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NEW PROPOSALS WOULD ELIMINATE TRANSPARENCY ON GMOS IN CANADA

Regulatory guidance changes would result in unregulated, unreported genetically engineered foods and seeds

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Contents

> This discussion focusses on the implications of new regulatory guidance proposals for transparency. Mutiple other reports and briefings from CBAN (2020-2022) discuss the risks posed by genome editing, and the risks to food and environmental safety posed by the proposals. See www.cban.ca/NoExemptions/Publications

April 13, 2022

Summary

Unregulated GMOs would be secret GMOs

Proposals from Health Canada and the Canadian Food Inspection Agency (CFIA) to exempt many new genetically modified organisms (GMOs) from regulation would jeopardize food and environmental safety. They would also remove the limited transparency on genetically engineered (genetically modified or GM) foods and seeds that currently exists for Canadians. Unregulated GMOs would be secret GMOs: Product developers would own and control all the information about new unregulated GMOs entering the market and would not be required to provide any information to the federal government. Companies would not be required to inform the government that these new unregulated GMOs exist.

- Health Canada and the CFIA are proposing to exempt some GMOs from government safety regulation: GMOs with no foreign DNA - produced through genome editing techniques (also called gene editing).
- Product developers would be permitted to release these unregulated GMOs without notifying the government.
- The regulatory exemptions would set up a system of corporate self-regulation for most or all gene-edited foods and seeds, where corporations have sole responsibility for safety assessments of their own products and control all the information about those unregulated GMOs.
- The proposals would result in unregulated, unreported, and potentially unsafe gene-edited GMOs on the market.
- As well as posing food and environmental safety risks, lack of information about which gene-edited products Canadians could be eating and growing would result in a profound loss of transparency, with social and economic consequences.
- The proposals are not consistent with regulatory department commitments to openness and transparency.

> “We believe that transparency regarding gene-edited products for food use is critical to maintaining public trust in the Canadian food supply.”
>
> — Karen McIntyre, Director General, Food Directorate, Health Canada, letter to the Canadian Biotechnology Action Network, 2021[1]

Introduction

Health Canada and the CFIA are proposing to remove government regulation for many new GMOs produced using the new genetic engineering techniques of genome editing (also called gene editing). If allowed to move forward, these changes would result in a profound lack of transparency on genetically engineered foods and seeds for Canadians.

The Departments are proposing to exempt new GM foods and plants that have no foreign DNA (produced using gene editing[2]) from regulation. This would mean that **federal government departments – and the public – would have no knowledge about these new GMOs entering the food system and environment** unless product developers decide to voluntarily provide it. The proposals would mean some unregulated, unreported, gene-edited foods and seeds on the market.

Health Canada recognizes that the proposed changes would create a new transparency problem. Therefore, it also proposes a new voluntary notification system called the "Transparency Initiative," through which the Department would encourage companies to voluntarily report unregulated GMOs. This would allow companies to decide which products to disclose or not disclose and, thus, not fill the newly created transparency gap. Instead of providing transparency, the initiative highlights the constraints that would be placed on the federal government if the Departments surrender their regulatory authority over these products. **The proposals would create a structural transparency problem with profound implications for government oversight and public accountability.**

Background

Genome editing (also called gene editing) techniques are a type of genetic engineering that results in the creation of genetically modified organisms (GMOs).

Health Canada and the CFIA are proposing to exempt many new genetically engineered (genetically modified or GM) foods and seeds from government safety assessments and government oversight: Genetically engineered seeds that have no foreign DNA and foods from genetically engineered plants that have no foreign DNA – produced through the new techniques of genome editing, also called **gene editing** – would be categorized as "non-novel" and exempt from regulation unless product developers flag a potential food safety or environmental safety risk. See www.cban.ca/no-exemptions/#Resources for details.

