Regulatory Directive DIR2014-01

Approach to Special Reviews

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1.0 Introduction

In Canada, pest control products, or pesticides, are regulated by Health Canada's Pest Management Regulatory Agency (PMRA) on behalf of the Minister of Health and under the authority of the *Pest Control Products Act*. The *Pest Control Products Act* prescribes both pre-market and post-market assessment of pesticides to determine the acceptability or continued acceptability of the health and environmental risks and value of a product for registration in Canada. Special review is one of the post-registration processes provided for under the *Pest Control Products Act*.

The PMRA's proposed approach to special reviews was published for consultation in Re-evaluation Note REV2013-18, *Proposed Approach to Special Reviews – Consultation Document*, in December 2013. A number of comments were received. These comments were taken into consideration in this final version of the document and are summarized in Appendix I.

This document outlines the requirements for special reviews as set out in the *Pest Control Products Act* as well as presents the approach to special reviews.

2.0 General Information about Special Reviews under the *Pest Control Products Act*

The *Pest Control Products Act* requires the PMRA to initiate a special review of a registered pest control product when there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable, or when an Organisation for Economic Co-operation and Development (OECD) member country prohibits all uses of an active ingredient for health or environmental reasons. Once these triggers have been met, in accordance with subsection 18(1), the registrant will be notified, and in accordance with subsection 18(2), other government departments will be contacted. The evaluation will be targeted to address the aspect(s) of concern related to the pest control product that prompted the special review.

At any point during the special review, section 20 allows the PMRA to cancel or amend the registration of one or more of the registered pest control products containing the active ingredient, if there are reasonable grounds to believe this is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle.

Before making a final regulatory decision, a public consultation will be carried out on the proposed decision including any proposed risk management measures. Following the publication of a final regulatory decision for a special review, any person may file a Notice of Objection. The Notice of Objection must be filed within 60 days of the decision date.

Triggers for Initiating Special Reviews

Section 17 of the *Pest Control Products Act* describes the conditions under which the Minister is obligated to initiate a special review.

- Under subsection 17(1), if the Minister has reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable, a special review is initiated.

> ***17.*** *(1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.*

- A federal or provincial government department or agency may provide information that relates to the health or environmental risks, or the value, of a pest control product. If after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable, a special review is initiated.

> ***17.*** *(3) Without limiting the generality of subsection (1), the Minister shall initiate a special review of the registration of a pest control product if a federal or provincial government department or agency has provided information to the Minister that relates to the health or environmental risks or the value of the product and if, after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.*

In addition, under section 14 of the *Pest Control Products Act*, after considering any information reported under the additional information (section 12 of the *Pest Control Products Act*) or mandatory reporting (section 13 of the *Pest Control Products Act*) provisions of the *Pest Control Products Act*, the Minister will determine whether or not a special review should be initiated. A special review will be initiated if the Minister has reasonable grounds to believe that the health or environmental risks of the pest control product are, or its value is, unacceptable as per subsection 17 (1).

> ***14.*** *After considering any information reported under section 12 or 13, the Minister shall determine whether a special review of the registration of the pest control product should be initiated.*

However, under subsection 17(2) of the *Pest Control Products Act*, initiation of a special review is required:

- if an OECD member country prohibits all uses of an active ingredient for health or environmental reasons.

> ***17.*** *(2) Without limiting the generality of subsection (1), when a member country of the Organization for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient.*

Any person may request a special review through a request made to the Minister in the form and manner prescribed.[1] The reasons for requesting a special review must be relevant to registered Canadian uses and, if based on subsections 17(1) or 17(3), may include scientific information or other relevant information relating to health or environmental risks or to the value of the product. If subsection 17(2) is the reason for the special review request, the requestor should provide information concerning the applicable decision (for example, the OECD decision, a news item about the decision, etc.) from an OECD member country that prohibits all uses of an active ingredient for health or environmental reasons.

3.0 Approach to Special Reviews

This document describes a step-by-step approach where the depth of and length of time to conduct a special review would be dependent on the complexity of the aspect(s) of concern associated with a given pest control product as well as the amount of information requiring assessment.

