Discussion Document DIS2022-01

Further Strengthening Protection of Health and the Environment:

Targeted Review of the *Pest Control Products Act*

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1.0 Context

Protecting the health of people living in Canada and the environment from the risks of pesticides is the purpose of Canada's pesticide regulatory system. The system ensures access to pest control products that can be used safely and effectively for agricultural, industrial and other purposes, and consumer products, such as insect repellents.

Pesticides help manage pests, pathogens, and invasive species and when used properly are valuable products that people living and working in Canada rely on every day.

Health Canada's Pest Management Regulatory Agency (PMRA) is the regulatory authority in Canada responsible for the federal regulation of pesticides (pest control products) and acts on behalf of the Minister of Health under the authority of the *Pest Control Products Act* and its regulations, including the Pest Control Products Regulations. The *Pest Control Products Act* received royal assent in December 2002, and came into force in June 2006. More details on the legislation is available in Annex 1.

In the interest of continuous improvement, PMRA has been working with key partners and stakeholders in recent years to address concerns related to the operation of the pesticide evaluation system in Canada and its transparency.

From recent consultations in 2018 and 2020 (see Annex 2), stakeholders have indicated that they are generally supportive of PMRA's planned approach for improving oversight of pesticides, and the importance of transparency for Canadians has been made clear. They also recommended that PMRA should provide engagement opportunities earlier in the pesticide re-evaluation process and new engagement opportunities on documents including draft risk assessments, enable easy access to more data, improve clarity on what information factors into PMRA's decision-making, and should have access to more real-world data and independent advice to better inform its regulatory decisions.

For many regulators including PMRA, COVID-19 has also prompted reflection and a rethink of the approach to engage and interact with stakeholders in more virtual ways that improve stakeholder engagement in the decision-making process.

On 4 August 2021, the Ministers of Health, Environment and Agriculture announced that $42 million will be invested in PMRA over three years to further strengthen its human and environmental health and safety oversight and protection, including improving the availability of independent data to further support pesticide review decisions, and the transparency of decision-making. The investment will also allow the creation of a new expert panel process to provide advice, as appropriate, prior to evidence-based decisions of PMRA on pesticides, including the establishment of maximum residue limits.

The Ministers also announced that a targeted review of specific elements of the *Pest Control Products Act* would be undertaken to ensure the pesticide approval process meets the expectations of Canadians in the areas of transparency and sustainability.

On 16 December 2021, the Minister of Health's mandate letter from the Prime Minister included the following commitment:

> To ensure Canadians are protected from risks associated with the use of pesticides and to better protect human health, wildlife and the environment, modernize and strengthen the *Pest Control Products Act* to ensure it supports transparency, use of independent scientific evidence and input to the decision-making process.

PMRA is currently advancing a Transformation Agenda (hereafter referred to as "Transformation") that includes a number of program change initiatives intended to: further strengthen human health and environmental protection through modernized business processes for the review of pesticides; improve transparency and public access to information and data across the regulatory pesticide processes; and increase the use of comprehensive, real-world data on water monitoring, crop production and pesticide use, as well as independent scientific advice. (Read more on Protecting public health and the environment: Transforming the Pest Management Regulatory Agency on Canada.ca.) To support implementation of these transformation initiatives, and in alignment with the Government's commitments, this targeted review of the related provisions of the *Pest Control Products Act* is being undertaken.

2.0 Objectives

This Discussion Document is intended to seek your input on specific questions to help inform the development of potential targeted legislative changes to the *Pest Control Products Act*. For ease of reference, PMRA has collated the list of questions in Annex 3 of this document.

As articulated in the Government's commitments in August and December 2021, the objective of this targeted legislative review, is to determine whether legislative changes to the *Pest Control Products Act* would be needed as PMRA:

1. further strengthens human health and environmental protection by modernizing business processes governing pesticide reviews;

2. improves transparency and stakeholder accessibility to information to bolster meaningful participation in decision-making; and

3. increases the use of real-world data and independent advice in the decision-making process to better inform decisions to protect human and environmental health.

PMRA is implementing broad engagement to seek input from the public, Indigenous communities, partners and other stakeholders on the measures required to achieve these objectives.

These consultations will serve to inform the development of a legislative proposal, if required, to achieve the objectives noted above. PMRA is also looking at approaches in other jurisdictions that have taken steps to improve their pesticide regulatory system.

