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Discussion Document

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Pre-Consultation on Proposed Modifications to the Pest Control Products Incident Reporting Regulation

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Foreword

The Pest Control Products Incident Reporting Regulations came into force in 2007. Since then, several potential improvements have been identified, some of which are based on stakeholder input. Six modifications are being proposed in order to make improvements to the Regulations.

The purpose of this document is to seek comments from stakeholders and the public regarding the proposed modifications to the Pest Control Products Incident Reporting Regulations.

Background

Pest control products are regulated in Canada under the federal *Pest Control Products Act*. Health Canada's Pest Management Regulatory Agency (PMRA) administers the act on behalf of the Minister of Health.

The Pest Control Products Incident Reporting Regulations legislate a surveillance program that requires registrants and applicants of pest control products to report any of the following to Health Canada:

- any incident involving effects on human and domestic animal health or the environment,
- packaging failures that could result in human exposure or injury,
- excessive residues in food, or
- scientific studies that indicate a new hazard or increased risk.

The Incident Reporting Regulations prescribe what information is required to be reported by registrants and applicants, as well as the time frames within which information must be reported. The Incident Reporting Regulations also include administrative requirements such as record keeping. The form and manner by which the information is to be reported by registrants or applicants is specified in supporting guidance documentation.

Incident reports may also be received directly from the public. This type of reporting is not regulated through the Incident Reporting Regulations and will not be discussed in this document.

PMRA evaluates all incident information in order to identify potential risks to health or the environment. Incident reporting helps to inform pesticide regulatory decisions.

On 1 October 2012, the Government of Canada released the Red Tape Reduction Action Plan report. The action plan details the systemic regulatory reforms to address the recommendations of the Red Tape Reduction Commission. It includes the One-for-One rule, which requires regulators to offset new administrative burden costs imposed on business with equal reductions in administrative burden from the stock of existing regulations.

In reviewing the Incident Reporting Regulations, PMRA has identified several administrative burden reductions that could be made without compromising the rigour of its oversight of incidents.

Overall, no new requirements would be imposed on the registrants as a result of the adoption of the proposed amendments. The proposed amendments are intended to address administrative efficiencies and streamline existing reporting requirements as well as to clarify existing reporting requirements. A slight reduction in administrative burden would be realized by the adoption of the proposed amendments.

Proposed Modifications to the Pest Control Products Incident Reporting Regulations

Health Canada is proposing and seeking comments on six modifications to the Incident Reporting Regulations.

1. Minor incident reporting

Currently, under sections 13 and 14 of the Incident Reporting Regulations, all incidents that are classified as minor, as well as moderate domestic animal incidents may be accumulated by registrants for a 12-month period and submitted within the prescribed time frames to Health Canada.

Proposal

The proposal would require all incidents classified as minor to be reported within the same time limit as those for the United States Environmental Protection Agency. This would simplify the reporting process for those international registrants who are required to report incidents in both countries. The proposal would allow minor incidents to be accumulated for 3 months (quarterly) instead of 12 months (annually), and to be submitted within 60 days following the end of the quarter.

Additionally, the proposal would affect the reporting time limits for annual summaries (subsection 15(3) of the Incident Reporting Regulations). This proposal would affect the incident reports classified as an incident that could result in one of the following outcomes:

- a minor effect on a human,
- a moderate effect on a domestic animal, or
- a minor effect on a domestic animal.

Rationale

Comments have been received by registrants indicating that the long time limit makes it cumbersome to manage the documentation and filing of reports. Additionally, the current staggered reporting time limit does not allow PMRA to obtain a “fixed” picture of the incident report data by calendar year. This has created significant difficulties for signal detection and evaluation, monitoring of registrant and applicant compliance with the Incident Reporting Regulations, and making comparisons with international data. Finally, it is important that PMRA has access to timely post-registration information regarding incidents related to pesticides. The 12-month reporting time limit has proven to be too long in terms of appropriate response time by PMRA.

A significant portion of the incident reports specified under Section 13 of the Incident Reporting Regulations are currently being submitted within three months of the registrant receiving them. This indicates that the majority of registrants are not waiting 12 months to report.

The proposed changes would be consistent with the reporting time limits of the United States Environmental Protection Agency for the same classification of incidents. This would simplify the reporting process for those international registrants who are required to report incidents in both countries.

By reducing the current 12-month reporting time limit to quarterly reporting, there will be minimal change in the registrant workload. However, there will be significant benefit to PMRA with regards to the processing and evaluation of these incident reports. As with section 12 of the Incident Reporting Regulations, registrants may submit incident reports at any time prior to the quarterly time limit. There would be a slight increase in the administrative burden on registrants if this proposal is implemented.

