Court File No.: T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH

Respondent

Rule 318 CERTIFIED TRIBUNAL RECORD

(Part 3)

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37(A)	Item xx AMC Aug 24, 2022 Response FCA recommendation	
38.	FW Tiger Team project plan	
38(A)	SG TT Describing Leg and RA Framework	SCP and Irrelevant redacted

Mozaffar, Hilda

From: Singal, Tina (HC/SC)
Sent: Monday, April 11, 2022 1:56 PM
To: Bissonnette, Frédéric (HC/SC); Conti, Margherita (HC/SC)
Cc: Mathew, Regi (HC/SC); Silva, Minoli (HC/SC); Girard, Stephanie (HC/SC); Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Satchwill, Trevor (HC/SC); Colley, Adam (HC/SC); Halevy, Miriam (HC/SC); Stiege, Stacie (HC/SC); Larmour, Shela (HC/SC)
Subject: FOR APPROVAL: AMC Tiger Team deck
Attachments: AMC_TT scope_13 Apr 2022.pptx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Fred and Margherita,

Attached is the deck for the presentation to AMC on the Tiger Team scheduled for this Wednesday April 13.

Can you please provide comments/edits by **10 am Tuesday April 12**? Sorry for the quick turnaround (but the deck is short).

Thanks,

Tina Singal
(she/elle)

Stakeholder Engagement Unit
Value Assessment and Re-evaluation Management Directorate
Pest Management Regulatory Agency
Health Canada / Government of Canada
tina.singal@hc-sc.gc.ca / Mobile: 613-852-1453

Unité de mobilisation des intervenants
Direction de l'évaluation de la valeur et de la gestion des réévaluations
Agence de réglementation de la lutte antiparasitaire
Santé Canada / Gouvernement du Canada
tina.singal@hc-sc.gc.ca / Mobile: 613-852-1453

Health Canada Santé Canada

Canada

TIGER TEAM: Describing PMRA's Legislative and Risk Assessment Framework

Presentation to AMC on April 13, 2022

Frédéric Bissonnette and Margherita Conti

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Background

- On February 2, 2022, the Federal Court of Appeal (FCA) issued a decision related to the Safe Food Matters' (SFM) appeal of PMRA's decision to not establish a review panel for the re-evaluation decision for glyphosate.
  - PMRA must redetermine SFM's and Mary Lou MacDonald's Notice of Objection request from 2017 in accordance with the guidance provided by the FCA in paragraph 65 of the Reasons for Judgment.
- The FCA in paragraph 65 set out a long list of criteria for PMRA to consider, including other provisions in the Pest Control Products Act (PCPA) such as the preamble [redacted]
- A Tiger Team was created to assess the FCA's criteria (docket A-85-20, see Annex 1) and develop any necessary updates to the documents outlined below to clarify PMRA's interpretation of the relevant sections of the PCPA and the factors set out in section 3 of the Review Panel Regulations (Regulations).

The decision on the redetermination of the Objections will be undertaken separately.

Tiger Team Scope

Notice of Objection templates and guidance

- Update the Notice of Objection (NoO) internal guidance to develop the criteria around the two factors in the Regulations that must be considered and update the templates to address the FCA criteria.
- Explanations will be added to external guidance to clarify terms such as “scientifically founded doubt”.

> ! External NoO guidance is currently under development (independent of the Tiger Team’s work). RD will be responsible for ensuring the document aligns with the outcomes of the Tiger Team’s work.

Evaluation / Decision publication templates

- Draft wording describing the relevant parts of the PCPA on science reviews and the risk assessment framework used by PMRA for the following documents [redacted]
  - Proposed and Registration Decision (PRD, RD)
  - Proposed Maximum Residue Limit (PMRL)
  - Proposed and Re-evaluation Decision (PRVD, RVD)
  - Proposed and Special Review Decision (PSRD, SRD)

> ! There will be delays to publications as the templates are updated.

Note: This a subset of the decision documents that require updates. RD and VRD will have to update other decision documents (Annex 2)

Tiger Team

- Executive leads: Frédéric Bissonnette and Margherita Conti

- Team members:

Directorate	Representative
EAD	Vedad Izadi
HED	Haris Gisavi
HED	Trevor Satchwill
POD	Miriam Halevy
RD	Stacie Stiege
Transformation	Adam Colley
VRD	Tina Singal, Mei Qi

Target timelines and expected deliverables

- **May 31:** NoO internal SOPs and templates
- **June 22:** Proposed and Special Review Decision (PSRD, SRD) templates updated
- **July 15:** Proposed and Re-evaluation Decision (PRVD, RVD) templates updated
- **July 22:** Proposed and Registration Decision (PRD, RD) templates updated
- **July 29:** Proposed Maximum Residue Limit (PMRL) templates updated

? Currently, NoO decisions are posted to the Public Registry in the language of the request. **Should measures to increase visibility of NoO decisions be considered?** Note, this could impact the workload for the Tiger Team as well as timelines for the addressing the FCA decision on the SFM NoO.

- All timelines include time allotted for AMC review, legal review and approvals.
- Timelines presume **this is a priority initiative**.

! The Tiger Team is composed of senior evaluators and section heads tasked to Agency priority files. Core submission work will be delayed.

Tiger Team recommendations for AMC consideration

Recommendation 1:

Noting the impact on submission timelines, support the proposed scope and timelines for this priority initiative.

Recommendation 2:

Include within the scope of the Tiger Team's work, a proposal to increase transparency for some decisions [redacted].

ANNEX 1: Reasons for Judgement – Docket A-85-20

[65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:

- The specific text, context and purpose of the preamble of the Act;
- The definitions of “health risk” and “acceptable risks” in subsections 2(1) and 2(2) of the Act;
- Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;
- The meaning of “a scientifically based approach” when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;
- The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;
- The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;
- The specific threshold to be met when assessing “scientifically founded doubt” pursuant to the factors set out in section 3 of the Regulations;
- The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations.

[66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.

[redacted]

Mozaffar, Hilda

From: Girard, Stephanie (HC/SC)
Sent: Tuesday, October 4, 2022 2:51 PM
To: Silva, Minoli (HC/SC); Stiege, Stacie (HC/SC)
Subject: RE: FCA tiger team items
Attachments: AMC_TT scope_13 Apr 2022.pptx; AMC BN_13 APR 2022.doc

When Tina was first presenting the project to AMC, it was decided to focus on the two items that Stacie tackled, but it sounded to me that other things had to be done eventually. Attaching material as a refresher.
[redacted]

S

From: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Sent: 2022-10-04 2:20 PM
To: Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Subject: RE: FCA tiger team items

I think the tiger team did cover it all – in two ways. One was the templates for the decisions and the other was the NoO Framework.
M

From: Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>
Sent: 2022-10-04 12:46 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: FCA tiger team items

Hi Stacie
I have copied all the items in the FCA judgment that were suggested for the PMRA to do. The Tiger team covered some of that but not all. Can you indicate in the attached document which one are, in your opinion, completed?
Thanks

Stéphanie
Senior Advisor, CRO - RD
cell: 613-297-1742

Health Canada Santé Canada

Canada

Describing PMRA's Legislative and Risk Assessment Framework

Presentation to AMC on April 13, 2022

Frédéric Bissonnette and Margherita Conti

YOUR HEALTH AND SAFETY... OUR PRIORITY.

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- Team members:

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HED	Haris Gisavi
HED	Trevor Satchwill
POD	Miriam Halevy
RD	Stacie Stiege
Transformation	Adam Colley
VRD	Mei Qi

Target timelines and expected deliverables

Target timeline	Expected deliverables	Team lead
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July 29	Proposed Maximum Residue Limit (PMRL) templates updated	Trevor Satchwill

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! The Tiger Team is composed of senior evaluators and section heads tasked to Agency priority files. Core submission work will be delayed.

Recommendations for AMC consideration

Recommendation 1:

Noting the impact on submission timelines, support the proposed scope and timelines for this priority initiative.

Recommendation 2:

Include within the scope of the Tiger Team's work, a proposal to increase transparency for some decisions [redacted]

ANNEX 1: Reasons for Judgement – Docket A-85-20

[65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:

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- Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;
- The meaning of “a scientifically based approach” when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;
- The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;
- The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;
- The specific threshold to be met when assessing “scientifically founded doubt” pursuant to the factors set out in section 3 of the Regulations;
- The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations.

[66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.

[redacted]

Mozaffar, Hilda

From: de Luna, Lilian (HC/SC)
Sent: Friday, April 22, 2022 4:45 PM
To: Stiege, Stacie (HC/SC); Silva, Minoli (HC/SC)
Subject: FW: NoO criteria-HIGH PRIORITY and URGENT
Attachments: TT_NoO criteria.docx; TT-NoO Criteria-ssms comments1.docx

Importance: High

Follow Up Flag: Follow up
Flag Status: Completed

Dear Stacie and Minoli,
Apologies for the delay in providing this to you. Here are our comments for your consideration.
There are two documents attached to this message. The first one is the document that we received from the Tiger Team through Stacie, which requested our comments (original document). The second document is one where we added our comments in track changes. Most of our comments are on the section that begins with the sentence: "In considering an application, the PMRA determines:" Instead of adding our comments directly on the original document, we placed it in a second document to make it easier to follow.
Thank you,
Lilian

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-04-21 1:52 PM
To: de Luna, Lilian (HC/SC) <lilian.deluna@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: NoO criteria

Hi Lilian,

Attached is the Tiger Team first stab at the criteria. I will be sending it to [redacted] tomorrow. If you have any comments, please let me know before 10am tomorrow.

Thanks,
Stacie

Draft Notice of Objection Criteria

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

(a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;

(b) the decision to which the notice relates and the date on which the decision was made;

(c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(d) the evidence to support the objection, including scientific reports or test data.

Establishing Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

(a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA determines:

- If the scientific basis for the objection is directly linked to ~~within scope of~~ the decision for the pest control product. In doing so, the following ~~may~~will be considered:
    - The basis for the objection is on an aspect of the evaluations conducted with respect to the health or environmental risks or the value of the product prior to taking the decision.
    - It is on an aspect that did or could be reasonably expected to the change the outcome of the health or environmental risk evaluation and as a result the regulatory decision ~~could drive decision-making~~ for the pest control product, since the intention of a panel is to recommend whether the decision should be confirmed, reversed or varied.
- If the evidence supporting the objection can be used in an evaluation. In doing so, the following ~~may~~will be considered:
    - Whether the information was available prior to taking the decision (date of the decision).
    - The information meets the criteria for scientifically acceptable for use in the evaluation of a pest control product. (refer to guidance doc) (see Appendix A)

If the evidence provided in support of the objection, considered ~~in concert~~ with all information available at the time of the decision, ~~on the line of evidence~~ ~~for the basis of the objection~~, presents uncertainty in the evaluation and the decision. ~~In doing so, the following are considered:~~

Commented [ST(1]: From HC Weight of Evidence doc (2019):
Multiple sources and types of evidence may be gathered or submitted and considered in context of "all" available evidence to date. Depending on the regulatory data requirements, the full spectrum of sources and types of evidence may include: ~~randomized controlled clinical trials~~, company and/or third party generated studies of a proprietary nature, peer-reviewed, published scientific literature, expert opinion reports, decisions and analysis reports from regulatory authorities, incident reports, adverse reactions submitted to regulatory authorities, and unpublished data.

Commented [ST(2]: In guidance, include list of what would not meet the criteria. Examples:
- Questions on statutory elements
- Science policy / Tools used by the PMRA in conducting assessments, however inputs / interpretations can be part of an objection
- Common / internationally accepted assessment practices

Provide an appendix that maybe further explains terms or provides examples.

Commented [S(3]: and whether it was used in the assessment.

- ~~Does the information change the evaluation conclusions when assessed and considered with all available, acceptable information.~~

- If there is an uncertainty or issue identified with the evaluation, the ability of a potential panel to be able to provide a recommendation on whether the decision should be confirmed, reversed or varied. The following would be considered:
  - If this area of science is relatively new with little available expertise, particularly in a regulatory context.
  - If the evidence, as the basis of objection, relies on credible scientific rationale providing a markedly different or an opposite conclusion to the evaluation

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	Assessment Criteria for Scientifically Acceptability of the Evidence
A Single Study	PMRA information note[1]
Review with a few selected list of studies from all relevance science	PMRA information note. Health Canada Weight of Evidence document[2]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[1] Information Note: (canada.ca)

[2] weight-evidence-general-principles-current-applications.pdf (canada.ca)

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [ST(4]: Introduce concept of conflicting viewpoints

Commented [I(5]: 'may be' or 'would be' - make same for all?

Commented [G(6]: I took an attempt of saying that in the event that an objector submits international scientific organization/regulatory authorities decisions/scientific rationales to us during the NoO process that we were not aware of, and has a different/opposite conclusion, then we should explore the need for a panel? Similar to the example, I discussed during the meeting - If an objector had sent the IARC glyphosate document and had we not known about it, would that be enough evidence to involve a panel?

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Commented [G(7]: Since we discussed this in meetings, I added a little appendix here to define evidence and types of evidence we may receive. Hope this is what we intended for. Feel free to edit or if you like me to expand this, send me message.

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Draft Notice of Objection Criteria

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

(a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;

(b) the decision to which the notice relates and the date on which the decision was made;

(c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(d) the evidence to support the objection, including scientific reports or test data.

Establishing Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

(a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering a Notice of Objection, the PMRA will take the following steps:

1) Determine if the scientific basis for the objection is directly linked to the decision for the pesticide. In doing so, the following will be considered:
    a. The basis for the objection must be linked to one of the evaluation aspects included in the decision. (These evaluation aspects include the health risk assessment, environmental risk assessment or the value of the product. The majority of PMRA's public consultations are based on decisions that include all aspects; however, some special reviews may focus only on one aspect.)
    b. The basis for the objection must be linked to an evaluation aspect that can reasonably be expected to change the outcome of the regulatory decision for the pesticide.
2) Determine if the evidence provided in support of the objection can be used in an evaluation for the pesticide. In doing so, the following will be considered:
    a. Whether the information was available to the PMRA prior to making the decision (date of the information vs. date of the decision),
    b. Whether the PMRA had already considered the evidence in the decision,
    c. Whether the information meets the criteria for being considered scientifically acceptable for use in the evaluation of a pesticide (see Appendix A).
3) Determine if the evidence provided in support of the objection presents uncertainty for the evaluation and the decision. (This point should be considered in the context of all information available to the PMRA at the time of the decision.)
4) If it is determined that the evidence provided in support of the objection presents uncertainty for the evaluation and the decision, PMRA will determine how the evidence should be reviewed:

Commented [ST(1]: From HC Weight of Evidence doc (2019):
Multiple sources and types of evidence may be gathered or submitted and considered in context of "all" available evidence to date. Depending on the regulatory data requirements, the full spectrum of sources and types of evidence may include: ~~randomized controlled clinical trials~~, company and/or third party generated studies of a proprietary nature, peer-reviewed, published scientific literature, expert opinion reports, decisions and analysis reports from regulatory authorities, incident reports, adverse reactions submitted to regulatory authorities, and unpublished data.

Commented [dLL(2]: Should this be reviewed within the NoO? What conditions should be met to strike a review panel

Commented [ST(3]: In guidance, include list of what would not meet the criteria. Examples:
- Questions on statutory elements
- Science policy / Tools used by the PMRA in conducting assessments, however inputs / interpretations can be part of an objection
- Common / internationally accepted assessment practices

Provide an appendix that maybe further explains terms or provides examples.

Commented [ZS(4]: Should we say see Appendix "X" which lists the types of evidence we would look at such as what Tina listed. And have a list of evidence that don't meet the criteria which Tina and Jamie have noted.

It goes back to how the PMRA defines "evidence".

Commented [ZS(5]: There is a section in DIS2007-01 2.1.2 Criteria for establishing a review panel that has some valid points that maybe included in step 3:
In doing so, the following will be considered:
a. whether the information in the notice raises doubt as to the interpretation of the scientific information, on which the decision was based;
b. whether the information in the notice raises any disagreements as to the applied methodology of the scientific information, on which the decision was based;
c. whether the information in the notice raises concern(s) as to the relative weights given to data impacting on the risk assessment of the scientific information, on which the decision was based;
d. whether the information in the notice raises concern(s) regarding the conclusion reached during the decision making process.

a. An internal review (by scientists not involved in the initial decision) or,
b. An external review (by a panel of scientific experts).

The intention of either review would be to recommend whether the decision should be confirmed, reversed or varied.

In deciding whether an internal or external review should be conducted, the following will be considered:

c. Whether an external review is warranted, particularly in a regulatory context and for new areas of science where expertise may be limited.
d. Whether the evidence provided in support of the objection presents a credible scientific rationale that may result in a markedly different evaluation and a reversal of the decision.

If an internal review will be undertaken, depending on the type and extent of the evidence provided in support of the objection, the information would be reviewed outside the framework of the NoO, under a new Category A/B submission (e.g. a new study provided to PMRA by the registrant to mitigate health risks from occupational exposure) or a new Category N - Special Review (e.g. a recently published study provided to PMRA by an NGO to demonstrate environmental risks to non-target organisms).

If an external review will be undertaken, the information would be reviewed under a new Category H.1.3 submission.

Appendix A: Evidence Type and Criteria for Scientific Acceptability

Evidence Type	Assessment Criteria for Scientifically Acceptability of the Evidence
A Single Study	PMRA information note[1] ~~(add the title and date)~~
Review with a few selected list of studies from all relevant science	PMRA information note. Health Canada Weight of Evidence document[2]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organization's guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[1] Information Note: (canada.ca)

[2] weight-evidence-general-principles-current-applications.pdf (canada.ca)

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [ZS(6]: We need to make it clear that this internal review will be done outside the framework of the NoO via a PA-1 Submission or a special review

Commented [dLL(7]: It would be good to add the criteria that we would use to decide when we would establish a review panel. Please see Susha's comments above.

Commented [dLL(8]: Stakeholders may consider the Cat A/B timelines (as indicated in MOSP) to be too long.

Commented [dLL(9]: Comment from Jamie Munro: We need to ensure timelines for completion of a special review arising from a NoO are short/reasonable.

Commented [G(10]: Since we discussed this in meetings, I added a little appendix here to define evidence and types of evidence we may receive. Hope this is what we intended for. Feel free to edit or if you like me to expand this, send me message.

Commented [dLL(11]: Should the review be conducted within the NoO?

Commented [dLL(12]: Could we add the tile of the document and the year it was published?

Mozaffar, Hilda

From: Bissonnette, Frédéric (HC/SC)
Sent: Tuesday, July 12, 2022 10:52 AM
To: Stiege, Stacie (HC/SC); Silva, Minoli (HC/SC)
Subject: FW: NoO Decision framework v9.docx
Attachments: NoO Decision framework v9.docx

Fyi. [redacted] Replaced with a draft watermark.

From: Bissonnette, Frédéric (HC/SC)
Sent: 2022-07-12 10:51
To: Morrison, Michelle (HC/SC) <michelle.morrison@hc-sc.gc.ca>
Subject: NoO Decision framework v9.docx

Use this version instead (I fixed a couple of typo and added a watermark).

thx

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required the Regulations, PMRA will consider the information as set out in Part 2.

Should the required information listed above not be included in the notice of objection or if the scientific basis is unclear this would factor into PMRAs considerations of whether to establish a review panel. The objector will be informed in writing of the decision

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    c) If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

[1] **Reliable Science**: science that is credible and unbiased.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
    a) Is there is a lack of consensus among government scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
    b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
    c) Is the PMRA of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

Part 3 Next Steps

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), and the objector is consulted and agrees in writing, the objector will be informed and no panel will be established and the decision will be placed in the Public Registry on the PMRA's website.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made after considering the recommendations of the review panel and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision or until the panel is dissolved. The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientific Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Health Canada (2019) Information Note[2] : determining study acceptability for use in pesticide risk assessments

Narrative Review with a list of a few selected studies	Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada.
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Mozaffar, Hilda

From: Silva, Minoli (HC/SC)
Sent: Thursday, September 8, 2022 7:32 PM
To: Stiege, Stacie (HC/SC)
Cc: Satchwill, Trevor (HC/SC); Gisavi, Haris (HC/SC); Qi, Mei (HC/SC)
Subject: FW: revised NoO Decision Framework
Attachments: NoO Decision framework v16 clean.docx

Follow Up Flag: Follow up
Flag Status: Completed

FYI [redacted]
Thanks
Minoli

From: Silva, Minoli (HC/SC)
Sent: 2022-09-08 7:30 PM
To: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca>
Cc: Bissonnette, Frédéric (HC/SC) <frederic.bissonnette@hc-sc.gc.ca>; Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>; Morrison, Michelle (HC/SC) <michelle.morrison@hc-sc.gc.ca>
Subject: revised NoO Decision Framework

Hi Sabrine
This document was approved by AMC 2 weeks ago and has since been revised. Could you circulate it among AMC members for their approval please?
Thank you
Minoli

Minoli Silva
Director | Directrice
Review and Science Integration Division | Division des examens et de l'intégration scientifique
Pest Management Regulatory Agency | Agence de règlementation de la lutte antiparasitaire
Health Canada | Santé Canada
Minoli.Silva@hc-sc.gc.ca
Telephone | Téléphone: 613-769-3406

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a registration decision involving a major new use; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by the Director General of the Value and Re-evaluation Directorate for Notice of Objections involving pre-market registration decisions or the Chief Registrar for Notices of Objection involving post-market registration decisions, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the information required by section 2 of the Regulations, set out above, PMRA will consider the information as set out in Part 2 below.

The objector will be informed in writing if the notice of objection cannot be considered because it does not contain all of the information required by section 2 of the Regulations.

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the *PCPA* and section 2 of the Regulations be met, PMRA will consider section 3 of the Regulations.

Section 3 of the *Review Panel Regulations* states:

The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In evaluating a Notice of Objection, the PMRA will generally consider the following Notice of Objection Review Panel Criteria:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health risks or environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) Is the scientific basis for the objection directly linked to the evaluation of the pest control product?
    b) Was the evidence supporting the objection considered in the evaluation?
        i. Was the information available prior to publishing the decision?
            a. If the information was available, then was it considered in the assessment?
        ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product? (See Appendix A)
    c) Does the scientific basis of the objection and the evidence provided in support of the objection, when considered with all scientifically reliable[1] information available and considered by PMRA at the time of decision, present uncertainty in an aspect of the evaluation?

[1] **Reliable Science**: science that is credible and unbiased.

These criteria are directed at a science-based review of the objection and will inform whether there may be scientifically-founded doubt concerning an aspect of the evaluation on which the final decision was based.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
    a) Is there is a lack of agreement among federal regulatory scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
    b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
    c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?
        i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?
        ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice of the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If PMRA is of the view that the objection raises sufficient scientific concern about the registration, it will assess whether the decision should be suspended until the review panel has provided its final recommendation. The decision to suspend will be placed in the Public Registry on the PMRA's website.

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

<u>Appendix A: Criteria for Scientific Acceptability</u>

Evidence submitted in support of the Notice of Objection	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2]: determining study acceptability for use in pesticide risk assessments?
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada (2018) Weight of Evidence[3]: General principles and current applications at Health Canada met?
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca) [Last accessed 04-08-22]

[3] Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada. weight-evidence-general-principles-current-applications.pdf (canada.ca) [Last accessed 04-08-22]

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO [Last accessed 04-08-22]

Mozaffar, Hilda

From: Silva, Minoli (HC/SC)
Sent: Tuesday, July 26, 2022 4:37 PM
To: Stiege, Stacie (HC/SC)
Subject: RE: NoO decision framework v11
Attachments: NoO Decision framework v11.docx

Follow Up Flag: Follow up
Flag Status: Completed

Few editorial changs and added a couple of comments.
Thank you
Minoli

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-07-26 3:22 PM
To: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: NoO decision framework v11

Hi Minoli,

Can you take a quick look at this before I send it back to [redacted]?

Thanks,
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a registration decision involving a major new use; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by the Director General of the Value and Re-evaluation Directorate for Notice of Objections involving pre-market registration decisions or the Chief Registrar for Notices of Objection involving post-market registration decisions, who will determine if a panel should be established

Commented [SM(1): [redacted]

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required by the Regulations, PMRA will consider the information as set out in Part 2.

~~Should the required information listed above not be included in the notice of objection~~ ~~objector will be informed in writing of the decision~~ ~~to reject the notice of objection.~~ The objector will be informed in writing if the notice of objection cannot be considered because it does not contain all of the information required by s.2 of the Regulations. Where the required information is included , PMRA will consider the notice of objection as set out in Part 2.

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Regulations, which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In assessing an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health or environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) Is the scientific basis for the objection directly linked to the evaluation of the pest control product?
        i. Is the basis for the objection on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision?
        ii. Does the objection concern an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) Was the evidence supporting the objection considered in the evaluation?
        i. Was the information available prior to publishing the decision (date of the decision) ?~~and~~
            a. If the information was available, then ~~W~~was it considered in the assessment?

[redacted]

Commented [SM(9]: Note: The regulations say "and" not "or"

Formatted: Highlight

ii. Does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product? (See Appendix A)

c) Does the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, present uncertainty in an aspect of the evaluation?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
   a) Is there is a lack of agreement among federal government scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
   b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
   c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?
      i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'
      ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice of the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If PMRA is of the view that the objection raises sufficient scientific concern about the registration, it will assess whether ~~the need to suspend~~ the decision should be suspended until the review panel has provided it's final recommendation. The decision to suspend will be placed in the Public Registry on the PMRA's website.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [SM(10]: Replaced 'consensus' and removed the provincial scientists as there are provincial "agencies" who are much like the NGOs.

Commented [ST(11]: Jordan flagged this as a statement that could be problematic.
-What if one regulator has a different opinion?
The regulatory framework in different jurisdictions may also be a factor. There may be differences in registered use pattern, or hazard based elements such as with the EU.

Should this criterion be about the interpretations of a specific study, a specific DACO, or the overall assessment? Or this criterion could be rolled into the lack of consensus in a).

