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Comments submitted by the Canadian Biotechnology Action Network To Bureau of Microbial Hazards, Food Directorate, Health Canada

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RE: Consultation: Proposed new guidance pieces for the Novel Foods Regulations, focused on plant breeding

The Canadian Biotechnology Action Network (CBAN) is writing to object to the regulatory guidance proposals put forward by Health Canada relating to foods from genetically engineered plants.

In particular, our comments answer the consultation questions:

- “Does the guidance align with the goal of a regulatory approach that is based on the level of food safety risk posed by specific products of plant breeding?”
- “Does the voluntary transparency initiative serve its purpose to inform Canadians what non-novel gene-edited products are on the market? Can we do more to achieve this objective?”

Please note that CBAN intends to provide further comment with a second submission to Health Canada, to address the primer on gene editing: *A Primer on Gene editing technologies in relation to Health Canada’s product-based regulatory framework for Novel Foods* (Annex 2 of the consultation document *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”?*)

The Canadian Biotechnology Action Network (CBAN) brings together 16 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups across Canada: Canadian Organic Growers, Check Your Head, Council of Canadians, Ecology Action Centre (NS), Ecological Farmers Association of Ontario, GE Free BC Network, Greenpeace Canada, Growers or Organic Food Yukon, Inter Pares, National Farmers Union, No More GMOs Toronto, GMO-Free PEI, Organic Agriculture Protection Fund of SaskOrganics, Union Paysanne, SeedChange, Vigilance OGM. CBAN is a project on the shared platform of MakeWay Charitable Society. www.cbancanada.ca

Table of Contents

A. Summary	3
Notes on terminology	3
Summary comments	3
Overview	3
Summary	5
Summary recommendation	7
B. The stated goals are unmet	7
There is a lack of clarity and predictability	8
The proposals jeopardize food safety	9
The proposed guidance would undermine public trust	9
The guidance would not support innovation	11
The proposed guidance is not aligned with international approaches	12
C. Genome editing should be regulated and products should undergo rigorous, independent scientific safety assessment	12
Genome editing creates unintended effects that require investigation	12
Gene editing is novel, there is no history of safe use, and Health Canada has little experience regulating (has no “familiarity” with) genome edited products	14
D. The guidance proposals are not science-based	17
1. Corporate self-regulation is not science-based	17
2. The “Voluntary Transparency Initiative” would fail to provide transparency by placing decision-making in the hands of product developers and makes necessary the need for Health Canada to maintain regulatory authority over all genetically engineered foods	20
3. Retransformants cannot be presumed to be “identical”	23
E. Key Recommendations	26

A. Summary

Notes on terminology

Genetic engineering is commonly referred to as genetic modification by the Canadian public, in the Canadian media, and in the North American marketplace. In addition, French-speaking Canada uniformly refers to *modification génétique*. The term genetic modification is used to refer to genetic engineering in international agreements and in most national regulatory systems around the world.

However, Health Canada uses the term genetic modification to include multiple technologies including genetic engineering and conventional plant breeding. In the regulations: “genetically modify” means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation. For the public, Health Canada now describes a genetically modified food as “a food that comes from an organism (plant, animal or microorganism) that has had one or more of its traits changed on purpose.”

Health Canada does not use the term “genetic engineering” in the consultation documents but refers, on five occasions, to “biotechnology” in those places where we might expect a reference to genetic engineering. The consultation documents do, however, explicitly refer to “gene editing” which is a collection of genetic engineering techniques that is widely called “genome editing” in the scientific literature.

Summary comments

Overview

Health Canada is proposing changes to the implementation of regulation for genetically engineered foods that would amount to an abdication of Health Canada’s responsibility to regulate for the health and safety of Canada’s food supply. We object to this proposed devolution of responsibility for food safety assessment from Health Canada to product developers. There is an inherent conflict of interest in product developers determining if regulations apply to their own products, and in developers determining their safety. This is a shift from government regulation of genetically engineered products to corporate self-regulation. It would jeopardize food safety, result in less transparency for the public and the agri-food industry, further erode public trust, and put the possibility of improved democratic governance of the use of genetic engineering in food and farming further out of reach.

The proposed guidance would allow unknown, unregulated genetically engineered foods onto the market:

- The proposed erosion of Health Canada's role as regulator is not in the public interest
- The proposals would not provide transparency to the public
- The proposed guidance does not reflect current scientific findings but rests on a presumptive conclusion about the level of risk posed by genome editing

The proposed guidance would leave the responsibility for the safety determinations of some genetically engineered foods to product developers themselves, amounting to an abdication of Health Canada's responsibility to ensure the safety of the Canadian food supply. Thus far, all the genetically engineered foods eaten by Canadians have fallen under the "Novel Food Regulations" and have been subject to government oversight. However, the new guidance proposes to remove regulation from some foods derived from genetically engineered plants, in particular those produced through the newer genetic engineering techniques of genome editing (gene editing), to allow these genetically modified organisms (GMOs) onto the market without any government safety assessment. This removal of government oversight would result in unregulated genetically engineered foods entering the market, some or all of which may also be unreported to the government.

The new genetic engineering techniques of genome editing require government oversight and rigorous, independent, scientifically-based safety assessment. There is no history of safe use with genome editing in our food supply. The proposals rest on a presumptive conclusion about the level of risk posed. The proposals do not reflect the scientific findings which clearly show a range of possible off-target and on-target effects resulting from using the processes of genome editing, even in plants. These effects need to be screened for, detected and evaluated for their potential impacts on food safety. The proposed definition of foreign DNA as a regulatory trigger is therefore dangerously simplistic. It is a negligent approach that is far from being precautionary and is not inclusive of all the risks posed by genome editing. The new novel trait definitions significantly narrow the scope of risk assessment; allowing a large range of possible food safety risks to go unassessed, and allow product developers themselves to determine the safety of many genome-edited products. All products of genome editing should be regulated and subject to rigorous scientific government assessment.

In 2021, responses to two petitions calling for mandatory labelling of genetically engineered foods, the Minister of Health stated, "The Government of Canada considers issues of food safety to be of the utmost importance."¹ However, the proposed guidance could jeopardize food safety and would further undermine public trust in the Canadian food supply and how it is regulated.

Current regulation of genetically engineered products is limited to evaluations of safety, to the exclusion of non-scientific considerations such as economic, social and cultural impacts. It is also restricted to a product-by-product assessment that leaves some questions about potential system-wide and long-term impacts unasked. Health Canada's proposals expose the need for a new policy approach that is responsive to public concerns and enables public participation in decision-making over the use of genetic engineering in food and farming. The need for an overarching approach is additionally highlighted by the fact that Health Canada's proposals are just the first in a series of planned consultations to change the regulatory guidance for other genetically engineered organisms including on the environmental release of genome edited plants, the safety of foods derived from genome edited animals and microorganisms, and the production of genome edited animals.

Summary

The core proposal of the new guidance for Novel Food Regulation would remove government regulatory authority from some genetically engineered foods, allowing product developers to determine product safety without government oversight. This proposal and the related proposal for a “Voluntary Transparency Initiative” would set the precedent for introducing genetically engineered organisms into our food system without any government oversight and without any notification to government. This precedent would diminish the role of Health Canada in ensuring the safety of Canada’s food supply. It would jeopardize food safety. It would also mean less transparency for the public and would further undermine public trust in our food system and regulation. These changes would also put Canadian regulation of genetically engineered foods at odds with the regulatory approach of some of our trading partners and consequently put some export markets at risk. This latter issue is of particular concern as we await a consultation on forthcoming proposals from the Canadian Food Inspection Agency for new regulatory guidance for the environmental release of genetically engineered plants.

