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National Farmers Union commentary on the Canadian Food Inspection Agency's proposal for the regulation of gene-edited plants

Summary

The Canadian government is now in the process of deciding how to regulate plants developed using new technologies known as "gene editing" or "genome editing". Gene editing is a relatively new set of genetic engineering techniques used to alter the DNA of plants, animals and micro-organisms to change their phenotype (observable characteristics).

The Canadian Food Inspection Agency (CFIA) is responsible for regulating genetically modified plants (GMOs) for environmental safety. It does this under the authority of the *Seeds Regulations - Part V*, which sets out the criteria for whether plants are considered "Plants with Novel Traits" (PNTs) and if so, how they are regulated.[1] Currently, all genetically modified plants are subject to Part V and must be approved by the CFIA before they can be put on the market. The CFIA is proposing a change to how it interprets this regulation so that most new plants created by gene editing will become exempt from Part V of the *Seeds Regulations,* allowing them to be released into the environment (that is, planted) without any regulatory oversight or notification. As a result, companies could sell these products without providing any data to the CFIA, nor notifying the regulator, the public, or farmers that they are gene edited.

Health Canada is responsible for food and feed safety, and must evaluate and approve PNTs used for human food or animal feed, and notify the public before they can be sold in Canada. Both Health Canada and the CFIA are proposing new "regulatory guidance" documents focussing on PNTs developed through gene editing technology. A regulatory guidance does not change the regulation, but it tells the regulators how to interpret it when they apply it to individual cases. **A regulatory guidance should help people or companies understand what they need to do to comply with the regulation; it should not change the intent of the regulation.**

Health Canada held a consultation on its proposed guidance relating to the regulation of gene edited foods in April and May 2021 (see the National Farmers Union submission here), and plans to report on what was heard in the fall of 2021.

The CFIA's proposed guidance would allow plant developers (biotechnology companies) to decide for themselves whether their product meets the CFIA's criteria for regulation as a PNT. It proposes to exempt from regulation genetically engineered plants that do not contain foreign DNA if they are not expected to result in any of four environmental impacts the CFIA lists. In addition, the proposed criteria would exempt some genetically engineered plants that have a trait previously approved by the CFIA, even if the approved trait was in another plant species or developed using different technology.

Ongoing CFIA approvals therefore progressively eliminate "novelty" and expand the grounds for exemption. Furthermore, the guidance proposes to allow plant developers to request official CFIA letters to confirm their product is exempt from regulation, and that these letters could be kept confidential. Such letters could be used to set precedents for plant developers to avoid regulation in other countries, or could be used to advance private commercial deals. Instead of providing a transparent safety assessment to protect the public interest, by offering these letters the CFIA would be providing a service to private corporations in secret.

Regulation is an element of our democratic governance system. Regulation puts boundaries around the activities of individuals and companies through a publicly accountable process. Regulatory authority is both enabled and limited by laws passed in Parliament. Regulations are developed and implemented by civil servants accountable to their department's Minister. Regulations in accordance with legislation come into effect only after the relevant Minister or Cabinet as a whole approves them. Thus, there is a direct line of accountability between regulations and Canadians through Parliament.

Both the CFIA and Health Canada present the current discussion around regulation of genetically modified plants as a safety issue, when in reality, it is an issue of power. The regulatory guidances that the CFIA and Health Canada are proposing both significantly shrink the public regulator's role and expand the scope of private companies' ability to act without restraint. It can be argued that the proposed regulatory guidances are not consistent with the regulation, and that Health Canada and the CFIA are overreaching their authority by using regulatory guidances to change the intent of the regulation. These proposed regulatory guidances create pathways for progressively reducing public oversight and expanding the unregulated introduction of genetically engineered plants, particularly those produce through gene editing. The purpose of Part V of the Seeds Regulations is to regulate the introduction of novel plants, not to deregulate them. Consultation discussion documents[2] present an uncritical view of gene editing technology, minimizing risks, yet both its newness and its potential to make so far unimagined changes to plant genomes means that careful, well-informed public oversight of its application is needed.

A tiny number of multinational corporations have control of gene editing technology via the patents they hold: Corteva holds exclusive patents to key CRISPR/Cas technologies. ChemChina (Syngenta), Bayer, BASF also have numerous important patents relevant to gene editing. These four companies not only control over 60% of the world's seed market, but they are also dominant in pesticides, other chemicals and pharmaceuticals. They are accountable to their shareholders, and their duty is to increase shareholder value by maximizing profit.

