June 30, 2022

To: PMRA Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario AL: 6606D2 K1A 0K9
By Email to: pmra.publications-arla@hc-sc.gc.ca
And to: hcminister.ministresc@canada.ca

Re: Comments on Discussion Document 2022-01: Further Strengthening Protection of Human Health and the Environment.

To Whom it May Concern:

We are writing to provide our comments on Discussion Document DIS2022-01, Further strengthening protection of health and the environment: Targeted review of the Pest Control Products Act (**Dis Doc 2022-01** or **Discussion Document**) presented for consultation by the by the Pest Management Regulatory Agency ("**PMRA**") on March 21, 2022. The Discussion Document sets out 3 objectives, and asks for answers to questions on each. The list is in Annex 3 to the Discussion Document. In early June, PMRA added an additional question for Discussion.

The following contains our comments relating to the objectives and the questions. A table of contents can be found at the end of this document.

PMRA also says it will also take comments on the full *Pest Control Products Act* (**PCPA** or the **Act**), since the full PCPA currently stands referred to Parliament for a broader legislative review. We provide high-level thoughts on this at the end of this letter.

Introductory Premise:

The primary objective of the PCPA is to prevent unacceptable risks to individuals and the environment from the use of pest control products (**PCPs**) (s. 4). This is considered a principle of protection. The ancillary objectives are to further this primary, protective objective (s.5). They require the PMRA to:

- support sustainable development without compromising future generations;
- minimize the risks of PCPs and encourage innovative sustainable pest management strategies by facilitating access to PCPs that pose lower risks and by other appropriate measures;
- encourage public awareness by informing and providing information to the public and facilitating public participation in decision-making; and
- ensure that only PCPs that have acceptable value are approved for use.

The premise from which these comments are made is that proposed changes can be made if they further the primary objective of the Act, and align with the ancillary or secondary objectives. If they do not, then they should not be made, at least not in the context of the "Targeted Review" which is supposed to be about strengthening the protection of health and the environment.

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

As a starting point, "Modernized Business Processes" must be effective at improving the protection of Canadians and the environment. As such, the processes are acceptable under the Targeted Review if they improve the validity of the assessments and evaluations of pesticides, and support the ability of PMRA to evaluate pesticide products on a timelier and more thorough basis.

The "Modernized Business Processes" are not appropriate in the Targeted Review if the aim is to promote increasing the rate at which pesticides can be reviewed in order to get on the market. We have a concern that the latter aim may be at play, particularly since the Discussion Document indicates such efforts were in place prior to the Targeted Review.

We make the second point that in the private sector, "modernized processes" include timeline targets, accurate "best-in-class" data and methodologies, and reporting requirements. All of these should form part of the conversation on "modernized business processes" in the public arena.

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

Implementing a continuous oversight approach.

The *Discussion Document* presents "continuous oversight" as a positive measure, and it definitely has the potential to be so. PMRA is overloaded with work, and evaluation and re-evaluation bottlenecks are occurring at the "point-in-time" evaluation moments. If "continuous oversight" measures will allow for the loosening up the bottlenecks, they should be promoted.

However, it is absolutely necessary that the regulatory point-in-time evaluation timelines be kept in place, if not improved upon. The reason is that pesticides pose risks, often unacceptable risks, to humans and the environment, and no delays in evaluating such risks can be tolerated from the perspective of ensuring protection of human health and the environment. Legislated point-in-time moments ensure accountability of both the regulator and the registrants, and thereby engender trust in the process. Removal of these legislated moments would be disastrous for public trust.

Timely decision making requires timely access to data, and data must be provided on a continuous, adequate basis in order for the "continuous oversight" approach to work. The time frames for making decisions must be pre-set, clear and unwavering, and no delays should be permitted.

The onus for proving acceptable risk is, at all times, on the registrant – which we use herein as the party wanting a pesticide decision. The barrier in the PCPA for implementing continuous oversight is the Act does not contain an incentive for providing data when required. Said another way, there must be disincentives to the registrant for not complying with "continuous oversight" milestones.

A recommendation is that if the registrant does not provide the data when required (which means the appropriate assessment cannot be made), the consequence should be that the requested decision not be made. Suggested repercussions are:

- When applying for registration, then the entire registration for all uses should be delayed until the data is provided (no partial registrations);
- In a re-evaluation, the registration should be amended to remove the aspect of the registration to which the data relates (and if the data relates to the entire registration, the entire registration should be revoked);
- In the context of a new use, the new use should be delayed until the data is provided and assessed.

We have suggestions on measures which would help PMRA with its re-evaluation bottleneck and help improved continuous oversight. One suggestion is to raise administrative renewals to legislatively mandated renewal timeframes, and require that these renewals continue to be every five years. This would incent the registrants, who have the onus of providing data for continued registration, to ensure that the data is made available.

A second suggestion is to require that both the environmental and the health risks be assessed concurrently, rather than through a piece meal approach that closes one assessment but not the other. The piecemeal approach allows the pesticide product to stay on the market when it may cause unacceptable risks to either human health or the environment, which is not protective. It also causes the file to drag on, which does not help the workload of PMRA. If either a health or risk assessment cannot be completed because of lack of data, then (as suggested above), the aspect of the registration to which the data relates should be removed.

A third suggestion is to change the legislated point-in-time requirement from mandating that re-evaluations be "initiated" every 15 years, to a requirement that they be "completed" every 15 years. Under the current "initiated" wording, re-evaluations taken many years longer than the public believes or expects, and many years longer than is protective. This change would also allow the file to not drag on, and ensure that the registrants are diligent in fulfilling their onus of showing the risks of their products are acceptable.

Review Process Efficiency.

Optimization of information management is an excellent idea. A recommendation is that these process efficiencies be expanded to allow PMRA to conduct systematic literature reviews. This would provide assessors with direct access to scientific literature instead of having to rely on third parties and registrants for the current scientific literature.

The importance of having PMRA scientists on staff with up to date resources for conducting and understanding the current scientific literature cannot be emphasized enough. If a team of researchers is able to create a valid scientific database for PMRA on pesticides, then current literature could be available on a timely basis to the evaluators. This would greatly improve efficiency.

