

National Farmers Union BRIEFING NOTE regarding proposed regulatory guidances for plants and seeds produced using new biotechnologies (gene editing) – **April, 2022**



Recommendations to Health Canada:

- All gene-edited products, including those with no foreign DNA, should be regulated as novel and therefore subject to government safety assessment and pre-market notification.
- We recommend that all retransformants continue to be assessed as new Plants with Novel Traits (PNTs).

For detailed rationale please see [NFU brief regarding Health Canada proposed guidance](#)

Recommendation to Canadian Food Inspection Agency:

- All genetically engineered seeds, including those developed using gene-editing technology, should be regulated as PNTs and therefore subject to Part V of the Seeds Regulations.

For detailed rationale please see [NFU brief s regarding CFIA proposed guidance:](#)

SUMMARY OF OUR CONCERNS

- Farmers are stakeholders
- Regulatory guidance is meant to clarify, not change regulations
- Canada’s commitment to science is jeopardized
- Guidances are not “Future-proof”
- Regulation is needed for public trust
- Gene edited plants ARE novel and must be regulated as such
- Transparency requires regulatory authority
- Unregulated products are high risk for market rejection
- Mandatory regulation would provide certainty
- Gene editing not necessarily beneficial to farmers
- Government has a mandate to protect
- Decision needed

Farmers are stakeholders

At an early stage in developing the regulatory guidances, the definition of “stakeholders” was limited to regulated parties instead of all who are affected by the regulation. As a result of having spent too much time with the regulated parties and not with farmers, the regulators missed significant impacts that the Minister of Health and Minister of Agriculture and Agri-Food need to know about before making a decision.

Farmers are stakeholders because farmers plant seeds, grow crops, and our livelihood depends on marketing them for a good price. Many farmers will be using the products of new biotechnologies known as genome editing or gene editing. Many of us also use crops grown by others, for example as feed for livestock and ingredients in on-farm food processing. We are sensitive to our own production costs as well as to customers’ needs, wants and the prices they are willing to pay. We are also stewards of the land and our farming decisions affect the viability of our future farming environment.

Gene edited products need regulation because farmers use the products (seed). Organic certification prohibits genetically engineered products, including those produced using new biotechnologies. There may be an



international debate on the acceptability of gene editing in agriculture, and farmers will pay the price of controversy.

The regulation of gene edited products also has implications for food processors. Some farmers do on-farm processing, most sell to food processors directly or indirectly through the commodity market. When serving a sensitive market, farmers and food processors we need to be able to trust that we're using non-gene edited products.

Regulatory guidance is meant to clarify, not change regulations

Regulatory guidance is a tool to assist regulated parties with compliance. Regulatory guidance should not change the intent of the regulation. Clearly, the intent of both the Novel Food Regulationsⁱ and Part V of the Seeds Act Regulationsⁱⁱ was to regulate PNTs and not provide mechanisms that allow companies to avoid regulation.

Canada's commitment to science is jeopardized

The proposed guidances assert that all the science needed to safeguard health and environmental safety is already exists and is known in relation to gene edited seeds that have no foreign DNA. This is contrary to the process of science, which is always creating new knowledge. These guidances must not cause Canada to depart from long-term commitment to science-based decision-making and regulation.

Guidances are not "Future-proof"

We do not know what technology and outcomes will occur in the future, and can't know in advance whether they will need more oversight.

Requiring regulation now ensures that regulators will have the ability to deal with unforeseen problems and new technologies in the future; whereas exempting gene-edited plants from regulation now means that Health Canada and CFIA will not have tools if oversight is needed in the future.

Developing and maintaining regulatory authority for all gene-edited plants will ensure that Health Canada and CFIA staff will grow in knowledge as new biotechnology techniques are invented and applied. As public servants, working in the public interest independently of industry, these scientists will be in a position to safeguard Canadians from emerging and unexpected risks if and when they occur.

Ensuring that all gene edited plants are subject to government safety assessment before release into the environment and onto the market will reduce the risk of surprises when plants do not function as expected, and will provide tools for the regulator to monitor and manage any surprises that do occur.

Regulation is needed for public trust

Good, public interest, science-based, transparent regulation is essential for maintaining public trust in the food system and in government itself. The lack of transparency and the abandonment of science represented by these proposed guidances will harm public trust in Canada and Canada's international reputation. It will harm Health Canada's capacity to protect the health of Canadians, and will harm CFIA's capacity to maintain a quality food supply, protect the environment and protect markets for Canadian producers.

Gene edited plants ARE novel and must be regulated as such.

New findings about the ability of gene editing technology to overcome cells' defenses shows that gene editing does create novel plants that have no history of safe use in Canada or elsewhere. Even when there is no foreign



DNA incorporated, there is no way that these genetic changes could have ever occurred before in nature. The food safety and environment health impacts of these products has never been experienced by humans or ecosystems before.

