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Reducing the regulatory burden of plant biotechnology regulations in Canada

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Abstract

Regulations within the crop agriculture industry exist to ensure that products undergoing risk assessment prior to commercialization are safe for the environment and human consumption. Since 1995, these regulations have provided safe crops and foods for Canadians to consume, as no commercialized innovative product has caused any post-commercialization health or environmental problems. However, Canada suffers from a gap in its innovation pipeline in that far more investments go into the innovation pipeline than products come out. Canada is a global top ten nation in terms of innovation investments yet drops over ten positions when it comes to outputs. Additionally, Canada is one of the lowest ranked on the G30 list of countries in terms of regulatory burden on the economy. This article describes updates to the regulatory framework for plant biotechnology, highlighting recent changes regarding regulation of gene editing technologies and how these changes respond to previously identified innovation barriers.

Key words: barriers, commercialization, gene editing, innovation, regulatory burden

Introduction

In May 2022, Health Canada (2022) announced that if a new crop variety developed through the application of gene editing technologies did not contain any foreign DNA in the commercialized variety or meet a list of five specific food safety related criteria,[1] it would not be regulated as a novel food, instead, it would be treated as a conventionally developed variety. One year later, the Canadian Food Inspection Agency (CFIA) made an identical announcement (CFIA 2023*a*), which was followed in May 2024 with the announcement from the Feeds Division within the CFIA that gene-edited varieties were safe for livestock feed and would not require additional regulatory oversight (CFIA 2024*a*) provided they did not impact a short list of specific feed safety criteria. The result of these announcements is that in Canada, most gene-editing technologies that do not contain foreign DNA will be viewed as conventionally developed varieties and would not be subject to the additional time and cost required from plant with novel trait (PNT) regulations. The CFIA previously indicated that all herbicide tolerant crop varieties developed will be regulated as equivalent to PNTs, regardless of whether or not foreign DNA is present, such as through mutagenesis and has developed an expedited process for conventional (including mutagenic) herbicide tolerant varieties (CFIA 2009; CFIA 2023*b*). These announcements pertaining to treating gene editing technologies as equivalent to conventional mutagenic technologies are important clarifications for the future of crop innovations and investments in Canada.

Innovations within the agriculture sector offer tremendous potential for achieving both the Paris Accord and the United Nation's Sustainable Development Goals (SDGs). Reductions in greenhouse gas (GHG) emissions following the adoption of genetically modified (GM) crops indicate the contribution these technologies offer to mitigating climate change (Awada et al. 2021; Sutherland et al. 2021; Brookes 2022; Smyth et al. 2024). The adoption of GM crops has additionally provided benefits that contribute to achieving the top three SDGs: 1) ending all forms of poverty, everywhere; (2) improving nutrition and increasing food security contributing to ending hunger, while increasing sustainable agriculture; and (3) pro-

[1] The five criteria are as follows:
1. Foods derived from plants with genetic modifications that do not alter an endogenous protein in a way that introduces or increases similarity with a known allergen or toxin relevant to human health;
2. Foods derived from plants with genetic modifications that do not increase levels of a known endogenous allergen, a known endogenous toxin, or a known endogenous anti-nutrient beyond the documented ranges observed for these analytes in the plant species;
3. Foods derived from plants with genetic modifications that do not have an impact on key nutritional composition and/or metabolism;
4. Foods derived from plants with genetic modifications that do not intentionally change the food use of the plant; and
5. Foods derived from plants with genetic modifications that do not result in the presence of foreign DNA in the final plant product (Health Canada 2022).

moting and ensuring improved human health at all ages (Smyth 2022). However, for the full potential of these beneficial technologies to be realized, the regulatory frameworks need to be risk appropriate (Kalaitzandonakes et al. 2015; Van Eenennaam et al. 2021; Brookes and Smyth 2024). A recent assessment of global GM crop adoption identifies that only one-third of the benefits from GM crop adoption have been realized due to regulatory barriers and government bans (Hansen and Wingender 2023).