Our intent is to maintain what is working well and build from there. While in recent consultations many stakeholders have told PMRA that they believe that the *Pest Control Products Act* is solid and fit for purpose, they have identified a number of areas that could benefit from improvement. PMRA is not planning a complete overhaul of its pesticide regulatory system, but is rather looking at targeted improvements.

That said, PMRA is open to receiving all comments from stakeholders regarding the *Pest Control Products Act* and will consider the input as it develops advice for the Government on possible legislative amendments.

In terms of a broader legislative review, the *Pest Control Products Act* includes a seven-year review clause whereby the administration and operation of the Act are examined by an appropriate Standing Committee of Parliament. The Act and its administration currently stand referred to Parliament for review (as per s. 80.1 of the *Pest Control Products Act*).

3.0 Guiding Principles

In creating the *Pest Control Products Act*, Parliament acknowledged that the use of pest control products poses potential risks to the health and safety of individuals and to the environment (which includes wildlife), while also playing a significant role in diverse areas of the economy and other aspects of the quality of life throughout Canada. Parliament also acknowledged that pest control products of acceptable risk and value can contribute significantly to sustainably meeting needs for human health protection, food and fibre production and resource utilization and to conserve or enhance natural resources and the quality of the environment, in an economically viable manner.

As a result, the Act creates a legislative framework for a scientifically-based national registration system that addresses risks to human health and the environment both before and after registration, including minimizing risks by, for example, encouraging the development and use of alternative approaches, strategies and products by facilitating access to pest control products that pose lower risks.

Specifically, in assessing risks to individuals, consideration is given to aggregate exposure to pest control products, cumulative effects of pest control products and the different sensitivities of vulnerable populations. As such, only efficacious pest control products of acceptable risk can be registered, taking into consideration conditions of registration established to minimize adverse health impact or pollution of the environment.

Persons whose interests and concerns are affected by a decision must be afforded a reasonable opportunity to participate in the regulatory process. Finally, the Act requires the regulatory system be administered efficiently and effectively and in a manner that recognizes the various interests and concerns affected, minimizes the negative impact on economic viability and competitiveness, and allows Canada to fulfil its international obligations in relation to pest management.

Bearing the above in mind, PMRA's *Pest Control Products Act* review (the Review) will be guided by the following principles:

- Further strengthen protection of human health and the environment;
- Build on strengths of the current system, from past and existing reform efforts, and on what we have heard to date;
- Continue to design a regulatory approach to decisions that remain science-based, within a framework that is timely, transparent and accountable;
- Bring forward proposals that make meaningful improvements and achieve objectives;
- Engage the public, Indigenous communities, partners, and other stakeholders in a timely and effective manner to inform the approach; and
- Maintain an approach with a clear focus on expected results.

4.0 Scope

4.1 Objective 1 – Further Strengthening Human Health and Environmental Protection through Modernized Business Processes Governing Pesticide Reviews

4.1.1 Current Legislative Requirements

To meet the primary objective of the *Pest Control Products Act*, Health Canada scientists rigorously review scientific information to determine if a pesticide is acceptable for use in Canada and will not harm humans and the environment when used as directed on the label.

Health Canada applies a life-cycle approach that is in line with international best practices, composed primarily of pre- and post-market activities, as well as a number of monitoring and reporting activities.

Health Canada works with its international counterparts to undertake joint scientific reviews of applications, and leverages the regulatory effort of other jurisdictions as much as possible under current processes.

4.1.1.1 Pre-Market Evaluation

Unless otherwise authorized, the *Pest Control Products Act* requires that before a pesticide is imported, sold, or used in Canada, PMRA must ensure that it has value and that it can be used safely, taking into consideration any specified conditions of registration.

Following the initial registration of a pesticide, the registrant must apply to amend the registration before there can be any changes to the way the product is used or manufactured.

4.1.1.2 Maximum Residue Limits

The *Pest Control Products Act* also provides the authority for the Minister to specify any necessary maximum residue limits (MRLs) for a pesticide, its components or derivatives as part of the process of registering a product or amending a registration. In addition, the authority exists to specify MRLs for unregistered products and uses.

As part of the assessment process of pesticides, Health Canada must determine whether the consumption of residues that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. The amount and nature of the residue varies by pesticide and by crop. Proposed MRLs undergo a dietary assessment that considers the potential contribution of all residues, and are established well below levels that are known to pose risks. Any person may make an application to the Minister to specify maximum residue limits. The Canadian Food Inspection Agency monitors MRLs on food. For further information visit the webpage for the National Chemical Residue Monitoring Program and Chemistry Food Safety Oversight Program Annual Report on Canada.ca.