Gene editing IS genetic engineering and the plants developed using gene editing ARE novel.

“Genome editing has the unprecedented power to make large parts of the genome accessible to change, by overriding the natural mechanisms of genome organization such as repair mechanisms or backup genes. Thereby, New GE techniques can cause pervasive changes in the genome of plants and animals, without inserting additional ‘foreign’ genes.”ⁱⁱⁱ

Many peer-reviewed studies published within the last five years show that gene editing techniques can produce novel genotypes and biological characteristics by altering areas of the genome that are essential for survival and are normally protected from mutation. When such a protected area is cut by gene editing “scissors” such as CRIPR/Cas9, the cell will re-insert the target sequence, which genetic scissors will then cut again and again until the cell’s own repair fails and the gene-edited change is established. Genome editing would also change non-target genes that contain the same DNA sequence as the one targeted by the genetic “scissors”. Gene editing would force genetic change all sites within the genome that contain the target sequence, preventing the cell from maintaining its normal function in those areas.

Further, gene editing “scissors” can create plants with larger structural changes to their DNA, by moving genes to new locations, deleting genes, adding duplicate genes, scrambling or reversing the order of the DNA code sequences within chromosomes. The health and environmental impacts of these changes are unknown.

Such genetic changes are non-random: the possibility they would ever occur naturally is vanishingly small. Thus, claims made by proponents that gene-edited plants that do not contain foreign DNA are “identical” to conventionally bred plants are false. The technology’s power, and attraction, is its ability to overcome cells’ evolutionary mechanisms that protect certain areas of the genome from mutation.

This persistence and overriding of the cell’s own protective mechanisms makes genome editing a novel technology with novel capacities and consequences unlike any other. The resulting organisms do not have a history of safe use and their safety must therefore be assessed.^{iv}

Transparency requires regulatory authority

Regulatory authority over all gene edited products would ensure that Health Canada and CFIA will be provided with the information they need to ensure transparency. Companies may pledge to voluntarily provide lists of gene edited products that are deemed “non-Novel” according to the guidance’s faulty definition (as described above), but this cannot be considered transparency. The companies have a vested interest in not revealing whether a product is gene edited, as illustrated by the story of Cibus canola:

- **Falco™ Cibus canola** – A 2016 media story promoting Cibus’s soon to be launched new canola variety said “SU canola is Cibus’s first commercial seed product that was developed using a patented gene-editing procedure known as the rapid trait development system (RTDS)^v. In 2019 Cibus launched its two Falco™ canola varieties, saying in its media release “Cibus is a biotechnology company using advanced technologies to develop desirable plant traits for the global seed industry by precisely editing a plant’s genes without the integration of foreign genetic material.”^{vi} However, after a public interest group published a method to detect gene editing in these varieties, Cibus asked the CFIA to change its Decision Document to say the plant’s herbicide tolerance trait was selected through spontaneous mutation, and



not by oligonucleotide-directed mutagenesis as originally stated.^{vii} Oligonucleotide-directed mutagenesis is a gene editing technique used to change one gene sequence within a genome.

The only way to ensure transparency is to ensure the company must obtain regulatory approval before marketing.

Unregulated products are at high risk for market rejection

Gene edited products are controversial. They are prohibited in certified organic production, a strong and growing market in Canada.^{viii} Consumer rejection of controversial products can be a strong enough market force to cause rejection even where products have regulatory approval. Thus, to protect markets, all gene edited plants must be regulated to ensure they are subject to pre-market notification (Health Canada) and PNT identification (Seeds Act Regulations), allowing farmers to make informed choices of seed if they are producing for a sensitive market, and allowing food processors and grain buyers to segregate product if necessary to avoid market rejection and/or price discounts.

Losses due to market rejection go beyond the individual farmer who might have inadvertently delivered a variety not accepted in the particular market. The whole load may be rejected, causing losses for other farmers; and Canada may be seen as an unreliable supplier, resulting in discounted prices for all Canadian farmers selling the commodity. Implications for market destruction are immense, as the following stories illustrate:

Triffid Flax – *The genetically engineered “Triffid” flax was approved by the CFIA in 1996 and by Health Canada in 1998, and registered as a PNT variety. After extreme pressure from farmers and organizations due to concerns over market impact, the variety was cancelled in 2001 so that Triffid was never grown commercially or sold in Canada. However, in late 2009, testing in Europe and elsewhere picked up widespread contamination leading to headlines such as “Japan finds GMO in Canadian flaxseed shipments”^{ix} Prior to Triffid, 70% of Canada’s flax exports went to Europe, but sales dropped by 95% from a high 400,000 tonnes/year to only 20,000/year in 2011 after it was detected in shipments. The costs of market loss and rehabilitating the seed supply were borne by all flax farmers, not just those whose crops contained the unregistered variety.*