Currently the Act contemplates PMRA asking other departments and governments and committees and the registrants about the current science. This is not timely and does not provide the public with any assurances that PMRA has not been provided with biased science.

The committee process of Health Canada also does not create trust in the process. For example, the scientific advisory committee for the Transformation Agenda was just announced, without any transparency or justification provided for the inclusion of some members and the inclusion of others.

We do not have trust in this advisory committee. Some reasons are that, as we understand it, it is a closed process and the committee will be asked pre-set questions which obviates the committee providing advice on approach.

Any time science is provided by third parties, rather than directly accessed by PMRA evaluators, there will be criticisms and suggestions of bias from one side or the other. PMRA need not shield itself from criticism of its decision-making. This is part of the transparency and accountability process, and the law protects PMRA from liability so long as its decision-making was reasonable.

Risk-based Management.

The premise of this strategy is to make a judgement on whether a pesticide is high or low risk, for the goal of deciding which ones are to be assessed for risk. This contains a reasoning fallacy, and runs counter to the premise of the PCPA that pesticide products need to be assessed for risk.

In addition, the concept of the registration of "lower-risk" pesticides does not make sense, because only pesticides that pose "acceptable" risks are allowed to be registered under the PCPA. A pesticide with low risk still presents a risk, such that there cannot be a "reasonable certainty of no harm" associated with a "lower-risk" pesticide.

The desire of the PMRA appears to be process efficiency, and it is proposing making a front-end judgement on what should "from the get-go" be allowed to be used on pests to manage them without requiring assessment. However the premise of the PCPA is that all pest control products undergo a risk assessment, and the reason for this is that it is only after assessment of the product that PMRA can have a "reasonable certainty" that no harm to human health or the environment will arise from use of the product. Without assessment, there is not certainty.

Rather than constructing this "short-cut" to assessments that are required under the PCPA, we suggest that PMRA take steps to eliminate the back-log that has been created by delay on the part of the registrants in providing data required for risk assessments. PMRA can use its statutory powers to cancel the relevant registrations, as allowed in the Act.

It is our understanding there is a concern that certain substances that are used to manage pests have required registration, in instances where such registration was not needed. Perhaps one way to solve this this issue is to be clearer in the definition or meaning of a "pest control product".

A "pest control product" could be redefined as an item that is <u>designed and manufactured to kill pests</u>, whether on an acute, chronic or other basis. This aligns with the idea that a "product" is "produced" by design and with effort, as opposed to an item or thing found in nature or used as a food or food ingredient.

This wording aligns with the economic model that sees a registrant putting money and time into developing a product and the regulatory model that sees this registrant needing to prove acceptable risk with the end goal of receiving money for its product. The concept of "risk" does not generally need to be established with items found in nature or with food, and these items are not produced with the end goal in mind of making money from them as products to kill pests.

Such a redefinition also aligns with the second, ancillary objective of the PCPA of promoting innovative, sustainable pest management strategies and facilitating access to lower risk items (provided the wording is appropriately revised).

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

The response to this question will consist of a discussion of MRL issues, and then some thoughts on additional discussion questions suggested by PMRA.

Domestic MRLs

In the Discussion Document PMRA says "Any person may make an application to the Minister to specific maximum residue limits", however the actual wording (set out in sec. 10(2)) is that "any person may make an application to the Minister to specify maximum residue limits pursuant to subsection (1)."

Subsection 10(1) concerns the specification of MRLs for products and uses and that are not registered in Canada. Maximum residue limits must be understood in relation to the food to which pesticides are applied that Canadians eat. This food may be grown in Canada or elsewhere, but in either case it is food eaten by Canadians.

Thus under Subsection 10(1), if a pesticide product that is applied on food is a new unregistered product to Canada, or if there is an application for registration for a new use of a pesticide product that is already registered, then any person can make application to establish the MRL.

To be protective, the risk assessment for the establishment of the MRLs for pesticides applied to food grown in Canada requires a full risk assessment, meaning an assessment of the environmental and health effects of the pesticide. The human health risk assessment is required, both because Canadian bystanders and applicators are exposed, and also because the pesticide-laden food is consumed by Canadians.

An environmental risk assessment is required because the pesticide is applied in Canada. Pesticides when applied can travel in air further than previously believed, and affect and surface water, thereby requiring an environmental risk assessment. Higher levels in the environment can be expected as well because of run-off into the environment and air contamination and drift, and therefore MRLs should also require an environmental exposure assessment.

PMRA may take the view that "buffer zones" protect the environment from the run-off and air contamination, but this is not the case. The literature shows that agricultural pesticides can drift and travel through the air, and be found in locations outside of "buffer zones".

For example, PMRA in RVD2017-01 identified risks from glyphosate to terrestrial plants, freshwater algae, freshwater plants, marine/estuarine invertebrates, amphibians and marine fish, and put in place "spray buffer zones" to protect these organisms. It assumed this rendered these risks as "not of concern", however this was not verified. By way of example, it has been shown that glyphosate drifts and evidently travels through the air outside of buffer zones as evidenced by its presence at the highest mountain ranges in Germany, far away from its application sites in agricultural areas. (See Pesticides and pesticide-related products in ambient air in Germany).

By way of further example, chlorpyrifos was used for years as an agricultural pesticide in Canada. It has since been shown to exhibit a "grasshopper effect", described as follows: "In a process known as global

distillation, prevailing ocean and wind currents bring contaminants to the Arctic where they are subsequently trapped by the cold climate. This process is often referred to as the "grasshopper effect," as chemicals repeatedly evaporate and condense while in their journey toward the Arctic."

Import MRLs

One scenario is when a pesticide that is unregistered in Canada is present in food imported into Canada. This qualifies as an unregistered product that needs to be registered. Any person, usually the applicant/registrant, would make the application for the MRL as part of the process of applying for a registration decision.

When a pesticide that is registered in Canada is present on food imported into Canada, Canada must be certain that the pesticide was applied in the foreign country in a way that is consistent with standards for Canadian protection. Accordingly, examination of the field trial data that underlies the establishment of the foreign MRL should be reviewed for consistency with Canadian standards. Adjustments to the level should be made for inconsistencies, favouring adjustments that are conservative from the Canadian principle of protecting health. In addition, a Canadian dietary exposure assessment should be conducted to include such imported food and it should apply the Canadian thresholds and safety factors.

