

# Exploring a Potential Role for the Risk21 Roadmap and Matrix in the Canadian Re-evaluation Process for Pesticides

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**November 2-3, 2016: PMRA sponsored HESI Risk21 workshop [Ottawa, Canada]**

A 1.5 day workshop was planned at the RA Centre, Clark Hall to present the science of risk assessment as envisioned by the RISK21 collaboration to emerging and established Health Canada scientists and regulators.



**Risk 21 Approach and Matrix [2018 >]**

PMRA-HESI co-lead effort exploring the feasibility of using the Risk21 approach and matrix as an alternative option that incorporates a **health risk-based** approach into the PMRA-categorization process identified in DIR2016-04

**Acknowledgement:**

Raechel Puglisi,  
GWU MPH Practicum Student

**In Canada, pest control products, or pesticides, are regulated by Health Canada's Pest Management Regulatory Agency [PMRA] under the authority of the Pest Control Products Act.**

**Subsection 16(1), Pest Control Products Act: PMRA may initiate a re-evaluation of a registered pesticide if there has been a change in the information required or the procedures used by PMRA to determine that the pesticide meets health, environment and value standards.**

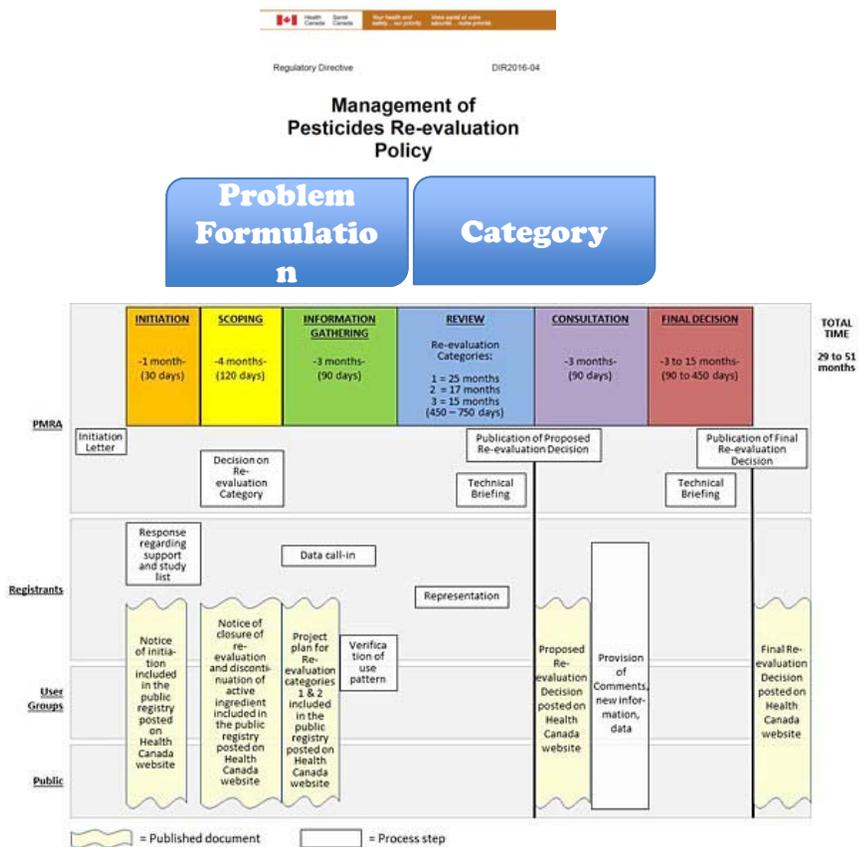
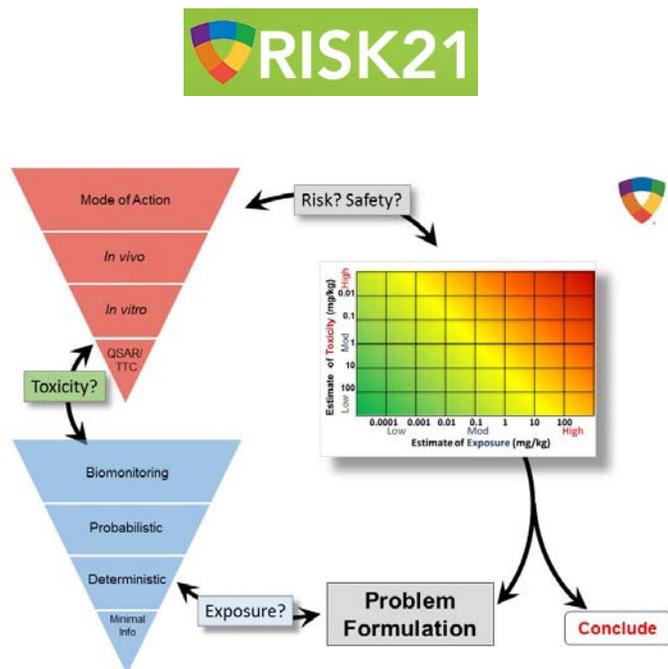
**Subsection 16(2), Pest Control Products Act: PMRA required to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on the most recent major decision affecting the registration, including its initial registration.**



