted under the proposed notice. Further, triclosan and its breakdown products may be present in sludge waste used as fertilizer from wastewater treatment processes. Wastewater treatment facilities should review how triclosan can be removed from sludge.

The Hydromantis study found triclosan to be detected at the highest concentrations in sewage sludge, with levels increasing significantly after treatment in the digested biosolids, in raw

sludge at 43,683 mg/dry weight, and in digested solids at a higher level at 60,798 mg/d – a 17% increase.[8]

Recommendation: Wastewater treatment facilities should be subject to the P2 planning notice as they remain a significant source of releases of triclosan to soil, and the aquatic environment.

Concerns with timing issues with the proposed P2 plan notice

First, the development and implementation for P2 plans is too long. Triclosan was initially recognized as toxic by the government in 2012. Allowing three additional years for companies to reduce use, after several more years of solidifying the pollution prevention plan, is unacceptable. Companies have been aware that triclosan is toxic for six years now, many of whom have sensibly shifted away from its use entirely. Allowing triclosan to continue existing at harmful levels in the Canadian environment is unnecessary and damaging. Triclosan persists and bioaccumulates in waterways, allowing its continued existence at harmful levels is unacceptable and could have long lasting negative effects to environment. Implementation timeframe of these plans should be reduced significantly. The current proposal will mean no mandatory reduction of triclosan is necessary for at least 9 years after it was first found toxic under CEPA. The proposed timeframe for implementation is unacceptable.

The proposed notice does not include a completion date when P2 Plans will no longer be required. Any new user or importer of triclosan or products of triclosan will be subject to the notice in an open ended approach. This approach entrenches the use of triclosan in the Canadian market rather than shift away from it, despite its known impact to the environment. It also does not provide a trigger for the government to conduct a substantial review of the effectiveness of P2 plans to protect the environment and human health from triclosan. The P2 plans requirements for NPEs specified an end date to complete P2 implementation.

Recommendation: Shorten the 3 year timeframe proposed for implementation.

Recommendation: Include an end date of no more than 5 years to apply P2 plans on triclosan.

We are available to discuss our comments and recommendations.

[8] CCME (2010) Emerging Substances of Concern in Biosolids: Concentrations and effects of treatment processes. Final Sampling Report, June 30, 2010.

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