Notice of Intent NOI2023-01

Notice of Intent: Strengthening the regulation of pest control products in Canada

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1.0 Purpose

This Notice of Intent (NOI) informs Canadians, regulated parties, Indigenous organizations, and other interested stakeholders and partners that Health Canada is seeking feedback on proposed amendments to the Pest Control Products Regulations to strengthen protection of human health, the environment and wildlife from risks posed by pesticides in Canada, and in particular to:

- Facilitate access to confidential test data (CTD), including for research and re-analysis purposes;
- Increase transparency for maximum residue limit (MRL) applications for imported food products;
- Give the Minister of Health the explicit authority to require submission of available information on cumulative environmental effects and require the Minister to consider cumulative effects on the environment during risk assessments where information and methodology are available; and
- Strengthen consideration of species at risk in risk assessments by giving the Minister the explicit authority to require the submission of available information on species at risk.

Canadians are invited to send their comments on the proposed amendments up to 60 days from the date of publication of this document.

2.0 Context

The purpose of the federal pesticide regulatory system in Canada is to protect human health, the environment and wildlife from the risks of pesticides. Health Canada's Pest Management Regulatory Agency (PMRA) is the federal government authority responsible for the regulation of pesticides. The *Pest Control Products Act* and its regulations provide the legislative framework for the regulation of pesticides federally.

On 4 August 2021, the Ministers of Health, Agriculture and Agri-Food and Environment and Climate Change announced that the Government of Canada would be investing $42 million in Health Canada's PMRA to further strengthen its human and environmental health and safety oversight and protection, and improve the transparency of the pesticide review process.

In Spring 2022, the PMRA launched a targeted review of the *Pest Control Products Act* and consulted a broad range of interested stakeholders and partners, including Indigenous organizations, through a *Discussion Document, DIS2022-01, Further strengthening protection of health and the environment: Targeted review of the Pest Control Products Act*.

The targeted review sought feedback on whether changes to the *Pest Control Products Act* are needed to modernize and strengthen Canada’s pesticide regulatory system, in particular to: further strengthen human health and environmental protection by modernizing business processes governing pesticide reviews; improve transparency and stakeholder accessibility to information to bolster meaningful participation in decision-making; and increase the use of real-world data and independent advice in the decision-making process to better inform decisions to protect human and environmental health.

A What We Heard Report was published in Fall 2022 providing an overview of what Health Canada heard through this consultation process, including suggestions on ways to improve transparency and/or strengthen health and environmental protections.

We heard from some stakeholders, namely pesticide manufacturers and user groups, that amendments to the *Pest Control Products Act* were not needed at this time and that much of the transformation agenda could be implemented through existing policy and regulatory channels. We also heard from some non-governmental organizations (NGOs) that the PMRA should undertake a broad review of the *Pest Control Products Act*, and several comments and suggestions were received in support of amendments to the legislation.

This proposal, which complements several policy initiatives currently underway, is a key step as part of Health Canada's initiative to strengthen the protection of human health and the environment from risks posed by pesticides and improve transparency of its decision-making process.

This proposal focuses on the following areas, and is informed by what we heard:

- Facilitate access to CTD, including for research and re-analysis purposes;
- Increase transparency for MRL applications for imported food products;
- Give the Minister the explicit authority to require the submission of available information on cumulative environmental effects and require the Minister to consider cumulative effects on the environment during risk assessments where information and methodology are available; and
- Strengthen consideration of species at risk by giving the Minister the explicit authority to require the submission of available information on species at risk.

For information on other regulatory modernization efforts, please consult the Forward Regulatory Plan page on the Health Canada portion of the Canada.ca website.

3.0 Proposed amendments

As noted, the Government of Canada is considering amending the Pest Control Products Regulations to strengthen the regulation of pesticides in response to the views heard through the targeted review of the *Pest Control Products Act*.

3.1 Facilitate access to confidential test data, including for research and re-analysis purposes

CTD is defined in the *Pest Control Products Act* as test data to which access may be refused under the *Access to Information Act*.

Currently, access to CTD is limited in that it is only available for inspection under the process set out in section 43 of the *Pest Control Products Act*. Subsection 43(1) requires that a person who wishes to inspect CTD must submit an application and an affidavit stating that they do not intend to use the test data, or make the test data available to others, in order to register a pest control

product in Canada or elsewhere, or to amend a registration. If the Minister is satisfied that the criteria set out in subsection 43(1) are met, the Minister shall permit the person to inspect the CTD.

