PMRA Transformation including

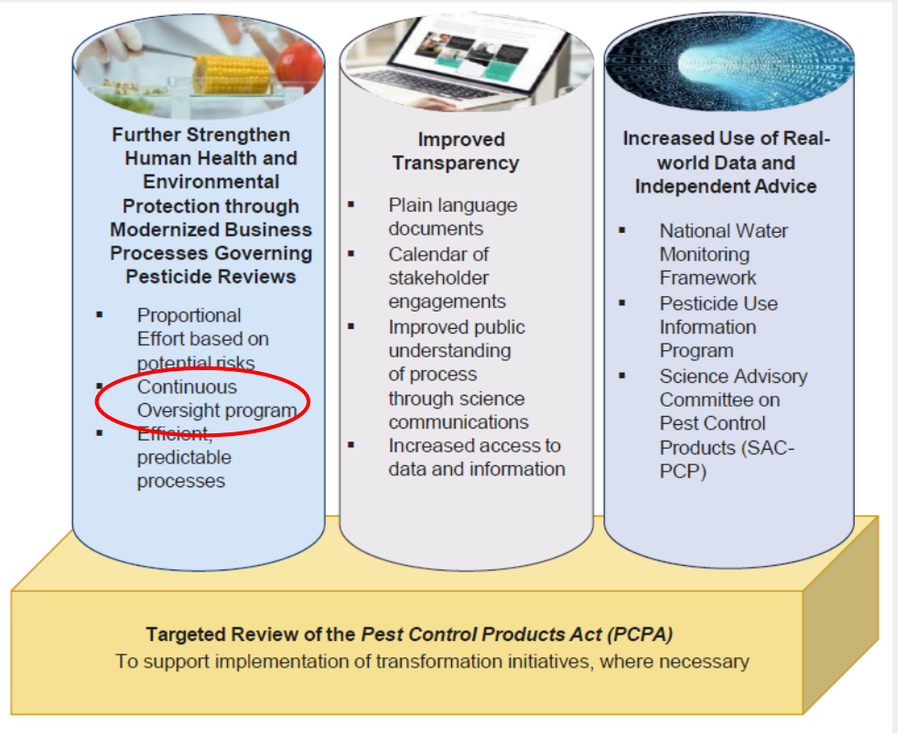
- Continuous Oversight
- Access to Confidential Test Data
- IT Modernization
- Annual Charge Fee Consultation
- Audit of sales records

Joe McCarthy, Principal Regulatory Consultant
March 26, 2024

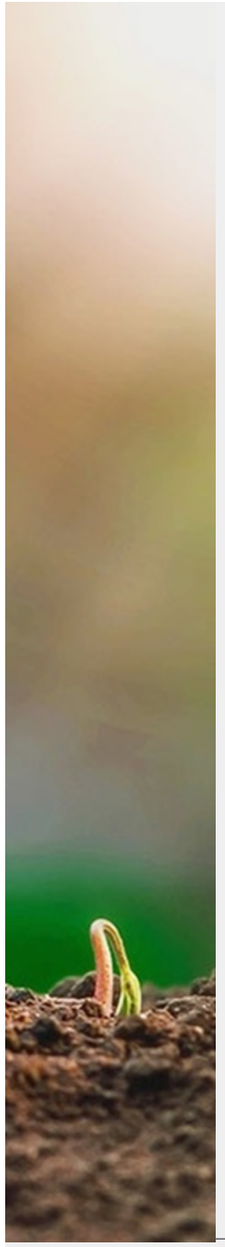
PMRA Transformation Continuous Oversight

PRO2024-01 Proposed policy on continuous oversight of pesticides

PMRA Transformation Agenda

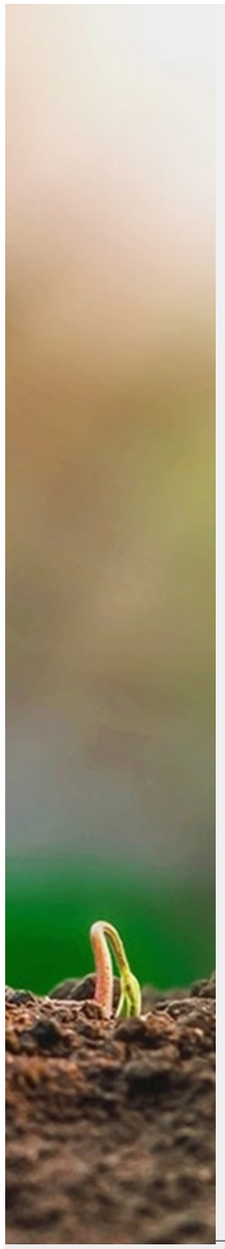


- Started in Spring 2022 to Modernize business process, improve transparency, increase use of real word data and a targeted review of the Pest Control Products Acts.
- The continuous oversight concept was identified as one of the practices to use with a modernized business process.



PRO2024-01 Proposed policy on continuous oversight of pesticides

- Consultation document published January 3, 2024. 60-day comment period closed March 3, 2024.
- Current practice is that after approval active ingredients and their uses are Re-evaluated at a “point in time” at least every 15 years.
- Or a Special review may be initiated if the PMRA has reasonable grounds to believe that health or environmental risks, or the value of a pesticide may no longer be acceptable.
- The point in time model is not considered efficient because new data may have been available for years before a re-evaluation was initiated.
- This approach will create a continuous oversight throughout the pesticide lifecycle.
- Continuous oversight contributes to the re-evaluations, it does not replace the re-evaluations or special reviews.



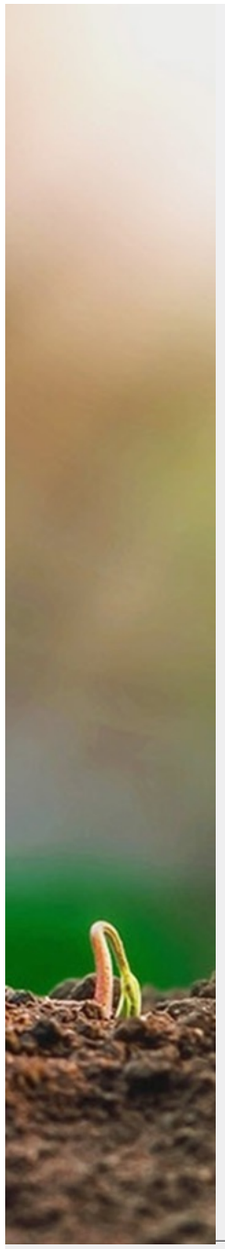
PRO2024-01 Proposed policy on continuous oversight of pesticides

4 key actions under Continuous oversight proposal

1. Scientific literature and regulatory information.
2. Pesticide incident reporting program.
3. Pesticide water monitoring.
4. Chemistry information for technical grade active ingredients.

