Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

# Discussion Document

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# Preliminary Consultation on a Regulation respecting Reconsideration of Registration Decisions

*(publié aussi en français)*

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## Foreword

The new *Pest Control Products Act* (new PCPA) was given Royal Assent on December 12, 2002. It includes a process for the reconsideration of major registration decisions. A major registration decision is a decision to grant or deny an application to register a new active ingredient or major new use, i.e., a use that might result in significantly increased health or environmental risks, or a decision to maintain, amend or cancel a registration following a re-evaluation or special review.

In order to implement the reconsideration process, new regulations must be made to replace the regulations respecting Review Boards under the existing PCPA. The Discussion Document presents the content of a proposed regulation and seeks comments.

Please submit your comments within 30 days of the date of this publication to the Publications Coordinator, Pest Management Regulatory Agency (PMRA). There will also be an opportunity to comment on the proposed regulations when they are pre-published in the *Canada Gazette*, Part I.

The new *Pest Control Products Act* (new PCPA) was given Royal Assent on December 12, 2002. It includes a process for the reconsideration of certain decisions about registrations and authorizations to export. These statutory provisions accommodate greater public participation in the decision-making process. The reconsideration of decisions allows interested parties access to a less formal avenue than that offered by a judicial review process. Although the results of the reconsideration process are not binding on the Minister, the recommendations must be considered by the Minister.

The reconsideration process is initiated by section 35 of the new PCPA which allows any person to file a notice of objection to a major registration decision or to a decision to issue, amend or cancel an authorization to export. A major registration decision is a decision to grant or deny an application to register a new active ingredient or major new use, i.e., a use that might result in significantly increased health or environmental risks, or a decision to maintain, amend or cancel a registration following a re-evaluation or special review.

In order to implement the reconsideration process, new regulations must be made to replace the regulations respecting Review Boards under the existing PCPA. This Discussion Document presents the content of a proposed regulation respecting the reconsideration of registration decisions and seeks comments. At present, there are no plans to make regulations respecting export authorizations since the export of pesticides is adequately regulated by the *Export of Substances Under the Rotterdam Convention Regulations* under the *Canadian Environmental Protection Act* which came into force in December 2002.

## Background

The registration decisions that are subject to reconsideration are the same ones on which the public must be consulted before the decisions are reached. The public consultation provisions in subsection 28(1) of the new PCPA are as follows:

**28.**(1) The Minister shall consult the public and federal and provincial government departments and agencies whose interests and concerns are affected by the federal regulatory system before making a decision

(a) to grant or deny an application

(i) to register a pest control product that is or contains an unregistered active ingredient, or

(ii) to register, or amend the registration of, a pest control product if the Minister considers that registration or amendment of the registration may result in significantly increased health or environmental risks;

(b) about the registration of a pest control product on completion of a re-evaluation or special review;

The consultation is to take place by the issuing of a consultation statement which is to include a summary of the evaluations of the product's health and environmental risks and value, as well as the proposed decision and rationale. The statement may include any other information the Minister considers necessary for the consultation. The Minister may include confidential test data in the statement where it is considered to be in the public interest. The role of the consultation statement is to inform the public of the proposed decision and the rationale for it. Sufficient information is to be provided to enable meaningful comments on the proposed decision.

The comments received must be considered and summarized in the decision statement to be issued following the consultation. While the public may submit any type of comment they choose, only those comments which relate to the basis on which the decision is proposed to be made will have an influence on the final decision.

The final decision is subject to reconsideration. Any person may file a notice of objection to the decision which may lead to the establishment of a panel to review the decision and recommend whether the decision should be confirmed, reversed or varied.

## (A) Reconsideration of decisions

### (I) notice of objection

Subsection 35(1) of the new PCPA provides that a notice of objection is to be "in the form and manner directed by the Minister". The form and manner in which a notice of objection is to be filed would be set out in a guidance document, taking into account the provisions of section 62 of the new PCPA concerning the delivery of documents.

The regulation would specify the information which the notice is to contain. In addition to basic information such as the name of the objector, etc., the notice would indicate the substantive matter to which the objection related, i.e., the health risks, environmental risks, and/or value of the product, and the scientific basis for the objection. Information such as scientific reports or test data that would provide evidence for the objection would also be included. This would serve to focus attention on those matters that are appropriate for a review panel to consider should the Minister decide to establish one.

Subsection 35(1) of the new PCPA provides that a notice of objection be filed within 60 days after the decision statement is made public. The decision statement mentioned above would include the date when the 60-day notice period ends.

### (ii) Minister's discretionary authority

A review panel must be established in accordance with any regulations that have been enacted. However, the decision to establish a panel is discretionary. That gives rise to two important questions: (I) by whom can that discretionary authority be exercised; and (II) on what basis should it be exercised, that is, what criteria should be applied in deciding whether to grant or refuse a reconsideration request.

