

# Health Canada and the CFIA should assess the safety of all genetically engineered foods and seeds

# New regulatory guidance proposals would remove government oversight and transparency

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 (genetically modified organisms or GMOs) 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 the 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 new GMOs 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. Genome editing can be imprecise, and cause unexpected and unpredictable effects.
- 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.

### **GENE-EDITED FOODS AND SEEDS NEED REGULATION**

Genome editing, often called gene editing, is a collection of new genetic engineering techniques that alter the genetic material (usually DNA) of plants, animals and other organisms. These techniques aim to insert, delete or otherwise change a DNA sequence at a specific, targeted site in the genome.

Genome editing, generally, uses DNA cutters that are guided to a location within an organism's DNA and used to cut the DNA. This cut DNA is then repaired by the cell's own repair mechanism, which creates "edits" or changes to the organism. The most frequently used genome editing technique is called CRISPR-Cas9 or CRISPR, but other techniques follow similar principles.

Genome editing can be imprecise, and cause unexpected and unpredictable effects. Many studies have now shown that genome editing can create genetic errors in the genome-edited organism, such as "offtarget" and "on-target" effects. These effects can lead to unexpected and unpredictable outcomes, such as changes in protein composition, in the resulting GMO.

#### **Further information:**

CBAN Comments submitted to the Canadian Food Inspection Agency 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-CFIAconsultation-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-HCregulatory-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/CBANcomments-to-HC-consultation-on-gene-editingprimer-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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