Monitoring of scientific literature and regulatory information

- Continuous monitoring of Studies and reports published in peer-reviewed science journals; Scientific databases (aka “grey literature) such as government science journals, monographs and programs, pesticide monitoring, biomonitoring and draft/preliminary risk assessments on pesticides; Final decisions and associated documentation (reference lists) related to a pesticides by an OECD a regulatory authority; Indigenous knowledge related to the effects of pesticides, where available.
- PMRA intends to use a combination of automated search, dataset alerts and Health Canada Library serves to conduct the searches.
- PMRA is committed to making public the proposed methodology and criteria for conducting searches.
- Information identified through the search will be screened to determine of the information is relevant.



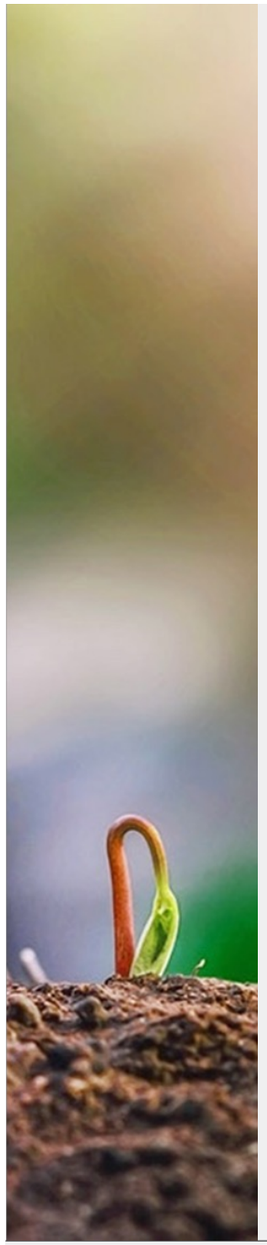
PRO2024-01 Proposed policy on continuous oversight of pesticides

1. Monitoring of scientific literature and regulatory information

Relevancy of data identified.

Does the information or study…

- Relate the assessment of health and/or environmental risks of a pesticide?
- Is it applicable to pesticide registered in Canada, or not registered in Canada but used on imported foods.
- Is the source credible?
- Includes sufficient detail and information to permit risk characterization and/or conclusions to be drawn?
- Includes sufficient detail of purity, dose, durations, controls, test species and/or test model.



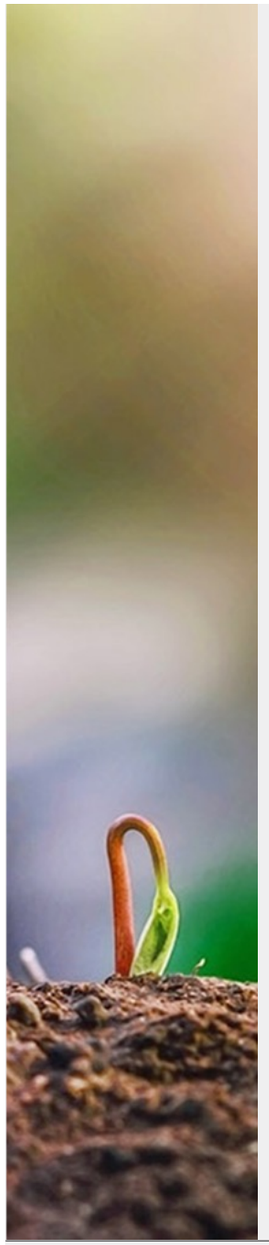
PRO2024-01 Proposed policy on continuous oversight of pesticides

1. Monitoring of scientific literature and regulatory information

If identified as relevant, then what?

Triage assessment and actions.

Triage of relevant study	Action
Information suggestive of: • greater health or environmental hazard than that determined at the last science review; • an increase or new health or environmental risk relative to what had been determined at the last science review; **Example:** A study that suggests the pesticide is more toxic than was considered in the PMRA risk assessment.	If the study or information provides reasonable grounds to believe that the risks are unacceptable, the PMRA will initiate a special review to conduct a full review of the study or information for the aspect of concern.
Information where the results are equivalent, or already accounted for in, the existing risk assessment. Information is not expected to change the outcome of the PMRA risk assessment. **Example:** A study that describes an effect at a dose that is higher than the level already used in the PMRA risk assessment.	Summarize study findings and retain the study for further assessment at the next science review point (for example, the next re-evaluation).
Information is not currently appliable to the risk assessment framework or registered use pattern in Canada. Study does not impact the outcome of the current PMRA risk assessment. **Example:** A worker exposure study related to a use that is not applicable in Canada.	Summarize study findings and retain the study for future consideration, if necessary.



PRO2024-01 Proposed policy on continuous oversight of pesticides

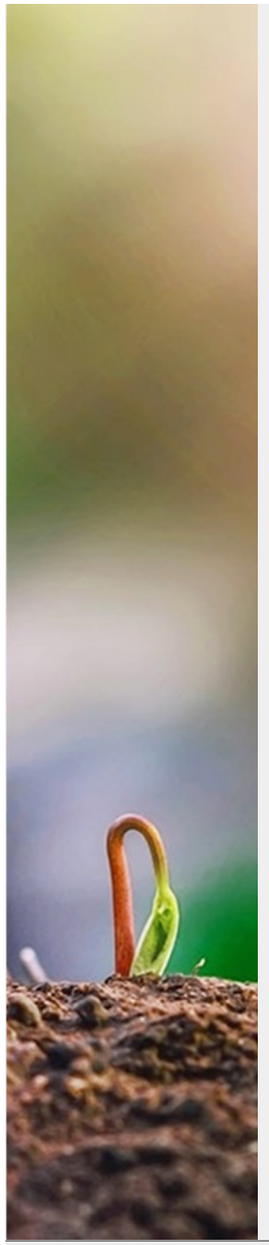
2. Pesticide incident reporting program

Registrants are required to report

- Adverse effects that occur in Canada on humans, animals, terrestrial or aquatic plants.
- Adverse effects that occurs in the USA and are a human death, a major effect on a human, or a domestic animal death.
- Packaging failure that could result in human exposure or injury.
- Scientific studies that suggest an increased risk.
- Identification of a new hazard, risk, or undetected component or derivative identified in a pest control product.

