CPMA ACDFL

Plant Biosafety Office
Plant Health and Biosecurity Directorate
Canadian Food Inspection Agency
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Ottawa, Ontario K1A 0Y9

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Submitted Via Email

To Whom It May Concern:

RE: *Consultation – Proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations*

On behalf of the Canadian Produce Marketing Association (CPMA), it is my pleasure to provide our comments to the Canadian Food Inspection Agency (CFIA) consultation on *Proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations.*

Below you will find CPMA's overarching comments on areas of critical importance to the fresh fruit and vegetable industry in relation to plant breeding and gene editing technologies, along with our comments in response to CFIA's key questions as seen in the online questionnaire on the *Proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations.*

About CPMA

Based in Ottawa, CPMA is a not-for-profit organization representing companies active in the marketing of fresh fruit and vegetables in Canada, from the farm gate to the dinner plate spanning the entire produce industry. The Association's members include major growers, shippers, packers, and marketers; importers and exporters; transportation and logistics firms; brokers, distributors, and wholesalers, retailers, and foodservice distributors; and fresh cut operators and processors. Founded in 1925, CPMA is proud to represent domestic and international members who are responsible for 90% of fruit and vegetable sales in Canada.

General Comments

- To begin, we would like to take this opportunity to highlight the important benefits that plant breeding and gene editing technologies offer for the fresh fruit and vegetable sector, including increased crop productivity through herbicide tolerance, pest and disease resistance, prolonged

shelf-life, the development of food without allergens, improved nutrition, better taste, resistance to cold temperatures and harsh environments, as well as the ability to reduce post-harvest food waste. As we face significant global challenges around food security and climate change, these innovative technologies can help farmers and food processors adapt to changing climate and pest pressures while continuing to grow safe, high quality, affordable food for Canadians and consumers around the world.

- In addition, it is important to recognize the successful safety record of plant breeding in Canada and across the globe. In Canada, we have witnessed the commercialization of over 6000 field crop varieties developed with traditional and modern plant breeding methods, with no product recalls due to safety.

- CPMA would like to emphasize that the Canadian fresh fruit and vegetable sector must be able to access and utilize gene editing and plant breeding tools to stay competitive globally. A 2019 Royal Bank of Canada (RBC) report found that with the right combination of skills, capital and technology, agriculture could add $11 billion to Canada's GDP by 2030. However, the RBC report also found that Canada's share of global agtech investment is only 3.4%, falling behind countries such as Brazil and India, putting Canadian producers at a competitive disadvantage. Leadership in innovation, coupled with an efficient and evidence-based regulatory system, is necessary to secure Canada's position as a leading supplier of fresh fruits and vegetables. CPMA also echoes the Canada Grains Council's assertion that innovation in production technologies leads to innovation throughout the supply chain, with positive impacts for job creation and Canada's long-term competitiveness.

- In 2017, the Barton Report identified our agri-food sector as a significant potential driver of economic growth for Canada. The Agri-food Economic Strategy Table has set ambitious domestic and export targets to realize this potential, while also recognizing that an agile, streamlined regulatory approach, including in relation to plant breeding, will be required to meet them. CPMA is appreciative of Health Canada's efforts to modernize Canada's regulatory approach for plant breeding by improving guidance and clarity for product developers on the interpretation of Canada's novelty-based regulatory triggers. We believe these efforts will not only help grow our agricultural exports and speed the economic recovery moving out of the COVID-19 pandemic, but also help to address some of Canada's pressing domestic food, health, and environmental challenges.

- CPMA recognizes and supports the federal government's prioritization of measures to address the challenges of a changing climate and promote environmental sustainability. Plant breeding and gene editing technologies can play an important role in these efforts, as key tools to enable food security for an increasing global population while also mitigating against increased land use for agriculture and allowing for the development of crops more able to adapt to more difficult environmental conditions. In Canada, CropLife Canada estimates that 50% more farmland would be needed to grow what we do today without biotech crops and pesticides – a land area equivalent to the combined area of the provinces of New Brunswick, Nova Scotia and Prince Edward Island. Increased land use that threatens natural habitats, wildlife and biodiversity is of concern to the global community and this concern must be a cornerstone of decision-making that integrates a responsible and sustainable approach to production, especially as countries work to adopt the UN Sustainable Development Goals and as Canada seeks to meet its own terrestrial

conservation targets. In addition, technologies like gene editing can help plants capture and store more carbon, reducing excess carbon emissions by up to 46%.