**November 29, 2016: DIR2016-04**

**Describes the updated re-evaluation process, which includes the adoption of this new Regulatory Directive and associated internal processes aimed at enhancing transparency, predictability, and stakeholder engagement**

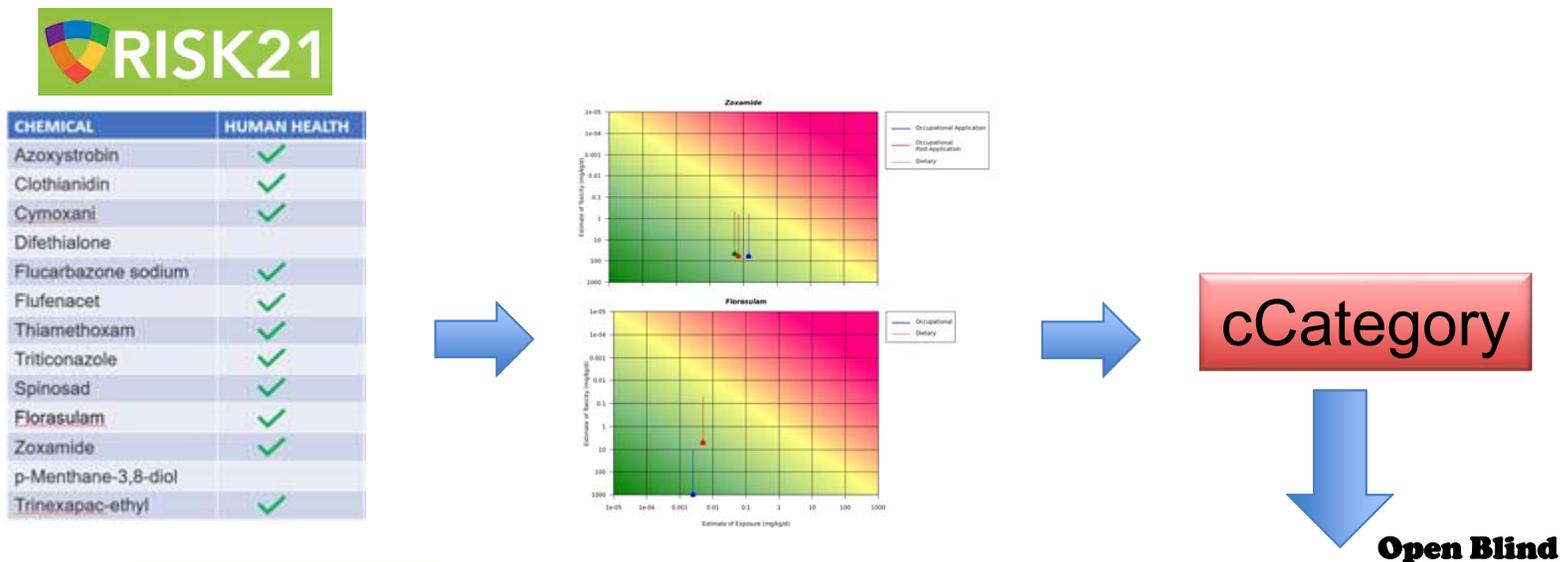




**PMRA-HESI Risk 21 pilots**

- 1) Double-Blinded, Pilot Analysis Comparing a Risk 21 Approach and Tool generated cCategorization with PMRA's Category.**
- 2) Pilot Evaluating the Risk 21 Approach and Tool to Determine Additional Efficiencies for a Particular PMRA Re-evaluation Category.**