Already in Canada, there is an almost complete lack of transparency in the current regulation of genetically engineered (commonly also called genetically modified or GMa) foods and seeds, in all the steps of the safety assessment process (summarized in the table on page 7 and described in CBAN's report on GMO regulation posted at www.gmoinquiry.ca/regulation), and very limited information for the public about GMOs that could be on the market.

a Health Canada and the CFIA broadly define "genetic modification" to include products of conventional plant breeding as well as genetic engineering. However, for the purposes of this discussion, and in line with terms commonly used by the public and used in international agreements, we use the term genetic modification to refer to genetic engineering, which includes techniques of genome editing.

Since there is no mandatory labelling of genetically engineered foods in Canada, transparency for the public is already very limited. **The federal government does not track which GMOs are on the market but Health Canada and the CFIA list approved GMOs** inside the wider lists of "Novel foods" and "Plants with novel traits,"[b] along with (usually) a summary of the approval decision. However, by exempting many new GMOs from regulation, and thereby **eliminating government safety assessments and case-by-case approval decisions for these GMOs**, the federal government would be allowing these products onto the market without even the limited transparency currently provided by these lists of approved products and their related "Decision Documents."

Currently, genetically engineered products are only regulated if product developers or government regulators determine that they are "novel." The existing definition of "novelty" is already narrow and opens the door for some genetically engineered foods and seeds to be defined as "non-novel" and thereby skip government regulation. However, all genetically engineered foods and seeds currently on the market have been determined to be "novel" and thus subjected to government safety assessments and approval decisions.[c] **Instead of making changes to ensure that all GMOs are regulated, Health Canada and the CFIA are proposing to further narrow the definition of novelty, to exempt many future genetically engineered foods and seeds. These unregulated gene-edited GMOs could quickly comprise most or all of the GMOs in the food and agriculture system. The federal government would not know which GMOs exist and could be on the market.**

These proposed broad regulatory exemptions jeopordize food and environmental safety. They do not reflect the scientific findings, which show that using gene editing can result in a range of possible unintended effects in organisms that could have impacts on food and environmental safety.[3] Narrowly focussing on the presence of foreign DNA in a food or seed as a trigger for government safety assessment overlooks **many possible safety issues that could result from unexpected effects caused by the process of gene editing**.[4] For example, unexpected effects could result in alterations to biochemical pathways or protein composition, which could have implications for food and environmental safety.[5] The proposed guidance assumes the safety of a wide range of genetically engineered products. This assumption of safety would extend into the future, to apply to GMOs produced by gene editing techniques that have not yet been developed (For further discussion of the safety concerns see www.cban.ca/NoExemptions/Publications).

These proposals are being put forward at the same time that all federal government departments are implementing commitments to Openness and Transparency. The Canadian Food Inspection Agency says that it "plays a key role in protecting the health and safety of Canadians and is committed to greater transparency and openness."[6] With more openness and transparency, the CFIA says, "Canadians will better understand how and why regulatory decisions are made and will be able to use this information to make well-informed choices for themselves, their families and their businesses."[7] **In this case, however, for many new gene-edited GMOs, no regulatory**

b These lists of approved Novel foods and Plants with novel traits include non-GM as well as GM (LMO/Living Modified Organism) products and are, therefore, not accessible tools for the general public and are also, arguably, therefore, not transparent. This issue is discussed in CBAN's 2015 report "Are GM Foods and Crops Well Regulated?" www.gmoinquiry.ca/regulation.

c A waxy corn developed by Corteva with the use of the genome editing technique CRISPR-Cas9 is the only genetically engineered food posted by Health Canada as "non-novel" https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/requesting-novelty-determination/list-non-novel-determinations.html#wb-auto-4 however, the company has no plans to commercialize it. See CBAN's "Product Profile: GM Waxy Corn – Corteva" https://cban.ca/wp-content/uploads/GM-Waxy-Corn-Corteva-product-profile-CBAN.pdf

decisions would be made, and no information would be available for Canadians.

