

Global regulatory harmonization session – A Canadian Focus

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Outline

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Pesticide Regulation in Canada



- Health Canada’s Pest Management Regulatory Agency (PMRA) is the federal authority responsible for regulating pesticides in Canada.

Primary Objective

To prevent unacceptable risks to the health of Canadians and the environment from the use of pesticides.

- Evidence-based Decision Making

	HEALTH	ENVIRONMENT	VALUE
TOXICITY	<ul style="list-style-type: none"> • Poisoning • Cancer • Neurological, Endocrine • Birth defects • Genetic mutations 	<ul style="list-style-type: none"> • Acute (poisoning, death) and chronic (survivability, reproduction, development) of animals, plants, fish, pollinators, insects, etc. 	<ul style="list-style-type: none"> • Need for the pesticide in Canada • Effectiveness at controlling pest • Benefits to health or environment (i.e. control of disease or invasive species) • Social and economic impact in Canada
EXPOSURE	<ul style="list-style-type: none"> • Food and drinking water • Pesticide users • Bystanders • Special consideration for women, children, seniors 	<ul style="list-style-type: none"> • Presence in water, air, soil • Bioaccumulation in environment • Modelling and monitoring environmental levels 	
REGULATORY DECISION <ul style="list-style-type: none"> • Reasonable certainty that no harm to human health, future generations or the environment will occur 			

Legislative Authority

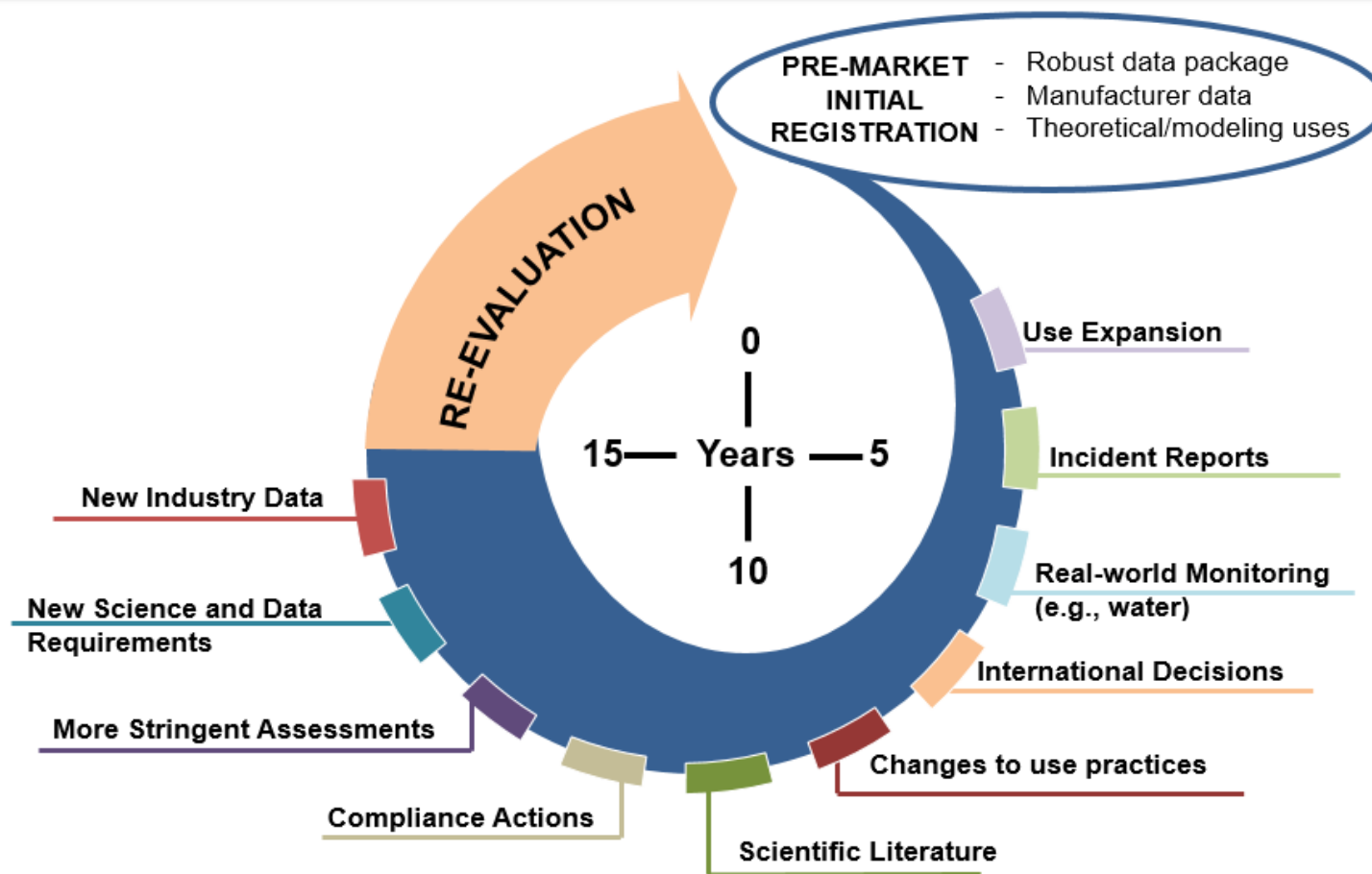
Pest Control Products Act (PCPA)

- All pest control products imported, manufactured or used must be registered unless excluded or exempted from application under the PCPA.
 - Risk and value must be acceptable. Sustainable development must be supported.
 - Periodic re-evaluation of chemicals already in the marketplace to ensure continued acceptability (~15 years).
 - Notice of Objection to registration decisions. Transparency and public consultations.
- **Pest Control Products Regulations (PCPR)**
 - Outlines the requirements for: New and Amended Applications, Product labels, Data protection, Product renewals.
 - **Food and Drugs Act (FDA)**
 - Recognizes maximum residue limits (MRLs) established under the PCPA (Bill C-28)
 - Established a default MRL of 0.1 ppm when an MRL is not specified under the PCPA.