The Global Innovation Index (2023) ranks Canada in 9th position in terms of innovation inputs, however, when assessed for outputs from innovation processes, Canada drops to 20th. Canada also ranks very high in university-industry research and development (R&D) collaborations, at 7th. When it comes to investing in, and incentivizing investments for, creating markets of the future, Canada is ranked 17th (WEF 2020). Further, the 2018 World Competitiveness Report ranked Canada 53rd with respect to government regulatory burden (WEF 2019). Canada has a lengthy and long-established commercialization lag and removing regulatory barriers is crucial to increasing R&D investments and reducing the lag. R&D investments in agriculture account for a very small portion of overall global R&D investments at 5%, which in 2011, accounted for an estimated US$69 billion (Pardey et al. 2015). Since 1960, public sector R&D investments have steadily declined, from 57% in 1960 to 47% in 2011 (Pardey et al. 2016). Further, agricultural R&D investments in high-income countries dropped from 69% to 55% between 1980 and 2011 as agricultural R&D investments transitioned towards medium-income countries.

The costs of regulatory burdens are not directly evident to society and consumers. While regulatory delays reduce the return on investment for technology development firms, they also reduce consumer access to improved products. The delay in commercializing these improved products can mean, for example, that less efficient production processes are utilized for longer periods requiring higher levels of inputs or energy to produce, or that products with lower environmental impacts take longer to reach consumers. In one of the few studies that have quantified the costs of not adopting the most effective technologies once available, Biden et al. (2018) examined the costs of Australia's decision to enact a moratorium on the commercialization of GM canola production. GM canola was approved in 2004, but Australia's canola-producing states enacted moratoriums that lasted from 2008 to 2010 and took as long as 2020 to be fully removed across all states. The environmental and economic costs of these various state moratoriums from 2004 to 2014, have been estimated to be: the application of an additional 6.5 million kg of chemicals; 7 million additional field passes were made, requiring 8.7 million liters of diesel; 24 million kgs of GHG were released; the environmental impact of the additional chemicals applied was 14% higher; and Australian farmers lost the opportunity to increase their farm revenues by A$485 million (Biden et al. 2018). These foregone benefits from the adoption of GM canola in this example provide insights into the unseen costs of the failure to adopt innovative technologies as rapidly as is possible, once they are commercialized.

The cost of regulatory barriers can be measured in reductions in R&D. Canada's biotechnology regulatory framework regulates the product, not the process, resulting in PNTs being assessed based on their novelty. All plants developed by GM technologies are automatically regulated as PNTs. Historically, other than GM varieties, all other varieties have been assessed for novelty based on containing a trait of interest that differs from expression levels in previous varieties. While this could describe any product of plant breeding, other than GM, the varieties that have required approval were mostly herbicide tolerant products developed with mutagenesis. A 2018 survey of 100 public and private plant breeders in Canada (Smyth et al. 2020) found that one-third of breeders discontinued developing a new variety when they self-determined it would require PNT regulation, one-fifth deliberately reduced the traits being expressed in the development variety to ensure it would not meet PNT regulation requirements, and one-quarter indicated that PNT regulations discourage investment in the development of new crop varieties.

This article compares the announcements by Health Canada and the CFIA with the results from our 2018 survey of plant breeders to gain insights as to what degree the previously identified barriers to innovation have been addressed and/or mitigated through the recent regulatory announcements of the use of gene-editing technologies.

Plant with Novel Traits Regulatory Framework

Worldwide, one can distinguish between two types of regulatory frameworks for new crop varieties: process-based frameworks and product-based frameworks. The European Union (EU) adopted a process-based regulatory framework in 2003, with the establishment of the European Food Safety Authority (EFSA). In establishing EFSA, the EU also decoupled its scientific risk assessment process from its variety approval process. In the EU, EFSA assesses scientific evidence submitted for risk assessment and has consistently delivered decisions identical to those in GM producing countries. The decoupling of risk assessment from variety approval has proven to stifle innovation as since 2003, the EU has only approved one GM variety for commercial production, as variety approvals are determined by the European Commission's Standing Committee on the Food Chain and Animal Health (Smart et al. 2015). This Standing Committee comprises bureaucrats from the various Member States, who can come from ministries with very little understanding of agricultural risk assessment, such as consumer affairs, often opposed to the commercial production of GM crops. To approve GM crops for commercial production in the EU, a double majority is required, that is, 55% of Member States must support approval, with these states representing 65% of the total EU population. Approving a single GM variety for commercial production in over 20 years confirms that the regulatory approval system is incapable of functioning.