The significance of the policy implications, and the possible food safety and market impacts, of these proposals is enhanced by the role of these Health Canada consultations as the first in a multi-year process to review regulatory guidance relating to the safety assessment of all genetically modified organisms, including of foods derived from genome edited animals. These piecemeal public consultations on stepwise changes are being pursued in a context where the Canadian public has been shut out of decision-making over and information about the introduction of genetic engineering in our food system.² For example, GMO regulation in Canada focuses on safety questions alone, excluding assessments of non-scientific considerations such as potential social and economic impacts, considerations that should involve consulting farmers and consumers. Current policy allows for genetically engineered products to enter the market without a risk-benefit analysis, and without mandatory labelling. In the case of this consultation, Health Canada asks what more it can do to provide Canadians with information about non-novel gene-edited products on the market, when the Canadian public could not have been clearer (over 80% of Canadians in all polls over twenty years³) about their demand for mandatory labelling of all genetically engineered foods.

Health Canada’s core proposal to surrender regulatory authority over genome-edited foods deemed to be non-novel. This would remove the ability of Health Canada to track all foods from genome-edited plants that could be entering the market (the federal government does not track what genetically engineered products are on the market). This is a significant gap in public information that could have profound impacts on public trust and on the ability of Canadian farmers to maintain or secure markets. To fill this gap, Health Canada proposes what it calls a “Voluntary Transparency Initiative” which abjectly fails to meet its stated goal of providing transparency. Instead of fixing the newly-created problem of possible unreported, untracked genetically engineered foods on the market, the proposal for this initiative sharply illustrates the need for Health Canada to retain regulatory authority over all genetically engineered foods, including those from gene-edited plants.

- **The use of genome editing should trigger regulation.** All foods from genome-edited plants should be considered as novel for the purposes of regulation. Genome editing has no history of safe use in our food system. The use of these newer genetic engineering techniques should trigger regulation.

- **It is overly simplistic to define the presence of foreign DNA as a regulatory trigger.** The definition of foreign DNA as a novel trait leaves other risks unattended and unevaluated. This focus on foreign DNA as a risk factor is not fully reflective of the scientific literature; it is not science-based.
- **Health Canada should retain regulatory authority over all genetically engineered foods.** The proposal to add a regulatory trigger such that foods derived from plants that have foreign DNA are defined as novel, leaves those genome-edited plants that have no foreign DNA in a class of potentially non-novel foods, whereby product developers themselves are left to assess further relevant safety questions relating to other novelty triggers. This amounts to corporate self-regulation and it would jeopardize food safety.

Health Canada's proposals rest on a number of assumptions and conclusions about genome editing that we contest. Health Canada's primer on genome editing, provided as an annex to one of the consultation documents, is not comprehensive (and was corrected after CBAN asked for missing references). In particular, the primer discusses predictable off-target effects but not the full range of possible off-target, on-target or near target effects. In at least this way, the primer does not fully reflect the "current scientific knowledge" that we argue is relevant to food safety and regulation. We do not agree that these proposals take into account "the evolving scientific knowledge about the safety of these foods." Current knowledge is, in fact, insufficient. The technologies are still under development and the scientific literature is dominated by studies on the efficiency and efficacy of genome editing tools while very little safety research has been performed.

Health Canada and other departments continue to describe their regulation of genetic engineering as science-based. This claim is already undermined by the fact that current regulatory decisions are based on confidential business information submitted by product developers, with little or no peer-reviewed science. The guidance proposals would further undermine the claim to science-based regulation by deepening dependence on corporate science. In fact, for many new genome-edited products entering the food supply, the proposals would result in an absolute dependence on corporate science: product developers would be permitted to determine themselves which of their genome-edited products can safely enter the Canadian food system, without any government oversight.

Instead, Health Canada should choose a science-based, precautionary response to the advent of the new genetic engineering techniques of genome editing in order to ensure food safety and public trust. The potential uses of genome editing are of great interest to many stakeholders in the agri-food industry. This enthusiasm, however, is not a reason to relieve companies of regulatory requirements but, instead, underscores the need for rigorous safety assessment and independent oversight. Health Canada should respond to a broad interest in using new genetic engineering techniques by strengthening government oversight. A wave of genome-edited foods, plants, and animals in Canadian agriculture, resulting in many more products for domestic consumption and export, should be met with rigorous regulation for safety by government. Instead, the scenario created by Health Canada's proposals would be a flood of new products - some possibly unidentified - coming to market based on unknown corporate safety determinations.

The primary mandate of Health Canada in relation to our food system is to ensure health and safety, however Health Canada's consultation lists other goals that, in the implementation of these proposals, would threaten to compromise this mandate. **Health Canada's job is to be an independent regulator on behalf of the Canadian public.** The public relies on Health Canada to ensure food safety but the proposed changes would diminish the role of Health Canada in fulfilling its mandate. The changes would reduce Health Canada's role to a passive one in relation to an anticipated wave of foods from genome-edited plants. The proposed changes would elevate product developers to the role of sole safety assessors. We reject this shift to corporate self-regulation of genetically engineered foods as dangerous and negligent.

Summary recommendation

Health Canada should **retain regulatory authority over all genetically engineered foods**, including all of those derived from plants produced through genome editing. Health Canada should assess the safety of all genetically engineered foods and not leave any safety assessments to product developers.

Genome editing should trigger regulation and safety assessment. The use of genome editing should be defined as a novelty trigger, replacing the proposed definition of foreign DNA as a novelty trait. The processes of genome editing have no history of safe use in our food system and evidence clearly shows that genome editing processes can create a range of unintended effects that need to be detected and evaluated. Health Canada should choose precaution in the regulation of genome-edited foods, reflecting its obligation to ensure the health and safety of the Canadian food supply. At a minimum, all new genetically engineered products, including those of genome editing, should be assessed for safety by regulators and tracked by our government

B. The stated goals are unmet

The primary mandate of Health Canada in relation to Canada's food system is to ensure health and safety, however, Health Canada's consultation lists many other goals.

In its summary of the proposals, Health Canada states that, "These new guidance pieces will maintain the health and safety of Canada's food supply, and:

- maintain the product-based system
- align with international approaches (to the extent possible)
- better facilitate a risk-based approach where oversight is commensurate to the level of risk posed by the product
- provide clarity and predictability in the regulatory interpretation of novel products of plant breeding
- support innovation and the introduction of new technologies which result in the production of safe food"⁴

In its introduction to the consultation, Health Canada states, “Our intent is to ensure the guidance:

- provides greater clarity, predictability and transparency regarding the regulation of novel foods derived from plants, including those developed using gene editing technologies
- provides an efficient and predictable pathway to commercialization for new products”⁵

The proposals are elsewhere noted as aiming to:

- enhance public trust, and
- take account of the current scientific knowledge.

The stated goals of the guidance are not met.

There is a lack of clarity and predictability

The objective to provide clarity to product developers with these new proposals fails in many places. The descriptions of the proposals in the consultation documents are often convoluted, vague or imprecise. In particular, the language used in the proposals defining retransformants is imprecise. In that consultation document, there is common use of many unscientific terms and terms/concepts where no definition is provided. This imprecision raises questions about the exact meaning of the details in those proposals themselves and their scientific foundations. It also raises questions about how vague or specific any resulting finalized guidance text might be. Those product developers with limited or no experience navigating the regulatory process and those with little familiarity with terms specific to the Canadian regulatory context, may struggle to interpret such undefined, imprecise terms and vague instructions.

In fact, **lack of predictability is an inherent feature of the Guidelines**. The current lack of clarity and predictability for product developers (and the public) is partly due to the fact that the existing Guidelines allow for a great deal of flexibility on the part of product developers and regulators to decide which information is required to determine the regulatory status and safety of a particular product. The Guidelines are “not intended to define explicitly all the data that might be required in the course of a safety assessment.” The proposals do not fundamentally address this level of unspecified request to developers.