- CPMA also emphasizes that regulatory alignment and international standardization between government bodies regarding plant breeding and gene editing technologies is necessary to remove barriers to the movement of fresh produce and bolster the economic competitiveness of the produce sector, which is highly integrated around the globe. It is also important to note that consumer confidence in the safety of the food supply is eroded when jurisdictions have different regulations. Our largest trading partner, the United States, has already moved to exempt agricultural innovations that are the products of plant genome editing from being regulated. The European Union (EU) has also recently demonstrated greater openness towards a risk-based approach, rather than a precautionary one, for plants that are genetically modified. A recent E.U. publication on plant breeding and gene editing techniques emphasizes that these innovations have the potential to contribute to a more sustainable food system in line with the objectives that have been set through the E.U. Green Deal and Farm to Fork Strategy.

- Finally, CPMA strongly urges the Government of Canada to take a risk-based approach to plant breeding and gene editing technologies, and to consider adopting the same approach as the United States regarding products of plant genome editing, so that products can enter the Canadian market at the same time as they become available in the U.S., which would help to maintain the Canadian industry's competitiveness in the highly integrated fresh produce sector.

Theme 1: Determining when a plant qualifies for an exemption from Part V

1. **How clear is the guidance on how exemptions for equivalent plants would work?**

- The guidance is clear. CPMA is supportive of Section 2.1 of the CFIA's draft guidance, which recognizes that virtually all products developed by conventional breeding techniques qualify for an exemption from *Part V* of the *Seeds Regulations*, based on being substantially equivalent to the lines they are derived from. Furthermore, CPMA is pleased to see that the same kind of exemption has been extended towards gene editing techniques that introduce genetic changes that are comparable to conventional breeding.

- That being said, CPMA does have some concerns regarding the overly broad interpretation of identified outcomes, which could create confusion regarding the exemption status of conventionally bred plants. We elaborate on this concern in greater detail as part of our response to Question 3, under Theme 2.

2. **If you are a plant developer, would it be useful to your work to receive an exemption opinion letter?**

   Yes. Exemption opinion letters can help ensure that plant developers have clarity regarding authorization requirements, to improve the predictability of the assessment process, and can mitigate administrative burden for both industry and government. Clarity and transparency are vital to ensuring that plant developers have the information they need to increase the overall quality of a submission package and to determine if they must make a submission under the

approval process. CPMA encourages CFIA to provide an opinion letter to plant developers that includes information such as the plant species, a summary of the trait(s) and how they function, as well as the rationale for the opinion. CFIA should also provide sufficient resources to maintain a timely response regarding exemption letter applications and would like to echo CropLife Canada's comments requesting a 90-day service standard to facilitate this process.

3. Would it be useful to make information in CFIA's exemption opinions publicly available?

- Yes, CPMA encourages that CFIA makes the information in CFIA's exemption opinions publicly available. CPMA echoes CropLife Canada's comments which highlight that exemption opinions will allow industry to get a better sense of the regulatory status of different commodities at the development stage, especially as this information may be required to facilitate international trade. CPMA would like to note that making this information publicly available will provide plant developers with the information that they need to determine if they must make a submission under the approval process.

4. What information should be included in any list of exempt plants?

- CPMA recognizes the importance of providing plant developers with as much information as possible to ensure that regulations do not impede their ability to innovate and stifle economic competitiveness. CPMA supports the inclusion of all the key points of information from CFIA's online questionnaire on the *Draft guidance for determining whether a plant is subject to Part V of the Seeds Regulations*. These points of information include the developer's name, product name/identifier, plant species, plant trait(s), method of trait development, rationale for exemption, antecedent line(s) (if applicable where a previous authorization was cited), intended use: Food/Feed/Environment, regulatory status: Food/Feed/Environment and access to the opinion letter as written. Allowing for this information to be made available to plant developers will help ensure that they have the clarity that they need to meet all authorization requirements under *Part V of the Seeds Regulations* and improve the predictability of the assessment process and the overall quality of a submission package.

5. Should it be mandatory or voluntary that CFIA publishes the opinion in a public list of exemption opinions?

- CPMA is supportive of the position of CropLife Canada that the publication of CFIA exemption opinions should remain voluntary, but should be strongly encouraged. A plant developer willing to publicly release an opinion letter should have the opportunity to redact any information that is confidential to their enterprise. As CFIA has already noted as part of the online questionnaire on the *Draft guidance for determining whether a plant is subject to Part V of the Seeds Regulations*, a mandatory publication could serve as a disincentive to participation and further impede CFIA's goal of improving transparency and clarity for plant developers.

