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National Farmers Union submission to Health Canada regarding public consultation on Proposed new guidance for Novel Food Regulations focused on plant breeding

The National Farmers Union (NFU) is pleased to assist Health Canada by providing comments on the proposed new regulatory guidance in regard to foods derived from plants developed through new genetic technology (gene-editing or genome editing) and in regard to pre-market assessment of foods derived from retransformants.

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.

We have carefully reviewed the consultation documents and offer the following comments.

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"?

Summary of proposed change

Health Canada regulates plants with novel traits under the authority of the Food and Drug Regulations. The proposal under discussion would not alter the regulation itself, but would change the "regulatory guidance" that instructs Health Canada how to interpret the regulation.

Canada's Plants with Novel Traits (PNT) approach to regulating biotechnology is unique in that the trigger for regulation is not the technology used to develop the plant, but the plant's novelty (newness). Division 28 of Part B of the Food and Drug Regulations define "novelty".

novel food means

(a) a substance, including a microorganism, that does not have a history of safe use as a food;
(b) a food that has been manufactured, prepared, preserved or packaged by a process that
    (i) has not been previously applied to that food, and
    (ii) causes the food to undergo a major change; and
(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
    (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
    (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
    (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (***aliment nouveau***)

The proposed regulatory guidance would change the interpretation of Division 28 of Part B so as to exclude most products of gene-editing from regulation. The proposed regulatory guidance would encourage plant developers to voluntarily inform Health Canada of the unregulated gene-edited products they plan to sell.

Health Canada intends to apply similar regulatory guidance to animals and microorganisms. Health Canada also states that these new pieces of guidance represent the first phase of a broader, multi-year effort to modernize guidance for all Novel Foods as defined under the Regulation.

The current interpretation triggers Health Canada safety assessment of the gene-edited plants. The current regulatory guidance defines "history of safe use" thus:

> *A substance may be considered to have a history of safe use as a food if it has been an ongoing part of the diet for a number of generations in a large, genetically diverse human population where it has been used in ways and at levels that are similar to those expected or intended in Canada. The fact that a product has had a history of use according to the above definition in a jurisdiction with a similar food safety system would increase the level of confidence in the evidence presented.*

The guidance lists the kinds of information needed to support a claim that a product has a history of safe use, and requires reliable, high quality information and reference sources. The proponent must also make this information available to consumers in a consistent manner.

Gene-editing is a powerful tool.

The purpose of new genetic technologies used in plant breeding is to create new varieties, and it allows plant developers to introduce traits that would not be possible using traditional breeding techniques. Gene-editing, also called genome editing, refers to techniques such as Oligonucleotide directed mutagenesis (ODM), Zinc finger nuclease technology, CRISPR/Cas, Meganucleases, Cisgenesis, Grafting on a transgene rootstock, Agro-infiltration, Reverse Breeding, and Synthetic Genomics. New, even more powerful gene-editing tools are also being developed, such as Retron Library Recombineering, which uses bacterial genetic constructs to generate millions of simultaneous mutations.

It is widely understood that gene-editing is a powerful tool. The primer Health Canada prepared for this consultation says:

> *Plant developers have indicated that gene editing will be used to introduce new or alter existing characteristics to improve agricultural performance, nutritional composition, and/or consumer preference of plants (Zhang et al., 2018). The ways plant developers will use gene editing tools to accomplish these objectives could involve introduction of small insertions or deletions at precise genomic sites, precise deletions of larger segments of genomic DNA, as well as insertions of whole genes and their regulatory elements in ways that would be considered rDNA (Chen et al., 2019; Zhang et al., 2018). Furthermore, plant developers have indicated that gene editing can help identify useful characteristics in regions of plant genomes that developers currently have difficulty manipulating using conventional breeding methods. As a result, gene editing has the potential to identify and improve new characteristics within the plant species not previously accessible to plant developers*. (p 12 Annex 2: A Primer on Gene editing technologies in relation to Health Canada's product-based regulatory framework for Novel Foods)

Clearly, Health Canada recognizes that plants developed using gene-editing technology, and the foods derived from them are both different from previously existing plants and produced by means of genetic engineering, and are thus "novel" according to the Regulation and the current Guidance.

The proposed guidance would not change the regulatory definition of novel foods, but would narrow the interpretation by deeming as "non-novel" those foods derived from plants with genetic modifications that

- do not change a protein into a known allergen or toxin relevant to human health; or
- do not increase levels of an allergen, toxin or anti-nutrient that is already present beyond the documented range; or
- do not have an impact on key nutritional composition and/or metabolism; or
- do not change the food use of the plant; or
- are not the result of the insertion of foreign DNA.

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.

Absence of foreign DNA is not proof of safety

Many anticipate gene-edited plants will be produced through the use of an "editor" comprised of foreign DNA, to alter DNA sequences and then remove the "editor" DNA after it has made changes to the genome.

The assumption that the presence or absence of foreign DNA determines safety, or is a major determinant of safety, is not supported scientifically

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 "paragraphs". Some of the foreign DNA gene-editing tools used to direct and cut 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.

