Proposed Re-evaluation Decision PRVD2026-05

Ozone and its associated end-use products

(publié aussi en français)

21 October 2026

This document is published by the Health Canada Healthy Environments and Consumer Safety Branch. For more information, please contact:

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Health Canada Santé Canada

Canada

ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2026-5E (print version)
H113-27/2026-5E-PDF (PDF version)

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Table of contents

Proposed re-evaluation decision for ozone and its associated end-use products 1
Next steps 2
Other information 2
Additional scientific information 2
Science evaluation 3
1.0 Background 3
2.0 Human health assessment 3
2.1 Toxicology assessment 3
2.2 Dietary exposure and risk assessment 4
2.3 Occupational and non-occupational exposure and risk assessment 4
2.3.1 Occupational exposure and risk assessment 4
2.3.2 Non-occupational exposure and risk assessment 5
2.4 Aggregate exposure and risk assessment 5
2.5 Cumulative assessment 6
2.6 Health incident reports 6
3.0 Environmental assessment 6
3.1 Environmental incident reports 6
4.0 Value assessment 7
List of abbreviations 8
Appendix I Registered Products Containing Ozone in Canada as of 14 July 2026 9
Appendix II Registered uses of ozone in Canada as of 14 July 2026 10
References 11

Proposed re-evaluation decision for ozone and its associated end-use products

Under the authority of the *Pest Control Products Act,* all registered pesticides must be regularly re-evaluated by Health Canada to ensure that they continue to meet health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches, and policies to all re-evaluations.

Ozone is a soluble gas that, when dissolved in water, functions as a powerful oxidizing agent and a broad-spectrum antimicrobial. Ozone is used to control zebra mussels in water intake systems and as a sanitizing/disinfecting agent for hard non-porous surfaces, including food contact surfaces. Aqueous ozone kills bacteria and fungi by damaging the cytoplasmic membrane through ozonolysis and also by oxidation of proteins which leads to a loss of organelle function. It kills molluscs (zebra mussels) by oxidation of organic matter which leads to toxic and lethal effects.

There are no manufacturing concentrates or technical actives registered. One restricted-class and one commercial-class ozone generating device are registered. Currently registered products can be found in the Pesticide Product Information Database and in Appendix I.

This document presents the proposed re-evaluation decision for ozone and the Science evaluation on which the proposed decision is based. All products containing ozone that are registered in Canada under the *Pest Control Products Act* are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period,[1] during which the public (including the pesticide manufacturers and stakeholders) may submit written comments to the Pesticides Publications Section. The final re-evaluation decision will be published after taking into consideration the comments received during the consultation period that are directly related to this proposed re-evaluation decision.

Health Canada, under the authority of the *Pest Control Products Act*, has conducted all evaluations considered necessary with respect to the health and environmental risks and value of ozone based on available scientific information in accordance with subsection 16(6) of the *Pest Control Products Act*. Health Canada is proposing for public consultation, pursuant to section 28 of the *Pest Control Products Act*, the continued registration of ozone and associated end-use products registered for sale and use in Canada under section 21 of the *Pest Control Products Act*.

Based on the current use pattern of ozone, the potential dietary, occupational, residential, and environmental risks are considered to be acceptable when the registered ozone-generating devices are used according to operating instructions and label directions. As a result of this re-evaluation, no additional mitigation measures are proposed.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Next steps

Upon publication of this proposed re-evaluation decision, the public, including registrants and stakeholders, are encouraged to submit comments during the 90-day public consultation period.

Health Canada will accept written comments on this proposal up to 90 days from the date of publication of this document. Comments on the proposed decision can be submitted during the consultation period to Health Canada through Pesticides Publications Section, or the Public Engagement Portal (Public Engagement Forms - Consultation Comment). For more information or if you have questions, contact the Pesticides Information Service.

Before making a re-evaluation decision on ozone under section 21 of the *Pest Control Products Act*, the comments received during the consultation period that are directly related to this proposed decision, such as comments directed to the science evaluation, will be taken into consideration in preparation of the final re-evaluation decision document. A science-based approach will be applied in making a final decision on ozone. In accordance with subsection 28(5) of the *Pest Control Products Act*, Health Canada will then publish a final re-evaluation decision document, which will include the decision, the reasons for it, a summary of the comments received directly related to the proposed re-evaluation decision during the consultation period, and Health Canada's response to these comments.