Vedad (EAD) had some comments on this section.

[redacted]

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Criteria for Scientific Acceptability

Evidence submitted in support of the Notice of Objection	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2] : determining study acceptability for use in pesticide risk assessments?
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada met?
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Mozaffar, Hilda

From: Girard, Stephanie (HC/SC)
Sent: Tuesday, October 4, 2022 12:46 PM
To: Stiege, Stacie (HC/SC)
Cc: Silva, Minoli (HC/SC)
Subject: FCA tiger team items
Attachments: Reasons for Judgement.docx

Hi Stacie
I have copied all the items in the FCA judgment that were suggested for the PMRA to do. The Tiger team covered some of that but not all. Can you indicate in the attached document which one are, in your opinion, completed?
Thanks

Stéphanie
Senior Advisor, CRO - RD
cell: 613-297-1742

Reasons for Judgement – Docket A-85-20

In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:

Item	Completed?
The specific text, context and purpose of the preamble of the Act;	
The definitions of "health risk" and "acceptable risks" in subsections 2(1) and 2(2) of the Act;	
Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;	
The meaning of "a scientifically based approach" when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;	
The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;	
The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;	
The specific threshold to be met when assessing "scientifically founded doubt" pursuant to the factors set out in section 3 of the Regulations;	
The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations.	
[66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.	

From: Singal, Tina (HC/SC)
Sent: April 12, 2022 10:04 AM
To: Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Satchwill, Trevor (HC/SC); Colley, Adam (HC/SC); Halevy, Miriam (HC/SC); Stiege, Stacie (HC/SC)
Cc: Larmour, Shela (HC/SC)
Subject: RE: Tiger Team update

Hi everyone,

You should have received an invite for AMC, note it's taking place this afternoon. **We're Item 9, currently scheduled at 2:35pm**.

Reminder, if you haven't already commented on the criteria, please do so: TT_NoO criteria

Hope you can attend.

-Tina

From: Singal, Tina (HC/SC)
Sent: 2022-04-07 11:11 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>
Subject: RE: Tiger Team update

Hey everyone,

The draft AMC deck is available for comment. Still waiting on a date. Please review and comment by COB Friday April 8 so I can move it along for Fred and Margherita to review.
draft AMC deck

It would be ideal if you can brief your management on the Tiger Team scope and workplan in advance of us bringing the item to AMC.

Once we have the AMC date, I'll put in a request for team members to be able to observe the meeting (not sure what the response will be, AMC has been limiting attendance).

Thanks!
-Tina

From: Singal, Tina (HC/SC)
Sent: 2022-04-06 9:01 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>
Subject: Tiger Team update

Hey Tiger Team,

Just wanted to give you a quick status update.

- I met with Fred and Margherita yesterday and they were fine with our proposed scope and workplan. Scope to be confirmed at AMC, particularly around external guidance for NoO.
- I'm trying to get us into AMC next week, but the agendas are full for the next couple weeks. All items on the forward agendas are for information so I'm trying to see if we can bump something to make room. **Adam**, most items are for Transformation so is this something you can help with on your end?
- You should have all received a link to my One Drive folder on the Tiger Team. All relevant docs are there, I can put our source docs there too if folks want. You'll be seeing the AMC deck in there within the next day or so.

Next steps:

- By **COB Friday April 8**: Everyone should have commented / edited on the draft NoO criteria (TT_NoO criteria).
- By **COB Friday April 8**: Stacie should have a list of all the relevant NoO SOPs and templates we have to update or establish.

If you any questions, let me know.

Thanks,
-Tina

Draft Notice of Objection Criteria

Sections 2 and 3 of the *Review Panel Regulations* provide:

Notice of Objection

~~2~~12 A notice of objection referred to in subsection 35(1) of the Act shall include

(a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;

(b) the decision to which the notice relates and the date on which the decision was made;

(c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(d) the evidence to support the objection, including scientific reports or test data.

Establishing Review Panels

~~3~~23 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

(a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA determines:

- If the scientific basis for the objection is directly linked to ~~within scope of~~ the decision for the pest control product. In doing so, the following ~~may~~will be considered:
  - The basis for the objection is on an aspect of the evaluations conducted with respect to the health or environmental risks or the value of the product prior to taking the decision.
  - It is on an aspect that did or could be reasonably expected to the change the outcome of the health, ~~or~~ environmental risk or value evaluation and as a result the regulatory decision ~~could drive decision-making~~ for the pest control product, since the intention of a panel is to recommend whether the decision should be confirmed, reversed or varied.
- If the evidence supporting the objection can be used in an evaluation. In doing so, the following ~~may~~will be considered:
  - Whether the information was available prior to taking the decision (date of the decision) and whether it was considered and used in the assessment ()
  - The information meets the criteria for scientifically acceptable for use in the evaluation of a pest control product. ~~(refer to guidance doc)~~ (see Appendix A)
- If the evidence provided in support of the objection, considered ~~in concert~~ with all scientifically reliable information available at the time of the decision, ~~on the line of evidence for the basis of the objection~~, presents uncertainty in the evaluation and the decision. ~~In doing so, the following are considered:~~

Commented [ST(1]: From HC Weight of Evidence doc (2019):
Multiple sources and types of evidence may be gathered or submitted and considered in context of "all" available evidence to date. Depending on the regulatory data requirements, the full spectrum of sources and types of evidence may include: ~~randomized controlled clinical trials~~, company and/or third party generated studies of a proprietary nature, peer-reviewed, published scientific literature, expert opinion reports, decisions and analysis reports from regulatory authorities, incident reports, adverse reactions submitted to regulatory authorities, and unpublished data.

Commented [ST(2]: In guidance, include list of what would not meet the criteria. Examples:
- Questions on statutory elements
- Science policy / Tools used by the PMRA in conducting assessments, however inputs / interpretations can be part of an objection
- Common / internationally accepted assessment practices

Provide an appendix that maybe further explains terms or provides examples.

Commented [redacted]

Commented [redacted]

Commented [redacted]

Commented [S(6]: and whether it was used in the assessment.

Commented [Q(7R6]: and whether it was considered and used in the assessment.

- ~~Does the information change the evaluation conclusions when assessed and considered with all available, acceptable information.~~

- If there is an uncertainty or ~~issue~~ a lack of scientific consensus identified with the evaluation, the ability of a potential panel to be able to provide a recommendation on whether the decision should be confirmed, reversed or varied. The following ~~would be~~ may be considered:
  - If this area of science is relatively new with ~~little available expertise~~ limited regulatory guidance developed or available expertise, particularly in a regulatory context.
  - If the evidence, as the basis of objection, relies on credible scientific rationale providing a markedly different or an opposite conclusion to the evaluation)

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	Assessment Criteria for Scientifically Acceptability of the Evidence
A Single Study	PMRA information note[1]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[2]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[1] Information Note: (canada.ca)

[2] weight-evidence-general-principles-current-applications.pdf (canada.ca)

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [S(8]: a lack of scientific consensus may be better wording than 'issue'. However, Haris provided some good wording for this in the following bullets

Commented [ST(9]: Introduce concept of conflicting viewpoints

Commented [I(10]: 'may be' or 'would be' - make same for all?

Commented [S(11]: Regulatory guidelines lag behind the science so the scientific expertise may exist but not an accepted regulatory framework. Some alternate wording for consideration.

Commented [G(12]: I took an attempt of saying that in the event that an objector submits international scientific organization/regulatory authorities decisions/scientific rationales to us during the NoO process that we were not aware of, and has a different/opposite conclusion, then we should explore the need for a panel? Similar to the example, I discussed during the meeting - If an objector had sent the IARC glyphosate document and had we not known about it, would that be enough evidence to involve a panel?

Formatted: Normal, No bullets or numbering

Commented [G(13]: Since we discussed this in meetings, I added a little appendix here to define evidence and types of evidence we may receive. Hope this is what we intended for. Feel free to edit or if you like me to expand this, send me message.

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Formatted: Line spacing: Multiple 1.07 li

From:	Stiege, Stacie (HC/SC)
Sent:	July 27, 2022 3:40 PM
To:	Larmour, Shela (HC/SC); Benedict, Christina (HC); Satchwill, Trevor (HC/SC); Gisavi, Haris (HC/SC); Izadi, Vedad (HC/SC); Halevy, Miriam (HC/SC); Qi, Mei (HC/SC); Colley, Adam (HC/SC)
Cc:	Silva, Minoli (HC/SC)
Subject:	Tiger Team documents
Attachments:	RVD main text v3.docx; NoO Decision framework v12.docx

Hi Everyone,

The two documents (NoO Criteria and Legislative/RA Frameworks) are attached. We are trying to get these on the AMC agenda for next week. The aim is to get a decision on the NoO Criteria and for a discussion of the Frameworks. Minoli will present the item but the Team will be invited to be present for any questions that come up regarding the Frameworks. Please feel free to share these documents with your management teams.

I will be escaping the city from August 1-12. Mei has agreed to be the point person for the Team next week.

Thanks,
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a registration decision involving a major new use; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by the Director General of the Value and Re-evaluation Directorate for Notice of Objections involving pre-market registration decisions or the Chief Registrar for Notices of Objection involving post-market registration decisions, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the information required by section 2 of the Regulations, set out above, PMRA will consider the information as set out in Part 2 below.

The objector will be informed in writing if the notice of objection cannot be considered because it does not contain all of the information required by section 2 of the Regulations.

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Regulations, which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In assessing an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health risks or environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) Is the scientific basis for the objection directly linked to the evaluation of the pest control product?
        i. Is the basis for the objection on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision?
        ii. Does the objection concern an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) Was the evidence supporting the objection considered in the evaluation?
        i. Was the information available prior to publishing the decision (date of the decision)?
            a. If the information was available, then was it considered in the assessment?
        ii. Does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product? (See Appendix A)

c) Does the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, present uncertainty in an aspect of the evaluation?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
   a) Is there is a lack of agreement among federal government scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
   b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
   c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?
      i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'
      ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

Commented [redacted]

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice of the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If PMRA is of the view that the objection raises sufficient scientific concern about the registration, it will assess whether the decision should be suspended until the review panel has provided it's final recommendation. The decision to suspend will be placed in the Public Registry on the PMRA's website.

Commented [redacted]

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, ~~without delay,~~ to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Criteria for Scientific Acceptability

[1] **Reliable Science**: science that is credible and unbiased.

Evidence submitted in support of the Notice of Objection	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2] : determining study acceptability for use in pesticide risk assessments?
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada met?
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Health Canada Santé Canada

Canada

TIGER TEAM: Describing PMRA's Legislative and Risk Assessment Framework

Presentation to AMC on April 13, 2022 (TBC)

Frédéric Bissonnette and Margherita Conti

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Background

- On February 2, 2022, the Federal Court of Appeal (FCA) issued a decision on the Safe Food Matters' (SFM) appeal of PMRA's decision not to establish a review panel for the re-evaluation decision for glyphosate.
  - PMRA must redetermine SFM's and Mary Lou MacDonald's Notice of Objection request from 2017 in accordance with the guidance provided by the FCA in paragraph 65 of the Reasons for Judgment.

- The FCA in paragraph 65 set out a long list of criteria for PMRA to consider, including other provisions in the Pest Control Products Act (PCPA) such as the preamble, [redacted]

- A Tiger Team was created to assess the FCA's criteria (docket A-85-20, see Annex 1) and develop any necessary updates to the documents outlined below to clarify PMRA's interpretation of the relevant sections of the PCPA and the factors set out in section 3 of the Review Panel Regulations (Regulations).

The decision on the redetermination of the Objection will be undertaken separately.

Tiger Team Scope

Notice of Objection templates and guidance

- Update the Notice of Objection (NoO) internal guidance ~~and external guidance~~ to include updates to templates to describe relevant parts of the PCPA and Regulations considered in the decision for internal decision making and communication with requesters.
- Definitions will be added to external guidance to clarify terms such as “scientifically founded doubt”.

? Should external NoO guidance be included in the Tiger Team’s scope?

Evaluation / Decision publication templates

- Draft wording describing the relevant parts of the PCPA on science reviews and the risk assessment framework used by PMRA for the following documents [redacted]
  - Proposed and Registration Decision (PRD, RD)
  - Proposed Maximum Residue Limit (PMRL)
  - Proposed and Re-evaluation Decision (PRVD, RVD)
  - Proposed and Special Review Decision (PSRD, SRD)

! There will be delays to publications as the templates are updated.

Note: This a subset of the decision documents that require updates. RD and VRD will have to update other decision documents (Annex 2).

Slide 3

I(0 remove "external" in second bullet
Izadi, Vedad (HC/SC), 2022-04-07T15:50:10.249

H(1 We say in the first line that we will update the internal and external NOO guidance... Why are we asking if it is in the TT mandate?
Halevy, Miriam (HC/SC), 2022-04-07T17:28:33.669

H(2 I think the "evaluation/Decision..." section may need to be edited for clarity.
Halevy, Miriam (HC/SC), 2022-04-07T17:55:37.443

S(3 add "and risk managment"

Objections are on the decision and not specifically on the scientific risk assessment. PMRA decisions take into risk management, and may deviate from the recommendations of the evaluation team
Satchwill, Trevor (HC/SC), 2022-04-08T19:40:35.879

[redacted]

S(7 In discussing with RD, it was confirmed that the guidance doc is being covered off in another initiative and does not need to be included in the Tiger Teams scope.
So I changed the text in the first box to read: "External NoO guidance is currently under development (independent of the Tiger Team's work). RD will be responsible for ensuring the document aligns with the outcomes of the Tiger Team's work."
Singal, Tina (HC/SC), 2022-04-11T17:33:30.650

Tiger Team

- Executive leads: Frédéric Bissonnette and Margherita Conti

- Team members:

Directorate	Representative
EAD	Vedad Izadi
HED	Haris Gisavi
HED	Trevor Satchwill
POD	Miriam Halevy
RD	Stacie Stiege
Transformation	Adam Colley
VRD	Tina Singal

S(3

Timelines and expected deliverables G(0

- **May 31:** NoO internal SOPs and templates
- **June 22:** Proposed and Special Review Decision (PSRD, SRD) templates
- **July 15:** Proposed and Re-evaluation Decision (PRVD, RVD) templates
- **July 22:** Proposed and Registration Decision (PRD, RD) templates
- **July 29:** Proposed Maximum Residue Limit (PMRL) templates
- **Nov 2:** Consultation begins on external NoO guidance

? Currently, NoO decisions are posted to the Public Registry in the language of the request. **Should measures to increase visibility of NoO decisions be considered?** Note, this could impact the workload for the Tiger Team as well as timelines for the redetermining the SFM NoO decision. S(1

- All timelines include time allotted for AMC review, legal review and approvals.
- Timelines presume this is a priority initiative S(2

! The Tiger Team is composed of senior evaluators and section heads tasked to Agency priority files.

Slide 5

G(0 I recommend adding 'Target' before 'timelines. Just in case other priorities cause delays to these dates and our actual dates of meeting these deliverables are different.
Gisavi, Haris (HC/SC), 2022-04-08T13:23:01.217

S(1 suggest '... addressing? the FCA decision on the SFM NoO.
Satchwill, Trevor (HC/SC), 2022-04-08T19:43:43.475

S(2 spell out the implications:
Core submission work will be delayed.
given all the PMRA and Transformation work has such tight timelines, there is no scope to flip-flop on priortization.
Satchwill, Trevor (HC/SC), 2022-04-08T19:47:36.385

S(3 I've made all the suggested edits.
Singal, Tina (HC/SC), 2022-04-11T17:34:02.634

S(4

C(0

Questions for AMC

L(3

- Should external NoO guidance be included in the Tiger Team's scope?
  - Annex 3 provides a summary of currently available external facing guidance on the criteria.
- Should measures to increase visibility of NoO decisions be considered?
- Does AMC support the deliverables and timelines presented?

S(2

Slide 6

C(0 I think this should be positioned as recommendations from TT for approval by AMC - not questions
Colley, Adam (HC/SC), 2022-04-07T17:39:31.037

G(1 I agree. I think we need the external guidance at the end of the day ...
Gisavi, Haris (HC/SC), 2022-04-08T13:34:30.824

S(2 add:
'noting the impact on submission timelines.'
Satchwill, Trevor (HC/SC), 2022-04-08T19:49:33.886

[redacted]

S(4 I've reworked this slide.
Singal, Tina (HC/SC), 2022-04-11T17:35:33.667

ANNEX 1: Reasons for Judgement – Docket A-85-20

[65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:

- The specific text, context and purpose of the preamble of the Act;
- The definitions of “health risk” and “acceptable risks” in subsections 2(1) and 2(2) of the Act;
- Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;
- The meaning of “a scientifically based approach” when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;
- The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;
- The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;
- The specific threshold to be met when assessing “scientifically founded doubt” pursuant to the factors set out in section 3 of the Regulations;
- The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations.

[66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.

H(0

[redacted]

[redacted]

ANNEX 3: Chronology of current Notice of Objection process

Date	Activity	Description of criteria
Oct 2007	Public consultation on *DIS2007-01: Reconsideration of Decisions Under the New Pest Control Products Act*	**Criteria for Establishing a Review Panel** The decision whether to establish a panel must be made on the merits of the case presented by the objector who filed the notice. In general, the following criteria will be considered in determining whether to establish a panel: • whether the information in the notice raises doubt as to the interpretation of the scientific information, on which the decision was based; • whether the information in the notice raises any disagreements as to the applied methodology of the scientific information, on which the decision was based; • whether the information in the notice raises concern(s) as to the relative weights given to data impacting on the risk assessment of the scientific information, on which the decision was based; • whether the information in the notice raises concern(s) regarding the conclusion reached during the decision making process; • whether the advice of one or more expert scientists would be useful and appropriate in responding to the issue(s) identified in the notice; and • whether the Minister has not already received such above noted advice. Objections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a panel.
Jan 2008	*Review Panel Regulations* (SOR/2008-22) came into force	**Establishing Review Panels** **3** The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel: (a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and (b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.
Jan 2009	Public guidance on the new PCPA provisions, *Getting Involved in Canada's Pesticide Regulatory Process*	"The PMRA will consider the Notice of Objection and will establish a review panel to examine the regulatory decision in question if the rationale is found to be valid and scientifically based."

Mozaffar, Hilda

From: Satchwill, Trevor (HC/SC)
Sent: Thursday, July 14, 2022 10:51 AM
To: Silva, Minoli (HC/SC)
Cc: Stiege, Stacie (HC/SC); Munro, Jamie (HC/SC); Satchwill, Trevor (HC/SC)
Subject: RE: [redacted] comments on the NoO internal SOP
Attachments: Item 8_NoO Decision framework v10 [redacted] TS.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Minola,

Thanks so much for your continued help with this. I added some comments onto your version to capture some of the AMC discussion, and some other edits/thoughts for consideration.

Trevor

From: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Sent: 2022-07-13 6:52 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Munro, Jamie (HC/SC) <jamie.munro@hc-sc.gc.ca>
Subject: FW: [redacted] comments on the NoO internal SOP

Hi Trevor
Please see v10 [redacted].
I narrowed the government scientists to Canadian government scientists but am unsure about this now. If you have a better idea please reword.
Thank you
Minoli

[redacted]

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

Commented [SM(1]: When we decide the NoO is science based and should be reviewed we have been sending an e-mail saying we will have a new team of scientists assessing this and we say we will ensure impartiality.

Formatted: Highlight

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required by the Regulations, PMRA will consider the information as set out in Part 2.

Should the required information listed above not be included in the notice of objection or if the scientific basis is unclear this would factor into PMRAs considerations of whether to establish a review panel. The objector will be informed in writing of the decision

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and~~,~~ environmental risks and~~or~~ value of the pest control product? To assess this question PMRA will consider:**
    a) Is~~If~~ the scientific basis for the objection ~~is~~ directly linked to the evaluation of the pest control product?~~.~~ ~~The following will be considered:~~
        - Is ~~T~~the basis for the objection ~~is~~ on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision~~.~~?
        - Does ~~T~~the objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.

    b) Was~~If~~ the evidence supporting the objection ~~could have been used~~ considered in the evaluation?~~.~~ ~~In doing so, the following may be considered:~~
        - ~~o~~ Was ~~Whether~~ the information ~~was~~ available prior to publishing the decision (date of the decision) and ~~whether it~~ was it considered in the assessment?~~.~~
        - Does ~~T~~the information meet~~s~~ the criteria for scientific acceptability for use in the evaluation of a pest control product?~~.~~ (See Appendix A)

Commented [redacted]

Commented [redacted]

Commented [ST(4]: Verbatim with 3(a) of the regs Similar edit requested by Janine (EAD)

Commented [ST(5]: AMC recommended a numbered list so that each point can be referenced clearly [e.g. point 1 a) i of Section 3]

Commented [SM(6]: Thinking of one situation where re-eval consulted certain growers regarding agronomic feasibility of some mitigation measures but missed the celery growers. Celery growers objected. Looking at this criteria now, we would have to consider a panel or find an off ramp (eg: change the label) so they can withdraw!

Commented [redacted]

c) Does~~If~~ the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, presents~~s~~ uncertainty in an aspect of the evaluation~~.~~?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
   a) Is there is a lack of consensus among Canadian government scientists with respect to the ~~e~~evidence presented in the objection, and could it affect the outcome of the evaluation?
   b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
   c) Is ~~the PMRA of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where~~ there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

Commented [ST(8]: I am not sure the intent is to limit this GoC scientist, but I defer to the rest of the TT.
This could be rephrased to make it clear that PMRA will decide.
PMRA will consider the degree of consensus among government regulatory scientists (or scientific opinion of competent regulatory authorities?) with respect to …

Commented [ST(9]: Jordan flagged this as a statement that could be problematic.
-What if one regulator has a different opinion?
The regulatory framework in different jurisdictions may also be a factor. There may be differences in registered use pattern, or hazard based elements such as with the EU.

Should this criterion be about the interpretations of a specific study, a specific DACO, or the overall assessment? Or this criterion could be rolled into the lack of consensus in a).

Vedad (EAD) had some comments on this section.

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until a final decision is made after considering the recommendations of the review panel The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: ~~Evidence Type and~~ Criteria for Scientific Acceptability

Evidence submitted in support of the Notice of Objection~~Type~~	**Assessment Criteria for Scientific Acceptability of the Evidence**

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[1] **Reliable Science**: science that is credible and unbiased.

A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2] : determining study acceptability for use in pesticide risk assessments?-
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada met?-
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

Formatted: Font: (Default) Times New Roman

[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Mozaffar, Hilda

From: Silva, Minoli (HC/SC)
Sent: Monday, July 11, 2022 5:44 PM
To: Stiege, Stacie (HC/SC)
Subject: RE: NoO Criteria v9
Attachments: NoO Decision framework v9.docx

I made a few tweaks. Could we make the appendix A a little more self explanatory?
Also the footnotes seem odd.
Please remove comments and ask Trevor to [redacted].
Minoli

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-07-11 3:09 PM
To: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: NoO Criteria v9

Can you please look this over?

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

Commented [redacted]

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required the Regulations, PMRA will consider the information as set out in Part 2.

Should the required information listed above not be included in the notice of objection or if the scientific basis is unclear this would factor into PMRAs considerations of whether to establish a review panel. The objector will be informed in writing of the decision

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    c) If the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [redacted]

Commented [redacted]

Commented [redacted]

Commented [SM(5]: Is there some reason we have this as a footnote instead of in the body of the text?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
    a) Is there is a lack of consensus among government scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
    b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
    c) Is the PMRA ~~is~~ of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

Part 3 Next Steps

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), and the objector is consulted and agrees in writing, the objector will be informed and no panel will be established and the decision will be placed in the Public Registry on the PMRA's website.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made after considering the recommendations of the review panel and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision or until the panel is dissolved. The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientific Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Health Canada (2019)~~PMRA~~ I~~i~~nformation N~~n~~ote[3] : determining study acceptability for use in pesticide risk assessments

Commented [SM(6]: Is this evidence supporting the objection? I find this Appendix a little difficult to understand.

[3] ~~Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca)~~

Narrative Review with a list of a few selected studies	~~PMRA Information Note. Health Canada Weight of Evidence document~~[3] Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada.
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[3] ~~Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada. weight-evidence-general-principles-current-applications.pdf (canada.ca)~~

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Mozaffar, Hilda

From: Qi, Mei (HC/SC)
Sent: Thursday, June 9, 2022 8:23 AM
To: Stiege, Stacie (HC/SC)
Subject: RE: Panel decision framework

I'm looking at the doc now and will let you know if I have any comments before noon

---

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-09 8:11 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thanks Vedad!

I'm planning to send out a version with all of the comments addressed tomorrow which we can all share with management later today or tomorrow. That said, we might have to have a quick meeting, I haven't had a chance to look at all the comments yet.

Thanks,
Stacie

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-06-08 4:55 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

From: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Sent: 2022-06-08 4:09 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi everyone,

A few minor comments, riffing off the comments from Adam and Miriam.

Thank you,
Trevor

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-08 3:05 PM
To: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

From: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>

Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted]. Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Mozaffar, Hilda

From: Qi, Mei (HC/SC)
Sent: Friday, August 5, 2022 10:44 AM
To: Silva, Minoli (HC/SC)
Cc: Satchwill, Trevor (HC/SC); Stiege, Stacie (HC/SC); Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Halevy, Miriam (HC/SC)
Subject: RE: Tiger Team documents
Attachments: NoO Decision framework v13.docx; RVD main text v5.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Minoli,

Please find attached revised documents.

A couple of notes on the revisions:

1. NoO document: Haris has revised and added all necessary footnotes. Also under 2a) track changed "……federal government scientist" to "PMRA scientists".
2. RVD text: Revised based on comments from HED[redacted] and VRD. [redacted]

Pease let me know if you have any question.

Thanks,
Mei

From: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Sent: 2022-08-04 2:33 PM
To: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Cc: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Subject: RE: Tiger Team documents

So….which one of you wonderful people will [redacted] and send us a clean copy to forward to AMC secretariat?
Minoli

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Sent: 2022-08-04 11:42 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Tiger Team documents

Hi all,

Please find attached revised RVD text doc with track changes and let me know if you have any question/comments.