4.1.1.3 Post-Market Evaluations

In the post-market context, the *Pest Control Products Act* requires that PMRA initiate the re-evaluation of each pesticide at least every 15 years after the most recent major decision. The re-evaluation ensures that pesticides registered for use in Canada continue to meet current health and environmental safety standards. Re-evaluation incorporates new risk assessment approaches and data requirements, where relevant, that have been developed since the pesticide's previous major assessment.

The Act also requires that PMRA conduct a special review to address specific concerns that may be identified as a result of new information, unless there is already another post-market review that can examine that same concern. A special review must be initiated when:

- there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable; and

- an Organisation for Economic Co-operation and Development (OECD) member country prohibits all uses of a pesticide's active ingredient for health or environmental reasons.

Information triggering a special review can come from mandatory incident reporting, compliance and enforcement activities, provincial or territorial monitoring work, foreign regulatory decisions, academic studies, or a request from the public.

If at any time, the Minister considers that the health and/or environmental risks of a pesticide may be unacceptable, then the Minister has the tools to make changes to a registration, up to and including cancellation.

While stakeholders consulted in 2018 and 2020 (See Annex 2) were generally in agreement that the *Pest Control Products Act* worked well, they made a number of recommendations where improvements could be made in the current regulatory system. For example, some stakeholders

requested that re-evaluations and special reviews should only be required when there are risks of concern, rather than based on time or other non-scientific triggers.

4.1.2 Proposed Measures to Strengthen Human Health and Environmental Protection

PMRA intends to implement modernized processes to increase health and environmental protection while bringing efficiencies and risk-based oversight to the pesticide review process.

As described above, the current *Pest Control Products Act* has broad powers for PMRA to request and assess information throughout the regulatory lifecycle of a pesticide.

PMRA, in consultation with key partners and stakeholders, has identified areas for improvement in its review processes. Specifically, PMRA is seeking to:

- modernize from a point-in-time model to a continuous oversight lifecycle approach. This includes expanding and formalizing use of pesticidovigilance data throughout the pesticide's regulatory lifecycle to better inform regulatory decisions;

- improve regulatory processes for increased efficiency and timely assessment and management of risks; and

- introduce a risk-based approach to allow PMRA to direct resources where they are most needed to make timely decisions for overall improved health/environmental protection.

Implementing a continuous oversight approach

The present pre-market review and post-market re-evaluation approach presents a number of challenges to PMRA and stakeholders. The current point-in-time evaluation approach does not always permit the timing of actions on pesticides of concern to be adjusted in line with risk. It is also important for PMRA to receive, assess and act on information early enough to be aware of issues and to manage risks and hazards as they arise. Furthermore, current practices are contributing to an increasing workload leading to delayed regulatory decisions to protect health and the environment.

Moving forward, it is PMRA's intention to improve its ongoing line of sight on emerging pesticide risks, and not be bound to a universal point-in-time (i.e. 15-year) re-evaluation cycle for taking required action. Continuous oversight and an integration of how PMRA identifies, assesses, tracks and addresses pesticide risks will result in more predictable and timely decision-making. The improved process proposed by PMRA will be further informed by increased access to water monitoring, crop production and pesticide use information (see Section 4.3). The expectation is that the new and more flexible approach will result in, smaller, less complex and more timely re-evaluations, as well as more efficient decision-making throughout the regulatory lifecycle.

Another important challenge identified by stakeholders in previous consultations is the need for timely and transparent information regarding ongoing risks assessments, and what additional data should be considered by PMRA as part of its risk assessments. This challenge contributes to stakeholder concerns regarding the predictability of regulatory decisions. Further, under the

current approach, information is submitted late in the review process and PMRA has to redo its risk assessments. Process improvements aim to increase the transparency of regulatory processes, support earlier submission of key information, reduce duplicate efforts and increase predictability of decision-making.

These measures will require the development of new policies and/or amendments of existing policies. PMRA is proposing to review the *Pest Control Products Act* provisions requiring the initiation of a re-evaluation every 15 years to ensure it has the necessary flexibility to enable implementation of a continuous oversight approach.

