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Regulatory Proposal

PRO2019-01

Draft Science Policy Note: Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the *Pest Control Products Act*

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Introduction

The Minister of Health's primary mandate under the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. As per subsection 2(1) of the *Pest Control Products Act*, a "pest control product" includes¹ active ingredients, formulants² and contaminants.³ Paragraph 43(5)(b) of the *Pest Control Products Act* authorizes the Minister to establish, maintain, and make available to the public, a list of formulants and contaminants that the Minister considers to be of health or environmental concern. This list is made available to the public through publication in the *Canada Gazette* and on the Canada.ca website.

In 2005, to increase transparency in the regulatory system for pesticides, Health Canada's Pest Management Regulatory Agency (PMRA) established the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern (the List). In accordance with paragraph 43(5)(b) of the *Pest Control Products Act*, the identity and concentration of a formulant or contaminant on the List in a pest control product that is registered in Canada are not considered confidential business information and the public will be able to have access to it. For example, the identity of formulants on the List must be disclosed on pest control product labels as a condition of registration.

This document describes the proposed approach and criteria for maintaining the List, and also how the List will be used. It is an update to the version that was published in 2005. See the Notice of Intent NOI2019-01, *Proposed Amendments to the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*, which is also published for a 60-day public comment period.

1.0 General Approach

Existing policies, regulations and risk management strategies will be used for identifying formulants or contaminants of concern for addition to the List. Formulants or contaminants will only be added to the List if they are found in pest control products that are currently registered in Canada.

The PMRA's Regulatory Directive DIR2006-02 *Formulants Policy and Implementation Guidance Document* outlines how formulants of concern are identified. Contaminants of concern are identified as chemicals designated for reduction and/or elimination under an international treaty/convention that Canada has ratified or a Canadian government policy/risk management strategy, including the Toxic Substances Management Policy 1995 (TSMP 1995), the Montreal Protocol on Ozone Depleting Substances, the Minamata Convention, and the Government of

¹ Unless stated otherwise in the *Pest Control Products Act* and Regulations.

² In the *Pest Control Products Act*, a formulant is any component of a pest control product that is added intentionally to the product and that is not an active ingredient (for example, sugar).

³ For the purposes of the List, a contaminant is a substance that inadvertently occurs in a pest control product, such as a by-product of a chemical reaction or industrial process (for example, chlorinated substances).

Canada's Risk Management Strategy for Lead (February 2013). These policies, regulations and risk management strategies have set criteria and have already undergone public consultation.

2.0 Criteria

2.1 Formulants of Health or Environmental Concern

The PMRA policy on formulants in pest control products is described in Regulatory Directive DIR2006-02. It requires that formulants in pest control products be accurately identified and assessed for human health and environmental risks. Formulants will be included on or excluded from the List as follows:

- Formulants that have been determined to be of significant concern as identified on the Formulants Policy List 1 (see DIR2006-02) and are present in pest control products currently registered in Canada will be added to the List.
- Formulants that have been determined to be potentially toxic based on either structural similarity to List 1 formulants or data suggestive of toxicity, as identified on the Formulants Policy List 2 (see DIR2006-02), would not be on the List of Formulants and Contaminants of Health or Environmental Concern until the concern has been confirmed. Formulants re-assessed and determined to be of toxicological concern will be reclassified to List 1 under the PMRA Formulants Policy and subsequently added to the List.

2.2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-type Reactions

- Formulants that are identified in the Formulants Policy as allergens known⁴ to cause anaphylactic-type reactions and are present in pest control products currently registered in Canada will be added to the List.

2.3 Contaminants of Health or Environmental Concern

Contaminants will be included on or excluded from the List based on criteria and designation under existing international treaties/conventions that Canada has ratified or domestic risk management strategies and policies. The contaminant will also have to be present in a currently registered pest control product in Canada to be included on the List.

Contaminants of concern are identified as chemicals designated for reduction and/or elimination under an international treaty/convention that Canada has ratified or under domestic risk management strategies and policies, including:

- TSMP 1995 and Regulatory Directive DIR99-03 PMRA's Strategy for Implementing the Toxic Substances Management Policy

⁴ Zarkadas, M. et al. 1999. Common Allergenic Foods and Their Labelling in Canada: A Review. Canadian Journal of Allergy and Clinical Immunology, Vol. 4, No. 3, 1999.