Under the *Pest Control Products Act*, the public may inspect CTD used to support pesticide registration decisions (for example, to register a product or maintain a registration) or proposed decisions in the case of post-market reviews (in other words, re-evaluations and special reviews). However, the visual inspection of data that is currently available does not support further re-analysis of the data or its use for research purposes.

Prior to the COVID-19 pandemic, access to inspect CTD was only allowed by applying for access to the physical "reading room", a controlled environment located at the PMRA's offices in Ottawa, where an individual was permitted to view the documents under supervision. To prevent copying of data, electronic devices were not permitted. Note-taking was allowed if the applicant provided consent on the application form to have the notes photocopied by Health Canada. Since the pandemic, access to inspect CTD has been provided remotely via encrypted USB key with robust data protection software.

NGOs and academics who participated in the Spring 2022 consultation indicated that the current approach does not provide sufficient access to data and can act as a barrier to further improving the trust that Canadians have in their pesticide regulatory system. Several pesticide manufacturer organizations noted that while Canada's pesticide regulatory system is already very transparent, a lack of timely access to data and information, and a lack of understanding about the PMRA's decisions reduces Canadians' overall confidence in the federal pesticide regulatory system.

To facilitate access to CTD, including for research and re-analysis purposes, Health Canada is proposing to amend the Pest Control Products Regulations to enable inspection of CTD for research and re-analysis purposes. This amendment would provide access to CTD in a manner that would allow an individual to conduct their own data analysis, while maintaining the appropriate levels of protection against unfair commercial use of the data (as required by international treaties to which Canada is a signatory). These changes would support better understanding of the PMRA's evaluation conclusions and would facilitate public participation in the regulatory process and the development of independent data on pesticides. Confidential business information (CBI) and privacy information would continue to remain protected.

Views are requested on this proposal.

3.2 Increase transparency for MRL applications for imported food products

The PMRA sets science-based pesticide MRLs on food products to help ensure that the food Canadians eat is safe. Section 9 of the *Pest Control Products Act* provides the authority for the Minister to specify any necessary MRL for a pesticide, its components, or derivatives as part of a registration application and decision.

Authority also exists under the *Pest Control Products Act* to specify MRLs for unregistered products and uses in accordance with section 10 of the *Pest Control Products Act*. An application may be submitted to the PMRA to specify an MRL for imported foods that are treated with a pesticide used in another country.

In May 2022, the PMRA struck an MRL technical working group (TWG) composed of industry, government, and NGO representatives to provide feedback on technical issues related to the potential legislative and operational changes concerning MRLs. Stakeholders, as well as the TWG, generally agreed that the current process for establishing MRLs is effective and does not require adjustment; however, the PMRA could improve transparency and communication, such as by adopting a "notification process", to inform the public when an application to change an import MRL has been received and accepted for review.

Health Canada is proposing amendments to the Pest Control Products Regulations that would increase transparency for MRL applications for imported food products by requiring the PMRA to issue a public notification for section 10 MRL applications once an application has been accepted for review.

The notice would be published for information purposes and precede the PMRA scientific review to help improve transparency and timely public access to information. It would describe why the MRL is being requested, the country or authority the application is suggesting to align with, and the types of studies conducted to support the MRL application. Early notification will enhance the public's knowledge of the application and increase timely participation in the decision-making process and understanding of the request. As is done currently, once the review is complete, the PMRA would publicly consult on the Proposed MRL (PMRL) decision.

Views are requested on this proposal.

3.3 Give the Minister the explicit authority to require the submission of available information on cumulative environmental effects and require the Minister to consider cumulative effects on the environment during risk assessments where information and methodology are available

The purpose of the PMRA's environmental risk assessment is to determine whether adverse effects from the use of pesticides may occur to organisms and to the natural environment itself. Similar to the approach for assessing the risks to human health, the environmental risk assessment analyzes the exposure (environmental fate and behaviour) and hazard (toxic effects on organisms) and characterizes the risks posed by pesticides.