Refer to Appendix I for details on specific products impacted by this proposed decision.

Other information

The relevant confidential test data on which the proposed decision is based (as referenced in the References Section of this document) are available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information, please contact the Pesticides Information Service.

Additional scientific information

No additional scientific data are being requested at this time.

Science evaluation

1.0 Background

Ozone is a soluble gas that, when dissolved in water, functions as a broad-spectrum antimicrobial that is used to control zebra mussels in water intake systems and as sanitizing/disinfecting agent for hard non-porous surfaces, including food contact surfaces.

There are no technical grade or manufacturing products containing ozone registered in Canada. There are two ozone-generating devices registered in Canada.

- The restricted class end-use product, Wedeco Ozone Generator, is registered for the control of zebra mussels in the service water system of the Lennox Generating Station in Ontario. The device generates ozone on site, in a closed system, by corona discharge through concentrated oxygen, and the ozone is then injected into the cooling water at a maximum continuous rate of 0.5 ppm.
- The commercial-class end-use product, lotus® PRO, is registered to control bacteria and fungi on indoor food and non-food contact commercial and industrial hard non-porous surfaces. The lotus® PRO ozone generating device is connected to a cold-water supply line and uses electricity to convert oxygen from the air into ozone. The device infuses filtered water with up to 1.7 ppm ozone to create stabilized aqueous ozone (SAO).

Appendix I lists all products containing ozone that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all the uses for which ozone is presently registered.

2.0 Human health assessment

2.1 Toxicology assessment

Information on the toxicity of ozone was previously reviewed by Health Canada (Canada, 2008a; Canada, 2008b, Canada, 2022). Acute and short-term exposure to ozone is associated primarily with effects on the respiratory system, including decrements in lung function, respiratory symptoms, inflammation and morphological changes. Inhalation of ozone can cause dryness of the mouth, coughing, and irritation of the nose, throat, and chest. It may cause laboured breathing, headaches, and fatigue. Absorption through intact skin is not expected. Ozone can be an irritant to the eyes, causing minor inflammation. Although highly concentrated ozone is harmful to humans, ozonated water is less toxic. SAO is not likely to be a dermal irritant or sensitizer. Due to the low levels of ozone in SAO, it is not likely to be toxic by the oral, dermal, and inhalation routes, nor irritating to the eyes or respiratory tract.

Toxicology reference values for human health risk assessment were not established, and qualitative health assessments were considered adequate. The *Pest Control Products Act* safety factor characterization was not required. The required hazard warning statements are included on the current end-use product labels. No additional mitigation measures are proposed.

2.2 Dietary exposure and risk assessment

There are no direct food uses for the registered ozone-generating devices. Indirect food exposure as a result of the use of SAO as a disinfecting agent on food and non-food contact commercial and industrial hard non-porous surfaces is expected to be negligible due to the low ozone levels in SAO, high reactivity and relatively short half-life of ozone in water, and a short contact sanitization time (Canada, 2022; Canada, 2023). The lotus® PRO label includes a precautionary statement to prevent contamination of food with SAO during application and storage.

The use in commercial food preparation facilities is exempted from the *Pest Control Products Act* under paragraph 3(1)(c) of the Pest Control Product Regulations. However, it was supported by a letter of acceptance from the Canadian Food Inspection Agency, a letter of no objection from Health Canada's Bureau of Chemical Safety, and provincial letters of acceptance (Canada, 2022; Canada, 2023).

SAO generated by lotus® PRO is not intended for drinking and its use, as an indoor surface disinfectant, is not expected to result in contamination of drinking water sources (Canada, 2022; Canada, 2023). The Lennox Generating Station must comply with the environmental compliance approvals (ECA) (No. 2624-6MASFH), issued by the Ontario Ministry of the Environment, Conservation and Parks, which specify technical and operational conditions (including limits for ozone concentrations in the effluent). The concern for contamination of drinking water sources with ozone is low taking into consideration the existing conditions of use and the high reactivity and short half-life of ozone in water (Canada, 2008a; Canada, 2008b; Canada, 2016).