To be protective, the risk assessment concerning pesticides applied to food NOT grown in Canada requires only a Canadian health risk assessment, since the Canadian environment is not exposed during application, and the health risk assessment does not require an examination of the health risks to bystanders or applicator, since exposure to such people would have occurred outside of Canada.

However, the health risk assessment for pesticides on such imported foods must be Canadian and reflect the Canadian context and Canadian legal standards. In this regard, the health assessment must take into consideration the applicable factors set out in sec. 11(2) of the PCPA (the **Factors**). Also, because Canadians will be eating such foods, they should be included in the dietary risk assessment.

The application for the establishment of MRLs in this scenario would be made by the party desiring to import the foods into Canada.

Import and Domestic MRLs/Tolerance Limits Should be Distinguished

If there is a food crop that is both grown in Canada and imported into Canada, then the MRLs between the two should be distinguishable. The reason is that the levels of pesticides in the imported food is determined by the application rates, use scenarios, agricultural settings and other criteria applicable in the foreign country, which most likely are different than those of Canada. To allow the MRL of the imported food to apply to both the imported and the domestic Canadian food would be to conflate pesticide MRL values levels that should not be conflated. It would bring the criteria of the other country into Canada. As such, it does not present an accurate reflection of the levels of pesticides in food, and so cannot be justified.

It also presents a disconnect between the basis for establishing an MRL in Canada and the resulting enforcement. A domestic MRL is (or should be) set based upon the number of applications, application rates and pre-harvest intervals set by field trial studies based in Canada. If a food is permitted a higher MRL than that set by the field trial studies, there is no way to ensure compliance with the Canadian application requirements.

(A side but key point throughout the entire MRL discussion is that the entire pest control regulatory scheme does not verify that pesticides are being applied according to the label directions.)

PMRA is of the view that conflating the domestic and foreign MRLs is protective because PMRA uses the higher MRL in its dietary exposure assessment, which is a conservative approach. In practice, the dietary exposure assessment invariably indicates the levels of pesticides in food are safe. However the reason for this is that the dietary exposure assessments are flawed. In particular, PMRA uses ADI and Acute Reference Doses that are based on problematic endpoints, they do not take into account increased consumptions of certain foods, and they apply a deterministic rather than a probabilistic approach for aggregate and cumulative risk assessments. For more information, see our article "Glyphosate MRL Proposal not based on Sound Science" and the submission to PMRA linked in that article.

In the conflation scenario, if it was ever the case that a dietary threshold was exceeded for a crop that is both domestic and imported, then the registration for both types of crops would need to be revoked, based upon the reasoning of PMRA. This could well present trade issues.

Rather than conflating the import and domestic MRL, PMRA might consider determining the quantities of the crop that are imported into Canada and the quantities eaten overall, and allocate a percentage to both imported and domestic crops consumed by Canadians. This percentage could then be applied to the dietary exposure assessment, such that the "import" percentage of crops would be assigned the imported MRL, and the domestic percentage would be assigned the Canadian MRL.

This would allow removal of the problematic MRL from the "risk basket" without raising trade issues, and alleviate concerns with accuracy of the dietary exposure assessment and justification raised previously.

Increases in Domestic MRLs Require a Full Risk Assessment

Any increases in Maximum Residue Limits for domestic foods requires a full risk assessment for the pesticide in question. The reason is the level of MRLs permitted will most likely impact the quantities of pesticides that are to be applied to crops. Given that, as mentioned above, there is no mechanism for validating the pesticides are being applied according to the labels, there is no reasonable certainty that growers will not use greater quantities of pesticides or apply them more frequently, provided they stay on side of the MRL requirements. In such a case, there will be an increased exposure effect on the quantities of pesticides in foods, on occupational applicators, and the environment.

As indicated, the environment is affected by agricultural applications, and the concept that pesticide applications can be contained by a buffer zone no longer holds true. Evidence shows pesticides can travel in air and water to locations distant from their location of application.

Increases in Import MRLs Require a Health Risk Assessment

Any increases in MRLs for imported foods requires a Canadian health risk assessment, failing which the lower default MRL should apply to the imported foods.

Increases to MRLs: Timing and Other Considerations

The request for an increase in MRLs should only be allowed at the times of initial registration, re-evaluation or special review. They MRL levels should be tied to and supported by the risk assessment conducted for these major registration decision.

Why? Because as indicated above, an increased MRL may result in increased exposure to both human health and the environment, and so a full risk assessment is required in order to be protective. The conduct of a full risk assessment takes up valuable PMRA resources.

Also, there is no acceptable justification for allowing requests for increasing MRLs during the interim periods. Such requests take up valuable PMRA personnel and resources. There are basically 2 reasons for such requests: 1) the manufacturer wants to sell more pesticides, or 2) more pesticides are needed because the original quantities are no longer effective.

The former is not an acceptable justification and does not align with the protective purposes of the PCPA. With respect to the justification that more pesticides are needed because the original ones are no longer effective, this reasoning does not align with the secondary objectives of the PCPA.

One secondary objective is to encourage sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures. These other measure include the development and use of alternative, non-toxic, ecological pest control approaches, strategies and products, as set out in preamble to the Act.

Another secondary objective is to ensure that only PCPs that have acceptable value are approved for use. The preamble to the Act says they should be registered only if it is shown that their use would be "efficacious", which means the PCP will achieve the desired result of managing pests.

A third secondary objective is to support sustainable development without compromising future generations. "Sustainable development" under the *Canadian Environment Protection Act* means "development that meets the needs of the present without compromising the ability of future generations to meet their own needs".

An increased quantity of pesticides does not support, but rather runs counter to these secondary objectives. It runs counter to the objective of encouraging sustainable pest management strategies on its face.

It also runs counter to the objective of ensuring the use of the PCP would be efficacious, particularly in situations where an increase is requested because pests have developed, or are likely to develop, a tolerance to the pest control products. The PCP is such a situation is not working, so the efficacy argument must fail.

