

# PMRA Transformation Update

MRL Harmonization Workshop May 24, 2023

#### Background

- Ministerial announcement on August 4, 2021:
  - Pause on all MRL increases until spring 2022
  - Review of the PCPA to increase transparency and strengthen health and safety
  - Creation of an expert advisory committee
  - Additional resources to the PMRA \$42 million for transformation
- Significant political intervention in a routine science-based regulatory process



#### **PMRA Transformation**



#### **Opportunities and Concerns**

#### The need to get it right

- Transformation opportunities:
  - Improve science communication and understanding behind PMRA decisions
  - Utilization of real-world data to help refine the risk assessment
  - Address PMRA resource challenges
- Transformation concerns:
  - Jeopardizing science-based decision-making process
  - Reducing predictability and timeliness of decisions
  - Decreasing process efficiencies
  - Impacting public trust
  - Unique Canadian registrant obligations and impact ability to bring innovative tools to Canada



## Stakeholder Engagement

- Ambitious stakeholder engagement schedule (60+ meetings)
- Public Consultation on the Targeted Review of the Act concluded in June 2022
- No prioritization of issues, lack of focus making engagement difficult
- Consultation fatigue



#### **Pause on MRL Increases**

- Pause on MRL increases 658 days today and counting
  - PMRA working on communication material
- No indication as to when the pause will be lifted
- Impacts Canada's reputation as a science-based regulator as well as create unnecessary misalignment with the US
- Impacting the minor use registration process in Canada



#### **Review of the PCPA Act**

- Large consensus among stakeholders that transformation activities could be completed without opening the Act
- No official indication from PMRA on whether it will be recommended that the Act be opened
- Concerns remained that there is more risks than benefits with opening the Act
- Expect to get clarity on government's intention by the summer/fall 2023



#### **Modernized Business Practices**

- Continuous oversight
  - Building different check points between registrants and regulators along product life-cycle to allow for early identification, and when needed, action on risk
- Proportional effort
  - Design a framework to direct scarce resources to the areas in most need of review.
- Consultations scheduled for the fall 2023

#### **Real World Data, Transparency**

- Real World Data and Independent Advice
  - Water monitoring piloting national watering program (2021-2022)
  - Use information pilot projects with horticulture industry
  - Scientific Advisory Committee 6<sup>th</sup> meeting scheduled for June. Have not consulted on any scientific questions
- Transparency
  - Plain language decision documents
  - "Open by Default" approach to data
  - Import MRL petition process



## **Next Steps**

- Final year of the \$42 million funding
- Ambitious implementation timelines: program details finalized in 2023 for implementation in 2024
  - Continued engagement required by all stakeholders as details on most activities still in development
- Continued need to press for the unjustified pause on MRL increases to be lifted
- Recognition and approach to the new reality of non-agriculture stakeholder views and political considerations in Canada



## Questions?