Starlink Corn - *In 2000, the USA approved genetically engineered Starlink corn for use as animal feed, but not for human consumption due to concerns about it possibly being allergenic. The company attempted to segregate feed and human consumption sales. However, Starlink corn was later found in food products such as taco shells. The affected products were recalled, and the seed developer, Aventis (now Bayer) had to set up the StarLink Enhanced Stewardship program to remove it from the commodity system, at a cost of up to one billion dollars. Farmers who did not grow Starlink had losses due to price discounts related to the contamination, and obtained a \$100 million settlement from the companies.*

Unapproved corn event - *In April 2020 the Ontario Agri Business Association and the Grain Farmers of Ontario issued a joint statement^x to farmers notifying them that certain genetically engineered stacked trait corn hybrid varieties were being sold which had not yet been approved by major export markets, including the European Union. Sales to Europe account for 65% of total value of Canadian corn exports. Farmers growing these varieties were asked to check with their buyer before delivering, and if they were not willing to take the corn, the farmers were responsible for finding another buyer that would accept the corn for domestic feed/food use. The onus was thus placed on farmers to protect the valuable export market.*



Hormone beef situation with Europe - There are some markets where consumer rejection is a bigger factor than regulatory or legal barriers. In the late 1980s Europe banned beef produced using certain synthetic hormones. Canada contested this decision at the World Trade Organization and, after many years, got a favorable decision. Europe, however, decided to pay the penalty for maintaining the non-tariff trade barrier. In 2017, Canada dropped the trade challenge and under CETA obtained market access for 50,000 tonnes of hormone treated beef annually. In spite of generous market access, less than one percent of Canada's beef exports go to Europe.

The proposed regulatory guidances would prevent farmers from having full confidence about the gene edited status of their seed. The proposed creation of a category of unregulated, non-novel gene-edited seed and plants that are not subject to mandatory disclosure would unfairly place all the risks of market rejection on farmers.

Mandatory regulation would provide certainty

Plant developers would like certainty in regard to regulation. The best way to provide this is to ensure all gene edited plants and seeds are regulated as PNTs. Companies can then include regulatory process in their planning.

The companies involved in biotechnology are large and highly profitable, and already have the capacity to deal with Health Canada and CFIA regulations. While some proponents claim gene editing will make plant development more accessible to smaller companies, this is unlikely due to the need to deal with strict and complex patent rights and licensing agreements in order to commercialize products^{xi}. If gene edited products are safe and beneficial and provide significant benefits, they should be marketable and profitable enough to support the cost of compliance with regulation. Requiring all gene edited products to be assessed by government companies will have predictability and will not need to assess whether their product triggers regulation.

Gene editing not necessarily beneficial to farmers

Gene editing is ultimately only available to large multinational seed and agro-chemical corporations because of the dynamics of intellectual property rights regimes, the existing monopoly market position of these companies and the costs of taking an edited genome from concept to final product. Companies planning to sell gene edited seed and plants would collect "economic rent" from farmers on their products by restricting access to the seed through patent rights, and through their ability to use gene edited plants and seeds as a platform to sell profitable related products such as proprietary herbicides, fungicides, and fertilizer formulations. This dynamic creates dependency on a system of purchased seed and inputs that accelerates the transfer of wealth from farmers to corporations.

The business model for gene edited plants has not changed since the introduction of the first genetically engineered herbicide-tolerant products. They not only provided Monsanto with revenue from annual seed sale royalties, but also from sales of their brand-name herbicide. Once genetically engineered and patented traits were introduced to canola, and following the Percy Schmieser patent infringement case, access to conventional seed plummeted and the cost of canola seed rose dramatically, to the extent that today there is virtually no non-GM canola seed on the market. A regulatory framework that fast-tracks gene edited products is likely to have a similar result, increasing seed prices and significantly reducing access to non-gene-edited seed for a wider range of crop kinds.

When genetic engineering was first developed, we saw many of the same promises of cheaper food for consumers, less pesticide use, better nutrition, and beneficial agronomic qualities, as we see today with those promoting gene editing technology. Yet, in reality, genetic engineering has provided limited traits, and adoption



of genetically engineered crops increased pesticide use, accelerated pest adaptation to herbicides and insecticides, increased farmer costs, and did not improve food flavour or nutrition. 100% of transgenic crops on the market in Canada are herbicide tolerant, and many are also insect resistant. Globally, nearly all GM acres are planted to corn, soy, cotton or canola and are located in only a handful of countries.^{xii} Meanwhile, in the 25 years since GMOs were introduced, Canada has lost over 30 percent of our farmers^{xiii}, farmers costs have gone up, and net farm incomes have remained stagnant.