Lack of predictability is also a product of the definition of novelty, and the focus on products versus process. It is also a function of case-by-case product assessment. In this respect, the further narrowing of novelty definitions in the guidance provides little enhanced predictability, with **one exception: The one area of clarity and predictability provided is in the proposed definition of foreign DNA as a novel trait**. However, we argue that this proposed definition would undermine the ability of Health Canada to regulate for safety. This definition could serve to encourage developers to focus on using those techniques that would avoid this regulatory trigger and thereby facilitate a flood of unregulated genome-edited products entering the market. As discussed by Narwaz and Kandliker (2021), “a focus on ‘transgenes or not’ may also open the door to manipulation by developers: already, developers have utilized this historical focus on transgenics as a means to circumvent public opposition, using terms such as ‘new plant breeding technologies’, ‘precision breeding’, ‘new mutagenesis’, and

‘accelerated breeding technology’, with the goal of downplaying the similarity of these techniques to GM (Kuzma 2016; Bain et al. 2019). In other words, this approach may make it easier for developers to shunt new techniques into the ‘no regulation’ category.⁶

The proposals jeopardize food safety

Health Canada says that the proposals aim to present guidelines that are “commensurate with the level of risk”. Health Canada calls this a “risk-based approach” but this approach makes a predetermined assessment of risk that should instead be evaluated through individual government product safety assessments.

The proposals are founded on incomplete scientific analysis of the unintended effects that can result from genome editing, along with assumptions about the ability of the plant breeding process to control for unintended effects and the ability of product developers to regulate themselves. The proposals overlook a range of risks that can result from using genome editing techniques that may impact food safety: The proposition that the absence of foreign DNA can function as one indicator that a plant could be non-novel, without a regulatory requirement for product developers to conduct unbiased screening for off-target effects and any screening for on-target effects, is not supported by the science. In this respect, the proposed guidance **does not reflect current scientific knowledge**. For further discussion please see CBAN’s report “Genome Editing in Food and Farming: Risks and Unexpected Consequences” (2020).⁷ See further discussion in section C.

The proposed guidance would undermine public trust

Health Canada names the goal of enhancing public trust “in these products and the regulatory system” however, allowing some genetically engineered foods onto the market without government oversight would undermine public trust in both. **Implementing this guidance could initiate a crisis of legitimacy for Health Canada and deepen a public trust crisis for the agri-food industry.**

In 2001, The Royal Society of Canada’s Expert Panel on the Future of Food Biotechnology stated their concern over the lack of transparency in regulation and its relation to public trust: “The lack of transparency in the current approval process, leading as it does to an inability to evaluate the scientific rigor of the assessment process, seriously compromises the confidence that society can place in the current regulatory framework used to assess potential risks to human, animal and environmental safety posed by GMOs.”⁸ The core recommendations of the Expert Panel remain unaddressed and the level of public concern over the use of genetic engineering in food and farming, including concerns over government regulation for safety and unmet demands for more transparency, has not diminished in the over twenty years since the technology entered our food system. For example:

- In a 2012 poll, 76% of Canadians answered “no” to the question “Would you say that the Canadian government has provided you with adequate information about genetically modified foods so that you can make an informed decision about these foods?”⁹
- In a 2015 poll conducted for CBAN, 57% of Canadians said they were not confident in the government’s safety and regulatory systems for genetically modified foods.¹⁰

- that same poll, of the 88% of Canadians who said they wanted mandatory labelling, 47% said they were concerned about government transparency in regulation and 46% said they were concerned about corporate control.
- Agriculture and Agri-Food Canada's 2019 survey on consumers perceptions of food also found Canadians emphasising safety, transparency and the need for high standards: 84% of Canadians said that ensuring food safety is very important in building trust, with 66% mentioning transparency about how food is produced and processed.¹¹
- In that same 2019 survey, half of Canadians (50%) said they believe the government should ensure Canadian food standards meet or exceed those of other countries, and that the industry is supported by a strong regulatory system (49%).
- The Canadian Centre for Food Integrity reported that, **in 2020, 38% of Canadians said they want more regulation in relation to genetic modification.**¹²

In the past five years in particular, enhancing public trust in the food system has become a preoccupation of the agri-food industry, resulting in significant government and industry investments.¹³

The proposal of the “Voluntary Transparency Initiative”, which is explicitly aimed at enhancing public trust, would utterly fail to provide transparency to the public. Instead, it would likely increase public confusion and further erode public trust. Rather than resolve the transparency problem created by unidentified, unreported genome-edited foods coming to market, the initiative highlights this important implication of the proposed surrender of government regulatory authority over these products. The proposal to create the Voluntary Transparency Initiative signals the need to carefully examine the possibly profound transparency gaps created by guidance proposals that would pass decision-making to product developers without any government oversight. Please refer to further discussion on this initiative in section D.2.

The proposed changes to regulatory implementation may also hinder the ability of the ministry to assure Canadians of food safety as secured through Health Canada’s regulation. For example, the Minister of Health responded to petitions e-2416 (January 25, 2021)¹⁴ and e-2877 (March 22, 2021)¹⁵ that called for mandatory labelling of genetically modified foods by assuring Canadians that, “Health Canada is responsible for provisions related to public health, food safety and nutrition, through the establishment of **science-based polices and standards, to ensure that all foods, including those that are genetically modified or genetically engineered, are safe and nutritious**” [emphasis added]. The Minister’s statement that, “Assessments of novel foods are conducted under the Food and Drug Regulations...which prohibit the sale of these products until Health Canada has completed a full assessment to confirm their safety”¹⁶ would still be correct but would **no longer apply to all genetically engineered foods.**

The guidance would not support innovation

The goal to provide an “efficient and predictable pathway to commercialization for new products” would come **at the expense of the other stated goals** and would compromise Health Canada’s ability to achieve its primary mandate to protect the health and safety of Canada’s food supply. While Health Canada should strive to create efficient processes in regulation, such efficiencies should not come at the expense of adequate oversight. The articulation of regulation as a “pathway to commercialization,” in particular, is at odds with Health Canada’s primary food safety mandate.

The guidance as proposed could simultaneously support “the introduction of new technologies” while also ultimately undermining their success in the market. This is because the proposals do not support public trust in those products and their regulation. While products of genome editing may come to market faster through an “efficient and predictable pathway to commercialization” under this new guidance, they would not be supported by independent safety assessments and government oversight. Private companies rely on government regulation to help secure consumer confidence and market access.¹⁷ Without the regulatory system to provide legitimacy and public trust, the marketing of genetically engineered foods, including those produced by genome editing, is likely to continue to be met with a high or an increased level of public controversy, in both domestic and in international markets.

In regards to novel foods, Health Canada’s role is currently restricted to product safety assessment and this also limits the type of innovation that such regulatory guidance could support. In our assessment, the stated goal to support innovation through this updated guidance **risks equating support for innovation with support for new products and technologies. We assert, however, that innovation in agriculture should be understood more broadly.** We stress that innovation is not the sole domain of “product developers” but also belongs to farmers, communities and those creating new farming systems. Innovations in agriculture that contribute to food security and nutrition, economic development, and sustainability are both technical and social.¹⁸ The government should expand the focus of its “Innovation Agenda”¹⁹ to be more inclusive, to support investments in innovations such as agroecological practice, farmer-led participatory plant breeding, and farming systems, that may not result in marketable products.²⁰

In fact, the market release of unreported genome-edited products **could put other innovations in agriculture at risk.** It could mean significant market losses. For example, comingling and contamination could result in rejections of entire crop kinds in sensitive markets, and the threat of comingling may lead some customers could choose alternative markets as a precautionary measure to protect product integrity. The proposed addition of unreported genome-edited foods to the market would also put organic farming systems at more acute risk from GM contamination. Whether isolated incidents or widespread or ongoing contamination events, the consequences of GMO escapes in Canada have included the temporary or permanent loss of export markets, lower crop prices in the short or long-term, the loss of access to a particular crop, and the loss of farm-saved seed.²¹ Widespread GM canola contamination in Canada meant that most organic farmers lost the option of growing canola; GM flax contamination changed the flax export market for Canadian farmers; and GM alfalfa commercialization in Canada poses an immediate contamination threat to organic farming systems and other farm operations.

Additionally, there is no cost-benefit analysis conducted as part of government approvals of genetically engineered foods, crops and animals. Instead, it is left to the market to decide if these innovations have value (in the context of factors which significantly limit market choice such as the lack of product labelling and an unprecedented degree of corporate consolidation in the seeds and agrochemical markets²²). **The fact that new genetic engineering techniques are new innovation does not mean that they are intrinsically valuable.** Support for the growth of the biotechnology sector as an economic driver is embedded in government policy²³ but the benefits of applications of genetic engineering are not evaluated in regulation.

