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Mr. Stan Rodriguez
VP, Regulatory Affairs,
Vinyl Institute of Canada
Suite 3, 1425 North Service Rd. E.
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BY EMAIL

Dear Mr. Rodriguez:

**Re: Technical Review of Selected References in “Science Assessment of Plastic Pollution”:
Focus on Vinyl**

Introduction

The Vinyl Institute of Canada (VIC) is preparing comments on the Government of Canada’s proposal to classify “plastic manufactured items” as “toxic” under Section 64 of the Canadian Environmental Protection Act (CEPA). It is likely that this proposal is based in part on the recently completed Science Assessment of plastic pollution (Government of Canada, 2020, referred to as “the Science Assessment”). The Science Assessment includes the conclusion that “In keeping with the precautionary principle, action is needed to reduce macroplastics and microplastics that end up in the environment.” There are no recommendations specific to vinyl (also referred to as PVC in this report).

The VIC contracted the undersigned to review selected documents cited in the Science Assessment and comment on them from the perspective of whether they support a classification of vinyl as “toxic” under CEPA, including an examination of whether the application of the precautionary principle to vinyl is supported by the information reviewed.

Background

In October 2020, the Government of Canada proposed adding “plastic manufactured items” to the Schedule I list substances classified as “toxic” under the Canadian Environmental Protection Act, 1999 (CEPA). Section 64 sets out the criteria for considering a substance toxic:

“Substances are considered harmful if they are entering or could enter the environment in quantities or concentrations or under conditions that: have or may have

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

Among other things, adding a substance to Schedule I of CEPA permits the substance to be regulated, with management measures to mitigate an adverse effect.

Designation of “plastic manufactured items” as “toxic” under CEPA would pave the way for Canada to implement proposed measures to ban a variety of plastic items by 2021 (ECCC, 2019).

Interestingly, polyvinyl chloride (PVC; vinyl) is the only plastic identified by name in ECCC (2019). None of the non-PVC plastics that make up most of the articles proposed to be banned are identified within the document.

Approach

Much of the literature cited in the Science Assessment is either specific to other (non-PVC) plastics, or about plastics as a group. For the current review, the VIC identified 16 papers cited in the draft Science Assessment that specifically consider PVC. The papers selected by the VIC focused mainly on adverse effects of microplastics. Three additional references were reviewed to gain a high-level view of the prevalence of PVC in marine plastic pollution. Each paper was considered in the context of whether it supported a conclusion that vinyl is “toxic” under the CEPA Section 64 definition.

Attachment A contains brief summaries of the 19 papers reviewed, highlighting their relevance to assessing risks related to vinyl. For each paper, a conclusion is provided of whether the information supports a determination of “toxic” under CEPA.

The Science Assessment concluded that action be taken based on the precautionary principle. Therefore, this report also discusses whether the information reviewed supports the conclusion that the precautionary principle should be applied to vinyl.

Throughout this document, citations correspond to those in the Science Assessment.

Findings

None of the references reviewed support a conclusion that vinyl is “toxic” under the CEPA Section 64 definitions, at least in the chemical toxicity sense (entanglement is discussed below). While some laboratory studies report adverse effects following exposure to PVC in various species, these tended to use high doses, limiting their relevance. Some of the studies reviewed used more realistic exposure levels and did not observe adverse effects. The human evidence is also equivocal. For example, Prata (2018), which tabulated occupational exposure studies, did not differentiate between exposures to vinyl chloride and PVC, confounding the assessment of PVC’s contribution to the observed outcomes.

There is some evidence that vinyl may represent a relatively minor component of plastic pollution. Neither Horm et al. (2019) or Zhou et al. (2018) mention vinyl particles in samples taken from thousands of kilometers of beaches in California and China, respectively. Further, de Haan (2019) found little PVC in floating plastic pollution; PVC was grouped with several other minor components that together accounted for 5.5% of the total.

The studies selected by the VIC for this review did not address the issue of entanglement, so this report cannot comment on the possible role of PVC in this phenomenon.

Precautionary Principle Context

The precautionary principle as stated in CEPA is as follows:

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

This risk management principle describes how Canada makes decisions in the face of scientific uncertainty. Essentially it can be distilled to the notion of “erring on the side of caution.” However, the statement does not define or prescribe what is considered “serious or irreversible damage”, or how “cost effectiveness” should be measured.

CEPA Section 64 provides some guidance on the first point. In essence, whether a substance is harmful depends on how much and where it is entering the environment, and whether it could cause adverse effects in that context. While the Science Assessment may provide convincing evidence of abundant plastic pollution in the environment, the contribution of vinyl is much less clear.

