



# Notice of Intent

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## List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New *Pest Control Products Act*

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## Introduction

The new [Pest Control Products Act](#) (PCPA), which was given Royal Assent on December 12, 2002, is designed to protect human health and safety and the environment by regulating products used for the control of pests. A “pest control product” includes active ingredients, formulants<sup>1</sup> and contaminants<sup>2</sup>. The new PCPA authorizes the Minister of Health to establish and maintain a list of formulants and contaminants that the Minister considers to be of concern. This list will be made available to the public in the *Canada Gazette*.

To increase transparency in the regulatory system for pesticides, Health Canada’s Pest Management Regulatory Agency (PMRA) is establishing a list of Pest Control Product Formulants and Contaminants of Health or Environmental Concern (referred to hereafter as the “List”). In accordance with the new PCPA<sup>3</sup>, the identity and concentration in a pest control product of a formulant or contaminant on the List are not considered as confidential business information. This means the public will be able to have access to information on the identity and concentration of substances on the List.

This document describes the proposed approach and criteria for establishing and maintaining the List. The document also describes how the List will be used and how it will impact existing policies or programs, such as formulants and research policies as well as the Own Use Import Program.

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<sup>1</sup> In the new PCPA, a formulant is any component of a pest control product that is added intentionally to the product and that is not an active ingredient (e.g., sugar)

<sup>2</sup> For the purposes of the List, a contaminant is a substance that inadvertently occurs in a pest control product such as a byproduct of a chemical reaction or industrial process (e.g., chlorinated substances).

<sup>3</sup> For specific legal wording on the new List, please refer to subsection 43(5) (b) and for the confidential business information, to subsection 43(4) or (5) of the new PCPA.

## 1.0 General Approach

Existing policies and regulations will be used for identifying formulants or contaminants of concern. The policies used are the Toxic Substances Management Policy, the Montreal Protocol on Ozone Depleting Substances and the PMRA Formulants Policy. These policies have set criteria and have already undergone public consultation.

The [Toxic Substances Management Policy](#) (TSMP) sets out a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. Under the TSMP, Track 1 substances are persistent<sup>4</sup>, bioaccumulative<sup>5</sup> and toxic<sup>6</sup>. Track 1 substances are not allowed to be registered as pest control products, but certain pest control products that were registered before the TSMP came into effect (1995) may still contain Track 1 contaminants that are inadvertently produced in small quantities during manufacturing. The PMRA, in collaboration with registrants, has been taking measures to reduce the presence of Track 1 substances in pest control products. Track 1 substances will be on the List if they are present in quantifiable concentrations in registered pest control products in Canada. The PMRA's Strategy for Implementing the Toxic Substances Management Policy is presented in Regulatory Directive [DIR99-03](#).

The Montreal Protocol on Substances that Deplete the Ozone Layer was adopted on September 16, 1987. Substances that are designated under the Montreal Protocol are controlled in Canada under the [Ozone-depleting Substance Regulations, 1998](#), of the *Canadian Environmental Protection Act*. These controlled substances that are determined by the PMRA to be formulants or contaminants of health or environmental concern in registered pest control products would be included in the List. Currently, no formulants or contaminants listed in these regulations are found in registered pest control products in Canada.

The PMRA policy on formulants in pest control products is described in the PMRA *Formulants Program* Regulatory Directive [DIR2004-01](#). It requires that formulants in pest control products are 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 Regulatory Note [REG2005-01](#), *PMRA List of Formulants*) will be included on the List.

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<sup>4</sup> A substance that breaks down with great difficulty under normal conditions.

<sup>5</sup> The ability to accumulate along food chains (e.g., from small animals to larger animals to humans).

<sup>6</sup> To be able to cause harmful health effects.

- 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 REG2005-01), 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.
- Formulants that are allergens known to cause anaphylactic-type reactions will be on the List.