PMRA Actions

- Required to evaluate if Incident reports warrant a special review.
- If no special review initiated, information is retained for consideration in next application, re-evaluation for other reviews.



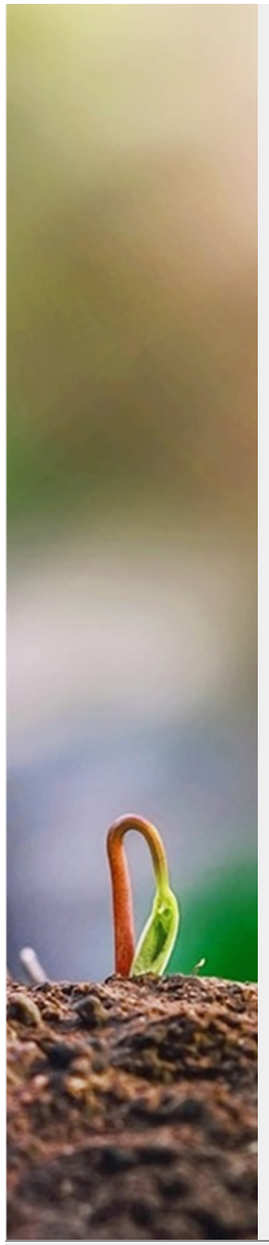
PRO2024-01 Proposed policy on continuous oversight of pesticides

3. Pesticide water monitoring

- Pilot project started in 2022.
- 84 surface water sites and 4 ground water sites across Canada.
- Tests for 190 pesticides currently in use.
- Data also generated by other federal, provincial & Territorial agencies, researchers and pesticide companies.

PMRA Actions

- Screen detected concentrations against Aquatic Life Reference Values (ALRV) and Human Health Reference Values (HHRV).
- If a pesticide is found to exceed the reference values, the PMRA will determine whether a special review is warranted.



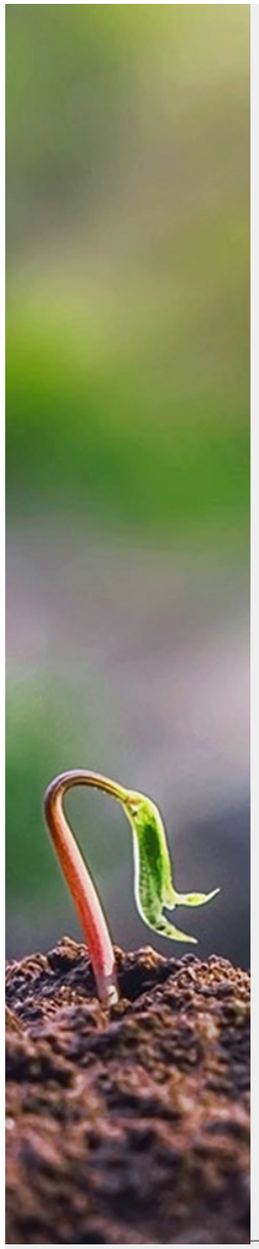
PRO2024-01 Proposed policy on continuous oversight of pesticides

4. Chemistry information for technical grade active ingredient (TGAI) products

PMRA Actions

Will require registrants to submit:

- Updated Statement of Product Specification Form (SPSF) Form 6003 including the concentration of the active ingredient, impurities and/or contaminants.
- Detailed description of the current manufacturing method (DACO 2.11.1-2.11.4, M2.8, M2.9).
- Recent commercial production data, such as quality control data, indicating the active ingredient concentration, manufacturing location and date as well as impurities or contaminants monitored during the production process. (DACO 2.13.3, M2.10).



PRO2024-01 Proposed policy on continuous oversight of pesticides

How PMRA will use relevant information collected through continuous oversight

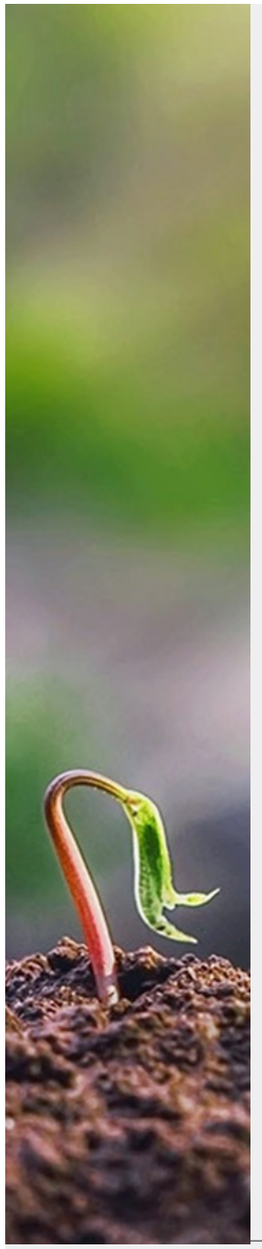
Special review

If the study or information provides reasonable grounds to believe that the risks are unacceptable, the PMRA will initiate a special review to conduct a full review of the study or information for the aspect of concern.

Re-evaluations

Information collected through Continuous oversight will be used for ongoing scoping throughout the pesticide lifecycle such that when a re-evaluation is initiated the consideration of available information and identification of re-evaluation requirements are already well established.

The PMRA intends to be more transparent with stakeholders about the re-evaluation requirements identified through continuous oversight, including anticipated data needs.



PRO2024-01 Proposed policy on continuous oversight of pesticides

How PMRA will use relevant information collected through continuous oversight

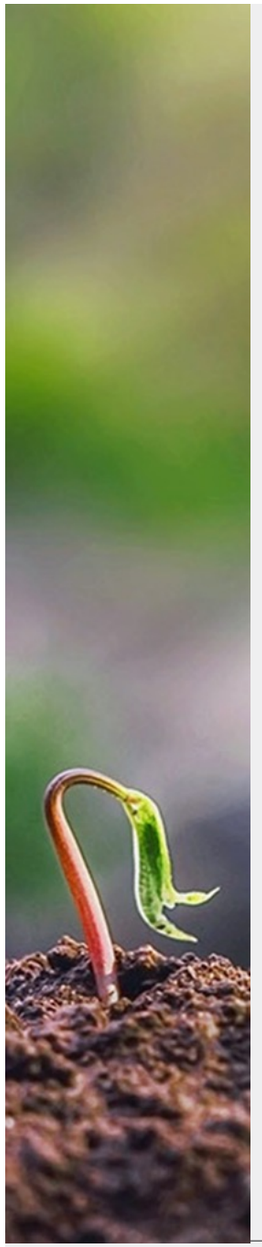
Applications to register or amend the registration of a pesticide

"in addition to the submitted data and information from the applicant, the PMRA will consider the information collected through continuous oversight (for the scientific literature, foreign regulator decisions)."