To consider the question of cost effectiveness of management measures, a cost-benefit approach may be helpful. There is a substantial cost to both government and industry for implementing and enforcing regulations. In the case of vinyl, the benefit, if any, has not been demonstrated clearly. Therefore, it is arguable whether any regulatory action, for example, banning vinyl single-use plastics, would represent a “cost-effective” measure.

Finally, it is important to avoid inadvertently overestimating the threat posed by a chemical hazard. As noted previously, studies are often conducted at very high doses to try to elicit any effects that could occur – i.e. in a precautionary manner that overestimates real world exposure. Any adverse findings can be perceived by some people to represent a “threat of serious or irreversible harm.” While it can be appropriate to use high doses to see whether effects *could* occur, a real-world exposure scenario should form the basis of risk management decisions.

Disclaimer

This report was prepared by the undersigned solely for the account of the Vinyl Institute of Canada. The material documented herein reflects the author’s best judgment in light of the information available to the author at the time of preparation. Any use which a third party makes of this report, or any reliance on, or decisions made, by third parties based on this report are the responsibilities of such third parties. The author accepts no responsibility for damages, if any, suffered by any third parties as a result of decisions made, or actions taken, based on this report.

Closure

This completes my report for the current assignment. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,



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Toxicology, Risk Assessment and Risk Communication Specialist

Cc: Aíne Curran, Executive Director, Vinyl Institute of Canada

Encl. Attachment A – Review of Selected References

REFERENCES

ECCC (2019). A proposed integrated management approach to plastic products to prevent waste and pollution. <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/plastics-proposed-integrated-management-approach.html>.

Government of Canada (2020). Science Assessment of Plastic Pollution. <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/science-assessment-plastic-pollution.html>

ATTACHMENT A

Summary of Selected Studies

Citations as per “Science Assessment of Plastic Pollution,” Government of Canada, 2020

Agarwal et al. (1978)

- One dose of PVC powder (25mg) instilled intratracheally and caused various histopathological and biochemical changes. Effects were reversible as particles cleared.
- Route of exposure not relevant for dose-response evaluation.
- Single dose limits usefulness for dose-response evaluation.
- Route of exposure and particles < 5 microns not suitable for evaluating physical risks of vinyl products in the environment (e.g. entanglement)
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Bakir et al. (2016)

- Investigated importance of adsorbed substances on microplastic particles as a contributor to exposure to hydrophobic pollutants.
- Modelling study that included PVC and PE
- Concluded that microplastics do not contribute significantly to exposure to these substances, even when ingesting up to 5% by weight microplastics in the diet.
- Authors note that other studies that reported sorption-related exposures to be significant used higher concentrations than reported in the natural environment.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Chen et al. (2019)

- The ability of endocrine-disrupting chemicals to leach from plastics, and the *in vitro* toxicity of leached substances, was investigated.
- “All of the plastics selected for study were hard plastics (fragments and objects made of plastic with thick walls of ~1–3 mm) consisting of polyethylene”
- Vinyl is not discussed.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

De Haan (2019)

- Examined abundance of different floating microplastics in the Mediterranean Sea.
- PVC was not one of the main plastics found (note – higher density may make it more likely to sink).
- More than 80% of microplastics were high density polyethylene, polypropylene and polystyrene.
- PVC was a relatively minor component: it was one of several other plastics that, together, accounted for 5.5% of the total.
- Indicate that PVC represents a small portion of microplastics in this location
- Relevance to Canadian context not clear.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Espinosa et al. (2019)

- Investigated effects on European sea bass of PVC and PE particles in food at two doses.

- PVC caused an increase in phagocytic burst activity of head kidney leucocytes.
- Authors characterized it as a mild depression of immunity and oxidative stress, and suggested that longer-term exposures could cause irreversible effects.
- Relevance to species in Canada is not clear.
- Generally mild effects do not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Horn et al. (2019)

- Microplastics were quantified in beach sediments collected along an approximately 900km length of the California coastline.
- Microplastics were present at every one of the 51 beaches that were sampled.
- PVC is not mentioned among the types of plastic found, which included polypropylene, isotactic polypropylene, atactic polypropylene, polyacrylate, polyethylene, and polyester.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Jovanovic et al. (2018)

