

Comment from the Canadian Genome Enterprise:



GenomeCanada



Ontario Genomics



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Consultation Response to Health Canada's Proposed guidance for Novel Food Regulations

Improving safety and standard of service to benefit breeding innovation

Prepared by:

The Genome Enterprise:

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The Genome Enterprise is a federated ecosystem of regional Genome Centres and technology platforms united by Genome Canada to invest in mission-driven research and innovation (R&I) in genomics and biotechnology. We bring together regional players to create national solutions that provide economic and social benefits for all Canadians. The Genome Enterprise connects ideas and people across public and private sectors to innovate new applications for genomics, invests in large-scale science and technology to fuel innovation, and translates discoveries into applications and solutions across key sectors of national importance, including health, agriculture, forestry, fisheries & aquaculture, energy, mining, and the environment.

Key terms:

CFIA – Canadian Food Inspection Agency

HC – Health Canada

NF – Novel Food

NFR – The Novel Food Regulations

GE – Gene-editing

NBT – New plant breeding technologies

R&I – Research and Innovation

GE³LS – Genomics and its Environmental, Economic, Ethical, Legal and Social aspects

Executive summary:

- The Genome Enterprise endorses the proposed guidance as presented. The guidance outlined in the two consultation documents (1,2) offers a viable and productive path to updating our regulatory assessment needs in addressing the risks and benefits of new plant breeding technologies (NBT) such as gene-editing (GE).
- This regulatory update will ensure the safety of Canadians while supporting our farmers and agricultural innovators to the benefit of our economy and global competitiveness. Our science- and risk-based regulatory structure offers opportunities for regulatory innovation. We support the direction HC/CFIA is taking towards agricultural, animal, and microbial food products.
- The quality of the science presented is appreciated, clearly demonstrating the efficacy and safety of GE approaches to plant breeding. The retransformants process will benefit from this technical assessment and provide consumer safety while accelerating plant breeding strategy and development. The focus on food safety and nutritional composition is an example of the adaptability of Canada's novel food trait regulatory framework and is a well-informed approach to regulating the next wave of biotechnology-enabled foods.
- Consultations with our stakeholders revealed that public perception and acceptance of novel foods could present both opportunities and barriers to realizing the value of investments in public or private innovation. Strategically engaging early and often with the public will ensure that our Canadian is prepared to implement these innovations.

Context

As a global agricultural powerhouse whose economy depends on agricultural commodity exports, Canada is at a critical evolution in its regulatory system. Our unique, novel food-based regulatory framework ensures the safety of our foods and food system for Canadians without compromising on our ability to create innovative solutions that address unmet market needs or help us stay ahead of a changing environment and global economy. The proposed guidance changes and additions at the heart of this consultation do not compromise this legacy of safety in order to speed up the regulatory process or increase the level of predictability enjoyed by breeders when setting up breeding strategies and R&I program objectives.

By focusing on the guiding principle of food safety instead of the breeding technology used, our food system will be able to develop and implement innovative advances in GE and plant breeding that will make critical contributions in the coming years to make our food systems more sustainable and more resilient to climate change. The rapidly accelerating growth of the alternative protein market shows that new markets for agricultural products are constantly being created and expanded. We must ensure that our regulatory system can capitalize on the speed and flexibility in breeding made possible by GE to build our position as an agricultural powerhouse in an increasingly competitive global market.

Comment on the safety of Canadians

Our system must continue to prioritize the safety of Canadian citizens by focusing on risk mitigation rather than risk elimination. Progressively updating our plant breeding guidance to focus on food safety rather than breeding technology will allow us to harmonize our regulatory system with those found in rapidly expanding agri-food markets such as the United States, Argentina, or Brazil. This framework ensures the safety of Canadian citizens while overcoming the challenges in regulating these fast-moving technologies.

We appreciate and endorse the guidance as explicitly intended to decrease the time to regulatory assessment and applaud the commitment to a 120-day retransformant pre-market safety assessment as presented in the guidance. Speeding up the process without sacrificing the quality of the safety assessment will be a hallmark of the Canadian approach.

By putting the safety of our food and food supply at the forefront of regulatory consideration, our system is positioned to enhance engagement opportunities with our citizenry. Since the lack of public acceptance can significantly hinder the adoption of an exceptional technology, social engagement must be pursued to further de-risk the path to value realization for our public and private sector breeders.

Comment on safety of GE and other NBTs

Genome Canada and the Centres have a twenty-year history of funding genomics R&I, building knowledge pools, research ecosystems, and technology platforms that have established and grown the genomics and biotechnology research and engineering disciplines. We have made hundreds of millions of dollars in investments in plant breeding, agriculture, and agri-food over those 20 years, all underpinned by an extensive peer-review process. Based on this research expertise and research-based outcomes, our evidence-based position is that that GE technology and other NBTs are highly useful tools to produce safe and nutritious foods.

This position is bolstered by extensive research and consultations with experts providing evidence for the safety of the approach (3-5). Provided that regulators focus on the safety of the food product, the use of gene-editing can be considered safer even than traditional breeding techniques. With GE, the changes to a food's nutritional profile are more precise and directed with fewer to zero unintended changes introduced in the plant. Compare this with traditional crossbreeding approaches, which incorporate thousands of modifications with every breeding cycle. Both the evidence and the theory are aligned in demonstrating the safety of foods bred through GE.

Annex 2 in the NFR guidance document effectively and efficiently summarizes the evidence demonstrating the safety of GE and other NBTs. We agree with the content and position.