The proposed guidance is not aligned with international approaches

Canada's trading partners have divergent regulatory approaches to the new genome editing techniques and this reality is recognized in Health Canada's qualification of their goal to align regulation with international approaches "to the extent possible". Given the state of current international debate and the differing regulation of our trading partners, **Health Canada cannot yet choose a direction that is in alignment with international approaches.** Choosing to remove or reduce the regulation of genome editing at this time would therefore jeopardize some of Canada's export markets. Rather, **the approach to regulate all products of genome editing would protect Canada's domestic and export markets, and Canadian farmers.** In this context of divergent approaches, in choosing the approach to remove regulation as outlined in the proposals, **Health Canada is advocating for the biotechnology industry at the expense of export market certainty and safety assurances.**

C. Genome editing should be regulated and products should undergo rigorous, independent scientific safety assessment

Genome editing creates unintended effects that require investigation

Food safety concerns raised by GMOs do not rest on the presence or absence of foreign DNA, but on the unexpected and unpredictable effects arising from the genetic engineering procedure. This is relevant in relation to genome-edited crops that may not contain foreign DNA in the resulting GMO (SDN-1 and -2). Genetic errors can be caused by genome editing irrespective of whether or not genes for a novel trait have been introduced. For example, intentionally disabling one single gene could have important consequences for other traits in the plant²⁴. Defining foreign DNA as a regulatory trigger rather than genome editing is dangerously simplistic and reductionistic, and could jeopardize food safety.

As discussed in our June 2020 report "Genome Editing in Food and Farming: Risks and Unexpected Consequences" (enclosed), genome editing can cause genetic errors, including off-target effects in the genome, unintended on-target effects, interference with gene regulation, and intended and unintended insertion of DNA.²⁵ These genetic errors can lead to unexpected and unpredictable effects in the resultant genome-edited organisms. Unexpected and unpredictable effects can include changes in the chemistry, biochemical pathways or protein composition, which could all be important

for food and environmental safety. Such effects will not necessarily manifest as easily detected unintended traits, nor be easily removed if they are genetically tightly linked to the intended trait(s).²⁶ In addition, unintended traits may not be observed immediately but could be a product of gene-environment interactions, for example, only apparent during times of stress such as drought.²⁷ Hence, genetic errors need to be investigated thoroughly for any potential adverse effects.

Even since our report publication in June 2020, there are new findings of genetic errors in experiments on genome-edited human cells and animals that should be considered as relevant to the regulation of genome editing in plants.²⁸ This is because many of the effects, such as off- and on-target effects and unintended DNA insertion, are caused by the process, not the nature of the host organism. There have also been new papers specific to errors in plants.²⁹

Health Canada's proposal to define the presence of foreign DNA as a novel trait negates necessary examination for potential unintended effects resulting from the processes of genome editing. Testing to confirm the absence of foreign DNA in a GMO, and research to assess the possible impacts of any intentionally inserted foreign DNA, should not be prioritized in a way that minimizes or excludes screening genome-edited GMOs for other off-target and unintended on-target effects. The current proposals would result in regulatory guidance that ignores the genetic errors and unintended effects that can be caused by genome editing and cisgenesis, and that may have an impact on food and environmental safety.

Health Canada does not conclude that the absence of foreign DNA automatically means a genome edited food is as safe as its conventional counterpart: the definition of foreign DNA as a novel trait is accompanied by four other novelty triggers in the guidance that attend to broad categories of food safety issues. However, these triggers are not inclusive of all the risks posed by the use of genetic engineering techniques including those of genome editing.

The narrowly defined novelty trigger of foreign DNA would mean that product developers would make their own safety determinations for many foods from genome edited plants, without any government oversight. Health Canada would be asking product developers to conduct their own safety assessments, according to novelty as defined, and would be assuming that this work is undertaken and done sufficiently to ensure safety. This devolution of responsibility from Health Canada to product developers themselves is unacceptable. The proposed new definition of the absence of foreign DNA as a signal of non-novelty will apply to many genome-edited plants for food where **there a strong scientific rationale to stringently regulate for safety.**

With genetic engineering technologies, it is not only the intended effects or traits that are relevant, but also unintended effects. Regarding the other proposed novelty triggers, such increased levels of an endogenous allergen, an endogenous toxin or an endogenous anti-nutrient beyond the documented range, such determination would depend on an analysis that would need to be examined by regulators. We maintain that such **claims to non-novelty cannot be divorced from the risk assessment process itself.**

In its description of the proposed Voluntary Transparency Initiative, Health Canada says it would encourage developers of self-determined non-novel genome-edited GMOs to conduct some form of biased screening for off-target effects such that developers can submit "confirmation that any DNA sequence in the plant's genome which may be susceptible to "off-target" edits based on the gene editing technology used have been analyzed." In addition to the problem that this request is voluntary, this request completely **overlooks the potential for unintended on-target effects and neglects the possibility of unpredicted off-target effects that would be detected via unbiased screening.**

Additionally, this proposed narrow approach to defining novelty is not “future proof” and would not provide the flexibility, as articulated in the Guidelines, to “take into consideration future scientific advances.” The current Guidelines acknowledge that, “the types of studies considered appropriate to demonstrate the safety of a novel food change with scientific knowledge and development”. Regulating all genome edited products as novel would provide Health Canada with the ability to adjust to changing scientific knowledge. For example, in addition to research on multiplexing, there are many different techniques of genome editing in development.³⁰ This guidance framework would compromise the ability of regulators to respond to new information that may arise in this fast-paced field.

Gene editing is novel, there is no history of safe use, and Health Canada has little experience regulating (has no “familiarity” with) genome edited products

Genome editing is novel. For example, genome editing can open up new areas of the plant’s genome to DNA changes that are not accessible by conventional breeding: as Health Canada acknowledges, “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.” Many of the applications of genome editing are still experimental and may cover a whole range of techniques in development and yet to be developed.

There is no history of the safe use of genome editing. Additionally, Health Canada and the CFIA have little experience regulating products of genome editing and therefore have no “familiarity” with genome editing. Thus far, only two products of genome editing have been approved for market release in Canada (though the novel trait of the first of these - the herbicide tolerant canola from Cibus - is no longer described by the company as a product of the genome editing technique ODM³¹).

The two products underwent different levels of safety assessment: Cibus’ GM canola was regulated as a novel food and the GM waxy corn from Corteva was determined by Health Canada to be non-novel and was not therefore subject to a full safety assessment, though it was nonetheless subject to government oversight.^a These cases signal important issues that support the conclusion that Health Canada should increase its information requirements and scrutiny of all genome edited products rather than hand safety assessment over to product developers.

1. Cibus’ herbicide tolerant canola

Health Canada and the CFIA published Decision Documents (2013) that summarized their safety assessments of an herbicide tolerant canola (event 5715) from the company Cibus.³² However, at the request of Cibus in February 2020, the CFIA edited its document to remove references to the company’s proprietary ODM technology, in order that the canola not be “misinterpreted” to be the product of this genome editing technique.³³ Cibus had widely described its canola as gene-edited³⁴ until 2020,³⁵ months ahead of the publication of an open-source detection test for the product.³⁶ Cibus now argues that their herbicide tolerant trait is not the product of ODM itself, though ODM was used in the process.³⁷

^a It is unknown to the Canadian public if Health Canada and the CFIA are currently assessing any other genome edited crops, such as Corteva’s herbicide tolerant/insect resistant corn DP915635 which is under assessment in Europe, due to the departments’ interpretation of Confidential Business Information.

