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Via email: hc.bmh-bdm.sc@canada.ca

Re: Comments on Health Canada's proposed new guidance for the Novel Foods Regulation, focused on plant breeding

To whom it may concern:

About Us

The Saskatchewan Flax Development Commission (SaskFlax) represents the farmers that grow flax in the province of Saskatchewan. SaskFlax is funded by farmers through a levy on flax sold. The levy is used to fund research, including the development of new flax varieties, and market development. SaskFlax was established in 1996 and has funded over \$6 million of research during the last 25 years.

Why Plant Breeding Innovation Matters to the Saskatchewan Flax Development Commission and to Canada's Grain Value Chain

Canada's grain sector is proud of our hard-earned reputation as one of the world's largest suppliers of safe, sustainable and high-quality grains. That reputation is due in no small part to the science- and risk-based regulatory environment we have in Canada and preserving that reputation is key for our sector's future success. We believe that the Government of Canada's efforts in this area will not only help grow our agricultural exports and speed the post-covid economic recovery, but also help to address some of Canada's pressing domestic food, health, and environmental challenges.

The 2017 Advisory Council on Economic Growth (in a document known as the Barton Report) identified Canada's agri-food sector as having great potential to drive economic growth for the nation. The Agri-food Economic Strategy Table later called for decisive action from policy makers to realize this potential, and set an ambitious target of \$85 billion annually in exports by 2025. The table recognized that a number of structural and cultural changes would be needed to reach this target, including agile and streamlined regulatory approaches. This included modernizing 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 appreciate Health Canada's efforts to help bring this recommendation to fruition and believe that efforts in this area will not only help grow our agricultural exports and

speed the post-covid economic recovery, but also help to address some of Canada's pressing domestic food, health, and environmental challenges.

For the Saskatchewan Flax Development Commission

For the flax industry plant breeding innovation was determined to be a valuable tool for developing new flax varieties that would provide solutions for flax growers. The Flax Council of Canada, Saskatchewan Flax Development Commission, and Manitoba Flax Growers Association funded research to develop a herbicide tolerant flax variety. The concerns about how a gene edited flax variety would receive approval in Canada was a factor in continued funding for the research. Without a clear path for approval of a gene edited flax variety the risk for approval was deemed as one reason for halting the research. The flax industry continues to look at gene editing as a tool for developing plant characteristics that would benefit the flax industry and farmers.

Trade, Economic Growth and Jobs

Canadian exports of cereals, oilseeds and pulses add over \$25 billion to the Canadian economy every year, but our sector is facing intense and increasing competition in global markets. We have also seen more and more examples of Canadian research investments in plant breeding innovation falling behind those of other countries. This results in less innovation for Canadian farmers placing them at a competitive disadvantage to their global counterparts. Canada needs leadership in innovation as well as an efficient and science-based regulatory system to secure our position as a leading supplier of safe and high-quality products. Furthermore, innovation in seed leads to innovation throughout the value chain, generating new research, expanding the range of new products available to farmers and consumers alike, creating jobs and helping to drive Canada's long-term competitiveness.

Sustainability & Climate Change

Climate change impacts our health, economy, and environment, all of which are intrinsically linked to farming and sustainable land management. As the global population grows, higher yields will be needed without bringing more land into production and using fewer inputs. Canada's 63,500 grains and oilseed farms can help to meet this challenge, but they need access to improved varieties that can better withstand drought, flooding, more extreme weather and expanding pest and disease pressures. Seed innovation can also enable new cropping practices that reduce fossil fuel use, use inputs more effectively and capture carbon from the environment more efficiently, furthering our sector's contribution to Canada's climate change and sustainability goals.

Health of Canadians & Food security

Higher yielding, more nutritious crop varieties developed using cutting-edge gene editing methods have already been made available to consumers in the US, Japan, Argentina and Brazil, while Canadians have not had access to the same options. These include a soybean variety that produces oil with less saturated fat, tomatoes that are high in a naturally occurring compound that lowers blood pressure, and soon, wheat that is higher in fiber. Beyond the development of specialty products like these, gene

editing tools are also being used to reduce post-harvest food waste, for example by developing plants that have reduced losses during harvest or longer shelf life. Plant breeding innovations have the potential to improve consumer access to nutritious and affordable food, and to increase food security in Canada and globally.

Praise for the Proposed Approach

To enable Canadian plant scientists and innovators to realize the potential described above, Canada needs agile regulations and policies, built on a solid foundation of the best available science. We are pleased that Health Canada has put forward a proposal that will help our sector achieve these goals while maintaining Canada's high standards of safety. We note in particular that the proposed approach appears to offer a number of beneficial outcomes:

1. Canadian plant breeders using conventional plant breeding methods will now be on a more level playing field with their international counterparts.