For the following application types,

Category A.2.0 – Major new use.
Category B.3.1 – Application rate increase.
Category B.3.2 – Change to application timing.
Category B.3.12 – Label use expansion (new use).
Category D.3.2 – User requested minor use label expansion.

*"If the assessment of the submitted information and **the information collected as part of continuous oversight trigger the need** for additional information from the applicant, **the submission will be put on hold** to request the information as per the Management of Submissions Policy."*



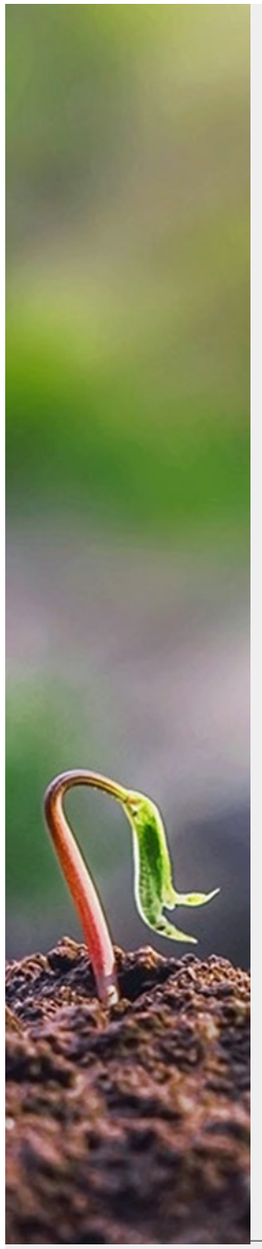
Access to Confidential Test Data (CTD)

Public may inspect data used in support of a decision to

- Register or amend a pest control product.
- Continue a registration or cancel a registration after a re-evaluation or special review.

Under the Pest Control Products Act CBI may only be declared for

- Formula, manufacturing or quality control processes relating to a pest control product.
- Methods for determining the composition of a pest control product.
- The monetary value of sales and other financial or commercial information provided pursuant to the Act & Regulations.
- The identity and concentration of the formulants and contaminants in a pest control product, other than those considered to be of health or environmental concern that are identified on a list to be made available to the public.
- Information that can be refused under Access to Information Act.



Access to Confidential Test Data (CTD)

Current process to inspect test data

Person wishing to inspect the data must

- Submit application form.
- Submit an affidavit under oath stating the purpose of the inspection and a declaration that they do not intend to use the test data or make it available to others to register or amend a pesticide in Canada or elsewhere.
- No fee.

Registrants

- Are notified an application has been received and the affiliation, but not identity of the requestor.
- This is a notification only, no right to consent or object.

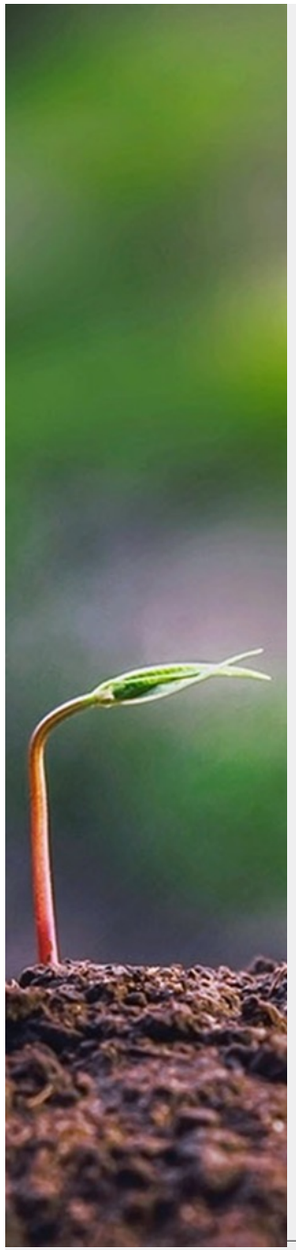
Inspection of data

In person in Ottawa at PMRA's reading room.

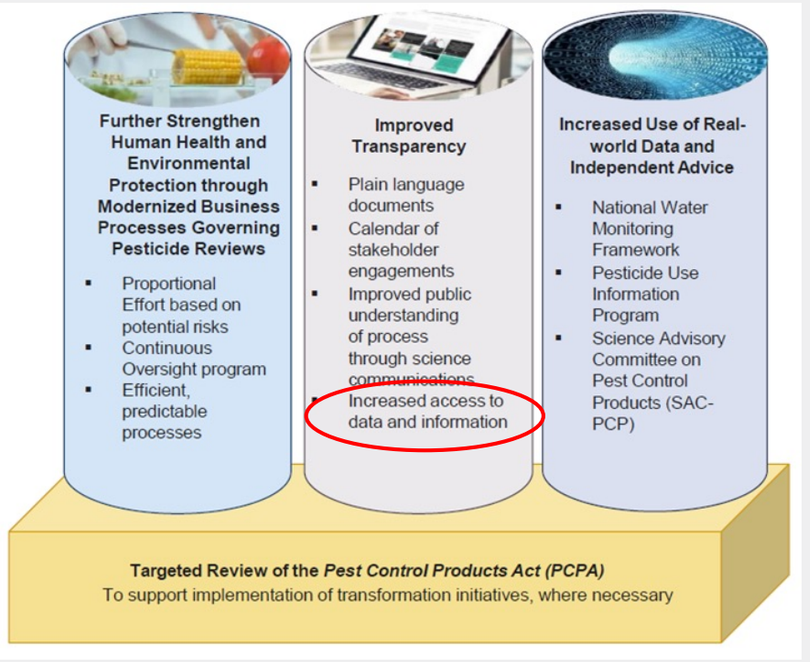
- Electronic devices such as cell phones, laptops, digital cameras, and personal digital assistants are not permitted in the Reading Room. Data is provided in electronic format with computers ports disabled, no internet of Wi-Fi access.
- *No right under PCPA S.43 to make copies of data*. Handwritten notes may be made but PMRA will retain photocopies of notes.

Remote inspection (pilot project since at least 2020)

- Encrypted USB provided to requestor. Additional digital rights management measures prevents copying, sharing, and printing features watermarking, document expiry, environmental controls, verification of document access, and password protection.
- Must be received in person by requestor and signed for.
- USB must be returned to PMRA.