We will come back to MRLs when discussing the Codex initiative.

Pesticide Regulatory Lifecycle

The complexity and extent of available information increases after initial registration.



Biopesticides

- **Types**

- Microorganisms (microbials)
- Pheromones & other semiochemicals
- Non-conventional chemicals (low-risk natural substances)
 - Food items (e.g., table salt, vinegar, citric acid); plant extracts and oils (e.g., vegetable or mineral oils); plant growth supplements (e.g., phosphorus acid, plant growth regulators); inert materials (e.g., diatomaceous earth/silicon dioxide)
- Macroorganisms (invertebrate biological control agents)
 - Currently do not require registration

- **Tiered Approach**

- Streamlining of data requirements and evaluation approaches are proportionate to the evidence of risk, but with an understanding that 'natural' or 'low risk' does not mean 'no risk'
- Data requirements for registration are tiered (i.e., staged) starting with basic data requirements to address potential human health and environmental risks, with progression to higher tiers dependent on results of the lower tier studies

Biopesticides

- **Regulatory Directives**
 - Guidelines for the Registration of Microbial Pest Control Agents (MPCAs) and Products
 - Pre-submission consultation meetings particularly important for MPCAs
 - Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals
 - Guidelines for the Registration of Non Conventional Pest Control Products
 - Includes characteristics to help determine if an active is a non-conventional pest control product
 - Essential Oil-based Personal Insect Repellents (EOPIR)
 - Addresses unique human health requirements to assess high direct exposures to essential oils

Biopesticides

- **Science-Policy Initiatives**

- **Foods used as pest control products**

- Regulatory proposal that is investigating options for exempting certain non-conventional chemicals from registration, including certain food items of interest to the organic agriculture sector.
 - List of candidates is available here: https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/regulatory-proposals/2018/product-exemptions/document.html#pest_control

- **Antimicrobial Resistance (AMR)**

- Potential for certain microbial agents (bacteria, filamentous fungi) to produce AM secondary metabolites

- **New Approach Methodologies**

- HESI-PMRA Risk 21 pilots that explored the utility of the Risk 21 approach for less complex re-evaluations
 - “One size **does not** fits all” – exploration also confirms that such an approach may not be applicable for e.g., MPCAs

Global Regulatory Harmonization Initiatives

- **OECD**

- **Biopesticides (EGBP)**

- PMRA has led or contributed to the preparation of all issue papers, guidance and working documents on data requirements and risk assessment approaches for microbials, semiochemicals and botanicals

- **RNA interference (EGRNAi)**

- PMRA is participating in OECD efforts to develop considerations for environmental and human health risk assessments of RNAi (aka dsRNA) based pesticides
 - 2019 OECD Conference on RNAi-based Pesticides
 - 2020 Working Document: “Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-Based Pesticides”

- **CODEX**

- **Maximum Residue Limits (MRLs)**

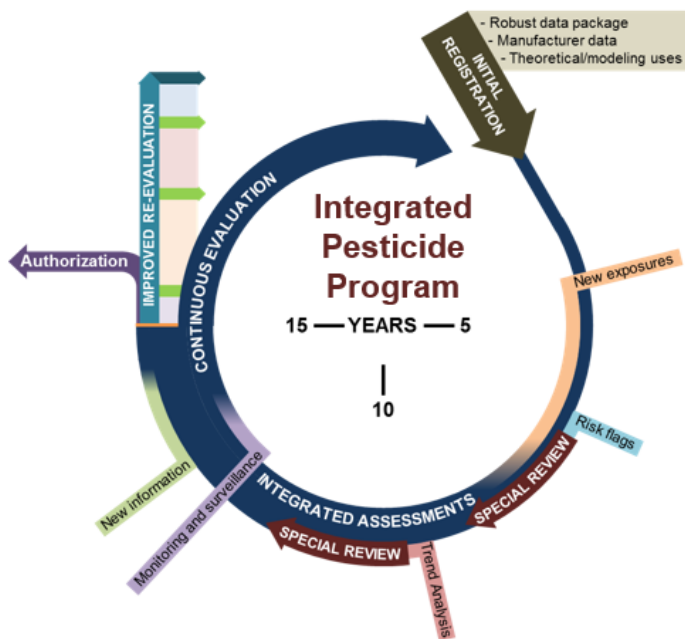
- PMRA participated in WG-Compounds of Low Public Health Concern Exempted from CXLs
 - 2020: “Draft Guidelines for Compounds of Low Public Health Concern that May be Exempted from the Establishment of Codex Maximum Residue Limits or Do Not Give Rise to Residues”
 - Guidelines to be presented for consideration at Codex Committee on Pesticide Residues (2021)

PMRA's Program Renewal Initiative

- PMRA is currently exploring a Program Redesign, as follows:

Integrated Pesticide Program:

1. Continuous evaluation and management of pesticide risks
2. Authorize lower risk pesticides
3. Improved Re-evaluation Process



Expected Outcomes

- ✓ Risk based approach to management of pesticides
- ✓ Increased protection of health and environment by addressing risks sooner
- ✓ All pesticides continue to have oversight
- ✓ New information is continuously integrated into the overall assessment
- ✓ Smaller less-complex re-evaluations

Implementation

- Majority of changes can be implemented within existing Legislative framework
- Requires moderate investments:
 - Expand existing pre-market programs
 - New national water monitoring programs
 - Implement new processes
 - Increased transparency measures

Questions?