Thanks,

Mei

From: Qi, Mei (HC/SC)
Sent: 2022-08-04 9:49 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Tiger Team documents

Hi Vedad and all,

As you may already know, the documents will be taken to AMC next week. I understand that Trevor will present the RVD text and Minoli will present the NoO document.

For NoO document, I think Stacie kept comments with responses. I will take a look at the footnote and try to figure out what to do.

Unfortunately, some of us still have challenges when using OneDrive. I believe the documents Stacie shared with us at the bottom of this email were the most recent versions.

Btw, I have received some comments on the RVD text doc (on an older version) from HED senior management, and will try to incorporate them into the most recent version before sharing.

Thanks,
Mei

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-07-29 12:06 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Tiger Team documents

Hi Stacie,

I just noticed the attached NoO criteria still has edits outstanding (I don't know which ones) – e.g. the appendix has footnote 2, with no actual footnote.
Maybe for the RVD main text doc, we could use OneDrive, so everybody's edits are captured in a single document, vs multiple versions over email.

Thanks,
Vedad

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-07-27 3:40 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Tiger Team documents

Hi Everyone,

The two documents (NoO Criteria and Legislative/RA Frameworks) are attached. We are trying to get these on the AMC agenda for next week. The aim is to get a decision on the NoO Criteria and for a discussion of the Frameworks. Minoli will present the item but the Team will be invited to be present for any questions that come up regarding the Frameworks. Please feel free to share these documents with your management teams.

I will be escaping the city from August 1-12. Mei has agreed to be the point person for the Team next week.

Thanks,
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a registration decision involving a major new use; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by the Director General of the Value and Re-evaluation Directorate for Notice of Objections involving pre-market registration decisions or the Chief Registrar for Notices of Objection involving post-market registration decisions, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the information required by section 2 of the Regulations, set out above, PMRA will consider the information as set out in Part 2 below.

The objector will be informed in writing if the notice of objection cannot be considered because it does not contain all of the information required by section 2 of the Regulations.

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Regulations, which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In assessing an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health risks or environmental risks or value of the pest control product? To assess this question PMRA will consider:**
    a) Is the scientific basis for the objection directly linked to the evaluation of the pest control product?
        i. Is the basis for the objection on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision?
        ii. Does the objection concern an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) Was the evidence supporting the objection considered in the evaluation?
        i. Was the information available prior to publishing the decision (date of the decision)?
            a. If the information was available, then was it considered in the assessment?
        ii. Does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product? (See Appendix A)

c) Does the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, present uncertainty in an aspect of the evaluation?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
   a) Is there is a lack of agreement among ~~federal government~~ PMRA scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?
   b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
   c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?
      i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'
      ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

Commented [redacted]

Commented [redacted]

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice of the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If PMRA is of the view that the objection raises sufficient scientific concern about the registration, it will assess whether the decision should be suspended until the review panel has provided it's final recommendation. The decision to suspend will be placed in the Public Registry on the PMRA's website.

Commented [redacted]

Commented [redacted]

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, ~~without delay,~~ to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Criteria for Scientific Acceptability

[1] **Reliable Science**: science that is credible and unbiased.

Evidence submitted in support of the Notice of Objection	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2]: determining study acceptability for use in pesticide risk assessments?
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada (2018) Weight of Evidence[3]: General principles and current applications at Health Canada met?
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca) [Last accessed 04-08-22]

[3] Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada. weight-evidence-general-principles-current-applications.pdf (canada.ca) [Last accessed 04-08-22]

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO [Last accessed 04-08-22]

Mozaffar, Hilda

From: Colley, Adam (HC/SC)
Sent: Wednesday, June 8, 2022 1:49 PM
To: Stiege, Stacie (HC/SC); Larmour, Shela (HC/SC); Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Satchwill, Trevor (HC/SC); Halevy, Miriam (HC/SC); Qi, Mei (HC/SC)
Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_AC.docx

Follow Up Flag: Follow up
Flag Status: Completed

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted] Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

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This is to provide information regarding the reconsideration process specified in the *Pest Control Products Act* and the Review Panel Regulations. It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Commented [CA(1]: Minor point but "major amendment" is used to define major registration decision. Suggest just stick with Act wording.

Note. This is section of Act under consideration for PCPA review.

Commented [CA(2]: I feel like "recommendation" and "consideration by PMRA senior management" leaves too much implied flexibility given the intended purpose of this framework. Propose something like:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established"

Part 1

Section 2 of the Review Panel Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
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c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
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Part 2

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Review Panel Regulations (the Regulations), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
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    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. In doing so, the following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the overall outcome of the health ~~risks~~, environmental ~~risks~~ or value evaluation and the registration conditions of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to making the decision (date of the decision) and whether it was considered and used in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    - If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.
2. **Would the advice of expert scientists assist in addressing the subject matter of the objection?**
    - If there is a lack of consensus identified with the evaluation within Health Canada and the Minister believes that a panel may be of benefit.
    - If this area of science is relatively new with limited regulatory guidance developed or available expertise, particularly in a regulatory context.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [CA(3]: Idea here is to focus on aspects that actually change the outcome of the risk assessment.

A change to a risk assessment variable that in the end makes no change to the conditions of use or conclusion of the assessment should not be included

Commented [SS(4]: with the evidence presented in the NoO and whether it could affect the evaluation

Commented [CA(5R4]: prefer the wording in the comment above that is more precise

Commented [SS(6]: expand to include in the context of the law, regulations and policies

Commented [CA(7R6]: Agree with expanding as in above comment

- If the Minister is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is broad and substantial public interest in the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review or until the panel is dissolved.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Information Note: (canada.ca)
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Commented [redacted]

Commented [CA(9]: Could part 3 be more simply discretion for the Minister if in the public interest to do so. I feel like the current wording is likely to cause problems that ppl will be of opinion that matter has "broad and substantial public interest in the health or environmental risks" and therefore creates a challenging situation to justify not establishing panel

Mozaffar, Hilda

From: Halevy, Miriam (HC/SC)
Sent: Wednesday, June 8, 2022 3:05 PM
To: Colley, Adam (HC/SC); Stiege, Stacie (HC/SC); Larmour, Shela (HC/SC); Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Satchwill, Trevor (HC/SC); Qi, Mei (HC/SC)
Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_ACMH.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

From: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
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[redacted]

[redacted]

[redacted]

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Note. This is section of Act under consideration for PCPA review.

Commented [HM(2]: Adam, I politely and respectfully disagree. The team of evaluators only provide recommendations and it is senior management that makes the decisions. If we don't want to parse out the process we can say" PMRA" will consider… and use the text you proposed.

Commented [CA(3]: I feel like "recommendation" and "consideration by PMRA senior management" leaves too much implied flexibility given the intended purpose of this framework. Propose something like:

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Appendix A: Evidence Type and Criteria for Scientifically Acceptability

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[2] Information Note: (canada.ca)
[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
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Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_ACMHTS.docx

Follow Up Flag: Follow up
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@Adam – are there ideas in place to determine if an issue should go to a SAC vs a panel or vice versa?

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Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_ACMHTSVI.docx

Follow Up Flag: Follow up
Flag Status: Completed

Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

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Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Information Note: (canada.ca)
[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [redacted]

Commented [CA(16]: Could part 3 be more simply discretion for the Minister if in the public interest to do so. I feel like the current wording is likely to cause problems that ppl will be of opinion that matter has "broad and substantial public interest in the health or environmental risks" and therefore creates a challenging situation to justify not establishing panel

Commented [ST(17R16]: There may be situations where the PMRA SAC does not have the expertise or availability to take on some of the issues. A Panel may provide a complementary channel for this.
@Adam – are there ideas in place to determine if an issue should go to a SAC vs a panel or vice versa?

Commented [IV(18R16]: Ditto TS question - when to do a review panel, vs consult the SAC?? Clarity here required.

Mozaffar, Hilda

From: Halevy, Miriam (HC/SC)
Sent: Monday, June 13, 2022 8:20 PM
To: Stiege, Stacie (HC/SC)
Subject: FW: ACTION: REVIEW AND COMMENTS: NOO decision framework - comments from Jordan
Attachments: NoO Decision framework v5.docx

Follow Up Flag: Follow up
Flag Status: Completed

Jordan's

From: Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>
Sent: 2022-06-13 4:26 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Cc: Kivi, Michelle (HC/SC) <michelle.kivi@hc-sc.gc.ca>; Ramos, Julie (HC/SC) <julie.ramos@hc-sc.gc.ca>
Subject: FW: ACTION: REVIEW AND COMMENTS: NOO decision framework

Miriam,

Thanks for this. Some comments attached.

Sincerely,

Jordan

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-10 8:43 AM
To: Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>; Kivi, Michelle (HC/SC) <michelle.kivi@hc-sc.gc.ca>
Cc: Ramos, Julie (HC/SC) <julie.ramos@hc-sc.gc.ca>
Subject: ACTION: REVIEW AND COMMENTS: NOO decision framework

Hello Jordan and Michelle,

This document is sent to you to review and provide comments. The plan (not finalized) is to take it to SMC and following that to AMC. I took part in the WG that drafted and reviewed this document. Track changes was left intentionally to show the comments and changes that were incorporated. Please provide me with comments by June 15, 2022 COB.

Thank you!
Miriam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-10 8:32 AM
To: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>

Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning,

Attached is the latest version of the NoO decision framework. Thanks to everyone for their input and guidance. Please share with your management. I will work with Fred to see where it will be taken for discussion with the DGs. At this point, I think it might be SMC, possibly next week.

Thanks,
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major ~~amendment to a~~ registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established
~~This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.~~

This document provides~~is to provide~~ information regarding the reconsideration of decisions process specified in the *Pest Control Products Act* and the Review Panel Regulations. It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notices of Objection ~~applications~~

Section 2 of the Review Panel Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Commented [HJ(1]: I would recommend starting with what the Act says, and then explicitly introducing the other criteria we want to apply (e.g., "major registration dec'n", "science basis for an NoO") with an explanation for why we are including the (with reference to the objectives of the Act, etc).

Commented [HJ(2]: The online guidance should refer to the relevant parts of the Act and Regs that create the requirements (such as needing to provide a science based objection". This is missing at present: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pdf/pubs/pest/_fact-fiche/involved-participer-eng.pdf

Commented [HJ(3]: While reasonable, it isn't mentioned in s. 35. Apparently it is in the Review Panel Regs, so v ... [1]

Commented [HJ(4]: While we use this terminology in practice, it isn't referenced in s. 28. ... [2]

Commented [GH(5]: I agree that this should be grounded in the PCP Act: ... [3]

[redacted]

Commented [HJ(7]: Will a team of evaluators be struck to review Notices that have no scientific rationale? Or ... [5]

Formatted: Font: (Default) Times New Roman, 12 pt

Commented [HJ(8]: What is this framework?

Formatted: Font: (Default) Times New Roman, 12 pt

Commented [HJ(9]: If this is a science dec'n, should it say SMC, with the dec'n maker being the ED or CR?

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Commented [HM(10]: Adam, I politely and respectfully disagree. The team of evaluators only provide ... [7]

Commented [CA(11]: I feel like "recommendation" and "consideration by PMRA senior management" leaves t ... [6]

Commented [IV(12]: Agree with Adam and Miriam. CH suggestion, replacing highlighted text w: ... [8]

Commented [SS(13]: From Mei: should this be legal requirements

Commented [HJ(14]: The don't appear to be applications

Commented [redacted]

Commented [redacted]

[redacted]

[redacted]

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Review Panel Regulations (the Regulations), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expect scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product?**
    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product, ~~. In doing so,~~ the following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the ~~overall~~ outcome of the health ~~risks~~, environmental ~~risks~~ or value evaluation ~~and the registration conditions~~ of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation, ~~. In doing so,~~ the following may be considered:
        - Whether the information was available prior to ~~making~~ publishing the decision (date of the decision) and whether it was considered ~~and used~~ in the assessment.
        - Whether ~~T~~the ~~information~~ evidence provided meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    - If the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [HJ(19]: What if the objection was about an aspect they say we overlooked?

Commented [HJ(20]: How are we going to assess this? Do we have a description or some examples?

Commented [ST(21]: Suggest removing 'overall'. The typical re-eval decision is continued registration with additional mitigation measures. Depending on the use pattern, mitigation may involve cancellation of certain uses or products. Cancellation of anything is significant regulatory action.
Further, PA1 subs tend to be product based (1 or 2 EPs) while PA2 subs are TGAI based and often involve a broader range of EPs.

Commented [IV(22R21]: Agree

Commented [CA(23]: Idea here is to focus on aspects that actually change the outcome of the risk assessment.

A change to a risk assessment variable that in the end makes no change to the conditions of use or conclusion of the assessment should not be included

Commented [HJ(24]: The first bullet (re: scientific basis) says that those considerations "will" be considered. Here is says "may". Is this on purpose?

Commented [redacted]

Commented [HJ(26]: Is this a universal term?

How do we evaluate credible and unbiased? GLP? We should be specific if possible.

I suspect that some of those objecting could say that many of the studies we used are not "unbiased" since they are provided by industry.

We might need to explain the different between "scientific acceptability" and "scientifically reliable" evidence.

Commented [HJ(27]: How are we defining uncertainty? Since science is never 100% certain, what level of uncertainty is a concern?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection?**
    - If there is a lack of consensus identified with respect to the evidence presented in the objection, and whether it could affect the evaluation, within ~~Health Canada~~PMRA and the Minister believes that a panel may be of benefit.
    - If the area of science is relatively new with limited regulatory guidance available and the PMRA determines that the advice of the panel will aid in the regulatory decision-making process. ~~If this area of science is relatively new with limited regulatory guidance developed or available expertise and the Minister believes that a panel may be of benefit, particularly in a regulatory context.~~
    - If the Minister is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is broad and substantial public interest in the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3 Next Steps

When it is determined that the objection raises a scientifically founded doubt as to the validity of the evaluations ~~has merit~~ and advice of scientific experts(s) would be useful and appropriate in responding to the ~~issue(s)~~doubt(s) identified in the notice, a panel will be established. The objector who filed the notice and the affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review ~~or until the panel is dissolved~~.

Where ~~a request to reconsider a registration decision is refused~~ the Minister decides not to establish a panel, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for ~~refusal~~ the decision will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[2]

[2] Information Note: (canada.ca)

Commented [HJ(28]: At all, or just if it would affect the outcome (e.g., change from acceptable to unacceptable, or change RM measures, etc)?

Commented [HJ(29]: This should say either PMRA or "the Minister", not both.

Commented [HJ(30]: Do we mean at the PMRA level, or at the int'l (e.g., OECD) level?

Commented [HJ(31]: The above references the Minister. We should be consistent re: whether we will refer to the Minister or the PMRA.

Commented [redacted]

Commented [HJ(33]: How are we going to define this?

Commented [CA(34]: Could part 3 be more simply discretion for the Minister if in the public interest to ... [14]

Commented [ST(35R34]: There may be situations where the PMRA SAC does not have the expertise or availab ... [15]

Commented [redacted]

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Commented [HJ(38]: This is different from the regs, which say that the panel would just "assist in address ... [17]

Commented [HJ(39]: Should clarify which actions are legal requirements (e.g., the notice) and which are ... [18]

Commented [HJ(40]: Since the objection needs to raise "scientifically founded doubt as to the validity of the ... [19]

Commented [redacted]

Commented [HJ(43]: If there are reasonable grounds to believe the registration unacceptable risk, then there ... [22]

Commented [HJ(44]: Should say what we mean by this. The Act just says the final dec'n is made after conside ... [23]

Commented [HJ(45]: Why would the suspension end at this point? Do we mean it would end if the NoO is ... [24]

Commented [HJ(46]: Should this say "where the Minister decides not to establish a review panel", to be consis ... [25]

Commented [HJ(47]: s. 35(5) of the Act says the reasons go to the person who filed the NoO. Does it also go i ... [26]

Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

Commented [HJ(48]: how did we come up with this definition?

[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Page 1: [1] Commented [HJ(3] **Hancey, Jordan (HC/SC)** **6/13/2022 10:21:00 AM**

While reasonable, it isn't mentioned in s. 35. Apparently it is in the Review Panel Regs, so we should cite that, so it is clear what is law and what is policy

Page 1: [2] Commented [HJ(4] **Hancey, Jordan (HC/SC)** **6/13/2022 10:22:00 AM**

While we use this terminology in practice, it isn't referenced in s. 28.

[redacted]

Page 1: [3] Commented [GH(5] **Gisavi, Haris (HC/SC)** **6/9/2022 8:13:00 AM**

I agree that this should be grounded in the PCP Act:

- **35 (1)** Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.

Public Consultation

Minister to consult

- **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; or

I think this is important to make a clear distinction here if PMRLs are also subjected to this process. Otherwise, we should fully expect to receive several NoOs when we wrap up the decision on glyphosate MRL

[redacted]

Page 1: [5] Commented [HJ(7] Hancey, Jordan (HC/SC) 6/13/2022 10:28:00 AM

Will a team of evaluators be struck to review Notices that have no scientific rationale? Or will there be a triage?

Page 1: [6] Commented [CA(11] Colley, Adam (HC/SC) 6/8/2022 1:38:00 PM

I feel like "recommendation" and "consideration by PMRA senior management" leaves too much implied flexibility given the intended purpose of this framework. Propose something like:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established"

Page 1: [7] Commented [HM(10] Halevy, Miriam (HC/SC) 6/8/2022 2:12:00 PM

Adam, I politely and respectfully disagree. The team of evaluators only provide recommendations and it is senior management that makes the decisions. If we don't want to parse out the process we can say" PMRA" will consider… and use the text you proposed.

Page 1: [8] Commented [IV(12] Izadi, Vedad (HC/SC) 6/8/2022 4:28:00 PM

Agree with Adam and Miriam. CH suggestion, replacing highlighted text w:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established."

[redacted]

[redacted]

[redacted]

[redacted]

Page 3: [14] Commented [CA(34] Colley, Adam (HC/SC) 6/8/2022 1:31:00 PM

Could part 3 be more simply discretion for the Minister if in the public interest to do so. I feel like the current wording is likely to cause problems that ppl will be of opinion that matter has "broad and substantial public interest in the health or environmental risks" and therefore creates a challenging situation to justify not establishing panel

Page 3: [15] Commented [ST(35R34] Satchwill, Trevor (HC/SC) 6/8/2022 4:02:00 PM

There may be situations where the PMRA SAC does not have the expertise or availability to take on some of the issues. A Panel may provide a complementary channel for this.

@Adam – are there ideas in place to determine if an issue should go to a SAC vs a panel or vice versa?

[redacted]

Page 3: [17] Commented [HJ(38] Hancey, Jordan (HC/SC) 6/13/2022 4:06:00 PM

This is different from the regs, which say that the panel would just "assist in addressing the subject matter"

I suspect that some stakeholders might question what we mean by "useful and appropriate", especially b/c those words aren't in the regs.

Page 3: [18] Commented [HJ(39] Hancey, Jordan (HC/SC) 6/13/2022 4:09:00 PM

Should clarify which actions are legal requirements (e.g., the notice) and which are administrative practices (e.g., informing the objector)

Page 3: [19] Commented [HJ(40] Hancey, Jordan (HC/SC) 6/13/2022 2:33:00 PM

Since the objection needs to raise "scientifically founded doubt as to the validity of the evaluation", is seems unlikely that it can be resolved quickly and efficiently

[redacted]

[redacted]

Page 3: [22] Commented [HJ(43] Hancey, Jordan (HC/SC) 6/13/2022 4:11:00 PM

If there are reasonable grounds to believe the registration unacceptable risk, then there needs to be a special review. Is that what we are saying here?

The regs (s. 36) don't say that suspicion of acceptable risk is needed to suspend. The bar could be lower.

Also, the scientific doubt doesn't need to create concern that the whole registration is unacceptable – just that the validity of the evaluations (which in the case of special review or an amendment could be quite narrow) are in doubt. So, again, I think the bar for suspension is lower than whether the entire registration could pose unacceptable risk.

Page 3: [23] Commented [HJ(44] Hancey, Jordan (HC/SC) 6/13/2022 4:15:00 PM

Should say what we mean by this. The Act just says the final dec'n is made after considering the recommendations of the review panel.

Page 3: [24] Commented [HJ(45] Hancey, Jordan (HC/SC) 6/13/2022 4:17:00 PM

Why would the suspension end at this point? Do we mean it would end if the NoO is withdrawn before the review is completed?

If the suspension is done b/c of "sufficient concern that the registration may pose unacceptable risks", why would a suspension end before a final dec'n is reached?

Page 3: [25] Commented [HJ(46] Hancey, Jordan (HC/SC) 6/13/2022 4:20:00 PM

Should this say “where the Minister decides not to establish a review panel”, to be consistent with 35(5)? It isn’t characterized as a “refusal” of a request in the Act.

Page 3: [26] Commented [HJ(47] Hancey, Jordan (HC/SC) 6/13/2022 4:22:00 PM

s. 35(5) of the Act says the reasons go to the person who filed the NoO. Does it also go in the Register? If so, should cite the section

Mozaffar, Hilda

From: Halevy, Miriam (HC/SC)
Sent: Tuesday, July 12, 2022 4:19 PM
To: Bissonnette, Frédéric (HC/SC)
Cc: Stiege, Stacie (HC/SC); Hancey, Jordan (HC/SC); Kivi, Michelle (HC/SC); Halevy, Miriam (HC/SC)
Subject: FW: Comments on NOO Decision Framework and Response Letters
Attachments: Item 8_SMC_Briefing gly 2017-3047 July 7 POD Comments.DOC

Follow Up Flag: Follow up
Flag Status: Completed

Hello Fred,

Following SMC last week, Directorates were requested to provide input on the SMC package that includes the response letter and the NOO criteria. Please see POD's response below and Jordan's comments in the attached document. Please note that there was a more recent version of the NOO document that was circulated today and as such the comments in the attached document may need to be reviewed and adjusted to the changed text.

Here are a few considerations:

- From an efficiency point of view, in general, all proposals [redacted] before finalizing a recommendation for SMC/AMC. This can avoid situations where a decision needs to be revisited after the decision in light of legal advice received after the initial SMC / AMC decision.
- Consider tasking the SAC with reviewing and providing advice on any scientific elements (i.e., as opposed legal or policy aspects) of the NOO Framework and Criteria, such as the definition of the term "scientifically founded doubt".
- [redacted]
- The Federal Court of Appeal (FCA) issued the decision related to the Safe Food Matters' (SFM) appeal of PMRA's decision on glyphosate and in paragraph 65 the court states that "PMRA should have regard and communicate how it had regard at least to the following" (listed below).
- *"[65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:*
  - *The specific text, context and purpose of the preamble of the Act;*
  - *The definitions of "health risk" and "acceptable risks" in subsections 2(1) and 2(2) of the Act;*
  - *Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;*
  - *The meaning of "a scientifically based approach" when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;*
  - *The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;*
  - *The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;*
  - *The specific threshold to be met when assessing "scientifically founded doubt" pursuant to the factors set out in section 3 of the Regulations;*
  - *The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations."*

Full judicial Decision: https://www.canlii.org/en/ca/fca/doc/2022/2022fca19/2022fca19.html

Thank you.
Miriam Halevy, Ph.D.
(she/elle)
Senior Policy Analyst
Office of Policy and Strategic Advice
Policy and Operations Directorate
Pest Management Regulatory Agency
2720 Riverside Drive Ottawa ON K1A 0K9
E-Mail: Miriam.halevy@hc-sc.gc.ca

DATE: July 7, 2022 **ITEM#**

PROTECTED B

Science Management Committee Briefing

SUBJECT/ISSUE: Redetermination of the Glyphosate: Notice of Objections (NoO) Submission number 2017-3047 to the Re-evaluation Decision Document (RVD2017-01: *Glyphosate*)

CLASSIFICATION: Discussion

TIME NEEDED: 20 min

NAME OF SPONSOR: Frédéric Bissonnette (RD)

A. BACKGROUND

- The purpose of this briefing note is to present the redetermination of the Glyphosate Notice of Objections (NoO) Submission number 2017-3047 in response to the Federal Court of Appeal's decision to set aside PMRA's original decision (January 11, 2019).
  This item was last brought to SMC on May 12, 2022

- As per the *Pest Control Products Act* and the guidance document DIS2007-01, any person may file a notice of objection (NoO) on a scientific basis, requesting the reconsideration of a major registration decision, on which the public was previously consulted, within 60 days after the decision.

- The re-evaluation of glyphosate for all registered uses as an herbicide for the control of a broad range of weeds was completed and the decision (RVD2017-01: *Glyphosate*) published on April 28, 2017.
  - The decision was to grant continued registration of products containing glyphosate with requirements of additional label updates to further protect human health and the environment.

- Eight Notices of Objections were received in response to the re-evaluation decision, RVD2017-01: *Glyphosate*.
  - **June and July 2017**: SMC determined that these NoOs were eligible for review and supported establishing a team of PA1 evaluators to review them.
  - **November 2018**: SMC, based on the findings of the review team concluded that the information provided in the NoOs did not raise scientific-founded doubt as to the validity of the PMRA re-evaluation of glyphosate and that the advice of expert scientists would not assist in addressing the subject matter of the objections.

Commented [HJ(1]: Should there be a reference to the Review Panel Regs in the background: https://laws-lois.justice.gc.ca/eng/regulations/SOR-2008-22/page-1.html#h-745945

Commented [HJ(2]: Note: the PCPA doesn't say this.

- **January 2019**, decision letters were sent to objectors.