Access to Confidential Test Data (CTD)

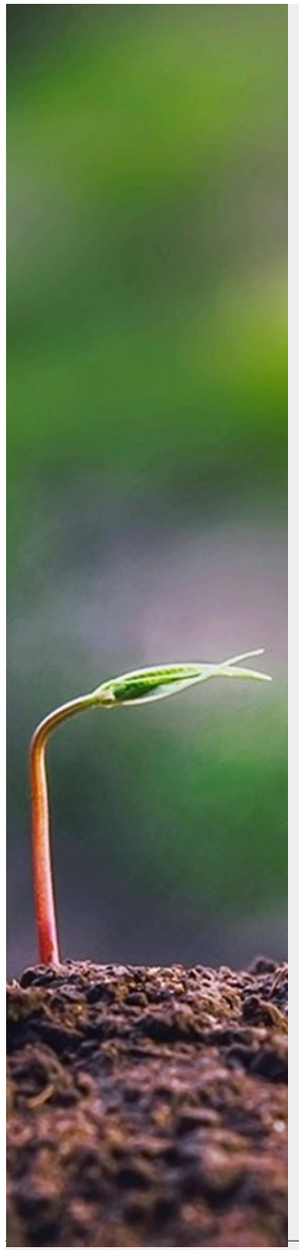


Notice of Intent NOI2023-01, Strengthening the regulation of pest control products in Canada

"To facilitate access to CTD, including for research and re-analysis purposes, Health Canada is proposing to amend the Pest Control Products Regulations ***to enable inspection of CTD for research and re-analysis purposes****. This amendment would provide access to CTD in a manner that would* ***allow an individual to conduct their own data analysis****, while maintaining the appropriate levels of protection against unfair commercial use of the data"*

No formal consultation public yet, but proposal likely to include

- Create a secure online portal to apply for access and view data.
- Permit data to be searchable to be found within larger documents.
- Allow data to be downloaded, printed, saved so that it can be analyzed calculated, and manipulated.



IT Modernization: new web based eIndex builder.

e-Index Builder - B1.2 New TGAI.xml

File Edit Tools Help

Row No.	Data Numbering Code(s)	Title	Author(s)	Report Date	Company Report No.	No. of P...	e-File Location	Volume No(s)	EPA MRID No.	Cross Refe...
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4	0.8		Joe McCarthy							N
5	0.8.7					1				N
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7	1.1.2		Joe McCarthy							N
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9	2.11.1, 2.11.2, 2.11.3									N
10	2.11.4									N
11	2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4									N

Data Numbering Code(s): 1.1.2 PROPOSED LABEL - French

Add Selected

M1.2 PRODUCT PROFILE AND PROPOSED USE PATTERN
M1.3 INTERNATIONAL REGULATORY STATUS OF THE MPCA AND EP
M10.0 VALUE (INCLUDING EFFICACY)
M10.1 SUMMARY
M10.2 PERFORMANCE ASSESSMENT

Cross Reference: Yes / No
PMRA Document No.
Application No. -

Confidential Business Information: Yes / No
Applicant DER: Yes / No

Owner | Owned by a 3rd Party?
Multiple Owners?

For studies, these fields cannot be blank, or populated with 'n/a'.

Please provide a sufficiently descriptive title.

Title
Author(s) Joe McCarthy
Report Date | Select | Clear

Lab Name
Lab City
Lab Country -- Please Select --
Lab Report No.
Study Carried Out Under -- Please Select --
Published: Yes / No
Document Group

Company Report No.
No. of Pages
Volume No(s)
EPA MRID No.