The proposed regulatory guidances would enhance the power of Corteva, ChemChina, Bayer, BASF and other major seed and chemical companies to shape the future of Canada's agriculture and food system in their own interests. By providing these companies with tools to increase their ability to profit from seed, chemicals and the work of farmers who grow the food and manage the farms, the federal government would be enabling these corporations to become even more powerful while foreclosing on the ability of future regulators and policy-makers to intervene in the public interest.

Information about how to participate in the CFIA's consultation is included at the end of this document.

What is gene editing?

The purpose of new genetic technologies used in plant breeding is to create new varieties. Gene editing proponents highlight the power of the technology to make radical changes to plants not only faster, but also which are not possible through traditional plant breeding methods. Gene editing can also be used to change the DNA of animals (including humans), fungi and single-celled organisms. Gene editing, also called genome editing, uses techniques such as CRISPR/Cas to change DNA at a specific target on the plant, animal or microbe's genome. The genome is the complete set of genes or genetic material present in a cell or organism. CRISPR is the most well-known gene editing tool today, but new, even more powerful gene editing tools are being developed.[3]

Gene editing technology can be used to change the function of a plant's own DNA by either silencing or forcing the expression of specific genes, removing genes, and/or changing the location of genes within the genome. It can also be used to add new genetic sequences at specific locations. It is expected that many gene-edited plants will be produced by using an "editor" sequence comprised of "foreign DNA" (originally found in another organism) to alter the plant's own DNA and then removing the "editor" DNA after it has made changes to the genome. In spite of being changed by this process, the plant's now-rearranged DNA is not considered "foreign" even though it has been changed in ways not possibly through natural biological reproduction.

With gene editing, plant developers can make changes to specific sites in a plant's genome, but they do not have complete control over the results. Cells "read" DNA instructions that direct them to produce specific proteins. DNA "words" consist of series of molecular base-pairs arranged in a specific order in the spiraling DNA molecule. Gene editing technology breaks apart existing sequences at the target site in the genome and relies on the cell's own repair mechanism to knit the DNA molecule back together, either with a new sequence added or an existing sequence removed. The process does not always behave as predicted. The gene editor may change other parts of the genome as well, resulting in "off-target effects". The changes to the target site may also result in unintended effects, referred to as "on-target effects". The gene editing process may cause the cell to rearrange its own DNA – scrambling the genetic "words" and giving them new meanings. It may result in large amounts of DNA being erased, removing whole "paragraphs" from the book, or many duplicate sequences may be inserted, adding new "paragraphs". Some of the foreign DNA gene editing tools used to direct and cut DNA may also incorporate themselves unexpectedly into the plant's original DNA. Many of our important food crops, such as wheat and corn are polyploid – they have multiple pairs of chromosomes, increasing both their genetic complexity and the opportunity for gene editing errors.

As we saw in summer 2021's extreme heat and drought, stress can cause plants to express atypical characteristics such as earlier maturity, shorter height, fewer seeds in cereal crops and in biennials such as carrots and beets, going to seed in their first year – even when they have not been genetically engineered. New research in the area of epigenetics – the intergenerational effects of environmental stresses on gene expression – is showing that organisms can inherit changes caused by parents' experience without changing its DNA. Emerging scientific knowledge about epigenetics could have important implications for understanding risks and complex outcomes of gene editing over time.

In short, full knowledge about gene editing does not yet exist, the plant developer does not have complete control over the actions of the genetic material used to change the plant's genome, and the plant's response to changes in its genome are not entirely predictable. What may seem like small changes in the sequence of genes may cause the plant to "read" its DNA in a new way, causing it to produce unpredicted proteins, turn on normally "silent" genes, and silence genes that are normally expressed. These unpredicted proteins and unexpected expression or silencing of genes may affect the engineered plants' environmental impact, and may affect the plants' physiology generally, or when stressed in particular ways.

Even when the gene editing process results in exactly the changes plant developers intend, the point of using gene editing technology is to create a new genome that did not exist before, to do it quickly, and in many cases, to change parts of the genome that conventional, non-genetic engineering breeding techniques do not affect. There is not a one-to-one correspondence between genes and proteins or traits – there is still much that is not known about the relationship between DNA and individual cells and whole organisms. Thus, a full inventory of the genome sequence of gene-edited plants cannot provide full knowledge of how the altered genes will function in the living organism.