In short, 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 food safety, and may affect the plants physiology generally, or when stressed in particular ways.

Even when the gene-editing process results in the exact result plant developers intend, the point of using gene-editing technology is to create a new genome that did not exist before, and could not have been produced using conventional non-genetic engineering techniques. There is not a one-to-one correspondence between DNA 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.

Proposed guidance contradicts the regulation

On one hand, Health Canada understands that gene-editing is a powerful new technology that can change plant genomes in significant ways that are not possible using traditional plant breeding methods; yet on the other hand, the proposed guidance assumes that the results of these genetic manipulations require no regulatory oversight as long as there are no obvious novel traits or safety issues, or no foreign

DNA is left behind. The rationale Health Canada provided for this narrowed interpretation of "novel" is based on assumptions and arguments, not on empirical scientific evidence. As such, proposed guidance thus appears to improperly contradict the intent of the regulation when Division 28: Novel Foods was adopted by Order in Council.

Regulatory guidance is properly used to interpret regulations in plain language to help to regulated parties understand and comply. In this case, the wide gap between the regulation itself and the proposed regulatory guidance raises serious questions. The wording of the proposed regulatory guidance creates an exception to the regulation by stretching the meaning of "novel" beyond the breaking point. Clearly, Division 28 of Part B of the Food and Drug Regulations defines "novel" to include all genetically engineered plants that have no history of safe use. The regulatory guidance developed by Health Canada officials contradicts the regulation approved by Cabinet. It is contrary to the rule of law for the bureaucracy to substantively change the effect of a regulation under the pretext of interpretation. The proposed regulatory guidance would, if adopted, overreach the department's authority by appropriating the power of elected Cabinet. This overreach could also result in Health Canada being liable in the event harm occurs as a result of a decision to use regulatory guidance to avoid conducting safety reviews of plants derived from gene-editing.

Who decides what is or is not novel?

The proposed guidance would rely on plant developers to assess whether they believe their new variety is "novel" according to the proposed narrow interpretation. Deeming a new plant "non-novel" releases the plant developer from the requirement to report its existence to Health Canada before putting it on the market. Section B.28002 (1) and (2) of the Food and Drug Act Regulations requires pre-market notification of novel foods as follows:

> **Pre-Market Notification**
> **B.28.002 (1)** No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food
>
> (a) has notified the Minister in writing of their intention to sell or advertise for sale the novel food; and
>
> (b) has received a written notice from the Minister under paragraph B.28.003(1)(a) or subsection B.28.003(2).
>
> (2) A notification referred to in paragraph (1)(a) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:
>
> (a) the common name under which the novel food will be sold;
>
> (b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
>
> (c) a description of the novel food, together with
>
> (i) information respecting its development,
>
> (ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
>
> (iii) details of the major change, if any,
>
> (iv) information respecting its intended use and directions for its preparation,

(v) information respecting its history of use as a food in a country other than Canada, if applicable, and

(vi) information relied on to establish that the novel food is safe for consumption;

(d) information respecting the estimated levels of consumption by consumers of the novel food;

(e) the text of all labels to be used in connection with the novel food; and

(f) the name and title of the person who signed the notification and the date of signing.

Health Canada proposes to establish a "Voluntary Transparency Initiative" (VTI) where companies may inform Health Canada when they plan to put a product they believe is non-novel onto the market. Health Canada would then examine and assess a limited "postcard" of information provided by the company. If Health Canada agrees that it is non-novel, the product would be listed on a public VTI database. If Health Canada believes it may in fact be novel, then the company would be required to submit more data for Health Canada regulators to examine, to potentially determine that the product is "novel" and thus subject to a government safety assessment.

From the company's perspective, participating in the VTI is a risk – there will be additional costs to bring its gene-edited product to market if Health Canada disagrees with their determination and requires them to adhere to the Pre-Market Notification requirements. If Health Canada aims to maximize company participation in the VTI, it has a strong incentive to agree with the company's own "non-novel" assessment. The VTI appears designed to fail both as a measure to promote transparency and as a mechanism to prevent novel gene-edited foods from escaping safety assessments under the Food and Drugs Act regulations.

Duty to regulate in the public interest

Health Canada is a public regulator with a duty to safeguard the health of Canadians.

The Health Minister's Mandate Letter reminds us that Canadians expect government "to be diligent, honest, open and sincere in our efforts to serve the public interest" and that the Ministry has a "responsibility to substantively engage with Canadians, civil society and stakeholders, including businesses of all sizes, organized labour, the broader public sector and the not-for-profit and charitable sectors. You must be proactive in ensuring that a broad array of voices provides you with advice …" The Mandate letter reiterates the government's commitment to "evidence-based decision-making that takes into consideration the impacts of policies on all Canadians …" The letter includes the expectation that the Minister will "work closely with your Deputy Minister and their senior officials to ensure that the ongoing work of your department is undertaken in a professional manner and that decisions are made in the public interest."

As a public regulator, Health Canada has a mandate to protect Canadians from unsafe food, health and consumer products. Its decisions as to whether to approve the safety and quality of new products are to be made in the best interests of Canadians and supported by scientific evidence.