The proposed regulatory guidances would disproportionately benefit large corporations that already hold monopoly positions in the global seed and agrochemical markets. Allowing them to put gene edited PNTs onto the market quickly and without government safety oversight or mandatory disclosure of the technology used would intensify their market power, allowing them to demand even higher royalties, and higher prices for crop inputs.

Policy makers also need to recognize that conventional plant breeding is able provide benefits to farmers, consumers and the food system that equal or exceed the promises made by proponents of gene editing. By using traditional methods, plant breeders develop varieties that maintain mechanisms of resilience conferred by millennia of evolution while offering diversity of traits that respond well to our changing agro-ecosystems. Using seed developed through conventional plant breeding techniques preserves farmer autonomy and flexibility, allowing space for farmer-driven innovation to occur on farms in response to the specific problems farmers encounter all across Canada's diverse farming geography.

The farmer is the foundation of the food system. When we have more autonomy, and can retain the benefit from the crops we produce on our farms and in our communities, we can contribute more to the well-being of our society. When our incomes and autonomy are increasingly constrained by powerful corporations, farmers experience ever greater economic and psychological stress, and rural prosperity and social cohesion declines.

Government has a mandate to protect

Canada's federal regulatory policy articulates the government's duty to "ensure that regulations result in the greatest overall benefits to current and future generations of Canadians" and that in carrying out this duty, departments and agencies must ensure they protect and advance the public interest and support good government, by protecting the health, safety, security, social and economic well-being of Canadians, and the environment; that the regulatory process is modern, open, and transparent; decision-making is evidence-based; and that regulations support a fair and competitive economy.^{xiv}

The proposed regulatory guidances in regard to plants and seed developed using new genetic technologies do not embody these principles.

Decision needed

The Ministers of Health and Agriculture and Agri-Food Canada are able to safeguard these important democratic values by ensuring Health Canada and CFIA revise the proposed regulatory guidances to ensure all gene-edited plants and seed are subject to government safety assessment, identified as Plants with Novel Traits, and mandatorily listed for the public to ensure transparency.



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- ⁱ Food and Drug Regulations Division 28, Novel Foods https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-54.html#h-574622
- ⁱⁱ Seeds Act Regulations, PART V, Release of Seed https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._1400/page-13.html#h-511799
- ⁱⁱⁱ Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks, Christoph Then with Lucy Sharratt www.testbiotech.org | www.cban.ca | March 2022 https://cban.ca/wp-content/uploads/New_GE_unintended_effects.pdf
- ^{iv} Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks, Christoph Then with Lucy Sharratt www.testbiotech.org | www.cban.ca | March 2022 https://cban.ca/wp-content/uploads/New_GE_unintended_effects.pdf
- ^v Cibus is on track to launch SU Canola into Canada in 2017, Western Producer, March 3, 2016. <https://www.producer.com/news/cibus-is-on-track-to-launch-su-canola-into-canada-in-2017/>
- ^{vi} Cibus Launches New Seed Brand Falco™, Bringing Change and Choice to North American Canola Growers, Cision News Release distribution service - News provided by Cibus, Jan 31, 2019, 17:11 ET <https://www.newswire.ca/news-releases/cibus-launches-new-seed-brand-falco-tm-bringing-change-and-choice-to-north-american-canola-growers-873752619.html>
- ^{vii} Cibus' canola, the mysterious origin of the mutation, par Eric Meunier, 29 september 2020, <https://www.infogm.org/70547-cibus-canola-mysterious-origin-of-mutation?lang=fr>
- ^{viii} The Organic Food Market in Canada and Its Global Influence , EDC Economics Research and Analysis Department, November 2020. <https://www.pivotandgrow.com/wp-content/uploads/2021/01/canada-organic-report-2020.pdf>
- ^{ix} Japan finds GMO in Canadian flaxseed shipments, by Reuters Staff, November 16, 2009 <https://www.reuters.com/article/canada-us-trade-gmo-flax-idCATRE5AF10020091116>
- ^x Marketing of corn hybrids not approved for use in Europe, Joint statement from Ontario Agri Business Association and the Grain Farmers of Ontario, April 21, 2020 <https://www.oaba.on.ca/files/cornhybrids.pdf>
- ^{xi} Patents on Genome Editing in Canada, CBAN Fact Sheet, March 2022 <https://cban.ca/wp-content/uploads/Patents-on-Genome-Editing-cban-March-2022.pdf>
- ^{xii} GMO Inquiry: Where in the World are GM Crops and Foods? Canadian Biotechnology Action Network (CBAN), 2015. <https://cban.ca/wp-content/uploads/where-in-the-world-gm-crops-foods.pdf>
- ^{xiii} Census of Agriculture, Number and area of farms and farmland area by tenure, Census of Agriculture historical data, 1921 to 2016
- ^{xiv} Cabinet Directive on Regulation, Treasury Board of Canada Secretariat. <https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/cabinet-directive-regulation.html>