This lack of precision in the developer's own description of the technology, and in the Decision Document themselves, underscores the need for more data from companies, more public data, and a higher degree of government scrutiny over these details. In addition to its relevance in safety assessment, such data can be important for farmers and for international trade in particular. For example, the Cibus canola was promoted in Canada as non-GMO³⁸ while fitting the regulatory definition of a GMO in Europe (it still does).³⁹ The consequences of unknowingly comingling varieties that have differing market acceptance status can affect the whole sector, not just those farmers who are growing for sensitive markets. In the case of contamination from Triffid flax, for example, market rejection included the entire crop kind, flax prices dropped, and it took years and millions of dollars to regain a market share.⁴⁰ All farmers who grew flax varieties suffered, regardless of whether their crop had been found contaminated with Triffid.

Furthermore, the details of the Cibus product transformation remain contested. While the documentation in the public domain remains incomplete, some argue that the company's data indicates that the mutation conferring herbicide tolerance may be an off-target effect directly caused by application of ODM.⁴¹ The level of uncertainty and controversy surrounding the facts of the first genome-edited plant suggests the need for Health Canada and the CFIA to more tightly oversee product developer plant characterizations to ensure accurate information for regulators, and for use by both consumers and farmers.

2. Corteva's GM waxy corn

Health Canada determined that a corn, genome-edited to be waxy (to have an altered starch profile) from Corteva (DowDuPont) was "non-novel" and therefore did not need to undergo a government safety assessment.⁴² (There is no public information about any determination from the CFIA.) The example of Corteva's GM genome-edited waxy corn illustrates of the need for Health Canada to retain regulatory authority over all genome-edited products rather than leave safety assessments (and novelty determinations) to the product developer. It also illustrates the need for Health Canada to expand its understanding of what needs to be evaluated in safety assessments of genome edited products to well beyond a focus on the presence of foreign DNA.

Corteva calls this GM product, "Next-generation waxy corn – a flagship case of SDN-1/NHEJ genome editing via CRISPR/Cas9"⁴³ and it is particularly important to examine because it is, with the exception of the Cibus canola, the first food from a genome-edited plant to be regulated by Health Canada, and it is the first to be determined as non-novel by Health Canada. This example is also important because Corteva has made it clear that they are using this product to test the regulatory response to agricultural products developed using CRISPR/Cas (SDN-1).⁴⁴

Corteva scientists published a peer-reviewed report (Gao et al 2020)⁴⁵ explaining how their waxy corn was genome edited and detailing the subsequent analysis done to screen for unwanted foreign DNA and genetic errors. The publication of such data is not, however, something that accompanies all genetically engineered products coming to market and there is no guarantee that, in the absence of government regulation and requirements, such data will appear in the scientific literature. Currently, though the science behind GMO safety is largely corporate science (privately generated and owned) and is not publicly accessible, such science is submitted to Canada's regulators for review. **Without government oversight, most or all of the science behind non-novel genome-edited GMOs on the market would not only be inaccessible to the public (as is currently the case) but also to government.**

In their paper, the developers of the GM waxy corn explain their use of DNA sequencing to confirm that no foreign DNA remained in the GMO. While most first-generation genetically engineered crops generally only have one plasmid inserted, this genome-edited corn has six separate plasmids fired randomly at the corn's genome, possibly increasing the potential for genetic errors. Although such genes are removed by cross-breeding, their insertion can produce the deletions and rearrangements of host DNA as seen in first generation GM crops, such as Roundup Ready soy.⁴⁶ Any such deletions and errors would be in addition to any genetic errors caused by the genome-editing process. However, the analysis for off-target effects is unsatisfactory and **the analysis of on-target effects is non-existent.**

Corteva used “biased” searching of only predicted sites for off-target effects: Corteva analysed 15 predicted off-target sites in a total of 48 plants and did not observe any off-target effects⁴⁷. A more robust approach would have used whole genome sequencing to search for any off-target effects across the whole genome (‘unbiased’ searching), as detailed by Modrzejewski et al. (2019)⁴⁸ and recommended by Kawall et al. (2020).⁴⁹

Corteva did not search for any unintended on-target effects, such as possible rearrangements or deletions of the corn’s own DNA. Nor did they examine for any effects such as exon skipping, which could lead to the misreading of DNA. **The lack of such searching for on-target effects has been cited as a concern in the development of genome-edited plants:** “Recently, Kosicki et al. have reported on unintended on-target changes, such as large chromosomal deletions, insertions and inversions, in mouse embryonic stem (ES) cells and human differentiate cells. Such chromosomal rearrangements are not always easy to detect unless long-range PCR or long-read next generation sequencing (NGS), such as PacBio, are used. Therefore, quite possibly, in many plant studies where targeted mutagenesis was performed using CRISPR/Cas, such unintended genomic changes might have remained undetected since the above-mentioned techniques were rarely used for genotyping CRISPR/Cas induced mutations in plants.”⁵⁰

We note that Health Canada’s proposal to encourage product developers to submit information via the Voluntary Transparency Initiative includes a request for developers to screen for “confirmation that any DNA sequences in the plant’s genome which may be susceptible to ‘off-target’ edits based on the gene editing technology used have been analysed.” This request for biased screening validates the relevance of screening for off-target effects for safety assessment and opens up the question about the relevance of unbiased searching for other off-target effects, as well as screening for possible on-target effects.

D. The guidance proposals are not science-based

1. Corporate self-regulation is not science-based

The proposed guidance would further undermine the ability of the federal government to claim that Canada's regulation of genetically engineered organisms is science-based. **The changes would deepen Health Canada's reliance on private science**, going as far as to accept product developer safety assessments without any government evaluation. This fails to meet the standards of "sound science" as there would be no independent scientific review of the evidence generated by developers. Furthermore, Health Canada would not have access to this evidence, used by product developers to determine non-novelty status and safety. **Reliance on unseen, corporate safety assessments is not science-based. The outcome will be a reliance on product developer claims to safety without the presentation of evidence.**

The Government of Canada describes current federal regulation as "science-based" despite the fact that regulatory decisions on genetically engineered products are largely based on evaluations of private corporate science rather than peer-reviewed science in the public scientific literature, and despite the fact that the decisions themselves are not peer-reviewed as was recommended by The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology in 2001.⁵¹

Health Canada does not conduct any safety testing of its own but approves GM foods based on information submitted by the product developer, often entirely generated by that developer. This information may contain little or no peer-reviewed data, and there may or may not be any additionally relevant studies in the scientific literature. There is also no guarantee that product developers submit all of the studies they have conducted – studies that provide evidence of harm can be omitted. The developer-submitted data packages are classified as "Confidential Business Information" and cannot therefore be accessed by the public or independent scientists, even through Access to Information requests. Instead, final approval decisions and related data are summarized for the public - without a high level of detail - in short (generally 1-3 page) "Decision Documents". In relation to those unregulated genome-edited foods, the proposals would do away with this minimal amount of detail currently provided to the public. The importance of the Decision Documents, along with current novel food listing, is discussed in the Guidelines: "In light of widespread interest in novel foods and, in particular, those produced by the techniques of biotechnology, the Food Directorate is of the view that mechanisms to inform the public about such new products are needed." (Please see our further commentary in D.2 on the proposed "Voluntary Transparency Initiative").

This regulator reliance on information that is generated and owned by private companies or institutions already means that the science behind Canada's GM food approvals is not in the public realm. The bulk of the science is not published, peer-reviewed science, and is not therefore part of the scientific literature, available to the scientific community for comment and use. The Royal Society of Canada's Expert Panel concluded that, without access to the science behind GM food approvals, "there is no objective way for the public or independent scientists to evaluate fully the scientific rigor of these assessments."⁵² The Panel was clear that, "Peer review and independent corroboration of research findings are axioms of the scientific method, and part of the very meaning of the objectivity and neutrality of science."⁵³ **Without peer review, the information behind Canada's GM food approvals cannot be assumed to be good science, or indeed "science" at all, and Canada's regulation cannot be called science-based.**

It is well established in the scientific literature that industry-funded studies tend to produce results that are more favourable to the funder.⁵⁴ While decisions to approve genetically engineered foods have all been made with the use of corporate-submitted data packages, all of this Confidential Business Information has, thus far, been accessible to and reviewed by Health Canada regulators and, with the exception of Corteva's GM waxy corn, summarized for the public in Decision Documents.^b However, under the new guidance, **corporations would be free to put some products of genetic engineering on the market without a Health Canada review.** This means that **Health Canada would no longer have access to this corporate science**, would not verify the quality of the non-peer-reviewed data, and not act as an independent control on corporate science.

