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A PUBLICATION OF THE NATIONAL FARMERS UNION, 2717 WENTZ AVENUE, SASKATOON, SK S7K 4B6
PHONE: 306-652-9465 • FAX: 306-664-6226 • E-MAIL: NFU@NFU.CA

Precision, power and precaution: gene editing

–by Cathy Holtslander, NFU Director of Research and Policy

Technologies are not simply tool sets, but are both created by and profoundly influence the societies that develop and use them. New technologies not only change how things are done in the physical world; they affect social relationships at the same time. How technologies are governed – who has a say in how they are used – has a huge effect on their impacts on people and the ecosystems we live in, as the Canadian philosopher Ursula Franklin articulated so clearly in the 1989 Massey Lecture series "The Real World of Technology".

Multinational seed/biotech/agro-chemical corporations own, use and/or control access to gene editing technology itself and to its products via patents and licensing agreements, and national governments create the boundaries on how they can be deployed. These multinationals have much to gain from increasing their power over the genetics of our food supply. When they talk about gene editing, they assume everyone believes that all technological change is progress, inevitable, and always good. When seeking broad public support, they frame gene editing as minor housekeeping that can tidy up genomes, tweak and speed up plant breeding. But when speaking to investors, they highlight its ability to make radical changes to plants faster than, or in ways not possible with traditional plant breeding methods. When lobbying governments, they falsely claim that because the resulting plant does not (usually) contain DNA from another species, gene edited plants are no different from traditionally bred varieties and thus argue that no regulation is needed.

Gene editing technology has major disruptive potential – both socially and biologically. Citizens like us -- and policy makers who will be making decisions about whether, how and under what conditions gene editing should be used – need to take a critical perspective when we inquire into how gene editing works, as well as its intended, unintended and unknown impacts, including outcomes from the use of products created by this technology.

Gene 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. Gene editing technology can change the function of a plant's own DNA by silencing or forcing the expression of specific genes, removing genes, and/or changing the location of genes within the genome. It can also 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" (from another species) to alter the plant's own DNA and then removing the "editor" after it has changed the genome. The plant's now-rearranged DNA is not considered "foreign" even when it has been changed in ways not possible through natural reproduction.

Older genetic engineering methods also introduce specific DNA sequences, but without control over where on the genome they are inserted. The "precision" of gene editing is its ability to identify a gene sequence that already exists within the plant's genome, then use "editor DNA" to snip at that point. The cell's own repair mechanism then incorporates the genetic change in that location. However, even though plant developers can make changes to specific sites in a plant's genome, they do not have complete control over the results, because editing process does not always behave as predicted.

Cells "read" DNA instructions that direct them to produce specific proteins. DNA "words" consist of molecular base-pairs arranged in a specific order in the spiraling DNA molecule. The gene editor may change other parts of the genome as well, resulting in "off-target effects". Changes at the target site may 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.

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

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expressed. These unpredicted proteins and unexpected expression or silencing of genes may affect the engineered plants' environmental or health impacts, and may affect the plants' physiology generally, or when stressed in particular ways. There is no one-to-one correspondence between genes and proteins or traits.

New research in the area of epigenetics – the intergenerational effects of environmental stresses on gene expression – is showing that an organism 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.

There is still much that is not known about the relationship between DNA and individual cells and whole organisms. Even 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 newness of gene editing technology, its potential to irreversibly change the genetics of our food system, and the ability of gene edited products to independently reproduce themselves once they are released into the environment, demand a critical examination and a precautionary approach by citizens and policy makers. ▪

For more technical information on gene editing techniques, see ***Genome Editing in Food and Farming: Risks and Unexpected Consequences*** by the Canadian Biotechnology Acton Network at https://cban.ca/genome-editing-in-food-and-farming-risks-and-unexpected-consequences/ .

For more about how technology affects social and power relationships, read or listen to ***The Real World of Technology*** by Ursula Franklin at https://www.cbc.ca/radio/ideas/the-1989-cbc-massey-lectures-the-real-world-of-technology-1.2946845 or https://houseofanansi.com/collections/all/products/the-real-world-of-technology-1

How—or whether—Canada regulates gene editing has far-reaching implications

–by Cathy Holtslander, NFU Director of Research and Policy

The Canadian government is deciding how to regulate plants developed using new technologies known as "gene editing" or "genome editing", 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).

Gene editing 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 (biotech companies). The CFIA and the Health Canada consultations do not provide an opportunity for a full and meaningful public discussion. If implemented, their proposed changes would make it impossible for Canadians to have the needed public debate before gene-edited plants are introduced into our food and agriculture system.

The Canadian Food Inspection Agency (CFIA) is responsible for regulating genetically engineered 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. Currently, all genetically engineered 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 be considered "not novel" and thus exempt from Part V of the *Seeds Regulations,* allowing them to be released into the environment 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.**

The CFIA's proposed guidance would allow plant developers (biotech 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 who are accountable to their 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 engineered plants as a safety issue, when in reality, it is an issue of power. The proposed regulatory guidances 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. 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.