The changes are also being proposed at the same time that the Minister of Health, with the Minister of Agriculture and Agri-Food and the Minister of Environment and Climate Change, commit to improving transparency in pesticide regulation through a "Transformation Agenda."[8] As per the Minister of Health's Mandate Letter from the Prime Minister in December 2021, the Minister is asked to deliver on the commitment, "To ensure Canadians are protected from risks associated with the use of pesticides and to better protect human health, wildlife and the environment, modernize and strengthen the Pest Control Products Act to ensure it supports transparency, use of independent scientific evidence and input to the decision-making process."[9]

The significant changes discussed in this document to how and which GMOs are regulated would be made through proposed updates to the regulatory guidance documents used to interpret how the *Novel Food Regulations* and the *Seeds Regulations* are implemented by Health Canada and the CFIA. In 2021, Health Canada and the CFIA held separate public consultations on the proposals. The final decisions about whether or not to go ahead with the proposals rest with the Minister of Health, and the Minister of Agriculture and Agri-Food.

"From the time its Transparency Agenda was first initiated in 2011, transparency and openness have been key considerations underpinning the CFIA's values. The Agency would continue to expand its existing transparency and openness practices and take on new ones to meet growing public expectations."

– Canadian Food Inspection Agency, Openness and Transparency Framework 2019-2022[10]

Regulatory exemptions create a new transparency problem

Transparency for the public would be eliminated if government regulation is removed.

If, as proposed, new regulatory guidance allows many new gene-edited GMOs to be released onto the market and into the environment without any government approval process, Health Canada and the CFIA would eliminate the limited transparency that currently accompanies this regulatory process.

The creation of broad regulatory exemptions would mean that Health Canada and the CFIA would be surrendering their regulatory authority over these GMOs. Government departments would hand safety assessments over to product developers. This means that the government departments would not have access to information from product developers about these new GMOs, including any company science used to determine their safety, or even any notice that the products exist, unless provided voluntarily. The government would have no authority to require that companies to provide this, or any other, information. The proposed regulatory guidance

would, therefore, create a new transparency problem.

GMOs are already invisible to the general public because GM foods are not labelled in grocery stores. **Now, the proposals would make many new gene-edited GMOs invisible to the federal government.**

Health Canada and the CFIA would:

- **not conduct safety assessments for many new GMOs;**
- **not know which new GMOs could be in the food system and environment;**
- **not be able to require companies to provide this information.**

CURRENT VS. PROPOSED GMO REGULATION

CURRENT REGULATION OF GENETIC ENGINEERING	NEW PROPOSALS TO REGULATE GENE-EDITED FOODS AND SEEDS THAT HAVE NO FOREIGN DNA
Government regulators assess product safety, relying on confidential information from product developers.	Product developers would assess the safety of their own products, and would not share their secret/proprietary safety data – government departments would have no authority to ask for access to this information.
Product developers have regular, direct access to government regulators through the approval process.	Product developers would become the regulators because the government approval process would be removed.
Government regulators (usually) publish one public document describing each approved GMO and its safety determination.	Product developers would determine the safety of new GMOs and decide if the public gets any notice or description of them.
The government publishes a list of approved “novel” products, which includes approved GM and non-GM foods and seeds.	Many new GMOs would not appear on any public list unless product developers voluntarily disclose this information.
No mandatory labelling of genetically engineered foods in the grocery store.	Incomplete government or public knowledge about which genetically engineered foods exist and could be in the food system.

Corporate self-regulation is not transparent

These regulatory exemptions would create a system of corporate self-regulation in which product developers assess the safety of their own products without any government oversight. **These companies would have complete control over what information the government and public**

have about their unregulated products.

For those genetically engineered foods and plants that have no foreign DNA, **product developers would have the power** to:

- Decide if their products are safe for Canadians to eat and, with some exceptions, safe for release into the environment;
- Decide if the federal government and public should be notified that a new GM product exists;
- Decide what information, if any, the government and public can have about those GM products, such as information about which gene editing technique was used.

