Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Proposal PRO2006-01

Compliance Policy

At Health Canada's Pest Management Regulatory Agency (PMRA), compliance policy, programs and enforcement activities are aimed at protecting human health and the environment from the risks from non-compliance with the *Pest Control Products Act* (PCPA) and Regulations. This document updates Backgrounder B98-01, *Compliance and Enforcement Policy Guideline*, published on 12 June 1998. Further policy and procedures will be developed in support of new authorities described in the PCPA (2002).

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1.0 Foreword

Canadians expect their federal government to provide laws and regulations that will protect them and their society. These laws must be enforced in a fair, consistent and predictable manner. The role of the federal government includes the following:

- to encourage and promote compliance;
- to inspect for compliance; and
- to respond to situations of non-compliance.

The majority of the regulated community will comply with regulations if they understand and have the ability to comply with them. For a minority, deterrence is necessary. The effectiveness of a deterrence approach depends upon:

- the perception by the potential violators that they are likely to be detected;
- a quick response when infractions are detected; and
- penalties that encourage violators to change their behaviour.

The PMRA has been entrusted "to protect human health and the environment from unacceptable risks associated with pest control products." This strategic objective will be achieved, in part, through policy, programs and strategies that "help to ensure that pest control products are used legally, according to label instructions." The PMRA is responsible, in partnership with other regulators, for developing strategies and programs so that the regulated community has the knowledge, will and ability to comply with the PCPA and Regulations.

Achieving compliance outcomes involves a complex analysis of the causes of non-compliance and selecting the most effective program and/or activity from a range of available options. The PMRA generally follows an established conformity continuum used by many compliance and enforcement officials. This continuum ranges from conformity through education to responses to situations of non-compliance.

Compliance is also promoted and facilitated by informal commitments and industry initiatives, e.g., product stewardship. The PMRA supports this approach as a valid means to extend the span of compliance motivated activities as well as increasing the probability that compliance goals and objectives will be attained.

Please refer to the glossary in Appendix I for definitions of the terms used in this document.

2.0 Introduction

This document outlines guiding principles for the fair, consistent and predictable application of the *Pest Control Products Act* and Regulations and the *Administrative Monetary Penalties Act* and Regulations.

This document is also intended to increase transparency by providing a clear description of the PMRA's role in delivering a national compliance and enforcement program that includes the delivery of compliance promotion activities, inspections, investigations and related laboratory analysis functions under the PMRA mandate.

This document will describe:

- the principles established to help ensure fair and equitable application of compliance and enforcement responses;
- the risk management principles applied in the area of compliance and how these principles are used in exercising judgement and discretion in targeting and responding to situations of non-compliance; and
- the programs and measures the PMRA uses to promote, verify and enforce compliance with the PCPA and Regulations.

3.0 Legislation and Regulatory Requirements

The Agency's mandate originates from the following:

Pest Control Products Act **(PCPA) and Regulations**
The PCPA and Regulations regulate the import, packaging, manufacture, distribution, labelling, sale and use of products that control pests.

Agriculture and Agri-Food Administrative Monetary Penalties Act **(AMPs Act)**
The AMPs Act provides the authority to issue official warnings and impose monetary penalties to persons who have violated designated provisions of the PCPA and Regulations.

Regulatory Requirements
The regulation of pest control products results in registration of products determined to have acceptable risks to human health and the environment. The terms and conditions of registration are found on the product label and may also be outlined in specific documents or regulatory directives. Achieving compliance with regulatory requirements is critical in managing the risks associated with pest control products in Canada.

4.0 Policy Statement

The following guiding principles govern the PMRA in the administration of the PCPA and Regulations:

Fairness
The PCPA and Regulations will be administered in a manner that is fair and equitable.

The PMRA will follow a predictable, uniform and national approach to enforcement for all regulated products, irrespective of where or by whom these products are sold, manufactured, packaged, labelled, imported, distributed, stored or used.

A non-discriminatory and unbiased approach to enforcement will be followed.

Transparency
The PMRA will provide access to and support understanding of compliance information and processes used to conduct its business.

Consistent with and in the spirit of the *Privacy Act*[1] and the *Access to Information Act*[2], the PMRA makes information on compliance and enforcement activities available to the public.

As a result, Canadians are informed on compliance issues and benefits.