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.

Gene-edited seed will be covered by patents and be patent protected in the same way that other genetically engineered varieties are today. Gene editing will likely be used to introduce new traits into a wider variety of crop kinds, including cereals, as well as flax, camelina, potatoes, horticultural crops, and pulses. 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 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.

The framework adopted for regulating gene-edited plants 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. The proposed CFIA guidance also covers gene edited trees, which is clearly outside of both the CFIA's expertise and the intent of the *Seeds Regulation*. The implications of the CFIA's proposed pathway to deregulation has implications that go beyond agriculture and food.

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*.

For the NFU's submissions to the CFIA and Health Canada consultations and our full commentary on the CFIA's proposed regulatory guidance, go to https://www.nfu.ca/policytypes/nfu-briefs/ . ▪

Proposed MRL increase for glyphosate leads to pause, planned consultations

–by Cathy Holtslander, NFU Director of Research and Policy

In July 2021, the National Farmers Union (NFU) submitted comments to the Pesticide Management Regulatory Agency (PMRA) on proposed changes to Maximum Residue Limits (MRLs) for glyphosate in certain pulse and cereal crops.

The strong public response to this issue led to the federal government's decision to suspend the consultation. The Ministers of Health, Agriculture and Environment jointly announced that there would be no increases to MRLs for any pesticide until at least spring 2022. They also committed to additional funding for independent research on pesticides and a plan to consult on specific provisions of the *Pest Control Products Act* (2002) to consider ways to balance how pesticide review processes are initiated in Canada and to increase transparency.

The NFU's submission highlighted the fact that our members are increasingly concerned about the health, agronomic and environmental impacts of pre-harvest glyphosate use, and that we adopted a position opposed to the pre-harvest spraying via our democratic policy development process in 2014.

Nations set their own MRL standards which apply to imported foods. Canadian exports are subject to the importing country's MRL limits. Canada's MRL affects the allowable residue in foods consumed by Canadians whether they are imported or domestically produced. The PMRA's existing process for deciding on MRLs is based on the residue limits commonly found as a result of prevailing agricultural practices.

The PMRA proposed to raise MRLs for dry beans from 4 ppm to 15 ppm, lentils, chickpeas and dry peas from 5 parts per million (ppm) to 10 ppm, barley bran and pearled barley go from 10 to 15 ppm, oat groats/rolled oats and oat bran rise from 15 to 35 ppm, while wheat bran and wheat germ increase from 5 to 15 ppm. The primary source of glyphosate residue in foods is uptake by plants that are sprayed prior to harvest when they exceed 30% moisture.

Increasing these MRLs would enable more, and earlier use of glyphosate for pre-harvest spraying as there would be less risk of exceeding the MRL by applying before the crop reaches the 30% moisture stage. Higher MRLs would increase the risks of damage from spray drift and increase potential for health risks from glyphosate residues in Canadian food (both home grown and imported).

Canada's existing MRLs for glyphosate are lower than both US and international CODEX Alimentarus limits, but the proposed MRLs were higher for all but barley and wheat. Higher levels of glyphosate residues in key agricultural commodities such as lentils and durum wheat, would jeopardize export sensitive markets such as India and Italy. Higher Canadian MRLs would also reduce barriers for food processors wishing to import pulse crops from countries with lower limits than ours. This would increase Canadian consumers' exposure to glyphosate residues, above the current levels and above levels experienced by consumers in other countries, particularly as demand for legume-based plant protein products increases.

The CFIA's National Chemical Residue Monitoring Program (NCRMP) is responsible for monitoring MRL compliance, and focusses on testing foods sold in Canadian retail outlets. The program's 2016 internal audit found serious deficiencies, including that the program does not publish its annual reports, only making them available on request after a delay of several years, and the raw data collected is never made public. The government relies on commercial processes to deal with MRL issues for bulk commodities. If companies purchasing grain and pulses risk losing sales due to customers' rejection of high residue levels, they will have an incentive to test loads and reject them at the elevator. It is not appropriate for public policy to rely on private enforcement for compliance.

The NFU brief to the PMRA recommended: no MRL increase for glyphosate; amend herbicide labels to prohibit pre-harvest glyphosate spraying; effective MRL enforcement and compliance measures; Canadian Grain Commission monitoring of export shipments for MRL compliance; increase CFIA monitory and promptly publicize reports and raw data; PMRA investigate linkages between glyphosate application and subsequent fusarium infection, and Health Canada investigate the epigenetic impacts of glyphosate exposure on humans, livestock, plants and soil micro-biota.

The full NFU brief is on the website at https://www.nfu.ca/policy/submission-to-pmra-on-glyphosate-proposed-maximum-residue-limit/

If and when the *Pest Control Products Act* consultation occurs, the NFU will certainly participate, and advocate for a precautionary approach, independent science, promotion of pest management practices that protect biodiversity, and regulation in the public interest. ▪