

Health Canada and CFIA proposals for new regulatory guidance on the safety assessment of genetically engineered foods and plants

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 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 if product developers do not determine a food safety or environmental safety risk.

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

OUR KEY RECOMMENDATIONS

Health Canada and the CFIA should retain regulatory authority over all genetically engineered products to ensure safety and transparency.

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.

OUR KEY CONCERNS

The Canadian Biotechnology Action Network (CBAN) objects to this proposed devolution of responsibility for safety assessment from government regulators to product developers:

- Health Canada and the CFIA are proposing to surrender their regulatory authority over some genetically engineered products.
- Health Canada and the CFIA would have no ability to require information from product developers about these unregulated products, and they may go entirely unreported.

- 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 genetic engineering techniques of genome editing, should be subject to government safety assessments.
- Narrowly focussing on the presence of foreign DNA as a trigger for government safety assessment is simplistic and overlooks many possible safety issues that could result from genome editing.
- The proposals from Health Canada and the CFIA do not reflect the scientific findings which show that genome editing can result in a range of possible unintended effects, that need to be detected and evaluated for their potential impacts on food and environmental safety.
- The government would be asking Canadians to accept corporate safety assurances: to accept unseen corporate safety assessments and corporate science, without any government checks.
- Canadians rely on Health Canada and the CFIA to be independent regulators of genetically engineered products, to ensure food and environmental safety.
- Implementing the proposed guidance would undermine public trust in both the food system and government regulation.

Department	Health Canada	Canadian Food Inspection Agency
Public consultation	March 25 - May 24, 2021	May 19 – Sept 16, 2021
Scope	Foods from genetically modified plants	Genetically modified plants including trees
Proposal	Proposed new guidance for Novel Food Regulations focused on plant breeding https://www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding.html	Guidance for determining whether a plant is subject to Part V of the <i>Seeds Regulations</i> https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/eng/1619740964754/1619741042405
Consultation documents	<p>1. 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”? https://cban.ca/take-action/no-exemptions/consultation-documents/</p> <p>2. Proposed Health Canada Guidance on the pre-market assessment of foods derived from Retransformants under of Division 28 of Part B of the Food and Drug Regulations (the Novel Food Regulations) https://cban.ca/take-action/no-exemptions/consultation-documents/</p>	<p>1. Summary of the guidance for determining whether a plant is subject to Part V of the <i>Seeds Regulations</i> https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/summary-of-the-guidance/eng/1619736173981/1619739540987</p> <p>2. Draft guidance for determining whether a plant is subject to Part V of the <i>Seeds Regulations</i> https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/draft-guidance/eng/1619540046303/1619540212691</p>

Further information:

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>

CBAN Introduction to Genome Editing, June 2020 <https://cban.ca/wp-content/uploads/Genome-Editing-Intro.pdf>

CBAN Report: Genome Editing in Food and Farming: Risks and Unexpected Consequences, June 2020 <https://cban.ca/wp-content/uploads/Genome-Editing-Report-2020.pdf>

CBAN Report: Are GM Foods and Crops Well Regulated?“, 2015 <http://gmoinquiry.ca/regulation/>

Updates and analysis from CBAN www.cban.ca/NoExemptions



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

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