Step 1: Preliminary Analysis
Step 2: Announcement of Special Review
Step 3: Assessment of the Aspect(s) of Concern
Step 4: Publish a Proposed Special Review Decision and Consult the Public
Step 5: Publish a Final Special Review Decision

[1] The Special Review Request Form will be made available on the Pesticides and Pest Management portion of Health Canada's website, on the Forms webpage, at www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/form/index-eng.php or may be requested through the Pest Management Information Service.

Step 1 – Preliminary Analysis

The PMRA will carry out a preliminary analysis of the relevant information in its possession in order to determine whether a special review is warranted. The purpose of the preliminary analysis phase is to determine the basis for which a special review is considered (in other words, whether it is based on a prohibition in an OECD member country or other information in the Minister's possession). Furthermore, in most cases it is important to determine early in the process the aspect(s) of concern that warrants further investigation, as well as to identify what additional information may be required from registrants.

Regulatory decisions by an OECD member country:
Before a special review is initiated on the basis of an OECD member country's decision to prohibit all uses of an active ingredient, a preliminary analysis of the decision is necessary to confirm that it meets the conditions prescribed under subsection 17(2):

- The decision is from a member country of the OECD;
- All pest control product uses relating to the active ingredient have been prohibited; and,
- The prohibition is based on health or environmental reasons.

In determining whether the conditions set out in subsection 17(2) have been met, relevant information from other regulatory authorities and other sources as appropriate will be considered. If the above conditions are met, a special review will be initiated.

Other potential special reviews:
In all of the scenarios other than where there is an applicable OECD decision, the relevant information in the Minister's possession will be analysed before a decision as to whether a special review will be initiated. This preliminary analysis will determine whether there are reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable. Consequently, the PMRA will consider relevant information relating to the aspect(s) of concern.

A special review will be initiated if the preliminary analysis indicates that there are reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable. A special review may not be initiated if the aspect(s) of concern is not applicable to the Canadian situation, for example, the active ingredient(s) is not registered in Canada.

Step 2 – Announcement of Special Review

When a special review is required based on the preliminary analysis, registrants will be formally notified and an announcement will be published. If there is a requestor, they will also be informed of the decision. If considered necessary, the PMRA will require the registrant to provide information relating to the aspect(s) of concern under special review in accordance with subsection 18(1). After a special review is initiated, the PMRA will request that other federal/provincial government departments and agencies provide available information relevant to the aspect(s) of concern subject to special review. At any point, the PMRA may request additional information from the registrant under paragraph 19(1)(*a*).

Step 3 – Assessment of the Aspect(s) of Concern

The aspect(s) of concern that prompted the special review will be evaluated, as required by subsection 18(4) of the *Pest Control Products Act*. A scientifically based approach will be used for evaluating the aspect(s) of concern related to the pest control product that prompted the special review.

A registration may be cancelled or amended at any time during the course of the special review if the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment.

Step 4 – Publish a Proposed Special Review Decision and Consult the Public

Upon completion of the assessment (Step 3), the PMRA will publish a proposed special review decision for consultation. The purpose of the consultation is to invite comments from the public and stakeholders for consideration by the PMRA prior to issuing the final special review decision.

Step 5 – Publish a Final Special Review Decision

After considering any comments received, the PMRA will publish a final decision statement.

Appendix I Comments and Responses

The PMRA received comments in response to Re-evaluation Note REV2013-18, *Proposed Approach to Special Reviews – Consultation Document*, from stakeholders including registrants and non-governmental organizations with interests in human health or the environment. The PMRA has consolidated and summarized the comments received and provides responses below.

The comments have been grouped as indicated below:

- Triggers of Special Review and Interpretation of the *Pest Control Products Act*
- Approach to the Preliminary Analysis and Announcement of Special Review
- Approach to the Assessment of the Aspect(s) of Concern
- Other Comments

Triggers of Special Review and Interpretation of the *Pest Control Products Act*

Comment relating to the legislative requirements for the special review process

The document should include specifics on the legal and procedural details on how the PMRA will conduct special reviews according to the *Pest Control Products Act* requirements. Additional details should be provided for provisions in sections 12, 13, and 14 with respect to triggering a special review, and, for sections 18, 19, and 20 with respect to the process; in particular, section 20 since it relates to cancellation or amendment and provides the Minister with the authority to apply the precautionary principle during special review.

PMRA Response

The PMRA has revised the document to include additional details on the legislative and procedural requirements.