What would the proposed CFIA guidance change?

The CFIA proposes to exempt most new plants created by gene editing from Part V of the *Seeds Regulations*. Exempt plants may be released into the environment (that is, planted) without any regulatory oversight or notification.

The current regulatory guidance states that "PNT status is determined by the presence of a novel trait in a plant, **irrespective of the method used to introduce it**."[4] [emphasis in the original]

In the proposed guidance, gene-edited plants would be covered by Part V only if they are species that have never been grown as a crop in Canada before, or if they contain foreign DNA, or if they have a trait that would likely cause any of four environmental impacts listed in the regulation:

1. make it more difficult to control by removing a management option;
2. introduce or enhance a toxin, allergen, or other compound that could negatively affect non-target organisms in the environment;
3. improve its survival in the wild enough to become an invasive weed; or
4. would cause or enhance a plant pest or create a reservoir for a plant pest (any species, strain or biotype of plant, animal, or pathogenic agent injurious to plants or plant products).

The proposed guidance would exempt gene-edited plants when product developers determine that their new traits did not cause any of the above four impacts and if the foreign DNA used to introduce these novel traits is subsequently removed.

For the purpose of regulation, the newness or "novelty" of a plant hinges on the concept of "substantial equivalence" which the CFIA defines as having "no meaningful difference in the specific use and safety of the plant compared to plants of that species that have been grown in Canada." Decisions made using substantial equivalence cannot be verified scientifically, as the concept is based on assumptions and subjective criteria that are neither defined nor made public.

Under the proposed guidance, new plants with traits deemed substantially equivalent to plants previously approved without conditions will be exempt from Part V. As time goes on, fewer and fewer gene-edited plants will be covered by Part V. Past approvals of plants OR traits will be considered adequate to support environmental release of new plants without further review, even when the trait in question is introduced into a different species from that of the original approval.

The CFIA has previously approved GMOs that have caused the negative environmental impacts that are supposed to trigger regulation: herbicide tolerant crops (for example, RoundUp Ready) have reduced weed management options and accelerated the evolution of herbicide resistant weeds; insect resistant (Bt) crops have promoted the evolution of Bt-resistance in plant pests such as corn rootworm, and have had negative impacts on non-target species; herbicide tolerant crops have increased potential to become invasive in natural ecosystems.[5] Since gene-edited plants with these traits would also be considered "substantially equivalent" to previously approved GMOs, there is a severe lack of clarity as to whether these negative environmental impacts would actually trigger regulation under Part V.

It is up to plant developers to determine whether their new gene-edited plant is subject to Part V. There is a strong incentive for them to minimize potential environmental risks and to be lax in their efforts to detect any foreign DNA that might have become incorporated into the edited genome, in order to avoid the costs going through the regulatory process. If they believe their product is exempt, they may request an official letter from the CFIA to confirm the exemption. The CFIA's consultation survey asks whether these letters should be made public. If they are kept confidential, the CFIA would be performing a private service in secret for the benefit of seed developers seeking an official declaration that their product is not subject to Canada's regulations, while denying the public the ability to know whether the plant is gene edited.

The CFIA may disagree with the plant developer and determine that the plant is subject to Part V after all. The proponent has recourse appeal this decision if it disagrees. In contrast, if members of the public disagree with a CFIA decision, they have no recourse.

For the complete text of the proposed CFIA guidance, click here.

What are the issues?

Lack of public debate

The NFU's long-standing policy on genetically engineered foods states that "all Canadians—farmers and non-farmers alike—must engage in an informed debate on the genetic modification of food. Citizens must examine genetically modified (GM) food in the largest possible social, historical, environmental, economic, and ethical context. After that debate, citizens—not the corporations that promote these products—must decide whether to accept or reject GM food." (Read the complete policy here).

During the development of the proposed regulatory guidances, the CFIA and Health Canada held at least eight meetings with the biotech and pesticide lobby group CropLife Canada, and several additional meetings with "stakeholders" that included CropLife. In January 2020, Health Canada established a

government-industry working group with representatives from CropLife Canada, the Canadian Seed Trade Association (now Seeds Canada) and the Canada Grains Council (which has CropLife's President and CEO as its vice-chair), with CFIA representatives as observers, to inform development of its regulatory guidance.[6] Both Health Canada and the CFIA actively sought the advice of the companies it regulates, and designed the proposed guidance documents according to the industry's priorities.