Comments

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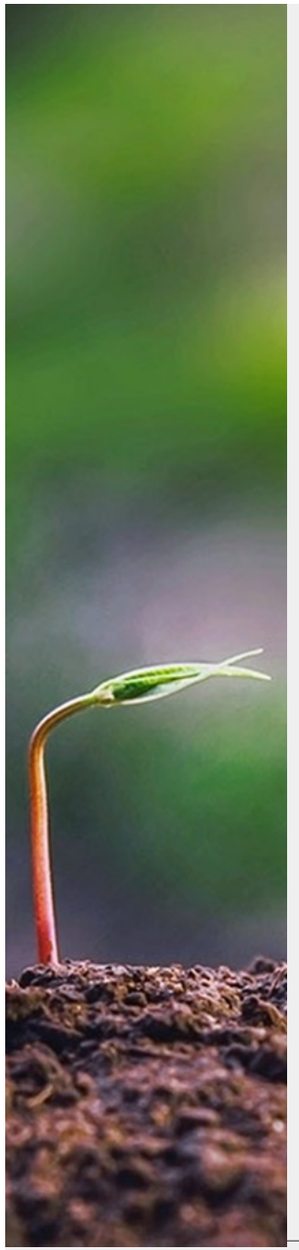
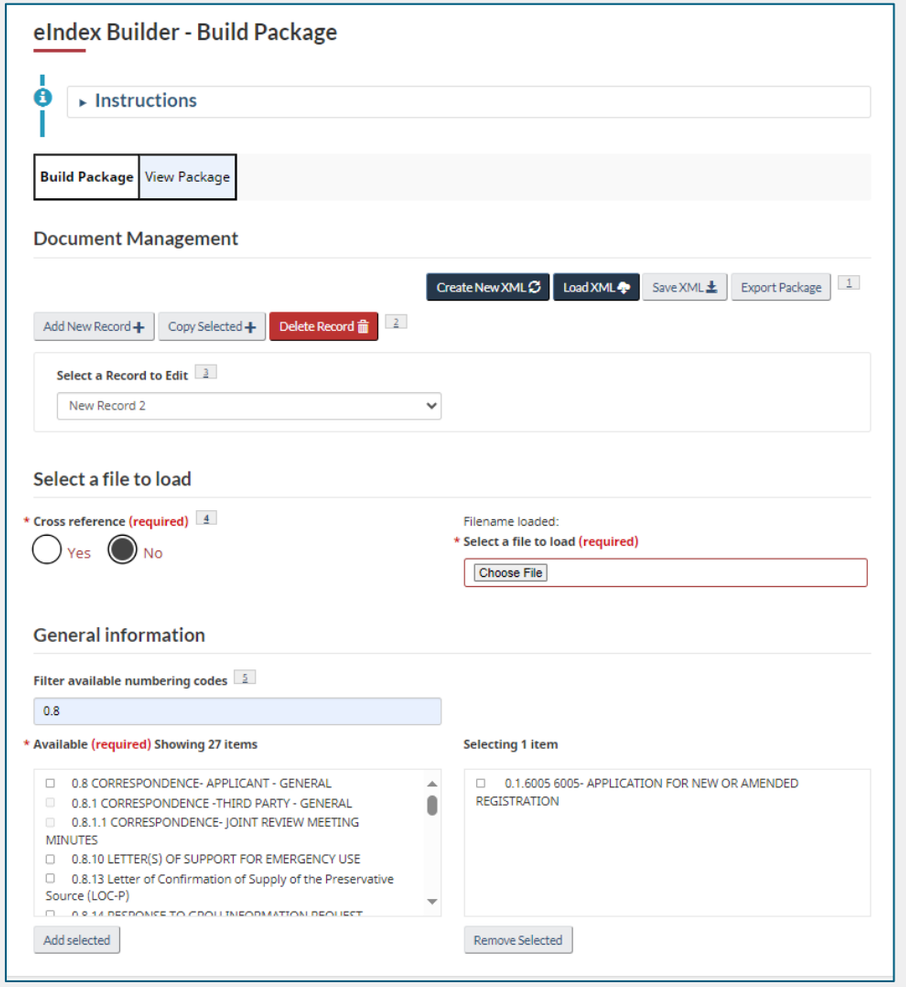
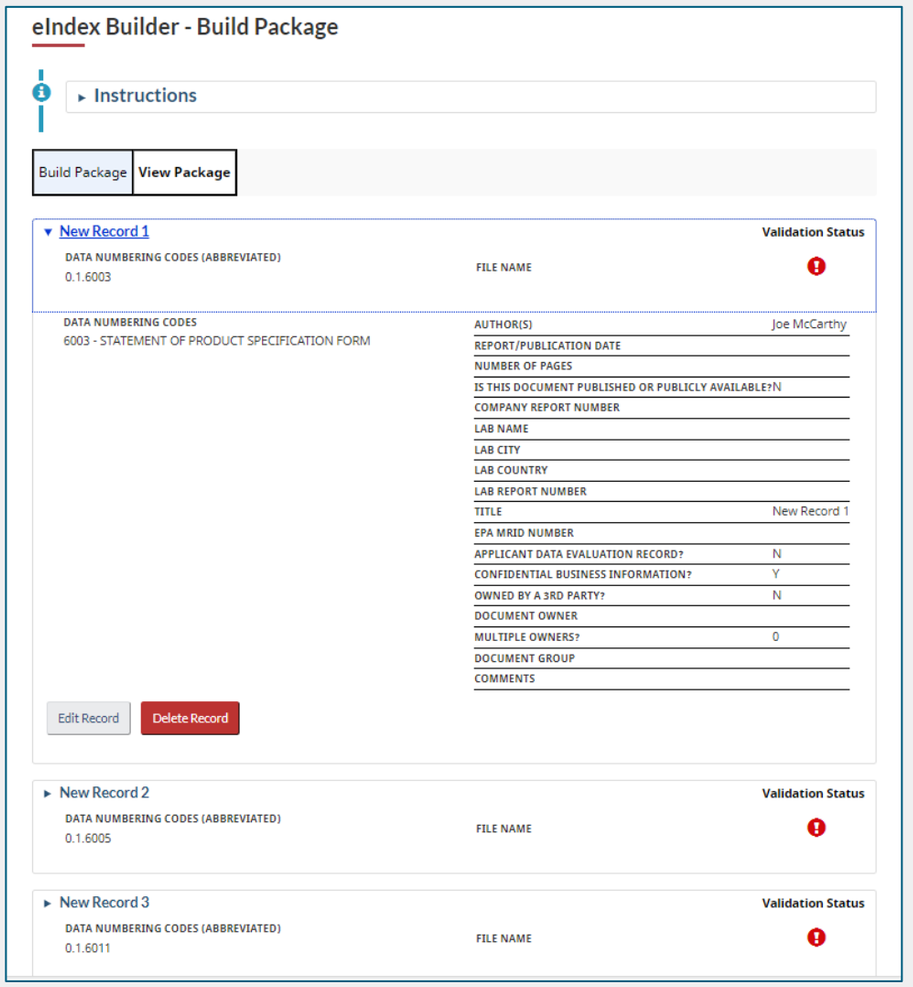
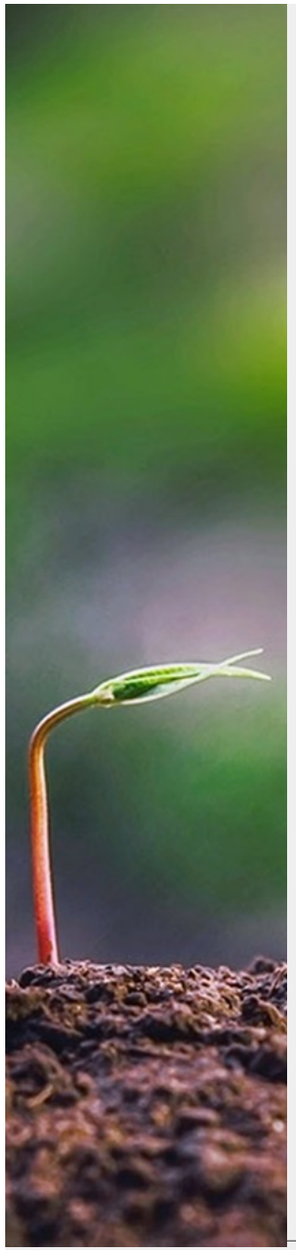


