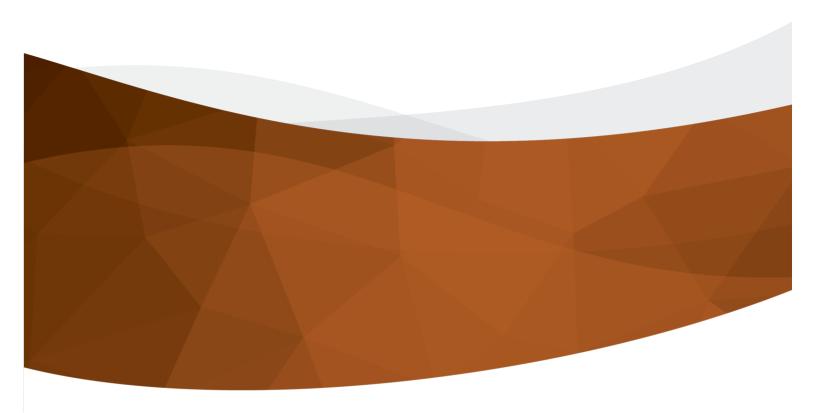


Compliance and Enforcement Policy for Pesticides





Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre : Politique de conformité et d'application de la loi sur les pesticides

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Disclaimer

This document does not constitute part of the *Pest Control Products Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

1.0 Purpose

This compliance and enforcement policy summarises Health Canada's national approach to compliance and enforcement for pest control products, commonly referred to as pesticides¹. It explains how Health Canada undertakes activities to assist regulated parties in achieving compliance, and informs Health Canada's decision making for compliance activities and enforcement actions that are transparent, consistent, fair and predictable. This document supersedes Regulatory Directive DIR2007-02 Compliance Policy, published on June 15, 2007.

Health Canada's compliance and enforcement policy for pesticides is relevant primarily to the following legislation administered by Health Canada:

- Pest Control Products Act
- Pest Control Products Regulations
- Pest Control Products Sales Information Reporting Regulations
- Pest Control Products Incident Reporting Regulations
- Agriculture and Agri-Food Administrative Monetary Penalties Act
- Agriculture and Agri-Food Administrative Monetary Penalties Regulations Respecting the Pest Control Products Act and Regulations
- Pest Control Products Fees and Charges Regulations

The <u>full list</u> of Acts and regulations applicable to the regulation of pesticides in Canada can be found on Health Canada's website.

2.0 Background

The regulatory environment for pesticides features rapidly evolving science and technology, an increasingly global marketplace, and evolving pest pressures which require an agile management approach. In this complex environment, a robust pesticide compliance and enforcement program is essential to protect the health and environment of Canadians through effective oversight of all pesticides and activities. To support these objectives, Health Canada engages with other levels of government, other federal departments and agencies, international organizations and stakeholder groups.

3.0 Scope

This policy applies to the products, activities, and parties subject to the *Pest Control Products Act* (the Act). A pesticide is any product, organism or substance that is manufactured, represented, distributed or used for controlling, destroying, attracting or repelling any pest or for mitigating or preventing its injurious, noxious or troublesome effects.

¹ "Pest control product" is the term defined in <u>Pest Control Products Act s.2</u>. For the purpose of this policy, "pesticide" is used to mean "pest control product" as set out in that definition.

Examples of pesticides regulated under the Act include, but are not limited to:

- Animal repellents
- Biopesticides²
- Devices
- Flea and tick products
- Insect repellents
- Insecticides, herbicides and fungicides
- Material and wood preservatives
- Plant growth regulators
- Pool and spa products
- Rodenticides
- Sanitizers
- Treated articles

Regulated activities under the Act include, but are not limited to:

- Advertising
- Disposing
- Exporting
- Handling
- Importing
- Labelling
- Manufacturing

- Packaging
- Possessing,
- Selling
- Distributing
- Storing
- Transporting
- Using

Regulated parties under the Act include, but are not limited to:

- Exporters
- Importers
- Marketers
- Manufacturers

- Distributors and retailers (including online)
- Registrants
- Shipper
- Users

4.0 Guiding Principles

Health Canada's <u>Compliance and enforcement policy framework</u> identifies the following principles that guide compliance and enforcement activities.

a) Accountability

Health Canada is accountable to Parliament and to Canadians to help ensure that the compliance and enforcement actions and decisions are consistent with:

- its mandate, values, policies, legal and operational frameworks;
- the public interest; and
- any applicable international requirements.

² For example microorganisms (microbials) and pheromones.

b) Fairness, consistency and impartiality

Health Canada applies Acts and regulations in a fair, consistent and impartial manner. Qualified and authorized personnel, including inspectors and analysts, carry out their compliance and enforcement activities in ways that are reasonable, professional, unbiased and unprejudiced.