Gene editing is powerful new genetic engineering technology that has the potential to be disruptive to Canada's food and agriculture system. How, where, and in whose interest the techniques might be used, are matters that concern all Canadians, not just product developers. The CFIA consultation, and the recently closed Health Canada consultations do not provide an opportunity for a full and meaningful public discussion. The proposed guidance would foreclose on the possibility of Canadians having the needed public dialogue about gene-edited plants before they are introduced into our food and agriculture system.

Not science-based

The CFIA claims to use a science-based decision-making process. Its emphasis on science appears to be less about its dedication to science than a justification for maintaining a narrow focus on technical matters in order to exclude legitimate and valid public concerns about its decisions' broader implications. In the proposed regulatory guidance, the CFIA undermines its claims to science-based regulation in several ways. By exempting gene-edited plants on the grounds that they do not contain foreign DNA the CFIA is equating the absence of foreign DNA with absence of risk. This approach ignores a basic tenet of science: that science is continuously creating knowledge and new research reveals new understandings. The government vigorously promotes innovation, yet with the proposed guidance, the CFIA firmly rejects any scientific curiosity about the known or future impacts of such innovations.

The proposed exemption of gene-edited plants that do not contain foreign DNA or which are "substantially equivalent" to previously approved PNTs would deny public access to information about these genetically engineered plants and make it impossible for CFIA to seek information needed to evaluate their long-term effects on the environment. The expanding regulatory exemptions release the CFIA from this duty, and put the burden, costs and risk of future impacts onto farmers and the general public by default.

The proposed guidance also unscientifically assumes knowledge about the future with its exemptions of gene-edited versions of plants with previously approved traits. It assumes all outcomes that are possible with gene editing fall within the range of outcomes that are already familiar to CFIA regulators. This exemption also lumps together a wide range of specific genetic changes that result in the "substantially equivalent trait" but has no scientific curiosity about potential unintended genetic changes that result in characteristics (or undocumented traits) that in reality become part of the plant's phenotype, that is, part of its observable characteristics when grown under a range of conditions in the environment.

The proposed guidance relies on private companies to determine whether their product is subject to the regulations, so there is no transparency as to what, if any research supports their decisions. The CFIA thus cannot evaluate the company's conclusions. If a company decides its product does require CFIA approval, the CFIA merely reviews the company's own data package. Information submitted for

regulatory approvals is considered confidential business information and cannot be released under the *Access to Information Act*. Denying public access to data is unscientific, as the process of science is based on openness. Science advances through peer review of studies, replicating experiments and applying new ideas to test past conclusions. By protecting and promoting secrecy of the data used to support approvals and commercialize products, the CFIA contradicts its stated commitment to science-based decision-making.

Foreseeable harm to sensitive markets

New genetic technologies are controversial. There are sensitive markets where gene-edited plants are not accepted by consumers and/or where national regulations require rigorous government approvals. Not all countries have finalized their regulatory approach to gene-edited plants. The CFIA's proposed regulatory guidance would exempt many gene-edited plants not only from any environmental assessment, but also from any public notification requirements. There would be no transparency as to whether a new variety grown in Canada was the product of gene editing. For sensitive markets, this could result in rejection of Canadian exports of crops that are known or suspected to include gene-edited varieties. When Canadian flax was contaminated with the deregistered GMO flax variety Triffid, all flax farmers, regardless of whether their seed was contaminated, suffered losses due to widespread market rejection and the costs of rehabilitating the flax seed supply. A similar situation is foreseeable as a result of exempting many gene-edited plants from Canada's regulations.

International standards for certified organic production prohibit the use of gene-edited plants.[7] Without public notification of all gene-edited varieties, organic farmers risk inadvertently planting prohibited seed and potentially contaminating organic bulk shipments. This would harm the individual farmer, the farmers whose grain was admixed with the prohibited variety, and potentially all farmers growing that crop if there was widespread rejection in important markets.

Cross pollination of conventionally bred crops with gene-edited varieties is another route for contamination and market loss. While the CFIA guidance includes consideration of gene flow as a factor in determining whether a new plant should be regulated, history shows that the CFIA does not consider the impacts of this this risk on farmers whose livelihood would be affected. GM alfalfa was approved even though the CFIA was fully aware that alfalfa is an outcrossing, insect-pollinated crop and that feral alfalfa growing in ditches, old hay fields, and on other non-agricultural land that would be a vector for uncontrolled gene flow. Since GM alfalfa has been approved, a gene-edited alfalfa variety that does not contain foreign DNA or with traits deemed substantially equivalent to the approved glyphosate resistant and/or low lignin alfalfa would be exempt from Part V under the proposed guidance.

