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Notification of Water Modelling version update

Health Canada's PMRA uses water modelling software called Pesticide in Water Calculator (PWC) to estimate concentrations of pesticides in ground and surface waters as part of the risk assessment process. This model is also used by the US EPA and has been updated. Health Canada has started to implement PWC version 2.0; the US EPA is using PWC version 2.001. There are no changes in modelling between the two versions, thus Health Canada has not implemented the change to version 2.001. The PWC model can be found on the US EPA website (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>). Health Canada is conducting testing for more complicated water modelling scenarios; therefore, PWC version 1.52 will continue to be used to confirm results between the two versions. Health Canada's documentation for water modelling will indicate which version of the model (PWC 1.52 or PWC 2.0) has been used.

Amendments to the Incident Reporting Regulations

- Amendments to the Incident Reporting Regulations will come into force in January 2022. The Incident Reporting Program of PMRA will hold an information session on November 24th for Registrants to highlight the changes that will affect their work. An invitation will be sent out.
- The changes are outlined in the Canada Gazette II <https://canadagazette.gc.ca/rp-pr/p2/2019/2019-06-12/html/sor-dors173-eng.html> and include those to the timeline to report incidents, the trigger for submitting an annual summary, and only having to classify the most serious incidents.

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Sunsetting of the NAFTA Label Program

The purpose of this communique is to inform applicants that the NAFTA Label Program is no longer in effect since October 2021. The program, initiated in 2007, allowed the cross-border movement of approved products between Canada and the United States. The decision to close the program is based on the low utilisation of the program as well as availability of other mechanisms currently in place that accomplish similar goals. In Canada, the Grower Requested Own Use Program permits growers to import equivalent products registered in the US. As a result the PMRA will remove all NAFTA statements from the labels of the five remaining products that are impacted during the review of the next open application for those products.

PMRA's process for 90-day "on-hold" requests for additional data/information

The purpose of this communique is to remind Applicants of the way in which the PMRA manages 90-day "on-hold" requests for additional data/information during the science evaluation stage.

As part of the submission review process, the PMRA may request additional data/information and allows 90-days for the applicant to submit the requested data/information. As indicated in the *Management of Submissions Policy*, the PMRA will issue one consolidated Notice of Deficiencies to the extent possible. However, in the event that deficiencies are identified by a second science review stream during the course of the first "on-hold", a second Notice of Deficiencies will be issued and a new timeline of 90 calendar days from the time of the second Notice will be assigned. This new timeline will serve as the deadline for receipt of all data/information.

Some flexibilities were provided during the pandemic but in the interest of ensuring that open submissions with the PMRA are being managed efficiently and effectively, and that data/information is being provided in a timely manner, the PMRA will:

- Expect a response before the end of the 90-day deficiency response deadline. A response may be in the form of adequate data to satisfy the identified deficiency, a request to withdraw the submission or a written request for an extension of the deadline.
- Require a written rationale for extension requests, indicating the additional time being requested for providing the outstanding data/information, and the reason for it. These rationales will be assessed to determine if the extension can be granted.

- Not be sending out reminders regarding the approaching deadlines. In the event that a response, or request for an extension to the timeline, is not received by the 90-day deadline, the submission will be denied in accordance with subsection 7(5) of the Pest Control Products Act. Fee reimbursements will be processed as appropriate.
- Apply the same standard to those submissions for which an extension to the deadline was granted; a response must be received by the new deadline; otherwise the submission will be denied in accordance with subsection 7(5) of the Pest Control Products Act.

Should you have any questions regarding your submissions that may be impacted, please contact the Submission Coordinator responsible for your submission.

Update to Pesticide Product Information Database for Increased Transparency

A new registration status was added to the Pesticide Product Information Database (PPID) to indicate when products are undergoing phase-out following a final re-evaluation or special review decision. Historically, any product undergoing phase-out following a re-evaluation or special review decision would appear as "Full Registration" in the PPID until the date of expiry, at which point its registration status would change to "Cancelled" and the registration would become historical. The new registration status, "**Phase-out**", now appears in the search functionality of the PPID and the PMRA has begun the implementation of the change in status for all pest control products undergoing phase-out following a re-evaluation or special review decision.