- On **February 11, 2019**, Mary Lou MacDonald and Safe Food Matters Inc. challenged Health Canada's decision not to establish a panel of external scientific experts to review the conclusions on the health risks of glyphosate in the final re-evaluation decision with a Judicial Review.
  - **February 13, 2020,** the Federal Court issued its judgement which upheld Health Canada' decision not to establish an expert panel to review the re-evaluation decision.
  - **March 13, 2020,** Safe Food Matters appealed the decision to the Federal Court of Appeal (FCA), which was heard on December 9, 2021.
    - Friends of the Earth Canada / Les Amis de la Terre, The David Suzuki Foundation, and Environmental Defence Canada Inc. were interveners in this appeal.

  - On **February 2, 2022,** the Federal Court of Appeal (FCA) set aside PMRA's decision on Safe Food Matters' Notice of Objection and sent the matter back to PMRA for re-determination based on the guidance provided in the FCA's reasons.
    - The FCA did not question the science underlying the re-evaluation decision. Rather, the Court called upon Health Canada to provide a more comprehensive explanation of how various aspects of the Act apply to the decision.
    - As a result the PMRA must now reconsider the Safe Food Matters' notice of objection, taking into account the Court's guidance set out in its reasons for judgment.

  - On **April 25, 2022** the PMRA notified Safe Food Matters that its NoO, submission number 2017-3047, has been reopened to allow the redetermination of the NoO. An evaluation team has been established from HED to re-evaluate the NoO submission number 2017-3047.

B. ASSESMENTAND RECOMMENDATIONS.

The PMRA created a tiger team to address the recommendations of the FCA decision to be applied to all of PMRA's regulatory decisions. (See AMC presentation April 13, 2022: *Describing PMRA's Legislative and Risk Assessment Framework*).

- The tiger team developed a document, *The Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection* (appendix I) which was presented to SMC June 16, 2022.
- The team also revisited the Framework for Risk Assessment and Risk Management of Pest Control Products to address recommendations of the FCA.

Commented [HJ(3]: If LSU reviewed the document for legal risk it should be mentioned. [redacted]

The objections submitted by Safe Food Matters were revisited based on these criteria developed in response to the FCA's guidance.

NoO Review Panel Criteria 1 (b)(c) and 2 (a)(b)(c) have not been met: The evidence

provided in support of the objection, in conjunction with all scientifically reliable[1] (credible and unbiased) information available and considered by PMRA at the time of the re-evaluation decision (RVD2017-01), does **not** present uncertainty in any aspect of the evaluation. No new scientifically-based data, or similar data that would not have been previously taken into consideration in the lines of evidence during the re-evaluation of glyphosate, were provided by the objector. There is consensus by science experts, and uniformity in global regulatory evaluations related to the health and environmental risks, and value of glyphosate.

Commented [HJ(4]: I don't think Safe Food Matters would agree. It is possible that SAC members would challenge this statement. Suggest deletion

Thus, the risk assessment for the glyphosate re-evaluation, which showed no health concern from the registered uses of glyphosate, remains valid and protective of the Canadian population.

Science Evaluation Team Recommendation: Following careful examination, this response to the Notice of Objection has concluded that Safe Food Matters Inc. has failed to provide scientific information and data that raised a scientifically-founded doubt to justify and/or support their concerns for the toxicology and exposure components of the human health risk assessment of glyphosate. More specifically, there were no data or similar data provided that would not have previously been taken into consideration in the lines of evidence that were used in support of the human health risk assessment during the re-evaluation of glyphosate. Further, given that Health Canada's conclusions on the regulatory acceptability of glyphosate are consistent with those resulting from independent reviews by multiple scientific experts from all other major pesticide regulatory authorities internationally, there is no merit in establishing an expert review panel.

D Recommendation

- Do not convene a review panel and allow the continued registration of products containing glyphosate as per the re-evaluation decision (RVD2017-01: *Glyphosate*).
- The draft letter to the Objector is in Appendix II.

V. SMC Decision

- TBD

C. NEXT STEPS

- If SMC's decision is to close the NoOs:
  - Finalize review documentation;
  - Finalize the letter to the Objector (in Appendix II), including the responses attached;
  - Letter will be reviewed and approved by SMC members if required;
  - Send the letter to translation;

[1]Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca)

- Send the letter to the Objector, and post it on the Public Registry.

Appendix I

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to amend a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

Commented [HJ(5]: Has LSU provided advice on the legal risk of this definition (which isn't in the Act) or its use in this process?

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required the Regulations, PMRA will consider the information as set out in Part 2.

Should the required information listed above not be included in the notice of objection or if the scientific basis is unclear or incomplete this would factor into PMRAs considerations of whether to establish a review panel. The objector will be informed in writing of the decision

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To asses this question PMRA will consider:**
    a) If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    b) If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product.
    c) If the evidence provided in support of the objection, considered with all scientifically reliable[2] information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider:**
    a) If there is a lack of consensus identified with the evidence presented in the objection, and whether it could affect the outcome of the evaluation, and the PMRA determines that advice from a panel of experts may be of benefit to address that doubt.

Commented [HJ(6]: How do we assess "credible and unbiased"? Do we need to specify that?

Commented [HJ(7]: Perhaps the SAC could weigh in on this

Commented [HJ(8]: How do we define consensus? Does everyone need to agree or just most people? If it is the majority, how big a majority?

Commented [HJ(9]: Shouldn't this say if there is "scientifically founded doubt"? That is the first test. Using "lack of consensus" seems to introduce a new test / concept that needs definition.

[2] **Reliable Science**: science that is credible and unbiased.

b) If the area of science is relatively new with limited regulatory guidance available and the PMRA determines that the advice of the panel will aid in the regulatory decision-making process.
c) If the PMRA is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Commented [HJ(10]: Do we need to define this? Do we mean OECD protocols? Internal PMRA protocols? Or, do we mean that the scientific evaluation techniques are not available to PMRA?

Commented [HJ(11]: Do we mean "uniformity" literally (i.e., every country in the world says the same thing"? If not, we should use a different term (e.g., most / all major regulators) to qualify this.

Part 3 Next Steps

Commented [HJ(12]: Should indicate which steps are required by the Act / Regs, so it is clear to PMRA and the public which are legal obligations, and which are a matter of administrative discretion

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), and the objector is consulted and agrees in writing, the objector will be informed and no panel will be established and the decision will be placed in the Public Registry on the PMRA's website.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made after considering the recommendations of the review panel and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision or until the panel is dissolved. The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientific Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[3] : determining study acceptability for use in pesticide risk assessments
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[4]
Systematic Review	Did the systematic review follow PMRA's or an international

[3] Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca)

[4] Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada. weight-evidence-general-principles-current-applications.pdf (canada.ca)

	scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[5]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

Commented [HJ(13]: Is this the dictionary definition? If not, where does this definition apply?

[5] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Appendix II Draft Letter

Reference No. 2017-3047

Mary Lou McDonald
Safe Food Matters Inc.
9 Boardwalk Dr. Unit 107
Toronto, ON
M4L 6T1

Dear Ms. McDonald,

Re: Notice of Objection to Re-evaluation Decision RVD2017-01, Glyphosate

Your notice of objection, filed under subsection 35(1) of the *Pest Control Products Act* (PCPA), regarding the re-evaluation decision for glyphosate has now been reviewed and assessed in accordance with the PCPA and *Review Panel Regulations*.

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection requesting the reconsideration of a major registration decision within 60 days after the decision is made public. The purpose of a Notice of Objection is to identify the area of science supporting the registration or re-evaluation/special review decision to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation. ~~The~~ Health Canada's Pest Management Regulatory Agency (PMRA) undertakes the review of a ~~n~~Notice of ~~o~~Objection pursuant to subsection 35(3) of ~~the~~ PCPA~~*the Act*~~.

Commented [HJ(14]: Are these three purposes?

Are these requirements rather than purposes? If req'ts, where are these established?

PMRA has taken all reasonable measures to ensure impartiality in assessing a Notice of Objection. The information submitted to support the Notice of O~~o~~bjection was reviewed by PMRA scientists who were not involved in the re-evaluation of glyphosate.

The following information was received and reviewed in support of your ~~n~~Notice of ~~o~~Objection:

- Notice of Objection Form
- Notice of Objection document
- Glyphosate in Chickpea - CFIA tests
- Glyphosate in Wheat Bran - CFIA

The PMRA considered the following criteria established in accordance with section 3 of the *Review Panel Regulations*~~review panel regulations~~, to determine if a review panel should be established.

Section 3 of the Review Panel Regulations states:

The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

~~c)~~ a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

~~d)~~ b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

~~NoO~~ **Notice of Objection Review Panel Criteria:** Based on section 3 of the regulations, in evaluating a ~~n~~Notice of ~~o~~Objection, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To asses this question PMRA will consider:**
   - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
     - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
     - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
   - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
     - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
     - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product.
   - If the evidence provided in support of the objection, considered with all scientifically reliable[6] (credible and unbiased) information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.
2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question, PMRA will consider:**
   a) If there is a lack of consensus identified with the evidence presented in the objection, and whether it could affect the outcome of the evaluation, and PMRA determines that a panel may be of benefit.

[6] Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca).

Commented [HJ(15]: Confirm if you need italics and ensure consistency

Formatted: Indent: Left: 0.5", No bullets or numbering

Commented [HJ(16]: Need consistency with this. Sometimes capitalized, sometimes not

Commented [HJ(17]: Since the review is done, should this say "considered"?

Commented [HJ(18]: "considered"?

Also, this repeats the intro sentence

Commented [HJ(19]: Considered?

Commented [HJ(20]: The objector will say there is a "lack of consensus"

b) If the area of science is relatively new with limited regulatory guidance available and PMRA determines that the advice of the panel will aid in the regulatory decision-making process.
c) If PMRA is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Commented [HJ(21]: The objector will say there is a "lack of uniformity"

Your objection was considered according to the criteria outlined above and the PMRA concluded that:

- The notice of objection did not raise scientifically founded doubt as to the validity of the evaluations, on which the decision was based. The evidence supporting the objection was already used in the evaluation; the information was available prior to publishing the decision and it was considered in the assessment. The evidence provided in support of the objection, considered with all scientifically reliable information available considered by PMRA at the time of decision, did not present uncertainty in an aspect of the evaluation.
- The advice of expert scientists would not assist in addressing the subject matter of the objection. There is no lack of consensus regarding the evidence presented in the objection, and whether it could affect the outcome of the evaluation.

Commented [HJ(22]: Objector might "object" to this statement

- **A detailed response to the issues raised in the notice of objection can be found below.**

The Minister of Health's primary objective under the *Pest Control Products Act* (PCPA or the Act) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses value and risks to human health and the environment both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products of acceptable value and risk be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent adverse health impact or pollution of the environment.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

Acceptable risk for the environment and heath, and acceptable value are defined under the Act as follows:

environmental risk, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration

health risk, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

value, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

The objections submitted questioned PMRA's assessment of the health risks. The PMRA's responses to the objections are as follows:

Comment I:
"Desiccation with Glyphosate on Crops Causes MRL Exceedances"

Safe Food Matters (SFM) Inc. cited peer-reviewed scientific literature indicating that the early application of glyphosate as a desiccant (i.e., applying glyphosate to a crop earlier than the registered label use), or the application of glyphosate when seed/grain moisture content is too high, resulted in exceedances of Maximum Residue Limits (MRLs) for some crops. SFM also referenced a third party analysis of data obtained from the Canadian Food Inspection Agency (CFIA) that (erroneously) reported exceedances in wheat bran and chick pea samples. While Safe Food Matters Inc. correctly stated that food containing a pesticide residue that does not exceed the established MRL does not pose a health risk concern, they made the incorrect assertion that foods that do exceed the established MRL do pose a health risk and thus endanger human health.

Health Canada Response:

Glyphosate is approved for "pre-harvest use", not as a "desiccant"
Crops naturally mature and begin to senesce in the fall. This is the natural drying down of the crop. When weeds are present in the mature crop, the drying-down process is slower and can delay harvest operations. In addition, the presence of the weeds makes it more difficult to harvest the crop. Killing the weeds with an herbicide allows the crop to dry down more rapidly, but, in the case of glyphosate, this is through the removal of the green weed plants, not by direct drying of the crop by the herbicide.

Herbicides that are registered for use as a crop desiccant are typically **fast-acting contact herbicides** that quickly kill off the living crop, and the labels of such products clearly indicate the crop desiccant use. In contrast to a desiccant use of an herbicide, some herbicides are

registered for pre-harvest weed control. When this is the case, the label will clearly indicate the pre-harvest application timing, similar to a crop desiccant use, but the label indicates that the pre-harvest application is for the purpose of weed control, typically control of perennial or winter annual weeds. When herbicides are applied pre-harvest to a crop for weed control, the removal of the green, living weeds can facilitate harvesting operations, as the dead weeds pass more easily through the combine, but also because removal of the weeds allows for the natural drying down of the crop as it senesces. It is the removal of the weeds that contributes indirectly to the **natural drying** of the crop, not the effect of the herbicide on the crop itself.

Glyphosate-based herbicides are not registered for use as a crop desiccant. There are no explicit crop desiccant uses on glyphosate-based herbicide labels. The characteristics of glyphosate are **not amenable** to its use as a desiccant – it is slower acting, particularly under cooler environmental conditions leading up to harvest, and it is required to be translocated within the plant to be effective. Glyphosate is registered for pre-harvest application to certain crops (among other registered application timings), and the labels are clear that the pre-harvest applications are for the primary purpose of controlling perennial weeds that are present at the time of harvest. The label then indicates there may be additional harvest management benefits, by drying down crop and weed vegetative growth. **This reference to drying down of the crop is in relation to the natural drying process** that is further facilitated by the removal of weeds present at harvest; it is not a crop desiccant use. While the wording in the final glyphosate re-evaluation decision document (RVD2017-01) does not precisely distinguish a crop desiccant use from a pre-harvest weed control use, it is the product labels and the claims on them that are the primary source of information relating to the registered uses of a product.

The Notice of Objection claimed that glyphosate is used on crops in Canada as a pre-harvest desiccant. As stated above, it is important to note that glyphosate is registered in Canada and elsewhere for **pre-harvest** use on several crops for weed control, for the purpose of killing green weed biomass present in the field at the time of harvest, thereby facilitating harvest. Although the terms “desiccant” and “pre-harvest use” are sometimes used interchangeably, particularly by media and public communications, to refer to the harvest benefit of glyphosate, there is a technical difference. As noted above, glyphosate is a registered pre-harvest use intended to kill green weed biomass present in the field thereby helping the natural drying down of the crop, but it is not registered as a “food crop desiccant” in Canada. This is fully explained in Lovell 2012, one of the articles referenced in the Notice of Objection:

> Although glyphosate products are not desiccants, it’s a common misconception that glyphosate applied prior to harvest will act as a crop desiccant. “There is often a blurring of the term,” says [Clark] Brenzil [provincial weed specialist with the Saskatchewan Ministry of Agriculture]. “Farmers will often say ‘we’re desiccating with glyphosate’ and that’s not the case. Glyphosate kills plants; then it’s left to Mother Nature to dry them down.”
>
> More correctly, says Brenzil, farmers use a pre-harvest application of glyphosate to control perennial weeds. “The glyphosate circulates in the plant and gets down to the roots and controls that perennial weed,” he says. “Pre-harvest is a particularly good time

of year to achieve that, particularly the further north you go."

Glyphosate is approved for pre-harvest use only when the moisture content of the seed/grain of the target crop is less than 30%. This specific use of glyphosate, that is, the "pre-harvest use", is the term used herein in response to this Notice of Objection.

Glyphosate application when seed/grain moisture content is higher than 30% may result in an MRL exceedance

The NoO cited references, which investigated the relationship between seed/grain moisture content and residue levels, show that residues of glyphosate can exceed the maximum residue limits (MRLs) for specific crops if applied as a pre-harvest treatment when the seed moisture content in wheat, canola, red lentils, dry beans and field peas is 40% or greater. This scientifically valid information does not raise scientifically-founded doubt, as similar data were taken into consideration during the registration and re-evaluation of glyphosate, which resulted in the specification on registered glyphosate products labels in Canada, that application **must** be conducted at **less than 30%** moisture content. MRLs for these specific crops were based on crop residue data that were conducted in accordance with this specific use pattern. In other words, as indicated in the response to comments provided in the final glyphosate re-evaluation decision document (RVD2017-01), glyphosate residues on specific food commodities were measured in crop field trial studies that were conducted according to how the product was intended to be used, including the specified 30% or less seed moisture content. Crop field trial studies are required to register a pesticide for each specific use, as per PMRA Residue Chemistry Guidelines (Dir98-02). Therefore, the field trial data used for the establishment of MRLs for glyphosate also sets the conditions that must be adhered to in order to comply with the MRLs, that is, the maximum legally allowed amount of glyphosate residue that may remain on foods when glyphosate is used according to label directions. As the information provided does not highlight any new scientific evidence, this comment does not raise any scientifically-founded doubt nor would the advice of expert scientists provide any further insight on this issue.

MRL exceedance does not automatically equate to a human health risk

MRLs are legally specified under the *Pest Control Products Act* and are enforced by the Canadian Food Inspection Agency (CFIA). The conditions of registration, i.e., the label directions for use, are legal requirements that must be observed by the user in all circumstances. MRLs are set at a level that is reflective of Good Agricultural Practices, well below the amount of residue that could present a human health concern. MRLs are derived using a statistical method intended to ensure that maximum levels calculated for potential residues in treated foods of plant and animal origin will not be underestimated. MRLs are used for monitoring purposes to help ensure the safety of Canada's food supply. When Good Agricultural Practices are followed, including the use of pesticides according to the approved label directions/conditions, residues in foods should comply with MRLs. However, an exceedance of an MRL (see examples below), does not automatically equate to a health risk of concern. That said, when a pesticide residue level exceeds the MRL, follow-up actions for non-compliant products are initiated by CFIA in a manner that reflects the magnitude of the potential health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

Of the cited references, one study by Cessna et al., (2002) reported an MRL exceedance in one out of a total of three flax seed samples from crops treated at 0.9 kg a.i./ha, even though glyphosate was reportedly used according to the registered use pattern. Specifically, a flax crop treated at a seed moisture content of 25% resulted in glyphosate residues at 3.27 ppm, thus slightly exceeding the Canadian MRL of 3 ppm for flax seed. When this residue value of 3.27 ppm in flax seed was incorporated into the dietary risk assessment, it did not alter the risk assessment; both the chronic and acute risks were less than 1% of the acceptable daily intake (ADI) and less than 1% of the acute reference dose (ARfD), respectively. Hence, a single MRL exceedance on its own does not provide scientifically-founded doubt that dietary risk from glyphosate is of health concern, and overall compliance with glyphosate MRLs has also been shown to be very high (see below).

CFIA Monitoring Data

The Notice of Objection also cited an opinion piece by Mitra (2017) that analyzed CFIA monitoring data from food samples tested for glyphosate residues in 2015-2016. Mitra reported glyphosate MRL exceedances in chickpea and wheat bran commodities. However, none of the samples in the Mitra report, in fact, had residues that exceeded the MRL for chickpea (4 ppm for bean) or wheat bran (15 ppm for wheat milling fractions, excluding flour). As such, this analysis by Mitra that incorrectly labelled violations where there were no MRL exceedances, is neither reliable science nor does it raise scientifically-founded doubt. Further to this, the summary report published by the CFIA entitled "Safeguarding with Science: Glyphosate Testing in 2015-2016'' indicated that only 1.3% of all samples tested had residues that exceeded MRLs. These non-compliant data were evaluated by the PMRA and no human health concerns were identified.

The 2015-2016 data analyzed in the 2017 Mitra report is a subset of the CFIA glyphosate monitoring data from 2015-2017. CFIA's analysis of the complete set of monitoring data from 2015-2017, reported 3 of 137 chickpea samples (data not reported by Mitra), or 2%, as having MRL exceedances whereas none of the 100 wheat bran samples were in violation (Kolakowski et al., 2020). Note that although Kolakowski et al. (2020) was published after the publication of the RVD, this article is included here to provide a complete picture of the full data set, as the PMRA conducted a health risk assessment on all exceedances. This article identified that the highest glyphosate residues were found in chickpea flour (4.14 ppm to 12.5 ppm vs the MRL of 4 ppm in 3 non-compliant samples out of 57 samples) and in flour and dried forms of other beans (8.24 ppm and 8.6 ppm vs the MRL of 4 ppm in 2 non-compliant samples out of 169 samples). These exceedances were subject to a human health risk assessment by PMRA and no health concerns were identified. More specifically, the PMRA used the highest level of 12.5 ppm in chickpea flour and the highest level found in other beans (8.6 ppm) to represent the residue for **all** chickpea and bean commodities, which is a highly conservative assumption. These residue levels are in contrast to the 5 ppm US tolerance for beans, (which includes chickpeas), that PMRA used in the dietary risk assessment conducted for the glyphosate re-evaluation (Note: PMRA used the higher US tolerance of 5 ppm rather than the Canadian MRL of 4 ppm in the re-evaluation, to be protective). Even with the higher residue levels for chickpea and other bean commodities, the overall **contribution** to both acute and chronic dietary risk, was less than 1% of the ARfD or the ADI for most population subgroups, and the overall dietary risk was not a concern (12 – 45% of

the ARfD for all population subgroups and 20 – 70% of the ADI for all population subgroups).

As demonstrated in the above examples, exceedance of MRLs in/on a food does not equate to health risk of concern as MRLs for glyphosate are set at a level that is well below the level that could pose risk to humans. Furthermore, the monitoring data show that only a very small proportion of samples tested by the CFIA had residues of glyphosate above MRLs and that none of them were of health concern. As the CFIA's surveillance data is already one of the tools that PMRA uses in monitoring and assessing risk, and no health risks of concern have been identified to date, no further action from PMRA is required to address this point at this time.

Comment II:
"Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01"

Safe Food Matters Inc. stated that it would appear that an examination of the risks arising from dietary exposure to crops that have been desiccated with glyphosate was not part of the Re-evaluation, and maintained that such an examination is necessary, particularly given that mechanisms by which MRLs can be exceeded in desiccated crops, and that data from the CFIA indicates that exceedances are occurring.

Health Canada Response:
This comment appears to arise from the confusion in terminology for pre-harvest use versus desiccant, as explained in the previous section. In PRVD2015-01, in Appendix V, page 99, under "Supervised residues trial studies" it states, "The data support a maximum seasonal rate of 6.2 kg ae/ha in pre-emergent applications and 0.9 kg ae/ha **in pre-harvest applications** for forage crops (PHI 3-7 days) and all other crops (PHI of 7-14 days)." As explained in the response to Comment I, glyphosate is not registered as a desiccant on any crop in Canada, but is registered and used pre-harvest as an herbicide to kill green weed biomass present in the field and facilitate harvest. Thus, the dietary risk assessment conducted during the re-evaluation encompasses all registered food uses, including the pre-harvest use on crops. Furthermore, as indicated in the response to Comment I above, there is reasonable certainty of no harm to human health from the approved uses. As these uses were already included in the human health risk assessment, no further action from PMRA is required to address this point.

Comment III:
Evidence that Dietary Exposure of Desiccated Crops has Increased

Safe Food Matters Inc. expressed concern regarding PMRA's use of CSFII – 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals, and United States WWEIA (What We Eat in America) consumption data to assess dietary risk in the re-evaluation of glyphosate. Safe Food Matters Inc. argued that a dietary risk assessment using these data is inadequate because of the evidence that current levels of consumption and production of desiccated legumes like chickpeas and lentils has increased dramatically. Accurate numbers showing the increase in consumption would increase the numbers for the calculations of glyphosate exposure through diet.

Health Canada Response:
PMRA's dietary exposures assessments (for new actives and re-evaluations, such as for glyphosate) relies upon the "Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™), and uses the most recent version available at the time of the assessment. The PMRA commenced the re-evaluation of glyphosate in November 2009, and the dietary assessment was completed on August 2, 2013. The most up-to-date version of the DEEM-FCID™ program at that time (Version 2.14), incorporated consumption data from US Department of Agriculture (USDA)'s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998".

Although a newer version of the software, using more recent food surveys, was released before the PMRA's 2017 final Re-evaluation Decision, the PMRA did not change the assessment model mid-stream, since it is PMRA's practice to not change the methodology used in conducting the risk assessment that was presented in the consultation document (PRVD2015-01) and, as in the case of glyphosate, there were no health risk concerns based on a highly conservative (i.e., Tier I) risk assessment.

The newer version of the DEEM-FCID™ software became available in the fall of 2013, which uses food consumption data from the United States' National Health and Nutritional Examination Survey, What We Eat in America (NHANES/ WWEIA) from 2005 to 2010. The PMRA compared the exposures from the consumption data from CSFII and NHANES/ WWEIA, which showed that there were no significant differences in exposure between these two versions. In addition, an analysis of Canadian dietary consumption data from the Canadian Community Health Survey (CCHS) and American consumption data from WWEIA also showed no significant differences. The WWEIA data were adopted by the PMRA primarily due to its larger sample size, the fact that it is a continuous survey and that it represents the most recent food consumption data available (SPN2014-01). As such, even with more recent versions of DEEM with updated consumption data, dietary exposure is not expected to be of concern.

It is also important to note that the residue input in DEEM is not directly related to each use scenario of the pesticide. Rather, if a pesticide is registered for several different use scenarios (e.g., pre-emergent use, early post-emergent use and pre-harvest use), then the residue level input in DEEM (a single value in ppm) is that of the **highest** residue observed among all the scenarios tested. Therefore, if the pre-harvest use results in the highest residue levels, it will be assumed that **all** legume crops that are consumed contain residues at levels expected from pre-harvest use. This is a highly conservative assumption. In addition, the dietary risk assessment conducted for the glyphosate re-evaluation assumed 100% of registered crops to be treated, which is also a very conservative assumption. These assumptions are designed to help ensure the assessment is protective of any potential dietary risks.

