May 24, 2021

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

RE: *Proposed Changes to Health Canada's Guidance on the interpretation of Division 28 of Part B of the Food and Drug Regulations (Novel Food Regulations) and the on the pre-market assessment of foods derived from Retransformants under the Novel Food Regulations*

Dear Reviewing Official:

Thank you for the opportunity to comment on the Proposed Changes to Health Canada's Guidance on the interpretation of Division 28 of Part B of the Food and Drug Regulations (Novel Food Regulations) and the on the pre-market assessment of foods derived from Retransformants under the Novel Food Regulations.

The North American Export Grain Association (NAEGA) is a member driven not-for-profit trade association that provides for and promotes policies, rules and commercial practices that support efficient international trade in grains, oilseeds, and their derived products. Private and publicly owned companies and farmer-owned cooperatives who export North American agricultural production to customers around the world support NAEGA through membership and volunteer expertise. NAEGA contract, policy and practice guidance are widely adopted and influential globally.

NAEGA is working with its members, their customers, counterpart organizations around the world, government officials and other stakeholders to accommodate new technologies used in crop production. Addressing related commercial and regulatory challenges while providing for a competitive, compliant, informed, and responsible market environment for the crops our members buy, and sell is a critical element of our work.

NAEGA supports Health Canada's efforts to update and modernize the Novel Food Regulations to account for products of new plant breeding innovations such as gene editing. We also agree with the need for the clear, predictable, and transparent regulation of products of plant breeding including those developed using gene editing technologies.

We believe that commercial solutions are the most effective and preferable means to meet customer needs for unique commodities. We seek to minimize government interference with commercial activity related to meeting customer needs. It is important to utilize, and for the grain export industry to participate in, appropriate, relevant, and effective national and international

proceedings where policies and regulatory action affecting the industry will be negotiated or discussed. All governments regulatory procedures and statutory authority need to ensure regulatory decisions reflect sound science, foster increased consumer confidence, and support a competitive and informed commercial response to market conditions.

NAEGA also supports the utilization of plant breeding innovation and other safe technologies and modern agricultural practices that enhance the production of safe, affordable, and sustainable food and energy for global consumers. Commercial seed products currently on the market have enabled growers to increase yields of safe crops for use as food, feed and for further processing, while at the same time protecting the environment by decreasing the use of crop inputs and expanding the use of conservation tillage. These technological advances also have been successful in enhancing the productivity and competitiveness of North American growers, grain handlers, processors, and exporters, and resulted in substantial benefits for consumers.

Feeding a growing world population and providing an abundant supply of competitively priced agricultural products necessitates that the grain handling and marketing industry is enabled to competitively, cost-effectively, and seamlessly source and market North American agricultural products in domestic and foreign markets.

Commerce in grains and oilseeds are tied to global sourcing. It is an irrefutable fact that a sustainable supply of these basic commodities depends upon adequate fungibility – that is, the ability to source supplies of a given crop that have a degree of substitutability and relatively comparable value regardless of the geographic production area from which they originate. Grain supplies that can be comingled without concern over their regulatory status can be accessed in a timely, efficient, and competitively priced manner in response to buyer demands, providing time-and-space utility that is essential to achieving supply integrity and food security. Production and logistics systems that benefit from an adequately fungible supply of grains and oilseeds are critical.

Providing grains and oilseeds from Canadian as well other origins is predicated on informing the consumptive value chain with consistent and credible information on the safety and use of all production technologies. All crops, even if produced from what may be determined as not novel technology, need such transparency. A combination of consumer needs to know and inconsistent international regulation make this need for transparency particularly acute for crop biotechnology.

Hence in response the Proposed Changes to Health Canada's Guidance on the interpretation of Division 28 of Part B of the Food and Drug Regulations (Novel Food Regulations) and the on the pre-market assessment of foods derived from Retransformants under the Novel Food Regulations:

1. **We urge Health Canada to develop and implement measures the ensure sufficient notification of those products, whether considered novel or not, prior to Commercialization.** We appreciate that Health Canada recognizes the need for transparency when it comes to new plant breeding technology, and the proposed Voluntary Transparency Initiative (VTI) has the laudable goal of providing consumers with a clearer understanding of the gene-edited products in the Canadian market with the goal of enhancing public trust in these products and the regulatory system. The information

requested from plant developers is also appropriate and is the sort of information that global consumers and governments would request.