IT Modernization: new web based eIndex builder



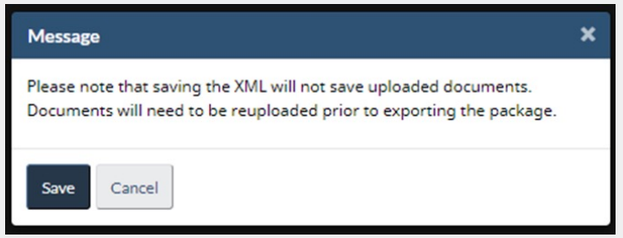




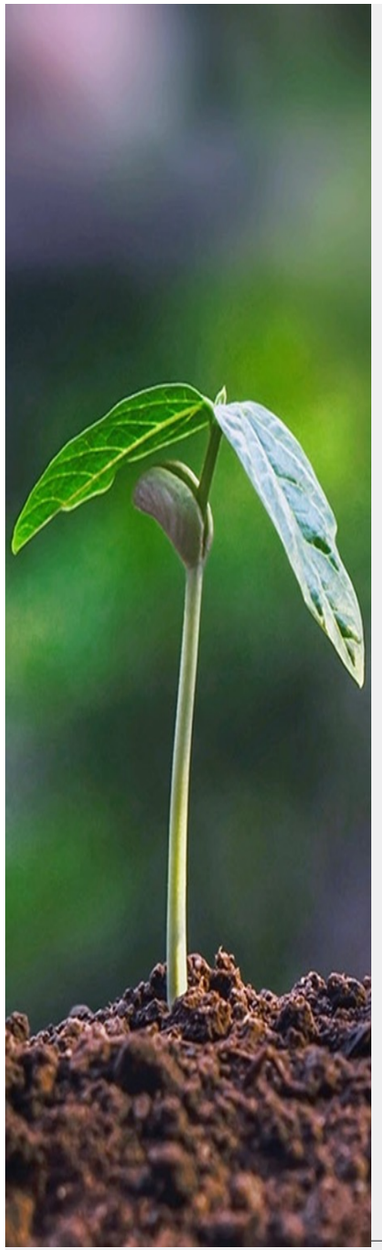
IT Modernization: new web-based e-Index builder.

Challenges:

- Can't see the entries altogether and need to flip back and forth between the Build and View tabs, even then you can't see all the information on one screen.
- Can't attach documents unless you are ready to finalize the file for submission, or they will disappear.



- When the eIndex is saved and reopened later, you must reload all the documents again and validate/save each & every record again.
- Not able to pick where to save the xml file, nor what to name it when you create it. It will automatically save to downloads folder.
- Error messages received when you do not click validate and save for each entry - in general there are far too many steps.
- You now need to put in the number of pages and the document title for a document. For something like incident reports this seems unnecessary.
- If you close the window or tab, or click back on the browser, you lose any changes, there is no warning about closing the window or leaving the page.
- Saving a PMRA Regulatory Zip file (PRZ) file does not automatically create an XML (eIndex file).
- Not user-friendly and no engagement with stakeholders prior to launch and no webinar scheduled.



IT Modernization: Structured Label Pilot

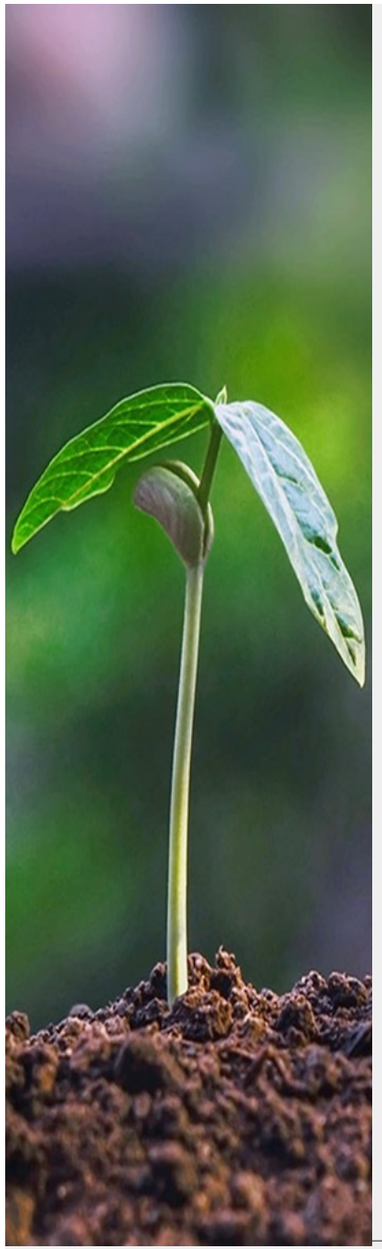
- A structured label is the same as the current pdf label, except that it is **highly organized and formatted**.
- Label Information is entered into **defined data fields** instead of a Word document.
- These data fields are what give the label it's structure, provide context for the information contained, and allow for **enforcement of standardized label wording and terminology**.

Important Dates & Schedule

Dates*	Release	Deliverables
July 2023	R1	Develop: **1.** Principal Panel **2.** Use Index**
November 2023	R2	Update: **1.** Principal Panel **2.** Use Index Develop: **3.** Secondary Panel **4.** Verified Use Information (VUI) report
March 2024	R3	Update: **1.** Principal Panel **2.** Use Index **3.** Secondary Panel **4.** Verified Use Information (VUI) report Develop: A.I.R. database to manage label review and workflow

* Timeline dependent on feedback and results of each Release

** Pilot to prioritize Use Index data requirements & product types included in re-eval 5-year plan

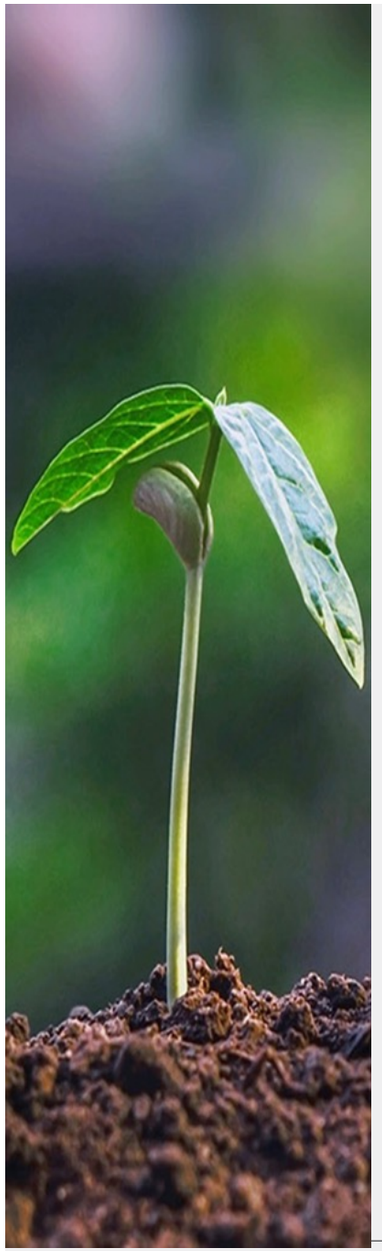


PMRA Consultation on a proposal to update fees for pest control products

- Announced January 31st, 2024. Consultation will be open for 60 days, until ~~March 31~~ April 14th, 2024.
- Focused on updates to the PMRA Annual Charges.
  Annual charges are intended to fund re-evaluations and post registration compliance & enforcement.
- Does not apply to fees for new applications, amendments, notifications or renewals.