The Notice of Objection also referenced data from the US pulse production from 2011 to 2016 (Bond 2017) and Canadian principal field crop supply and disposition from 2010 to 2016 from Statistics Canada. Projected rather than actual values for 2017 and 2018 were also presented. The US data showed pulse production increasing from approximately 2.8 billion pounds (2011/12) to

5 billion pounds (2015/16), a 1.8-fold increase. The Canadian data reported total domestic consumption of pulses and special crops increasing from 769,000 metric tonnes (2010-2011) to 1,968,000 metric tonnes (2015-2016), which is a 2.5-fold increase. The Notice of Objection argued that this increase of consumption of pulses and special crops, particularly those subject to pre-harvest use of glyphosate, is evidence and data that are required for an accurate current assessment of glyphosate. It also claimed that the dietary risk assessment conducted for the re-evaluation of glyphosate is inadequate from an evidentiary perspective because it did not consider the evidence that current levels of consumption and production of legumes like chickpeas and lentils, which can be treated pre-harvest, has increased dramatically. As such, accurate numbers showing the increase in consumption would increase the glyphosate exposure estimates through diet.

While PMRA acknowledges the increase of production and consumption of pulses since 2010, this increase is not expected to result in dietary risks of concern (i.e., risks above 100% ADI or 100% ARfD) from glyphosate exposure for the following reasons:

1) The critical commodity analysis of the dietary exposure assessment conducted for the glyphosate re-evaluation, which identifies the specific food commodities that contribute the most to the dietary exposure, showed that no food commodity from pulse crops contributed more than 1% of the total exposure for any population subgroup. However, even if pulse crop consumption increased substantially, because the current dietary exposure estimates are based on highly conservative assumptions, exposure would still be well within acceptable levels (see below).
2) The dietary exposure estimates were well below the ADI, as well as the ARfD: 20 – 70% of the ADI and 12 – 45% of the ARfD for all population subgroups. Thus, a considerable portion of these reference values remains 'available' before any exposure concerns would be identified.

In conclusion, the production and consumption figures provided do not raise any concerns with regard to the health risks associated with eating all foods that may be treated with glyphosate, including pulses. As such, the information provided does not raise a scientifically-founded doubt on the validity of the human health risk assessment conducted during the re-evaluation. Accordingly, there is no merit in establishing a panel of experts, as the evidence provided when taken together with all other lines of evidence included in the conservative risk assessment, does not indicate any potential health risk of concern.

Comment IV:
"MRLs for Unregistered Products Have Not Been Set as Required by the Act"

Safe Food Matters Inc. referenced the 2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture, which stated that the use of glyphosate for the use of "Crop Staging for Pre-harvest Applications" on the crops canary seed, mustard, chickpea, lupin and faba bean is registered under the URMULE program, and because of this "the manufacturer assumes no responsibility for herbicide performance. Those who apply glyphosate to chickpea, lupin, faba bean, canary seed, camelina or mustard do so at their own risk."

Safe Food Matters Inc. claimed that there was no indication in the re-evaluation of glyphosate that the use of desiccation/ pre-harvest management on these additional crops has been assessed for health risks or that MRLs have been established for these crops subject to this use.

Health Canada Response:
The Notice of Objection cited sections 9, 10 and 11 of the *Pest Control Products Act* (PCPA), and stated that section 10 applies to User Requested Minor Use Label Expansions (URMULEs). However, this statement within the Notice of Objection is erroneous, as URMULEs are for Canadian registered uses of registered products, and as such, sections 9 and 11 of the PCPA apply to URMULEs, not section 10.

Furthermore, URMULE submissions were previously reviewed by the PMRA to assess the health risk from glyphosate residues that may result from pre-harvest use on camelina (sub no. 2010-6219), pearl millet (sub no. 2009-2317), canary seed (sub no. 2014-5021), mustard (sub no. 2010-1153), chickpea (sub nos. 2015-1580 and 2005-2797), and lupin and faba bean (sub no. 2005-2797). As there were no health risks of concern, these uses were registered and added to the MONSANTO ROUNDUP WeatherMax with Transorb 2 Technology Liquid Herbicide (PCP# 27487) label at various times, upon completion of the respective submission reviews (i.e., Residues in food commodities resulting from the pre-harvest use of glyphosate on these crops were determined to not pose health risks of concern to any segment of the population, including infants, children, adults and seniors).

Section 9 of the PCPA states that "When making a decision regarding the registration of a pest control product, the Minister shall, if necessary, specify any maximum residue limits for the product or for its components or derivatives that the Minister considers appropriate in the circumstances." Given that the use on pearl millet grain is for animal feed only, an MRL was not established for this commodity, as PMRA does not specify MRLs for animal feed. In addition, an MRL was not established for canary seed since, at the time of registration, canary seed was not considered a food use.

For camelina, mustard, chickpea, lupin and faba bean, the internationally recognized principle of crop grouping was used for the purposes of establishing MRLs, which is described below.

Crop groupings are used in many countries around the world and allow for crop field trial residue data on a "representative" crop to be extended or used as a proxy for other crops within the same crop group. A crop group or subgroup is comprised of crops that are similar in terms of crop morphology (physical characteristics of the crop); growth habits; and the part of the crop that is edible (e.g., the beans inside the bean pods of bean plants). From all the crops listed in a crop group, between two and seven crops are chosen to be representative of the entire group, which are:

a) most likely to contain the highest pesticide residues (based on both supporting data and professional expertise), and
b) most likely to be a major crop in terms of production and/or consumption.

As all crops within a crop group have a similar plant structure and the same part of the crop is eaten, it is expected that pesticide residues for the representative crop will be the same or higher than residues for all other crops within the group when the pesticide is applied the same way.

MRLs are specified under the PCPA for gold of pleasure seeds (camelina) and mustard seeds (condiment type and oilseed type) at 10 ppm, based on residue data for canola, the representative crop for rapeseeds (crop subgroup 20A).

Glyphosate was registered for pre-harvest use on beans (including chickpea, lupin and faba bean) in 1992, based on field trial studies for "white bean", which is the former industry terminology for dry common beans. An MRL of 4 ppm was established on beans as a result of this registered use. Between 2005 and 2015, the PMRA received URMULE submissions to support the use of glyphosate on a variety of specific beans including chickpea, lupin and faba bean, to further clarify the "bean" use on the label. As mentioned above, the PMRA assessed the health risk from the glyphosate residues in/on these specific beans under the URMULE submissions. Therefore, as previously noted, the existing MRL of 4 ppm for beans also applies to chickpea, dried lupin, and dried faba bean, since residues on these crops fall into the same crop group.

As mentioned in the response to Comment III, the dietary risk assessment conducted during the re-evaluation encompasses all registered food uses, including all registered pre-harvest uses on food crops such as camelina, mustard, chickpea, lupin and faba bean, and was not a health concern. As these uses were already included in the human health risk assessment, no further action from PMRA is required to address this point.

Comment V:
"Label Amendments Don't Address Risk"

Safe Food Matters Inc. states that the risk to human health from consuming crops that have been desiccated with glyphosate when moisture content is high is not mitigated by the proposed label amendments from the re-evaluation. It argues that there is no reasonable certainty that no harm to human health or future generations will result from dietary exposure to glyphosate, given that

1) **no label statements were proposed that would mitigate risk to human health from desiccation, and**
2) **any such label statements would not with reasonable certainty be effective due to the following:**
    a. **visual indicators of moisture content in the plant are subjective,**
    b. **the different stages of maturity in indeterminate plants such as pulse crops, and**
    c. **the unpredictability of the weather which can affect moisture content.**

Health Canada Response:
As indicated in response to Comment I, the labels are explicit that pre-harvest applications must be done when grain moisture is less than 30%. The visual indicators on the labels provide

additional guidance in terms of how to determine when that moisture threshold is reached, with the moisture content as part of the directions of use. Applications to crops with greater than 30% moisture content in the grain would be inconsistent with the label directions and considered non-compliant. It should also be noted that it is relatively simple for growers to take a small sample of the grain and have it quickly tested for moisture content to ensure that the timing of pre-harvest applications is correct.

As described in the responses to previous comments from the Notice of Objection, the residue data used to establish MRLs were based on this specific pre-harvest use pattern. The resulting MRLs were then used to conduct the dietary risk assessment for the glyphosate re-evaluation, which did not identify any health risks of concern.

It is acknowledged that some pulse crops have an indeterminate growth characteristic, which leads to continuous seed production and "mature pods at the bottom of the plant and greener material at the top" (Brenzil 2012). This may result in application of glyphosate to crops that have seed at the top that are higher in moisture content than the seed at the bottom. However, since the seed at the top would not be fully mature at the point of harvest, this seed would not be marketable. Furthermore, there are strict standards by the Canadian Grain Commission that must be respected for pulses to ensure the quality of seed; as such, the immature seeds would not be allowed to enter commercial channels.

In addition to the fact that growers must follow the directions of use on the label, it should also be noted that it is not in the best interest of growers to use a pre-harvest application of glyphosate when grain moisture content is greater than 30%, since incorrect timing of pre-harvest herbicides can

a) have a negative impact on crop maturity;
b) interrupt the process of seed filling, resulting in yield loss; and
c) as mentioned by the objector, result in more herbicide residue in the seed (Brenzil 2012).

As no new scientific data were provided, no scientific-founded doubt has been raised. As such, there is no merit in establishing an expert review panel.

Comments VI, VII, and VIII:
"No Consideration of Whether Labels are Followed"
"Enforcement of Any Imposed Label Requirements on Desiccants Not Likely"
"Unlikely that Following Labels Will Bring No Harm, since Statutory Regime Contemplates Exceedances of MRLs Even When Labels are Followed"

Safe Food Matters Inc. presented three concerns regarding the effectiveness of labelling and label enforcement: a) citing the percentage of non-compliance according to PMRA's 2015-2016 Compliance and Enforcement Report; b) arguing that enforcement of any requirements regarding moisture content on the labels would be practically and administratively difficult, thus requirements would be unlikely followed; and c) presenting the possibility of MRLs being exceeded even when labels are followed, thus it is uncertain that no harm will result from glyphosate exposure.

Health Canada Response:
There are specific regulatory mechanisms by which compliance with labelling for pest control products is enforced. For example, it is an offence under the Act if a pest control product such as glyphosate is not used in accordance with the label directions. The Regulatory Operations and Enforcement Branch of Health Canada monitors compliance through inspections and compliance programs that investigate adherence to pesticide label directions. Furthermore, as described previously, the CFIA monitors pesticide residue levels in food commodities and reports MRL exceedances to the PMRA, which are assessed for health risks and subsequent follow up action by CFIA, as warranted. To date, the few glyphosate MRL exceedances identified have not resulted in any risks of concern to Canadians and glyphosate exposure via residues in the diet is well within acceptable levels.

Regarding other concerns on the effectiveness and enforcement of labelling, these are unfounded, non-scientific assertions and, therefore, fall outside of the scope of the Notice of Objection process under the Regulations.

As no new scientific data were provided, no scientific-founded doubt has been raised. As such, there is no merit in establishing an expert review panel.

Comment IX:
"Reductions of Safety Factor Without Scientific Rationale"

Part A
Safe Food Matters Inc. referenced the aggregate risk assessment in PRVD2015-01 conducted for children 1 to less than 2 years old, that examined dermal exposure to glyphosate along with incidental oral exposure (hand-to-mouth) from contact with treated lawns/turf in conjunction with chronic dietary exposure (food and drinking water). This aggregate exposure scenario initially assumed a glyphosate application rate of two applications with a seven day interval. At that application rate, the aggregate MOE for children (1 to < 2 years old) did not reach the target of 100. Therefore, refinements to the risk assessment were required.

Safe Food Matters Inc. claimed that in response to this finding, PMRA changed the aggregate assessment without a reliable scientific rationale, to one application of glyphosate with a seven-day time-weighted turf transferable residue average for the entire aggregate assessment for all populations. The average residues of glyphosate were calculated over a seven-day span, rather than assuming exposure to residues immediately after application. In addition, Safe Food Matters Inc. stated that this refinement of the aggregate risk assessment in effect reduced the 10-fold safety factor by changing the application rates, since the 10-fold factor would have been exceeded had the application rates stayed the same.

Health Canada Response to Part A:
The approach of conducting the aggregate risk assessment for children 1 to less than 2 years old,

who may be exposed to glyphosate, followed the method described in Science Policy Note SPN2003-04: *General Principles for Performing Aggregate Exposure and Risk Assessments*.

As described in PRVD2015-01, the initial risk assessment for children 1 to <2 years old exposed to glyphosate, the target MOE of 100 was not reached when aggregating chronic dietary exposure (food and drinking water) and postapplication exposure (dermal and incidental dietary) from entering turf treated with two applications, 7 days apart. As per SPN2003-04, "the PMRA believes, however, that the co-occurrence of high-end food, drinking water and residential exposure scenarios will often be impossible or, at best, highly unlikely." As such, the assumptions in the aggregate risk assessment were adjusted to represent a more realistic scenario, which included the use of the following:

- Canadian MRLs instead of American tolerances/Codex MRLs for barley, oats and wheat, since 99% of these crops consumed in Canada are produced in Canada;
- A typical application pattern of only one application at the maximum application rate; and
- A 7-day time-weighted average turf transferrable residue value.

Using the parameters described above, the refined (i.e., more realistic) aggregate risk assessment for children 1 to <2 years old resulted in a calculated MOE that reached the target MOE of 100. The target MOE of 100 was not reduced in the aggregate risk assessment.

Part B

Safe Food Matters objected to reductions of the PCPA safety factor from 10-fold to 1-fold for most populations and to 3-fold for the ARfD for females 13 – 49 years of age, asserting there was no scientific rationale with regards to the serious endpoint of cardiovascular malformations in the rabbit developmental toxicity study. Safe Food Matters indicated that the tempering of the concern surrounding the "serious endpoint" based on the presence of maternal toxicity does not appear to be permitted, based on the approach outlined in SPN2008-01.

Health Canada Response to Part B:

The basis for this objection is the objector's alternate interpretation of SPN2008-01[7], the document pertaining to how the PMRA applies the PCPA safety factor. This document was written by the PMRA; however, prior to finalization of this document, the PMRA published a draft document for consultation, held two stakeholder workshops, and received comments from expert scientists. In the re-evaluation of glyphosate, the PMRA considered the PCPA factor in a manner consistent with SPN2008-01, and applied similar principles of other regulatory jurisdictions.

[7] PMRA (Pest Management Regulatory Agency), 2008, Science Policy Note (SPN2008-01): The Application of Uncertainty Factors and the *Pest Control Products Act* Factor in the Human Health Risk Assessment of Pesticide. Available online from http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2008-01/index-eng.php [Last accessed May, 2022]

Due to study-specific and complex considerations that must be taken into account in each situation, SPN2008-01 does not list all possible findings where the level of concern for serious effects (such as malformations) may be reduced in the presence of maternal toxicity. However, this scenario is addressed by the first paragraph of Section 4.1 of SPN2008-01:

"Under the new PCPA, the PMRA must apply a default 10-fold factor (the PCPA factor) unless the PMRA concludes, based on reliable data, that a different factor is appropriate for the protection of infants and children. Determination of the magnitude of the factor involves evaluating the completeness of the data with respect to exposure of and toxicity to infants and children as well as potential for prenatal or postnatal toxicity (see Figure 2). Incomplete toxicology databases are not equally incomplete and all prenatal and postnatal toxicities are not of equal concern. For these reasons, the PMRA makes specific case-by-case determinations as to the size of the PCPA factor if reliable data permit. An integrative approach is taken to optimize use of all available information. A PCPA factor less than or equal to 10-fold or, in very rare circumstances, greater than 10-fold may be employed in an assessment. Given the extensive data typically available for a given pesticide, the PMRA believes that in most instances, there will be sufficient reliable data to conduct an individualized assessment of the factor necessary to assure the safety of infants and children."

In determining whether the PMRA can reduce the PCPA factor, the PMRA takes into account contextual information such as the impact of a chemical on the health of the maternal animal. Concern is lessened when fetal toxicity occurs in the presence of maternal toxicity since maternal toxicity, in and of itself, can result in effects on the fetus that is not specific to the mechanisms of toxicity of the chemical. Decreased maternal body weight or body weight gain at sensitive stages of development can result in changes in the fetus independent of direct chemical insults on the fetus. For some effects, protecting maternal health will serve to limit fetal exposure and toxicity. Conversely, a higher level of concern reflected in retention of a PCPA factor of 10-fold is accorded to serious effects that are observed in the fetus at doses that do not adversely affect the maternal animal. In addition, this was the only study in the rabbit, amongst several developmental and reproductive toxicity in rats and rabbits, where there was any evidence of fetal toxicity at the maternal lowest adverse effect level (LOAEL), as offspring effects typically occurred at higher doses than in maternal rabbits. Thus, the weight of evidence supports the conclusion that glyphosate levels that do not cause toxicity in maternal animals would not cause toxicity in the offspring.

The objector provided a different interpretation of SPN2008-01 but did not provide any evidence to support their objection. As such, the objection does not raise a specific scientifically-founded doubt as to the validity of the evaluations. In addition, given the consistency with other international scientific regulatory authorities, and the fact that PCPA factor applied in this assessment offers even more fetal protection relative to some other international jurisdictions, further advice of expert scientists would not assist in addressing the subject matter of the objection.

Summary: Following careful examination, this response to the Notice of Objection has concluded that Safe Food Matters Inc. has failed to provide scientific information and data that raised a scientifically-founded doubt to justify and/or support their concerns for the toxicology and exposure components of the human health risk assessment of glyphosate. More specifically, there were no data or similar data that would not have previously been taken into consideration in the lines of evidence that were used in support of the human health risk assessment during the re-evaluation of glyphosate. Further, given that Health Canada's conclusions on the regulatory acceptability of glyphosate are consistent with those resulting from independent reviews by multiple scientific experts from all other major pesticide regulatory authorities internationally, there is no merit in establishing an expert review panel.

NoO Review Panel Criteria 1 (b)(c) and 2 (a)(b)(c) have not been met: The evidence provided in support of the objection, in conjunction with all scientifically reliable information available and considered by PMRA at the time of the re-evaluation decision (RVD2017-01), does **not** present uncertainty in any aspect of the evaluation. No new scientifically-based data, or similar data that would not have been previously taken into consideration in the lines of evidence during the re-evaluation of glyphosate, were provided by the objector. There is consensus by science experts, and uniformity in global regulatory evaluations related to the health and environmental risks, and value of glyphosate.

The risk assessment for the glyphosate re-evaluation, which showed no health concern from the registered uses of glyphosate, remains valid and protective of the Canadian population. As a consequence, there will be no further action taken on this Notice of Objection.

Should you have any questions regarding this letter, please submit them to the Notice of Objection e-mail account (pmra.noo-ado.arla@hc-sc.gc.ca) and we will respond as soon as possible. Please quote Reference Number 2017-3047 in any correspondence regarding the Notice of Objection to the re-evaluation of glyphosate.

Sincerely,

Frédéric Bissonnette
Chief Registrar
Pest Management Regulatory Agency

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Zhang, T. 2015. Evaluation of Herbicides as Desiccants for Lentil (*Lens culinaris* Medik) Production. MSc thesis, University of Saskatchewan, Saskatoon.

Mozaffar, Hilda

From: Duncan, Lisa (HC/SC)
Sent: Thursday, June 16, 2022 10:52 AM
To: Stiege, Stacie (HC/SC)
Subject: NoO comments
Attachments: NoO Decision framework v6.docx

Lisa Duncan, M.Sc.
(she | elle)
Director | Directrice
Submission, Information Management and Business Analysis Division | Division des demandes d'homologation, de la gestion de l'information et de l'analyse des activités
Pest Management Regulatory Agency | Agence de réglementation de la lutte antiparasitaire
Health Canada | Santé Canada

lisa.duncan@hc-sc.gc.ca
Telephone | Téléphone: 343-540-5842
Government of Canada | Gouvernement du Canada

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection ~~applications~~

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

[redacted]

Commented [redacted]

Commented [DL(2]: Shiva seemed to want more clarity here (re major new use?)

Commented [GH(3]: I agree that this should be grounded in the PCP Act:

- **35 (1)** Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.

Public Consultation
Minister to consult

- **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; ... [1]

[redacted]

Commented [DL(5]: Clarify if economic or financial is included in value? Jamie Munro comment. It may be considered but we do not have the flexibility like the US to carry out a cost benefit against the risks.

[redacted]

[redacted]

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expect scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To asses this question PMRA will consider:**
    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)

[redacted]

- If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider:**
    - If there is a lack of consensus identified with the evidence presented in the objection, and whether it could affect the outcome of the evaluation, and the PMRA determines that a panel may be of benefit.
    - If the area of science is relatively new with limited regulatory guidance available and the PMRA determines that the advice of the panel will aid in the regulatory decision-making process.
    - If the PMRA is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3 Next Steps

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), and the objector is consulted and agrees, the objector will be informed and no panel will be established and the decision will be placed in the Public Registry on the PMRA's website.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made after considering the recommendations of the review panel and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision or until the panel is dissolved. The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**

[1] **Reliable Science**: science that is credible and unbiased.

Commented [redacted]

Commented [DL(12]: Or?

Commented [redacted]

Commented [redacted]

Commented [DL(15]: What about objections to re-eval or SR decisions as outlined in paragraph 1 of this document? I take the point in paragraph 1 that we outline registration decisions to include post market decisions, but wonder if we would need to specify if we would the re-eval or SR decision be suspended until the review panel makes a decision and is dissolved?

Commented [DL(16]: Again wondering if we need to include broader wording to include

A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Information Note: (canada.ca)

[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Page 1: [1] Commented [GH(3] Gisavi, Haris (HC/SC) 6/9/2022 8:13:00 AM

I agree that this should be grounded in the PCP Act:

- **35 (1)** Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.

Public Consultation

Minister to consult

- **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; or

I think this is important to make a clear distinction here if PMRLs are also subjected to this process. Otherwise, we should fully expect to receive several NoOs when we wrap up the decision on glyphosate MRL

[redacted]

Mozaffar, Hilda

From: Satchwill, Trevor (HC/SC)
Sent: Thursday, July 14, 2022 10:51 AM
To: Silva, Minoli (HC/SC)
Cc: Stiege, Stacie (HC/SC); Munro, Jamie (HC/SC); Satchwill, Trevor (HC/SC)
Subject: RE: [redacted]
Attachments: Item 8_NoO Decision framework v10 [redacted]

Follow Up Flag: Follow up
Flag Status: Completed

Hi Minola,

Thanks so much for your continued help with this. I added some comments onto your version to capture some of the AMC discussion, and some other edits/thoughts for consideration.

Trevor

[redacted]

[redacted]

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to amend a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

Commented [SM(1]: When we decide the NoO is science based and should be reviewed we have been sending an e-mail saying we will have a new team of scientists assessing this and we say we will ensure impartiality.

Formatted: Highlight

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Should the notice of objection contain the above information required by the Regulations, PMRA will consider the information as set out in Part 2.

Should the required information listed above not be included in the notice of objection or if the scientific basis is unclear this would factor into PMRAs considerations of whether to establish a review panel. The objector will be informed in writing of the decision

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and~~,~~ environmental risks and~~or~~ value of the pest control product? To assess this question PMRA will consider:**
    a) Is~~If~~ the scientific basis for the objection ~~is~~ directly linked to the evaluation of the pest control product?~~.~~ ~~The following will be considered:~~
        - Is ~~T~~the basis for the objection ~~is~~ on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision~~.~~?
        - Does ~~T~~the objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.

    b) Was~~If~~ the evidence supporting the objection ~~could have been used~~ considered in the evaluation?~~.~~ ~~In doing so, the following may be considered:~~
        - ~~o~~ Was ~~Whether~~ the information ~~was~~ available prior to publishing the decision (date of the decision) and ~~whether it~~ was it considered in the assessment?~~.~~
        - Does ~~T~~the information meet~~s~~ the criteria for scientific acceptability for use in the evaluation of a pest control product?~~.~~ (See Appendix A)

Commented [redacted]

Commented [redacted]

Commented [ST(4]: Verbatim with 3(a) of the regs Similar edit requested by Janine (EAD)

Commented [ST(5]: AMC recommended a numbered list so that each point can be referenced clearly [e.g. point 1 a) i of Section 3]

Commented [SM(6]: Thinking of one situation where re-eval consulted certain growers regarding agronomic feasibility of some mitigation measures but missed the celery growers. Celery growers objected. Looking at this criteria now, we would have to consider a panel or find an off ramp (eg: change the label) so they can withdraw!

Commented [redacted]

c) Does~~If~~ the evidence provided in support of the objection, considered with all scientifically reliable[1] information available considered by PMRA at the time of decision, presents~~s~~ uncertainty in an aspect of the evaluation~~.~~?

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider the following:**
   a) Is there is a lack of consensus among Canadian government scientists with respect to the ~~e~~evidence presented in the objection, and could it affect the outcome of the evaluation?
   b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?
   c) Is ~~the PMRA of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where~~ there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

Commented [ST(8]: I am not sure the intent is to limit this GoC scientist, but I defer to the rest of the TT.
This could be rephrased to make it clear that PMRA will decide.
PMRA will consider the degree of consensus among government regulatory scientists (or scientific opinion of competent regulatory authorities?) with respect to …

Commented [ST(9]: Jordan flagged this as a statement that could be problematic.
-What if one regulator has a different opinion?
The regulatory framework in different jurisdictions may also be a factor. There may be differences in registered use pattern, or hazard based elements such as with the EU.

Should this criterion be about the interpretations of a specific study, a specific DACO, or the overall assessment? Or this criterion could be rolled into the lack of consensus in a).

Vedad (EAD) had some comments on this section.

Part 3 Next Steps

When it is determined that the objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based or the advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where a review panel is established and the objector withdraws the objection, PMRA may dissolve the panel as set out in section 37 of the PCPA.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until a final decision is made after considering the recommendations of the review panel The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to establish a review panel to review a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: ~~Evidence Type and~~ Criteria for Scientific Acceptability

Evidence submitted in support of the Notice of Objection~~Type~~	**Assessment Criteria for Scientific Acceptability of the Evidence**

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[1] **Reliable Science**: science that is credible and unbiased.

