Bureau of Microbial Hazards
Food Directorate
Health Canada
251 Sir Frederick Banting Driveway
Ottawa, Ontario K1A 0K9

May 21, 2021

Submitted Via Email

To Whom It May Concern:

RE: *Consultation – Proposed new guidance for Novel Food Regulations focused on plant breeding*

On behalf of the Canadian Produce Marketing Association (CPMA), it is my pleasure to provide our comments to the Health Canada consultation on *Proposed new guidance for Novel Food Regulations focused on plant breeding*.

About CPMA

Based in Ottawa, the Canadian Produce Marketing Association (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.

Comments

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 Health Canada's key questions related to the *Proposed new guidance for Novel Food Regulations focused on plant breeding*.

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.

- 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.

- Furthermore, 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.

- 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.

- Finally, 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 they set to achieve through the E.U. Green Deal and Farm to Fork Strategy.

- 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.

Comments on Health Canada Questions for Discussion

1. **Does this new guidance improve clarity, helping plant developers and interested parties determine which plant-derived foods are, and are not, novel foods?**

    - CPMA supports Health Canada's proposed guidance regarding the safety of plant breeding and gene editing. We are encouraged by the inclusion of new guidance as part of Division 28 of the *Novel Food Regulations* that provides clarity and predictability to plant developers and other interested stakeholders. This guidance states which foods from products of plant breeding do not require pre-market notification as novel foods, identifies characteristics that would pose a potential safety concern and would be considered a "novel food" requiring a pre-market assessment, and delineates plant developer responsibilities relating to the characterization of a new plant variety.

    - CPMA would like to draw Health Canada's attention to submissions made by CropLife Canada and the Canada Grains Council that outline certain areas of the proposed guidance that require further clarity to ensure that the ongoing interpretation of the guidance can achieve the intended goals of improved clarity, international alignment, and a risk-based approach that supports innovation.

- As noted above, regulatory alignment with our trading partners is essential to maintaining Canada's economic competitiveness. CPMA is therefore pleased to note that reducing uncertainty around the scope of products that may require pre-market assessment as a novel food brings Canada closer to the approach followed by other countries. As the Canada Grains Council has noted, other jurisdictions safely manage conventional plant breeding without the involvement of regulatory processes that apply to products of biotechnology. This is achieved by following guidance based on international food safety standards, through national programs such as variety registration, or by utilizing other industry-led standards, tools and practices.

- CPMA is also supportive of Health Canada's recognition that "off-target" changes in DNA are not unique to gene editing and occur through conventional plant breeding, which already has a long history of safe use. Along with the government's recognition in Section 2.2 of the guidance that gene editing and plant breeding techniques do not present any unique safety concerns compared to conventional methods of plant breeding, and that plant developers have the ability and expertise to identify and eliminate safety concerns, this guidance will provide greater certainty for plant developers.

2. Is it clear that plant developers and interested parties can consult with Health Canada to help them make their determination on which plant-derived foods are, and are not, novel foods?

- Yes. As part of the pre-market safety assessment for Novel Foods derived from retransformants, CPMA is pleased to see that Health Canada encourages petitioners to make use of the pre-submission consultation process and would like to emphasize that Health Canada must provide sufficient resources to maintain a timely response process. This process is especially important to ensure that plant developers have clarity regarding information requirements and to improve the predictability of the assessment process and the overall quality of a submission package.

3. Does the guidance on the pre-market assessment of foods derived from retransformants clearly describe the information requirements for the assessment of these products?

- CPMA is generally pleased that pre-market safety assessments of eligible retransformants will be conducted under an expedited service standard of 120 calendar days. Since Health Canada clearly identifies the criteria that must be met to be eligible for the expedited service standard as part of the pre-market assessments for tier one or two products, it is important that no significant delays unfold and that the 120-day service standard is respected as part of this process.

- CPMA has greater concerns about Health Canada's proposed 410-day average service standard for pre-market safety assessments for products that are novel and unlike any previously assessed novel food, especially since Health Canada also clearly identifies the information requirements needed for novel foods derived from retransformants as part of

the premarket assessment. Although it is understandable that a thorough evaluation needs to be conducted to ensure that new products with different genetic modifications and different modification methods are safe for the health and safety of Canadians, it is important that pre-market assessments be conducted in a timely manner so that they do not become a barrier to innovation and economic competitiveness. 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 pre-market safety assessment process in Canada.

