

Updates to Biopesticide Regulation in Canada

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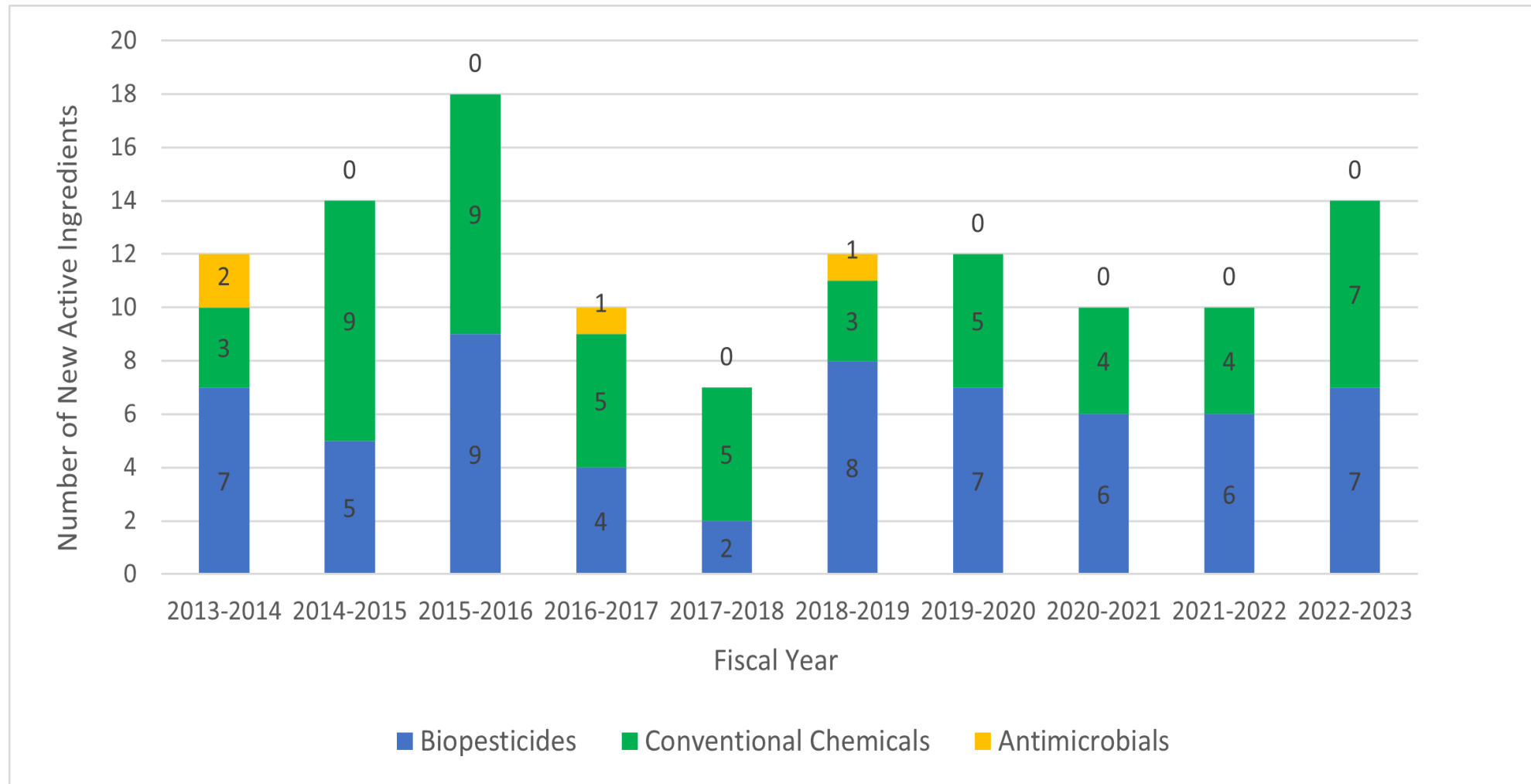
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- Overview of biopesticides registered in Canada
- Transformation at PMRA
 - Continuous Oversight
 - Proportional Effort
- Fee review
- Cannabis and industrial hemp guidance document
- OECD projects
- dsRNA Info Note
- Regulating gene-edited organisms for pest control