A Single Study	Does the study meet the criteria in Health Canada (2019) Information Note[2] : determining study acceptability for use in pesticide risk assessments?-
Narrative Review with a list of a few selected studies	Are the criteria listed in Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada met?-
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[3]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

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[3] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major amendment to a registration; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

This is to provide information regarding the reconsideration process specified in the *Pest Control Products Act* and the Review Panel Regulations. It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1

Section 2 of the Review Panel Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Part 2

Commented [CA(1]: Minor point but "major amendment" is used to define major registration decision. Suggest just stick with Act wording.

Note. This is section of Act under consideration for PCPA review.

Commented [HM(2]: Adam, I politely and respectfully disagree. The team of evaluators only provide recommendations and it is senior management that makes the decisions. If we don't want to parse out the process we can say" PMRA" will consider… and use the text you proposed.

Commented [CA(3]: I feel like "recommendation" and "consideration by PMRA senior management" leaves too much implied flexibility given the intended purpose of this framework. Propose something like:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established"

Commented [IV(4]: Agree with Adam and Miriam. CH suggestion, replacing highlighted text w:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established."

Commented [IV(5]: Replace with "This document provides…"

Commented [QM(6]: Is this the appropriate description? Or rather the legal requirements and tasks that PMRA to carry out?

Commented [QM(7]: It might be easier for readers/evaluators if we add subtitles?

Suggestion:

Part 1: Information required for NoO applications
Part 2: Criteria to consider for establishing a review panel
Part 3: Next steps

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Review Panel Regulations (the Regulations), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expect scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product?**
    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. In doing so, the following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the overall outcome of the health ~~risks~~, environmental ~~risks~~ or value evaluation and the registration conditions of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to making the decision (date of the decision) and whether it was considered and used in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    - If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.
2. **Would the advice of expert scientists assist in addressing the subject matter of the objection?**
    - If there is a lack of consensus identified with the evaluation within Health Canada and the Minister believes that a panel may be of benefit.
    - If this area of science is relatively new with limited regulatory guidance developed or available expertise, particularly in a regulatory context.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [QM(8]: PMRA vs the PMRA, we are told it should be PMRA

Commented [ST(9]: Suggest removing 'overall'. The typical re-eval decision is continued registration with additional mitigation measures. Depending on the use pattern, mitigation may involve cancellation of certain uses or products. Cancellation of anything is significant regulatory action.
Further, PA1 subs tend to be product based (1 or 2 EPs) while PA2 subs are TGAI based and often involve a broader range of EPs.

Commented [IV(10R9]: Agree

Commented [CA(11]: Idea here is to focus on aspects that actually change the outcome of the risk assessment.

A change to a risk assessment variable that in the end makes no change to the conditions of use or conclusion of the assessment should not be included

Commented [QM(12]: There is also a period between the SMC and the publication date, new information could show up during this period. [redacted]

Commented [redacted]

Commented [QM(14]: Should this be here since we have the next bullet saying on information's acceptability

Commented [SS(15]: with the evidence presented in the NoO and whether it could affect the evaluation

Commented [CA(16R15]: prefer the wording in the comment above that is more precise

Commented [IV(17R15]: Agree

Commented [redacted]

[redacted]

[redacted]

Commented [redacted]

- If the Minister is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is broad and substantial public interest in the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review or until the panel is dissolved.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

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Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Information Note: (canada.ca)
[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [redacted]
Commented [redacted]
Commented [redacted]
Commented [redacted]
Commented [redacted]
Commented [redacted]
Commented [redacted]

[redacted]

Mozaffar, Hilda

From: Silva, Minoli (HC/SC)
Sent: Thursday, June 9, 2022 5:51 PM
To: Stiege, Stacie (HC/SC)
Subject: FW: Panel decision framework
Attachments: NoO Decision framework v4_ACMHTSVISLMQ.docx

I agree with [redacted].
I also agree that there is [redacted].
I don't see much value in the other comments but you know how they fit.
[redacted]

Good luck!
I'm off as of 10 a.m. tomorrow.
Minoli

From: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Sent: 2022-06-09 9:41 AM
To: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Sorry Haris, I had already started on the previous version…….

A few comments from me.

Thanks,
Mei

From: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>
Sent: 2022-06-09 8:38 AM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi all,

I just had a chance to look at this and added a couple of comments with a minor edit.

Thanks,
Haris

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-09 8:11 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thanks Vedad!

I'm planning to send out a version with all of the comments addressed tomorrow which we can all share with management later today or tomorrow. That said, we might have to have a quick meeting, I haven't had a chance to look at all the comments yet.

Thanks,
Stacie

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-06-08 4:55 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

From: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Sent: 2022-06-08 4:09 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC)

<vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi everyone,

A few minor comments, riffing off the comments from Adam and Miriam.

Thank you,
Trevor

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-08 3:05 PM
To: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

From: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted]. Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major amendment to a registration; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

This is to provide information regarding the reconsideration process specified in the *Pest Control Products Act* and the Review Panel Regulations. It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1

Section 2 of the Review Panel Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Part 2

Commented [CA(1]: Minor point but "major amendment" is used to define major registration decision. Suggest just stick with Act wording.

Note. This is section of Act under consideration for PCPA review.

Commented [HM(2]: Adam, I politely and respectfully disagree. The team of evaluators only provide recommendations and it is senior management that makes the decisions. If we don't want to parse out the process we can say" PMRA" will consider… and use the text you proposed.

Commented [CA(3]: I feel like "recommendation" and "consideration by PMRA senior management" leaves too much implied flexibility given the intended purpose of this framework. Propose something like:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established"

Commented [IV(4]: Agree with Adam and Miriam. CH suggestion, replacing highlighted text w:

"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established."

Commented [IV(5]: Replace with "This document provides…"

Commented [QM(6]: Is this the appropriate description? Or rather the legal requirements and tasks that PMRA to carry out?

Commented [QM(7]: It might be easier for readers/evaluators if we add subtitles?

Suggestion:

Part 1: Information required for NoO applications
Part 2: Criteria to consider for establishing a review panel
Part 3: Next steps

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Review Panel Regulations (the Regulations), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expect scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product?**
    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. In doing so, the following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the overall outcome of the health ~~risks~~, environmental ~~risks~~ or value evaluation and the registration conditions of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to making the decision (date of the decision) and whether it was considered and used in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    - If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.
2. **Would the advice of expert scientists assist in addressing the subject matter of the objection?**
    - If there is a lack of consensus identified with the evaluation within Health Canada and the Minister believes that a panel may be of benefit.
    - If this area of science is relatively new with limited regulatory guidance developed or available expertise, particularly in a regulatory context.

[1] **Reliable Science**: science that is credible and unbiased.

Commented [QM(8]: PMRA vs the PMRA, we are told it should be PMRA

Commented [ST(9]: Suggest removing 'overall'. The typical re-eval decision is continued registration with additional mitigation measures. Depending on the use pattern, mitigation may involve cancellation of certain uses or products. Cancellation of anything is significant regulatory action.
Further, PA1 subs tend to be product based (1 or 2 EPs) while PA2 subs are TGAI based and often involve a broader range of EPs.

Commented [IV(10R9]: Agree

Commented [CA(11]: Idea here is to focus on aspects that actually change the outcome of the risk assessment.

A change to a risk assessment variable that in the end makes no change to the conditions of use or conclusion of the assessment should not be included

Commented [QM(12]: There is also a period between the SMC and the publication date, new information could show up during this period. [redacted]

Commented [redacted]

Commented [QM(14]: Should this be here since we have the next bullet saying on information's acceptability

Commented [SS(15]: with the evidence presented in the NoO and whether it could affect the evaluation

Commented [CA(16R15]: prefer the wording in the comment above that is more precise

Commented [IV(17R15]: Agree

Commented [redacted]

Commented [redacted]

- If the Minister is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is broad and substantial public interest in the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review or until the panel is dissolved.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[redacted]

[2] Information Note: (canada.ca)
[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

[redacted]

Mozaffar, Hilda

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-09-14 12:37 PM
To: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Subject: FW: NoO criteria, legislative and RA frameworks in decision documents

Hi Sabine,

All of the comments received have been incorporated in the attached documents. Can you please circulate them to the SMC members? I believe that these are now the final versions.

Thanks,
Stacie

From: Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Sent: 2022-09-12 2:17 PM
To: Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>; PMRA SMC Members / ARLA CGS Membres (HC/SC) <pmrasmcmembers-arlacgsmembres@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Fallon, Janice (HC/SC) <janice.fallon@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

I have few minor comments.
Thank you for the work on this.

Regi

From: Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>
Sent: 2022-09-12 11:05 AM
To: Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>; PMRA SMC Members / ARLA CGS Membres (HC/SC) <pmrasmcmembers-arlacgsmembres@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Fallon, Janice (HC/SC) <janice.fallon@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

Hi all,

Comments under the Legislative Framework included in the attached RVD template also apply to the SRD and RD templates(i.e., citing relevant versions of the Act), for consideration.

As such, I'm including just the one template with comments.

Thanks
Connie

From: Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>
Sent: 2022-09-12 9:20 AM
To: Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>; PMRA SMC Members / ARLA CGS Membres (HC/SC) <pmrasmcmembers-arlacgsmembres@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>; Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Fallon, Janice (HC/SC) <janice.fallon@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

No further comments.

From: Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>
Sent: 2022-09-12 8:03 AM

To: PMRA SMC Members / ARLA CGS Membres (HC/SC) <pmrasmcmembers-arlacgsmembres@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>; Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Fallon, Janice (HC/SC) <janice.fallon@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

Hi Sabrine,

I have provided some minor comments/suggested revisions to the attached RVD, SRD and RD templates. I provided input to the updated NoO in a separate email to AMC.

Thanks,
Janine

From: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca> **On Behalf Of** PMRA SMC Members / ARLA CGS Membres (HC/SC)
Sent: 2022-09-08 3:12 PM
To: Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>; Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Fallon, Janice (HC/SC) <janice.fallon@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

As discussed at SMC this morning, please provide comments by Monday, Sept. 12 COB.

Thank you,

Sabrine

From: Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>
Sent: 2022-09-08 2:42 PM
To: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca>
Cc: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Subject: FW: NoO criteria, legislative and RA frameworks in decision documents

Hi Sabrine, Can you please send this message out to SMC members again and let them know that we need comments back by Monday Sept. 12 COB. Many thanks!

From: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca> **On Behalf Of** PMRA SMC Members / ARLA CGS Membres (HC/SC)
Sent: 2022-09-02 1:25 PM
To: Moase, Connie (HC/SC) <connie.moase@hc-sc.gc.ca>; Murray, Janine (HC/SC) <Janine.Murray@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>; Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>
Cc: Sleeth, Stephanie (HC/SC) <stephanie.sleeth@hc-sc.gc.ca>; Leblanc, Sandy (HC/SC) <sandy.leblanc@hc-sc.gc.ca>; Proulx, Nicole (HC/SC) <nicole.proulx@hc-sc.gc.ca>; Betts, Christina (HC/SC) <christina.betts@hc-sc.gc.ca>; Fallon, Janice

(HC/SC) <janice.fallon@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

---

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-09-02 1:19 PM
To: Najem, Sabrine (HC/SC) <sabrine.najem@hc-sc.gc.ca>
Cc: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>
Subject: FW: NoO criteria, legislative and RA frameworks in decision documents

Hi Sabrine,

Can these documents please be circulated to the SMC members? They are a follow up to an item that went to AMC on August 24th.

Thanks,
Stacie

From: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Sent: 2022-09-02 12:59 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: NoO criteria, legislative and RA frameworks in decision documents

Hi Stacie,

Please find attached revised RVD and SRD templates, and let me know if you have any question.

Thanks,
Mei

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-09-01 3:29 PM
To: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: NoO criteria, legislative and RA frameworks in decision documents

Hi Everyone,

I have updated all the documents to incorporate everyone's comments. The only real change to the Criteria is rewriting Part 2 1c) for clarity. I have gone through each of the decision documents to ensure that all incorporated changes were made on each document. I hope I haven't missed anything.

I believe the next steps on this work will be to table drop or share these with SMC through the secretariat for final approval.

Thanks to all of you for your help getting us to this point,
Stacie

Mozaffar, Hilda

[redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-08-17 8:11 AM
To: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: v14 of the Framework

As requested…

Mozaffar, Hilda

From: Qi, Mei (HC/SC)
Sent: Wednesday, July 27, 2022 1:59 PM
To: Stiege, Stacie (HC/SC); Izadi, Vedad (HC/SC); Gisavi, Haris (HC/SC); Satchwill, Trevor (HC/SC); Halevy, Miriam (HC/SC); Colley, Adam (HC/SC)
Subject: RE: NoO Decision Framework v11
Attachments: NoO Decision framework v11 [redacted] MQ.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Stacie and all,

A few comments for your consideration.

Thanks,
Mei

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-07-27 11:54 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Subject: FW: NoO Decision Framework v11

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

Mozaffar, Hilda

[redacted]

From: Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Sent: 2022-06-09 9:41 AM
To: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>
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Subject: RE: Panel decision framework

Sorry Haris, I had already started on the previous version…….

A few comments from me.

Thanks,
Mei

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Sent: 2022-06-09 8:38 AM
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Subject: RE: Panel decision framework

Hi all,

I just had a chance to look at this and added a couple of comments with a minor edit.

Thanks,
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Sent: 2022-06-09 8:11 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
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Subject: RE: Panel decision framework

Thanks Vedad!

I'm planning to send out a version with all of the comments addressed tomorrow which we can all share with management later today or tomorrow. That said, we might have to have a quick meeting, I haven't had a chance to look at all the comments yet.

Thanks,
Stacie

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-06-08 4:55 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

From: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Sent: 2022-06-08 4:09 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi everyone,

A few minor comments, riffing off the comments from Adam and Miriam.

Thank you,
Trevor

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-08 3:05 PM
To: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

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Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

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Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
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Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted] Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Mozaffar, Hilda

From: Qi, Mei (HC/SC)
Sent: Thursday, June 9, 2022 9:41 AM
To: Gisavi, Haris (HC/SC); Stiege, Stacie (HC/SC); Izadi, Vedad (HC/SC); Satchwill, Trevor (HC/SC); Halevy, Miriam (HC/SC); Colley, Adam (HC/SC); Larmour, Shela (HC/SC)
Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC); Hart, Connie (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_ACMHTSVISLMQ.docx

Sorry Haris, I had already started on the previous version…….

A few comments from me.

Thanks,
Mei

From: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>
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To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
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Thanks Vedad!

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Thanks,
Stacie

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<mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
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Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted]. Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major amendment to a registration; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

This is to provide information regarding the reconsideration process specified in the *Pest Control Products Act* and the Review Panel Regulations. It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1

Section 2 of the Review Panel Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

Part 2

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Note. This is section of Act under consideration for PCPA review.

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"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established"

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"This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established."

Commented [IV(5]: Replace with "This document provides…"

Commented [QM(6]: Is this the appropriate description? Or rather the legal requirements and tasks that PMRA to carry out?

Commented [QM(7]: It might be easier for readers/evaluators if we add subtitles?

Suggestion:

Part 1: Information required for NoO applications
Part 2: Criteria to consider for establishing a review panel
Part 3: Next steps

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the Review Panel Regulations (the Regulations), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
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In considering an application, the PMRA will consider:

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    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to making the decision (date of the decision) and whether it was considered and used in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)
    - If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.
2. **Would the advice of expert scientists assist in addressing the subject matter of the objection?**
    - If there is a lack of consensus identified with the evaluation within Health Canada and the Minister believes that a panel may be of benefit.
    - If this area of science is relatively new with limited regulatory guidance developed or available expertise, particularly in a regulatory context.

[1] **Reliable Science**: science that is credible and unbiased.

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A change to a risk assessment variable that in the end makes no change to the conditions of use or conclusion of the assessment should not be included

Commented [QM(12]: There is also a period between the SMC and the publication date, new information could show up during this period. [redacted]

Commented [redacted]

Commented [QM(14]: Should this be here since we have the next bullet saying on information's acceptability

Commented [SS(15]: with the evidence presented in the NoO and whether it could affect the evaluation

Commented [CA(16R15]: prefer the wording in the comment above that is more precise

Commented [IV(17R15]: Agree

Commented [redacted]

Commented [redacted]

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When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

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Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**
A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[redacted]

[2] Information Note: (canada.ca)
[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

[redacted]

Mozaffar, Hilda

From: Gisavi, Haris (HC/SC)
Sent: Thursday, June 9, 2022 8:38 AM
To: Stiege, Stacie (HC/SC); Izadi, Vedad (HC/SC); Satchwill, Trevor (HC/SC); Halevy, Miriam (HC/SC); Colley, Adam (HC/SC); Larmour, Shela (HC/SC); Qi, Mei (HC/SC)
Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC); Hart, Connie (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v4_ACMHTSVISLHG.docx

Hi all,

I just had a chance to look at this and added a couple of comments with a minor edit.

Thanks,
Haris

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-09 8:11 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thanks Vedad!

I'm planning to send out a version with all of the comments addressed tomorrow which we can all share with management later today or tomorrow. That said, we might have to have a quick meeting, I haven't had a chance to look at all the comments yet.

Thanks,
Stacie

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-06-08 4:55 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
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Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO

decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

From: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Sent: 2022-06-08 4:09 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi everyone,

A few minor comments, riffing off the comments from Adam and Miriam.

Thank you,
Trevor

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-08 3:05 PM
To: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

From: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
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Subject: RE: Panel decision framework

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
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Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
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Public Consultation

Minister to consult

- **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
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... [2]

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[3] weight-evidence-general-principles-current-applications.pdf (canada.ca)
[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Commented [redacted]

Commented [GH(16): I edit this line to clarify it based on my understanding.

I think this is all saying that for new alternative approaches (NAMs) that are supposed to be coming in and replacing traditional animal toxicity testing, we may like the advice of expert scientists in cases where the regulatory applications of NAMs will not be available or limited. Similar to the cases where the USEPA office of pesticides have sought the advice of the USEPA Science advisory panel on regulatory applications of NAMs.

Commented [redacted]

[redacted]

[redacted]

[redacted]

Commented [SS(21): [redacted]

Commented [CA(22): [redacted]

[redacted]

[redacted]

Commented [redacted]

[redacted]

Page 1: [1] Commented [GH(2] **Gisavi, Haris (HC/SC)** **6/9/2022 8:13:00 AM**

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I think this is important to make a clear distinction here if PMRLs are also subjected to this process. Otherwise, we should fully expect to receive several NoOs when we wrap up the decision on glyphosate MRL

Page 1: [2] Commented [IV(5] **Izadi, Vedad (HC/SC)** **6/8/2022 4:28:00 PM**

Agree with Adam and Miriam. CH suggestion, replacing highlighted text w:

“This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.”

[redacted]

Mozaffar, Hilda

From: Colley, Adam (HC/SC)
Sent: Wednesday, June 8, 2022 9:34 PM
To: Izadi, Vedad (HC/SC); Satchwill, Trevor (HC/SC); Halevy, Miriam (HC/SC); Stiege, Stacie (HC/SC); Larmour, Shela (HC/SC); Gisavi, Haris (HC/SC); Qi, Mei (HC/SC)
Cc: Benedict, Christina (HC/SC); Silva, Minoli (HC/SC); Hart, Connie (HC/SC)
Subject: RE: Panel decision framework

Follow Up Flag: Follow up
Flag Status: Completed

Looping back on the SAC question.

[redacted]

Separate from NoO context there is guidance for staff on when questions can/should go to SAC. The SAC secretariat will be issuing an email shortly directing staff to internal guidance and resources on SAC. Stay tuned for that in the coming weeks.

Adam

From: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>
Sent: 2022-06-08 4:55 PM
To: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Hart, Connie (HC/SC) <connie.hart@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Thank you Stacie! Comments attached.

Question - Will we be given an opportunity to brief our respective management teams before this moves any further? Would now be a good time to do that, or better to wait until you send the next clean version of this out? Also, this NoO decision framework seems uncoupled from the RVD template text, which is in a much more draft a state. Will you be moving these forward to AMC as two distinct items on different timelines?

Thanks!
Vedad

From: Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>
Sent: 2022-06-08 4:09 PM
To: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC)

<vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi everyone,

A few minor comments, riffing off the comments from Adam and Miriam.

Thank you,
Trevor

From: Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>
Sent: 2022-06-08 3:05 PM
To: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hello,

Just one comment in response to Adam's comment.

Thank you.
Miriam

From: Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Sent: 2022-06-08 1:49 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Couple of comments from me on decision framework.
Thank you. Happy to discuss as needed.
Adam

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-08 12:54 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Hi Everyone,

I've created a clean copy of the decision framework document (attached) [redacted]
Please let me know by COB tomorrow if you have any comments

Thanks,
Stacie

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted]. Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Mozaffar, Hilda

From: Gisavi, Haris (HC/SC)
Sent: Wednesday, June 15, 2022 1:24 PM
To: Stiege, Stacie (HC/SC)
Subject: RE: Panel decision framework
Attachments: NoO Decision framework v6.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Stacie,

I edited the references of the table to make them all consistent in terms of descriptors used. This version is attached. We may also get a question on whether the definition around reliable science is clear enough. [redacted] but will think about it more to see if I can provide more context around this definition.

Thank you for leading us through this work and other tiger team work. As always, much appreciated. ☺

Thanks again,
Haris

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-15 10:39 AM
To: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: RE: Panel decision framework

Good morning Everyone,

I've done my best to incorporate as many comments as I could and cleaned it up a bit more. It will be brought for discussion to SMC tomorrow. I will let everyone know the time when I find out.

Please pass my thanks along to everyone who provided comments.
Thanks,
Stacie

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-10 8:32 AM
To: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>; Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Cc: Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning,

Attached is the latest version of the NoO decision framework. Thanks to everyone for their input and guidance. Please share with your management. I will work with Fred to see where it will be taken for discussion with the DGs. At this point, I think it might be SMC, possibly next week.

Thanks,
Stacie

Draft Criteria to Consider in Deciding Whether to Establish a Review Panel following receipt of a s. 35(1) Notice of Objection

As per the *Pest Control Products Act*, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying application to effect a major registration decision; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or a special review.

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will consider the information provided according to the Notice of Objection framework to determine if a review panel should be established, and bring these recommendations to PMRA senior management. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established

This document provides information regarding the reconsideration process specified in the *Pest Control Products Act* and the *Review Panel Regulations* (the "Regulations"). It describes the role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act.

Part 1 Information required for Notice of Objection ~~applications~~

Section 2 of the Regulations sets out the information that must be included in a Notice of Objection:

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;
b) the decision to which the notice relates and the date on which the decision was made;
c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
d) the evidence to support the objection, including scientific reports or test data.

[redacted]

Commented [redacted]

Commented [GH(2]: I agree that this should be grounded in the PCP Act:

- **35 (1)** Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.

Public Consultation
Minister to consult

- **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; or

I think this is important to make a clear distinction here if PMRLs are also subjected to this process. Otherwise, v ... [1]

Commented [redacted]

[redacted]

Commented [redacted]

Commented [redacted]

[redacted]

Part 2 Criteria to consider for establishing a review panel

Should the criteria in subsection 35(1) of the Act and section 2 of the Regulations be met, PMRA will consider section 3 of the *Review Panel Regulations* (the "Regulations"), which reads:

Establish Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
b) whether the advice of expect scientists would assist in addressing the subject matter of the objection.

In considering an application, the PMRA will consider:

1. **Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health, environmental risks or value of the pest control product? To asses this question PMRA will consider:**
    - If the scientific basis for the objection is directly linked to the evaluation of the pest control product. The following will be considered:
        - The basis for the objection is on an aspect of the evaluations conducted with respect to the health risks, environmental risks or the value of the product prior to making the decision.
        - The objection concerns an aspect of the evaluation that could be reasonably expected to affect the outcome of the health, environmental or value evaluation of the pest control product.
    - If the evidence supporting the objection could have been used in the evaluation. In doing so, the following may be considered:
        - Whether the information was available prior to publishing the decision (date of the decision) and whether it was considered in the assessment.
        - The information meets the criteria for scientific acceptability for use in the evaluation of a pest control product. (See Appendix A)

[redacted]

- If the evidence provided in support of the objection, considered with all scientifically reliable [1]information available considered by PMRA at the time of decision, presents uncertainty in an aspect of the evaluation.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question PMRA will consider:**
    - If there is a lack of consensus identified with the evidence presented in the objection, and whether it could affect the outcome of the evaluation, and the PMRA determines that a panel may be of benefit.
    - If the area of science is relatively new with limited regulatory guidance available and the PMRA determines that the advice of the panel will aid in the regulatory decision-making process.
    - If the PMRA is of the view that the advice of expert scientists would assist in addressing the subject matter of the objection where there is a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is subject to the matter of the objection.

Part 3 Next Steps

When it is determined that the objection has merit and advice of scientific experts(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and affected registrant(s) or applicant(s) will be advised in writing. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), and the objector is consulted and agrees, the objector will be informed and no panel will be established and the decision will be placed in the Public Registry on the PMRA's website.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until, a final decision is made after considering the recommendations of the review panel and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision or until the panel is dissolved. The objector will be informed of the decision in writing and the decision will be placed in the Public Registry on the PMRA's website.

Where a request to reconsider a registration decision is refused, the reasons for the refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

Appendix A: Evidence Type and Criteria for Scientifically Acceptability

Evidence Type	**Assessment Criteria for Scientific Acceptability of the Evidence**

[1] **Reliable Science**: science that is credible and unbiased.

A Single Study	PMRA information note[2]
Narrative Review with a list of a few selected studies	PMRA information note. Health Canada Weight of Evidence document[3]
Systematic Review	Did the systematic review follow PMRA's or an international scientific organizations guidance on conducting systematic reviews, such as the WHO guidance[4]?