This reliance on product developer safety assessments is not science-based. This approach rests on the assumption that product developers will do the necessary work of fulsome safety assessment. However, without regulatory requirements, there is no guarantee that product developers will do the required research, and no way to verify that they have done so. For example, there is no reason to expect that all developers will publish studies describing their technologies/products and the safety assessments thereof in the peer-reviewed scientific literature (as published by Corteva⁵⁵). This means that the science behind some or all of these unregulated GMOs – including basic information about the technology used to create them – could be unknown to the public, and to the federal government.

Health Canada cannot rely on product developers to undertake the necessary safety assessment. For example, in the proposal relating to the Voluntary Transparency Initiative, Health Canada would be encouraging developers to voluntarily provide “Information regarding which analyses were performed to confirm that the new plant variety does not contain any DNA sequence related to the gene editing technology used in the plant’s development.” This request would suggest to product developers that they should check for the presence of foreign DNA and not just assume its absence, as was the case with Recombinetics’ hornless cows. The example of the Recombinetics cows shows that developers may declare the absence of foreign DNA without actually testing for it.⁵⁶ That case demonstrates the need for regulators to require and review corporate data.⁵⁷ The case also suggests the need for developers to employ the latest detection tools. To this, Health Canada tacks on the request that, “Furthermore, confirmation that any DNA sequences in the plant’s genome which may be susceptible to “off-target” edits based on the gene editing technology used have been analysed.” This request indicates Health Canada’s acknowledgement of the importance of screening for (some, predicted) off-target effects in safety assessment, while leaving this detection and evaluation entirely to product developers.

In the consultation documents, Health Canada relies heavily on a discussion of “plant breeding practices that support food safety.” Health Canada says that, “The data generated during plant variety development, as well as the post-commercialization variety stewardship, is of high quality and of sufficient rigor to adequately support the conclusion that this class of products is safe...”, however this data is generated for specific purposes such as ensuring the intended trait functions as expected and testing agronomic performance. These purposes are not inclusive of all safety questions, do not generate all the data needed, and are not equivalent to safety assessment. Health Canada describes plant developers as “experts in their plant variety and the plant species in relation to its use in food, and related to food safety” but this expertise does not necessarily extend to that relating to genome editing, is not necessarily relevant to all the potential safety issues, and is no substitute for a full scientific evaluation from independent government regulators. **The product development process is not sufficient to ensure safety and is not designed for this purpose. The plant development process should not be equated with or substituted for safety assessment.**

^b Five of Health Canada’s most recently approved novel foods (approved 2019/09/09 – 2020/09/30) are listed without such Decision Documents.

Developer plant product characterisation is largely focussed on examining the intentional characteristic(s) and, with regards to genome editing, in removing the genome editing tools (foreign DNA). In relation to retransformants, Health Canada argues that, “These [insertional] unintended effects are accounted for in the practices used by plant developers. Developers produce thousands of plants containing the same inserted DNA and, through analysis, select the ideal plant (i.e., no unintended effects observed),” but such selection of the ideal plant does not necessarily mean that a developer has found or addressed unintended effects, particularly those that are not associated with an unintended trait. For example, developers do not necessarily carry out in-depth compositional analyses (“omics” molecular profiling) to look for unintended toxins and allergens or increased ranges/levels thereof. Such tests by product developers are not widely evident in the peer-reviewed scientific literature and such tests cannot be expected if Health Canada does not require them. Furthermore, where unintended effects are discovered relating to the new characteristic, product developers may be unable to address them if they are linked to the gene of interest, without losing the new desired change. Furthermore, with vegetatively propagated crops, such as potato, banana, and fruit trees, genetic errors cannot be bred out.

The fact that a genetically engineered plant can function as intended does not rule out the possibility that there are undetected unintended effects that could have an impact on food safety. Evidence shows that unintended and unpredicted changes may remain undetected in commercialized products for years.⁵⁸ For example, in 2003, an independent study found that the structure of the transgene in Monsanto’s GM corn MON810 differed from the description provided to regulators by the company, a discovery that the authors say suggests a genomic rearrangement involving the transgene insertion site.⁵⁹ In 2013, European regulators discovered a “hidden” gene that was present in many commercialized GM crops: a substantial segment of the multifunctional Gene VI from Cauliflower Mosaic Virus.⁶⁰ Because it had not been identified, this gene was not examined as part of government product safety assessments.⁶¹ The high level of unintended traits found, even in highly-selected commercial genetically engineered plants, suggests that developers and regulators are not fully controlling for unintended effects.⁶² In many cases there is not enough data to determine whether these negative impacts arise from the transgene, unintended changes at the transgene insertion site, genome-wide unintended effects or a combination.

We also note that Health Canada refers to the timeframe to complete safety assessments as a “service standard.” This language implies that Health Canada is providing a service to a client, which in this case is the product developer. However, Health Canada provides a valuable **public service** to Canadians. This service – a duty and responsibility – is to ensure food safety, with accountability to the public.

Ensuring health and safety is Health Canada’s mandate but this is not all that Canadians want from their food system and the governance of genetic engineering. Across departments, the regulation of the use of genetic engineering is defined solely by scientific questions, in a case-by-case product assessment. This regulation is then further narrowly defined in relation to the type of science engaged. It also excludes non-scientific considerations such as social, economic and cultural impacts, and does not involve public participation including any consultations with farmers, consumers, and Indigenous peoples.⁶³

Allowing product developers to assess the safety of some genetically engineered foods is a shift to corporate self-regulation that jeopardizes food safety and further undermines Canada’s claim to science-based regulation. This proposed downloading of regulatory responsibility to private companies and institutions is not acceptable.

2. The “Voluntary Transparency Initiative” would fail to provide transparency by placing decision-making in the hands of product developers and makes necessary the need for Health Canada to maintain regulatory authority over all genetically engineered foods

The “Voluntary Transparency Initiative” (hereinafter referred to as VTI) would fail to meet its stated goals of providing transparency and enhancing public trust. Instead, this proposal shines a light on some of the serious implications of allowing companies to determine the regulatory status and safety of their own products.

In respect to the proposed VTI that would result in a “List of Non-Novel Gene-Edited Plants for Food Use”, Health Canada says, “The goal of this initiative is to provide Canadians with a clearer understanding of the gene-edited products in the Canadian market with the goal of enhancing public trust in these products and the regulatory system,” and, “there is great interest from and benefit for regulators, plant developers, and the public in greater transparency regarding all products developed using these technologies that are present in the Canadian food supply.” Health Canada asks, “Does the voluntary transparency initiative serve its purpose to inform Canadians what non-novel gene-edited products are on the market? Can we do more to achieve this objective?”

We are pleased to see Health Canada articulate the need for transparency and recognize the public’s interest in this information. In fact, for over twenty years, polls have consistently shown that the majority (over 80%) of Canadians want mandatory labelling of genetically engineered foods.⁶⁴ **However, the proposed initiative would not meet its stated goals of enhancing transparency and public trust.** Instead, the proposal exposes the depth of the current lack of transparency that needs to be addressed.⁶⁵

The proposal for the VTI arises because Health Canada is proposing to exempt some genetically engineered foods from regulation and, in so doing, surrender regulatory authority over these GMOs. In the absence of regulatory authority, Health Canada is proposing to **encourage product developers to voluntarily report the existence of any unregulated genome-edited GMOs**, along with some specified information relating to the product developer’s assessment of product safety. This means that consumers, farmers, and the federal government itself will not necessarily be made aware of all the new unregulated GMOs that could be in our food system or intended for commercialization.