Any voluntary notification system for these GMOs, such as the "Transparency Initiative" proposed by Health Canada (see below), would rely on the cooperation of product developers whose primary objective is profit. There is an inherent conflict of interest in product developers determining if regulations apply to their own products, determining their safety, and determining which information to make available to the government and public.

Currently, these GMO product developers are, overwhelmingly, the biggest seed and pesticide companies in the world. The majority of GM foods and crops approved and currently on the market are owned by the three biggest biotechnology companies in the world: Bayer, Syngenta and Corteva. These same companies also lead in licensing agricultural patents on the use of the prime genome editing technique called CRISPR-Cas9.[11] These companies control around half of the global seeds and pesticides markets.[12]

Voluntary transparency is not transparent

Health Canada recognizes that their proposed changes would create a new transparency problem where unregulated GMOs would be unknown (unidentified/unreported). To address this new lack of transparency, Health Canada proposes to **"encourage"**[13] **industry to be transparent** via a voluntary notification system that it now calls the "Transparency Initiative." Instead of solving the problem, however, the proposed initiative highlights that the regulatory exemptions would leave Health Canada and the CFIA, the federal government and the public, **wholly depending on product developers to voluntarily disclose information.**

The proposed "Transparency Initiative" would be a voluntary notification system for unregulated (non-novel) GM and non-GM foods. Instead of relying on the current government list of approved novel foods, automatically generated by the Departments, there would be an additional list of the unapproved/unregulated non-novel foods that have been disclosed voluntarily by companies. While this list would provide notice of some unregulated GMOs, **this list may not include all, or even most of, the new GMOs coming to/on the market and there would be no way for the public or government to verify whether the information is true or complete.** The federal government would be unable to provide any assurance to the public that the list is complete. This would result in a profound lack of transparency for Canadians. **Such a system that only discloses partial, unreliable information cannot be called transparent.** Only mandatory reporting requirements can ensure transparency.

In their consultation document, Health Canada said, **"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" [emphasis added]. It also said, "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."[14] One of six questions that Health Canada asked the public in its 2021 consultation was: "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?"[15] **After the consultation, Health Canada renamed the proposed initiative from the "Voluntary Transparency Initiative" to the "Transparency Initiative."**[16]

"...renaming the proposed voluntary notification system for unregulated products from the "Voluntary Transparency Initiative" to the "Transparency Initiative" does not make the system transparent."

– Lucy Sharratt, Coordinator, Canadian Biotechnology Action Network, letter to the Prime Minister, March 4, 2022[17]

Transparency is necessary

Transparency in regulation serves a number of important purposes for good governance. The removal of transparency relating to new GMOs would have important consequences that go beyond just a lack of information about GMOs for the public.

Transparency is necessary for science-based regulation

"The claim that the assessment of biotechnology risks is 'science-based' is only as valid as the independence, objectivity and quality of the science employed."

— The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology, 2001[18]

The current lack of transparency in GMO regulation already has important consequences including, in the words of 2001 Royal Society of Canada's Expert Panel on the Future of Food Biotechnology, an "inability to evaluate the scientific rigor of the assessment process."[19] This is because the process to assess the safety of genetically engineered foods and seeds happens behind closed doors, based on confidential industry information.

Health Canada does not conduct any of its own safety testing, but approves GM foods for human consumption based on industry-submitted information. This information is often entirely industry-generated and rarely peer-reviewed (and therefore not available in the public scientific literature). The data packages that companies submit to Health Canada and the CFIA are classified as "Confidential Business Information" by the federal government and cannot be accessed by the public or independent scientists. Peer review is the process whereby scientists assess the work of others, and it is a fundamental and defining practice of science. Without peer

review, the data behind Canada's GM food approvals cannot be assumed to be good science, or indeed "science" at all.[20]

The regulatory guidance proposals would remove the existing government reviews of corporate data, which the government calls science-based regulation. Instead, **product developers would determine the safety of their own products based on data that is kept secret, even from government.** Government regulators would not have access to the science behind new unregulated GMOs entering the market. Health Canada and the CFIA would be assuming the health and environmental safety of unregulated GMOs instead of actually assessing their safety.

