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National Farmers Union submission to
Canadian Food Inspection Agency consultation
on guidance for determining
whether a plant is subject to Part V of the *Seeds Regulations*

The NFU is a voluntary direct-membership, non-partisan, national farm organization made up of thousands of farm families from across Canada who produce a wide variety of food products, including grains, livestock, fruits and vegetables. Founded in 1969, the NFU advocates for economic and social policies that advocate for the right of peoples to produce and consume healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and their right to define their own food and agriculture systems. The NFU is a leader in articulating the interests of Canada's family farms, in analyzing the farm income crisis, and in proposing affordable, balanced, and innovative solutions that benefit all citizens. NFU policy positions are developed through a democratic process at regional and national conventions.

The NFU's members are active farmers who have a vital interest in seed, whether they sow seeds directly as crop farmers, or rely on seed planted by other farmers and grown for livestock feed or forage. The proposed regulatory guidance clearly affects farmers, yet the CFIA's consultation process was timed to occur during the growing season when farmers are least available to study regulatory documents and prepare comments. In April, the President of the NFU twice requested the CFIA to delay the consultation, but was refused. The only accommodation was to extend the public review period from 90 to 120 days; however, most farmers are still busy with harvest as of the mid-September deadline.

In spite of the timing, we have carefully reviewed the consultation documents and offer the following comments. The NFU also endorses and reiterates the responses to the CFIA's online questionnaire submitted by the Canadian Biotechnology Action Network (see https://cban.ca/wp-content/uploads/CBAN-response-CFIA-consultation-questionnaire-2021.pdf).

The Canadian Food Inspection Agency (CFIA) is responsible for regulating genetically modified plants (GMOs) for environmental safety 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 authorized for unconfined environmental release and put on the market. The CFIA is proposing a new "regulatory guidance" focussing on PNTs developed through gene editing technology, which would change its interpretation of this regulation in order to exempt from Part V of the *Seeds Regulations* most new plants created by gene editing, allowing them to be released into the environment without any regulatory oversight or notification. The proposed guidance also means that the CFIA will have no access to any data about exempted gene edited plants.

A regulatory guidance does not change the regulation itself; it tells the regulators how to interpret the regulation when applied 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. The purpose of Part V of the *Seeds Regulations* is to regulate the introduction of novel plants, not to deregulate them. The proposed guidance creates a mechanism to progressively reduce public oversight and expand the unregulated introduction of genetically engineered plants, particularly those produced through gene editing. Thus, it can be argued that the CFIA is overreaching its authority by using regulatory guidance to change the intent of Part V of the *Seeds Regulations*. On these grounds alone, the proposed guidance should be withdrawn.

What the proposed CFIA guidance would 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 without any regulatory oversight or notification. The CFIA would not be provided with any data on exempt plants.

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**."[2] [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 foreign DNA (the gene editor sequences) used to introduce these novel traits is subsequently removed. However, the CFIA deems a

wide range of changes to a plant's DNA to be "within the genome", including DNA deletion of any size; loss or gain of gene function through deletion of regulatory elements; rearrangement of DNA sequence location; any multiplication of any sequence, genes, or entire chromosomes; insertion or edit of any DNA sequence derived from the gene pool by adding or replacing a gene from a related plant; random insertions generated through DNA repair mechanisms. It is clear that these are significant changes to the genome, but would not trigger assessment under Part V under the proposed guidance.

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 PNTs 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. 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 it should be mandatory for these exemption status letters to 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 would know, but would not be able to disclose to the public, that certain plants were developed using gene editing technology. If CFIA-confirmed exemptions are published as "non-PNTs" without revealing that the plant was developed using gene editing technology, it implies they are not products of genetic engineering. This would be both misleading and contrary to the CFIA's stated value of transparency.

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. This inequity unfairly prevents Canadian citizens from holding our public regulator accountable.

The regulatory guidance that the CFIA is proposing significantly shrinks the public regulator's role and expands the scope of private companies' ability to act without restraint. The CFIA's consultation discussion documents 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.

Outcomes of gene editing technology are not fully understood

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 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.

The proposed guidance's narrowed interpretation of "novel" is based on assumptions rather than evidence, and would create a pathway for product developers to avoid safety assessment even though such new genetically modified plants would have no history of safe use as a food.

Proposed guidance is not science-based

The CFIA's vision is "to excel as a science-based regulator, trusted and respected by Canadians and the international community." Yet the proposed regulatory guidance undermines its claims to science-based regulation in several ways and thereby damages public trust in both the food system and the regulator. By exempting gene-edited plants on the grounds that they do not contain foreign DNA, the CFIA equates the absence of foreign DNA with absence of risk. However, science is continuously creating knowledge and new research reveals new understandings. The government vigorously promotes innovation, yet the proposed guidance provides no space for applying scientific curiosity about 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 improperly release the CFIA from this duty, and unjustly puts 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 by exempting gene-edited 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 criteria 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 unexpected 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 assumption that the CFIA already knows all it needs to know about yet to be developed gene edited plants, and can thus approve them in advance is irresponsible in the extreme.