Conversely, product-based regulatory frameworks have been adopted by leading GM crop producing countries. The United States developed product-based regulations, which

are overseen by the US Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration and was the first country to commercially produce a GM crop, tomatoes in 1994. This regulatory framework has allowed the US to become the leading producer of GM crops, with an estimated 71 million hectares in 2019 (ISAAA 2020). Other early GM crop adopting countries, such as Argentina, Brazil, and South Africa, all developed product-based regulatory systems. Subsequent adopting countries such as Australia have also enacted product-based regulations. All of these systems assess the risk of the newly developed GM variety and then compare the risk to the risk of producing conventional, non-GM varieties. If there is no difference in the risk of producing a GM variety compared to a non-GM variety, then the variety is approved for commercial production.

In 1995, Canada implemented a science-based regulatory framework to regulate GM technologies, establishing the protocols to approve plants with novel traits (PNTs), novel foods and novel feeds (Smyth 2009; Gleim and Smyth 2018). In Canada, the CFIA and Health Canada act as the regulators of novel crops and the foods/feeds derived therefrom. PNTs are defined as containing new or modified traits, which have no history of safe use in Canada, or present potential environmental risks (CFIA 2017).

The Canadian framework employs a product-based regulatory system, which regulates the final product that is developed, and not the process used to create it. The framework evaluates PNTs' safety for both environmental and human health by assessing their potential impact on biodiversity, non-target organisms, and ecosystems' sustainability (CFIA 2017). Traits are approved if a risk assessment concludes the risk of the PNT is substantially equivalent to conventional crop varieties (Smyth 2020). The trait can then be incorporated into local varieties and as applicable, some crops are then subject to a subsequent variety registration process. Varieties that are not deemed to be PNTs are still subject to agronomic standards (i.e., disease resistance, lodging, milling quality, etc.) that differ for each variety. Those varieties that meet or exceed these standards are then approved by the CFIA's Variety Registration Office for commercial production. For the past thirty years, Canada has accumulated a vast depth of knowledge and experience regulating PNT crop varieties.

Health Canada and CFIA gene editing announcements

Gene editing differs from genetic modification in that it does not normally lead to GM crops,[2] crops to which genetic material has been transferred from other species and remains in the commercialized variety. The term gene editing refers to a group of methods that make it possible to precisely modify genome sequences by adding, removing, or altering genetic material at specific locations in the genome. The gene editing method that has recently received the most attention is CRISPR-Cas9, (clustered regularly interspaced short palindromic repeats) and CRISPR-associated proteins. Other methods of gene editing that have a potential for crop breeding are based on Zinc Finger Nucleases (ZFNs), Site Directed Nucleases (SDN), and Transcription Activator-like Effector Nucleases (TALENs). Another method of gene editing is Oligonucleotide-Directed Mutagenesis (ODM) used to produce herbicide tolerant canola (Songstad et al. 2017). While gene editing has been rapidly adopted by public and private plant breeding laboratories in many countries around the globe, regulatory uncertainty remains regarding whether gene editing will be regulated as equivalent to GM crops. One estimate indicates that if gene-edited varieties were regulated as equivalent to GM varieties the cost of developing gene-edited varieties would increase by US$14.5 million and take an additional 9 years (Lassoued et al. 2019).

Until May 2022, no regulatory certainty in Canada existed regarding how or whether gene editing would be regulated. Crops developed through gene editing that produce a genetically modified organism (GMO) or transgenic variety, were subject to the PNT regulatory framework, which was more stringent and involved lengthy and additional risk assessments. The main problem was that plant breeding advancements were constrained by the boundaries of a regulatory system created in the early 1990s, with the introduction of GM varieties. Consequently, this regulatory uncertainty carried a significant cost as public sector plant breeders were hesitant to employ the technology to develop new varieties, given the lack of confidence in receiving regulatory approval in key commodity export markets (Smyth et al. 2020).