PMRA Annual Charge Fee Current and proposed comparison

Current Fee Structure	Proposed Fee Structure
4% of annual gross sales in previous fiscal year for each registered Pest Control Product Maximum fee: $4,317.93 CAD per registration Minimum fee: $119.93 CAD per registration	$6,130 CAD per registration
	Small Business: $2,000 CAD per registration
	Biopesticides: $1,000 CAD per registration
	Niche products: $1,000 CAD per registration



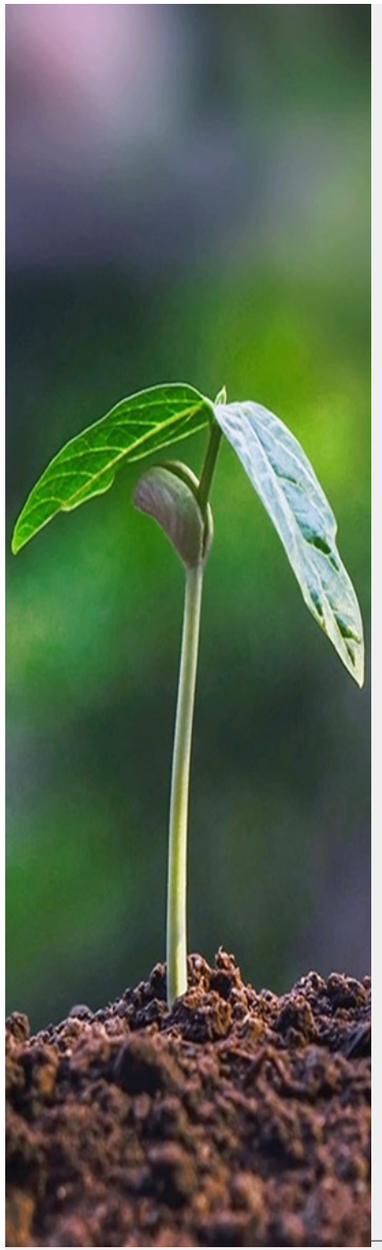
PMRA Consultation on a proposal to update fees for pest control products

Small business: (2,000 $CAD per registration)
Fewer than 100 employees, and less than $5 million (CAD) in annual gross revenues globally and from all product lines.

Biopesticides: (1,000 $CAD per registration)
Include microbials, semiochemicals and non-conventional pest control products**.** Examples of non-conventional products include but are not limited to Food items (vinegar, corn gluten), Plant extracts (essential oils, vegetable oils), inert materials (Diatomaceous earth), commodity chemicals (borax, sodium chloride)

Niche products: (1,000 $CAD registration)
pest control products where there is limited economic incentive to maintain registration but have high value uses, specifically:

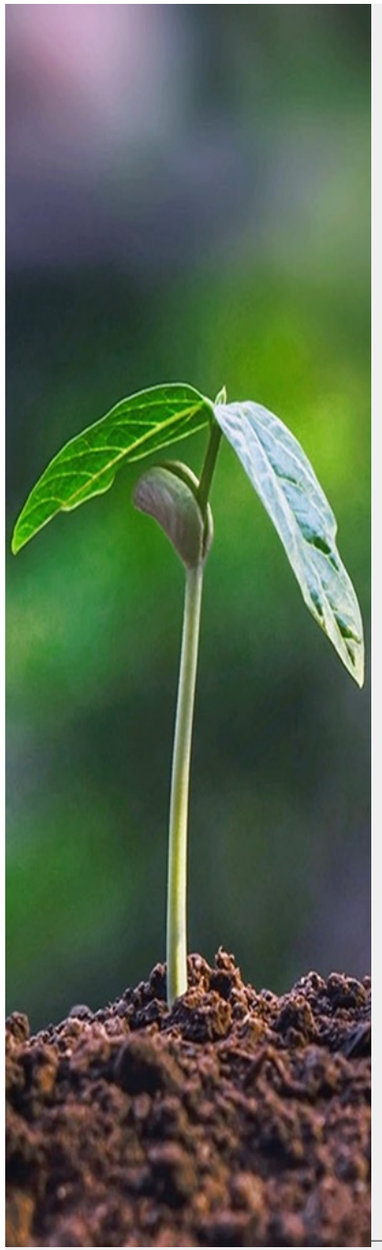
- low-acreage crops.
- products that support public health programs.
- products that support environmental protection, for example, to control invasive non-native species and protect species at risk.



PMRA Consultation on a proposal to update fees for pest control products

Next Steps

- The Consultation document may be accessed at this link,
  Consultation on a proposal to update fees for pest control products
- Comments may be submitted at this link
  Consultation Comment
- Complete Cost Benefit Analysis (CBA) questionnaire at this link
  Click here to complete the questionnaire
- Proposed Regulations (Gazette I) to be published for comment in Fall 2024
- Final Regulations (Gazette II) to be published in 2025, likely after April 1st.



Audit of sales records under 9(4) of the Pest Control Products Fees and Charges Regulations.

"Dear Registrant,

The Health Canada Pest Management Regulatory Agency determined, based on available information, that the certified sales records required under subsection 9(3) of the Fees and Charges Regulations, as a condition for receiving a reduced annual charge, are not adequate to calculate the annual charge.

As such, the PMRA require under subsection 9(4) of the Pest Control Products Fees and Charges Regulations that the registrant provide records of the sales in Canada for the 2022 and 2023 reporting periods that have been audited by a qualified independent auditor. Please be advised that the ***audited sales records*** *are required within* ***30 days*** *of this notice. If the audited sales records are not provided by the due date of 30 days of this notice,* ***the full 2022*** *($3,872.61 per registration)* ***and 2023 annual charge*** *($4,135.95 per registration) will be invoiced.*

Please note:
The audit of sales records must follow Canadian auditing standards (CAS) – CPA professional conduct: Auditor independence – Harmonized Rules for Professional Conduct (Rule 204) or the most recent version thereof and be performed by a qualified independent auditor. A qualified independent auditor must be a member in good standing with the Chartered Professional Accountants of Canada or the American Institute of Chartered Professional Accountants (United States), the Association of Authorized Public Accountants (United Kingdom) or the International Institutes of Accountants as approved by Health Canada.

If you are audited the PMRA will accept any one of the following,

- Chartered Accountant's Attestation
- Independent Practitioner's Report
- Reasonable Assurance Report
- Agreed upon Procedures engagement

Questions

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