A cumulative risk assessment is an analysis of the combined risks to human health or the environment from multiple agents or stressors. For example, cumulative risk assessments could consider the combined risk from pesticides with a common mechanism of toxicity. In the context of pesticide registration and re-evaluation, assessing cumulative effects of substances in environmental risk assessments is challenging. Exposures to pesticides in the environment are highly variable across locations and years, dependent on which crops are grown and which pesticides and rates are used. Given this context, public documents and websites of international

regulators including the PMRA, the United States Environmental Protection Agency (USEPA) and the European Food Safety Authority (EFSA) focus on cumulative health risk assessments. The PMRA and its domestic and international regulatory partners are seeking to develop new approaches and tools for assessing risks to the environment from cumulative effects. The PMRA will continue to collaborate with partners in these efforts.

In response to the discussion document, DIS2022-01, environmental NGOs put forward that the PMRA's environmental risk assessments of pesticides should require consideration of cumulative effects on the environment.

While available information on cumulative health effects is considered in the PMRA's health risk assessments under the *Pest Control Products Act* for major regulatory decisions where products have a common mechanism of toxicity, cumulative effects in environmental risk assessments are not currently considered due to lack of information and standard methodologies.

The PMRA is proposing to amend the Pest Control Products Regulations to require the Minister to consider the cumulative effects on the environment of pesticides that have a common mechanism of toxicity, where information and methodology are available. Additionally, the amendments would give the Minister explicit authority to require registrants and applicants to submit available information on cumulative environmental effects, so this information could be considered within the PMRA's environmental risk assessments. In cases where the information and methodology are available, regulatory decisions would be informed by an evaluation of cumulative environmental effects, thereby improving the protection of the health and environment of Canadians.

Views are requested on this proposal, particularly on:

- What kind of information should the Minister seek for assessing cumulative effects in environmental risk assessments?

3.4 Strengthen consideration of species at risk in risk assessments by giving the Minister the explicit authority to require submission of available information on species at risk

Under the *Pest Control Products Act*, "environment" encompasses biodiversity and wildlife, including species at risk. In protecting species at risk, the PMRA currently takes a layered approach. Firstly, the environmental risk assessment is conservative in its determination of effects on organisms, including by considering the most sensitive organisms, and through the application of uncertainty factors to build in a margin of protection. Additionally, when there are concerns for a particular species at risk through use of a pesticide, this is considered and incorporated into the environmental risk assessment and mitigation measures.

Moreover, the *Pest Control Products Act* requires that notices be sent to all provinces, territories ,and other relevant federal departments when re-evaluations or special reviews are initiated, to request information related to health or environmental risks or value. It further requires that these groups be consulted prior to any major regulatory decision being made. Information provided to

the PMRA in response to such notices can include information on wildlife and species at risk, particularly from our federal partners at Environment and Climate Change Canada (ECCC) and the provinces and territories.

Lastly, pesticide users are required to respect provisions of other legislation that are implicated when using pesticides, notably the *Species at Risk Act* (SARA) and *Fisheries Act*.

In response to the discussion document, DIS2022-01, some NGO stakeholders raised that risk assessments should be required to fully examine the impact of pesticides on Canada's species at risk to conserve and protect our biodiversity. Continued collaboration on this issue with a broad range of stakeholders, including with our federal partners, was also encouraged.

While the Minister has the authority under the *Pest Control Products Act* to require an applicant or registrant to submit information required to conduct a risk assessment, which can include information regarding wildlife and species at risk, the Pest Control Products Regulations does not include an explicit authority to require this information.

The PMRA is proposing to amend the Pest Control Products Regulations to strengthen the consideration of species at risk in its assessments by adding an explicit authority for the Minister to require registrants and applicants to submit available information on species at risk.

In addition, the PMRA would continue to maintain and enhance collaboration with regulatory partners, including ECCC, other government departments and the provinces and territories to obtain information to protect species at risk. These changes would acknowledge the importance of protecting species at risk and enhance the PMRA's ability to consider available information to further inform risk assessments and risk management decisions to protect species at risk.

Views are requested on this proposal, particularly on:

- What kind of information should the Minister seek for assessing species at risk in environmental risk assessments?

4.0 Next steps

Comments on this Notice of Intent from the public, stakeholders and partners can be provided up to 60 days from the date of publication of this document by:

1) email to pmra.regulatory.affairs-affaires.reglementaires.arla@hc-sc.gc.ca, or

2) by mail to the following address:

Regulatory Affairs and Applied Analysis Section
Policy and Operations Directorate
Pest Management Regulatory Agency
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The input gathered through this process will be considered and inform any policy or regulatory measures that the Government may propose. Any future regulatory proposal would be published in the *Canada Gazette*, Part I and subject to an additional comment period, as per Government of Canada's Cabinet Directive of Regulations.