Number of new active ingredients registered by PMRA from April 1, 2013 to March 31, 2023



Scope of Biopesticide Products Registered at PMRA

Product Types

- Insecticides, insect repellents
- Herbicides
- Fungicides
- Algaecides
- Devices to control rodents & insects
- Rodenticides
- Antifouling agents

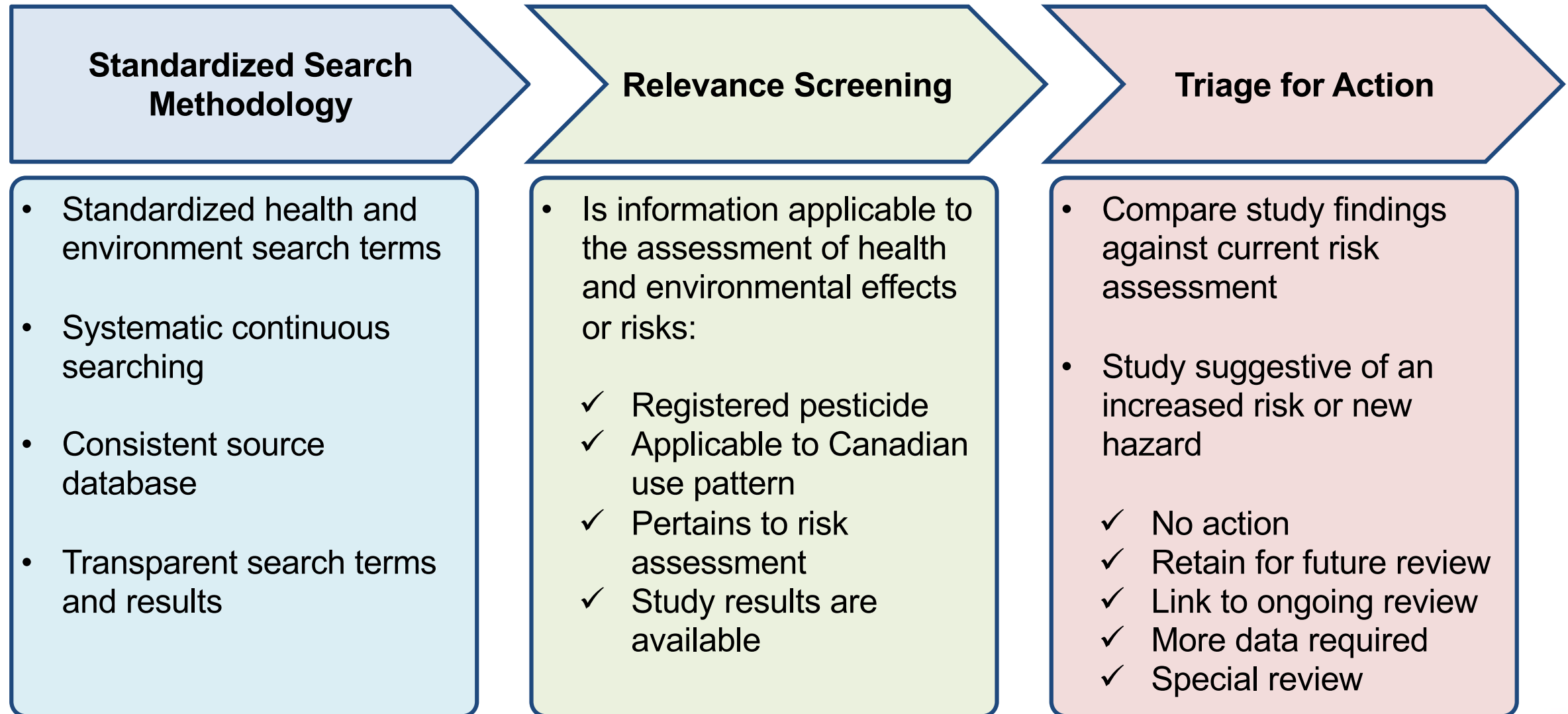
Use Categories

- Agriculture
- Forestry
- Lumber
- Aquaculture
- Inside homes
- Urban landscapes (golf courses, playgrounds, parks)
- Institutions/structures e.g., schools, hospitals, apartments