- No adverse effects were observed in gilt-head seabream fish fed microplastics in the diet, including PVC (low and high molecular weight).
- No effects on growth rate, no pathology, no accumulation in digestive tract, very little translocation of particles; concluded to be of low biological and toxicological significance.
- Authors noted that studies that found adverse effects used unrealistically high exposure levels.
- Suggests PVC and other plastic particles may not be harmful in the diet at realistic environmental concentrations.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Lamb et al. (2018)

- Studied association between disease in corals and plastic waste on reefs.
- Visual inspection of tissue loss and counting of plastic debris.
- No mention of PVC.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Lei et al (2018)

- Several different microplastics including PVC were evaluated for toxicity in zebra fish and a nematode (*C. elegans*).
- Authors state “Effects were more dependent on microplastic size than chemical composition.”
- Microplastics of similar size induced similar adverse effects in the intestine of zebra fish
- Microplastics exposure decreased nematode survival, but not dose-dependent
- Relevance of doses and exposure routes not discussed.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Peda et al. (2016)

- Investigated effects on European sea bass of native or polluted PVC microplastics in the diet.
- Polluted particles made by putting native particles in a contaminated harbour for 3 months.
- Microplastics caused structural and functional deterioration of intestine.
- Only one dose tested per treatment group (0.1% w/w) microplastics)

- Relevance of the single dose used in the study is not clear
- Relevance of species to Canadian context is not clear
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Piggott and Ishmael (1979)

- Compared *in vitro* toxicity and *in vivo* fibrogenicity in rats of a range of PVC formulations
- Toxicity was low *in vitro* and *in vivo*
- Mild reactions to PVC were similar to a foreign body reaction.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Prata (2018)

- Review article that asks whether airborne microplastics could affect human health.
- Summarizes studies of PVC and vinyl chloride exposure in occupational settings
 - Four of the citations are reports on one worker (3 reports) or three workers (1 report)
 - One study reported no adverse findings
 - Three studies reported a variety of respiratory effects in exposed workers.
- Does not identify which of the above studies relate to vinyl chloride exposure, PVC exposure or both.
- Relevance of occupational studies to environmental exposure is not clear.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Renzi et al. (2018)

- Mortality and immobilization of *Daphnia magna* exposed to microplastics was studied under fed and fasting conditions, including PVC
- Mortality and immobilization were increased to varying degrees by several plastics.
- However, PVC had no discernable effect.
- Concentrations tested were higher than environmental fresh water concentrations.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Slotmaekers (2018)

- Examined gudgeons from Belgian rivers for particles of microplastics ingestion
- 7 of 78 fish sampled contained one particle (6 fish) or two (1 fish) particles
- Only one of eight particles detected was PVC
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Stock et al. (2020)

- Examined effect of *in vitro* digestion on the size and shapes of microplastic particles, including PVC.
- Three-stage digestion: saliva, gastric fluid, intestinal fluid
- Concluded that the human digestive tract likely does not alter microplastic particles.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Volkheimer (1975)

- Examined translocation of ingested particles of PVC (in animals) and potato starch (in humans)
- Dogs were fed 200g PVC powder

- PVC found shortly thereafter in blood, urine, bile and cerebrospinal fluid
- Similar results in pigs, goats, rats, guinea pigs and chickens (doses not stated)
- Demonstrates potential for uptake of PVC at extremely high (and environmentally not relevant) doses
- Study looked only at movement of ingested particles into body fluids; it did not investigate adverse effects.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Wright et al. (2013)

- Study of marine worms exposed to unplasticized PVC in sediment at concentrations 1% and 5% by weight.
- Both exposed groups had reduced energy reserves vs. controls.
- Notes that on highly impacted beaches microplastics concentrations can reach 3%
- The paper mentions that 25% of microplastic particles in estuarine sediments are PVC.
 - 25% of 3% is 0.75%, which is lower than the lowest dose tested.
- 5% exposure group showed limited feeding activity vs controls.
- Relevance of dose is not clear.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Xu et al (2014)

- Examined a variety of effects over time in rats following a single intratracheal instillation of 10mg or 50 mg PVC powder.
- Reported that washing the particles to remove additives did not affect toxicity.
- Noted “Pulmonary changes were limited and reversible.”
- Dose and route of exposure not directly relevant to environmental exposures.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.

Zhou et al. (2018)

- Examined the distribution and morphology of microplastics in coastal soils adjacent to the Bohai Sea and the Yellow Sea.
- 120 soil samples from 53 sites along >3,000 km of coastline in Shangdong province, eastern China.
- Microplastics were identified and quantified.
- PVC was not among the plastics mentioned by the paper.
- Information does not support a determination that vinyl is “toxic” under paragraph 64 of CEPA.