An increased quantity of pesticides also runs counter to the objective of sustainable development, because pesticide use harms soil organic matter and thus leads to land degradation. An increased quantity of pesticides is associated with decreased quality of soil over time, which compromises the ability of future generations to meet their food needs. (Intergovernmental Panel on Climate Change,). Sustainable land management options identified by the International Panel on Climate Change are organic farming and integrated pest management (p.24), which are in direct contrast to allowing more quantities of pesticides to be applied to crops.

The European Commission is also clear that pesticide use is not sustainable. It recently added new rules to its Farm to Fork Strategy that will halve the use of pesticides by 2030, citing in part biodiversity decline in agricultural areas and stating "Reducing our dependence on chemical pesticides is therefore a key part of the process of building more resilient, sustainable food systems for 2030 and beyond."

Conditions for Increase

To be consisted with the protective scheme of the Act and the secondary objectives, certain conditions must be met for allowing an increase in MRLs. It must be shown, first, that there are no alternatives to use of the PCP, meaning no lower risk pesticides and no alternative, non-toxic ecological approaches, strategies and products are available.

Second, the applicant must demonstrate that the use of the increased levels would be consistent with the secondary objectives of the PCPA. They must be shown to be efficacious without impacting the risks associated with the use. In situations where pests have developed, or are likely to develop, a tolerance to the pest control products, the efficacy argument must fail.

In the case when there is a request for a decrease in an MRL, this would on its face reduce the risk from exposure to a pesticide. Such a request should be considered without requiring a full risk assessment, because it aligns with the protective purposes of the PCPA and the secondary objectives. If necessary, the applicant might be asked to make the case for the "value" of the reduction, i.e.. show that the use of a smaller quantity of pesticides can manage the pest, whether by way of lower risk pesticides or alternative pest management strategies.

Because such a request promotes the purposes of the Act, and would not require a full risk assessment so would not tax PMRA resources unduly, it should be permitted at any time and by any person. One requirement may be that applicant make the case for value outlined above.

Responses to Additional MRL Questions:

- *Question: Are there other models globally that PMRA should examine as it considers changes regarding MRLs?*

Response: The European model should be examined.

- *Question: Other countries are clearer on establishing MRLs for imports – should the PCPA be more explicit about setting "Import Tolerance Limits"?*

Response: Yes, as indicated above, import tolerances should be distinguished from domestic MRLs.

- *Question: What are your thoughts about greater recognition of Codex MRLs?*

Response: Codex MRLs should NOT receive greater recognition.

There should be no recourse to international organizations for setting MRLs if it is apparent the focus of the organization is "standardization" or trade. The reason is that a standardization focus seeks to level out residue levels to a common denominator, whereas the growing conditions and agricultural practices of Canada are not common but unique, as are the regulatory and label requirements utilized in Canada.

Standardization to a common denominator that reflects the conditions in Canada would be acceptable, provided these conditions are protective, but this is unlikely. The international organizations that are seeking standardization are generally, if not always, promoting higher MRLs, rather than proposing lower MRLs.

The reason is that these organizations are trade organizations, associated with free trade agendas, and they focus on "standardization" to facilitate trade in commodities that have levels of pesticide residues

and in pesticide products. Facilitating trade is a laudable goal, but a pesticide regulation focus on trade is not protective of the Canadian population or environment. Membership in these organizations, such as the JMPR, is dominated by representatives from the "for-profit" pesticide industry, and the motivation of increasing profit motivates views that promote increasing the levels of pesticides used on food i.e.. higher MRLs.

More importantly, the main purpose of pesticide regulation in Canada is to protect the health of Canadian and the Canadian environment, whereas other jurisdictions or organizations may not have codified or may not implement this purpose in their MRL standard setting process. Standardizing to the norms of these other entities would entail disregarding the protective purpose of the PCPA.

The standards set by JMPR promote increases in MRL levels, and as such are not protective of Canadians. Pesticides by their very nature pose risks, and increased quantities means increased exposure and therefore an increase in the exposure side of the risk equation.

The proposed increases of glyphosate set out in PMRL2021-10, recommended by JMPR, provide a good example of how the recommended proposals of organizations with a trade focus are not protective of Canadians or the environment. The problems with these recommended MRLs are set out in comments provided by Safe Food Matters Inc. and Prevent Cancer Now, and include the following:

- The estimation of MRLs are at high levels that are not rationally or scientifically connected to the actual field trial data, although they are supposed to be.

- The reason is that JMPR, and PMRA, used the OECD MRL Calculator. But the statistical manipulation used by this calculator "increases overestimations" in certain instances, and PMRA is even aware of this. It states that the OECD calculator "may lead, in some cases, to MRL proposals significantly greater than the highest residue". There is no justification for this, and it is not protective.

- The rates of application in the field trial studies used by JMPR can be many times higher than the permitted rates under the Canadian labels without justification or explanation. The resulting residue limits in the field trials would be higher than those that would occur if spraying occurred within the confines of Canadian labels. These higher limits are what are being proposed as the Canadian standard.

- In some instances in the field trials, there was no measurement of seed moisture content at the time of spraying, which means a fundamental premise for the trials (that the pesticide was applied according to label directions) was not followed.

- *Question:* Who should initiate import tolerance assessments and should there be more consultation and more information released publicly in the context of establishing import tolerances?

Response: As discussed above, import tolerances assessments should occur at the time of application for import. They require consultation as described and a health risk assessment.

- *Question:* Should there be a review cycle established for MRLs?

Response: MRLs should be set with and tied to the registration, and set at the time of registration. Petitions for increases can be permitted at the time for registration, but no increases should be granted unless the conditions for increase are met, as described above.

- *Question:* Do you agree that MRLs should be reviewed as part of the continuous oversight approach, when appropriate?

Response: Yes, because MRLs should be tied to the registration. When oversight concerns arise with respect to the registration that could impact MRLs, then the MRL should be reviewed as it relates to the oversight concern.

Objective 2 – Improved Transparency

Discussion Document DIS2022-01 "Further Strengthening Protection of Health and the Environment" of PMRA provides information on "Objective 2 – Improved Transparency". It states:

> "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 [confidential business information] and CTD [confidential test data] 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."

- Question: Would introducing plain language summaries of our pesticide decisions, as well as more plain language information on how we conduct our science, improve transparency?

