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Federal agency seeks input on transformation of pesticide regulation in Canada

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On March 21, 2022, Health Canada's Pest Management Regulatory Agency (PMRA) announced a targeted review of the *Pest Control Products Act*, as detailed in the "Discussion Document DIS2022-01: Further strengthening protection of health and the environment: Targeted review of the Pest Control Products Act" (the Discussion Document). The PMRA is currently soliciting feedback from stakeholders as the PMRA "develops advice for the Government on possible legislative amendments."

This Osler Update discusses the targeted review process, outlines key takeaways from the Discussion Document and considers implications for stakeholders.

Background

The PMRA is the federal regulatory authority in Canada responsible for the regulation of pesticides (pest control products), deriving its authority from the *Pest Control Products Act* (the Act) and its regulations, including the *Pest Control Products Regulations*.

All pesticides manufactured, imported, distributed or used in Canada must be registered by the PMRA or be otherwise authorized under the Act. The Act currently requires that all pesticides be re-evaluated on a 15-year cycle and gives the Minister of Health the authority to remove a pesticide from the Canadian market if the risks associated with the product are not acceptable. The Act also includes provisions aimed at ensuring transparency in the pesticide regulatory regime and requiring consultation on major pesticide registration and re-evaluation decisions (as well as on policies, guidelines and codes of practice related to pesticide regulation).

Between 2018 and 2020, the PMRA undertook consultations to obtain feedback on the Act and the PMRA. Building from that consultation process, the PMRA is now embarking on a "Transformation Agenda" that is built on "4 pillars of action":

- improved transparency
- increased use of real-world data and independent advice
- strengthened human health and environmental protection through modernized pesticide business processes
- targeted review of the Act

To help inform the PMRA's targeted review, the Discussion Document sets out a framework for stakeholders to provide feedback to the PMRA on potential legislative and policy changes.

Discussion Document: the PMRA's targeted review of the Act

The Discussion Document is structured around three objectives:

1. strengthening human health and environmental protection by modernizing business processes governing pesticide reviews
2. improving transparency and stakeholder accessibility to information to increase participation in decision-making
3. increasing the use of real-world data and independent advice in the decision-making process to better inform decisions to protect human and environmental health

For each of these objectives, the Discussion Document provides (i) an overview of the current legislative requirements that relate to the objective; (ii) proposed legislative and policy changes to further the objective; and (iii) specific questions for stakeholder feedback related to the objective.

Human health and environmental protection

Current legislative requirements

A key component of the regulatory regime established by the Act is reviewing scientific information and determining whether a pest control product is appropriate for use in Canada. For instance:

- During a pesticide's post-market evaluation — which is required to take place no later than 15 years after the most recent major decision regarding the pesticide (i.e., registration, amendment or re-evaluation) — the PMRA re-evaluates the pesticide for compliance with health and environmental safety standards, considering any new risk assessment approaches and data requirements that have developed since the last review.
- A special review of a pesticide must be initiated when new information reveals reasonable grounds to believe the pesticide's health or environmental risks are unacceptable.
- The Minister has authority under the Act to set maximum residue limits (MRLs) for a pesticide, its components and its derivatives, which inform the pesticide registration process.

The PMRA sees the current post-market approach as having certain limitations, such as:

- A post-market re-evaluation every 15 years makes it difficult to act on pesticides of concern in proportion with the potential risk they pose.
- Current practices "are contributing to an increasing workload" for the PMRA, delaying regulatory decisions, and contributing to stakeholder concerns about the predictability of regulatory decisions.

Proposed legislative and policy changes

In response to these perceived limitations, the PMRA is proposing to no longer be bound to a 15-year re-evaluation cycle and instead implement a "continuous oversight approach". To that end, the PMRA proposes to review the provisions in the Act that trigger pesticide reviews

every 15 years and recommend changes that make the Act conducive to the new approach.

The "continuous oversight approach" would enable the PMRA to assess and act on information and manage risks as they arise. While few details on this new approach are provided in the Discussion Document, the PMRA has indicated that the transition to a continuous oversight model will require the creation of new PMRA policies and/or amendments to existing policies. The PMRA expects the change to result in less complex and more timely re-evaluations, streamlined decision-making, and improved availability of timely and transparent information pertaining to ongoing risk assessment.

The PMRA is also proposing to

- implement risk-based management, to apply proportionality between the regulatory effort expended on a given pesticide and the risks it poses. In practice, this would result in the PMRA expending less effort on pesticides with risks that are well understood and managed, with increased oversight being directed to pesticides that require further assessment and regulatory action to manage the risks that they pose.
- introduce modern process management approaches, leveraging technological advances in digital information management and analysis to improve review efficiency, effectiveness and responsiveness. The Discussion Document provides no details on the approaches to be adopted, but the changes are expected to be reflected in PMRA policy.

Further, the PMRA intends to bring forward potential statutory amendments to the Act that would

- broaden the Minister of Health's ability to alter product labels without an application in certain circumstances
- make it easier to make risk-based authorizations and to exercise appropriate post-market oversight for products with low or well-characterized risks

Questions for stakeholder feedback

To inform potential legislative amendments and policy changes, the PMRA has posed the following questions related to these topics:

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

Transparency and stakeholder accessibility to information

Current legislative requirements

The Act mandates transparency and access, requiring that information and decisions be made available on a register and in an electronic public registry. The electronic registry includes information on applications, registrations, re-evaluations, special reviews, related non-confidential information, Health Canada evaluations, notices, consultation and decision statements and information on the regulatory process.

