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

Email: hc.bmh-bdm.sc@canada.ca

Thank-you for the opportunity to comment on the *Proposed New Guidance for Novel Food Regulations focused on plant breeding* including plants developed using gene editing technology and a predictable pathway for commercialization. The proposed Guidance aptly recognizes the evolving landscape for plant breeding and empowers Canada as an agriculture leader. It enables plant breeding innovation and ensures canola's competitiveness while maintaining high standards of food safety for Canadians.

CCGA represents Canada's 43,000 canola farmers on national and international issues, policies and programs that impact their farm's success. Canola is a staple of Canadian agriculture as well as science and innovation. Developed in the Prairies in the 1970's, it has grown to become a key oilseed globally with \$11.9 billion exported in 2020, the most widely seeded crop in Canada and the largest farm cash receipt earning farmers \$10.2 billion in 2020. Annually the canola sector provides \$29.9 billion to the Canadian economy and creates 207,000 full-time jobs.

An enabling environment for innovation

An integral component of our success has been continuous innovation in canola seed, as well as Canada's science and product based regulatory framework. Plant breeding, conventional or genetically modified, has provided canola farmers with effective disease management and weed control and has contributed to sustainable seeding and soil management practices. For example, herbicide tolerant canola has increased farm income, reduced soil erosion, sequestered carbon and contributed to the overall development and growth of our sector.

While Canada's novel traits framework has worked well in the past, advancements in plant breeding and science now necessitates greater certainty and global alignment to ensure Canada continues to attract investment in research and the best possible seed. To realize the promise of these advancements, Canada needs a regulatory framework that both ensures food safety and encourages research and commercialization of innovative varieties.

Gene-editing can further diversify solutions available to farmers. It provides an additional, more precise tool to plant breeders/developers reducing research timelines and costs and enabling enhancements to plant growth,

sustainability, and nutrition not previously available. Potential enhancements for canola include improvements to disease and agronomic management, to the potential of the canola plant, and to the production of more nutritious oil. Additionally, with growing environmental pressures, seed innovation could help farmers mitigate extreme weather events and allow for the reduction of fossil fuels, more effective use of inputs and improved carbon capture.

The proposed Guidance will provide better clarity to plant breeders/developers when determining novelty of traits produced through conventional and gene-editing techniques. The exceedingly rare instances when conventional plant breeding may result in a novel food are now more clearly defined providing a better understanding of regulatory triggers. Importantly, it recognizes that gene editing techniques are different than genetic modification and that they are as safe as conventional breeding, and outlines a food safety approach commensurate to risk. It also provides for tiers and expedited service standards for retransformants identical to those previously assessed to reflect the best available science and our history of safe use in Canada.

This, in turn, will generate more innovative varieties for farmers to select from and opportunity to diversify genetics at the farm-level. Plant breeders/developers will gain a better understanding of whether their expressed trait will require a premarket safety assessment and approval as a novel food in Canada. More regulatory certainty will reduce costs and time requirements removing an important barrier to innovation. It is CCGA's hope that the proposed Guidance will encourage additional research and more public and small- to medium- company participation in canola breeding where barriers related to plant novelty and approval of genetically modified varieties are difficult to overcome.

Canola's competitiveness

Canola farmers are concerned that access to gene-edited varieties will be delayed in Canada putting them at a competitive disadvantage. Under the current framework, these new varieties face more uncertainty and potential regulation than our main oilseed competitors and markets. The United States has published a clear decision-pathway, and the United States Department of Agriculture has provided guidance on what products fall under its regulations. Australia, Japan, Brazil, and Argentina have also established regulatory approaches to enable plant breeding innovation. Ultimately, any delay impacts farmers profitability and their ability to compete internationally.

In the U.S, traits developed through gene-editing technology focused on higher oil content for more productivity, on increased high oleic acid for functionality and nutrition, on pod-shatter resistance for increased yields and reductions in food loss, and on disease resistance for better management of existing and evolving pressures have already completed the USDA "*Am I regulated?*" process and do not require a pre-market assessment and approval.

The proposed Guidance aligns Canada with the regulatory approach to gene-editing adopted by the above countries and creates a platform to drive further global alignment. Canola farmers rely on international trade with 90% of canola exported as seed, oil, or meal. Our competitiveness relies both on predictable rules of trade and a level playing field. Global alignment of regulatory frameworks for gene editing will facilitate trade while maintaining food safety and realizing the potential of plant breeding innovation to address global challenges related to food

sustainability and security. It also supports Canadian leadership in international forums and better facilitates the development and use of international standards that underpin global trade.

High Standards for Food Safety

CCGA believes that the Guidance will provide increased certainty and predictability to breeders/developers while maintaining high standards for food safety. It appropriately maintains pre-market assessments and approvals for plants with foreign DNA and for characteristics that pose potential safety or nutritious concerns. Pre-market assessment and approval to ensure these traits are safe for human (and animal consumption and for the environment) is integral to the safety of our food supply and, more largely, Canadians' trust in their regulator and the food they consume.

CCGA supports voluntary notification for non-novel gene edited products. Farmers are proud of the crop they produce and recognize the importance of public trust in the food they grow. Notification provides for transparency, a record of non-novel traits and a common source of information for those interested in what plant breeding technique was used. It is also important to market access, as it collects information (even if not determined to be novel) potentially required when meeting customer requirements. To this end, we encourage Health Canada to continue to firmly defend the scientific basis on which these new areas of guidance have been developed.

The canola sector follows a Market Access Policy. It is a unique approach that balances the importance of innovation to farmers and market access to our sector. Overseen by the Canadian Canola Council, the policy supports our sector's commitment to transparency and information-sharing by requiring developers to disclose to our value chain information on varieties produced with gene-editing or new plant breeding technique. This Policy is in addition to the variety registration requirements of the Western Canadian Canola/Rapeseed Recommending Committee.

A Guidance for the Future

CCGA is also a member of the Canada Grains Council and endorses their submission. We support Council's suggestions for further improvement and clarification.

- Health Canada should ensure overly broad statements are narrowed so that the intent to focus on risk is clear. More specificity and certainty preserve today's intention and prevent differences in interpretation or unintentional changes over time. It will also help in communicating Canada's approach to plant breeders/developers and in Canadian leadership globally to generate alignment in regulatory approaches to gene-editing.
- As added transparency, the voluntary notification process should allow for notifications prior to 90 days before commercialization. Plans to bring a new variety to market is often known earlier, as farmers require time to factor a new variety into their crop rotation and the canola sector undertakes its Market Acceptance Policy. As the global landscape and customer demands evolve, early notifications may also be needed in some cases to support market access.

- The Guidance should apply equally to varieties developed outside and imported into Canada.

In conclusion, innovation is the backbone of Canada's canola sector. CCGA supports the proposed Guidance and believes it meets Health Canada's policy objectives to create better clarity, predictability, and transparency and to provide an efficient and predictable pathway towards commercialization for varieties developed with gene-editing. It aligns Canada globally, and supports government leadership internationally to align rules of trade and facilitate trade of gene-edited products.

Regards,

Original signed by

Dave Carey
Vice President, Government and Industry Relations
Canadian Canola Growers Association