Regulatory Directive DIR99-03

The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

The purpose of this Directive is to inform registrants, user groups, and other stakeholders about the Pest Management Regulatory Agency's strategy for the implementation of the Federal Government's Toxic Substances Management Policy (TSMP) for products regulated under the *Pest Control Products Act*.

In June 1995, the federal government released the TSMP - a policy developed to provide direction on the management of toxic substances and other substances of concern that are released into the environment. The policy applies to all substances that are subject to federal regulation. Although the impetus for the TSMP was to provide a means for managing substances that are not well regulated, the principles of the TSMP are relevant to chemicals that are used as pest control products.

The enclosed strategy was distributed as Regulatory Proposal Pro98-03 in November 1998, for information and comment. Many of the comments have been incorporated.

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Introduction

The Pest Management Regulatory Agency (PMRA) was established within Health Canada on April 1, 1995, by amalgamating the resources from the federal departments that were formerly involved in pesticide regulation: Agriculture, Health, Environment and Natural Resources. The mandate of the PMRA is to protect human health, safety and the environment by minimizing the risks associated with pesticides, while enabling access to pest management tools, namely, pest control products and sustainable pest management strategies. The PMRA uses a risk-management approach for the regulation of pest control products, consistent with the manner in which Health Canada undertakes regulatory activities for other products in the area of chemicals management.

The Toxic Substances Management Policy

The Toxic Substances Management Policy[1] is a federal government policy developed to provide direction on the management of substances that have been found to be toxic and other substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that are CEPA-toxic[2] or equivalent, predominantly anthropogenic, persistent and bio-accumulative) and full life cycle management to prevent or minimize releases of Track 2 substances (those that do not meet all of the four Track 1 criteria).

This policy applies to all substances that are subject to federal regulation, including those used as pest control products. The TSMP and the *Pest Control Products Act* (PCPA) have the same fundamental purpose: to protect human health and the environment. The PCPA is administered by the PMRA within Health Canada. The protection of human health and the environment is of primary importance in the regulation of pest control products in Canada.

Substances Regulated Under the *Pest Control Products Act*

Any substance that claims to have a pest control use is regulated under the PCPA. There are substances that have both pesticide and non-pesticide uses. Only the pesticide uses are regulated under the PCPA. Other substances that are contained in pest control products, e.g., formulants, adjuvants and contaminants, are also regulated as part of the pest control product under the PCPA.

Pest control products differ from many other substances that enter the environment, in that they are not by-products of another process but are intentionally released for a specific purpose.

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1 Appendix I provides a general description of the TSMP and its objectives.

2 As defined under the *Canadian Environmental Protection Act*, and described in Appendix I

The biological activity of most pest control products is what makes them valuable to Canadian society, while at the same time, it means the release of these products must be closely controlled. For this reason, the PCPA and policies affecting pest control products recognize and consider the environmental and human health risks as well as the value of the product.

PMRA Implementation of the Principles of the TSMP

Through detailed pre-market assessment and post-registration monitoring activities, pest control products have for many years been closely regulated. Many of the principles found in the TSMP are similar to those established for pest control products. The consolidation of pesticide regulatory activities within the PMRA (April 1995) and the planned revision of the PCPA are strengthening the life cycle management of pest control products in Canada. In accordance with the mandate given to the PMRA, the Agency is fostering sustainability in the context of pest management. The PMRA facilitates access to alternative products and coordinates development of long-term sustainable pest management strategies in a variety of user sectors, and thus provides a further catalyst for achieving the objectives of the TSMP.