Comment relating to the special review of inert ingredients in a pest control product

The PMRA should be capable of initiating a special review based on the toxicity of these inert ingredients. The “inert” chemicals are not included in the product testing and that would imply that they are biologically inactive. This practice is considered not sufficiently protective of human health and the environment. Also, these “inert” chemicals are not listed on the product label.

PMRA Response

The *Pest Control Products Act* defines a pest control product as a product, organism or substance that consists of an active ingredient, formulants and contaminants used as a means for controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects. In this context, a special review of a pest control product may be triggered by concerns relating to ingredients other than the active ingredient.

Other chemical ingredients, such as formulants, present in the pest control product are considered in the scientifically based assessment. Formulants that are of toxicological concern are disclosed on product labels.

Comment relating to the PMRA's reliance on third party requests or information for triggering special reviews

The document implies that special reviews will only be initiated when the PMRA is provided with information or a request is made by a third party and appears to ignore the other conditions under which a special review must be initiated.

PMRA Response

Section 2.0 of the document clearly identifies the triggers for a special review. To provide further clarity, Section 3.0 has been revised to make it evident that the information prompting the PMRA to initiate a special review may come from different sources such as a third party or regulatory actions occurring in other countries and jurisdictions.

Comment relating to information that the requestor must submit under subsection 17(2)

The consultation document requires that when a special review is triggered by subsection 17(2), the requestor must submit the "applicable decision for an OECD member country". The *Pest Control Products Act* does not legislate any such requirement, nor does it grant the Minister or the PMRA any authority to impose such a requirement.

PMRA Response

Section 2.0 of the document has been revised to remove the requirement for a requestor to submit the applicable decision of an OECD member country, and instead only requests information about the decision.

Approach to the Preliminary Analysis and Announcement of Special Review

Comment relating to the criterion of "not applicable to the Canadian situation"

The PMRA's proposed criterion of "not applicable to the Canadian situation" is very vague language and the meaning is unclear.

PMRA Response

The PMRA acknowledges this comment and the document has been revised for further clarity.

Comment relating to a minimum standard that must be applied for a special review request to proceed

The policy needs to indicate that the preliminary analysis is intended to weed out requests for a special review that do not meet a certain minimum standard.

PMRA Response

The purpose of preliminary analysis is to determine if there are grounds that warrant conducting a special review and if so, identify the aspect(s) of concern which would be the focus of the in depth review under Step 3 of the process. The preliminary analysis will determine if a minimum threshold has been met to trigger a special review.

Comment relating to the requirements under subsection 17(2) of the *Pest Control Products Act,* even if the specific OECD concerns have been evaluated recently

The current wording of the special review provision related to OECD countries limits Ministerial discretion to interpret the reasonableness of conducting a special review. It does not allow for consideration of previously conducted evaluations such as re-evaluation to determine if a special review is warranted, even if the specific area of concern cited by the OECD country has already been recently evaluated. Frivolous requests for special reviews under subsection 17 (2) could unnecessarily consume PMRA resources in the absence of a provision to assess the merit of conducting a special review during a preliminary analysis.

PMRA Response

The *Pest Control Products Act* requires the initiation of a special review, if the conditions outlined in subsection 17(2) have been met, regardless of whether other assessments were recently completed. In these cases, the preliminary analysis will only consist of confirming that the conditions as set out in subsection 17(2) have been met. However, relevant information in the possession of the Minister when the special review is being processed will be considered.

Comment relating to the determination of criteria under subsection 17(2)

The document should provide more details on how the PMRA will determine if criteria under subsection 17(2) are met. Registrants of the active ingredient(s) being considered for special review under 17(2) should be notified and allowed the opportunity to provide information that could help determine if criteria are met.

PMRA Response

The PMRA will perform a preliminary analysis of relevant information to determine if the criteria under subsection 17(2) have been met. The preliminary analysis may include information

from international partners to confirm the details of the OECD ban. Other applicable sources such as information from registrants may also be considered.

Registrants will be notified if a special review is required in accordance with subsection 18(1) and will then be given the opportunity to provide relevant information, if necessary.

Comment relating to communications with interested parties

a) Comments related to communications with registrants

It is our expectation that registrants will have a formal mechanism to respond to questions, submit outstanding data, and challenge assumptions before the final decision document is published. We also expect that communication with registrants through special review will not differ significantly from communication processes currently used in product reviews and re-evaluation.