Continuous Oversight of Pesticides Policy

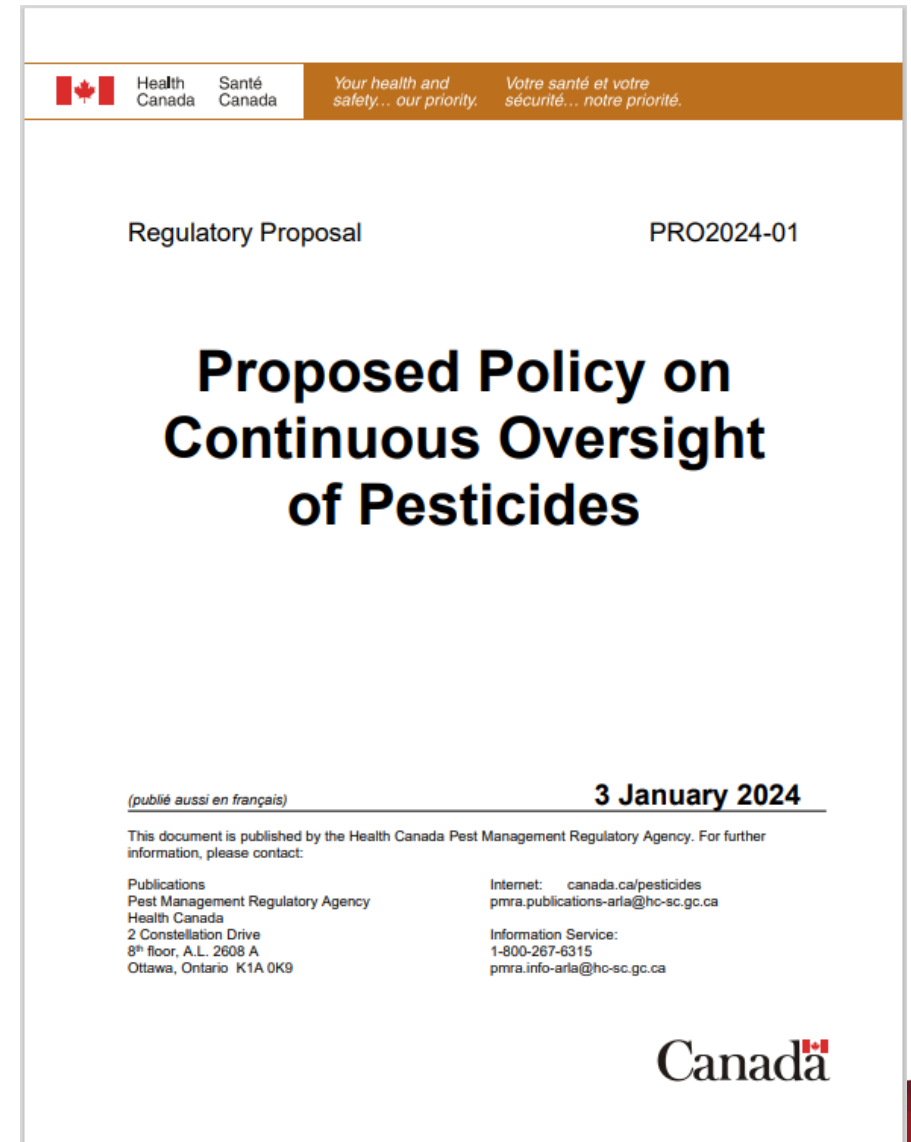
- Continuous oversight increases protection of health and environment through proactive identification and timely management of pesticide risks:
 - **Systematic collection** of science information on pesticides;
 - **Keep pace** with the evolving science of pesticides; and
 - **Regulatory actions** in response to new risks identified.
- Builds upon existing processes to create a standardized, transparent framework for how PMRA will identify and action evolving science information.
- Continuous oversight supports but does not replace other post-market programs such as special review and re-evaluation.

Continuous oversight high-level process



Continuous oversight policy

- The proposed Continuous Oversight of Pesticides policy was published on Jan 3, 2024, for a 60-day consultation.
 - 30 organizations/individuals provided comments on the policy
- PMRA is considering all comments received before finalizing the policy
 - Final policy is targeted for Spring 2024.