In May 2022, Health Canada made a significant policy shift regarding the regulation of gene-edited crops. The announcement clarified that new crop varieties developed through gene editing technologies would not be regulated as novel foods if they did not contain foreign DNA in the final commercialized product or contain traits that meet the above defined five specific risk-based criteria for human health. Instead, these crops would be treated similarly to conventionally developed varieties. This policy clarification has important implications for the agricultural biotechnology sector, regulatory frameworks, and the broader discourse on genetic modification considering its potential impact on innovation, regulation, and public perception.

One year later, in May 2023, the CFIA announced an update to the regulatory framework clarifying how gene-edited organisms will be classified and regulated. The new framework proposed that gene editing technologies do not present specific environmental or health concerns, and gene-edited plants are to be regulated like any other product of plant breeding based on the traits expressed.[3] However, the above-noted pronouncement by the CFIA (2009, 2023*b*) that any herbicide tolerant crop variety will always be regulated as equivalent to a PNT will still apply. Herbicide tolerant crops without

[2] Some gene editing technologies, such as SDN, can involve gene transfer, thus the commercialized variety could contain foreign DNA and be a GM crop.

[3] The CFIA specifies that for all PNTs, it is the proponent's responsibility to determine the PNT status and how the introduced trait could impact the environmental safety criteria. It is also the proponent's responsibility to notify the Plant Biosafety Office and receive an authorization for release.

Table 1. Summary of Canadian gene editing regulatory changes.

Timeframe	Regulatory status of gene editing technologies	Regulation change	Key outcome
Prior to May 2022	All gene editing technologies would be regulated as equivalent to PNTs.		
Health Canada—May 2022	Pertains to all gene editing technologies.	New crop varieties developed through gene editing technologies would not be regulated as novel foods if they did not contain foreign DNA in the final commercialized product or contain traits that meet five specific risk-based criteria for human health.	New varieties will be treated as equivalent to conventional varieties and not be subject to additional PNT regulations.
CFIA—May 2023	Pertains to all gene editing technologies.	Gene editing technologies do not present specific environmental or health concerns, and gene-edited plants are to be regulated like any other product of plant breeding based on the traits expressed. Herbicide tolerant crops without foreign DNA will not be regulated as novel foods or feeds and will not require review or approval by Health Canada, only the CFIA.	Streamlined 60-day process for herbicide tolerant crops that do not have foreign DNA.
CFIA, Feeds Division—May 2024	Pertains to all gene editing technologies.	Feed ingredients derived from gene-edited crops will be regulated like all other products of conventional breeding, based on the traits of the products, irrespective of the development method.	Clear and short list of specific feed related risk criteria that would trigger the need for a novel feed review, regardless of the breeding method used.

foreign DNA will not be regulated as novel foods or feeds and will not require review or approval by Health Canada, only the CFIA. The updated guidance also included a streamlined 60-day process for herbicide tolerant crops that do not have foreign DNA (CFIA 2023*b*).

This regulatory guidance addressed various stakeholders' concerns about innovation constraints in Canada due to unclear regulations, farmers' ability to access to innovative plant varieties or disproportionate regulatory requirements for plant lines developed in Canada compared to imported plants (CFIA 2023*b*). The announcement was developed following an open consultation with the Canadian public, including public and private plant breeders, agriculture industry members, non-profit organizations, and the associations representing Canadian farmers.

One year later, in May 2024, the Feeds Division with the CFIA released a third update about feed ingredients derived from gene-edited crops stating that they will be regulated like all other products of conventional breeding, based on the traits of the products, irrespective of the development method (CFIA 2024*b*). They identified a clear and short list of specific feed related risk criteria that would trigger the need for a novel feed review, regardless of the breeding method used. Through this last announcement, Health Canada and CFIA created a consistent policy and regulatory framework for gene-edited crops, feeds, and foods (Table 1).