The VTI would likely exacerbate consumer confusion about what products are on the market because the resulting “List of non-novel Gene-Edited Plants for Food Use” would be a list for the public of *some or all* of the unregulated GMOs that *may or may not* be on the market. This would **not be a list of genome-edited foods on the market but it would be a list of some unregulated genome-edited foods that could be on the market**. There would be no way for the public, or indeed Health Canada, to know if the list is complete. The public would be left to assume that the list is only partial: Not knowing whether the list is complete or partial means that the list does not provide transparency, and a partial list is of minimal to no use to Canadian consumers and farmers.

It is critical to note that the federal government does not track which genetically engineered, plants and animals are *actually on the market*⁶⁶ and no public statements should be made that suggest otherwise.

The proposed VTI would result in a list of some unregulated GMOs that companies say *they are interested in commercializing* – in fact, **the market status of these GMOs would remain unknown**.

Health Canada says that, “this voluntary system is to be used for products ready for commercialization and not for theoretical products” and that the VTI will encourage product developers to provide information, including the “intended date of commercialization”, at least 90 calendar days prior to commercialization. However, there is no apparent intention on the part of Health Canada to verify this information on commercial status and it would be difficult for the public to confirm that corporate notifications are not just posted to promote theoretical genome-edited products to attract investors, for example. Additionally, there are many reasons why a product intended for commercialization may not ultimately be sold. For example, our research has found that many genetically engineered foods currently listed by Health Canada as approved for use are not currently sold in Canada, including GM tomatoes, GM flax, and GM potatoes.⁶⁷ Health Canada says it will encourage product developers to name the “intended date of commercialization”. Instead, **Health Canada should establish mandatory labelling of all genetically engineered foods to provide transparency for the public and enable tracking and traceability.**

The example of how Canada’s standard for voluntary labelling is used (or, more accurately, not used) clearly illustrates the lack of utility in a request for voluntary disclosure where industry has an interest in not disclosing. Rather than establishing mandatory labelling for genetically engineered foods, a standard was created, published in 2004, for “Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering”. To our knowledge, no company has ever used the standard to voluntarily identify a genetically engineered food.⁶⁸ Transparency on genetically engineered foods can only be achieved via mandatory measures and not, as Health Canada appears to see it, as a request in negotiation with industry, in this case mediated by the biotechnology and pesticide industry lobby group CropLife Canada.⁶⁹

Similar voluntary initiatives from other departments have failed to provide transparency. These failures expose gaps in the system that should be fixed, not emulated. The CFIA’s “Biotechnology Notices of Submission Project”⁷⁰ fails to provide transparency: As with other departments, the CFIA does not notify the public about requests for approval of Plants with Novel Traits and, even if asked by the public, the Agency will not tell Canadians which GMOs are being assessed.⁷¹ Instead, the CFIA asks product developers for permission to share this information with the public via the Project. Our comparison of the CFIA’s list of approved PNTs and the list of plants posted via the Notices of Submission found at least two approved LMO events missing from the Notices of Submission (NS-B50027-4 and SSF-HC485-9), and there was no Notice of the Cibus canola. In 2013, the then Acting National Manager of the Canadian Food Inspection Agency made it clear why regulatory authority is key to providing such information to the public when she said, “It is important to note that in Canada **there is no legal requirement for developers to participate in the Notice of Submission process nor any ability for the CFIA to require developers to participate.”**⁷² [emphasis added]

The proposed VTI listing for corporately-determined “non-novel” products of genome editing would **rely on the cooperation of product developers** to disclose which unregulated GMOs they intend to commercialize and to provide information about the developer assessment of non-novel status and safety. Companies may be more or less inclined to provide this information for various reasons, and this willingness to disclose is likely to shift over time. In the case of genetic engineering thus far, the market has been dominated by the five largest agrochemical and seed companies in the world.⁷³ One of these, Corteva (DowDuPont), holds the most patents on CRISPR technology of any company or institution in the world.⁷⁴ These companies have shown an interest in avoiding public scrutiny of their products, as demonstrated by their decades-old campaign to stop mandatory GM food labelling in Canada and the US.⁷⁵ **The role of government is to require companies to disclose important information in the public interest where they may not be inclined to provide it.**

The VTI would leave farmers, and consumers, and the federal government itself, with incomplete and essentially meaningless information about genome edited products. The experience of the voluntary labelling system shows that it is possible that the VTI would provide no information whatsoever. This information void could have serious trade implications, would leave Health Canada with even less capacity for product tracing (to assist in possible future food recalls, for example), and would leave consumers with even less information about what genetically engineered foods could be on the market. Ultimately, the VTI would **reduce transparency** since, to date, all genetically engineered foods have, in one way or the other, been regulated and listed for the public.

Critically, the VTI would not just be a voluntary system for notifying the government of corporately-determined non-novel gene-edited foods intended for commercialization, it would also allow for **Health Canada's ad hoc review of product developer determinations of non-novel status.**

In addition to encouraging product developers to notify Health Canada about unregulated genome-edited GMO's heading to market, the VTI would also encourage them to submit some accompanying information. This is proposed to include how their product was developed, and how the developer determined that the product is not novel (and therefore needs no government safety assessment). Health Canada says it will develop a form for developers to fill out, encouraging product developers to submit, "at least 90 calendar days prior to commercialization", several areas of information "**for further review**" such as which analyses were performed to confirm that no unintended foreign DNA remains, confirmation that biased screening for predictable off-target effects was undertaken, and a "rationale to support the developer's self-determination that their new gene-edited plant is not Novel." This list suggests Health Canada acknowledges that some limited safety issues need to be examined, but then indicates that the department is not committed to examining them. Instead, Health Canada will do so on an **ad hoc basis**, if or when product developers voluntarily cooperate.

This means that only those products submitted voluntarily by developers will be subject to (minimal) government oversight. Others, possibly many or even most, would not. The VTI would create **an uneven playing field for product developers** where those who volunteer information are subject to government oversight and those who choose not to participate would avoid interaction with Health Canada. Participating in the VTI would create a risk for product developers where volunteering to be subject to a degree of government oversight could, 90 days ahead of commercialization, lead to a Health Canada novelty determination and subsequent government safety assessment. **The VTI therefore provides a further disincentive for developers to participate, and meet Health Canada's transparency goal.**

Health Canada makes it clear that this proposed ad hoc "further review" is not a safety assessment: "The Novel Foods Section will review the information provided and, **upon concurrence with the developer's rationale for the non-novel status of foods derived from their gene-edited plant**, will publish a summary of this information on Health Canada's website within 60 calendar days under a new table titled 'Health Canada's List of Non-Novel Gene-Edited Plants for Food Use'. **This review is not a pre-market safety assessment of the gene-edited plant, rather a determination of concurrence with the non-novel status of the foods derived from the gene-edited plant.**" [emphasis added] However, Health Canada adds that, "It is important to note that Health Canada reserves the right to conduct a pre-market safety assessment of foods derived from a specific gene-edited plant and request additional information if the Department believes that such foods meet the definition of a 'novel food', as described in this guidance." However, Health Canada, under these proposals, would have no way of knowing if information on all products has been submitted. **Health Canada is noting its right to conduct a pre-market safety assessment without securing this right.** Positioning safety assessment as something Health Canada has the right to do but will not be able to do, undermines the credibility of this approach.

Health Canada has not stated a goal associated with the part of the VTI that encourages submission of information for “further review”. What is the purpose of Health Canada requesting this information if not all developers are required to submit it? What is the purpose of Health Canada overseeing some, but not all, of the non-novelty determinations made by product developers? These logical inconsistencies raise questions about the intent of the guidance proposals.

Health Canada references the possibility of future regulatory change to compel product developers to provide information if corporations are found to not be reporting products through the VTI. However, **the sound solution to this problem is to regulate all products of genome editing as novel**, and to do so from the outset. If regulatory changes are to be considered, they should be considered in relation to strengthening government assessment of genetically engineered foods rather than finding ways around government oversight. **The information that Health Canada would encourage product developers to submit is information that Health Canada should be requiring and then evaluating.**

The VTI would institutionalize a voluntary approach to government oversight that could undermine the credibility of Health Canada. The VTI would send conflicting messages to product developers, and to the public, about the importance of safety assessment. The VTI would further obscure the regulation of an already controversial technology. Its creation would undermine public confidence in Health Canada’s ability to differentiate between public and private interests, and its commitment to scientifically evaluate the potential risks of the products of the new techniques of genome editing.