Before making a registration decision regarding a new pest control product, the PMRA conducts a comprehensive assessment of the risk and value specific to the proposed use. The value assessment considers whether the use of the product contributes to pest management, and if the application rates are the lowest they can be to effectively control the target pest. The risk assessment considers the inherent toxicity, persistence and bioaccumulative nature of the pest control product. It addresses human health and environmental concerns and, for each of these, considers the possible hazards associated with the product as well as the degree to which humans and the non-target environment may be exposed. Exposure estimates are a key component of the risk assessment process. As pest control products are deliberately introduced into the environment at quantifiable rates, potential short-term impacts of environmental exposures can be closely estimated. For long-term environmental exposure, the PMRA relies on persistence and bioaccumulation data as qualitative indicators as well as on any monitoring data that may be available. With the introduction of the TSMP, increased emphasis will be placed on assessing the long-term risks associated with the release of substances into the environment. Through this process and the criteria established in the TSMP, the PMRA determines whether active ingredients in new pest control products are likely to be considered candidates for Track 1 or Track 2 classification. Consistent with the TSMP, where a Track 1 substance results from the degradation or transformation of a parent substance in the environment, the parent substance may also be considered for Track 1 by the PMRA.

Pest control products will only be registered if the data requirements for assessing value and safety have been adequately addressed, evaluation indicates that the product has merit and value, and the human health and environmental risks associated with the proposed use are acceptable.

For registered products, ongoing surveillance, advances in analytical methods and improved evaluation processes already provide the means to uncover environmental or health concerns, particularly with older products. In implementing the TSMP, the PMRA will systematically screen registered products using the TSMP criteria for persistence and bioaccumulation to identify those that contain active ingredients that are candidates for Track 1. The results of this screening process will then be taken into consideration along with the surveillance data, in the setting of priorities for re-evaluation or special review by the PMRA. Once this assessment is complete, and Track 1 or 2 classification is assigned, the next step will be to work in consultation with stakeholders to develop appropriate management strategies in accordance with the long-term goal of virtual elimination or that of life cycle management, as appropriate.

The PMRA manages the risks associated with the use of pest control products through several means, including: setting conditions of registration, monitoring compliance with these conditions, and label improvement programs to support best management practices, including integrated pest management (IPM) strategies. Non-compliance with conditions of registration is a violation of the PCPA and may lead to suspension, cancellation, use restriction or phase out of pest control products. These management practices of the PMRA reflect the principles of the TSMP and meet the TSMP requirements for Track 2 substances. For Track 1 substances, these same management tools allow the PMRA to work towards the goal of virtual elimination. Outlined below are several examples of how these tools will be applied in managing Track 1 substances.

Identifying Track 1 Substances in Pest Control Products

Track 1 substances in pest control products may be identified in three ways, namely, by:

- comparing active ingredients, formulants and contaminants against the federal government's list of Track 1 substances (Appendix II);
- evaluating new active ingredients against the TSMP criteria for Track 1 designation; or
- evaluating currently registered active ingredients to identify those, if any, that meet the TSMP criteria for Track 1 designation.

As other Track 1 substances are officially identified by the federal government, the list of substances in Appendix II will be amended, and the additional substances will be included in the PMRA's TSMP activities.

Managing New Pest Control Products Containing Track 1 Substances

i) Active Ingredients and Formulants (non-active ingredients)

The risks associated with a pest control product containing an active ingredient or a formulant, that is a Track 1 substance, would generally be considered unacceptable, and such products would not be registered.

A product containing a Track 1 substance as an active ingredient or formulant may be registered only:

- in exceptional circumstances, e.g., emergency[3] or critical need[4] situations, and with the imposition of conditions of registration designed to minimize the risks associated with its use; or

- where significant risk reduction can be achieved, e.g., a product offering a significant reduction of health or environmental risks over those posed by an existing product registered for the same use.

In these situations, new pest control products containing a Track 1 substance as an active ingredient or formulant may be registered on a temporary basis, for one year. Registration would only be permitted provided that the conditions of registration can be designed to ensure that risks would be acceptable.

The conditions of registration may include a requirement to provide specific information, including environmental monitoring data. Consistent with the goal of virtual elimination of Track 1 substances, any request for continued registration of the product would be reviewed in light of the required information as well as any new information concerning health and environmental risks, and the continuing existence of exceptional circumstances.