Note: Evidence is defined as a collection (or body) of available facts or information that is deemed relevant for specific context

[2] Health Canada. (2019). Information Note: determining study acceptability for use in pesticide risk assessments. Information Note: (canada.ca)

[3] Health Canada. (2018). Weight of Evidence: General principles and current applications at Health Canada. weight-evidence-general-principles-current-applications.pdf (canada.ca)

[4] World Health Organization. (2021). Framework for the use of systematic review in chemical risk assessment. World Health Organization. https://apps.who.int/iris/handle/10665/347876. License: CC BY-NC-SA 3.0 IGO

Page 1: [1] Commented [GH(2] **Gisavi, Haris (HC/SC)** **6/9/2022 8:13:00 AM**

I agree that this should be grounded in the PCP Act:

- **35 (1)** Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.

Public Consultation

Minister to consult

- **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; or

I think this is important to make a clear distinction here if PMRLs are also subjected to this process. Otherwise, we should fully expect to receive several NoOs when we wrap up the decision on glyphosate MRL

Mozaffar, Hilda

From: Gisavi, Haris (HC/SC)
Sent: Wednesday, May 4, 2022 10:17 AM
To: Stiege, Stacie (HC/SC)
Subject: RE: Stiege, Stacie (HC/SC) shared "TT_NoO criteria" with you.
Attachments: Decision framework criteria.HG.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Stacie,

I added a few responses in the attached. Hope this helps and let me know if I can further or if I am missing anything.

Thank,
Haris

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-05-03 8:23 AM
To: Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Singal, Tina (HC/SC) <tina.singal@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Subject: FW: Stiege, Stacie (HC/SC) shared "TT_NoO criteria" with you.

Good morning Everyone,

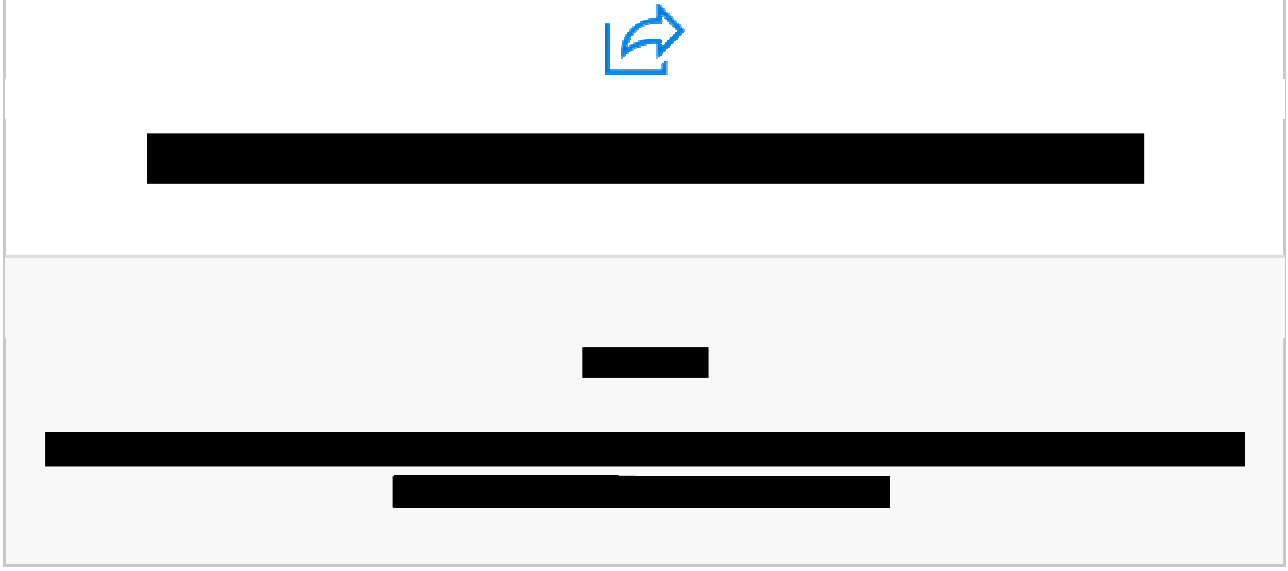
[redacted] I'll try to figure out how to share the document on OneDrive. In the meantime, you can provide your comments to me. [redacted]

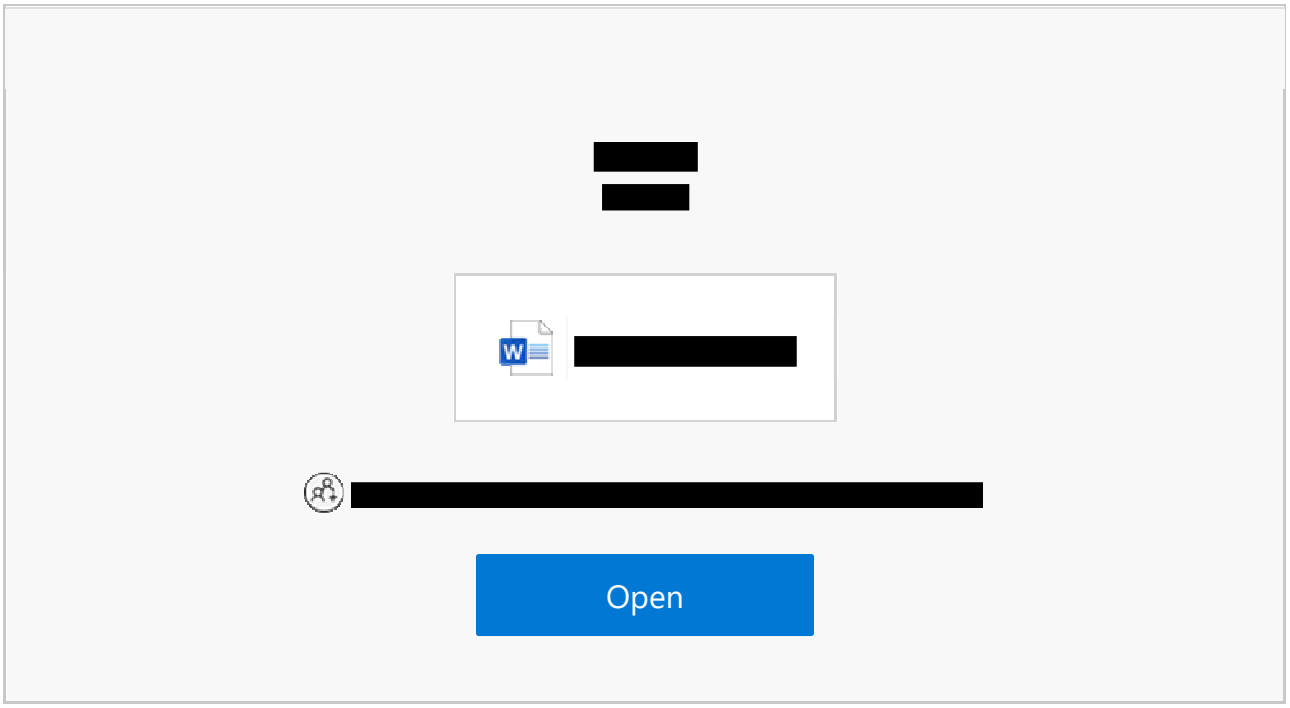
[redacted] I hope to have that ready in a couple of days.

Thanks,
Stacie

[redacted]

[redacted]





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Mozaffar, Hilda

From: Qi, Mei (HC/SC)
Sent: Friday, June 3, 2022 6:52 AM
To: Stiege, Stacie (HC/SC)
Subject: RE: Panel decision framework
Attachments: 2022-05-18 NoO Decision framework v3 ([redacted] MQ.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Stacie,

Please see a few comments in attached (a couple of them are in response to your comments in the bubbles) and let me know if you have any question.

Thx,
Mei

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-06-02 8:59 AM
To: Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Panel decision framework

Good morning Everyone,

As you know our original deadline to complete the criteria for when to establish a review panel was due by May 31st. However, with the storm/power outages that wasn't possible. I'm now aiming to get this completed in the next week or so.

Please see the latest version (attached) [redacted]. Comments can be sent to me, and I will organize a meeting if needed.

Thanks!
Stacie

Mozaffar, Hilda

From: Proceviat, Jason (HC/SC) <jason.proceviat@hc-sc.gc.ca>
Sent: Thursday, September 29, 2022 3:39 PM
To: Conti, Margherita (HC/SC); PMRA AMC Secretariat ARLA CGA (HC/SC); HC.F PMRA AMC DGs F.SC; HC.F PMRA AMC Directors F.SC
Cc: HC.F PMRA AMC Assistants F.SC; Stiege, Stacie (HC/SC); Qi, Mei (HC/SC)
Subject: RE: For final approval: NoO criteria, legislative and RA frameworks in decision documents

Nothing further from OPR either.
JP

From: Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>
Sent: 2022-09-29 3:17 PM
To: PMRA AMC Secretariat ARLA CGA (HC/SC) <pmraamcsecretariatarlacga@hc-sc.gc.ca>; HC.F PMRA AMC DGs F.SC <pmra_amc_dgs@hc-sc.gc.ca>; HC.F PMRA AMC Directors F.SC <pmra_amc_directors@hc-sc.gc.ca>
Cc: HC.F PMRA AMC Assistants F.SC <pmra_amc_assistants@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Subject: RE: For final approval: NoO criteria, legislative and RA frameworks in decision documents

No further comments. Thanks

From: PMRA AMC Secretariat ARLA CGA (HC/SC) <pmraamcsecretariatarlacga@hc-sc.gc.ca>
Sent: 2022-09-29 1:00 PM
To: HC.F PMRA AMC DGs F.SC <pmra_amc_dgs@hc-sc.gc.ca>; HC.F PMRA AMC Directors F.SC <pmra_amc_directors@hc-sc.gc.ca>
Cc: HC.F PMRA AMC Assistants F.SC <pmra_amc_assistants@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>
Subject: RE: For final approval: NoO criteria, legislative and RA frameworks in decision documents

Hello,

As a follow up to the email below, attached is the latest version of the Decision framework. There is a slight change of wording for criteria one compared to version 17.

Thanks,

Sabrine

From: PMRA AMC Secretariat ARLA CGA (HC/SC)
Sent: 2022-09-26 11:44 AM
To: HC.F PMRA AMC Members F.SC <pmra_amc_members@hc-sc.gc.ca>; Simmons, Heather (HC/SC) <heather.simmons@hc-sc.gc.ca>; Marshall, Christopher (HC/SC) <christopher.marshall@hc-sc.gc.ca>
Cc: HC.F PMRA AMC Assistants F.SC <pmra_amc_assistants@hc-sc.gc.ca>; Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: For final approval: NoO criteria, legislative and RA frameworks in decision documents

Good morning,

Please find attached the NoO Decision framework, the RVD, RD and SRD templates for final approval. If you have any further comments please direct them to Stacie Stiege and Mei Qi. Otherwise, your approval is required by the end of this week.

Thank you,

Sabrine

Mozaffar, Hilda

From: de Luna, Lilian (HC/SC)
Sent: Wednesday, March 30, 2022 1:14 PM
To: Stiege, Stacie (HC/SC)
Subject: FW: NoO SOP draft
Attachments: NoO SOP Draft 2 Cleanup 2022_02_24.docx

Follow Up Flag: Follow up
Flag Status: Completed

From: de Luna, Lilian (HC/SC)
Sent: 2022-03-17 2:19 PM
To: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Subject: FW: NoO SOP draft

As requested by Minoli.

Standard Operating Procedures for the Reconsideration of Decision Process (Notice of Objection)

Reference Documents

Pest Control Products Act (PCPA)
Review Panel Regulations SOR/2008-22 (RP Regs)
Discussion Document DIS2007-01, *Reconsideration of Decisions Under the New* Pest Control Products Act (DIS2007-01)
Health Canada Policy on External Advisory Bodies (2011)

Background

[PCPA, subsection 35(1)]
"Any person may file […] a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision […] is made public."

[PCPA, subsection 35(3)]
"After receiving a notice of objection, the Minister may […] establish a panel […] to review the decision and to recommend whether the decision should be confirmed, reversed or varied."

IMPORTANT NOTE:

- If the objection pertains to a re-evaluation decision/special review, the scientific review of the NoO is led by the Registration Directorate (RD).

- If the objection pertains to a registration decision, the scientific review of the NoO is led by the Value Assessment and Re-evaluation Management Directorate (VRD), more specifically by the Re-evaluation Coordination Sections.

- These measures are intended to ensure impartiality when assessing the validity of the NoO and determining if an External Review Panel should be established. [DIS2007-01, section 2.1.1]

I. Standard Operating Procedures for PMRA to Determine if External Review Panel Required

Step 1	Submission Setup: **LEVEL A**
Purpose	Enable tracking of the Notice of Objection (NoO)
Responsibilities	Re-evaluation Coordinator (REC) or Science Team Lead (STL) Information Management Section
Timeline (days)	*[7 days]*

There is no prescribed method by which Notice of Objection (NoO) applications must be submitted to the Agency. Therefore, the PMRA will accept NoO applications received by mail, email or via the Public Engagement Portal (PEP), and may be in the form of a letter, email message/attachments or PEP-form 7004 with/without attachments.

Regardless of the method and form of an NoO application, it is the responsibility of Level A staff to create a Category H submission and load all documents to the e-PRS Workbook, as follows:

- If the application is an objection to a re-evaluation decision/special review, then create a Category H.1.1 submission.
- If the application is an objection to a registration decision, then create a Category H.1.2 submission.

*Note 1: Create a separate Category H submission for each individual objection.

- Assign an STL (for H.1.1) or a REC (for H.1.2) as the AC for the submission.
- Enter the related Re-Evaluation or Registration submission(s) into the “Related Submissions” field.
- Enter the relevant active ingredient's 3 letter code in the "ACTIVES" field.

*Note 2: DO NOT link the NoO submission to any Registration (PCP) Numbers.

- Load all documents, regardless of their type (letter, email, rationale, scientific paper), under the following stream, document ID and filetype;
    - DIV_ID = APPL
    - DOC_ID = NOTICE_OF_OBJECTION
    - Filetype = PDF

*Note 3: It is the intention that the NoO Applications will be posted on the PMRA Public Registry. As such, they MUST be loaded to the above stream, document ID and filetype. Furthermore, each document should be loaded separately so that each has its own unique PMRA #.

Step 2	**Acknowledgement to the Objector, NoO Record in the Public Registry:** **LEVEL B**
Purpose	Transparency – notify the objector of successful receipt, and the public of the NoO
Responsibilities	REC or STL Document Flagging Officer (IM Section)
Timeline (days)	*[7 days]*

Send e-mail acknowledging receipt of the NoO to Objector (Draft Text Below).

*Note 1: All e-mail communications to the Objectors will be via the generic e-mail account - PMRA Notice of Objection / Avis d opposition ARLA (HC/SC) <pmra.noo-ado.arla@hc-sc.gc.ca>, in order to maintain the STL/REC's anonymity.

Move the Category H submission to Level **B IN QUEUE** in e-PRS.

A record of the submission will automatically appear in the Public Registry on the next day after the submission is moved to B in Queue. CHECK THE PUBLIC REGISTRY TO ENSURE THE SUBMISSION RECORD IS PRESENT AND THAT THE ACTIVE INGREDIENT IS IDENTIFIED.

The Document Flagging Officer will, via normal procedures, flag all NoO documents to the Public Registry. This process occurs twice weekly, so there may be a delay between the NoO submission record appearing in the Public Registry and the NoO documents being posted.

Standard Text

Dear XXXXX,

Please accept this e-mail as an acknowledgement that Health Canada's Pest Management Regulatory Agency (PMRA) has received your Notice of Objection submitted on <*DATE*>.

The PMRA acknowledges receipt of your Notice of Objection filed under subsection 35(1) of the *Pest Control Products Act*, to <*NAME OF PRVD/PRD*>.

- *IF LETTERS OF SUPPORT/ADDITIONAL INFORMATION PROVIDED:* Please note the PMRA acknowledges the letters of support/additional information from XXXXX in regards to the Notice of Objection you submitted.

You will be contacted as the Notice of Objection proceeds through the review process.

Please do not hesitate to contact the Notice of Objection e-mail account (pmra.noo-ado.arla@hc-sc.gc.ca**) if you have any questions.**

Thank you,

Officer responsible for Notice of Objection/Agent(e) en charge des avis d'opposition
Pest Management Regulatory Agency/Agence de réglementation de la lutte antiparasitaire
Health Canada/Santé Canada - Government of Canada/Gouvernement du Canada

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If we receive further communication from the objector, we respond to it accordingly to provide guidance.

Step 3	**Eligibility Screening LEVEL C**
Purpose	Verify if the NoO meets eligibility criteria
Responsibilities	REC or STL
Timeline (days)	*[21 days]*

Move the Category H submission to Level **C IN QUEUE** in e-PRS.

Screen the NoO to verify if it meets the eligibility criteria [RP Regs, section 2]:
1. Sufficient details have been provided by Objector [RP Regs, section 2(a)-(c)].
2. The NoO was filed within 60 days of the registration/re-evaluation/special review decision.
3. The submitted package includes scientific information to support the objection, including scientific reports or test data [RP Regs, section 2(d)]

The basis for objecting must be **on scientific grounds**.
IMPORTANT NOTE: The NoO is NOT an opportunity to submit **new** data/information for review that would have been submitted in response the consultation document (PRVD/PRD). Additional data/ studies conducted would be considered by PMRA under a new application.
- The assessment of the NoO allows PMRA to determine whether the objection raises scientifically-founded doubt as to the validity of the evaluations on which the special review decision was based.
- Objections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a Review Panel.

Eligibility Screen Activities
1. STL/REC to conduct thorough/detailed assessment of the scientific viability of the objection(s).
   - *if required*, STL/REC to directly contact Objector, in order to obtain clear understanding of the basis for the Objection.
   - *if required*, STL/REC to contact appropriate section head(s), for advice on specific aspects of the Objection.

2. STL/REC to present results of Eligibility Screen to Section Head/RD Director.

3. Based on results from the Eligibility Screen, STL/REC to present to SMC the ***recommendation***
   a) As the NoO did not pass the eligibility screen, the NoO will be closed (Verbal update can be given).
   b) NoO passed the eligibility screen and
      i) Proceed with an internal scientific review by a team of PMRA evaluators who were not involved in the original registration decision.
      ii) Internal scientific review is not required and a decision and/or recommendation by SMC sent to objector.

*Note 1: STL/REC to generate SMC Briefing Note (BN), which clearly presents details/reasons/rationale for recommendation on the eligibility of NoO.
- If evaluators were consulted, have them at the SMC presentation

SMC Decision Options:

1. If SMC decision is to *proceed with the internal scientific review* of the NoO:
   - Propose directorates/science teams required to address the NoO.
   - Proceed to step 4, *Update to the Objector*.
2. If SMC decision is to *reject the NoO*, as it did not meet the eligibility criteria:
   - Move the submission through Levels C/D to Level E IN QUEUE
   - Proceed directly to step 9, *Decision Letter*.

*Note 2: As per SMC process, if a BN was generated, then the NoO will go to SMC, once again, for a final decision.

Step 4	**Update to the Objector: LEVEL C**
Purpose	Transparency – notify the objector that the scientific review of the NoO will proceed
Responsibilities	REC or STL
Timeline (days)	*[7-14 days]*

If the submission is to proceed with an internal scientific review, send an update e-mail to the objector, informing them of the decision that the PMRA will evaluate the scientific basis of the request.

Standard Text

Dear XXXXXX,

This is to inform you that your Notice of Objection (NoO) to the <*NAME OF PRVD/PRD*> has been accepted and is currently being assessed by Health Canada's Pest Management Regulatory Agency (PMRA).

To ensure that the assessment remains impartial, your NoO is being reviewed by scientists within the PMRA who were not involved in the original re-evaluation of strychnine. The assessment of the NoO will allow the PMRA to determine if the objection raises scientific-founded doubt as to the validity of the evaluations on which the re-evaluation decision was based and if advice of an external expert panel of scientists would assist in addressing the subject matter of the objection.

Once the assessment has been completed, the outcome will be communicated to you in a letter. We anticipate that a decision will be reached by <*proposed date*> and if we encounter any delays you will be informed.

This notice is for your information only. No further communication will be sent to the objectors until a decision has been made.

Thank you,

Officer responsible for Notice of Objection/ Agent(e) en charge des avis d'opposition
Pest Management Regulatory Agency/Agence de réglementation de la lutte antiparasitaire
Health Canada/Santé Canada / Government of Canada/Gouvernement du Canada

Step 5	**Team Call: LEVEL C**
Purpose	Assign evaluators to review the NoO
Responsibilities	REC or STL
Timeline (days)	*[2 days]*

Send a team call email to DGs designated at SMC (cc Executive Assistants), requesting the names of evaluator(s) that will be assigned to review the scientific information. **Indicate that assigned evaluator(s) should not have been involved in the decision under review**. The team call email should include:

- Submission number(s)
- Any relevant background information
- 48-hour deadline for DGs to respond

Step 6	**Meeting with Review Team: Level C**
Purpose	Clarify roles and tasks
Responsibilities	REC or STL, review team, section head(s)

Timeline (days)	*[30 days]*

Populate DST with appropriate Evaluator identification information

Prior to the meeting:

Schedule a team meeting with the assigned evaluator(s) and their section head(s). The meeting invite should include:

- Submission number(s)
- Any relevant background information

Ask the review team to have a cursory look at the submitted information.

During the meeting:

Brief the review team on the following elements (detailed under step 7, *Science Review*):

- Reconsideration of decision process steps
- Roles and tasks of the review team
- Required deliverables

Inform the review team that:

- All process or policy-related questions regarding the decision under review go through the STL/REC.
- Communication among the team and with the STL/REC is encouraged; however, **there should not be any communication with original reviewers**, unless approved by managers. Science clarifications may be made with other subject matter experts within the directorate.

Establish a schedule with the review team, including target dates for each step, based on the amount and complexity of the information provided in support of the objection.

Step 7	**Science Review: Level D**
Purpose	Review information provided and provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the NoO
Responsibilities	Review team
Timeline (days)	*[180-360 days]*

Move the Category H submission to Level **D IN QUEUE** in e-PRS.

Any issues raised by the objector that pertain to the PMRA registration, re-evaluation or special review process (i.e. issues that are not science-based) are sent to the STL/REC without delay. The STL/REC consults with RD SH/Director to confirm if such issues should be addressed in the decision letter.

The science team proceeds to review the package to provide recommendations on:
- Whether the information in the NoO raises scientifically-founded doubt as to the validity of the evaluations on which the decision was based, of the health and environmental risks, and the value of the pest control product; and
- Whether the advice of expert scientists would assist in addressing the subject matter of the objection.
[RP Regs, section 3]

The following documents are prepared by each directorate's member of the review team:
1) Internal review/note to file, including recommendations on the suggested course of action (described as *Potential Outcomes* under step 8) as well as a reference list of documents used in the evaluation and provided by the objector
2) Input to SMC BN, including recommendations on the suggested course of action.
3) Memo to STL/REC should include the input into SMC BN and detailed comment(s)/response(s) to address each of the points raised by the objector; must be provided in the format used in Registration Decisions (RDs)/Re-evaluation Decisions (RVDs) documents,. The comment(s)/response(s) will be included as an appendix to the SMC BN and will be used to draft the decision letters.

Step 8	**Management Decision on NoO: Level D**
Purpose	Present review team conclusions and recommendations to SMC for decision
Responsibilities	REC or STL
Timeline (days)	*[30 days]*

Present review team conclusions and recommendations to SMC for decision.

Potential Outcomes

There are three possible outcomes of the PMRA's internal scientific review of the NoO.

1) The submitted information does not raise scientifically-founded doubt on the decision under review. An External Review Panel will not be established. No changes to the decision under review.

2) The submitted information raises scientifically-founded doubt on the decision under review. However, the issue can be resolved quickly and efficiently without the need for an External Review Panel.

a) Label amendments/mitigation measures are required.

The REC/STL communicates the label amendments to the registrant(s). Implementation of the label amendments requires the written consent of the registrant(s) [PCPA, section 24] before these can be communicated to the objector.

Label changes can be integrated through an already ongoing submission for the active ingredient/product under reconsideration. If there is no such open submission, the REC/STL requests that the registrant(s) makes a Category C application to amend its registration.

b) The decision under review is modified or reversed based on available information.

The REC/STL communicates to the registrant(s) that the PMRA intends to modify or reverse the decision under review without establishing an External Review Panel. The STL/REC requires the written consent of the registrant(s) [PCPA, section 24] before the decision can be communicated to the objector.

3) The submitted information raises scientifically-founded doubt on the decision under review, and advice from an External Review Panel is required.

SMC will decide if the decision under review should/should not be suspended until the Review Panel makes a final decision or is dissolved [PCPA, section 36]. Therefore, if an External Review Panel is required, the briefing note should address whether the decision under review is to be suspended.

*Note 1: As per SMC process, if a BN was generated, then the NoO will go to SMC, once again, for a final decision.

If SMC supports the establishment of a Review Panel, prepare a Memo to the Minister providing information on the NoO and SMC decision. If Minister's office approves SMC recommendation, then proceed to the next steps.

If required, prepare communications piece to explain the objections and SMC decision to establish a Review Panel.

Step 9	**Decision Letter: Level E**
Purpose	Transparency - inform objector and public of NoO outcome
Responsibilities	REC or STL
Timeline (days)	*[30-60 days]*

Move the Category H submission to Level **E IN QUEUE** in e-PRS.

Prepare the decision letter for the objector, signed by Chief Registrar, (using OBJ_DECISION_PDF in the Common stream), informing them of PMRA's decision (See potential outcomes in Step 8). If a Review Panel is established, the decision letter should specify whether the decision under review is to

be suspended. The decision letter should also state that a notice of the establishment of a review panel will be released to the public registry [PCPA subsection 35(4)]. The notice of Review Panel can also be sent to the objector(s) and Registrant(s). Consult with Legal Services if needed. Send the decision letter (in the preferred language communicated) by email to the objector. [PCPA, subsection 35(5)]

Step 10	**Closure of H.1.1/H.1.2 Submission: Level I**
Purpose	Finalize tracking of the Notice of Objection (NoO)
Responsibilities	REC or STL Document Flagging Officer (IM Section)
Timeline (days)	*[1 day]*

In the e-PRS Workbook, finalize the Decision Letter(s).