## **2.0 List Structure and Criteria**

### **2.1 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,
Part II	Formulants of health or environmental concern that are allergens known to cause anaphylactic-type reactions, and
Part III	Contaminants of health or environmental concern.

### **2.2 Criteria for the List**

A substance will be added to the List if it:

- meets the criteria for Toxic Substances Management Policy (TSMP 1995) Track 1 designation, namely, persistence in air, water, sediment or soil; bioaccumulation; toxicity; and is present in quantifiable concentrations; or
- is designated under the Montreal Protocol on Substances that Deplete the Ozone Layer and controlled under the Ozone-depleting Substances Regulations, 1998; or
- is designated under the PMRA Formulants Policy (2004) as a formulant of significant concern with respect to its potential adverse effects on human health and the environment, meeting defined criteria for causing cancer, toxic effects on the nervous system, chronic effects, adverse effects on the reproductive system and ecological effects; or
- is designated under the PMRA Formulants Policy (2004) as a formulant that is an allergen known to cause anaphylactic-type reactions; and
- occurs in a pest control product that is currently registered in Canada.

A draft of the List generated using the above criteria is shown in Appendix I.

### **3.0 Maintaining the List**

The proposed List and criteria for establishing and maintaining the List will evolve as new science emerges. The public will be notified of any changes made to the List or the criteria.

A formulant or contaminant will be removed from the List when it is no longer considered of concern; for example, when it is removed from the marketplace. Formulants or contaminants could be removed from the List following a PMRA reassessment or special review. The PMRA will maintain accurate and up-to-date formulation records for all registered pest control products to ensure those containing substances of concern are known and made public as appropriate.

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 PMRA's website.

### **4.0 Use of the List**

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

- information about substances on the List will not be protected as confidential business information; rather it will be made available on public request, through Material Safety Data Sheets and/or on pest control products labels; and
- it is intended that the List will be used in decision-making.

The use of the List is further described in Sections 4.1 to 4.4.

#### **4.1 Pest Control Products Labels**

Formulants on the List will be required to be disclosed on pest control product labels as a condition of registration. Formulants not on the List (e.g., those on Formulants Policy List 2) will not be required to be disclosed on pest control product labels unless deemed necessary on a case by case basis as a condition of registration. This constitutes a consequential change for the existing Formulants Policy (2004). The Formulants Policy will be revised to reflect this change. This policy is currently published as Regulatory Directive DIR2004-01. Information on currently registered pest control products, including labels, can be found on the EDDENet website.

## 4.2 Material Safety Data Sheets

Under the new PCPA, registrants will be required to provide Material Safety Data Sheets (MSDSs). Formulants and contaminants on the List will be required to be disclosed on MSDSs. This is consistent with what was indicated in the Regulatory Impact Analysis Statement for the proposed Pest Control Product Safety Information Regulations. More information on these regulations is available through the PMRA's website.

## 4.3 Research Authorizations

Research is essential to the development of pest control products. Before products can be registered, scientists have to conduct studies to demonstrate their products are safe and do what they are intended to do.

A request for a research authorization will have to be submitted for research projects with products that contain substances on the List.

More information on the research policies can be found in the following documents:

Regulatory Directive <a href="#">DIR98-05</a>	<i>Chemical Pesticides Research Permit Guidelines</i>
Regulatory Directive <a href="#">DIR97-02</a>	<i>Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals</i>
Regulatory Proposal <a href="#">PRO93-05</a>	<i>Research Permit Guidelines for Microbial Pest Control Agents</i>

## 4.4 Own Use Import

The Pest Control Products Regulations allow for foreign pest control products to be imported into Canada for the importer's own use, if the importer can demonstrate that the product is equivalent to a pest control product registered in Canada. Determining chemical equivalency of a foreign product to a registered pest control product involves a detailed and comprehensive analysis of the pest control product's active ingredients, formulants and contaminants. The Own Use Import (OUI) Program is intended to allow Canadian agricultural producers (users) access to competitively priced pesticides that are available in foreign markets. Under the OUI Program, only products equivalent to those registered in Canada can be imported.