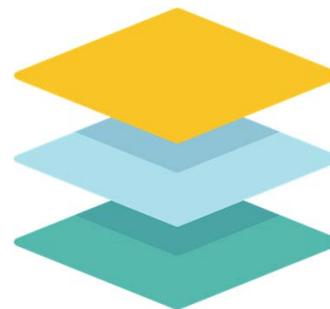
### Double-Blinded, Pilot Analysis Comparing a Risk 21 Approach and Tool generated cCategorization with PMRA's Category

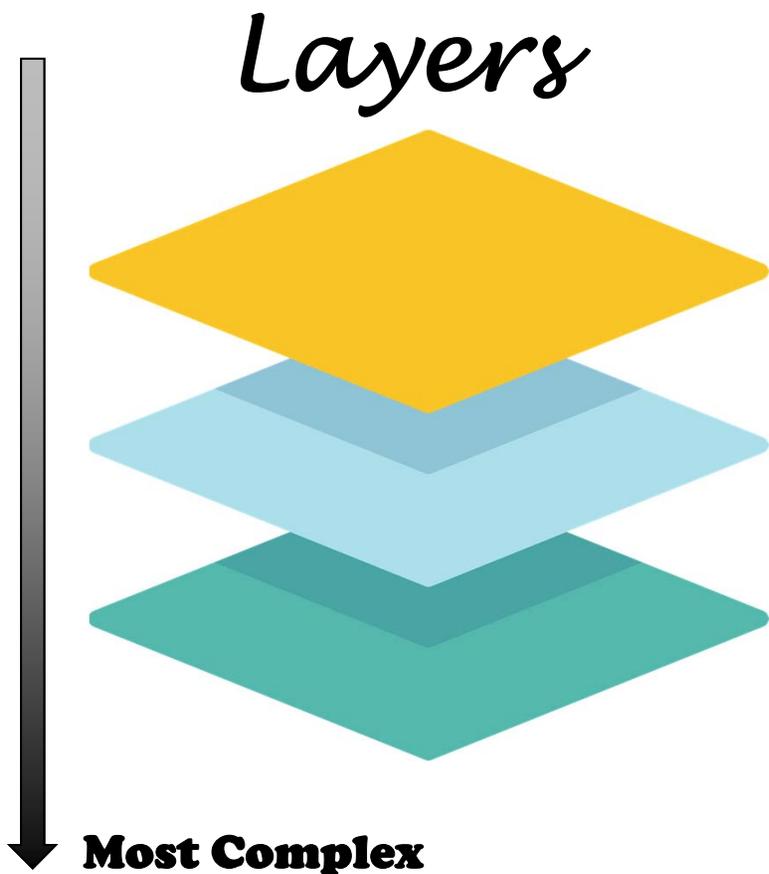


**Layer 1:** During the scoping phase, the Risk21 based “cCategory” can be considered as a Preliminary Categorization.

**Layer 2:** The 2<sup>nd</sup> layer would then involve the application of additional criteria, mandated by the PMRA, to further refine the Categorization as either Category I, II or III.

*Layers*





**Category 3 re-evaluations are those in which all components may be adequately addressed by previous reviews and a detailed new evaluation is not warranted; however, the outcome of a Category 3 re-evaluation could still require that product labels be updated to meet current labelling requirements.**

**Category 2 re-evaluations typically do not require additional information to be submitted to PMRA, yet they may include a detailed evaluation of some areas, such as updating a risk assessment using current assumptions or including additional new information in drinking water estimates.**