The exceedingly rare instances when conventional plant breeding may result in a novel food are now much more clearly defined. Reducing uncertainty about the scope of products that may require pre-market assessment brings Canada closer to the approach followed by other countries, where conventional plant breeding is safely managed without involvement of regulatory processes that apply to products of biotechnology, e.g., by following guidance based on international food safety standards, through national programs such as variety registration, or by using the many other industry-led standards, tools and practices aimed at providing safe and high-quality products to our customers.

2. Canadian research projects will benefit from greater certainty

Plant breeders will better understand if and when their research objective (e.g., a variety with resistance to a certain disease) will require a premarket safety assessment as a novel food. Applications for research funding and grants can now include more certainty about regulatory costs and timelines, thereby removing an obstacle that has limited research in the past. We feel this predictability will enable accurate project planning and use of limited research dollars.

3. Canada will be more closely aligned with like-minded countries, facilitating trade

Differences in the scope of products that trigger pre-market safety assessments among trading partners can lead to market access issues and disruptions to food supply chains. In this proposal, Health Canada has taken steps to better align Canada with the rest of the world, e.g., by characterizing products with foreign DNA as novel foods. In the longer term we believe this will support Canadian leadership in international forums and better facilitate the development and use of international standards that underpin global trade.

4. Farmers will have more seed varieties to choose from

Gene editing is a cost-effective and efficient tool, allowing plant breeders to do more with less. Public sector breeders, small companies, and researchers working in small or specialty crops will be able to participate in the most cutting-edge innovations to a

greater degree under Health Canada's clarified guidance. New products, markets and other opportunities can be accessed, thanks to a risk-commensurate regulatory path to market in Canada, appropriately tiered to familiarity.

5. Canada will maintain its reputation as a trusted, science-based and product-based regulator

Trust in the safety of the Canadian food supply depends in part on the effectiveness of Health Canada's regulatory programs, risk communication and transparency measures. Health Canada proposes a notification mechanism for gene edited products that we believe will help provide information and build trust in the safety of plant breeding innovation. This is beneficial, recognizing that foreign governments, consumers and other end-users of grain (e.g., processors, manufacturers) may seek information about gene edited products grown in Canada, even if they are not determined to be novel foods. We encourage Health Canada to continue to firmly defend the scientific basis on which these new areas of guidance have been developed. These efforts help to support Canada's reputation as a supplier of safe and high-quality grain.

Areas for Further Improvement and Clarification

Our organization fully supports the detailed responses submitted by the Canada Grains Council and CropLife Canada, where more specific details are provided. However, we note general areas where further improvements and clarifications in the proposed guidance are needed.

1. Health Canada should ensure overly broad statements are narrowed so that the intent to focus on risk is clear. For extra certainty, statements should be added to confirm plant breeding objectives that are out of scope, rather than relying solely on descriptions of those that would be considered novel. Similarly, further clarifying the intent and outcomes of new processes such as the voluntary notification will help ensure they are consistently interpreted in the long term.

2. Flexibility is needed to ensure voluntary notifications can be made earlier than 90 days prior to commercialization. Earlier notifications may be needed in some cases to support market access for Canadian products.

3. Requirements that apply to Canadian products should be designed so that they may also apply to products developed in other countries that are imported into Canada. This will help to further level the playing field between Canadian innovators and their international counterparts, as well as positioning Health Canada to pursue international alignment in the future.

The Grain Sector Remains Committed to Safety and Transparency

Attention to the above areas will help to ensure Health Canada's final guidance preserves the intended clarity for plant breeders, prevents unintentional changes over time, and will help put Canada on a more level playing field with international competitors.

While we applaud Health Canada's proposal, we also recognize there is a complementary role for industry to play to help ensure the successful adoption of plant breeding innovation in Canada. In particular, we would like to highlight the commitment of SaskFlax to transparency. We will continue our efforts to ensure information about gene edited products can flow through the value chain from seed company to end users, including Canadian consumers.

In closing we urge you to finalize and implement the proposed approach as soon as possible. In the longer term we hope that Health Canada will continue its efforts to share regulatory approaches internationally and work with like-minded countries to preserve science-based global standards and rules of trade. We encourage Health Canada to build on their regulatory cooperation activities and to fully leverage foreign reviews to accelerate approvals and use limited regulatory resources wisely. After this revised guidance is complete, further work will be needed to ensure that data requirements and regulatory approval processes reflect the level of risk and familiarity involved and we look forward to commenting on Health Canada's future work in this area.

Thank you for your efforts on this matter.

A handwritten signature in black ink, appearing to read "Greg Sundquist". The signature is fluid and cursive, with the first name "Greg" and the last name "Sundquist" clearly distinguishable.

Greg Sundquist
Chair
Saskatchewan Flax Development Commission