Health Canada and CFIA propose to exempt many gene-edited GMOs from regulation

Summary

Health Canada and the Canadian Food Inspection Agency (CFIA) are proposing new regulatory guidance (not new regulations) regarding the safety assessment of genetically engineered (genetically modified or GM) foods and plants.

Health Canada and the CFIA are proposing **to exempt many new genetically engineered foods and plants from government safety assessments and government oversight:**

> Genetically engineered plants and foods that have no foreign DNA – many of which would be produced through **the new genetic engineering techniques of genome editing, also called gene editing** – would be exempt from regulation unless product developers flag a potential food safety or environmental safety risk.

Many gene-edited genetically modified organisms (GMOs) would enter the market with no government safety review and no notification to the government. These GMOs would not be subject to any government approval process. This is a shift to corporate self-regulation of GMOs.

The proposals will change how our government conducts risk assessments of genetically engineered foods and seeds – by **eliminating government risk assessments for most new GMOs.**

The proposals would allow some unregulated, possibly some unreported, genetically engineered gene-edited foods and seeds onto the market.

THE SCOPE OF CHANGE

- The proposals would not change the regulations themselves, but would make significant **changes to the "regulatory guidance" that is used to interpret and implement existing regulations.** This means that making these changes does not require a debate in Parliament. Instead, the changes will be the result of discussions inside the regulatory departments (and many departmental meetings with industry associations) along with public consultations held March-Sept 2021, with **sign-off from the Minister of Health and the Minister of Agriculture and Agri-Food.** The Ministers are ultimately responsible for these changes and what they will mean.
- The proposals would **exempt most genetically engineered products that have no foreign DNA from regulation.** Most or all of these products will be developed using the new genetic engineering techniques of genome editing, commonly called **gene editing.** The changes are not a blanket exemption for genome edited products per se, but the outcome will be a broad exemption.
- The proposals would change government risk assessments for **the safety of foods from genetically engineered plants as well as the environmental safety of genetically engineered seeds (including trees).** These changes will be followed by changes to risk assessment for foods from genetically engineered animals and the environmental safety of genetically engineered animals and other GM organisms. The current proposed changes are just the beginning.

What will change?

Canada's regulatory system for genetic engineering does not specifically name genetic engineering: the Canadian government regulates "novel foods" and "plants with novel traits." Now, government regulators are proposing to dismantle the regulation of genetic engineering inside this system. The system will continue to exist, but its regulation of many or most genetically engineered foods and seeds will disappear.

The proposals would exempt many of those genetically modified organisms (GMOs) that do not have foreign DNA, and also implement fast-tracking and gradual regulatory exemptions for many other genetically engineered foods and seeds. The proposed changes would mean that many or most new genetically engineered foods and seeds would be exempt from any regulation and could therefore **come to market without a government safety assessment or any government oversight.**

So far, all the genetically engineered foods eaten in Canada have been regulated as novel under the federal system and undergone a government risk assessment, with the exception of one new genome-edited corn that Health Canada determined to be non-novel.[1] However, while some genome-edited products could still fit the definition of "novel" and therefore be subject to a government safety assessment, under the new proposals, many may circumvent the product approval system entirely. **There will be no approval process for many of these new GMOs.**

This is because Health Canada and the CFIA are proposing that if foreign DNA is not present in a GMO, and if the product developer has not identified a possible safety issue/"novel" characteristic, **then safety assessments can be left solely to product developers.** This is how, in the proposals, Health Canada and the CFIA would surrender their regulatory authority over most genome-edited organisms entering the food system.

Unseen corporate science

The proposed focus on the presence or absence of foreign DNA in a genetically engineered organism as a trigger for regulation is **not science-based** – it is simplistic and overlooks a range of possible unintended effects that can result from the process of genome editing, that may have impacts on food or environmental safety. This proposed focus reflects an **assumption of safety** for many genome-edited foods that is not scientifically justified. See CBAN's report at www.cban.ca/GenomeEditingReport.

If Health Canada and the CFIA exclude these products from regulation, **regulators will have no access to the science used to determine their safety.** The government would have no ability to require information from product developers, not even a notice of a new genome-edited food coming to market.

Proposed voluntary regulation

To compensate for this huge gap in transparency – where products do not require government approval and do not pass through any government process – Health Canada is proposing a **"Voluntary Transparency Initiative"** to "encourage" companies to voluntarily send the government a notice of any unregulated (determined by developers to be non-novel) genome-edited product intended for commercialization. This is a clear pathway for some unknown, unregulated genome-edited products to get to market.

