



Executive Summary of CropLife Canada Response to PMRA Consultation DIS2022-01

On March 21, 2022 Health Canada's Pest Management Regulatory Agency (PMRA) published Discussion Document DIS2022-01, *Further Strengthening Protection of Health and the Environment: Targeted Review of the Pest Control Products Act*, for consultation. The objective of DIS2022-01 is to seek stakeholder input to inform whether legislative changes are required to implement PMRA's transformation agenda, specifically targeted at: modernizing business processes, improving transparency, and increasing use of real-world data and independent advice in PMRA's decision-making.

In concert with the publication of DIS2022-01, PMRA established a number of technical working groups (TWG) to provide additional context to the various aspects presented in the consultation document and seek early feedback on several new proposed initiatives. CropLife Canada expressed concern with the expanding scope of this consultation, particularly the continued introduction by PMRA of significant new detail and additional information at every Transformation Steering Committee (TSC) and TWG session. While CropLife Canada actively participated in these various meetings, the pace at which they occurred made it challenging to engage comprehensively in the discussions. We feel that it is important that all elements are given proper and thoughtful consideration, including understanding the potential impacts these initiatives or proposed changes will have on registrants and the agricultural sector. Therefore, CropLife Canada intends to submit additional written input on modernized business processes and transparency in mid-to-late fall 2022. We appreciate this additional opportunity to comment that was confirmed by PMRA at its May 31st, 2022 TSC meeting.

The PCPA remains fit for purpose

CropLife Canada is of the view that the *Pest Control Products Act* (PCPA) remains fit for purpose and that any enhancements required for increased efficiency or transparency can be achieved without legislative changes. The PCPA is a rigorous and dynamic piece of legislation that has enabled a regulatory system that is protective of human health and the environment, ensuring that innovative products are introduced into the Canadian market at the same time as larger markets. Canada's regulatory system is both protective and amongst the most transparent of any major regulatory authorities around the world.

Objective 1: Modernized Business Processes

CropLife Canada continues to support the 2020 joint stakeholder recommendations to the Minister, delivered via the Pest Management Advisory Council (PMAC), that the PCPA is fit for purpose and that implementation of continuous oversight, as proposed in DIS2022-01, does not require legislative change.

CropLife Canada strongly believes that the current health and environmental reviews conducted by the PMRA are extremely robust. We object to the notion, which underlines the current Transformation Agenda, that the current human health and environmental protections are deficient. CropLife Canada is supportive of the efforts to modernize business processes, including proposals that will allow for earlier and more meaningful engagement with stakeholders. Such engagement, including a separate consultation on the draft risk assessment, would allow for a better-informed proposed re-evaluation decision, one that is far less likely to change as a result of receiving additional data later in the process. This in turn would result in a final decision better aligned with the proposed decision, which would in turn increase public trust in the overall decision-making process.

Proposed Amendments to the PCPA Ministerial Authorizations and Product Recalls

On May 11, 2022, while Bill S6 *An Act Respecting Regulatory Modernization* was being reviewed by the Senate Standing Committee on Agriculture and Forestry, Health Canada withdrew Part 6 of the Bill, which included proposed changes to the PCPA, to add it to the scope of the current consultation. CropLife Canada recognizes that proposed changes were widely consulted on by the PMRA in 2018-2019 and were the type of changes that were appropriate for a modernization bill, i.e., allowing the PMRA to address an overly complicated and outdated regulatory process for low and well-characterized risks products. CropLife Canada opposes the introduction of eligibility criteria for determining what constitute low and well-characterized risk products within the PCPA. Such level of detail is not appropriate for a legislation that needs to remain nimble and agile. CropLife Canada is of the view that it was unnecessary to expand



the already growing consultation's scope to include these proposed changes under DIS2022-01 and would recommend that they rather be put forward for adoption in next year's regulatory modernization bill.

Maximum Residue Limits (MRLs)

Legislative changes to the PCPA as they relate to MRLs or to change how MRLs are established are not required. There is a critical need, however, to strengthen risk communication on MRLs, in particular in providing information that would increase public understanding of the safety of MRLs. This would be achieved by explaining the scientific process that leads to their establishment, and their role in enabling global food trade. A change to an MRL, including an increase, does not equate to increased risk, and a fact that must be made clear to all stakeholders.

CropLife Canada requests that the current pause on MRL increases be lifted immediately. The pause is scientifically unjustified and is resulting in diminishing both, public trust in food safety and in the MRL setting process. It is also harming Canada's hard earned international reputation as a leader in science-based decision-making.

Objective 2: Improved Transparency

CropLife Canada believes that the PMRA has satisfied its legislative requirements surrounding transparency as outlined in the PCPA. Pesticide regulation is a complicated process, however, and as a result, stakeholders have commented that PMRA's regulatory decisions are difficult to understand. Increased transparency in the form of more timely access to PMRA review and risk assessment documents, along with policies and procedures would improve stakeholder understanding of the evolution from "data" to "decision" and overall confidence in the regulatory process. There are no barriers in the PCPA to prevent sharing of these documents with stakeholders, provided confidential business information is appropriately redacted.

In addition, CropLife Canada has long requested transparency improvements in the forms of earlier engagement in the regulatory process, proactive discussion on new and changing requirements, information regarding submission status/progress, and changes to re-evaluation workplans that may impact stakeholder expectations.

Objective 3: Use of Real-World Data and Independent Advice

CropLife Canada is of the opinion that "good data, are good data", whether the studies are generated by registrants or another source. Any "real-world data", including water monitoring and/or use information, used in the regulatory review process must be subjected to the same level of scrutiny as registrant generated data, considered in the appropriate context, as part of a weight of evidence approach. The inclusion of real-world data in PMRA reviews will result in less conservative risk assessments and be more reflective of the product use.

CropLife Canada members agree that real-world data could better inform PMRA reviews. It is important to note, however, that PMRA reviews available "chemical-specific" pesticide use information when it deems a product safe for use. Collection of any additional "chemical-specific" information requires significant effort on the part of stakeholders. As such, this information should only be requested when risk of concern has been identified by PMRA.

Conclusion

Legislative changes are not required to implement initiatives under PMRA's transformation agenda. We look forward to continued discussions with the PMRA as it develops specific proposals on how the integrated program will function. CropLife Canada's position is that any potential transformation initiatives must NOT jeopardize the ability of the PMRA to continue to fulfil its mandate, which is to prevent unacceptable risks to Canadians and the environment from the use of pest control products. Similarly, the science-based nature of the regulatory process must be protected, including ensuring that the PMRA's limited resources are first and foremost appropriately directed to its core work. The Canadian agriculture sector relies on PMRA's ability to make timely, risk-based decisions to maintain its competitiveness and continue to produce safe and sustainable food to feed Canadians and the world.

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