However, a voluntary process is almost certain to be insufficient to support Canada's interests. Not knowing what gene edited events are in grains and oilseeds places international markets in jeopardy. Without such knowledge, exporters and importers face unmanageable risks that have and will result in market failure. There is a clear history of technology and seed providers needing incentives beyond what are included in voluntary mechanisms to provide for an informed market. The potential for genome editing technology to be deployed more broadly and with lower market entry requirements exacerbates this problem.

Gene edited products will still be considered as novel by some governments, including Canada's export partners, which means some sort of assurance of safety and proof of what gene edited products may be in Canadian exports, whether that is one-time or per shipment, is going to be required. A mandatory transparency requirement or some other mechanism to incentivize transparency to ensure publicly available assurances of safety and needed consumer information is needed to facilitate markets. Notification of why a new plant developed through gene editing does not require a pre-market assessment, provided by the technology provider, and attested to by the government, seems reasonable and useful for the food industry, and provides public safety declarations and transparency for choice and compliance.

We recognize Health Canada may not have regulatory authority to require a mandatory notification, processors and exporters need a public affirmation from Heath Canada that gene edited products meet the safety requirements to be considered non-novel to allow for consumer choice and ensure regulatory compliance with Canada's key export markets. Alternatively, we would support a process where a notification via the List of Non-novel Determinations could be mandatory and allow consumers and exporters to see that the new products have been evaluated for safety.

2. **We further recommend that any notification period be greater than the proposed 90 days** suggested by the draft guidance and should occur as soon as information for the product is in the public domain.

3. **We request clarification on how other sections of Canadian law, such as the Food and Drug Act or Seeds Regulation, which contain food safety provisions ensuring food products placed on the market or registered seeds varieties do not present a risk, can or will be used to provide assurance of safety to key export markets that require such proof or approval.** Clarity in how these other sections of Canadian law provide assurance of safety, on a product-by-product basis, also need to be included in the guidance document. We note that Appendix X of CFIA's Procedures for the Registration of Crop Varieties in Canada under the Seeds Regulation, sets out a "Quality control system requirements for varieties subject to contract registration". These requirements apply to varieties where the biochemical or biophysical characteristics of a variety distinguish it

from the majority of registered varieties of the same kind or species and the variety may have an adverse effect on the identity of those registered varieties. Because these varieties have the potential to cause adverse effects if they enter the traditional commodity channel, there must be assurance of appropriate means of control, via "quality control systems" (QCS). There must be assurance that the systems are in place and that they are effective.

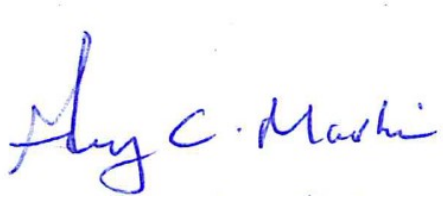
In the case of gene edited varieties that are unapproved for import in destination countries, Appendix X would apply as the discovery of the unapproved event in a shipment would lead to a negative impact on the registered variety as it would slow or even halt exports of that original variety and lead to a loss of consumer and government trust in that product, diminish sales and cost exporters both money and time, which would ripple through the value chain all the way down to the farmer and the seed provider. Before Health Canada reclassifies most gene-edited events as non-novel, and initiates a voluntary notification system, the guidance document should be updated to reflect which laws and regulations would apply in these cases where there may be a conflict.

4. **Finally, we encourage the tiered approach to pre-market assessment of retransformants as described in the guidance be clarified.** We understand that this tiered approach would only apply to plants that are deemed novel per Health Canada's guidance. Under the proposed changes, most plants developed through gene editing, will not fall into this tiered approach. If the guidance on pre-market assessment of retransformants only applies to products that are deemed novel, per the Novel Food Regulations, this should be clarified in the guidance.

We look forward to any opportunity to work with you in support of market facilitating biotechnology and other crop technology policies – including policies that effectively address marketability risks and impacts – to ensure the successful development and processing of foods for humans and animals from all agricultural cropping systems.

Thank you for the opportunity to comment on this important issue.

Sincerely,



Gary C. Martin
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