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 and undermines public trust in both the regulator and the regulated plants.

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 genetically engineered 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. More recently, the Grain Farmers of Ontario, Ontario Agri Business Association, and Seeds Canada have warned farmers about several genetically engineered corn varieties being sold in Canada that are not approved for the European market. The onus for protecting this market and avoiding another Triffid Flax situation is now on individual farmers -- even though this risk could have been prevented by delaying approval of these varieties until they were accepted by Europe, or by at least warning farmers of these facts before they purchased seed. All Canadian corn farmers are affected by price discounts that result from this increased risk of market loss due to contamination.

International standards[3] for certified organic production, as well as the Canadian Organic Standard[4], prohibit the use of genetically engineered plants, including those developed using gene-editing technology. 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, CFIA has not considered the impacts of this this risk on farmers whose livelihood would be affected. Genetically engineered 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 genetically engineered alfalfa has been approved as a PNT, 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.

The Canadian public in general, and Canadian farmers in particular, should not be faced with unknown and unidentified products of gene-editing that have not been assessed for environmental release by the CFIA. The proposed regulatory guidance would make it possible for plant developers to market gene-edited varieties to farmers without revealing they were products of this technology. Another Triffid situation would be virtually inevitable.

Duty to regulate in the public interest

The CFIA's statement of values includes "We maintain our regulatory independence from all external stakeholders. We have the courage to make difficult and potentially unpopular decisions and recommendations, free from personal bias."

Documents posted on the Health Canada website indicate that the CFIA was included as an observer in the Health-Canada/Industry *Working Group to inform the Development of Guidance for the Novel Food Regulations, focussed on plant breeding* which was established to "inform the development of draft guidance for the Novel Food Regulation, focussed on plant breeding in advance of the official consultation." Its members were senior staff at Health Canada and representatives from the CropLife Canada, Canada Grains Council, and Canadian Seed Trade Association (CSTA). CropLife and the CSTA are national lobby groups that represent the regulated parties – seed developers seeking to commercialize gene-edited crops. Canada Grains Council membership includes CropLife and the CSTA (now Seeds Canada) and companies such as Bayer, Syngenta, BASF, that are also members of CropLife and CSTA, and it has the Vice-Chair of CropLife Canada on its Board. The biotechnology companies these associations represent will be the main beneficiaries of a guidance that excludes gene-edited plants from government safety assessments and public disclosure. It appears that key aspects of the proposed guidance, such as voluntary pre-market disclosure and excluding modifications "within the gene pool" (absence of foreign DNA) from triggering regulation under Part V of the *Seeds Regulations*, were requested by these industry groups and have been incorporated into the CFIA regulatory guidance as well as in Health Canada's proposed guidance. This leads to the strong impression that the proposed regulatory guidance has been developed in the interests of the regulated parties and that the broader public interest has not been given due consideration.

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 absolves 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 Part V of the *Seeds 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*.

The results of gene-editing are not knowable in advance. Scientific knowledge is constantly increasing through a constant process of investigating, testing and disproving hypotheses, publishing results and designing new experiments. Gene editing technology is new and powerful, the changes it can make to genomes -- even "within the genome" -- are significant. The products of gene editing will be living organisms that can reproduce independently. A regulatory approach that says "we don't need to know" before any gene-edited products are put on the market is fundamentally unscientific. A regulatory guidance that denies the regulator any ability to assess, review and regulate most new gene edited plants is the opposite of responsibility. To also create a mechanism that allows these products to be marketed without identifying them as being developed through gene-editing is the opposite of transparency.

NFU recommendations:

All genetically engineered plants, including those developed using gene-editing technology, should be regulated as PNTs and therefore subject to Part V of the *Seeds Regulations*. This would ensure the CFIA maintains its ability to regulate genetically engineered seed in the public interest.

The NFU also reiterates the comments submitted to this consultation process by the Canadian Biotechnology Action Network, which can be found at https://cban.ca/wp-content/uploads/CBAN-response-CFIA-consultation-questionnaire-2021.pdf

The NFU appreciates the opportunity to provide comments to assist the CFIA in making informed decisions on critically-important issues. The NFU welcomes dialogue and encourages CFIA staff to contact us should we be able to clarify or provide any further information on the topic.

All of this respectfully submitted by
The National Farmers Union
September 15, 2021

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