Dietary risks are considered to be acceptable when the current operating instructions and label directions are followed. No additional mitigation measures are proposed.

2.3 Occupational and non-occupational exposure and risk assessment

2.3.1 Occupational exposure and risk assessment

Potential occupational and bystander inhalation exposures to ozone and measures to mitigate those exposures and any associated risks of adverse effects on the respiratory system were previously assessed by Health Canada (Canada, 2016; Canada, 2022; Canada, 2023).

Occupational exposures to ozone at the Lennox Generating Station could occur as a result of accidental leakages or emissions from the ozonated water system. Occupational exposure to ozone is expected to be minimal when Wedeco Ozone generator is used according to the operating instructions and the label directions. The existing control measures at the Lennox Generating Station include an ozone destruct unit that prevents off-gassing from ozonated service water into the air of the station, ozone and oxygen analyzers, audible alarm systems, emergency ventilation in the ozone generator equipment room, and manual and automatic procedures for shutting down ozone production. These control measures are calibrated to the occupational exposure limits (OELs) regulated under the *Occupational Health and Safety Act* of Ontario for ozone and oxygen (Canada, 2016). The Lennox Generating Station must comply with the ECAs (Nos. 5525-4NBH7G and 2624-6MASFH) issued by the Ontario Ministry of the Environment, Conservation and Parks, which specifies technical and operational conditions (including limits for ozone concentrations in the effluent and air emissions).

The current product label has warning and precautionary statements on the hazards of ozone and requires personal protective equipment, including the use of appropriate respirators when verifying airborne ozone levels under high or very high alarm conditions.

Occupational exposure to SAO, generated by lotus® PRO, may occur while dispensing the SAO to fill cleaning equipment (such as spray bottles, spray mops or mop buckets), or during application, and postapplication cleaning activities. Occupational exposure to SAO is expected to be minimal due to the low levels of ozone in SAO, the high reactivity and relatively short half-life of ozone in water, the use in well-ventilated areas and the limited use pattern (hard surface disinfectant/sanitizer only) (Canada, 2022; Canada, 2023).

Occupational risks are considered to be acceptable when products are used according to the operating instructions and label directions. No additional mitigation measures are proposed.

2.3.2 Non-occupational exposure and risk assessment

The registered ozone generating devices are not intended for use in residential settings; therefore, residential exposure is not anticipated.

The primary potential source of bystander inhalation exposure is the ozone emitted through the outlet stack of the ozone destruct unit at the Lennox Generating Station. The bystander exposure to levels of ozone in air originating from the outlet stack of the ozone destruct unit was previously assessed by Health Canada and found acceptable with the environmental controls in place (Canada, 2016). Also, the potential to affect recreational waters from Lake Ontario is considered low taking into consideration a low concentration of ozone in the effluent at the Lennox Generating Station and the high reactivity and relatively short half-life of ozone in water (Canada, 2008a; Canada, 2008b).

The lotus® PRO label includes a statement instructing the users to not apply SAO in a way that will contact workers or bystanders, either directly or through drift. The use of the ozone generating device lotus® PRO in commercial and industrial settings is not expected to result in bystander exposure when product is used according to label directions (Canada, 2022; Canada, 2023).

The potential risk to bystanders is considered acceptable when products are used according to the operating instructions and label directions. No additional mitigation measures are proposed.

2.4 Aggregate exposure and risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). Aggregate exposure was assessed by Health Canada and found to be acceptable (Canada, 2022). The aggregate risk from potential indirect dietary (food contact surfaces and drinking water) and non-occupational exposures (dermal and inhalation) to ozone is considered acceptable when ozone generators are used according to the current label directions. No additional mitigation measures are proposed.

2.5 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada considers the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. Dietary and residential exposures to elevated ozone levels were not anticipated under the current conditions of use; therefore, a cumulative risk assessment was not required (Canada, 2022).

2.6 Health incident reports

As of 15 July 2026, there was one human incident reported to Health Canada. The incident was not considered relevant to the currently registered products (Canada, 2022).