Review Process Efficiency

PMRA seeks to improve its review mechanisms by applying modern process management approaches and leveraging opportunities offered by technological advancements in digital information management and analysis. PMRA intends to optimize the use of digital tools to be more effective, efficient and responsive, thereby better achieving the objectives of the *Pest Control Products Act*. Resulting process changes will be reflected in PMRA's policy.

Risk-Based Management

A foundational goal of this initiative is to apply proportionality between the regulatory effort expended on a given pesticide and the risks it poses so that more resources can be allocated to higher risk pesticides, thereby improving the overall protection of human health and the environment.

PMRA will develop an approach to better understand the relative risks posed by pesticides and support application of regulatory oversight in a manner that is appropriate for those risks. By expending less effort on pesticides where risks are well understood and well managed with mitigation measures, PMRA will be better positioned to direct more resources towards pesticides requiring increased oversight, assessment and regulatory action to manage the risks that they pose. New approaches for lower-risk pesticides are an important component of this modernization work. While continuing to meet the *Pest Control Products Act*'s health and environmental objectives, less regulatory burden for these types of products will contribute to meeting the second ancillary objective of the *Pest Control Products Act*:

> ...seek to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures.

For registrants, there would be less burden associated with bringing these products to the Canadian market. For the user community, this approach should promote access to important pesticides that are recognized as posing lower risks to human health and the environment.

Implementation of a risk-based approach to introduce proportional oversight will enable PMRA to shift resources to the areas in need of greater oversight. Existing policies will need to be updated and new ones may be required to implement this approach.

4.1.3 Recent Statutory Changes

As we consider whether possible legislative changes might support the proposed transformation initiatives to modernize PMRA's business processes, it is important to note recent legislative changes that have already been made or have been signalled as under consideration in relation to in the *Pest Control Products Act* requirements for pesticide reviews. In 2019, amendments were made to the *Pest Control Products Act* to improve the approach to post-market special reviews. The amendments gave the Minister of Health discretion as it relates to the initiation of a special review. They also reduced duplication and gave PMRA more flexibility when special review triggers are met.

In the context of the Agri-food and Aquaculture targeted regulatory roadmap (Agri-food and aquaculture sector: Targeted regulatory review) PMRA has also signaled its intention to bring forward two specific legislative amendments related to regulatory processes:

- potential statutory amendments to the *Pest Control Products Act* to broaden the Minister of Health's ability to make label changes without an application in certain circumstances; and

- potential statutory amendments to the *Pest Control Products Act* to make it easier to make risk-based authorizations and to exercise appropriate post-market oversight for products with low or well-characterized risks.

4.1.4 Seeking Your Views

PMRA is seeking your views in relation to the *Pest Control Products Act* provisions that relate to modernizing business review processes and MRLs.

While stakeholders consulted in 2018 and 2020 (See Annex 2) were generally in agreement that the *Pest Control Products Act* worked well, they made a number of recommendations were improvements could be made in the current regulatory system. In the context of this review of the *Pest Control Products Act*:

- What barriers, if any, exist in the *Pest Control Products Act* to implementing continuous oversight?

- Are there any changes you would like to see in how MRLs are established?

See the Have Your Say section at the end of this document for details on how to submit comments.

4.2 Objective 2 – Improved Transparency

4.2.1 Current Legislative Requirements

The *Pest Control Products Act* currently includes a number of provisions relating to transparency and access. It requires that information and decisions be placed in a register and in an electronic public registry. The *Pest Control Products Act* also includes requirements to make the public aware when certain decisions are made. The public is allowed to have access to, and copies of, any information in the register that is not confidential test data (CTD), unless the CTD was made subject to public disclosure, or confidential business information (CBI). For more on this, please visit the webpage on Getting Involved in Canada's Pesticide Regulatory Process.

Further, when making decisions that require public consultation, the Act requires that a summary of any reports of an evaluation be provided to stakeholders and it permits the Minister to include confidential test information for consultation if it is in the public interest to do so. The Minister is also to take all comments into account in making major registration decisions and is required to explain the reasons for making those decisions.

A key set of issues that is important in the transparency context is how the review of all data, including industry-sponsored data, by PMRA can be done in an open and transparent manner to assure the public that regulatory decisions are based on sound science. A key question is how can more data be made available in a way that protects the proprietary interests of companies and does not create disincentives to innovation or contravene international agreements to which Canada is a signatory?