If the NoO is denied, move the submission through Level E PASSED to Level I REJECTED. This will cause the submission's "Outcome" in the Public Registry to change from PENDING to DENIED.

If a Review Panel is to be established, move the submission through Level E PASSED to Level I DONE. This will cause the submission's "Outcome" in the Public Registry to change from PENDING to COMPLETED.

If a Review Panel is established, refer to Part II: Standard Operating Procedures to Establish and Conduct Review Panel.

Once the submission is REJECTED or DONE, the Document flagging Officer will release the decision letter(s) to the Public Registry via normal procedures.

II. Standard Operating Procedures to Establish and Conduct Review Panel

Step 11	Submission Setup
Purpose	Enable tracking of the Review Panel
Responsibilities	REC or STL, Information Management Section
Timeline (days)	*[7 days]*

Ask the Information Management Section to:

- Create a Category H.1.3 submission in e-PRS.
- Add the STL/REC's officer number in the AC field.
- Cross-reference relevant files from the H.1.1/H.1.2 submission (e.g. decision letters).

Step 12	Prepare Workplan
Purpose	To identify the steps to be followed for Review Panel Process
Responsibilities	REC or STL, SH and Director
Timeline (days)	*[7days]*

The workplan will assign tasks, manage the workflow, track the various steps and identify milestones or deadlines.

Step 13	Letter to the Registrant(s)
Purpose	Transparency - inform registrant(s) of NoO outcome
Responsibilities	REC or STL
Timeline (days)	*[30-60 days]*

If a Review Panel is established, prepare the letter to the registrant(s), informing them of PMRA's decision regarding the establishment of a Review Panel related to the objection. The decision letter should specify whether the decision under review is to be suspended. Consult with Legal Services if needed. Send the letter by email to the registrant(s).

Step 14	Review Panel Record in Public Registry, Communications
Purpose	Transparency – notify the public of the establishment of a Review Panel
Responsibilities	REC or STL Document Flagging Officer
Timeline (days)	*[14 days]*

Prepare a Notice announcing the establishment of a Review Panel. Consult with Legal Services if needed. Send the Notice by email to the registrant(s) and the objector(s).

Note: The notice shall be loaded under Doc ID "REV_PANEL_PUBLIC_NOTICE_PDF_E/F" in the COMMON Stream of the e-PRS Workbook.

Move the Category H.1.3 submission to Level B IN QUEUE in e-PRS.

The Document flagging officer will then flag the notice to the Public Registry via normal procedures. (REV_PANEL_ PUBLIC_NOTICE_PDF_E/F).

[PCPA, subsection 35(4)]

Step 15	**Determination of the Review Panel's Terms of Reference (ToR)**
Purpose	Establishes the scope and limitation of the activities of the Review Panel
Responsibilities	REC or STL, review team, section head(s)
Timeline (days)	*[21 days]*

Draft the ToR and consult science directorates as appropriate. The following aspects should be considered:
- ToR requires that the Review Panel focus on the issues arising from the NoO (i.e., charge question).
- ToR should include a detailed work plan, with target timelines for the Review Panel procedures, and status updates for tracking purposes.

Present the ToR to SMC for approval.

The Minister may at any time make any changes to the ToR.

Note: The notice shall be loaded under Doc ID "REV_PANEL_TOR_PDF" in the COMMON Stream of the e-PRS Workbook.

[PCPA, subsection 35(6)

Step 16	**Selection of Review Panel Members**
Purpose	Identify the Composition of the Review Panel
Responsibilities	REC or STL, SH and DIR
Timeline (days)	*[30 days]*
Each Review Panel member must:	

- Possess scientific knowledge that allows evaluation of the subject matter of the objection;
- Not have been employed by the federal government within one year before the day on which they are appointed to the Review Panel;
- Have provided a written statement indicating that they are free from any actual or potential conflict of interest that relates to the decision under review; and
- Have undertaken in writing to disclose, without delay, any actual or potential conflict of interest that may arise and affect their duties as a member of the Review Panel.

[RP Regs, section 4]

- Each review panel member must provide a signed *Confidentiality Agreement Form* as per HC Policy on External Advisory Bodies (2011)

Minister will decide the composition of the review panel [RP Regs, section 4]. Recommendations for potential review panel members may be provided by the Science Directorates. Engage with potential members to assess their expertise, measure their interest and identify their availabilities. Request resumé from potential panel members, examine their credentials and select the members (minimum of one) [RP Regs, section 4]. Assess the responses from the *Affiliations and Interests Form* [HC Policy on External Advisory Bodies, 2011] to ensure there is no conflict of interest. The names of the recommended panel members will be presented to SMC for approval. Contact the selected Review Panel members to discuss logistics and confirm their participation. Determine if review panel members will serve as volunteers. If not, prepare a contract for panel members with Human Resources, following Treasury Board of Canada directives. Security clearance may be required if the panel members sign a contract.

The Review Panel must have a chairperson. The chairperson will preside over the hearings and manage the activities of the Review Panel [RP Regs, section 5(2)]. If the Review Panel is made up of one member, that member is the chairperson. If it is made up of more than one member, the chairperson is the member designated by the Minister [RP Regs, section 5(1)].

Step 17	**Orientation Meeting**
Purpose	Brief Review Panel and address initial questions or concerns
Responsibilities	REC or STL, Review Panel
Timeline (days)	*[21 days]*

Schedule an orientation meeting. Provide the Review Panel with the relevant documentation prior to the meeting. During the meeting, present background information (ToR, review procedure, timelines, etc.) and address any questions or concerns from the Review Panel.

Step 18	**Representation**

Purpose	Transparency – notify the public of opportunity for representations
Responsibilities	REC or STL, Review Panel Document Flagging Officer
Timeline (days)	*[45 days]*

During Review Panel hearings, any person should be given a reasonable opportunity to make representations in respect of the decision under review, in accordance with ToR [PCPA, subsection 35(7)], i.e.:
- The Public can provide comments on the documents considered in the PMRA evaluations and submit additional evidence or arguments related to the decision under review.

Prepare a notice to inform the public of the opportunity to make representations in respect of the decision under review [PCPA, subsection 35(7)]. The notice may also include the announcement to strike a review panel for the NoO (as per Step 14).
The notice will indicate that:
- Interested persons should submit written representations to the PMRA (via the generic e-mail account - PMRA Notice of Objection / Avis d opposition ARLA (HC/SC) <pmra.noo-ado.arla@hc-sc.gc.ca>) by the date specified.
-The representation must be specific to the question that the review panel experts will be reviewing.
- General comments regarding the decision will not be considered by the review panel experts.

Consult with Legal Services if needed. Send the notice (French and English) by email to the registrant(s) and the objector(s) with the decision letter indicating that a review panel is being established.

Note: The notice shall be loaded under Doc ID “REV_PANEL_PUBLIC_NOTICE_PDF” in the COMMON Stream of the e-PRS Workbook.

The Document flagging officer will then flag the subsection 35(7) notice to the Public Registry via normal procedures.

The STL/REC will communicate any information received from Representation to the Review Panel. Based on ToR, the Minister determines the acceptability of the request(s) to make a representation and the admissibility of the additional evidence.

Step 19	**Hearings**
Purpose	Assess all relevant information regarding the issue/charge question, while maintaining confidentiality and transparency
Responsibilities	REC or STL, Review Panel
Timeline (days)	*[60 days]*

The Review Panel may receive and accept any evidence or information it considers relevant to its mandate. The Review Panel may request and receive information and advice from persons who have not made an application to participate in the hearings. Any information received by the Review Panel must be submitted by the chairperson to the PMRA (REC/STL) for records (i.e. e-PRS) and for inclusion in the Register [PCPA, subsection 35(9)].

Review Panel hearings are open to the public [PCPA, subsection 35(8)] as observers, except when confidential information is being discussed [PCPA, subsection 44(3)]. Participants making representations are responsible for notifying the Review Panel in advance if they wish to discuss confidential information in the hearing. Panel members and participants in a hearing may have access to confidential information that is not found in the Public Registry only if they satisfy the access request requirements, i.e. sworn affidavit or statutory declaration [PCPA, subsection 44(6)].

Step 20	**Review Panel Conclusions**
Purpose	Provide final recommendations to the Minister on the decision under review
Responsibilities	REC or STL, Review Panel Document Flagging Officer
Timeline (days)	*[120 days] Note: this time period may be modified by PMRA depending on the depth and breadth of the charge question.*

The Review Panel will provide a draft written report to the PMRA [PCPA, subsection 38(1)] within the delivery date set out in the workplan. The PMRA may comment and ask clarification questions before a final report is submitted by the Review Panel. Place the Review Panel report in the Public Registry [PCPA, subsection 38(2)].

The report will contain findings, analysis and recommendations on the decision under review. It will summarize the evidence, the arguments, and provide an assessment, indicating where the Review Panel agrees and disagrees with the representations. The Review Panel does not have to reach unanimity. The Review Panel's report will document the differences of position of the panel members, if applicable. Recommendations provided by the Review Panel to the Minister are not binding.

Present the Review Panel's final report for approval by SMC. SMC will then recommend whether the decision should be confirmed, reversed or varied [PCPA, subsection 35(3)]. Send the SMC recommendation to DMO/MO for decision through a Memo to the Minister. [PCPA, subsection 39(1)].

Prepare an Information Note announcing the Minister's final decision, describing the information considered as well as summarizing the science evaluation and the reasons for the decision. Obtain approval by SMC, legal services and DMO/MO.

Note: The Information Note shall be loaded under Doc ID (SCOM_INFO_NOTE_PDF_E/F).

The Document flagging officer will flag the Information Note to the Public Registry via normal procedures. The Information Note may also be posted to another area of the PMRA website. [PCPA, subsection 39(2)].

Step 21	**Closure of H.1.3 Submission**
Purpose	Finalize tracking of the Review Panel
Responsibilities	REC or STL
Timeline (days)	*[1 day]*

In e-PRS, finalize all documents. Move the Category H.1.3 submission to Level I DONE.

Mozaffar, Hilda

From: Izadi, Vedad (HC/SC)
Sent: Friday, July 29, 2022 12:06 PM
To: Stiege, Stacie (HC/SC); Larmour, Shela (HC/SC); Benedict, Christina (HC/SC); Satchwill, Trevor (HC/SC); Gisavi, Haris (HC/SC); Halevy, Miriam (HC/SC); Qi, Mei (HC/SC); Colley, Adam (HC/SC)
Cc: Hart, Connie (HC/SC)
Subject: RE: Tiger Team documents

Follow Up Flag: Follow up
Flag Status: Completed

Hi Stacie,

I just noticed the attached NoO criteria still has edits outstanding (I don't know which ones) – e.g. the appendix has footnote 2, with no actual footnote.
Maybe for the RVD main text doc, we could use OneDrive, so everybody's edits are captured in a single document, vs multiple versions over email.

Thanks,
Vedad

From: Stiege, Stacie (HC/SC) <stacie.stiege@hc-sc.gc.ca>
Sent: 2022-07-27 3:40 PM
To: Larmour, Shela (HC/SC) <shela.larmour@hc-sc.gc.ca>; Benedict, Christina (HC/SC) <christina.benedict@hc-sc.gc.ca>; Satchwill, Trevor (HC/SC) <trevor.satchwill@hc-sc.gc.ca>; Gisavi, Haris (HC/SC) <haris.gisavi@hc-sc.gc.ca>; Izadi, Vedad (HC/SC) <vedad.izadi@hc-sc.gc.ca>; Halevy, Miriam (HC/SC) <miriam.halevy@hc-sc.gc.ca>; Qi, Mei (HC/SC) <mei.qi@hc-sc.gc.ca>; Colley, Adam (HC/SC) <adam.colley@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>
Subject: Tiger Team documents

Hi Everyone,

The two documents (NoO Criteria and Legislative/RA Frameworks) are attached. We are trying to get these on the AMC agenda for next week. The aim is to get a decision on the NoO Criteria and for a discussion of the Frameworks. Minoli will present the item but the Team will be invited to be present for any questions that come up regarding the Frameworks. Please feel free to share these documents with your management teams.

I will be escaping the city from August 1-12. Mei has agreed to be the point person for the Team next week.

Thanks,
Stacie

Mozaffar, Hilda

From: Silva, Minoli (HC/SC)
Sent: Tuesday, August 23, 2022 10:02 AM
To: Bissonnette, Frédéric (HC/SC)
Cc: Najem, Sabrine (HC/SC); Stiege, Stacie (HC/SC)
Subject: Summary document to accompany the NoO criteria and templates for AMC
Attachments: Item xx AMC Aug 24,2022 Response to FCA recommendation.doc

Morning Fred.
As discussed, here is a summary that Stacie and I generated of why we are coming to AMC. I didn't know the item number so left it blank.
Thanks
Minoli

Minoli Silva
Director | Directrice
Review and Science Integration Division | Division des examens et de l'intégration scientifique
Pest Management Regulatory Agency | Agence de règlementation de la lutte antiparasitaire
Health Canada | Santé Canada
Minoli.Silva@hc-sc.gc.ca
Telephone | Téléphone: 613-769-3406

AMC Item Summary for Planning Purposes

Item (Title)	Implementation of Federal Court of Appeal (FCA) recommendations
Proposed Date	August 24, 2022
Information/Update	When the FCA quashed PMRA's decision on the Safe Food Matters notice of objection, it made the following recommendations in the reasons for the judgement: *PMRA should have regard and communication how it had regard to, The specific text, context and purpose of the preamble of the Act;* • *The definitions of "health risk" and "acceptable risks" in subsections 2(1) and 2(2) of the Act;* • *Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;* • *The meaning of "a scientifically based approach" when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;* • *The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;* • *The specific role and purpose of a review panel, in contrast to the role and purpose of the* *PMRA, when it receives a notice of objection under subsection 35(1) of the Act;* • *The specific threshold to be met when assessing "scientifically founded doubt" pursuant to the factors set out in section 3 of the Regulations;* • *The criteria that would determine whether the advice of expert scientists would assist in* *addressing the subject matter of the notice of objection under section 3 of the Regulations.* *The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.* In response, PMRA has generated criteria to be considered in the evaluation of a notice of objection to determine when an external panel of experts are required to assess the subject in question. These criteria are to be applied to all letters responding to notices of objection. In addition, PMRA has also included the legislative and risk assessment frameworks into the decision documents (Re-evaluation Decision, Special Review Decision, Registration Decision) to respond to the recommendations related to the PCPA.
Rationale for Presentation to AMC	AMC approval of the final notice of objection criteria and text included in the decision documents.
Status with EDO	
Status with Sub-Committee	
Lead Directorate(s)	RD

Contact(s): Frédéric Bissonnette
Telephone:
Date submitted to EDO:

Mozaffar, Hilda

From: Singal, Tina (HC/SC)
Sent: Wednesday, March 30, 2022 12:21 PM
To: Stiege, Stacie (HC/SC)
Subject: FW: Tiger Team project plan
Attachments: SG_TT_Describing Leg and RA Framework.docx

Follow Up Flag: Follow up
Flag Status: Completed

From: Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>
Sent: 2022-03-30 11:07 AM
To: Singal, Tina (HC/SC) <tina.singal@hc-sc.gc.ca>; Bissonnette, Frédéric (HC/SC) <frederic.bissonnette@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>
Subject: RE: Tiger Team project plan

I attempted to reflect what we discussed briefly yesterday, for your consideration.

Steph

From: Singal, Tina (HC/SC) <tina.singal@hc-sc.gc.ca>
Sent: 2022-03-30 10:01 AM
To: Bissonnette, Frédéric (HC/SC) <frederic.bissonnette@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>
Subject: RE: Tiger Team project plan

Now with the attachment.

From: Singal, Tina (HC/SC)
Sent: 2022-03-30 10:00 AM
To: Bissonnette, Frédéric (HC/SC) <frederic.bissonnette@hc-sc.gc.ca>; Mathew, Regi (HC/SC) <regi.mathew@hc-sc.gc.ca>
Cc: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>; Conti, Margherita (HC/SC) <margherita.conti@hc-sc.gc.ca>; Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>
Subject: Tiger Team project plan

Hi Fred and Regi,

Can I get some initial comments/feedback on the draft project plan for the Tiger Team on the FCA decision?

Comments by COB Thursday March 31 would be appreciated.

Thanks,

Tina Singal
(she/elle)

Stakeholder Engagement Unit
Value Assessment and Re-evaluation Management Directorate
Pest Management Regulatory Agency
Health Canada / Government of Canada
tina.singal@hc-sc.gc.ca / Mobile: 613-852-1453

Unité de mobilisation des intervenants
Direction de l'évaluation de la valeur et de la gestion des réévaluations
Agence de réglementation de la lutte antiparasitaire
Santé Canada / Gouvernement du Canada
tina.singal@hc-sc.gc.ca / Mobile: 613-852-1453

Government of Canada Gouvernement du Canada

Canada

TIGER TEAM: Describing PMRA's Legislative and Risk Assessment Framework

Scope:

On February 2, 2022, the Federal Court of Appeal issued a decision related to the Safe Food Matters' appeal of PMRA's decision to not establish a review panel for the re-evaluation decision for glyphosate. In addition, the paragraph 65 of the judgement included details with broader implications for PMRA's regulatory decision framework. A Tiger Team was created to ~~The Tiger Team will~~ assess the criteria outlined in Section 65 of the Reasons for Judgment in docket A-85-20 (Annex 1) and develop any necessary updates to wording to clarify PMRA's interpretation of the relevant sections of the Pest Control Products Act (PCPA) and Review Panel Regulations (Regulations), outlined in Annexes 2 and 3, respectively.

The decision on the redetermination of the Objections will be undertaken separately.

Notice of Objection templates and guidance

Update the Notice of Objection internal and external guidance. Internal guidance will include updates to templates to describe relevant parts of the PCPA and Regulations that were considered in the decision for internal decision making and communication with requesters. Definitions will be added to external guidance to clarify terms such as "scientifically founded doubt".

Evaluation / Decision publication templates

Draft wording describing the relevant parts of the PCPA on science reviews and the risk assessment framework used by PMRA for the following documents where the decision explicitly require reasons under the PCPA:

- Proposed and Registration Decision (PRD, RD)
- Proposed Maximum Residue Limit (PMRL)
- Proposed and Re-evaluation Decision (PRVD, RVD)
- Proposed and Special Review Decision (PSRD, SRD)

The Tiger Team will focus primarily on describing the risk assessment framework.

Tiger Team:

Directorate	**Representative**
EAD	Vedad Izadi
HED	Haris Gisavi
	Trevor Satchwill
POD	Miriam Halevy
RD	Stacie Stiege
Transformation	Adam Colley
VRD	Tina Singal

The Tiger Team will report to Frédéric Bissonnette and Margherita Conti (TBC).

Expectations:

Representative role: Coordinate feedback and approvals from representative's directorate, and attend meetings when necessary.

Time commitment: varies (up to 3 days a week)
Time tracking code: Policies & Processes – Guidance & SOP

Project Plan (FY 2022-2023):

Notice of Objection templates and guidance

Task	Description	TT Rep	PMRA / HC Rep*	Target Date	Actual Date
Initial draft	Template wording including how the PCPA and Regulations were considered	Tina Singal	Shela Larmour	Apr 8	
Identify docs for updating	Identify which templates and internal guidance or SOPs need to be updated	Stacie Stiege		Apr 8	
AMC presentation	Present project scope and timelines	TT lead	AMC	Apr 13	
TT review	Circulate initial draft for TT review	All	Any necessary staff	Apr 14	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
AMC presentation	Definitions and descriptions to be presented to AMC	TBD	AMC	Apr 27	
Update documents	Incorporate any revised wording / definitions into templates and internal guidance	All		May 20	
DG review	DG review and approval, where appropriate, for the templates and SOPs	TT lead	AMC	May 27	
Docs ready for use	Finalize templates and update SOPs for use by PMRA staff	All		May 31	
AMC update	Provide update to AMC	TT lead	AMC		
Draft external SOP	Review and update current draft external SOP (Reconsideration of Decision under the PCPA)	All			

* Where relevant

Evaluation / Decision publication templates

Task	Description	TT Rep	PMRA / HC Rep*	Target Date	Actual Date
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
AMC update	Provide status update to AMC	TT lead	AMC	July 20	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

* Where relevant

ANNEX 1: Reasons for Judgement – Docket A-85-20

[65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:

- The specific text, context and purpose of the preamble of the Act;
- The definitions of “health risk” and “acceptable risks” in subsections 2(1) and 2(2) of the Act;
- Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;
- The meaning of “a scientifically based approach” when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;
- The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;
- The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;
- The specific threshold to be met when assessing “scientifically founded doubt” pursuant to the factors set out in section 3 of the Regulations;
- The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations.

[66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.

Annex 2: Relevant sections of the *Pest Control Products Act*

PREAMBLE:

An Act to protect human health and safety and the environment by regulating products used for the control of pests

WHEREAS the availability and use of pest control products pose potential risks, both directly and indirectly, to the health, safety and well-being of individuals in Canada and to the environment;

WHEREAS pest management plays a significant role in diverse areas of the economy and other aspects of the quality of life throughout Canada;

WHEREAS pest control products of acceptable risk and value can contribute significantly to the attainment of the goals of sustainable pest management;

WHEREAS the goals of sustainable pest management are to meet society's needs for human health protection, food and fibre production and resource utilization and to conserve or enhance natural resources and the quality of the environment for future generations, in an economically viable manner;

WHEREAS Canada and the provinces and territories have traditionally administered complementary regulatory systems designed to protect individuals and the environment, including its biological diversity, from unacceptable risks posed by pest control products, and it is important that such an approach be continued in order to achieve mutually desired results efficiently, without regulatory conflict or duplication;

WHEREAS it is in the national interest that the primary objective of the federal regulatory system be to prevent unacceptable risks to individuals and the environment from the use of pest control products,

the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health and the environment both before and after registration and applies to the regulation of pest control products throughout Canada,

pest control products of acceptable risk be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent adverse health impact or pollution of the environment,

in assessing risks to individuals, consideration be given to aggregate exposure to pest control products, cumulative effects of pest control products and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors,

pest control products be regulated in a manner that supports sustainable development, being development that meets the needs of the present without compromising the ability of future generations to meet their own needs,

the federal regulatory system be designed to minimize health and environmental risks posed by pest control products and to encourage the development and implementation of innovative, sustainable pest management strategies, for example by facilitating access to pest control products that pose lower risks, and encouraging the development and use of alternative, non-toxic, ecological pest control approaches, strategies and products,

applicable policies of the Government of Canada that are consistent with the objectives of this Act be duly reflected in decisions respecting the regulation of pest control products,

there be cooperation among federal departments in the development of policies to pursue the attainment of the objectives of this Act, and that those policies take into account advice from diverse sources throughout the country,

the provinces and territories and those persons whose interests and concerns are affected by the federal regulatory system be accorded a reasonable opportunity to parti-cipate in the regulatory system in ways that are consistent with the attainment of its objectives, and

the federal regulatory system be administered efficiently and effectively in accordance with the foregoing principles and objectives and in a manner that recognizes the various interests and concerns affected and, where consistent with the primary objective of the system, minimizes the negative impact on economic viability and competitiveness;

AND WHEREAS Canada must be able to fulfil its international obligations in relation to pest management;

NOW, THEREFORE, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

2002, c. 28, Preamble; 2016, c. 9, s. 32.

Scientific approach

7(7) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall

(a) apply a scientifically based approach; and

(b) in relation to health risks, if a decision referred to in paragraph 28(1)(a) or (b) is being made or has been made in relation to a pest control product,

(i) among other relevant factors, consider available information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools, and cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity,

(ii) apply appropriate margins of safety to take into account, among other relevant factors, the use of animal experimentation data and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors, and

(iii) in the case of a threshold effect, if the product is proposed for use in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.

Evaluation of health risks

10(3) When specifying maximum residue limits for a pest control product or its components or derivatives pursuant to subsection (1), the Minister shall evaluate only the health risks of the product or its components or derivatives.

Health risks to be considered acceptable

11(1) The health risks associated with maximum residue limits specified by the Minister under sections 9 and 10 must be considered to be acceptable by the Minister.

Relevant factors

11(2) If a decision referred to in paragraph 28(1)(a) or (b) is being made or has been made in relation to a pest control product, the Minister shall, in evaluating and determining whether the health risks associated

with maximum residue limits for that pest control product or its components or derivatives are acceptable under subsection (1),

(a) among other relevant factors, consider available information on

(i) aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools,

(ii) cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity, and

(iii) the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors; and

(b) in the case of a threshold effect, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph 7(7)(b)(ii) or 19(2)(b)(ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children, unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.

Evaluation of pest control product

16(6) After the re-evaluation is initiated, the Minister shall, in accordance with the regulations, if any, conduct any evaluations that the Minister considers necessary with respect to the health or environmental risks or the value of the pest control product and shall carry out the consultations required by section 28.

Evaluation of pest control product

18(4) After the special review is initiated, the Minister shall, in accordance with the regulations, if any, evaluate only the aspects of the pest control product that are within the scope of the special review and shall carry out the consultations required by section 28.

Scientific approach

19(2) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall

(a) apply a scientifically based approach; and

(b) in relation to health risks,

(i) among other relevant factors, consider available information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools, and cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity,

(ii) apply appropriate margins of safety to take into account, among other relevant factors, the use of animal experimentation data and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors, and

(iii) in the case of a threshold effect, if the product is used in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and

toxicity to, infants and children, unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.

Annex 3: Relevant sections of the *Review Panel Regulations*

Notice of Objection

2 A notice of objection referred to in subsection 35(1) of the Act shall include

(a) the name and address of the objector or, if the objector is a corporation, its corporate name and any other name registered with a province by which the objector identifies itself;

(b) the decision to which the notice relates and the date on which the decision was made;

(c) the scientific basis for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(d) the evidence to support the objection, including scientific reports or test data.

Establishing Review Panels

3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

(a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and

(b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.