Foreign products that contain a formulant on the List may be authorized for import under the OUI Program if they are equivalent to a pest control product that has been previously assessed, and determined to be acceptable and registered for that intended own use in Canada.

Information about the OUI Program can be obtained upon request to the PMRA.

## **5.0 Next Steps**

The List will be prepared for publication in the *Canada Gazette*. The List will come into effect once the new PCPA comes into force, i.e., once key regulations are made, including revisions to the Pest Control Products Regulations.



## Appendix I List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern

### Part I Formulants of health or environmental concern

Column I	Column II	Column III
Item	Formulant Name	CAS Registry Number*
1	Adipic acid, bis(2-ethylhexyl) ester	000103-23-1
2	Coal tar creosote	008001-58-9
3	Dimethyl formamide	000068-12-2
4	Diocetyl phthalate	000117-84-0
5	Hydroquinone	000123-31-9
6	Isophorone	000078-59-1
7	Rhodamine B	000081-88-9

### Part II Formulants of health or environmental concern that are allergens known to cause anaphylactic-type reactions

1. Fish\*\*
2. Milk\*\*
3. Peanuts\*\*
4. Soy\*\*
5. Sulfites\*\*
6. Tree nuts or their shells\*\*
7. Wheat\*\*

### Part III Contaminants of health or environmental concern

Column I	Column II	Column III
Item	Contaminant Name	CAS Registry Number*
1	Dichloro diphenyl trichloroethane (DDT)***	000050-29-3
2	Hexachlorobenzene***	000118-74-1
3	Pentachlorobenzene***	000608-93-5
4	Polychlorinated biphenyls (PCBs)***	

5 Polychlorinated dibenzo-p-dioxins substituted  
in at least the 2,3,7,8 positions\*\*\*

6 Polychlorinated dibenzofurans substituted in at  
least the 2,3,7,8 positions\*\*\*

\* "CAS Registry Number" means the identification number that is assigned to a chemical substance by the Chemical Abstracts Service Division of the American Chemical Society.

\*\* And any protein containing derivative, hydrolyzed plant protein, starch or lecithin of this allergen.

\*\*\* Identified as meeting the federal Toxic Substances Management Policy (TSMP) criteria as a Track 1 substance or substances, subject to virtual elimination from the environment.

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## References

### **Pest Management Regulatory Agency**

[www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca)

Regulatory Note REG2005-01, *PMRA List of Formulants*

[www.pmra-arla.gc.ca/english/pdf/reg/reg2005-01-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/reg/reg2005-01-e.pdf)

Regulatory Directive DIR2004-01, *Formulants Program*

[www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf)

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

[www.pmra-arla.gc.ca/english/pdf/dir/dir9903-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir9903-e.pdf)

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[www.pmra-arla.gc.ca/english/pdf/dir/dir9805-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir9805-e.pdf)

Regulatory Directive DIR97-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*

[www.pmra-arla.gc.ca/english/pdf/dir/dir9702-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir9702-e.pdf)

Regulatory Proposal PRO93-05, *Research Permit Guidelines for Microbial Pest Control Agents*

[www.pmra-arla.gc.ca/english/pdf/pro/pro9305-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/pro/pro9305-e.pdf)

### **Ozone-depleting Substances Regulations, 1998**

<http://laws.justice.gc.ca/en/c-15.31/sor-99-7/68673.html>

### **Canada Gazette**

<http://laws.justice.gc.ca/en/p-9.01/text.html>

### **Toxic Substances Management Policy (TSMP 1995)**

[www.ec.gc.ca/toxics/en/index.cfm](http://www.ec.gc.ca/toxics/en/index.cfm)

### **EDDENet (Electronic Dossier Delivery Evaluation Net)**

<http://eddenet.pmra-arla.gc.ca/4.0/4.01.asp>