Members of the public can access and obtain copies of any information in the register that is not confidential test data (CTD) (unless such data is made subject to public disclosure) or confidential business information (CBI). CTD is any scientific or technical information on the

risks or values of a pesticide, and CBI includes any information pertaining to manufacturing or quality control processes or methods to determine product composition and financial or commercial information.

The public may inspect, but not obtain copies of, CTD by attending a Reading Room in Ottawa to view the information. The Act also permits the disclosure of information to certain persons (including, among others, international organizations, provincial and foreign governments, medical professionals and federal and provincial agencies and departments) to obtain advice, to protect human health and the environment or to make a medical diagnosis or give medical treatment.

The Act also requires the public be made aware of certain decisions. When making decisions that necessitate public consultation, the Act requires a summary be provided to stakeholders. The summary must contain any evaluation report and can include CTD when the Minister considers it in the public interest. The Minister is required to consider all comments when making major registration decisions and to explain the reasoning behind those decisions.

Proposed legislative and policy changes

To meet its objective of improving transparency and access, the PMRA proposes to

- share relevant, timely and useable information and data in a more accessible manner
- provide easy access to members of the public and other stakeholders to participate meaningfully in the regulatory process and make informed decisions
- aid Canadians and stakeholders in their understanding of the regulatory and decision-making processes by identifying information that is useful and relevant

Specific proposed measures to meet these objectives include

- presenting information about pesticide consultation, decision documents, and summaries of new applications clearly, concisely, and in plain language
- implementing a more user-friendly system whereby pesticide data and information can be inspected without compromising confidential and commercially sensitive information
- reviewing the process and timing by which stakeholders receive information. For example, currently, registrants can make representations to the Minister before a decision is made, while other stakeholders are consulted at the decision stage.

Questions for stakeholder feedback

The PMRA is inviting input from stakeholders regarding what data interests them, their priorities and how access to PMRA information might be improved. Specific questions posed include

- Would introducing summaries of applications, 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 Act to increasing access to information, considering our obligations to protect CBI and our international commitments?

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

Real-world data and independent advice

Current legislative requirements

The Act broadly provides for the consideration and use of real-world data and independent advice, including by authorizing the PMRA to disclose confidential information to certain persons or bodies to obtain advice, and by providing authority to compel industry to submit incident reports containing scientific and sales reporting information. The PMRA is also authorized to compel registrants and applicants to provide data to inform pesticide reviews and encourages the submission of additional data from stakeholders in conducting reviews.

However, the PMRA indicates that comprehensive real-world data related to pesticide applications is lacking, creating perceived challenges in conducting pesticide evaluations. In particular, the PMRA has identified improved data related to water monitoring, pesticide use and crop production practices as being necessary to perform its regulatory mandate. In the absence of real-world data, the PMRA applies conservative assumptions in determining risk to human health and the environment, potentially generating more conservative decisions than may be required.

Proposed legislative and policy changes

To increase the use of real-world data, the PMRA

- intends to develop a national water monitoring program for pesticides. The program will consist of a framework to monitor Canada's lakes, rivers, wetlands and groundwater, and will complement a pilot program monitoring targeted sites, slated to begin in spring 2022. The pilot program will provide baseline data and information to inform the development of the national water monitoring program.
- is pursuing the development of a comprehensive pesticide use data program for the agricultural and non-agricultural sectors. The program would establish a systematic approach to identifying and gathering crop production and pesticide use data, and will be implemented through partnerships with federal and provincial entities, crop specialists, growers and other user communities and stakeholders.
- will leverage its relationship with Environment and Climate Change Canada and other partners to broaden the availability of scientific information, including on impacts to wildlife, to better inform oversight and decision-making as it relates to pesticide use.
- is establishing a Scientific Advisory Committee which will provide advice on the technical questions posed to the Committee by the PMRA. As no formal system currently exists for the PMRA to obtain independent external scientific advice, the creation of the Scientific Advisory Committee will bring the PMRA in line with other international pesticide regulatory organizations with expert panels, like the United States Environmental Protection Agency and the European Food Safety Authority.

These changes are anticipated to be implemented through changes to PMRA policies and business practices, and not through legislative amendments.

Questions for stakeholder feedback

To inform these objectives, the PMRA has posed the following question to stakeholders:

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

Conclusion

Through its targeted review of the Act, the PMRA "is not planning a complete overhaul of its regulatory system, but is rather looking at targeted improvements."

However, as framed in the Discussion Document, the PMRA's proposed legislative and policy changes could have significant implications for stakeholders, including industry. If changes are implemented as proposed, registrants can expect fewer burdens in bringing lower-risk pesticides to market, improved interface with the regulator and improved transparency and dialogue with the regulatory body. On the other hand, registrants of higher-risk pesticides can anticipate a greater compliance burden and potential heightened regulatory scrutiny.

Interested stakeholders have until May 20, 2022, to share their views to help inform the development of the proposed targeted legislative changes to the Act. Comments can be provided through a variety of means, including the PMRA's Public Engagement Portal comment form, regular mail and email. The PMRA's specific consultation questions (discussed above) are aggregated at Annex 3 of the Discussion Document, but the PMRA has indicated that it will consider all comments from stakeholders.

Please contact Richard J. King and Jennifer Fairfax if you would like assistance or further information. Osler lawyers regularly act for clients on pest control product regulatory matters, including providing compliance advice and assisting clients through the registration process.