- The Stockholm Convention, specifically those substances for which Canada has ratified the addition
- The Montreal Protocol on Ozone Depleting Substances
- The Minamata Convention
- Government of Canada's Risk Management Strategy for Lead (February 2013)

Releases of these designated contaminants from any sources cause concern. Therefore, the goal of these strategies is to reduce and ultimately eliminate, where feasible, the releases of these contaminants from all sectors contributing to the concern. These types of strategies provide general prevention measures related to best available techniques to minimize environmental releases. From a practical perspective for the pesticide sector, this is interpreted as minimization of these contaminants in pest control products.

3.0 List Structure

The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern has been constructed in three parts to facilitate reference. Substances will be listed as follows:

- Part I Formulants of health or environmental concern in pest control products registered in Canada
- Part II Formulants of health or environmental concern that are allergens known to cause anaphylactic-type reactions in pest control products registered in Canada
- Part III Contaminants of health or environmental concern in pest control products registered in Canada

4.0 Maintaining the List

The proposed List and criteria for establishing and maintaining the List will evolve as new science emerges. The PMRA will make additions to the List as needed when new formulants and contaminants of concern are identified.

A formulant or contaminant will be removed from the List when it is no longer considered to be of health or environmental concern or when it is no longer found in a registered pest control product in the Canadian marketplace.

Amendments to the List will be published in the *Canada Gazette*. The revised and consolidated List will be easily accessible to the public through the Canada.ca website.

For work planning purposes and to facilitate the maintenance of an up-to-date List, the PMRA expects to review the List and this Science Policy Note every five years to confirm that the criteria are still valid and whether or not formulants or contaminants should be added or removed from the List. The public will be consulted on any changes made to the List or the criteria.

5.0 Use of the List

There are two ways the List will be used to increase transparency:

- In accordance with paragraph 43(5)(b) of the *Pest Control Products Act*, information about the identity and concentration of substances on the List will not be protected as confidential business information and as such the public can have access to the information (for example, upon request from the PMRA); and
- In accordance with Regulatory Directive DIR2006-02, formulants on Part I and II of the List will be required to be disclosed on pest control product labels as a condition of registration.

6.0 Next Steps

The PMRA invites the public to submit written comments on this proposal up to 60 calendar days from the date of publication. The PMRA will consider all comments received during the 60-day consultation period while finalizing the science policy note and will publish it on the Pesticides and Pest Management Reports and Publications portion of Canada.ca.

Please forward all comments to Publications. Please provide your comments and include the following information: your full name and organization, telephone number, and complete mailing address or e-mail address.

Any inquiries should be directed to the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

References

Canadian Environmental Protection Act Virtual Elimination List

<https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/virtual-elimination-list/updated-february-4-2009.html>

Government of Canada Risk Management Strategy for Lead

<https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/environmental-contaminants/risk-management-strategy-lead.html>

Government of Canada Risk Management Strategy for Mercury

<https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/risk-management-strategy-products-mercury.html>

List of Formulants and Contaminants of Health or Environmental Concern

<https://laws-lois.justice.gc.ca/eng/regulations/SI-2005-114/index.html>

Minamata Convention

<http://mercuryconvention.org/>

Montreal Protocol

<http://www.un-documents.net/mpsdol.htm>

Ozone-depleting Substances and Halocarbon Alternatives Regulations, 2016

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2016-137/>

Persistence and Bioaccumulation Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/SI-2005-114/index.html>

Pest Management Regulatory Agency

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html>

Pest Management Regulatory Agency (PMRA) List of Formulants

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants.html>

PMRA Public Registry

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html>

Regulatory Directive DIR99-03, *The PMRA's Strategy for Implementing the Toxic Substances Management Policy*

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/1999/strategy-implementing-toxic-substances-management-policy-dir99-03.html>

Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2006/formulants-policy-implementation-guidance-document-dir2006-02.html>

Stockholm Convention

<http://www.pops.int/>

Toxic Substances Management Policy (TSMP 1995)

<https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/policy.html>