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3 Under provisions of Section 17(1) of the PCP Regulations, the Minister may register a product for a period not exceeding one year for the emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things (cf. Regulatory Directive Dir94-05, *Registration of Pesticides for Emergency Use*, March 3, 1994).

4 A product is deemed to be critically needed if it is to control a new pest problem or one for which registered products are no longer effective or acceptable in international markets, and the inability to manage the pest problem effectively would lead to severe economic hardship to the potential user. Consideration is also given to registration of additional products in situations where the availability of more than one product is required to manage the pest problem or the development of pest resistance.

ii) Microcontaminants

New pest control products containing a Track 1 substance as a microcontaminant may be registered:

- in exceptional circumstances, e.g., emergency or critical need situations, and with the imposition of conditions of registration designed to minimize the risks associated with its use;

- where significant risk reduction can be achieved, e.g., a product offers a significant reduction of health or environmental risks over those posed by an existing product registered for the same use, or a product replaces an existing product with a higher level of the same microcontaminant, resulting in a lower overall release of the substance; or
- where the Track 1 substance has been virtually eliminated. Conditions of registration will require that:

  < the level of microcontaminant in the product is very low[5];

  < the registrant demonstrates that the level of microcontaminant in the product is as low as can be achieved by the application of the best available technology from a manufacturing perspective; and

  < the use of the product in accordance with its proposed label is not expected to present unacceptable risks.

Provision to the PMRA of routine microcontaminant Quality Control data and environmental monitoring data may also be required. In all cases, conditions of registration would be imposed that are specific to the use scenario and are designed to ensure that risks are acceptable.

The registration validity period specified would not exceed five years. Consistent with the goal of virtual elimination of Track 1 substances, registration of the product would be reviewed as a condition of renewal in light of environmental-monitoring data, available alternatives and any new information concerning health and environmental risks

[5] Limits of quantification (LOQs) may be used as guidance for this purpose.

Managing Track 1 Substances Contained in Currently Registered Pest Control Products

The TSMP recognizes that social, economic and technical considerations must be taken into account in any management decision. Virtual elimination of Track 1 substances is a long-term goal to be implemented through a common sense approach.

In working towards the goal of virtual elimination, actions that may be taken include:

i) Track 1 Active Ingredients

- A systematic screening of registered active ingredients using the TSMP criteria for persistence and bioaccumulation to identify those that contain substances that are candidates for Track 1.

- Use of the TSMP criteria for persistence and bioaccumulation in the setting of priorities for re-evaluation or special review under the PCPA.

- Strengthen partnerships with industry, researchers, provinces and users to achieve reduction in use and replacement of actives of concern.

Note: Additional registrations would only be permitted in specific situations and provided conditions of registration can be designed to ensure that risks would be acceptable. For example, exceptional circumstances such as emergency or critical need situations, or where the products replaces an existing product for which it is a toxicologically or environmentally preferable alternative, or where the market is shared by products of similar chemistry and the total amount of the Track 1 substance entering the environment from pesticidal sources will not increase.

ii) Track 1 Formulants (non-active ingredients)

- In cooperation with registrants, strengthen the existing program to replace/reduce/eliminate formulants of concern, including Track 1 substances.

Note: Additional registrations would only be permitted in specific situations and provided conditions of registration can be designed to ensure that risks would be acceptable. For example, exceptional circumstances such as emergency or critical need situations, or where the products replaces an existing product for which it is a toxicologically or environmentally preferable alternative, or where the market is shared by products of similar chemistry and the total amount of

the Track 1 substance entering the environment from pesticidal sources will not increase.

iii) Track 1 Microcontaminants

- Review current levels of microcontaminants in pest control products for their continued acceptability.