- CPMA would also like to note our support of CFIA's proposed pre-submission consultation process to provide opinions to plant developers at any stage of development about whether a plant is subject to *Part V of the Seed Regulations*. CFIA should provide sufficient resources to ensure that the pre-submission consultation process provides timely feedback to plant developers.

Theme 2: Determining which plants are subject to Part V

1. **The guidance states that when a plant is considered to be a new crop kind in Canada, it is subject to Part V. Is this information clear?**

- Yes, this information is clear. CPMA is supportive of the inclusion of section 3.1 on what constitutes a new crop. This section highlights that the cultivation of a species previously found only in natural habitats, as well as the cultivation of a domesticated plant species that has not been previously cultivated as a crop in Canada, is considered as a new crop kind. Furthermore, the guidance notes that a species which has not been previously grown as a crop in Canada is subject to *Part V of the Seed Regulations*.

- CPMA would like to emphasize the importance of conducting the authorization process for plants that have not been previously grown as a crop in Canada in a timely manner. We also recommend that the Government of Canada should implement an expedited authorization process for the cultivation of a domesticated plant species that has not been previously cultivated as a crop in Canada if it has extensive history of safe use in another region or country.

2. **The guidance states that when a plant has foreign DNA, it is subject to Part V. Is this information clear?**

- Yes, the information is clear. However, CPMA emphasizes that the presence of foreign DNA does not itself reflect the actual potential for risk of the specific plant, as it is not the presence of foreign DNA, but the resulting characteristics of the organism, that may present hazards. Therefore, CFIA should not conduct extensive reviews of all such products based only on the presence of foreign DNA. This approach is not commensurate with risk and not a good use of government resources.

- CPMA would also like to strongly reiterate comments made as part of Canada Grains Council's submission that CFIA should include a tiered and risk-based assessment framework and a definition of "foreign DNA" that is clear and consistent with that employed by Health Canada. Such an approach would allow for better regulatory alignment between Canada and its trading partners.

3. **The guidance lists 4 outcomes that could negatively impact the environment. Are these 4 outcomes an appropriate way to define when a plant is subject to Part V? How clear are the 4 outcomes in the guidance and examples?**

- CPMA has some concerns about a lack of clarity in relation to CFIA's proposed guidance in defining the four identified plant breeding outcomes as part of Section 3.3. These outcomes include: a trait that would make a plant more difficult to control; a trait that introduces or enhances a toxin, allergen, or other compound; a trait that could reasonably displace other species or ecotypes; as well as a trait that could result in the creation or enhancement of a plant pest or a reservoir for a plant pest.

- Although the inclusion of these four criteria will help plant developers better understand the outcomes that will trigger pre-market assessments, CPMA is concerned that CFIA's interpretation

of the four plant breeding outcomes is overly broad. This could lead to assumptions that many common breeding outcomes require a pre-market assessment, and cause plant breeding investment to move to other countries and other markets to have access to new varieties sooner, putting Canadian industry at a competitive disadvantage. CFIA should provide greater clarity regarding the four identified outcomes, taking into consideration the following recommendations made by CropLife Canada:

- *Remove the list of examples provided in Appendix 3 of the draft guidance*
- *Consider the following edits to better clarify the four plant breeding outcomes and support the statement on conventional breeding and gene editing in section 2.1 of the CFIA proposed guidance document.*

1. *A trait that would make a **known invasive or noxious weed species** more difficult to control by removing a **primary** management option. **This considers potential for gene flow to a wild relative with inherently invasive or noxious characteristics.***

2. *A trait that introduces or enhances a **known** toxin, allergen, or other **known** compound that could reasonably be expected to have a negative impact on non-target organisms in the environment.*

3. *A trait that is **introduced to an invasive or noxious species, or species for which Canada is the center of origin (or could outcross to such species)** and could reasonably be expected to improve **or reduce** the survival of plants in unmanaged ecosystems to such a degree that **it** or other species or ecotypes are displaced or make it **unmanageable** ~~more difficult to control~~.*

4. *A trait that could reasonably be expected to result in the creation or enhancement of a plant pest, or a reservoir for a plant pest **in an unmanaged ecosystem to such a degree that other species or ecotypes are displaced or make it unmanageable.***

- *In order to clarify that the CFIA is not looking to assess products that are a result of routine conventional breeding practices, the emphasis for bullets three and four should be on a reasonable hypothesis that the fitness trait could change the survivability of a plant **to such a degree that it could displace itself or another species**. It would be valuable if the guidance could include a statement such as the following:*