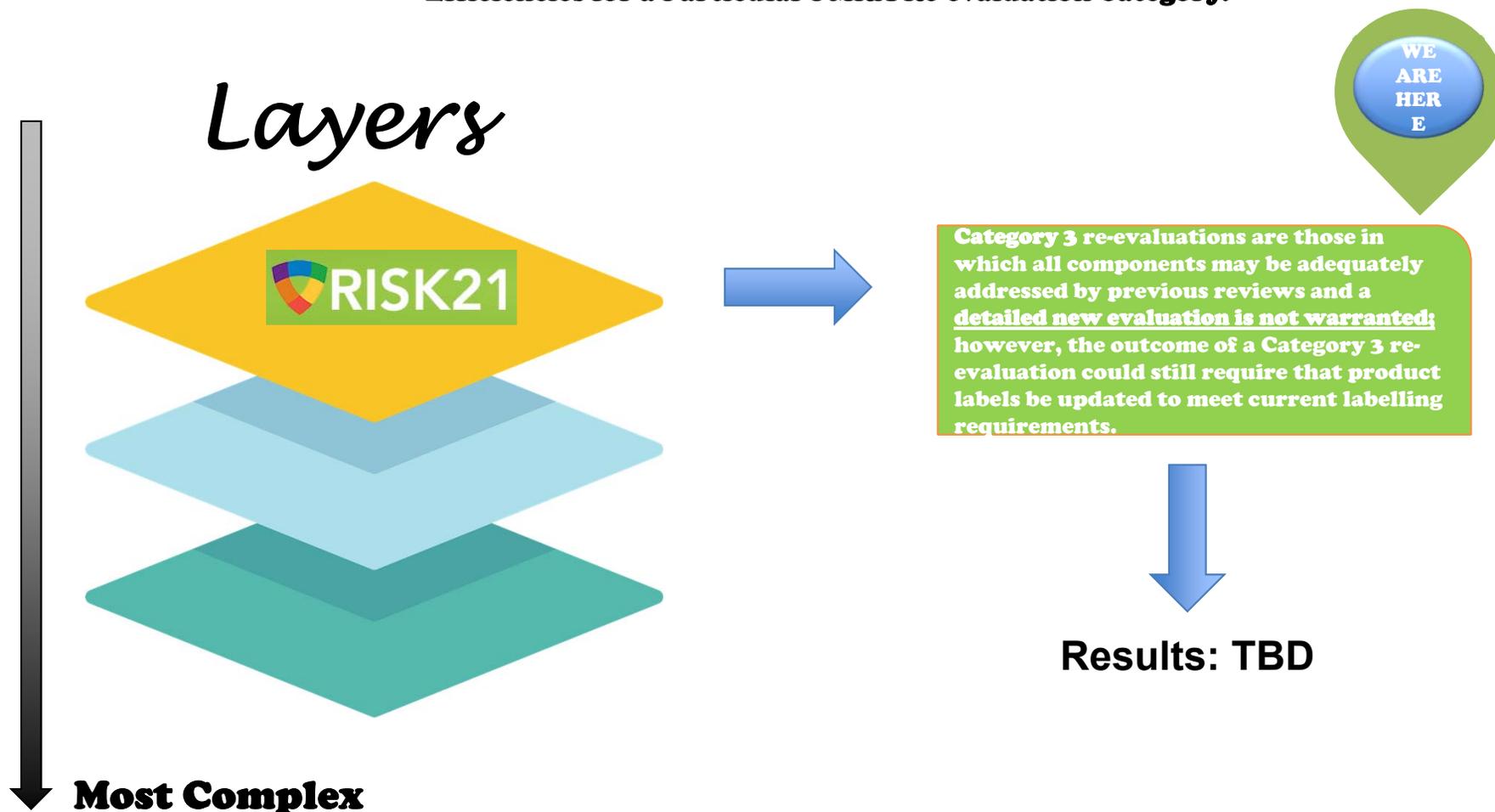
**Category 1 re-evaluations have the longest review timeframes and typically require the submission of information (refer to information gathering step) prior to proceeding with updating the risk assessments. Evaluations could include, but are not limited to review of the new studies and the application of revised toxicology endpoints in exposure assessments. In some cases, an active ingredient with a large number of uses, emerging science issues, and/ or extensive monitoring data can contribute to the increased level of effort and longer review timeline required to complete a proposed**

## **What makes a health risk re-evaluation more complex?**

- **Submission of data**
  - **Could result in changes to point-of-departures**
- **Extensive use pattern**
- **Metabolites of concern [includes transformation products]**
- **Significant changes in approaches to risk assessment**
  - **Requirement for a Pollinator risk assessment**
  - **Seed treatment**
- **Use of emerging and/or disruptive technology**
- **Hazard flags [e.g., repro/development]**
- **Pest Control Product Act Factor Assessment**
- **Parallel pre-market and Post-market**
- **Limited room in the “Risk Cup”**
  - **Typically, this requires refinements to the risk assessment**