Patents intensify corporate control

Gene-edited plants will be covered by patents. Seed of gene-edited crop varieties will be patent protected in the same way that other genetically engineered crops are today. Gene editing will likely be used to introduce new traits into a wider variety of crop kinds, including cereals such as wheat, barley and rye, as well as flax, camelina, potatoes, horticultural crops, and pulses such as peas, beans and lentils. Gene-edited varieties of these crops would be patented, requiring farmers who grow them to buy seed annually and pay royalties to the patent holder. Using farm saved seed of gene-edited varieties would be prohibited.

The ownership of gene editing related patents is highly concentrated. Corteva, the company made up of the former agriculture divisions of Dow and DuPont, was the first company licenced to use CRISPR/Cas9 for crops and it holds exclusive intellectual property rights for CRISPR/Cas technology applications in major crops as well as nonexclusive rights in other agricultural applications. Corteva has established a "patent pool" to control access to and use of CRISPR/Cas technologies through confidential licensing agreements with other companies. Syngenta, owned by ChemChina, also has many patents for gene-edited plants. The foundational patent holders license the technology to researchers for free, but any commercial application of the technology such as selling seed, is subject to conditions and royalties.

Some patent applications for gene-edited products are worded so broadly that they blur the distinction between gene editing and conventional breeding. There is concern that these patents could encompass conventionally bred varieties with the same or similar characteristics to those developed through gene editing. This ambiguity may be designed to allow gene editing patent holders to claim patent rights to the conventionally-bred varieties as well.[8] The overly-broad reach of some gene editing related patents combined with the lack of transparency as to whether a variety is gene-edited means farmers may be at greater risk of being sued for patent infringement if they unknowingly use seed covered by a patent.

Conclusion

The CFIA's proposed regulatory guidance would allow many plants produced using gene editing to be field tested and released into the environment with no regulatory oversight. It would eliminate access to the public documentation needed for independent researchers to investigate these plants' impacts on the environment or the food supply.

The regulatory framework adopted for regulating gene-edited regulation will also set the stage for the regulation of gene-edited microbes and animals (via the Canadian Environmental Protection Act) for a wider range of uses as food, bio-reactors, bio-chemical factories, soil additives, etc. While we have not discussed it in this paper, the proposed guidance is also covers gene edited trees, which is clearly outside of both the CFIA's expertise and the intent of the Seeds Regulation. Thus, the implications of the CFIA's proposed pathway to deregulation has implications that go beyond agriculture and food.

The absence of public regulation via exemption from Part V has the effect of privatizing the regulation of gene-edited seed: companies will use patents and licences to control access to the technology and police the use of these seeds. Unless tightly regulated, companies will pursue their own commercial interests without regard for broader societal consequences.

As a public regulator, empowered by laws and regulations passed by democratically elected Members of Parliament, the CFIA is accountable to the public, not to the companies it regulates. It has a duty to protect the public interest. The proposed regulatory guidance seeks to absolve the CFIA of its responsibility by creating a mechanism to progressively reduce and minimize its oversight of genetically engineered seed. This is contrary to the intent of the regulations itself, and thus should be rejected. All genetically engineered plants, including those developed using gene editing technology, must be subject to regulation under Part V of the *Seeds Regulations*.

Public Consultation – how to participate

The public consultation on the CFIA's proposed regulatory guidance is open until September 16, 2021. It takes the form of an online questionnaire. The Canadian Biotechnology Action Network (CBAN) has produced a useful guide to the questionnaire to assist members of the public to provide meaningful input. Click here to download the CBAN guide, then click here to complete the CFIA questionnaire or send an email to the Plant Biosafety Office at PBO@inspection.gc.ca .

References:

[1] Seeds Act Regulations, Part V https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._1400/page-20.html#docCont

[2] Share your thoughts: Guidance for determining whether a plant is subject to Part V of the Seeds Regulations, CFIA https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/eng/1619740964754/1619741042405

[3] Other gene editing technologies include Oligonucleotide directed mutagenesis (ODM), Zinc finger nuclease technology, Meganucleases, Cisgenesis, Grafting on a transgene rootstock, Agro-infiltration, Reverse Breeding, and Synthetic Genomics.

[4] Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits, https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/eng/1512588596097/1512588596818#a1

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