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Notice of Intent

NOI2021-01

Notice of Intent: Interim Order to Regulate Certain Ultraviolet Radiation-Emitting Devices and Ozone-Generating Devices under the *Pest Control Products Act*

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada 

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Purpose

The purpose of this notice is to inform the Canadian public and stakeholders of Health Canada's intention to develop an interim order (IO) that would bring certain ultraviolet radiation-emitting (referred to in this notice as "UV") and ozone-generating devices under the *Pest Control Products Act*. The IO would capture UV and ozone-generating devices used to control, reduce, destroy or inactivate bacteria, viruses or other microorganisms that are human pathogens. Certain devices, such as UV hand-held wands, would be subject to a pre-market assessment and must be registered prior to entering the Canadian market.

The IO would avoid regulatory duplication by exempting from the *Pest Control Products Act* any device classified as a Class II, III or IV medical device under the Medical Devices Regulations. The IO would also exempt certain UV devices from registration if they meet certain conditions (i.e., they would be authorized without the need for registration). Health Canada intends to develop regulatory amendments to the Pest Control Products Regulations to make the changes permanent.

Background

Since the beginning of the pandemic, there has been a significant increase in the sale and use of UV and ozone-generating devices intended to control or kill bacteria and viruses (including SARS-CoV-2 – the virus that causes COVID-19) on surfaces and objects, and in water and air. These devices are widely marketed for use in various settings, predominantly for use in domestic dwellings to kill bacteria and viruses on surfaces and objects such as cell phones, keys, remote controls, and the air in small to large sized rooms.

Health Canada has not yet received sufficient evidence to demonstrate that UV and ozone-generating devices are safe, nor as effective as claimed. These devices can pose serious health and safety concerns. For instance, depending on the UV wavelength, intensity, and duration of radiation exposure, exposure to ultraviolet light from these devices can result in serious injuries, including severe burns to the skin and eyes. Similarly, inhaling ozone can lead to decreased lung function, irritation of respiratory pathways, and inflammation of pulmonary tissues as well as irreversible lung damage leading to higher susceptibility of respiratory infections.

Due to serious health and safety concerns and the common availability of these devices, Health Canada's Pest Management Regulatory Agency (PMRA) intends to regulate certain UV and ozone-generating devices, and require that they be subject to safety and efficacy assessments and registration or authorization prior to entering the Canadian market. The Minister of Health may make an interim order under subsection 67.1(1) of the *Pest Control Products Act* if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

In 2018, the PMRA published Regulatory Proposal [PRO 2018-02, Pre-Consultation - Proposed Regulatory Amendments to the Pest Control Products Regulations \(Pest Control Devices\)](#), a proposal on the regulation of pest control devices including UV and ozone devices, on its website for consultation. A subsequent webinar was held with stakeholders including industry, and

provincial and territorial governments. Several comments were received seeking clarification regarding the proposed conditions for exemption from registration. Health Canada intends to publish Questions and Answers (Q&As) to provide additional clarification and guidance to stakeholders regarding the IO, the registration process, and the conditions under which certain devices would be exempt from registration (i.e., authorized).

Next steps

The IO and Q&As are expected to be published in spring 2021. Regulatory amendments are expected to be published in 2022.

Once the IO comes into force, only registered or authorized UV and ozone-generating devices will be permitted to be manufactured, imported, distributed, sold or used in Canada. Unregistered or unauthorized devices will be prohibited, and may be subject to compliance and enforcement action.

Please direct all questions and inquiries to:

Policy and Operations Directorate
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario
K1A 0K9
Email: hc.pmra.regulatory.affairs-affaires.reglementaires.arla.sc@canada.ca