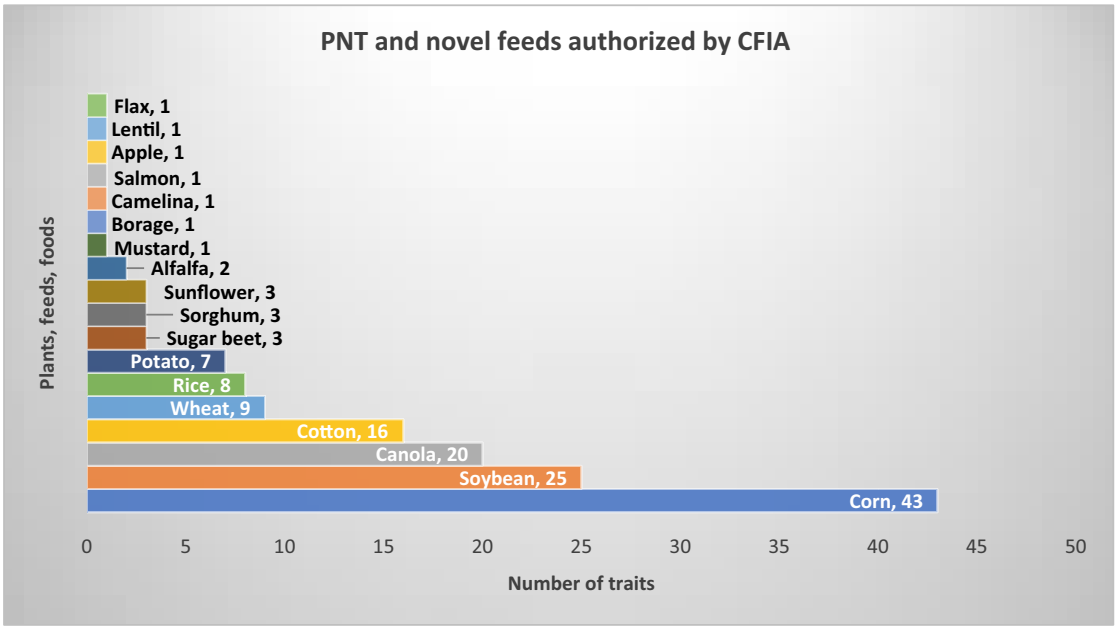
During the 1995–2024 interval, the vast majority of PNTs (89%) were developed by large multinational technology development companies (CFIA 2024*c*). Out of 146 applications for PNT determination, 15 belonged to small and medium enterprises (SMEs), and only one was developed by public breeders. Implicitly, most applications for new and improved traits were received from multinational companies for corn, soybean, canola, and cotton (Fig. 1).

The prohibitive costs of PNT approval have resulted in a significant disadvantage for public breeders from universities, research centers, and SMEs. Universities have expressed they have unwritten policies indicating that no PNT varieties would be developed due to the cost constraint of needing to have two entirely separate development systems. To ensure that no PNT variety crossed with a conventional variety, separate phytotrons, greenhouses, and land for field trials were required. These expenses were beyond the capabilities of universities and given these costs, Canadian universities have only developed one PNT variety, which occurred in the late 1990s. This issue is of significant importance as the absence of public researchers' involvement in biotech research and development is detrimental to the development of innovations and products at a country level.

Discussion

In 2018, an online survey of 100 public and private Canadian plant breeders was undertaken regarding PNT regulations and their impact on R&D and variety development (Smyth et al. 2020). As identified above, breeders indicated that PNT regulations had a substantial and negative impact on innovation, as one-third of all plant variety development innovations were discontinued once breeders realized new varieties would be regulated as PNTs. To gain a more detailed understanding of the impacts PNT regulations were having on plant breeders, 35 plant breeders were interviewed via telephone. The interviews were semi-structured, meaning that while the interviewer had a list of questions for the in-

Fig. 1. PNT and novel feeds authorized by CFIA
Source: CFIA (2024*c*).



terviewees, the latter were free to express their views on any topic related to the main questions. The interview addressed three main themes: novelty, regulatory regime, and gene editing.

Canada's science-based regulatory framework has resulted in an extensive accumulation of knowledge and experience in the production, risk, and regulation of PNT crop varieties. The ability for plant breeders to interpret novelty was negatively impacting all plant breeding programs and was predicted to have a greater negative impact on use of new technologies like gene editing. Therefore, the survey was designed to gain insights into how plant breeders viewed the existing regulatory framework concerning gene editing techniques and whether PNT regulations acted as a barrier to investment and innovation within Canada's agricultural industry.