**(I) who may exercise**

In accordance with paragraph 24(2)(d) of the *Interpretation Act*, the Minister's discretionary authority can be exercised by any official in Health Canada who is employed in an appropriate capacity. Officials who meet the capacity requirements of the *Interpretation Act* may exercise the authority as long as they are not disqualified from doing so by the regulation. It is proposed that the regulation specify that the decision on a notice of objection not be made by an official who participated in the decision to which the notice relates.

**(II) grounds for exercise**

The decision on a notice of objection must be made on the merits of the case presented by the person who filed the notice. In other words, the authority must be exercised on a case-by-case basis. It is important, however, that there be consistency in those decisions.

There is a close relationship between the information required in the notice of objection and the criteria used to decide whether a review panel should be established. The regulation would specify that a review panel be established if the Minister determines that the information in the notice of objection discloses a credible concern about the appropriateness of the evaluations of the scientific information that were conducted or of the conclusions that were reached, on which the decision was based. The concern should be one for which it would be useful and appropriate to seek the advice of one or more expert scientists.

**(iii) notification of decision**

**(I) where request is refused**

If the Minister decides not to establish a panel, subsection 35(5) of the new PCPA requires that the decision and the reasons for it be communicated in writing, without delay, to the person who filed the notice of objection. A standard form of notification could be developed to ensure consistency. Paragraph 42(2)(m) of the new PCPA requires that the decision and reasons be entered in the Register of Pest Control Products.

**(II) where request is granted**

Subsection 35(4) of the new PCPA provides that "The Minister shall give public notice of the establishment of a review panel". Consistent with the policy reflected in subsection 35(5) as noted above, a standard form of notification would be developed to advise the person who filed the notice that the request had been approved and that public notice of the establishment of the panel would be given in due course.

**(III) contents of public notice**

Subsection 35(7) of the new PCPA requires a panel to give any person a reasonable opportunity to make representations in respect of the decision under review in accordance with the terms of

reference. To assist interested persons in deciding whether to make such a request, the regulation would specify that the public notice provide relevant information concerning the decision under review, the terms of reference of the review, the right of persons to be heard, relevant procedural matters that may be established by the Minister under subsection 35(6) of the new PCPA or by regulation and advice on how to communicate with the panel concerning participation in the proceedings. A standard form of public notice would be developed and such notices would be placed in the Register.

#### (IV) terms of reference

Unlike the Review Board provisions under the existing PCPA regulations which allow the person requesting the review to identify matters to be raised before the Board, subsection 35(6) of the new PCPA provides that the Minister determine the terms of reference of a review panel. Consistent with the intent of the Act regarding public participation in the decision-making process, the terms of reference would ensure that the reconsideration process remain a science review and be confined to issues that could be properly dealt with by persons with scientific expertise without reliance on persons trained in the law.

### (B) Selection and appointment of panel members

#### (i) list of eligible panel members

It is proposed that the regulation require the Minister to maintain a list of eligible panel members consisting of persons recommended by the Pest Management Advisory Council or such other independent advisory body as the Minister may designate. Those qualified candidates would have expertise in areas of science that are relevant to the evaluation of the health and environmental risks and value of pest control products and should not have been employed in the federal public service during the preceding year.

#### (ii) selection from the list

Paragraph 24(2)(d) of the *Interpretation Act* also applies to the selection and appointment of review panel members. The regulation would specify that the official who selects candidates from the list and effects their appointment to a panel not be one who participated in the decision to be reviewed. In addition, selection for appointment to a particular panel would be restricted to persons having the appropriate expertise and who affirm that such service would not place them in a conflict of interest.

#### (iii) removal of appointees

The regulation would specify that an appointee would be removable only for cause, including inability or refusal to perform the service without undue delay, or evidence of a conflict of interest giving rise to a reasonable apprehension of bias.

### (C) Remuneration and support

The regulation would specify that panel members would be entitled to an honorarium as well as travel and living expenses in accordance with Treasury Board policy. Provision would be made for such administrative and other assistance as panels may require.

### (D) Review panel report

Subsection 39(1) of the new PCPA provides that the Minister shall confirm, reverse or vary the decision under review after considering the panel's recommendations. That responsibility may be performed by a duly qualified official in accordance with paragraph 24(2)(d) of the *Interpretation Act*. The regulation would specify that an official who participated in the decision under review not be permitted to participate in determining whether the decision under review should be varied or reversed on recommendation of a review panel.

### (E) Rules of procedure

The regulation would ensure that, as an advisor to the Minister, a panel would not be prevented by technical procedural rules from receiving and considering any information that it determines to be relevant to the task which it has been assigned. Nor should the conduct of the review be hampered by technical rules of evidence or procedure. The expertise of the panel members should be relied upon to a significant extent to enable them to determine what information is relevant to the terms of reference, how credible the information is and what weight to give to it.

## Content of Proposed Regulation

It is proposed that the following provisions be included in the regulation.