No. The reason "Transparency" is important is that public understanding of what PMRA is doing is required so that the public can hold PMRA accountable for its decisions. The public needs explanations about HOW the agency came to its decision, and what reasoning went into those decisions, rather than plain language explanations of the conclusions or approaches uses. PMRA should give the public the details on the specific science reviewed and judgements made based on that science, rather than "dumbing it down" in "plain language" summaries that do not provide the required information.

PMRA's decisions impact public health and the environment. These decisions are critical to the health of Canadians, and Canadians take them seriously. Because of this, under the scheme of the PCPA, the public has a critical role to play as a participant in pesticide decision making; and this role is to hold the PMRA accountable for its decision making that affects human health and the environment. This role

cannot be fulfilled unless the public has full access to the thinking and information reviewed, considered and relied upon in the decision-making process.

It is important to understand that transparency is not about engendering a sentiment of "trust" in the regulator just because they are the regulator. (Many of the communications from PMRA are boilerplate paragraphs that say "Just Trust Us"). Rather, transparency it is about gaining the trust of the public by deserving it, exemplified by sound scientific decision-making. The details of this decision-making are needed in order for the public to understand and feel confident in PMRA's decision-making that affects their health and therefore their lives.

The science relied upon by PMRA and the decision making based on that science needs to be made clear. Currently PMRA, at most, lists the studies it considered. More is needed. PMRA should explain the literature and scientific reviews it conducted, why certain studies were favoured over others, what PMRA understood as the finding of these studies, and how these particular studies impacted the risk conclusion drawn by PMRA – what weight they were given and why.

Direct access to Evaluation Reports, scientific monographs, and other internal PMRA memos that explain decision making is required. Under the law, as long as the PMRA acts reasonably in coming to its decisions and is doing its job, PMRA need not be concerned that review of its internal process will raise legal concerns (unless of course it was not acting reasonably). There is no reason that such documentation should not be shared directly with the public. The public needs to be able to see what PMRA sees and thinks.

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

The scientific literature and studies relied upon by PMRA in its decision-making should be made available, on a timely basis, as well as the reasoning of PMRA based upon this information (as described in greater detail above).

Links to the actual literature and studies should be provided directly and immediately upon publication of a consultation, without members of the public having to ask for them. A matrix should be developed to explain the selection process, weighting and decision taken with respect to the information.

In addition, it would be helpful if consultation documents set out the legal basis for the consultation e.g. is it a re-evaluation, special review or initial registration or other decision; what sections of the PCPA are involved; and what legal or policy requirements are in play i.e.. is there a consultation, does it include both environmental and health risk assessments and value assessments and if not, why not, etc.. The legal scheme underlying the decision-making process should be set out simply in the beginning of the consultation document. (This would also allow PMRA to ensure that it actually has the statutory authority to be making the decisions it is making).

Engagement of the public is critical in the pesticide decision-making, and members of the public are not compensated for their contribution. People have lives, and any delay in the provision of information by PMRA required for comments, and even the delay required in requesting the information and waiting for it without any understanding of when it will be delivered, has proved to be a real impediment to

providing comments. PMRA can sometimes take months to respond in any meaningful way to relevant questions and requests, which stymies the entire process.

Also extensions are granted to people who request more time because of the delayed provision of information which should have been publicly accessible in the first place, and this is in inequitable. If there is a delay in the provision of information to one person and that person is provided an extension for commenting, then the information should be provided to all and the comment period for all should be extended.

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

The obligations to protect CBI and international commitments are not onerous, as will be explained below. The definition of CBI is quite narrow, but the approach of PMRA to disclosure is overreaching, as will be explained. In the Discussion Document, PMRA was not identified about the "international commitments" for protecting confidentiality. No such obligations are set out in the PCPA.

In essence, Confidential Business Information (CBI) is information that relates to manufacturing and quality control process, methods for determining the composition of a PCP and monetary value/ financial/ commercial items. Confidential Test Data (CTD) is information that is scientific or technical respecting the risks or value of a pesticide that is consistently treated in a confidential manner by the owner of the information.

These definitions are quite narrow, although the CTD words "respecting the risks or value of a pesticide" could be eliminated. Scientific or technical information is on its face just information, and the determination of "risk" and "value" are judgements, based on the information. Also the CTD definition could be tightened up to revise "information", which is a wide word, to just "data", which is understood more as the data produced by the studies.

It is strongly suggested that changes be made to current statutory wording, rather than leaving the issue to regulation. The statute is the place for substantive principles, not regulations.

The presumption should be that data and information that relates to pesticides should be made public. Accessibility to such data and information is required to ensure accountability for sound decision-making, as described above. Any provisions in the PCPA or approach of PMRA that block access to such data and information should be removed, unless a legitimate, current commercial interest that can be shown to override the public interest in accessibility can be established by the commercial party. An approach more akin to "Vanessa's Law" is favoured.

PMRA should allow the designation of confidentiality only if the party seeking confidentiality can show that disclosure poses a real and substantial risk to that party's commercial interests. The law presumes that disclosure is in the public interest as it relates to protection of the environment and health, and this generally overrides the importance of any commercial interest. The party would have to show that the risk claimed is real and substantial, in that the risk is well grounded in evidence, and poses a serious threat to the commercial interest in question. It would also have to prove to PMRA that the commercial interest is important i.e.. it can be expressed in terms of a general public interest principle for maintaining confidentiality.

If these tests are met, then the data or information can be protected from full public disclosure, but measures that protect the confidentiality should be put in place to allow for disclosure on a protected basis, given the importance of disclosure to the public interest. For example, the data or information can be disclosed in a virtual reading room.

Even if there is a commercial interest, there is typically a one to two year time frame on the sensitivity of such information. A one to two year period is typically the period of confidentiality in private sector confidentiality agreements, signalling that information is no longer commercially sensitive after that timeframe.

By way of example, disclosure of use data is of significant public importance because it helps provide details on the actual exposure of Canadians and the environment to pesticides, so it should be disclosed. The monetary value of the sales in the prior 1-2 year period may be commercially sensitive, and could be considered CBI and not disclosed during that time frame, but disclosed thereafter.

A Note on Formulants and Contaminants

As has been mentioned before, PMRA should also assess the entire pest control product, not just the active ingredient, in order to fulfill its protective mandate, because Canadians and the environment and exposed to the entire product, not just the active ingredient.

