Notice of Intent NOI2024-01

Notice Of Intent: Revised Procedure For Category A, B, And L Application Data Deficiencies In Science Review

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1.0 Purpose

The purpose of this notice is to inform stakeholders that Health Canada's Pest Management Regulatory Agency (PMRA) intends to implement a limit of two opportunities to address recurring Review Stage data deficiencies in Category A, B, and L applications to register or amend the registration of a pest control product. The limit is specific to data deficiencies, or deficiencies in application completeness described under Section 7 of the *Pest Control Products Act.* The PMRA intends to make a targeted revision to the *Management of Submissions Policy* (MOSP) Section 4.2.1 (Science Evaluation) to reflect this limit. It is anticipated that the revised procedure will improve decision-making time and overall program performance. This proposal does not affect the scientific review itself, only the administration of recurring data deficiencies within a data element.

2.0 Background

The pre-market scientific assessment process to evaluate an application to register or amend the registration of a pest control product is described in detail in the MOSP. The MOSP also includes service standards for seven categories of review to support various types of applications for new or amended pest control products. It sets a performance target of completing 90% of reviews in each category within its service standard.

During the previous five years, there have been challenges in meeting pre-market program performance for Categories[1] A, B, and L.

A program analysis has identified various observations within these categories of applications that relate to these challenges and this proposal is part of the efforts undertaken by the PMRA to improve overall performance. Observations that led to this proposal are listed below:

- Total Times – described in the MOSP as the time between application receipt and registration, rejection, withdrawal, denial or completion – are longer than baselines described in Appendix I of the MOSP.
- The number of Review Stage deficiencies in applications is high and increasing (Review Stage is described in MOSP Section 4.2).
- The amount of time an application is "on-hold" – described in the MOSP as the time in which applicants prepare responses to application deficiencies – is one aspect that significantly affects Total Time.
- Applications with repeated Review Stage deficiencies that are placed on-hold multiple times have a significantly lower likelihood of being granted a registration compared to those with fewer or no deficiencies.
- On average, registrations are issued over two times faster for deficiency-free Conventional Category A applications compared to those with Review Stage deficiencies.

[1] See the MOSP for a description of submission categories

Applications with deficiencies can consume a disproportionate amount of time and effort from both the PMRA and applicants. Furthermore, lengthy on-hold times are associated with a lower likelihood of the product being registered as noted above. While these are not the only contributing factors, they indicate that meaningful improvements in both decision-making times (Total Times) and overall program performance could be realized by limiting the use of on-hold periods.

The number of opportunities available to an applicant to address recurring deficiencies within the same data requirement is not specified in Section 4.2 of the MOSP. Historically, the PMRA has implemented this element of the policy with some flexibility, particularly in recent years in which a number of applications and deficiency response efforts have been affected by issues related to the COVID-19 pandemic.

3.0 Revised Procedure For Category A, B, And L Application Data Deficiencies in Science Review

As part of its efforts to improve decision-making time and overall program performance, the PMRA intends to implement a limit of two opportunities to address recurring Review Stage data deficiencies.

The scope of this change is limited to data deficiencies identified during Science Review in Category A, B, or L applications. A data deficiency is defined as missing or incomplete information that is required for the Minister to complete the necessary evaluations of the pest control product required under the *Pest Control Products Act.* Examples of data deficiencies include, but are not limited to:

- The absence of a study required to evaluate an application to register or amend the registration of a pest control product
- A study that does not comply with applicable requirements such as Good Laboratory Practice, PMRA Guideline or Guidance, or an OECD Test Guideline

There is no modification to procedures currently in place to address a conclusion or preliminary conclusion of unacceptable risk or value made following the evaluations described in paragraph 7(3)(a) of the *Pest Control Products Act*.

Additionally, the following applications will not be subject to this change:

- Emergency use applications made under DIR2017-03, *Registration of Pesticides for Emergency Use: Revised Procedures*
- Needs identified by, or applications submitted by, Federal, Provincial, or Territorial governments

3.1 Amendment to section 4.2.1 of the MOSP

The PMRA intends to amend the MOSP Section 4.2.1, paragraph two, with the addition of the following text in bold:

> If deficiencies are identified by a single science review stream at any time during the review stage, a Notice of Deficiencies will be sent to the applicant, the submission will be placed "on-hold", and the review stage clock will stop. The science review stream to which the deficiencies apply will stop that portion of the review; however, the remaining science review streams will continue to actively work on the submission during this time if this is possible and determined to be efficient. The applicant is given a specified number of days (usually 90 calendar days) to fulfil the requirements outlined in the Notice of Deficiencies. There will be no reminders provided during the "on-hold" period. When the response is received within the required timeframe, the review stage clock will immediately restart and the affected science review stream will continue their review. **If the response is inadequate, a second Notice of Deficiencies may be issued in which case the preceding process will repeat. If, following the second Notice of Deficiencies issued for a recurring deficiency, the response is inadequate, the application may be denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application.** Lack of a response, **or an incomplete response to any Notice of Deficiencies** within the required time frame will result in the application being denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the submission.

4.0 Supplementary Notice to Applicants Regarding Deficiency Procedures in The MOSP Section 4.1.2, Screening

In recent years and as a result of the pandemic, the PMRA has been flexible in administering the deficiency procedure described in the MOSP Section 4.1.2 (Screening). There are no proposed changes to this section of the MOSP, however, this document also serves as a notice to applicants that as of 1 February 2025, the PMRA will adhere more closely to the deficiency procedure in this section of the MOSP.

5.0 Next Steps

Data deficiencies identified in Science Review in Category A, B, and L applications on or after 1 February 2025 will be subject to this Notice.

The PMRA's Policy and Guidelines web page will be updated with a copy of the MOSP revised as described in this Notice.

The PMRA will consider written comments regarding this Notice of Intent up to 30 days after the date of publication of this document.

Please forward your comments to the PMRA's Publications Section, and include:

Your full name and organization;
Your phone number; and,
Your complete mailing address or email address.

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