Results revealed that 77% of plant breeders believed regulations for novel crops, novel feeds, and novel food products needed to be updated to reflect the advances in scientific knowledge on the development of new crop varieties. One essential barrier identified was that the concept of "novelty" was not clearly defined in the regulations, as breeders deliberately develop new varieties that differ or are novel from existing varieties. Breeders indicated that all new crop varieties are novel from previous varieties and that there was no firm definition of what constitutes "novelty".

This was shown in the survey responses, where 34% of breeders indicated they ended innovative research due to the final product being considered a PNT, and another 19% altered breeding objectives to avoid having the final product be viewed as novel. Additionally, 14% of breeders decided not to commercialize a product after learning the product would be treated as novel. A further 18% of respondents experienced delays in commercializing a new plant variety in Canada, compared to other markets, due to their variety's PNT status, and 22% of breeders had at least one research proposal turned down due to uncertainty about regulatory costs. Unsurprisingly, over a quarter of the breeders surveyed viewed PNT regulations as a barrier to investment. Public breeders predominantly held this opinion and faced significant disadvantages, as they were unable to develop PNT varieties. The limitation stemmed from their lack of parallel development infrastructure due to space, time, and cost.

Interviewees' answers mirrored the survey findings. Breeders were willing to share their experiences and capitalized on the opportunity to articulate their answers and express their perspectives. Most of the interviewed breeders pointed out the necessity to update and revise the definitions used in the PNT regulatory framework, due to the vagueness and confusion of terms such as "novelty", "trait", or "outside the normal range". Breeders shared the following opinions on novelty.

> That's [novelty] very confusing because whenever, whether it's in classical breeding or whether it's gene editing, or whatever, we are always trying to introduce improvements to plants. […] And also clarify what's novel. Like there should be more clear-cut definition of what's novel. Novelty versus incremental improvement.

> I find that the concept of the plants with novel traits is a good starting point, but given the diversity that we have, not only in crop traits, but in feed compositions and all that, the idea of novelty has to be re-defined to really go outside of the circle of what would be considered non-material changes to either the plant itself or the feed ingredient itself.

> CFIA was basically saying that any significant change in anything could be triggered as novelty and they were saying that if someone comes up with a new line that outyields the checks

by 10%, they could consider that a novel trait, because "it's outside the normal range".

Public plant breeders are at a disadvantage compared to the private sector in terms of lack of infrastructure, resources, and bargaining power is exemplified by sharing various experiences related to the extensive approval delays and substantially increased costs when attempting to get a PNT through the regulatory process. Public breeders funded solely through grants lack access to fiscal resources once the project is complete and if the new variety has not received approval, there will often be no fiscal resources available to fund approval. Private firms have vastly different fiscal situations, that allow them to provide additional fiscal resources to complete the commercialization process.

> [Retracted researcher name] started in the early nineties and we got approval in 2015. And that part of the challenge with that time frame was [researcher name]'s group had submitted to Health Canada in the late nineties a safety dossier. But it wasn't complete and by the time Health Canada got back to [researcher name] with questions, his funding had run out. I think there was a two-year gap between the time he submitted and by the time they came back with some questions, he could no longer answer or find stuff for any number of reasons. But definitely there was no more money left for him to continue because his ADF grant had completed.

> Right now, it is so expensive to go through regulatory processes when you have a transgenic trait. For example, a form of herbicide tolerance like Roundup Ready we developed in 2006-2007, this is the first time we had it out in the field for the first time, and this is 2018 and we still haven't been able to register it. It is very, very expensive. I don't know how many millions of dollars it takes to get one transgene-regulated one around the world, if that's the cost, then you can make the comparison. I don't have that dollar figure. But it is very, very expensive.

> Yeah, and it has a reputation of being expensive. It means that public institutions, for the most part, are shut out of even collaborating with companies because they quote these several million-dollar kind of price tags for one event. What it means is that we can do proof of concept, but we can't actually participate in commercialization in most cases. I hope to be the exception to the rule, but in most cases, it just means that it's difficult to even develop a partnership with a company because they'll want to do it all in-house.