  "The CFIA recognizes that many crops of agriculture in Canada, or their wild relatives, could be considered invasive or center of origin species. In light of this, it should be understood that routine breeding practices to alter abiotic/biotic stress of these crops have not triggered Part V and are not intended to be captured by this new guidance. Traits like disease tolerance in wheat or earlier maturity corn have not historically presented any environmental risk or displaced other species, and as such these traits have not been subject to Part V. It will be up to the developer to use this historical context to determine if there is any reasonable hypothesis that a new trait from conventional breeding (or similar) could infringe on the survivability of itself or another species to such a degree it could be displaced, and if in doubt consult with the PBO".

- Finally, CPMA supports the recommendations made by the Canada Grains Council that CFIA should explicitly recognize in its guidance that no significant environmental risk has ever arisen

through the conventional breeding of established crops, and that CFIA should consider all conventional breeding activities involving a crop and trait combination to be exempt from *Part V of the Seeds Regulations*, provided the crop and trait category have never in the past resulted in environmental harm. Without this clarification, and given the potential for broad interpretation of the four plant breeding outcomes, it could be assumed that traits previously considered exempt could be subject to *Part V*.

Theme 3: Overall impressions of the draft guidance

1. **Overall, does the proposed guidance make understanding whether a plant is subject to Part V more predictable?**

- As noted above, CPMA has some concerns about a lack of clarity hindering the predictability of CFIA's *Proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations*. In particular, greater clarity is needed regarding regulatory exemptions under *Part V* and the triggers for the pre-market authorization process.

- CPMA commends CFIA for including language to indicate that plants that are the result of plant breeding and gene editing are mostly exempt from *Part V of the Seeds Regulations,* barring any environmental risks. However, CPMA would like to re-iterate that the four environmental risks which CFIA outlines as triggers for pre-market assessment are overly broad and unclear. In particular, there is significant concern that conventional breeders will be confused about when their products require assessment, causing plant breeding investment to move to other countries and other markets to have access to new varieties sooner.

Theme 4: Future program improvements for the environmental release of seed

1. **Beyond the scope of clarifying when a plant would be subject to Part V, what other program improvements would you want to see next?**

- CPMA echoes the concerns of CropLife Canada and the Canada Grains Council that the draft guidance lacks recognition of the expertise and practices of the agricultural industry in Canada. Our sector has a long track record of introducing new plant varieties without causing environmental harm. The guidance makes no reference to the many sources of information and advice available from academia, Agriculture and Agri-Food Canada, certified agronomists and crop advisors, commodity associations, provincial governments, and seed companies. Drawing attention to these many resources would further support growers and the environmental sustainability of their operations. We recommend that the CFIA aligns with the model provided in Health Canada's *Proposed new guidance for Novel Food Regulations focused on plant breeding* in including this information.

- CPMA reiterates that clear and reasonable timelines must be established and followed in the authorization process to avoid creating barriers to innovation and economic competitiveness. Furthermore, CPMA emphasizes that sound science transcends international borders, and we strongly urge the Government of Canada to leverage evidence and reviews conducted by trusted trading partners to streamline the authorization process for new products into Canada.

- We recognize CFIA's desire to boost transparency while encouraging regulatory compliance with the inclusion in Section 5 of a mechanism through the CFIA Complaints and Appeals Office through which plant developers can appeal an unfavorable authorization decision. We would emphasize that, given the significant impact to a plant developer that can result from unfavorable authorization decision, the Complaints and Appeals process should be sufficiently resourced to ensure that feedback and information is provided and exchanged in a timely manner.

In closing, CPMA is appreciative of the Canadian Food Inspection Agency's efforts to ensure that plant developers, other relevant stakeholders and the public have an opportunity to present their views on its *Proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations*. As noted above, plant breeding and gene editing technologies are, and will continue to be, of critical importance to the success of the fresh fruit and vegetable sector. Moving forward, it is crucial that the Government of Canada continues to collaborate with the fresh fruit and vegetable sector and the broader agricultural sector to establish an evidence-based, clear, and predictable regulatory approach to these technologies.

CPMA and Canada's fresh produce industry are keen to partner with government to find effective solutions to ensure that Canada's *Seeds Regulations*, policies, and guidance provide the clarity necessary for industry to innovate and be economically competitive, while continuing to protect the health and safety of Canadians as well as the environment.

We appreciate you taking the time to review our comments.

Sincerely,

Ron Lemaire
President