For confidential and commercially sensitive information, the *Pest Control Products Act* links the definitions of CBI and CTD to what may be refused disclosure under the *Access to Information Act.* The definition of CBI under the *Pest Control Products Act* includes information provided under the Act pertaining to manufacturing or quality control processes, methods for determining the product's composition, and financial or commercial information. CTD, which the Act allows the public to inspect, but not obtain a copy for their own use, is scientific or technical information on the risks and/or value of a pesticide.

The approach to facilitating inspection of CTD is currently through a Reading Room approach, whereby a person is required to come to Ottawa to view information at PMRA's offices. Measures to reduce barriers to access CTD, while maintaining information security, such as through the sharing of portable data storage devices, have recently been pursued in the context of the COVID-19 pandemic.

The *Pest Control Products Act* also currently includes the authority to allow disclosure of information to certain individuals or organizations for the purposes of, among other things, health and environmental protection and obtaining advice. Under the *Pest Control Products Act*, non-confidential information on applications, registrations, re-evaluations, and special reviews is required to be placed in an electronic public registry. This includes their status, any non-confidential information provided by applicants or registrants, evaluations of the information conducted by Health Canada, advice received, notices issued to registrants requesting more information, consultation and decision statements, etc. Any information on the regulatory

process (for example, policies, guidelines, codes of practice, and memoranda of understanding) is also required to be posted in the electronic public registry.

4.2.2 Proposed Measures to Improve Transparency

As a regulator, PMRA is committed to greater transparency and openness to further strengthen trust in our regulatory decisions. This is consistent with regulators around the world who are coming to understand that maintaining confidence and trust in their decisions requires enhanced public transparency.

Improving transparency is about sharing relevant, timely and usable information and data in a way that can be clearly understood. It also means providing easy access to enable members of the public and stakeholders to participate meaningfully in the regulatory process and help them make more informed choices. The public should be able to locate this information and perform searches to find the information that is relevant to them.

We intend to improve transparency in a meaningful way, which means identifying information that is useful and relevant to Canadians and stakeholders, to aid their understanding about the regulatory process and how decisions are made. In doing so, PMRA will continue to ensure that its approach respects its legal obligation to protect CBI.

From recent consultations (see Annex 2), we have heard that the information and data that is currently shared by PMRA, and the timing of when it is shared, are not meeting the information needs of stakeholders and the public.

As part of our approach to improve transparency, we are considering the following measures:

- Providing information that is written in clear, concise and plain language, to enable Canadians and stakeholders to have informed participation in the process, including, but not limited to:
    - pesticide consultation and decision documents; and
    - summaries from applicants of new applications.
- Enabling a more user-friendly and timely way for Canadians and stakeholders to inspect and access pesticide data and information that form the basis of PMRA's decisions
    - In pursuing this change, we will need to ensure that confidential and commercially sensitive information are clearly defined and appropriately protected.
    - We will need to better understand the types of information that Canadians and stakeholders believe would be most helpful to enable their meaningful participation in the regulatory process, and why.
    - We will need to review the process and timing by which information is provided to stakeholders in the context of regulatory decisions. For instance, registrants

have a right to make representations to the Minister regarding information considered before a decision is made, while all other stakeholders are consulted at the decision stage.

    - We will also need to examine the way CBI and CTD are set out in the *Pest Control Products Act*, considering other legislative models dealing with confidential information, and identify means to disclose certain confidential information in a less burdensome and more user-friendly way, while ensuring proper data protections are in place.

- Increasing access and sharing of PMRA scientific reviews and risk assessments

    - PMRA holds a large amount of information and data on pesticides used to assess their value, health and environmental risks in Canada. Providing public access to scientific reviews and risk assessments would enable independent re-analyses of data, foster new research questions, and help Canadians make better informed decisions about their health.

We would like to seek your views and suggestions on whether these measures would significantly contribute to improving transparency and/or whether other measures should be considered.

To maximize the benefits of transparency measures, we will need to better understand the types of information and data which stakeholders and the public are most interested in, building upon what we have already heard (for example, the applicant name, the application purpose). For instance, we would like to understand how, by providing improved access to data and information, we could enable independent re-analyses of data, foster new research questions, and build trust and confidence in our decision-making. We would also like to understand the priorities of stakeholders and the public to improve the information that we currently share or could share. Equally, we would like to understand how access to the information and data we share could be easier, and how our tools could be more useful and intuitive.

We will consider all suggestions and assess and prioritise those measures that may be taken forward. PMRA would implement the proposed transparency measures in a phased approach, taking into consideration a number of factors, including: what can be implemented by policy, whether legislative changes would be required, the extent the measure achieves the stated objectives, and practicalities of implementation.