Information on the formulants and contaminants should be disclosed to the pubic. It is well established that formulant and contaminants can be toxic in their own right, and cause the entire product to be more toxic than the stated active ingredient alone.

This has been shown, for example, in the study Major pesticides are more toxic to human cells than their declared active principles by Mesnage R, Defarge N, Spiroux de Vendômois J, Séralini GE.. Biomed Res Int (2014) 014:179691.10.1155 /2014/179691. The formulants in glyphosate-based-herbicides potentiate and/or cause additional cumulative effects on endocrine and reproductive pathways, such as interaction with androgenic and estrogenic pathways. [Controversies on Endocrine and Reproductive Effects of Glyphosate and Glyphosate-Based Herbicides: A Mini-Review]

Thus even though there may be a commercial interest in keeping this information confidential, the public interest in ensuring the formulants and contaminants do not render the product additionally harmful overrides the commercial interest. The Minister should publish the information on the formulants and contaminants of concern.

Approach of PMRA with Reading Room, Affidavits Etc.

The current approach of PMRA completely frustrates access to information, particularly confidential business information. As mentioned, the definitions of CBI and CT) in the Pest Control Products Act (PCPA) are quite narrow so the set of protected information should be quite narrow. In essence, CBI is information that relates to manufacturing and quality control process, methods for determining the composition of a PCP and monetary value/ financial/ commercial items . CTD is information that is scientific or technical respecting the risks or value of a pesticide that is consistently treated in a confidential manner by the owner of the information (CTD).

With respect to Confidential Test Data, under the PCPA section 43(8) a person can't make or obtain a copy of CTD, and the rationale is that the test data is to be protected from public disclosure. This does not apply, however, in the case where the Minister had decided it is appropriate or in the public interest to disclose the CTD in the context of a consultation, notice of objection or an evaluation report. It would be useful for criteria to be

developed for when disclosure would be appropriate or in the public interest, and set up a policy step by which the Minister /PMRA has to turn its mind to the issue.

The current process is overreaching with respect to the protection of CTD and is not efficient for many reasons. First, it is not just the test data information in a study that is withheld from public disclosure, but the entire study is withheld. This is not justified from the viewpoint of transparency.

Second, if a person wants to inspect the CTD, they must submit an application form and also sign an affidavit that must be commissioned. This all takes time. The Guidance Document "Inspection of Confidential Test Data Supporting Pesticide Registration Decisions" (Guidance Document) indicates that the person must make a submission to see CTD early in the process so that the CTD can be viewed before the closing of consultation periods. However, the person may not know they want to see CTD until later in their process of engaging in the consultation, which fact motivates members of the public to apply even if they don't know whether they want to see any CTD.

The experience has been that if the CTD has not been provided prior to the close of a consultation period, the period for providing comments may be extended to those who asked to see the CTD, but not other members of the public, which is not equitable and also does not serve transparency or efficiency or public participation in decision-making. By way of example, Safe Food Mattes Inc. (**SFM)n**and Prevent Cancer Now were granted an extension to provide comments in relation to PMRL2020-10 because SFM had requested CTD that was not provided until after the consultation period, but the request of SFM for an extension to the general public was not granted.

The affidavit process is cumbersome. Many people do not have ready access to a commissioner of oaths, and the fees can be significant. All that is attested to in the affidavit is the purpose for inspecting the CTD, and a statement that the person won't use the CTD to register a pest control product or amend a registration and won't make it available to others for such purposes. It appears the affidavit is to protect the competitive position of the registrant.

Given that it is very unlikely that the people who view the CTD would be competitors of the registrant, this affidavit requirement is unduly burdensome and time-consuming. The point is underlined by the fact that PMRA in the Guidance Document indicates CBI, which is what a competitor might have interest in, is removed from the CTD being inspected. Moreover, experience has been that many of the studies that are inspected are years old, long after competitors would want to have access to any business information.

The Guidance Document indicates the CTD should be viewed at a Reading Room location in Ottawa. This is not convenient for most Canadians and has been the subject of much criticism. Recently, PMRA appears to have provided USB sticks to people interested in seeing the CTD, which is a huge improvement. The USB must be viewed on a computer connected to the internet, so assurances that the connected computer is secure from all forms or inspection and tracking are needed from a privacy and security perspective.

With respect to the Reading Room scenario, the Guidance Document indicates that a person cannot photocopy the CTD, but they can take notes. However, the Guidance Document and PMRA practices go too far, in requiring that the person consent to the notes being copied and then retained on PMRA's file, for "compliance and administrative purposes". A person's notes, especially on sensitive issues like pesticide reviews, are proprietary and PMRA has no authority to take copies of them. The manual form provided by PMRA has a paragraph at the end that is reproduced below, whereas the online form does not. The paragraph should be deleted:

> I understand that if I wish to take notes while inspecting the confidential test data I must consent to having those notes photocopied and retained on file for administrative and compliance purposes. – Je comprends que si je souhaite prendre des notes lors de la consultation des données d'essai confidentielles, je dois permettre que ces notes soient photocopiées et conservées dans un dossier à des fins administratives ou légales

The Guidance Document indicates the Application Form will be provided to the registrant, and that although the person's name will not be provided, the organization to which they are affiliated will be. There is no reason for this, and if the affiliation reveals a person or organization that is critical of the registrant, the registrant will be motivated to oppose the disclosure. There is no reason in principle for such a revelation, as it does not change the nature of the character of the CTD.

For proper participation by the public to enhance decision-making, which the law says is one of the pillars of the PCPA, the public needs access to the science underlying the decision-making. Otherwise they are working from a vacuum. Test data and other information that would likely impact the competitive position of a party can and should be withheld from public access, and the public would likely not take an interest in such information in any event.

All other information in studies, but for such competitive information, is very relevant for decision-making purposes and should be made available without the need for applications, affidavits and protective protocols and accompanying delays and burdens. It has been pointed out that this is the approach of the European Food Safety Authority, and this is the preferred approach. Understanding and having ready access to such information and the treatment of it is critical for furthering accountability of both the registrant and the regulator. As such, it is fundamental to engendering trust in the registrants, the regulator and the process.