Unregulated GMOs would be released onto the market based on unseen, secret, corporate science. There would be no standards for the quality or extent of science done, nor any responsibility for corporations to reveal gaps or negative findings. Since most or all of this science would not be peer-reviewed, **by definition it cannot be called science and cannot be known or assumed to be sound science.**

Transparency is necessary for public engagement and government accountability

Transparency in regulation should serve a number of important, higher democratic purposes, such as enabling public engagement and supporting the ability of the public to hold the government to account. In the words of the federal government, transparency can ensure that "Canadians and Parliament are better able to hold the Government and public sector officials to account."[21] Transparency is only one step in creating processes of democratic decision-making.

However, the regulatory system for GMOs was not designed to enable public participation. Current GMO regulation excludes social and economic considerations in decision-making, focussing exclusively on narrow scientific criteria for safety assessment. There is no public participation in the regulatory process.[d] For example, there is no consultation with farmers about the risks or benefits of releasing new GM seeds onto the market.[22]

Transparency is necessary for public trust

"Future availability [of food biotechnology] would require two things, regulatory approval and public acceptance."

- Bob Ingratta, Vice-President of Regulatory Affairs, Monsanto Canada, 1993[23]

Transparency is often discussed by government as a tool to enhance public trust. For example, in 2014, Health Canada said, "As a regulator, Health Canada plays an important role in protecting the health and safety of Canadians and is committed to greater transparency and openness to further strengthen trust in our regulatory decisions."[24]

In 2001, The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology concluded that "the lack of transparency in the approval process, leading as it does to an inability to evaluate the scientific rigor of the assessment process, seriously compromises the confidence

d There is one invitation for the public to comment on GM seed approval submissions (voluntarily provided by developers). For a discussion of how this invitation does not provide for public engagement see CBAN's report "Are GM Foods and Crops Well Regulated?" www.gmoinquiry.ca/regulation

that society can place in the current regulatory framework used to assess potential risks to human, animal and environmental safety posed by GMOs."[25]

Twenty years later, this process is not any more transparent. The new proposals would remove the approval process for many new GMOs and, with it, the accompanying limited transparency. The changes can therefore be expected to further undermine public trust in both the food system and government regulation.

Transparency is necessary for farmer livelihoods and market stability

"The Canadian public in general, especially farmers, should not be faced with unknown and unidentified products of gene-editing."

– The National Farmers Union, Comments to the Canadian Food Inspection Agency consultation, September 15, 2021[26]

The loss of transparency regarding which GMOs could be on the market would have important economic and social consequences for farmers and businesses across the food and agriculture sector. The regulatory exemptions would allow companies to sell some gene-edited seed varieties to farmers without revealing that they are products of these genetic engineering techniques. Farmers would be wholly reliant on product developers for this information.[e]

The CFIA says that, "increasing openness and transparency would enhance general public and foreign market trust in Canada's regulatory system"[27] and yet the release of unidentified, patent protected,[28] gene-edited seeds would create uncertainty, even chaos, in fields and markets, threatening the livelihoods of some farmers and access to some markets. Over time, an increasing amount of unreported gene edited seeds in Canada's food and agriculture system would significantly increase the potential for unwanted GM contamination (adventitious presence) in fields, and in the food system and export shipments.