The following information is available to the public:

- compliance program plans and results;
- AMPs penalties and warnings; and
- information regarding the outcome of prosecutions.

Risk-management Based
The PMRA will use a risk management approach to compliance.

The PMRA considered the *Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks* (1 August 2000) and the Treasury Board Secretariat's *Integrated Risk Management Framework* (April 2001) when developing its compliance risk management approach.

Managing risk in the context of compliance provides a basis to target and select the situations of most concern where non-compliance is known or suspected to exist, i.e., integrating risk into decision-making in a systematic manner.

5.0 Compliance Activity

The following is a description of current PMRA programs and measures used in the promotion and inspection of compliance under the PCPA and Regulations.

1 R.S. 1985, c. P-21, as amended

2 R.S. 1985, c. A-1, as amended

Identifying Compliance
Compliance issues may be identified to the PMRA through the following avenues:

- PMRA compliance activities;
- voluntary reporting of suspected infractions; and/or
- results reported from other government agencies.

When a situation of non-compliance has been recognized, a risk analysis is performed as described in Section 6.0 to determine an appropriate management option.

Encouraging and Promoting Compliance
There are a number of activities conducted by regional and headquarters' staff that encourage and promote compliance. These activities support the collection, distribution and exchange of information and include:

- compliance education and outreach
- support for stewardship initiatives
- working agreements and partnerships with other regulators of pesticides
- partner consultations with other regulators of pesticides
- sector consultations with the regulated community

Inspecting for Compliance
Inspections are conducted to assess or verify compliance by registrants, distributors or pesticide users. The types of inspections include:

- monitoring inspections
- surveillance inspections
- contingency response inspections

6.0 Managing the Risk Resulting from Situations of Non-compliance

The potential for non-compliance in the regulated community is large when one considers the size of the regulated community in combination with the regulatory requirements that could lead to non-compliance. Consequently, the PMRA must routinely make complex decisions regarding priorities, i.e., efficient and effective compliance activities and programs that achieve desired compliance outcomes. This compliance risk management approach is designed to target regulated activities where actual/known or suspected non-compliance would result in an unacceptable risk of harm.

6.1 Compliance Risk Analysis

Risk analysis includes the following three basic components: impact characterization, likelihood analysis; and overall evaluation of risk level and tolerance. When conducting a compliance risk analysis, information may be collected from multiple and diverse sources, e.g., grower or industry groups, other provincial or federal regulators and registrants.

Impact Characterization
The impact (i.e., what did/could go wrong?) associated with non-compliance will be analysed by taking into account the effect(s) on the following:

- human health;
- the environment; and
- regulatory integrity.

Incidents and/or anticipated non-compliance need to be assessed for their resulting impact on humans and the environment. This will be addressed drawing on the PMRA's expertise in determining the risk to human health and the environment resulting from the situation of non-compliance.

Impact on regulatory integrity may be characterized in the following terms:

- compromised public confidence in the regulation of pesticides;
- compromised respect for compliance and of the regulatory framework in which pesticides are regulated; or
- increase in the number of repeat violators.

The impact from non-compliance will be assessed as either **significant, moderate or minor.**

Likelihood Analysis
The likelihood analysis, i.e., the probability that the impact will occur, is influenced by several possible factors including, but not limited to, the following list:

- economic priorities that either exist or are perceived to exist, e.g., resulting from a competitive marketplace;
- historical information that supports assumptions regarding behaviour;
- level of familiarity with or understanding of regulatory requirements;
- presence of complex regulatory decisions resulting in lack of clarity; and/or
- context, e.g., the extent of use of a product.