We are also looking at approaches taken in other federal statutes as well as internationally (refer to Annex 4).

4.2.3 Recent Changes

In terms of expanding access to information, in 2021, PMRA announced that it was moving ahead with the proposal to expand access to CTD and that as of 1 January 2022 the public, upon request, will be provided the opportunity to inspect data at the proposed decision stage for post-

market reviews instead of at the final decision stage. This will enable earlier input and comments in the context of decision-making.

4.2.4 Seeking Your Views

PMRA is seeking your views on the following questions in relation to the *Pest Control Products Act* provisions that relate to transparency:

- Would introducing summaries of applications, our pesticide decisions, and scientific risk assessments in plain language improve transparency?

- What information would you most need to access, why, and how could that information be best made available to you?

- What barriers exist in the *Pest Control Products Act* to increasing access to information, considering our obligations to protect CBI and our international commitments?

- How can PMRA improve the approach to consultation with the public on regulatory decisions?

See the Have Your Say section at the end of this document for details on how to submit comments.

4.3 Objective 3 – Increased use of real-world data and independent advice in the pesticide regulatory process

4.3.1 Current Legislative Requirements

The *Pest Control Products Act* currently provides broad provisions for the consideration and use of real-world data and independent advice:

- The Act has broad provisions for disclosing confidential information to certain persons or bodies from whom the PMRA requests advice for the purposes of the *Pest Control Products Act* (including the Pest Management Advisory Council); and

- The Act provides authority to compel industry to submit incident reports (including new scientific information) and sales reporting information.

Currently, PMRA can compel registrants/applicants under the Act to provide data in support of pesticide reviews. Where required, PMRA encourages submission of additional data from other stakeholders including the public.

PMRA makes science-based regulatory decisions and considers information from various sources such as other federal departments, including Environment and Climate Change Canada (ECCC) for environmental impacts and the Canadian Food Inspection Agency for food monitoring, provinces and territories, Canadian equivalent international jurisdictions, registrants, user groups, peer reviewed journals, academia and researchers.

However, under PMRA's existing approach to pesticide regulatory decision-making, limited availability of comprehensive, robust, real-world data in areas such as water monitoring and pesticide use and crop production practices have created challenges for pesticide evaluations.

PMRA currently has access to some water monitoring data, crop production, and pesticide use information from various sources including peer-reviewed journals, other federal departments, provinces and territories, grower groups and other pesticide users, industry and academia, which are considered in evaluations. However, more robust data are required for regulatory purposes. For example, gaps in available water monitoring data can limit human health and environmental risk assessments. In addition, the availability, timeliness and quality of information on current agricultural production practices, various pesticide use scenarios and exposures are key considerations in risk assessment and risk management decisions. Comprehensive water monitoring data and accurate characterization of pesticide use are critical for robust and timely pesticide regulatory decisions.

PMRA intends to further strengthen the protection of human health and the environment through access to more real-world data and better linkages with partners such as ECCC on issues related to the environment including wildlife, and species at risk. Increasing use of real-world data would allow for the early identification of areas where risks may be elevated and further investigation may be needed to inform regulatory action.

In cases where there is a lack of real-world data, PMRA must apply conservative assumptions with respect to risk assessment and risk management approaches to protect the environment and human health. This, in turn, can lead to more conservative regulatory decisions than may be required.

The generation and increased use of comprehensive, real-world data in PMRA's pesticide regulatory decisions would expand the evidence base and contribute to increased transparency and public trust. In recent consultations (Annex 2), all stakeholders expressed support for strengthening PMRA's information base for pesticide decision-making through enhanced water monitoring and pesticide-use information.

4.3.2 Proposed Measures to Increase Use of Real-world Data and Independent Advice

The Government of Canada has committed to improving the availability of data to support pesticide review decisions and strengthening human health and environmental protection.

PMRA will develop a national water monitoring program for pesticides in collaboration with other federal departments, provincial and territorial governments, academic experts, Indigenous groups, and various stakeholders.

To help establish a national monitoring program, PMRA will develop a framework for pesticide water monitoring programs in Canada's lakes, rivers, wetlands and groundwater. In addition, PMRA will facilitate a pilot program for pesticide water monitoring at targeted sites beginning in spring 2022. This pilot program will provide baseline data and information, and lessons learned will be considered in development of the national framework.