Health Canada staff are guided by the Values and Ethics Code for the Public Sector.

c) Transparency

Health Canada strives to make its compliance and enforcement actions and decision-making process clear and understandable to everyone. The department provides access to relevant, useful and timely information about compliance and enforcement while respecting privacy rights. One of the ways this is done is by publishing information on inspection and enforcement activities through transparency and openness initiatives. Regulated parties can expect to see an increase in the type and scope of compliance and enforcement decisions made public.

d) Targeted and outcomes focused

Health Canada chooses compliance and enforcement actions based on the potential for harm to human health or the environment, or to the integrity of the regulatory system. This enables effective use of resources.

e) Evidence-based

Health Canada bases its compliance and enforcement actions and decisions on the best available evidence, information and science. Evidence is assessed objectively, following both the departmental approach described in the Health Canada Decision Making Framework for Identifying, Assessing, and Managing Health Risks, and the PMRA Framework for Risk Assessment and Risk Management of Pest Control Products.

5.0 Roles and Responsibilities

Many parties have a role in advancing the objectives of the Act. The primary objective of the Act is to prevent unacceptable risks to individuals and the environment from the use of pesticides.

Health Canada

The Regulatory Operations and Enforcement Branch (ROEB) is responsible for the delivery of a national compliance and enforcement program for all pesticides regulated under the Act. ROEB carries out compliance promotion and monitoring, and takes enforcement actions that follow applicable laws, policies and guidance documents through teams of inspectors and analysts designated under the Act. Engagement with regulatory partners, including provincial, federal or international regulators, informs oversight of the pesticides, regulated parties and activities to which the Act applies.

The Pest Management Regulatory Agency (PMRA) is responsible for evaluating the health and environmental risks and value of pesticides. Prior to registering or otherwise authorizing the use of a pesticide, PMRA determines whether those risks, are acceptable and re-evaluates pesticides already on the market against modern scientific standards to determine their continued acceptability. The Agency also collaborates with provincial, territorial and federal departments, and international regulatory partners, to refine and strengthen pesticide policies and regulations.

Regulated Parties

The Act is a federal statute that applies to all Canadians, whether individuals or organizations. It speaks directly to all activities involving pesticides in Canada. All regulated parties are expected to comply with the Act and its regulations, including any conditions related to the use of the product set out on its label. Regulated parties must also observe the prohibition in the Act and the authorities of inspectors, and must not obstruct the inspector or make false or misleading statements to the inspector when they are carrying out their official duties.

6.0 Compliance and Enforcement Activities

The Act establishes a framework to minimize risks to health and the environment from the use of pesticides. This framework includes a set of prohibitions and possible penalties, fines and imprisonment, and provides for oversight of pesticides and activities conducted in relation to pesticides, including those imported, manufactured, sold or used in Canada.

Health Canada promotes and verifies compliance with the Act and its regulations, including any conditions such as those set out on the label, and takes enforcement actions in situations of non-compliance warranting action. Information to verify compliance is collected from internal and external sources, which may include consumers or regulatory partners, and is used to identify possible risks to health, the environment and the integrity of the regulatory system. Compliance and enforcement priorities are based on a risk management approach that involves identifying real or potential risks, understanding their likelihood and consequences, and taking steps to reduce these risks.

Applying a risk-based approach helps Health Canada to make informed regulatory decisions that focus its compliance and enforcement activities to address the highest risks to human health and the environment, and to target regulated parties appropriately. Health Canada manages risks from non-compliance through a variety of compliance and enforcement activities, including:

- Compliance promotion to actively prevent non-compliance.
- Compliance monitoring to assess and verify compliance, including:
 - o targeted compliance verifications based on known or suspected non-compliance,
 - o random compliance verifications, and
 - o compliance verifications performed to prevent repeat non-compliance, and
- Enforcement actions to address risks resulting from non-compliance.

Compliance Promotion

Raising awareness of regulatory obligations involves sharing information such as policy and guidance documents that are intended to increase regulated parties' understanding of their roles and responsibilities under the applicable legislation. In doing so, Health Canada supports regulated parties in complying with the Act and its regulations, including the conditions of use set out on the label, and strives to prevent non-compliance from occurring.

Health Canada also provides information to Canadians to enable them to make appropriate and safe choices. Canadians should stay informed about the potential human health and environmental risks of pesticides, and understand their obligation under the Act to use registered pesticides according to label directions.

Compliance Verification

A core activity for compliance and enforcement is to verify and determine levels of compliance with the requirements of the Act and its regulations, and any conditions such as those set out on the label. Where possible, the aim is to prevent potential harm from occurring and to address non-compliance and pursue corrective action.