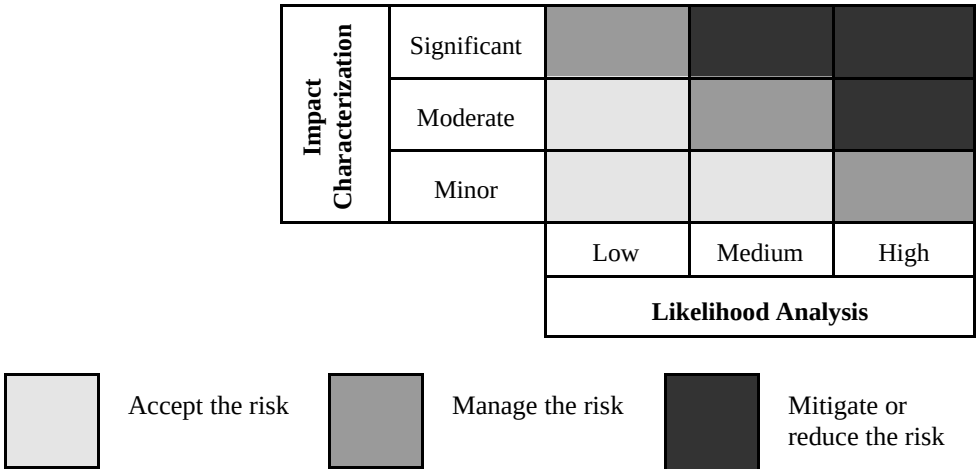
Likelihood will be assessed as **high, medium or low**.

Risk Tolerance

Establishing the risk level involves combining the results from the analysis of both the impact characterization and the likelihood analysis to determine the level of risk associated with an event of non-compliance (see Figure 1). The following model is consistent with other federal guidance documents such as those published by the following federal departments:

- Department of Fisheries and Oceans—*Integrated Risk Management Policy*;
- Health Canada (Health Products and Food Branch)—*Compliance and Enforcement Policy*; and
- Treasury Board of Canada Secretariat—*Integrated Risk Management Implementation Guide*.

Figure 1 Level of Risk and Corresponding Risk Tolerance



If the risk cannot be adequately determined, additional information must be gathered through sector consultations, mentioned in Section 5.0, in order to characterize the risk. The risk analysis process is then reinitiated in light of the new information.

6.2 Risk Management Options

The appropriate risk management option is associated with the determined level of risk tolerance as shown in Figure 1.

If the risks are determined to be acceptable, further compliance effort may not be necessary or, if deemed necessary, may be monitored and reviewed on a regular basis to verify that the level of risk remains acceptable.

A risk that is not acceptable will require a compliance program and/or an enforcement measure as outlined in sections 5.0 and 8.0 of this document.

7.0 Investigative Process

When the risks are not acceptable and a violation of the PCPA and Regulations is strongly suspected or known, the PMRA addresses these situations through an investigative process. The PMRA applies judgement and discretion in making decisions about an appropriate enforcement activity or response.

The PMRA considers whether there is knowledge/understanding, intent and the ability to comply with regulatory requirements. The following factors are also considered:

- the history of compliance, evidence of corrective action already taken;
- the degree of actual harm or potential harm as a result of non-compliance; and
- the level of response necessary to achieve and maintain continuing compliance.

8.0 Enforcement Activity

New enforcement measures will be available when the PCPA (2002) comes into force. These measures will be added to the current enforcement measures that are described in this section.

New Inspectors' Authorities
If an inspector has reasonable grounds to believe that a person has contravened the *Pest Control Products Act* or Regulations, the inspector may require the person to:

- stop or shut down any activity involved in the contravention; and/or
- take other measures to prevent the contravention, including the following:
  - modifying a pest control product or its labelling or disposing of the product so as to comply with this Act and Regulations; and
  - manufacturing, handling, storing, transporting, importing, exporting, packaging, distributing or using a registered pest control product in accordance with the conditions of registration.

Enforcement Responses
Enforcement is any action that is taken to induce, encourage or compel compliance. Options that are available include:

- education letter
- AMPs Warning or Penalty
- prosecution
- amend, suspend or cancel registration
- voluntary recall
- seizure and detention
- seizure and forfeiture
- denial of entry into Canada

Appendix I Glossary

compliance	state of conformity of a regulated party (including a corporation, individual or other legal entity) or a product with a legislative or regulatory requirements or a recognized standard.
enforcement	actions(s) that may be taken to encourage, induce or to compel compliance.
impact	effect resulting from an event of non-compliance.
inspector	a person designated by the Minister of Health for purposes of the PCPA.
integrated risk management (IRM)	a continuous proactive and systematic process to understand, manage and communicate risk from an organization-wide perspective. IRM incorporates risk management in the organization's structure, culture and key processes, including business planning, decision-making and performance reporting.
likelihood	the probability that the potential impact will be taking place.
risk	the measure of the degree of impact, defined as a combination of the probability and severity of adverse effects on organizational performance, health, property, the environment or other things of value.