



May 20, 2021

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

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

Dear Sir/Madam,

Please find following a submission from the Western Canadian Wheat Growers Association, regarding the Consultation: Proposed new guidance for Novel Food Regulations focused on plant breeding.

This is an issue of vital importance to the grain industry. The Wheat Growers have worked with Grain Growers of Canada and Canada Grains Council in developing the industry positions that each respective group has brought forward.

We look forward to further consultations and discussions around this industry issue.

Yours truly,

A handwritten signature in black ink, appearing to read "G. Jochum".

Gunter Jochum
President
Western Canadian Wheat Growers Association



Views regarding Health Canada's proposed new guidance for the Novel Foods Regulation, focused on plant breeding

May 20, 2021

About WCWGA

The Western Canadian Wheat Growers Association (WCWGA) welcomes this consultation and appreciates the opportunity to provide input both directly and through our involvement with other farm organizations. Gains made in production, market development and risk management often start with the seed which requires solid, sound policy to ensure safety while keeping Canadian Producers competitive.

Canadian farmers require access to the latest technology, not just to compete with other jurisdictions, but also to address many production and environmental challenges which may be specific to local geographies. Science and risk-based guidelines ensure technology providers, like seed and trait providers, will invest in Canada and give Canadian producers and consumers access to the most nutritious and safe food and in sufficient volumes. Those technology providers have choices where to prioritize their research investments, and all Canadian regulators can help ensure Canada is viewed as an advanced, forward-looking user of science and risk-based decisions.

WCWGA is an agriculture policy advocacy group of volunteer "opt-in" farmers. Celebrating 51 years of active agriculture advocacy and policy development, all of our members choose to voluntarily join the WCWGA and support our work with a membership fee that comes out of their own pocket.

Although "Wheat" is in our name, and was a significant foundational component of our organization, the WCWGA members represent all major grains, which is relevant as the regulations in question cover all crops.

Why Plant Breeding Innovation Matters to WCWGA members, farmers, consumers, customers and to Canada's Grain Value Chain

The year 2020 showed how vulnerable our economy can be, the importance of food security, and the benefit of consumers having trust in our regulations to ensure technology development continues. These innovation and technology advances will be required in order to manage any future curves that our economic and agricultural systems get thrown.

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That's why a flexible, science and risk-based regulatory framework is critical.

The WCWGA educates our members on technology such as gene-editing, as demonstrated by both an article and video interview in our April newsletter <https://mailchi.mp/wheatgrowers/april-2021-newsletter>. Canadian farmers care about and understand the need for such technology to address production and environmental challenges for both today, and tomorrow. Canada needs innovation-enabling regulations.

The 2017 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.

We've heard from Canadian scientists of technology made available by gene-editing already available including;

- Reduction of gluten proteins (improvement for coeliac disease) while maintaining quality;
- Influence of cadmium accumulation in durum wheat;
- Shortened cereal crops resulting in improved harvest indexes;
- Better optimization of gene pools, for quicker development of superior lines; and
- Promising new applications such as adapting wild germplasm for its benefits of disease resistance, while mitigating undesirable characteristics.

and the list goes on for oilseeds, vegetables and pulse crops.

We can only imagine what other solutions await Canadian producers if they're allowed access to new improved varieties with beneficial traits to solve other production, health and environmental challenges. And the reality is that these will concurrently benefit our economy when it needs help more than ever due to Covid-19.

Trade and the economy drive jobs, and we've seen the loss of investment in wheat breeding in the past few years in Canada. Canadian regulatory frameworks can help drive innovation while also meeting their responsibility to ensure safety to our food supply. This isn't a trade-off, and actually the two go hand-in-hand when enabling innovation using science such gene-editing and other modern breeding technologies.

WCWGA support the Proposed Approach

To enable Canadian plant scientists and innovators to realize the full 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. WCWGA support the Canada Grains Council's recommendations and observations, 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

WCWGA 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 WCWGA 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, WCWGA urges Health Canada 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.

The Western Canadian Wheat Growers Association gratefully submits these recommendations for the Health Canada Consultation on Plant Breeding Innovation. We look forward to the opportunity to discuss these recommendations further.

Further information regarding the WCWGA may be found at: www.wheatgrowers.ca