- To avoid a situation in which an application is rejected and the developer must make a re-submission, CPMA is pleased to see that Health Canada is committed to ensure that all criteria are met through a pre-submission consultation process. It is therefore crucial that this process ensures that applicants are provided with timely feedback if questions or issues arise regarding the information that they provide for the pre-market safety assessment.

4. Does the guidance align with the goal of a regulatory approach that is based on the level of food safety risk posed by specific products of plant breeding?

- CPMA is supportive of Health Canada's stated goal of a regulatory approach that is based on the level of food safety risk posed by specific products of plant breeding. We are pleased that Health Canada's proposed guidance focuses on the potential safety risks that stem from the outcomes to foods, while also recognizing that "plant developers are experts in their plant variety and the plant species in relation to its use in food, and related food safety".

- CPMA is supportive of Section 2.2 of Health Canada's proposed guidance which recognizes that plant developers are aware of the intended characteristics that may affect the expression of other characteristics which affect food safety, that they consider risks that new characteristics can pose to food safety, that they discard plants with characteristics that pose health safety risks, and that they continually monitor plant varieties for characteristics that may pose food safety risks even after commercialization. Recognizing that plant developers are experts when it comes to gene editing processes is a positive step; moving forward, it is important that Health Canada's Novel Food Guidelines continue to focus on the potential safety risks that stem from the outcomes to foods and not on plant breeding processes.

- CPMA is supportive of the inclusion of Section 3 of the guidance on "foods derived from genetically modified products of plant breeding that are not novel foods that require a pre-market notification". The inclusion of this section allows for a narrow interpretation of the *Novel Food Regulations* through its description of five categories of foods that would not add to Health Canada's body of knowledge about their safety and therefore not meet the threshold of novelty required for them to meet the definition of a "novel food". The inclusion of these five categories is important to ensure that plant developers have the

clarity that they need to apply to either the tier one or two pre-market assessments, and not go through the pre-market safety assessment for products that are considered novel and unlike any previously assessed novel food.

5. **Does the voluntary transparency initiative serve its purpose to inform Canadians what non-Novel gene-edited products are on the market? Can we do more to achieve this objective?**

    - CPMA is supportive of Health Canada's goal of providing Canadians with a clearer understanding of the gene-edited products in the Canadian market while enhancing public trust in these products and in the Canadian regulatory system. We are somewhat concerned that Health Canada's proposed list of non-Novel gene-edited products will not result in the desired clarity and public trust, but instead will cause greater confusion and unwarranted apprehension on the part of the public. Products for which there is an established history of safe use as a food, in which the food has been manufactured, prepared, preserved or packaged by a process that has been previously applied to that food, and/or in which a food is derived from a plant that exhibits characteristics that were previously observed in that plant, are still subject to all of Canada's food safety, plant health and labelling regulations and should therefore not be construed in any way as less safe than other foods. **We encourage Health Canada to continue to firmly defend the scientific basis on which these foods have been approved for market in Canada and to ensure that it consistently provides clear assurances to the public as to their safety.**

    - CPMA would also like to draw attention to comments and recommendations made by the Canada Grains Council and CropLife Canada regarding additional clarity required in relation to the proposed voluntary transparency initiative. We encourage Health Canada to consider these recommendations to ensure that the voluntary transparency initiative can meet the needs of the Government, plant developers and the public.

In closing, CPMA is appreciative of Health Canada's efforts to ensure that plant developers, other relevant stakeholders and the public have an opportunity to present their views on its *Proposed new guidance for Novel Food Regulations focused on plant breeding*. 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.

As this proposed guidance represents the first phase of a broader, multi-year effort to modernize guidance for all Novel foods as defined under the *Novel Food Regulations*, CPMA welcomes future opportunities to provide our comments and feedback. We also request that the Government publish a *What We Heard* report for this consultation with reasonable time allowed for stakeholder review. CPMA and Canada's fresh produce industry are keen to partner with government to find effective solutions to ensure that Canada's *Novel Foods 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.

We appreciate you taking the time to review our comments.

Sincerely,

Ron Lemaire
President