1 This is a GM "waxy" corn that may never come to market, from the company Corteva (DowDupont): See https://cban.ca/wp-content/uploads/GM-Waxy-Corn-Corteva-product-profile-CBAN.pdf This product was listed on Health Canada's newly created (2020) "List of non-novel determinations for food and food ingredients." This list shows some (not necessarily all) of the genetically engineered foods that are not regulated inside a broader list of "non-novel" foods: where product developers have voluntarily submitted their own assessment of non-novelty to Health Canada, and the department agrees.

Critically, Health Canada's proposed Voluntary Transparency Initiative would also encourage (but not require) product developers to submit several, limited areas of information about their product for an unspecified form of "further review" by government. This means that the Initiative would also serve as a system of, **unknown, voluntary, ad hoc government checks on corporate determinations** of product non-novelty/regulatory status. Only those products submitted voluntarily by developers would be subject to this (minimal and unspecified) government oversight.

The CFIA is proposing a similar voluntary system of regulation where companies can request an **"exemption opinion letter"** from regulators if they want the CFIA to validate that their GMO is exempt from regulation. By providing this option to request exemption opinion letters, the CFIA would be providing product developers with a stamp of approval if they want one (to help promote their product, for example), creating **an on-demand service for product developers.**

Fast-tracking other GMOs

The proposals from Health Canada also include other "updates" to regulatory guidance that would spell out different **"tiers" of regulation for GMOs** that are said to be "identical" to previously assessed GMOs. Health Canada calls these GMOs "retransformants" and proposes **a form of fast-track review** requiring less information from product developers. CBAN does not agree that such plants can be characterized as "identical", and argues that each genetic engineering "event," even those that use the same methods to create the same characteristics, can result in new and unintended effects. Initially, these proposals would particularly apply to fast-tracking approvals for more herbicide-tolerant crops, because these are the majority of GMOs approved thus far.

Similarly, the CFIA proposes to gradually exempt many other GM seeds from regulation. The CFIA says that other regulatory exemptions "will increase as more products are authorized" because of the "safety record" for these previously approved seeds. This means that even more genetically engineered seeds will be released without government safety assessments, approval decisions, or notifications to government. Long-term, this will lead to the **widespread use of genetically engineered seeds with undetermined origins and unknown impacts.**

Corporate self-regulation

The proposals will result in an important shift from mandatory government safety assessments of genetically engineered foods and seeds to corporate self-regulation of many new GMOs.

The proposals will result in **unregulated, unreported GM foods and seeds on the market.** Product developers (corporations and institutions) will have control over all the information relating to these GMOs, including any public notice that they even exist.

CBAN argues that the proposals will jeopardize food and environmental safety, will harm some farmer livelihoods, result in a profound loss of transparency for the Canadian public, including farmers, and further undermine public trust in Canada's food system and its regulation.

All genetically engineered products, including those with no foreign DNA, should be subject to mandatory government safety assessments.

More Information from CBAN

REGULATION:

- For more information, updates and action on the proposals: www.cban.ca/NoExemptions
- CBAN Comments submitted to the Canadian Food Inspection Agency (CFIA) re: guidance for determining whether a plant is subject to Part V of the Seeds Regulations, Sept 2021. https://cban.ca/wp-content/uploads/CBAN-response-CFIA-consultation-questionnaire-2021.pdf
- CBAN Comments submitted to Health Canada re: Proposed new guidance for Novel Foods Regulations, May 11, 2021. https://cban.ca/wp-content/uploads/CBAN-comments-to-HC-regulatory-guidance-May-11-2021.pdf
- CBAN Comments submitted to Health Canada re: primer on gene editing, June 23, 2021. https://cban.ca/wp-content/uploads/CBAN-comments-to-HC-consultation-on-gene-editing-primer-June-23-2021.pdf
- Are GM Foods and Crops Well Regulated?" – Report, 2015. www.GMOinquiry.ca/regulation/

GENOME EDITING:

- For more information about genome editing: www.cban.ca/gene-editing
- Introduction to Genome Editing – Factsheet, June 2020. www.cban.ca/GenomeEditingIntro
- Genome Editing in Food and Farming: Risks and Unexpected Consequences - Report, June 2020. www.cban.ca/GenomeEditingReport2020

cban
Canadian Biotechnology Action Network

cban.ca

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.

Contact: Lucy Sharratt, Coordinator | coordinator@cban.ca | 902 209 4906