PMRA Response

The PMRA wishes to clarify that the affected registrants will be formally notified if a special review is initiated and data may be requested. The proposed special review decision will be consulted and the comments received during consultation will be considered before making the final decision. Communications with registrants will not differ from communications processes currently in place for other types of assessments.

b) Comment relating to communications with other parties

There should be a procedure for individuals or bodies with special expertise to play a more active role in the review. The individual making a request for special review must be kept informed of its progress and told how the information provided is being used. As well, the PMRA should include consultation with the relevant associations (producers, distributors, and applicators) using the product(s) proposed for special review. Additional information on value and typical use pattern would be relevant for consideration.

PMRA Response

During the special review process, relevant stakeholders (for example, grower associations) may be consulted for additional information, such as use pattern and application rates to further refine the analysis/assessments.

Any person (for example, from the public, non-government organization or academics, associations) will have the opportunity to provide comments on the proposed special review decision during the consultation period. The PMRA will consider these comments before a final decision is published.

Approach to the Assessment of the Aspect(s) of Concern

Comment relating to the process for science-based assessment

More details should be provided especially on the science-based assessment of the aspect(s) of concern. Periodic re-evaluations are utilized for comprehensive review of active ingredients and could serve as the science-based review of the aspect of concern.

Clarification on how the PMRA determines what studies are considered in the special review (acceptable studies versus excluded studies) and the rationale for exclusion of select studies from the special review.

PMRA Response

The PMRA will use the same stringent scientifically-based risk assessments during the special review process as it does for all other scientific assessments (for example, new product registrations, re-evaluations). Relevant information currently in the Minister's possession as well as information prompting the special review will be considered in the context of the scope of the special review.

Comment relating to incorporating value into the assessment

The determination of acceptable risk and value is not possible solely through the lens of science. Consideration must be given to other factors such as social, health, safety, environmental and economic impacts and benefits.

PMRA Response

A scientifically based approach will be taken to assess the aspect(s) of concern. The acceptability of the health and environmental risks will be assessed in accordance with subsection 19(2) of the *Pest Control Products Act*. The value of a pest control product will be assessed in accordance with its definition in paragraph 2(1) of the *Pest Control Products Act*, which refers to the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration. This includes the product's efficacy, effect on host organism, health, safety and environmental benefits, social and economic impact, and relevant information will be considered.

Comment relating to the process if a re-evaluation is currently underway

Clarity is needed on how a request for special review will be dealt with if a re-evaluation is already underway. Existing federal programs and processes, such as re-evaluation should be considered during the preliminary analysis for special reviews and wherever possible timelines should be coordinated to efficiently support the evaluation.

PMRA Response

Re-evaluations and special reviews are two post-market assessment processes to determine the continued acceptability of the health and environmental risks and value of a registered pest control product. These two processes may move forward in parallel with one another. When there are reasonable grounds to initiate a special review while a re-evaluation is underway, a special review will be initiated on the aspect(s) of concern. Relevant information from existing PMRA reviews will be considered for both special review and re-evaluation.

Comment relating to the timeline for special reviews

The consultation document offers no guidance on what constitutes a “reasonable time” for the PMRA to decide whether to initiate a special review. A proposed timeline should be included in the announcement of a special review.

PMRA Response

The timeline for completing a special review will depend on factors such as the complexity of the aspect(s) of concern being assessed. In addition, other relevant elements may arise and require consideration in the special review. Therefore, a specific timeline will not be included as part of the announcement.

Other Comments

Comment relating to the monitoring of OECD member country decisions

The PMRA should be more proactive in reviewing information regarding bans in OECD member countries. There is no mention in the consultation document of what process the PMRA will use to monitor OECD countries’ prohibitions.

PMRA Response

The PMRA gathers information through participation in international working group meetings such as the OECD and the Rotterdam Convention, as well as from the publicly available databases.

Comment relating to concerns about data protection

The PMRA should reference any relevant data protection and compensation considerations that may be implicated during a special review.

PMRA Response

The PMRA acknowledges the concerns with respect to data protection; however, it is beyond the scope of this document.

Comment relating to international regulatory cooperation

Special reviews should be conducted with a commitment to international regulatory cooperation.

PMRA Response

The PMRA acknowledges the importance of international regulatory cooperation. The PMRA works with its international counterparts to align the processes used to regulate pest control products and protect the health of Canadians and the environment.