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

- A mentioned above, it would be helpful if consultation documents set out the legal basis for the consultation e.g. is it a re-evaluation, special review or initial registration, or other, what sections of the PCPA are involved, and what legal or policy requirements are in play i.e.. is there a consultation, does it include both environmental and health risk assessments and value assessments and if not, why not, etc.. The legal scheme underlying the decision-making process should be set out simply in the beginning of the consultation document. (This would also allow PMRA to ensure that it actually has the statutory authority to be making the decisions it is making).

- Consultation should be required for matters that are in the public interest i.e.. that have the potential to pose risks to the environment or the health of Canadians. Examples include the following:

    - Consultation should be required for increases to MRLs because increases are of public concern. It is in the public interest to do so. More on this is described in the MRL section above. This should be codified in the statute.

    - Consultation should also be required for URMULES. The fact that a use is "minor" or not put forward by a registrant with a commercial interest does not obviate the fact that the uses in URMULEs pose risks. For example, both chickpeas and mustard are URMULE crops, but they are grown in large quantities in Canada and consumed in large quantities by Canadians. The public has an interest.

    - Consultation should also be required for the Grower Requested Own Use or similar program to the extent the possibility exists that risks may be presented to the environment and human health.

- The science relied upon by PMRA and the decision making based on that science needs to be made clear. Currently PMRA, at most, lists the studies it considered in its consultation documents. More is needed. In the consultation document or the registry, PMRA should explain the literature and scientific reviews it conducted, why certain studies were favoured over others, what PMRA understood as the finding of these studies, and how these particular studies impacted the risk conclusion drawn by PMRA – what weight they were given and why. Direct access to Evaluation Reports, scientific monographs, and other internal PMRA memos that explain decision making is required as well.

- A member of the public wants to understand that PMRA heard and considered their comments. Development of a system that allows PMRA to show it heard the comment and considered it, and that supplies reasons to support this, would be an improvement. Some thoughts on improving the approach are set out below.

    - PMRA seems to define the "public" as certain environmental NGOs it has had interacted with on the past, and those who have signed up for newsletters. The list of invitees appears to be pre-selected by PMRA. This presumes that these NGOs actually represent the public, which is not necessarily true. Some people may not have signed up for interactions because they do not have expertise or interest in that particular consultation, but because of this failure they are not invited to future consultations. As an example, SFM was not invited to the initial conversations on a transformation agenda item, because it had not participate in a previously PMRA-led consultation.

    - A process that allows PMRA to extend beyond this narrow scope and pre-selected list might allow PMRA to engage with other concerned members of the public. For example, growers groups, alternative health practitioners and indigenous communities are not regularly part of the conversation and should be.

    - Rather than responding to comments from the perspective of "Just Trust Us", as described above, perhaps develop a process that allows public comments to be discussed and thought about, and then responded to.

- The Consultation Process for the Transformation Agenda was a good start, although it could be improved by:

    - initial discussion of what the topics for discussion should be, instead of being "pre-set" by the regulator

    - the roundtable approach which was adopted in some meetings. Without this approach, paid members of the pesticide industry dominate the conversation, and members of NGOs who are not paid are disinclined to spend numerous hours in attendance at meetings at which they are not heard, especially since NGOs often have small paid staff, if any, and the time commitments are large and were not expected.

    - timely provision of topics for discussion

    - providing summaries of the comments made, so that participants can understand that the points they made were appreciated

    - explaining the principles upon which the comments would be received and accepted or not. How do these comments impact anything?

- On issues for which PMRA may not have an immediate answer and that raise good points, PMRA should develop a process that allows for future consideration of these points and that involves the members of the public concerned into the future discussion on these points. They likely raise issues about risks that PMRA may not have considered, and should be addressed proactively. These issues could then perhaps be raised by PMRA to the registrant as part of the "continuous oversight" strategy.

The public will "trust" a regulator that is willing to consider new information and allow for changes in science and approach, at least more than a regulator that just provides boilerplate answers to concerns raised by public citizens who believe in the process. Engaging the public in these changes is key. The roundtable discussions were a good precedent, and the timely provision of discussion items is helpful.

To conclude on this point, transparency, is about giving members of the public full access to the information seen by PMRA when making its decision, and allowing members of the public to understand PMRA's reasoning in making its decision. This allows for a system in which PMRA can explain, respond to and be accountable to the

public about its decisions. Engaged members of the public include scientists, environmentalists, eaters, pesticide applicators, agronomists, and many others who care about pesticide risks.

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

In relation to this objective, a key concern is that PMRA does not currently directly access scientific literature. In order to be meet the primary objective of the PCPA of protecting health and the environment, the agency needs to have direct access to and understand directly the science and scientific literature on the risks of pesticides. Any reliance on third parties for science presents the risk of real or perceived bias in decision making. This does not align with purpose of the PCPA.

Direct access and review of the scientific literature on the part of PMRA is required for evidenced based decision making. Direct access is preferred over "advice" from an advisory committee, as currently contemplated, particularly since the committee is essentially closed-door and not accountable.

The paradigm of receiving advice and science from any third party is rife with opportunity for real and perceived bias and conflicts of interest, which does not help PMRA in its desire to increase public trust.

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

The data should be supplied directly to the public, rather than requiring the public to request it from PMRA. The wall between the public and access put up by PMRA is inefficient. It is also frustrating because it presents a delay to the member of the public in conducting their research and analysis.

In addition, for true evidence-based decision making, real-world data is required on pesticides in air. Pesticides can travel in air, and inhalation and dermal exposure are routes or exposure that require measurement of pesticides in air. As indicated above by way of example, glyphosate has been found at locations very remote from the location of application (such as the Black Forest), having travelled there by air.

Additional "real-world" data required for effective protection of Canadians concerns the levels of pesticides in our food. The contamination of food by pesticides should be measured and reported on regularly. The consumption of foods by Canadians containing pesticides must be measured. Currently PMRA relies on outdated consumption data on what Americans, not Canadians, eat, even thought Canadian data is available. See the SFM submission linked in "Glyphosate Proposal Not Based on Sound Science".

"Real-world" data is also required on the levels of pesticides in our bodies, for a true understanding of the risks to Canadians' health. Bio-monitoring data should be established or accessed.