3. Retransformants cannot be presumed to be “identical”

Health Canada has a second consultation document that outlines proposals for the regulation of foods from “retransformants identical to previously assessed GM plants” -“transformed with the identical sequence of DNA to introduce the same characteristic(s) in the new plant variety” - where Health Canada has a “substantial degree of familiarity” with the specific GM insert in question. Health Canada proposes that GM foods from plants agreed to be retransformants would be eligible for faster safety assessments with reduced information requirements determined by the “tier” of the retransformant.

This set of proposals is based on assumptions about the hypothetical comparative safety of GM plants and a discussion of “identical” plants where such plants will be, at best, similar. Health Canada’s unique definition of retransformants for the purpose of regulation (not a definition reflected in the scientific literature) and the rationale for regulating in the proposed tiers rest on additional arguments that we contest: that the types of genetic changes that can occur as a result of inserting DNA into a plant’s genome are no different from changes that could occur through conventional plant breeding, and that such insertional effects will be controlled through breeding practices or have been considered in the previous Health Canada reviews.

Health Canada’s proposals for the regulation of transformants have little precision in relation to how GM plants will be “**identical**” to previously assessed GM plants. Identical has a very specific scientific meaning, but the GM plants here will be, at most, similar and may have undetected differences. Health Canada relies on the analysis of Schnell et al. (2015)⁷⁶ to conclude that unintended genetic changes that may result from the insertion of DNA into a plant’s genome are “no different from those that can occur through conventional plant breeding or as a result of plant-environment interactions”. However, the Schnell paper concludes that “the insertional effects associated with genetic engineering are **similar** to the genetic changes that occur in conventionally bred plants. Based on

this **similarity**, insertional effects should present a **similar level** of risk as genetic changes associated with conventional breeding.” [emphasis added] **Similar types of changes do not mean the changes are “no different”, and the claim of similarity is a controversial point.** Many publications disagree with this analysis and instead point to specific changes to DNA associated with either Agrobacterium or particle bombardment methods of gene insertion.⁷⁷ We maintain that it is not correct to state that unintended effects resulting from genome editing are “no different” from those created by conventional breeding, and the claim that they pose a “similar level of risk” is not well founded in the scientific literature.

While the DNA sequence used to create one GMO can be identical to that used to create another, the insertional effects will not necessarily be identical, and in fact are highly unlikely to be.⁷⁸ These unintended effects are likely to be different, and there is much evidence in the scientific literature describing different unintended effects in different transformants. Therefore, molecular characterisation should be required to be analysed for each and every retransformant in order to assess food and environmental safety.⁷⁹

There is a lack of actual comparative data on unintended effects created with different breeding methods. There are no papers that compare (using whole genome sequencing and appropriate isogenic comparators, for example) the number or type of unintentional genome-wide mutations created when the same trait is introduced using genetic engineering versus a conventional plant breeding method such as radiation or chemical mutagenesis (Annex 3 of the first consultation document defines a wide range of techniques as “conventional methods of plant breeding”). In fact, given the current data on unintended effects of GM crops, it is reasonable to conclude that the unintended genetic changes remaining in commercial GM crops are likely to be different from those in conventionally bred plants, and extremely frequent.⁸⁰

As discussed in section D.1, the high level of unintended traits found, even in highly-selected commercial genetically engineered plants, suggests that developers and regulators are not fully controlling for unintended effects. In many cases there is not enough data to determine whether these negative impacts arise from the transgene, unintended changes at the transgene insertion site, genome-wide unintended effects or a combination. The evidence of genomic irregularities found in many commercial GM plants - including Roundup Ready soy and MON810⁸¹ - appears to contradict Health Canada’s statements that “these unintended effects are accounted for in the practices used by plant developers” and that with the “exception of the inserted DNA, the plant’s genome is **as similar** to its unmodified counterpart **as possible.**” [emphasis added]

Any combination of DNA insertions and alterations would need be assessed independently of their individual components. Combinatorial effects may be difficult to predict from other GM events. Trying to separate a transgene from its genetic background for safety assessment is a flawed concept, as is trying to separate unintended effects into those specifically caused by the transgene and those due to the transformation process. Transgenes disrupt and interact with the surrounding plant DNA in unpredictable ways and they interact with the rest of the genome, which is unpredictably impacted by the GM plant breeding processes, in unpredictable ways. Safety assessment based on such separate assessments will be intrinsically flawed and will fail to protect against potentially harmful unintended effects. If these aspects of the genetic engineering are not evaluated for unintended effects, they may well go undetected, even though they may later prove to be important. Each genetically engineered product should be assessed on a case-by-case basis, with assessment not limited to a focus on gene products without examining whole organisms or whole foods⁸² or “proxies”⁸³.

The consultation document on retransformants mentions that, “Since the *Novel Food Regulations* were enacted in 1999, Health Canada has evaluated the safety of foods derived from over 140 genetically modified (GM) plant varieties. In all cases, foods derived from these GM plant varieties were found to be safe for food use. As a result, there are some characteristics that Health Canada has assessed multiple times and have continually been determined not to pose a food safety concern. This extensive experience has allowed regulators to develop a substantial degree of familiarity with these characteristics.” Of these 140 varieties are limited to **16 crop types**, not all of them are the product of genetic engineering, and **the majority of approved genetically engineered traits are herbicide-tolerant.**^c Health Canada’s “familiarity” with GM approvals is therefore largely restricted to herbicide tolerant and Bt traits (mostly in corn, canola and soy), produced using first-generation methods of genetic engineering. We note, therefore, that the retransformation proposals will likely be applied initially to the approval of new herbicide tolerant crops.

Corveta’s herbicide tolerant/insect resistant corn DP915635⁸⁴ may provide a good case to explore the challenges that could be encountered in implementing the suggested “retransformation” guidelines as new techniques and platforms for transformation are developed. In this case, there were two transformation steps that could, seemingly, simply be categorized as “different modification methods.” The resulting GMO expresses the IPD079Ea protein for control of corn rootworm pests (which Health Canada has no familiarity with), as well as the phosphinothrin acetyltransferase (PAT) protein for tolerance to glufosinate herbicide, and the phosphomannose isomerase (PMI) protein that was used as a selectable marker during transformation, where the PAT and PMI proteins have been approved in several other GMOs.

Many new genome editing techniques and platforms could be developed and used in unanticipated, complex ways to develop GMOs that may fit the definition of either tier of retransformation, resulting in expedited, reduced review that could compromise safety.

We intend to follow up on the above discussion in a second, later submission.

^c By our calculation, of the 154 Plants with Novel Traits listed by the CFIA: 91 are herbicide tolerant and 65 of these are listed as “LMO” [Living Modified Organisms] (though this excludes the Cibus ODM canola); 38 are insect resistant LMOs.

E. Key Recommendations

Health Canada should regulate all genetically engineered foods including those produced by genome editing techniques. Health Canada should retain regulatory authority over all genetically engineered products.

The federal government should create an independent, arm's length scientific risk assessment authority in order to provide scientific guidance on regulatory decision-making concerning genome-edited and other genetically engineered products. This authority should be established to implement recommendation 9.3 of 2001 The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology: "The Panel recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non-governmental) and independent panel of experts. The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review."⁸⁵

Health Canada should establish mandatory labelling of all genetically engineered foods including those from the newer techniques of genome editing in order to provide Canadians with accurate, up-to-date information about which genetically engineered foods are on the market.

Further recommendations to address transparency:

- All regulatory departments [Health Canada, the CFIA, and Environment and Climate Change Canada] should publicly post when product developers request approval of a genetically engineered product and which products are undergoing a safety assessment.
- All regulatory departments should make the science behind genetic engineering product approvals available to the public.
- Statistics Canada should collect data on all genetically engineered crop plantings, in every province.

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