Any contamination from patent-protected gene-edited seed would put farmers at risk of legal action from patent holders.[29] Lack of transparency would enhance this risk because any farmer could be in a position of not knowing whether the seed they are growing is a gene-edited variety, whether seed contaminating their fields is gene-edited, and whether seed saving is restricted due to patents. Because the Canada Organic Standard prohibits the use of genetic engineering, including gene editing, this lack of information would particularly increase the costs and challenges for organic farmers and organic food businesses, gradually impairing the viability of the organic sector in Canada.[30]

For international markets that are sensitive to genetic engineering (markets for organics and other non-GM products) and markets in countries that continue to regulate all gene-edited food and crops, **the release of unregulated, unknown gene-edited products could result in the rejection of Canadian exports**, either because they are known or suspected to include gene-

e This information may or may not be made available through other means such as variety registration listings or corporate technology use agreements.

edited varieties.[31] The harm of market loss could extend to all farmers who grow the affected crop kind, and have broader economic impacts on the Canadian economy as a whole.

Recommendations

THE CANADIAN BIOTECHNOLOGY ACTION NETWORK recommends that the current regulatory guidance proposals be halted and re-designed to ensure government oversight and transparency over all genetically engineered foods and seeds. All genetically engineered food and agricultural products, including gene-edited products with no foreign DNA, need to be regulated.

THE NATIONAL FARMERS UNION passed a resolution at their 2021 Convention that "all foods and seeds produced through gene editing must be subject to government safety assessments and mandatory reporting to government."[32]

THE MANITOBA CROP ALLIANCE passed a resolution at their 2022 Annual General Meeting that took the position that "seeds produced through gene editing must be subject to government safety assessments and mandatory reporting to government just as other genetically engineered seeds are" and they also resolved to "call on the Ministers of Health and Agriculture and Agri-Food to commit to transparency in the regulation of all genetically engineered organisms for use in food and farming, including those produced through gene-editing."[33]

THE UNION OF ORGANIC GRAIN PRODUCERS OF QUEBEC passed a resolution at their 2022 Annual General Assembly asking the federal government:

- To oblige seed companies to include a genetic marker in varieties obtained by gene editing techniques, so that they can be distinguished by genetic testing, to ensure the traceability of gene-edited products to consumers;
- To make it compulsory to declare all gene-edited seed and to describe its characteristics;
- To establish a registry of gene-edited seeds, to be updated continuously, to be published and to made accessible to all actors of the agricultural and agri-food industry as well as to consumers.

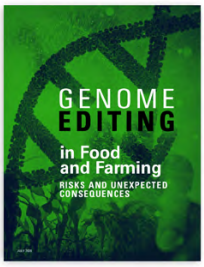
105 GROUPS from across Canada wrote together to the Minister of Health and the Minister of Agriculture and Agri-Food on November 17, 2021,[34] calling for government oversight and transparency of all genetically engineered foods and seeds and demanding that there be no regulatory exemptions:

> "We demand government oversight of all genetically engineered foods and seeds including those produced through gene editing. All genetically engineered foods and seeds should be subject to government safety assessments and mandatory reporting to government.
>
> We call on the Ministers of Health and Agriculture and Agri-Food to commit to transparency and independent science in the regulation of all genetically engineered organisms for use in food and farming.
>
> We oppose the sale of unregulated, unreported genetically engineered foods and

seeds. We oppose the proposals from Health Canada and the Canadian Food Inspection Agency (CFIA) that would allow many gene-edited genetically engineered foods and seeds onto the market with no government oversight."

Further Discussion

For a more fulsome critique of Health Canada's proposed "Transparency Initiative" and a discussion of the implications of Health Canada's proposed regulatory guidance, see CBAN's comments in the consultation: Comments submitted to Health Canada re: Proposed new guidance for Novel Foods Regulations, May 11, 2021. www.cban.ca/NoExemptions/HCconsultcomments



For background on government regulation of GMOs see CBAN's 2015 report "Are GM Foods and Crops Well Regulated?" www.gmoinquiry.ca/regulation

For information on gene editing see CBAN's report "Genome Editing in Food and Farming: Risks and Unexpected Consequences" www.cban.ca/GenomeEditingReport2020

For more information and analysis on the proposals see www.cban.ca/NoExemptions

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. CBAN is a project of MakeWay's shared platform.

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Endnotes

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