Engagement with regulated parties is useful for regulators to understand technical issues and other aspects of their operating context, but this engagement should not result in our public agency regulating in the interests of the regulated parties.

Documents posted on the Health Canada website indicate that a Health-Canada/Industry *Working Group to inform the Development of Guidance for the Novel Food Regulations, focussed on plant breeding* 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 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" from safety review, were requested by these industry groups and have been incorporated into the regulatory guidance. This leads to the 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.

Proposed guidance lacks scientific evidence and transparency

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. A regulatory approach that says "we don't need to know more" before any gene-edited products are put on the market is fundamentally unscientific. 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.

The Canadian public in general, and Canadian farmers in particular, should not be faced with unknown products of gene-editing that have not been assessed for safety by Health Canada.

Canadian farmers know that when unapproved crops are rejected by markets they are the ones who pay the costs.

We have not forgotten Triffid Flax, a de-registered genetically engineered variety that contaminated seed of certain varieties and which was discovered in shipments to Europe. The cost of market loss, decontamination and efforts to rebuild our market was in the billions of dollars, and was born by all flax farmers regardless of whether their crop was contaminated.

We have not forgotten Starlink Corn. This genetically engineered variety contained a human allergen and was approved only for feed and not for human consumption. However, it got mixed into the human food stream and was found in consumer products, resulting in massive recalls and litigation. The losses from this costly, but predictable error were also borne by farmers.

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.

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 or Starlink situation would be virtually inevitable.

The Canadian Organic standard and international organic standards, as defined by the International Federation of Organic Agriculture Movements (IFOAM), prohibit the use of gene-editing technology in certified organic production. The proposed guidance, by allowing non-transparent marketing of gene-edited varieties, creates a high risk that certified organic farmers will inadvertently use these prohibited varieties. This would have consequences for individual farmers and could have a severe impact on the whole organic market for affected crops within Canada and in all export markets.

Lack of transparency resulting from the proposed guidance would also make it impossible for Health Canada to identify and recall any gene-edited product in the event it caused an unintended and unpredicted health problem in consumers. The proposed guidance appears to blindfold and handcuff Health Canada when it comes to safeguarding consumer health.

NFU recommendations:

All gene-edited products should be regulated as novel and therefore subject to government safety assessment and pre-market notification. This would ensure Health Canada maintains its ability to regulate foods derived from gene-edited plants in the public interest. It would ensure farmers have access to the information they need to make informed choices about the seed they purchase and crops they grow. Mandatory reporting prior to marketing would reduce the risk of market rejection due to the presence of gene-edited varieties not acceptable in sensitive markets, including the certified organic market. Mandatory pre-market notification would also provide Health Canada with information needed for traceability in the event it needed to carry out its responsibilities if a recall of food derived from gene-edited plants was necessary.

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).

Health Canada also proposes to change its regulatory guidance in regard to transgenic and gene-edited plants in order to reduce regulatory requirements for plants with traits and/or DNA sequences that have previously been reviewed. Health Canada contends that it is possible for plant developers to make "identical" changes to the same variety using new technology, or to a different variety by using the same technology, and even to a different variety using new technology. These "identical" plants are called "retransformants".

This proposed regulatory guidance is based in assumptions and rationales, not in empirical evidence. It claims that any unintended genetic effects that result from introducing the same genetic sequence into a new plant variety, or introducing the same trait into a variety using gene-editing tools instead of

transgenic techniques, will be similar to unintended genetic changes that result from conventional breeding or previous transgenic manipulations. It suggests that plant breeders would be able to eliminate unwanted effects through plant breeding practices. It hands over responsibility to plant developers to self-regulate.

As explained above, gene-editing can introduce a number of different kinds of unintended effects that are not going to be discovered unless there is an intentional process to look for them. The assumption that retransformants will be identical cannot be supported either scientifically or logically. There would be no point for plant developers to produce identical products when they could easily just continue reproducing the original product. The difference is what makes it a new product. If our regulatory system is indeed science-based, it requires data and proof – not mere assumptions. "Identical" has a precise meaning: there are no differences between two items. Whether or not two things are identical cannot be known without taking meaningful measurements.

The proposed guidance would require only two previous instances of an "identical" transformation to move the new plant from full regulatory review to an expedited review with lower information requirements and shorter timelines. This is a very low bar for reducing regulatory oversight. The entire regulatory guidance only cites one study, which indicates that the scientific knowledge base to understand gene-edited plants that are retransformants is still at an early stage.

NFU Recommendation:

In light of the lack of robust scientific evidence and the newness of gene-editing technology, it would be prudent to continue requiring full data and review retransformants as new events. Once these products are on the market, it will be farmers and consumers that bear the risk if the proposed lighter regulatory treatments result in market rejection or food safety issues. We therefore recommend that all retransformants continue to be assessed as new plants with novel traits.

The NFU appreciates the opportunity to provide comments in this public consultation process to assist Health Canada make informed decisions on these critically-important issues. The NFU always welcomes dialogue and encourages Health Canada 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
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