Inspections are an opportunity to gather information for the purpose of verifying compliance. During inspections, designated inspectors may enter, inspect, and take appropriate actions, or require the regulated party to take appropriate actions. When carrying out official duties, inspectors may use the various powers provided under section 48 of the Act, including but not limited to:

- Visually examining a place (including a virtual place), pesticide(s), computer(s), device(s), package(s) and label(s);
- Reviewing documents and records;
- Taking samples for laboratory analysis; and
- Ordering the person to provide documents, information or samples.

Information gathered is assessed to determine if further regulatory action is required. When assessing compliance, Health Canada applies the targeted, outcomes-focused and evidence-based guiding principles described in this policy.

Enforcement

Enforcement actions aim to compel compliance or address non-compliance, and mitigate risks to the health or environment of Canadians. In verifying instances of alleged non-compliance, Health Canada examines the evidence to determine whether there has been a contravention of the Act or regulations, and any conditions related to the use of the product. If there has been a contravention, enforcement is typically reflective of the severity of the risks posed.

In situations of repeat non-compliance, enforcement may be escalated. Enforcement actions include but are not limited to:

- Issuing warning letters to non-compliant regulated parties identifying corrective actions.
- Issuing compliance orders to require regulated parties to take specific actions.
- Issuing administrative monetary penalties.
- Issuing public advisories or other forms of risk communication.
- Seizing and detaining products.
- Cancelling registration.
- Refusing entry of importations of unauthorized products in partnership with Canada Border Services Agency.
- Prosecuting.

Decision Factors

In assessing risks from non-compliance, Health Canada follows its operational policies, processes and procedures to determine the most appropriate level of intervention. Consideration is given to many decision factors, including:

- Health and environmental risk
 - o Real or potential risk to human health or the environment.
 - o Magnitude of the potential harm.
 - The likelihood of a health or environmental impact from the non-compliant action.
- Behaviour of the regulated party
 - o Whether the regulated party acted wilfully or recklessly.
 - The degree of co-operation and responsiveness offered by the regulated party once non-compliance is identified.
- Compliance history
 - o Previous compliance issues.
 - o Whether the non-compliance is a repeat occurrence.
 - o Actions taken by the regulated party to comply with the law.
- Other factors
 - o The likelihood that the same non-compliant behaviour will recur.
 - o The expected impact and success of compliance and enforcement actions.
 - o The need to maintain public confidence in the integrity of the regulatory regime.

Glossary

Administrative Monetary Penalties (AMPs): The *Agriculture and Agri-Food Administrative Monetary Penalties Act* provides a system of penalties and warnings for violations of several federal Acts including the *Pest Control Products Act*. The *Agriculture and Agri-Food Administrative Monetary Penalties Act* allows Health Canada to impose penalties without having to pursue formal prosecution.

Cancellation: The termination of a product registration as authorized or required by the *Pest Control Products Act*.

Compliance: The fulfillment of legal requirements by a regulated party with the *Pest Control Products Act*, the *Agriculture and Agri-Food Administrative Monetary Penalties Act*, and associated regulations.

Compliance Order: Written notice issued to non-compliant regulated parties to inform them of contraventions of the *Pest Control Products Act* and its regulations, and to require timely corrective actions.

Compliance Promotion: Actions taken to inform about roles and responsibilities prescribed by the *Pest Control Products Act* and its regulations for the purposes of attaining and maintaining compliance.

Compliance Verification: Activities conducted to gather and assess information for the purpose of verifying a regulated party's compliance with the *Pest Control Products Act* and its regulations, and to respond to non-compliance.

Contravention: The act of coming into conflict with a provision of the Act or its regulations.

Enforcement Actions: Specific actions by Health Canada in response to non-compliance to bring regulated parties into compliance with the *Pest Control Products Act* and its regulations.

Inspection: An activity carried out for gathering information (verbal, records, samples) for the purpose of assessing compliance of a given regulated party with the *Pest Control Products Act* and its regulations.

Prosecution: A legal proceeding which may be brought against an accused regulated party for contravening a provision of the Act or its regulations.

Public Advisory: A Health Canada notice used to inform the public of possible serious health or environmental hazards and to enable Canadians to make informed decisions concerning the continued use of pesticides.

Regulated Party: Any person subject to the *Pest Control Products Act* and its regulations. This includes individuals, companies and other organizations that register, own, manufacture, possess, handle, distribute, advertise, transport, store, import, export or use pesticides.

Seizure: The act of taking possession of a product under the authority of the *Pest Control Products Act* without the regulated parties' consent. Seizure deprives the owner of the item from freely doing anything with the item, but unlike forfeiture, he/she retains ownership of the item.

Violation: A contravention of the Act or the regulations or a refusal to perform any duty imposed under the Act that may be proceeded with in accordance with the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

Warning Letter: Letter sent to non-compliant regulated parties to notify them of contraventions under the *Pest Control Products Act* and its regulations and to request corrective actions.