3.0 Environmental assessment

Ozone may enter the environment as a result of Wedeco Ozone Generator use at the Lennox Generating Station either through emission from the outlet stack of the ozone destruct unit or as a discharge of ozone-treated water into Lake Ontario. The indoor use of the lotus® PRO generator is not expected to result in environmental exposure.

The risk to the environment resulting from the ozonated water system was previously assessed by Health Canada (Canada, 2008a; Canada, 2008b). In the aquatic environment, ozone will chemically degrade and will readily react with other compounds in water, including organic, dissolved and particulate matter; therefore, ozone will dissipate rapidly. Ozone is non-persistent and non-bioaccumulative. The level of ozone discharged to the environment through effluent is expected to be low due to its rapid degradation to oxygen in water and further dilution in the receiving water. Quarterly testing on rainbow trout and *Daphnia* using grab samples from the ozone-treated water (in other words, effluent water) and flow-through testing on rainbow trout exposed to diverted process water suggest the risk to non-target aquatic organisms is expected to be negligible. Risks to terrestrial animals are not anticipated under the registered use pattern.

The Lennox Generating Station must comply with ECAs (Nos. 5525-4NBH7G and 2624-6MASFH) issued by the Ontario Ministry of the Environment, Conservation and Parks, which specifies technical and operational conditions (including limits for ozone concentrations in the effluent and air emissions, monitoring, reporting, and controls).

The risk to the environment is considered acceptable when the registered ozone generators are used according to the operating instructions and label directions. No additional mitigation measures are proposed.

3.1 Environmental incident reports

As of 15 July 2026, no environmental incident reports involving ozone have been reported to Health Canada.

4.0 Value assessment

Ozone is a soluble gas that, when dissolved in water, functions as a broad-spectrum antimicrobial that can be used as an alternative to traditional surface sanitizers/disinfectants and is an effective method to control zebra mussels in water intake systems. Ozone has important value as a molluscicide and as a sanitizing/disinfecting agent for hard non-porous surfaces.

List of abbreviations

ECA	Environmental Compliance Approval
OEL	Occupational Exposure Limit
ppm	parts per million
SAO	Stabilized Aqueous Ozone

Appendix I Registered Products Containing Ozone in Canada as of 14 July 2026

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient
29041	Restricted	Ontario Power Generation	Wedeco Ozone Generator	Device	Ozone
34714	Commercial	Tersano Inc.	lotus® PRO	Device	Ozone

Appendix II Registered uses of ozone in Canada as of 14 July 2026

Use	Use-site category	Formulation	Application rate
Cooling Water. Ontario Power Generation, Lennox Generating Station	2	Device	0.5–0.6 ppm O_3
Food contact and non-food contact hard non-porous surfaces in commercial and industrial areas	15	Device	Up to 1.7 ppm O_3

References

Information considered for re-evaluation

Published information

PMRA Document Number	Reference
1621723	Canada, 2008a. Proposed Registration Decision, Hankin Ozone Generator. PRD2008-14. 22 July 2008.
1669811	Canada, 2008b. Registration Decision, Hankin Ozone Generator. RD2008-12. 27 November 2008.
2546860	Canada, 2016. Evaluation Report for Category B, Subcategory 4.6 Application; Wedeco Ozone Generator.
3413875	Canada, 2022. Proposed Registration Decision, Ozone Generating Device lotus PRO. PRD2022-16. 2 December 2022.
3443376	Canada, 2023. Registration Decision, Ozone Generating Device lotus PRO. RD2023-05. 7 March 2023.

Unpublished information

PMRA Document Number	Reference
2531118	Ontario Ministry of the Environment, 2006. Amended Certificate of Approval, Industrial Sewage Works, Number 2624-6MASFH, Issue Date: 7 March 2006. Ontario Power Generation Inc., PO Box 1000, Bath, Ontario K0H 1G0.
2531119	Ontario Ministry of the Environment, 2000. Certificate of Approval, Air, Number 5525-4NBH7G, Dated 18 August 2000. Ontario Power Generation Inc., Lennox Generating Station, Highway # 33 PO Box 1000, Bath, Ontario K0H 1G0.