> All the third-party labs, support and consultants, sure we've got all those numbers. But what about our own time? In-house time? The cash you burn waiting for regulatory approval and your pre-commercialization - knowing you can't do any commercial activity. If you're a bigger company and you've got marked products in the marketplace, well that's not as painful. But if this is your first product, and you're waiting to launch it and it's taking five years to get it released, that becomes a painful process.

During the interviews, a majority of breeders felt the need to advocate that gene-edited crops should be treated as conventional ones. The arguments ranged from explaining breeding techniques, what was the importance of saving time during a breeding process that is inherently a lengthy one, and the experience accumulated in the (then) 25 years of applying this framework to novel crops, feeds, and foods.

> Compared to conventional breeding, in my area of research, when you use conventional breeding, it may take six to ten years to generate or to improve a trait. Whereas with gene editing technology you can get improved traits within two, three years.

> For example, in the case of plants, whatever number of herbicide tolerances associated with the canola, inherent, selected by breeding, as well as by inserted genes, my commentary would be that, if there is a tolerance that is provided to the crop, that does not change the husbandry of the crop, or basically cause a material change in how the crop performs, I think there should be a grandfathering-in, or a check-off category under the plants with novel traits, as opposed to something which goes through a full blown registration for something which honestly, has very little material impact on either the quality of the crop, the range of the crop or the performance of the crop.

> But the problem we have with that is that we've known for example that genetically modified herbicide tolerant plants do not cause any more environmental issues than the plant that's a mutant. And yet, with all our years of work, we've still gone through all the testing and regulatory stuff again and again and again. It's just such a total waste of time and money. We know what the issues are with those kinds of plants. We know that if you have herbicide tolerance you will encourage the resistance to grow. But it's all manageable within certain parameters; we know how to deal with it in agriculture.

The cost of developing a new publicly developed variety is difficult to quantify, informal conversations with public sector plant breeders estimate the cost to develop and commercialize a new variety range between $2.5 and $3 million. If the time required to develop a new trait can be reduced from 6–10 years to 2–3, there would be a corresponding reduction in the development cost of new varieties. This would allow for the further development of new varieties as investments would be more efficient, ensuring higher returns on variety development investments.

Table 2 summarizes the main barriers that breeders identified in the survey and interviews carried out before the Health Canada and CFIA announcements. The changes made by the regulators indicate that they acknowledged and significantly removed barriers the breeders were confronted with. A comprehensive analysis of whether the barriers identified in the study were partially or completely removed after the regulations is not possible without surveying the breeders again on the differences they experience during the application processes. However, it seems straightforward that barriers such as the "need to update PNT regulations to reflect new technologies", and "the need to have gene-edited crops treated as conventional crops" were removed. Further, the gene-edited varieties that are not novel will benefit from significantly reduced delays and substantially decreased costs in bringing products to market due to not having to go through

Table 2. Main barriers identified by plant breeders prior to Health Canada and CFIA announcements.

Barrier
CFIA guidelines and concepts/definitions lack clarity.
Extensive approval delays to get PNTs through the regulatory process.
Substantial costs to get PNTs through the regulatory process.
Need to have gene-edited crops treated as conventional crops.
Need to update PNT regulations to reflect new technologies.
PNT regulations are a barrier for investment.
Breeders had to end innovative research due to final products being considered novel.
Breeders had to alter breeding objectives, so the product is not considered novel.
Breeders had to avoid commercializing a product after learning the product would be treated as novel.
Delays in commercializing a new plant variety in Canada, compared to other markets, due to their variety's PNT status.
Research proposal turned down due to uncertainty about regulatory costs.

a pre-market regulatory risk assessment. Breeders would not need to have research proposals turned down, end innovative research, alter breeding objectives, or avoid commercializing a new variety in Canada. However, unless gene-edited herbicide tolerant varieties contain foreign DNA, the streamlined process for conventionally bred herbicide tolerance, coupled with the clarifications about novelty and the use of gene-editing technologies to develop traits, all of the previously identified barriers listed in Table 2 appear to have been removed.