2. Modify reporting time limits for environmental incidents

Currently, the Schedule of the Incident Reporting Regulations specifies when environmental incidents are to be reported, based on the type and number of organisms affected.

Proposal

Remove the Schedule and replace reporting requirements with the following requirements:

- Environmental incidents in which all organisms except plants are involved will be required to be collected for one month and filed by the end of the following month (similar to section 11 of the Incident Reporting Regulations).
- Environmental incidents in which the organism involved is a plant will be required to be collected for three months and filed by the end of the following month (similar to section 12 of the Incident Reporting Regulations).

Rationale

The current Schedule was created in an attempt to harmonize with the incident reporting requirements of the United States Environmental Protection Agency. The Schedule has proven to be complex and challenging for registrants to follow. Additionally, the current Schedule specifies time frames that can impede the timely receipt of incident information by PMRA.

The proposed changes would mean that registrants would no longer be required to categorize their reports based on the number of organisms affected, which will simplify the process.

The proposed changes would impose a shorter time limit for the majority of environmental incident reports but would allow a slightly longer reporting time for a few of the complex incidents.

This proposed amendment would simplify the reporting requirements overall, and would slightly reduce the administrative burden on registrants.

3. Remove the requirement to report incidents classified as residues in food

Currently, registrants are required to report incidents when a pest control product or one of its components or derivatives is detected in food in an amount that would result in the sale of the food being prohibited under section 4 of the *Food and Drugs Act*.

Proposal

Remove the requirement for registrants and applicants to report incidents classified as residues in food (section 2(d) of the Incident Reporting Regulations).

Rationale

PMRA receives information regarding residues that exceed the maximum residue limits from the Canadian Food Inspection Agency. The removal of the requirement to report food residue incidents would result in savings to the registrant or applicant. Removing this requirement will eliminate duplication of work between PMRA and the Canadian Food Inspection Agency, and ease the burden on registrants.

4. Increase reporting time limit for packaging failure incidents from monthly to quarterly

Currently, incidents of packaging failure are required to be reported on a monthly basis (section 11(f) of the Incident Reporting Regulations).

Proposal

Change the current reporting time limit from monthly to quarterly reporting (similar to section 12 of the Incident Reporting Regulations).

Rationale

Reporting time frames were initially developed to reflect the potential severity of an incident report. Packaging failure incident reports received by PMRA to date do not indicate that the level of risk identified in these reports warrants the short reporting time limit of one month.

The proposal would change reporting time frames for packaging failure from monthly to quarterly reporting, slightly reducing administrative burden on registrants in this category of incident reports.

5. Modify subsection 14 (3.1) No longer a registrant

Under subsection 14(3.1), if a registrant ceases to be the registrant of a particular pest control product, they must file the incident reports described in section 13 about that product within the time limits described in paragraph (a) or (b).

Proposal

Require registrants who are no longer registrants to file all incident reports (as described in sections 10, 11, 12 and 13) within the time limits described.

Rationale

All relevant incident reports should be submitted to PMRA when a registrant ceases to be a registrant.

6. Change the trigger for the filing of an annual summary

The Incident Reporting Regulations require that registrants or applicants file an annual summary with respect to an active ingredient if the active ingredient is implicated in at least 10 incident reports filed in the same year. The incident reports can be of any category.

Proposal

It is being proposed that the trigger for filing an annual summary be modified so that such a summary would be required only if an active ingredient is implicated in 10 incident reports of the same category of incident (as per section 2) in the same reporting year.

Rationale

An annual summary that analyzes 10 or more incident reports that are similar to each other focuses more clearly on potential risks identified in the incident reports filed in that reporting year.

Modifying the annual summary criteria as proposed would reduce the number of summaries reported. There would be a reduction to the burden on registrants, while still allowing for the capture of the most pertinent annual summaries.

Invitation to Comment

The purpose of this document is to seek comments on the proposed amendments to the Pest Control Products Incident Reporting Regulations. Please review the document and provide your comments in writing. As you review the document and prepare your comments, follow these guidelines:

- Explain your views as clearly and concisely as possible.
- Be sure to distinguish between what you support and what you object to in the proposal.
- Provide the rationale for your views.
- Offer alternative ways to improve the proposal.
- Support your views and especially your concerns, wherever possible with facts, data or specific examples.
- Describe any assumptions that you had.
- Provide copies of any technical information or data you used in your comments.
- Include an electronic copy of your response to help us collate the comments received.

Please submit your comments within 30 days of publication of this proposal to the Publications Coordinator, PMRA. There will also be an opportunity to comment on the proposed regulation after it is republished in the *Canada Gazette*, Part I.