Transparency of continuous oversight findings

- PMRA is committed to being transparent with search, relevance and triage outcomes of continuous oversight
 - Search strategy used (terms, databases, dates)
 - List of citations identified
 - Relevant/Not relevant with rationale
 - Triage decision with link to any applicable notice
- Initially, reports will be quarterly. PMRA exploring options for automated solutions.

Authors, Primary	Title, Primary	Year	Periodic Full	Relevance Screening	Triage Status
Berlivet J, Payraastre L, Rebouillat P, Fougerat A...	Association between dietary pesticide exposure profiles...	2024	Environ Int.	Study is relevant	The study does not impact the current risk acceptability conclusion for the pesticide. The study will be retained for future consideration if required
Stephen C Boushell, Mengjun Hu	Postinfection Application of Fenhexamid at Lower Doses in Conjunction with...	2024	Phytopathology	Study is not applicable for risk characterization. Study pertains to the use of pesticide and not health or environmental risks	Not required

Updated chemistry process

- Confirm that the chemistry source manufactured consistent with the approved specifications and methods.
- A published chemistry work plan will be established.
 - Chemistry verification will now be separate from the current re-evaluation-based process.
 - Sources for each active ingredient will be considered at least once every 10 years.
- Verification of chemistry information does not replace the mandatory requirement for registrants to report any changes to product chemistry or manufacturing methods.
- New chemistry requirements will begin for chemical products this year.
 - PMRA will conduct a pilot for microbial products to further develop the process and required information
- A memo to registrants will be issued this spring outlining the new requirements and associated timelines.

Continuous Oversight Key Messages

- Continuous oversight increases protection of health and environment through proactive identification and timely management of pesticide risks
 - **Supporting the PMRA's science reviews and decision making** with up-to-date science and regulatory information on pesticide active ingredients and associated products.
- Continuous oversight implementation, beginning in Spring 2024, will consist of an agile, phased approach:
 - Pesticides will be systematically onboarded into continuous oversight.
 - Approaches will be refined and improved as we ramp up processes.

Proportional Effort Policy

- Proportional Effort is a framework within which a set of criteria are used to prioritize and categorize **already-registered active ingredients** as “higher priority” or “lower priority” to ensure that regulatory effort is proportional to the risk profile of the product
- Regardless of proportional effort designation, all pesticides are still subject to requirements under the PCPA, and will still undergo re-evaluation or could be subject to special reviews
- Goals:
 - to allow PMRA to re-prioritize workload, including re-evaluation backlog;
 - focus efforts on actives that are most in need of a fulsome review;
 - and begin transition to a more sustainable pesticide review approach that keeps pace with new re-evaluation initiations
- Targeting end of June for publication of Policy with subsequent consultation period

Fee review

- Fee regimes administered by Health Canada undergo periodic review at least every five years. The last review of pesticide fees resulted in updates to fees that came into force in 2017.
- Undertaking a phased approach to the pesticide fee review
 - Phase 1 (current proposal): update the annual charge payable for each registered pest control product
 - aimed at better reflecting current post-market regulatory costs
 - public consultation on the [fee proposal](#) was launched on January 31, 2024; comments welcome until **April 14, 2024**.
 - Phase 2 (planned for 2028): align fees to a transformed pesticide program, in particular modernized business processes that are now being implemented
 - this will include updating application fees to register new pest control products and amend existing registrations.

Current fee proposal

- This proposal would replace the existing annual charge and current sales-based mitigation.

Fee	Amount
Base annual charge*	\$6130
Mitigated annual charge for small businesses	\$2000
Mitigated annual charge for biopesticides	\$1000
Mitigated annual charge for certain niche products	\$1000

- Reduced charge for biopesticides would apply to microbials, semiochemicals and non-conventional pest control products; and reflects public interest in supporting the availability of biopesticides given the favourable risk profile of many of these products.