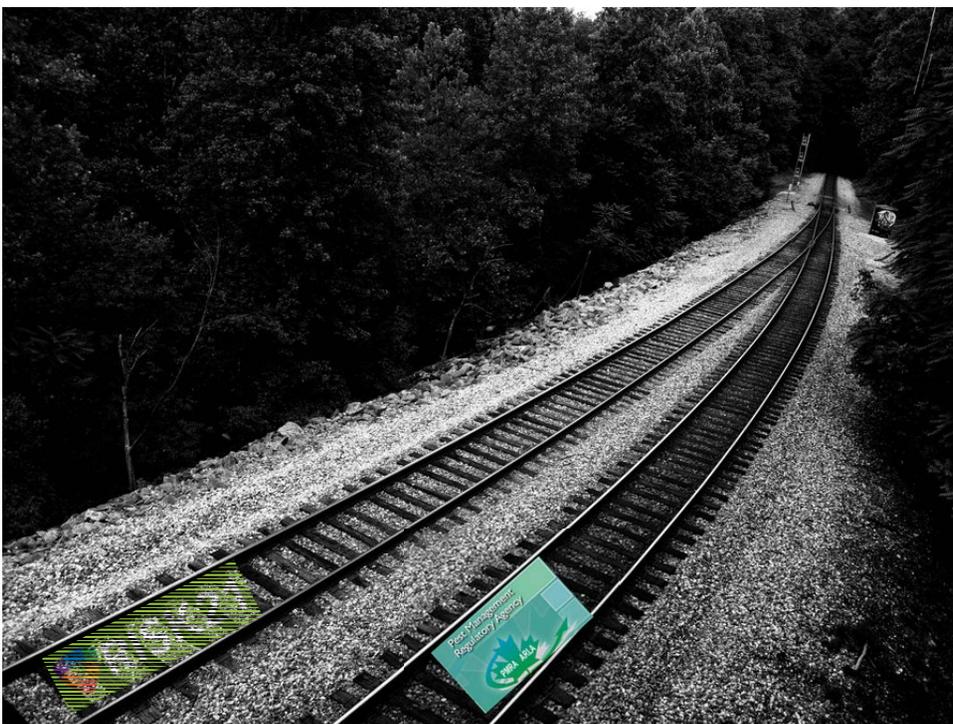
**PMRA's scoping exercise embodies risk-based principles; However, as the evaluation of risk is undertaken during the review stage, it is possible that, at this stage, a proposed Category is revised [e.g., Category 2 becomes 1 or vice versa].**

**Pilot Evaluating the Risk 21 Approach and Tool to Determine Additional Efficiencies for a Particular PMRA Re-evaluation Category.**



## Next Steps

### Potential to Link the PMRA-HESI Risk21 efforts with the ongoing PMRA, Post-Market Pesticide Re-evaluation Review Initiative?



#### Post-Market Pesticide Re-evaluation Review - Update

- In 2018, PMRA initiated a fulsome review of the re-evaluation program with a view to increasing both the efficiency and the effectiveness of the program.

*GOAL: To create a **sustainable** post-market review program that first and foremost continues to protect **health** and the **environment**, but is also efficient and streamlined from a stakeholder and regulator perspective.*

- In support of the program review, PMRA has:
  - Engaged with international counterparts to gather best practices
  - Engaged broadly across Canada with 140+ pesticide stakeholder groups
    - A *What Was Heard* report was published in May 2019
  - Completed detailed costing analysis of current re-evaluation program.
- PMRA is continuing to :
  - Develop and cost options to improve and stabilize the re-evaluation program
  - Conduct a lean assessment of internal re-evaluation processes.

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#### Post-Market Pesticide Re-evaluation Review – Next Steps

- PMRA is currently briefing the new Government on the review of the re-evaluation program.
- PMRA will consult on a new approach in the new year:
  - With the Pest Management Advisory Council (PMAC)
    - Multi-stakeholder advisory committee to the Minister of Health with representation from industry, users, academia, NGOs, Provinces and Territories
  - With the public and other stakeholder groups.
- In addition, PMRA will continue ongoing dialogue with external stakeholders, provincial and federal partners on ways to improve the re-evaluation program.

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