

Reverse New GMO Regulatory Guidance to Ensure Safety and Transparency

Summary:

The federal government has removed its pre-market regulation for some (many/most) gene edited seeds (those with no foreign DNA/those with no DNA from other species) as well as the foods derived from these genetically engineered (genetically modified or GM) plants. These gene-edited seeds and foods will not be assessed for safety by government regulators. Instead, product developers can assess the food and environmental safety of their own products without government oversight, and without any required notification to the government or public about the market release of these genetically modified organisms (GMOs).

The twin decisions by the ministers of health and agriculture place the interests of private industry above the federal government's responsibility to protect human health and the environment, come at the expense of transparency and choice for Canadian farmers and consumers, and threaten the livelihoods of many farmers.

Update:

Health Canada and the Canadian Food Inspection Agency (CFIA) have updated new regulatory guidance (not new regulations, but the interpretation of the regulations) regarding genetically engineered (genetically modified or GM) foods and seeds. The new guidance specifically address the regulation of genetically engineered foods and seeds that have no foreign DNA (those that will be produced by the new genetic engineering techniques of genome editing, also called gene editing).

The Minister of Health (May 18, 2022) and the Minister of Agriculture and Agri-Food (May 3, 2023) confirmed that **many new genetically engineered foods and seeds are exempt from pre-market regulation**, meaning there will be **no government safety assessments nor any government oversight for these products**:

Specifically, many genetically engineered plants that have no foreign DNA (produced through **the new genetic engineering techniques of genome editing**) and the foods from these plants will no longer trigger the *Novel Food Regulations* and Part V of the *Seeds Regulations*.

In this case, the federal government has handed product safety assessments over to product developers. The federal government also has no authority to request information from product developers about these GM foods and seeds.

The changes will mean:

- Gene-edited foods and seeds released without independent government safety checks of any kind,
- Unknown/unidentified genetically engineered gene-edited foods and seeds on the market,
- Unregulated field tests of many gene-edited crop plants.

Our Key Recommendations:

This devolution of responsibility for pre-market safety assessments from government regulators to product developers was achieved via changes to regulatory guidance documents that **should be urgently reversed**.

- Health Canada and the CFIA should **retain regulatory authority** over all genetically engineered products to ensure safety and transparency, and to promote public trust in our regulatory system and food system.
- Health Canada and the CFIA should **assess the safety** of all genetically engineered foods and plants: The use of the genetic engineering including the new techniques of genome editing should trigger regulation.
- Health Canada and the CFIA should require companies to notify the government of all genetically engineered foods and seeds on the market i.e. establish a **mandatory system for listing** gene edited and other genetically engineered products in the food system.

The regulatory exemptions are not science-based and jeopardize safety

The regulatory exemptions do not reflect the scientific findings which show that genome editing is not equivalent to traditional plant breeding and can result in a range of possible unintended effects. These unintended effects need to be detected and evaluated for their potential impacts on food and environmental safety. Narrowly focussing on the presence of foreign DNA as a trigger for government safety assessments is simplistic and overlooks many **possible safety issues that could result from unexpected effects caused by the process of genome editing**. For example, unexpected effects could result in alterations to biochemical pathways or protein composition, which could have implications for food and environmental safety. The proposed guidance is not science-based or future-proof because it assumes the safety of GMOs that have no foreign DNA, including those produced by future genome editing processes that have yet to be developed.

[The science is discussed in a report from CBAN and Testbiotech, March 2022.](#)

The regulation exemptions remove transparency

Health Canada and the CFIA have surrendered their regulatory authority over these genetically engineered products. This means that Health Canada and the CFIA have relinquished their ability to require information from product developers about these products, and **they may go entirely unreported**. The Departments are **relying on a voluntary system** of listing that asks companies to disclose their unregulated GMOs. Because the system does not require mandatory disclosure, farmers in Canada may not be informed that their seeds are genome edited, consumers will not have information about which GMOs could be sold in stores, and **the federal government will not know all the GMOs that could be in our food system or in our environment**. The government would lose the ability to track and trace GMOs, which would hamper the government's ability to respond to any possible safety, environmental, or economic impacts that may arise.

[The loss of transparency is detailed in a new CBAN briefing from CBAN, March 2022.](#)

Who opposes the exemptions to regulation:

105 groups wrote to the Ministers of Health and Agriculture and Agri-Food to ask for transparency and government oversight over all genetically engineered foods and plants.

Both the **National Farmers Union** and L'Union des producteurs agricoles passed resolutions at their 2021 conventions opposing the proposals.

SaskOrganics, the **Canadian Organic Trade Association** and **La Filière biologique du Québec** are demanding a mandatory listing of all gene-edited products.

The Future

Uphold the role of Canada's independent regulators

The ministers have allowed Health Canada and the CFIA to abandon their **important role as independent regulators** in relation to some new gene edited foods and seeds. Canadians rely on Health Canada and the CFIA to ensure food and environmental safety. Instead, the government is asking Canadians to accept corporate safety assurances: to accept unseen corporate safety assessments and corporate science, without any government checks. The new guidance will **undermine public trust** in both the food system and government regulation.

There is **an inherent conflict of interest** in product developers determining if regulations apply to their own products, and in determining their safety. All products of genetic engineering, including those produced through the newer techniques of genome editing, should be subject to pre-market government safety assessments.

Provide choice and competition in the marketplace

Permitting new gene-edited foods and seeds on the market without mandatory notification to the federal government creates **a de facto all-biotech food system**. The lack of transparency and traceability of these GMOs in the market will now result in the **inability of farmers and food businesses to provide non-GM choices**. In the absence of mandatory labelling of GM foods, many farmers and companies have invested in non-GM certification to provide non-GM food choices in the Canadian market. This includes investments in organic certification, in compliance with the Canadian Organic Standards that prohibit GMOs including all gene-edited products. Lack of GMO transparency will increase costs and ultimately, could mean the **loss of the ability to certify as organic and non-GM**. Whether because of regulation or consumer demand, many important export markets do not accept GM products and these markets will be in jeopardy.

There is a limited window of time to reverse the regulatory exemptions created in the guidance documents, to ensure safety, trust, and choice in the food system.

Further information:

CBAN briefing: Patents on Genome Editing in Canada, March 2022
www.cban.ca/GenomeEditingPatents

CBAN Report: Genome Editing in Food and Farming: Risks and Unexpected Consequences, June 2020
www.cban.ca/GenomeEditingReport2020

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The logo for the Canadian Biotechnology Action Network (CBAN) consists of the lowercase letters "cban" in a bold, green, sans-serif font.

The Canadian Biotechnology Action Network (CBAN) brings together 16 groups across Canada to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN is a project on the shared platform of MakeWay Charitable Society.

www.cban.ca