- Work in partnership with registrants to reduce/eliminate microcontaminants of concern in line with the best available technology from a manufacturing perspective and encourage the development of new technology.

- If the level of the microcontaminant remains unacceptable, work in partnership with registrants and other stakeholders to develop alternative products and/or pest control strategies to prevent or minimize releases, with the ultimate goal of virtual elimination.

Note: Provided conditions of registration can be designed to ensure that risks would be acceptable, additional registrations may be permitted.

The TSMP and Canada's International Position

International Trade

The ability of Canadian services and products to compete for domestic and international markets is critical to the Canadian economy. Pest control products often play a vital role in ensuring the high quality and acceptability of Canadian goods. The PMRA includes socio-economic and technical considerations in formulating regulatory decisions that are consistent with the responsibility to protect human health and safety and the environment. The PMRA is committed to a system of open communication and transparency, and will strive for a cooperative approach to move towards the goal of virtual elimination of Track 1 substances.

Environmental Initiatives

Canada will continue to actively participate in international fora, such as the risk reduction initiatives under the United Nations, North American Free Trade Agreement, and the Organisation for Economic Co-operation and Development Pesticide Programme. These activities address health and environmental problems associated with pesticide use as well as concerns about risks to users and the general public.

The long-range transport of persistent organic pollutants (POPs) is a high priority issue for the Government of Canada, particularly the Ministers of Health and Indian and Northern Affairs. The TSMP is critical to Canada's position in discussions and negotiations with the world community on managing toxic substances. The clarification of how the TSMP will be implemented by the PMRA will facilitate the development of consistent national positions and provide increased opportunities to influence approaches taken in international fora, and indeed, in other countries.

APPENDIX I *Canadian Environmental Protection Act* and Toxic Substances Management Policy (TSMP)

The *Canadian Environmental Protection Act* (CEPA), administered jointly by the Ministers of Health and Environment, provides a federal regulatory role in the management of toxic substances. CEPA was developed to ensure coverage of substances not captured under other federal legislation. Section 11 of CEPA defines "toxic" as follows:

For the purposes of this Part, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions

a) having or that may have an immediate or long-term harmful effect on the environment;

b) constituting or that may constitute a danger to the environment on which human life depends; or

c) constituting or that may constitute a danger in Canada to human life or health.

For a substance to be classified as toxic under CEPA there must be a possibility: that the substance will enter the environment; that living organisms will be exposed to the substance; and that a harmful effect will result from that exposure. The TSMP relies on the CEPA definition of toxic. Under the TSMP, a substance is "toxic" if, after scientific assessment and based on decisions taken under federal programs, it either conforms or is equivalent to "toxic" as defined in CEPA.

The TSMP has two key management objectives:

1. **Virtual Elimination of Track 1 Substances:** The TSMP may identify a substance as Track 1 if it is CEPA-toxic or equivalent, persistent, bioaccumulative and primarily the result of human activity. If all four criteria are met, the substance will be deemed Track 1 and designated for virtual elimination. Socio-economic factors are not considered when setting the ultimate goal of virtual elimination; however, the TSMP does recognize that social, economic, and technical considerations must be taken into account in any management decision. Therefore, virtual elimination of *Track 1 substances* is a long-term goal to be implemented through a common sense approach.

2. **Life Cycle Management of Track 2 Substances:** A substance may be identified as Track 2 if it does not meet all of the four criteria. The ultimate objective for *Track 2 substances* is life cycle management to prevent or minimize release.

APPENDIX II List of currently identified Track 1 substances

Aldrin
Chlordane
Dieldrin
DDT
Endrin
Heptachlor
Hexachlorobenzene
Mirex
Toxaphene
Polychlorinated dibenzo-p-dioxins substituted in at least the 2,3,7,8 positions
Polychlorinated dibenzofurans substituted in at least the 2,3,7,8 positions
Polychlorinated Biphenyls

None of these Track 1 substances are registered as active ingredients under the PCPA.