We also endorse the specific provision requiring the absence of CRISPR/Cas9/guide RNA components in the plant producing the retransformant or novel food product. While we are not aware of any evidence suggesting that retention of these components in the food create any health or safety risks, the relative ease with which they can be verifiably removed from the improved plant line ensures that this requirement should not be an onerous barrier to deploying the improved crop.

Comment on benefits to developers

The guidance will provide greater clarity on assessment requirements and regulatory risk when designing plant breeding programs and making strategic planning decisions. Earlier engagement in the pre-assessment process will decrease resource expenditures, as will HC/CFIA's commitment to communicating non-acceptability decisions "as early in the process as possible" (see page 6 of reference 2).

The shorter timeline to a decision for a retransformant assessment will further improve resource efficiency. Considering extensively studied traits as new baselines for novel food status assessment streamlines the registration process and provides an excellent update point to bring our technical knowledge informing regulatory decisions as up to the current state-of-the-art.

This increased speed, resource efficiency, and transparency are most important for public researchers at institutes and universities. Research shows that the challenges posed by NF trait regulations disproportionately impact public-sector plant breeders more than private-sector breeders (5). Public developers are particularly negatively affected by the current level of uncertainty and risk in using GE and retransformants to develop new food products. Research shows that most public sector plant breeders cannot innovate new products due to inadequate infrastructure, insufficient space and/or time, and high cost. One-third of public plant breeders indicated that lack of clarity on regulatory requirements had led them to abandon a breeding project or redirect it towards a less innovative one. HC/CFIA's commitment to speed, early engagement, and process clarity will positively impact public sector innovation capacity.

Comment on economic benefits

The economic incentives for updating our regulations on NF and retransformants using GE technology are numerous and substantial. Exports of commodities dominate Canada's agriculture and agri-food market. We are one of the top 5 agri-food exporters globally and one of the few net exporters of food products, establishing ourselves as an ag superpower.

Canada must quickly and effectively update our current regulations to maintain market competitiveness and global access while addressing climate change and repatriation of supply chains. We need to decrease the number of breeding projects abandoned due to regulatory uncertainty, and we need to reduce the time and cost of bringing products to market. Achieving both objectives will benefit Canadian developers and attract international investment from large agricultural multi-national enterprises. Both factors are required to accelerate the growth of our agriculture innovation ecosystem. They are also critical to retaining IP in Canada so that our investments in R&I will create value that will be recuperated in this country.

In our opinion, the current guidance significantly improves our nation's ability to increase the efficiency of developer efforts and attract private investment. Aligning with progressive international regulatory regimes will prevent trade limitations and disruptions and retain market access and competitive advantages for Canada. Contrast this with the European Union, where a restrictive approach to regulating breeding technologies exacerbates the gap between the EU and countries with more progressive, science-driven frameworks that focus on food safety and consumer health.

Recommendations for HC/CFIA

With genomics at our core, Genome Canada and the regional Genome Centres can provide support, inputs, and resources to ensure that our regulatory system promotes and supports the development and implementation of innovative solutions. Genome Canada has extensively supported research into the environmental, ethical, economic, legal and social implications of genomics (GE³LS). These studies have demonstrated, time and time again, that social values and beliefs will significantly affect the depth and breadth of acceptance of foods and product solutions.

We must ensure that Canadian citizens are comfortable with and prepared to take up and consume these products. A coordinated effort to develop novel regulatory guidance in collaboration with stakeholders investing in R&I and product development will further decrease uncertainty in the path towards regulatory approval. At the same time, it will make possible innovative regulatory solutions that will future-proof our pipeline of technology and product investments in agriculture and agri-food. As such, we recommend that:

1. Health Canada and the Canadian Food Inspection Agency (HC/CFIA) partner with organizations such as Genome Canada and other stakeholders in the genomics and biotechnology ecosystem to develop and executive innovative public engagement and outreach to build public understanding of the science and related consumer safety to smooth the path towards public acceptance and uptake of innovative solutions.
2. HC/CFIA work with R&I stakeholders such as funders, investors, and scaleup support organizations to take a mission-driven approach to proactive regulatory innovation. Working with these partners to build innovation sandboxes to address microbial and animal food regulations will allow us to strategically align funding, regulatory, and commercialization efforts to benefit all stakeholders along the innovation value chain.

Closing Statement

Genome Canada, the regional Genome Centres, and our ecosystem of genomics and biotechnology stakeholders fully endorse the proposed guidance at the heart of this consultation process. We are ready to contribute to efforts towards realizing these recommendations.

References

1. Proposed Changes to Health Canada Guidance on the interpretation of Division 28 of Part B of the *Food and Drug Regulations* (the *Novel Food Regulations*): When is a food that was derived from a plant developed through breeding a “novel food”?
2. Proposed Health Canada Guidance on the pre-market assessment of foods derived from Retransformants under Division 28 of Part B of the *Food and Drug Regulations* (the *Novel Food Regulations*).
3. Lassoued, Macall, Hesseln, Phillips and Smyth. 2019. Benefits of genome-edited crops: expert opinion. *Transgenic Research* 28: 247-256. DOI: 10.1007/s11248-019-00118-5
4. Lassoued, Macall, Smyth, Hesseln. 2019. Risk and safety considerations of genome-edited crops: Expert opinion. *Current Research in Biotechnology* 1: 11-21. DOI: 10/1016/j/crbiot/2019.08.001
5. Smyth, Gleim and Lubieniechi. 2020. Regulatory barriers to innovative plant breeding in Canada. *Frontiers in Genome Editing* 2: 1-9. DOI: 10.3389/fgeed.2020.591592