PMRA will also pursue the development and implementation of a comprehensive pesticide use data program for agriculture and non-agriculture sectors. Through collaboration and partnerships with federal and provincial partners, crop specialists, grower and other user communities, and other stakeholders, PMRA will develop a systematic approach to identify and gather crop production and pesticide use data.

PMRA will strengthen its linkages with partners, such as ECCC to broaden the availability of scientific information, such as impacts on wildlife, to inform its oversight and decision-making in relation to pesticide use in Canada.

The increased use of real-world data in continuous oversight and regulatory decision-making can be implemented through policy and amended business practices at PMRA. These measures do not require legislative changes.

In addition to increased use of real-world data, PMRA is also establishing a Science Advisory Committee to provide scientific advice in response to specific technical questions from PMRA. Other international pesticide regulatory organizations (for example, the United States Environmental Protection Agency and the European Food Safety Authority) have well established systems in place to obtain independent external science advice. Currently, PMRA lacks a formal external science advisory process and as a result has only established *ad hoc* advisory bodies on a small number of cases since 1995. As the Ministers of Health, Agriculture, and Environment announced in August 2021, the investment in PMRA will enable establishment of a new expert panel process to provide advice, as appropriate.

The establishment of the Science Advisory Committee will also help build trust in PMRA regulatory decisions. There are general provisions in the Act that permit the disclosure of CBI and CTD, in accordance with the regulations, to a body for the purpose of obtaining advice. The process to establish a new Science Advisory Committee for the PMRA has been initiated. The Science Advisory Committee will operate in accordance with its Terms of Reference established in accordance with the Health Canada Policy on External Advisory Bodies (2011), which can be found on the Health Canada Public Engagement section of Canada.ca.

4.3.3 Seeking Your Views

PMRA is seeking your views on the following questions in relation to the *Pest Control Products Act* provisions that relate to the use of real-world data and independent advice:

- Are there any issues PMRA should consider in terms of accessing, sharing and releasing comprehensive water monitoring and pesticide use data?

See the Have Your Say section at the end of this document for details on how to submit comments.

5.0 Next Steps

PMRA will consider all input received and will continue to engage with Canadians, partners and stakeholders as we determine the path forward.

We will also continue to work with federal, provincial and territorial partners, Indigenous peoples and various stakeholder groups to further discuss specific issues and proposed measures including policy and programmatic means of improving transparency, developing a national water monitoring framework and a crop production/pesticide use data program, and implementing risk-based and continuous oversight across the product life cycle.

This work will continue to inform policy and/or program changes in 2022-23.

6.0 Have Your Say

We are interested in your views on the specific questions identified herein to help inform the development of potential targeted legislative changes to the *Pest Control Products Act*. Please refer to Annex 3 for a complete list of questions for input.

The PMRA invites the public to submit written comments on this document up to 60 days from the date of publication.

Please forward your comments to PMRA Publications, and include:

- Your full name and organization;
- Your phone number; and,
- Your complete mailing address or email address.

Annex 1 Current Legislation

Health Canada's PMRA is the regulatory authority in Canada responsible for the federal regulation of pesticides (pest control products) and acts on behalf of the Minister of Health under the authority of the *Pest Control Products Act* and its regulations, including the Pest Control Products Regulations. The *Pest Control Products Act* received royal assent in December 2002, and came into force in June 2006.

Under the *Pest Control Products Act*, PMRA's mandate is to protect people living in Canada and the environment and ensure that the pest control products in the marketplace can be used safely and effectively.

All pesticides manufactured, imported, distributed, or used in Canada must be registered by PMRA or otherwise authorized under the *Pest Control Products Act* to ensure they meet Canadian health and environmental standards, bear the Canadian label and can be used safely and effectively according to label directions. The *Pest Control Products Act* provides the foundation for Canada's science-based approach to the regulation of pesticides in Canada.

The Act requires all pest control products be re-evaluated on a 15-year cycle, and gives the Minister of Health the authority to remove a pesticide from the market if the risks associated with the product are not acceptable. Under the Act, registrants must report incidents relating to pesticides and pesticide sales data. Furthermore, the Act provides substantial powers of inspection to ensure compliance and allows a court to impose fines of up to $1 million for the most serious offences.