Following the Health Canada and CFIA updates, Canadian plant breeders seem on par with their international peers, as they can commercialize gene-edited crop varieties without the burden of excessive approval time requirements and costs. The updated regulatory framework places Canadian breeders in a similar position to breeders from Argentina, USA, Brazil, or Australia. Further, without the PNT regulations as a barrier to investment, without delays of or even cancellations of commercialization of new plant varieties, the updated Canadian regulatory framework is expected to significantly increase Canada's competitiveness on domestic and international markets.

Conclusions

Between 2022 and 2024, three announcements by CFIA and Health Canada were made that gene editing technologies free of foreign DNA will be treated as conventionally developed varieties appears to remove many, if not all the barriers that breeders previously identified. A subsequent survey of plant breeders would be required to confirm this. This means products developed by gene editing are not novel by default, and novelty is determined on a case-by-case basis based on a new clarified set of risk-based criteria. The gene editing regulations currently state that if herbicide tolerance is one of the variety traits, it will "always" be regulated as a PNT. The streamlined 60-day process for non-foreign DNA herbicide tolerance means that public sector plant breeders wanting to develop or improve an herbicide tolerant trait may be more willing to do so, given that public breeders are not willing to develop PNTs. As indicated in the research findings presented, the probability that public breeders will avoid undertaking the development of a variety deemed to be a PNT is very high, as again, they will have to face high costs and lengthy regulatory time. This regulatory barrier remains unchanged for significant nutritional changes, or changing the food/feed uses of a crop variety. Determining that changes of this nature would trigger the additional PNT risk assessment can be viewed as detrimental to public institution breeders, which in turn will negatively impact innovation within the agriculture sector as well as the overall Canadian R&D sector.

The Canadian regulatory guidance on gene-edited crops has been designed to support research and development of new varieties with enhanced traits, input use efficiency as well as enhanced nutritional qualities. The decision to exclude gene-edited herbicide tolerant varieties from being regulated similarly to the rest of gene-edited crops remains a barrier to the development of new herbicide tolerant traits in crops.

In 1995, herbicide tolerant canola was commercialized in Canada, using transgenic and mutagenic technologies, and the subsequent herbicide tolerant canola varieties have been grown safely since after being regulated as PNTs. After 30 years of safe use, the question arises: is there scientific evidence to support regulating all herbicide tolerant varieties as PNTs varieties?

In 2018, one of the interviewed plant breeders was addressing the issues of risk, safe use, and lessons learned:

> Focus on what is the risk, not necessarily perceived or hypothetical risk, but actual risk. Also, take into consideration the years of safe uses that we have had. Take advantage of the knowledge we've gained through the experience of 20-some years using PNTs and technology. But really, without a lot of risks showing up, we have to have confidence in the work that's already been done so that we can keep building on that. So, moving forward, maybe, in some ways, a more simplified system of approval. Or maybe it's more complex, but potentially a tiered system, where if it's something like herbicide tolerance that has been done for 20 years, we know the systems, we know what's been done. It's been shown time and time again that there's not a ton of risks. Maybe instead of having to submit whole data packages, maybe a notification like we do with stacks, is sufficient.

Herbicide tolerant crops provide farmers with efficient and cost-effective in-crop weed control as they can adopt conservation tillage and minimize summerfallow practices in crop rotations (Sutherland 2021). Streamlining the process for non-foreign DNA herbicide tolerance after 30 years of full risk assessment for herbicide tolerance removes a significant previously identified barrier. While the requirement that non-foreign DNA herbicide resistance still complete a streamlined risk assessment is a great improvement, it noticeably differs from gene editing regulations in other key competitive crop producing countries such as Argentina, Brazil, and

the USA. Harmonizing this requirement with other country's gene editing regulations will become increasingly important over time. PNT regulations will remain a barrier to investment, impacting Canadian outputs from innovation processes.

As changing climates impact agricultural production, one strategy for mitigating the adverse impacts is to have an increasingly efficient regulatory framework for agricultural biotechnology. While the recent regulatory changes by Health Canada and the CFIA have removed many of the expert-identified barriers, clearly barriers remain. With the uncertainty regarding future crop production due to changing climates, ensuring that Canada's regulatory framework is risk-appropriate will reduce Canada's long-standing high regulatory burden as it is applied to investments in innovative plant breeding.

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Data availability

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Competing interests

The authors declare there are no competing interests.

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