1. A Review Panel List be established consisting of persons recommended by an advisory council established under section 5 of the new PCPA or any other advisory body designated by the Minister who:
   - are knowledgeable in an area of science relevant to the assessment of the health and environmental risks and value of pest control products, and;
   - have not been employed in the federal Public Service in the preceding year.

2. A person's name would be removed from the List if they no longer meet the eligibility requirements or if they requested their name be removed.

3. A notice of objection must include the following:
   - information to identify the objector and the decision to which the notice relates;
   - the substantive matter to which the objection relates, i.e., health risks, environmental risks, value;
   - the scientific basis for the objection; and
   - evidence to support the objection, including scientific reports or test data.

4. The decision as to whether or not to establish a review panel after receiving a notice of objection must not be made by any official who participated in the making of the decision to which the notice of objection related.

5. A review panel would be established when the following criteria are met:
   - the information in the notice of objection discloses a credible concern about the appropriateness of the evaluations of the scientific information that were conducted, or of the conclusions that were reached, on which the decision was based; and
   - the advice of one or more expert scientists would be useful in addressing the concern.

6. When it is decided to establish a review panel, the panel would consist of one or more persons selected from the Review Panel List who possess scientific knowledge relevant to the terms of reference.

7. A chairperson of the review panel would be appointed to preside at panel hearings and perform assigned functions. A second member could be designated to act in the place of the chairperson when the chairperson was absent or unable to act.

8. Review panel members would be required to provide a written statement indicating that service on the review panel would not result in a conflict of interest and any emerging conflicts would be reported immediately. Where a conflict is reported, the member would be removed from the panel if necessary to ensure impartiality.

9. In the absence of a conflict of interest, a panel member would only be removed at their request or where the member was unwilling or unable to carry out their responsibilities in a reasonable time frame. If a panel member was removed, a qualified replacement would be appointed from the Review Panel List unless the review could be properly completed by the remaining members.

10. The selection, appointment and removal of review panel members must not be done by any official who participated in the making of the decision under review.

11. Review panel members be paid:
    - an honorarium for each day of service; and
    - travel and living expenses while on travel status related to the review.

12. Payment of honoraria and expenses would be made on accounts approved and submitted by the chairperson.

13. A notice of establishment of a review panel would provide:
    - the panel's terms of reference; and
    - information on how individuals could apply to make representations to the panel.

14. An individual wishing to make a representation would be required to submit an application within thirty days of publication of the notice of establishing a review panel. The application would be required to state:
    - the area of the terms of reference about which the applicant wishes to make representations;
    - the form in which the applicant wishes to make the representations: and
    - the substance of the challenge in relation to the decision under review.

15. A review panel would:
    - approve only those parts of an application which it considered to be within the terms of reference of the review;
    - advise the applicant of its decision and reasons for approving or refusing the application; and
    - provide information on how the applicant's representation should be made and how it would be received.

16. The review panel would give those individuals whose applications had been approved a reasonable opportunity to make representations.

17. Review panel proceedings would be informal, expeditious and fair.

18. The review panel could conduct any or all of the review on the basis of written submissions only, provided all participants agreed.

19. Review panel hearings would be held in Ottawa, Ontario.

20. Participants in a hearing would be notified at least 20 days in advance of the time, date and location of the hearing.

21. The chairperson could permit an individual to make representations to the hearing via teleconference or video conference.

22. The review panel could receive and accept evidence and information that it considered relevant to its terms of reference, whether or not the evidence or information would be admissible in a court of law.

23. The review panel could request and receive information and advice from persons who had not made an application to participate in its proceedings or whose applications were refused.

24. The review panel would ensure that participants whose applications were approved and persons whose advice the panel had requested had access to, and the opportunity to make representations on, all information which the panel had accepted as relevant to its terms of reference.

25. A participant who wished to obtain access to confidential test data or confidential business information would be required to submit a written request to the review panel together with a written undertaking not to disclose the information to any person or use it for any purpose other than participation in the proceedings. Such a request would include an explanation of why such access was necessary.

26. The review panel would refuse a request for access to confidential information if it determined the explanation offered did not justify the request.

27. The regulation would require that a person must comply with an undertaking to not disclose confidential information.

28. An undertaking would not apply to any disclosure or use of information that is authorized by the person who provided the information.

29. Where the review panel was unable to reach unanimity, the panel's report would document any differences of position among the panel members.

30. The decision on any recommendation contained in the report of a review panel must not be made by any official who participated in the making of the decision under review.

## Invitation to comment

The purpose of this document is to seek your comments on the proposed regulation. Please review the document and provide your comments in writing. As you review the document and prepare your comments, please consider the following:

- Explain your views as clearly and as 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.
- Whenever possible, support your views and, in particular, concerns, with facts, data, or specific examples.
- Describe any assumptions that you used.
- Provide copies of any technical information or data you used in your comments.
- Please 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 when it is pre-published in the *Canada Gazette* Part I.