The *Pest Control Products Act* includes provisions mandating the transparency of the pesticide regulatory system. It formalizes the requirement for public consultation on major pesticide registration and re-evaluation decisions, as well as on policies, guidelines and codes of practice related to pesticide regulation. It also allows public inspection of the information and data reviewed by PMRA to approve pesticides for registration and used during re-evaluations and special reviews.

Canada's pest control regulatory regime also operates in an international context where Canada works cooperatively with trading partners and has to respect its obligations in its oversight of pesticides in Canada. PMRA works with its counterparts in other countries to improve the international alignment of processes used to regulate pest control products and ensure the protection of human health and the environment. For example, PMRA participates in the Working Group on Pesticides, initially established under the North American Free Trade Agreement, within Codex Alimentarius, the global food safety standard setting body, and through the Organisation for Economic Co-operation and Development Working Group on Pesticides.

Annex 2 Recent Reviews and Consultations

In recent years, PMRA has received feedback, actively consulted with the public and Canadian industry, and embarked on initiatives aimed at improving several aspects of the federal pest control product framework in Canada.

These consultations will build on learnings from these reviews and feedback received from recent consultations, including:

The 2015 Legislative Review

The Statutory Review of the *Pest Control Products Act*, Report of the Standing Committee on Health, April 2015

The 2015 Audit from the Commissioner of the Environment and Sustainable Development

2015 Fall Reports of the Commissioner of the Environment and Sustainable Development Report 1 Pesticide Safety

The Treasury Board-Led Regulatory Review

Agri-food and aquaculture sector: Targeted regulatory review, June 2019

PMRA-Led Consultations

What Was Heard Report - Post-Market Pesticide Re-evaluation Review , May 2019

2020 What Was Heard Report - Proposed Integrated Approach to Pesticide Evaluation - Stakeholder Engagement Sessions, April 2021

Consultation Summary: Consultation on Inspecting Confidential Test Data for Post-Market Reviews in the Reading Room, May 2021

What We Heard – Key Highlights

Through these initiatives, PMRA heard recurring themes and recommendations:

- There was general support for process modernization, including for a new proposed approach for continuous oversight of pesticides and how it improves the regulatory model overall.

- Strong support emerged for a re-evaluation system that ensures resources are available to manage pesticides that present the greatest risk to human health and the environment.

- Greater openness, transparency, and accessibility of processes are needed so that more meaningful and informed input can be provided into the decision-making process and so that decisions are clearly understood.

- Timing of engagement matters – some stakeholders want to be engaged earlier in the decision-making process (for example, at the draft risk assessment phase), some

stakeholders want more frequent engagement opportunities (for example, not just at the proposed decision phase), and some stakeholders want more time to provide feedback to PMRA (for example, expand feedback timing from 60 to 120 days).

- There is a need for a national pesticide water monitoring program and a framework to collect pesticide use information to better inform decision-making.

Annex 3 Questions for Input

For ease of reference the consultation questions are collated and reproduced below:

Objective 1 - Further Strengthening Human Health and the Environment through Modernized Business Processes Governing Pesticide Reviews

- What barriers if any, exist in the *Pest Control Products Act* to implementing continuous oversight?
- Are there any changes you would like to see in how MRLs are established?

Objective 2 – Improved Transparency

- Would introducing plain language summaries of our pesticide decisions, as well as more plain language information on how we conduct our science, improve transparency?
- What information would you most need to access, why, and how could that information be best made available to you?
- What barriers exist in the *Pest Control Products Act* to increasing access to information, considering our obligations to protect CBI and our international commitments?
- How can PMRA improve the approach to consultation with the public on regulatory decisions?

Objective 3 - Increased Use of Real-world Data and Independent Advice in the Pesticide Regulatory Process

- Are there any issues PMRA should consider in terms of accessing, sharing and releasing comprehensive water monitoring and pesticide use data?

Annex 4 Other Jurisdictions' Approaches to Improving Transparency

The approach adopted in Canada's *Food and Drugs Act*, through Vanessa's Law, presents a potential model to follow for pesticides. This could include adopting a definition of CBI that makes clear what is considered CBI, and any information that ceases to be CBI as a final decision is made and could be shared.

Another approach for disclosure of scientific data is the European Food Safety Authority approach where all pesticide studies and information submitted by industry in the risk assessment process, that disclosure would not be harmful to commercial interests, are accessible.

For the disclosure of regulator science reviews and risk assessments, the United States Environmental Protection Agency shares materials used in the decision-making process including pesticide scientific reviews, public comments received and other information to support decisions.