"Real world' data is also required on the levels of pesticide in species in the environment and representative species, for a true understanding of the risks to the environment. Such data should be established or accessed, rather than being "estimated". The estimations are based on assumptions that are problematic. For example, in many cases they do not reflect the Canadian context or reflect outdated inaccurate science. Or they assume that the relationship between the quantities of pesticides in the environment and the harms they cause is linear, which is not often the case.

A fundamental requirement for valid risk assessments of pesticide is an understanding of how pesticides affect the real-world. Access to real-world data on all exposure pathways, and measurement of real-world pesticide contamination is required. Direct access to and understanding of current relevant scientific literature and methodologies is also key. The data and information on pesticides must be as accurate and current as possible to best protect Canadians and the environment from the acknowledged risks of pesticides.

• Do you have views on Health Canada's [authorization] proposal and how it could be implemented?

On June 2, 2022, Health Canada introduced this fourth question, with the following explanation:

> "Health Canada's proposal is to amend the PCPA to create a new authorization pathway that will give the Minister of Health the power to authorize pest control products that meet criteria prescribed in regulation, if their risks and value are acceptable and to include mandatory public consultation provisions for this new authorization pathway. This proposal would also expand the current authorizations to persons under section 41 and provide for a recall power that is applicable to any pest control product that endangers human health or safety or the environment."

We do not support the proposal to amend the PCPA to allow a new authorization pathway. We are concerned because the pathway allows for authorizations based on criteria prescribed in regulation. Authorizations of pesticides are substantive decisions, that require full legislative thought and process for purposes of due process, transparency, legislative accountability and also to ensure compliance with the purposes of the PCPA. They should not be relegated to unnamed criteria that have not been established. In this regard, the proposal may even be unlawful.

High Level Comments on the Full Act

These comments are by no means complete, but form a basis for review of the full Act.

- The Act requires pesticide re-evaluations to be "initiated" every 15 years, but the re-evaluations themselves can take decades. Glyphosate had been on the market for almost 40 years by the time it was re-evaluated. Other jurisdictions mandate "completion" rather than "initiation" timelines.

  Recommendation: Require that pesticide re-evaluations be completed within 15 years.

- The definition of "Pest Control Product" allows for evaluations of just the "active ingredient". The real-word exposure is to the full pest control product, including its formulants, contaminants and other ingredients. As explained above, these can be more harmful than the active ingredient alone, or render the entire product more harmful than the active ingredient.

  Recommendation: Remove the option of defining a "Pest Control Product" as just the active ingredient alone.

- The cumulative effects assessment as set out in the Act requires a health risk assessment of cumulative effects of the pest control product and other pest control products that have a common

mechanism of toxicity. However the effects in the real-word on humans and the environment that are impacted by pest control products include effects of PCPs in combination with not only other PCPS but also with other substances. What is required is a true cumulative risk assessment, which means an assessment of the effect of the pesticide when combined with the other ingredients in the product, and when combined with other pesticide products, regardless of whether the additional pesticides have a "common mechanism of toxicity". The "common mechanism of toxicity" represent the combined effect known as a "dose addition" combination. Other combinations, as currently described in the literature, include "response addition", "synergism" and "antagonism".

Recommendation: Require a cumulative health and environment effects assessment (including the effects combinations described above) of the PCP with other substances having an effect on humans and the environment.

- The aggregate and cumulative assessments require higher tier assessments that require an appropriate methodology (a probabilistic rather than a lower tier deterministic approach). However PMRA is currently using a deterministic approach when it conducts aggregate and cumulative assessments, which is not providing reliable or representative data. Then to keep onside of threshold levels, PMRA is reporting such data at the 95th percentile, rather than the 99.9th, which is not protective and arguably reflects a "results-oriented" approach to risk assessment.

  Recommendation: Require application of higher tier assessments for cumulative and aggregate risk assessments, and reporting at the most protective percentile. (If the data is not available for such higher tier assessments, solutions could be found, such as using a small set of data and extrapolating and bringing in uncertainty factors.)

- The Act requires PMRA to conduct a "scientifically based approach" to its assessments, but does not explicitly require consideration of the most up to date and rigorous science and methodologies. As a consequence, PMRA is not taking into consideration good compelling science, such as epidemiological studies or studies showing mechanism of pathway and modes of action that were not evident prior (e.g. that glyphosate affects the human microbiome and also that it translocates right into the seeds human eats). PMRA is also not conducting appropriate cancer risk assessments. It is not "getting the science right" or "getting the right science". It is not accessing the "best-in-class" information available.

  Recommendation: Codify a requirement that the scientifically based approach include consideration of up-to-date science and methodologies and a thorough review of all science on the PCP that could identify and inform potential risks arising.

  This would include science relating to risks arising from modes of action, mechanism pathways, epidemiology, cancer, endocrine disruption, etc. Discussion on the wording for this recommendation can be refined.

This recommendation is underlined by the recent US 9th Circuit Court of Appeal decision on the approach of the US Environmental Protection Agency its registration review (risk assessment) of glyphosate.

- The Act defines "acceptable risk" (section 1(2)) as requiring a 'reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration." The conditions of registration are often label requirements. However there is no inquiry into whether the conditions of registrations actually work – i.e. whether they are effective at eliminating the risk. PMRA takes the view that it does not need to inquire into the efficacy of the conditions of registration, and that enforcement is not its problem.

  Recommendation: Place the onus on the registrant or PMRA in the Act to prove/ be of the view that the conditions of registration proposed will eliminate the risk.

- The Act speaks to the establishment of MRLs in sections 9 (registration decision) and section 10 (unregistered products or uses). It is not clear what a constitutes a "registration decision". Also, the concept of an "import MRL" is not set out, and arguably not permitted by the wording in section 10.

  Recommendation: Provide clarity on what constitutes a "registration decision", and also on the legal instrument, the legal means, by which "import MRLs" might be permitted.

Thank you for engaging in this process and accepting our comments. We hope they will be thoughtfully considered.

Sincerely,

Safe Food Matters Inc.
Gilmour, ON K0L 1W0
SafeFoodMatters@gmail.com
Per: Mary Lou McDonald, President