* replaces current maximum charge of \$4135.95

Consultation process and next steps

- Consultation on this fee proposal ends on April 14, 2024. Comments may be submitted using the PMRA online consultation comment form.*
- Cost-benefit questionnaire circulated to registrants/registrator associations in parallel.
- HC will consider comments received as it develops a regulatory proposal for updated fees, which will also be subject to consultation through the Canada Gazette process.**
- Implementation of the revised post-market fee structure would follow as soon as processes allow.

* comments can also be submitted by mail or email. Refer to the [Pest Management Regulatory Agency Publications Section](#) for contact information

** similar to US Federal Register process

Cannabis and Industrial Hemp Guidance

Due to the growth of the cannabis and industrial hemp industries since the legalization of recreational use and the resulting need for additional pest control products in these sectors, PMRA has reviewed its approach to registration of pest control products for use on these crops.

As a result, PMRA has developed guidance on:

- classification into Use Site Categories for both cannabis and industrial hemp;
- data requirements to assess additional potential risks for the treated commodities;
- label statements to provide additional guidance, including statements where risks have not been assessed or have been deemed unacceptable.

To date, mostly microbial and non-conventional pesticides have been registered for use on cannabis and industrial hemp grown for flowers.

- PMRA conducts risk assessments to ensure that pest control products do not pose unacceptable risks to human health or the environment.
 - Where applicable, the health evaluation includes a risk assessment for dietary, occupational and residential exposure.
- With the potential for cannabis and industrial hemp to be smoked or vaped, the PMRA must assess the exposure through inhalation.

PMRA engaged with cannabis industry stakeholders in January 2024 to solicit feedback on the proposed approach.

OECD Projects

- PMRA participates in various activities at the OECD level through membership in the Expert Group on Biopesticides
- Guidance document on baculoviruses has been published
 - General guidance on considerations for preparing regulatory submissions: Series on Pesticides No. 111, *Guidance document on Baculoviruses as plant protection products* (ENV/CBC/MONO(2023)21)
- Contaminants in microbial pest control products
 - The methodology section of the OECD Series on Pesticides No. 65, *Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products* (ENV/JM/MONO(2011)43/REV1) has been updated to include methods such as quantitative polymerase chain reaction (qPCR)
 - No change proposed to the list of pathogens or levels of detection
- Webpage *Manual on Concepts and Available Guidance for Microbials* is available
- Consensus documents on *Bacillus amyloliquefaciens* and *Beauveria bassiana* in progress

dsRNA Info Note

- In Canada, data requirements for dsRNA-based pesticides determined on a case-by-case basis
 - Pre-submission consultation required
 - Research authorizations required for any research conducted outside of laboratory
- OECD Working Documents
 - *Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-Based Pesticides*, Series on Pesticides No.104 [ENV/JM/MONO(2020)26]
 - *Considerations for the Human Health Risk Assessment of Externally Applied dsRNA-Based Pesticides*, Series on Pesticides No. 110 [ENV/CBC/MONO(2023)26]
- PMRA published [Information Note Regarding dsRNA-based Pesticides](#) in January 2024

Genetic Pest Control



- Gene-editing technology allows for the alteration of an organism’s DNA in order to change its traits that could then be used in pest-control applications. Many pest control applications employing gene edited organisms are now possible, including for disease vector control. Many of these would currently fall under the Pest Control Products Act (PCPA).
- PMRA sponsored the Canadian Council of Academies (CCA) report on the regulation of gene-edited organisms (“genetic pest control”) to obtain independent and transparent information on the scientific, ethical, and regulatory challenges surrounding the use of gene-edited organisms for pest control.
 - Sponsoring this report was part of PMRA’s efforts to proactively examine the science and regulatory aspects of these emerging technologies, with the aim of informing future regulatory approaches and frameworks.
 - The CCA is a not-for-profit organization that convenes expert panelists to assess complex scientific topics of public interest, to inform Canadian decision making. Assessments and reports are fully independent of sponsors.
- The CCA published the report [*Framing Challenges and Opportunities for Canada*](#) on November 8, 2023
 - Report emphasized concepts and considerations such as potential environmental risks, public engagement, and collaboration with other GoC and international regulators.
 - Overall, this input will enhance PMRA’s ability to make timely, transparent, evidence-informed decisions that incorporate the best available science to support the safe and sustainable use of regulated PCPs in Canada.



THANK
YOU!

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