Health Canada's proposed new regulatory guidance on genetically engineered foods

Proposal #1:

Allow some genetically engineered foods onto the market without government safety assessments

This proposal defines which genetically engineered foods would be "novel foods" in need of government regulation. The proposal is outlined in Section 3 (page 5) of the consultation document "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'?"[1]

CONCERNS:

- **Health Canada is abdicating its responsibility to ensure food safety.**
- **Health Canada is allowing corporate self-regulation.**
- **Health Canada is overlooking the potential food safety impacts that can result from the process of genetic engineering, particularly the new genetic engineering techniques of genome editing.**
- **The changes will undermine public trust in the food system and Health Canada's regulation for food safety.**

Health Canada is proposing to exempt some genetically engineered (commonly called genetically modified or GM) foods from regulation. This means that these GMOs (genetically modified organisms) would be allowed onto the market without government safety assessments. Instead, **product developers would assess the safety of their own products** and be able to release any that they deem safe onto the market without notifying the government (See CBAN Briefing on Proposal #2[2]). Specifically, Health Canada is proposing to allow product developers to assess the safety of foods **from genetically engineered plants that have no foreign DNA inserted**. Many of these GMOs would be created through the new genetic engineering techniques of genome editing, also called gene editing. **These GMOs would go unregulated unless product developers find a possible food safety problem**.

Health Canada lists five obvious potential safety issues ("novel traits") that it would ask product developers to check for. (See the consultation document for the exact wording. Further details can also be found in the Guidance for the Safety Assessment of Novel Foods 2006.[3]):

1. There is foreign DNA in the genetically engineered plant,
2. Intentional changes to a known (endogenous) protein are found to be allergenic or toxic,
3. There is a significant increase in levels of allergens, toxins, or anti-nutrients that are already known to be in the plant,
4. The new genetically engineered trait changes the nutritional composition or metabolism of the food,
5. There is a proposed new food use of the plant. For example, the developer is proposing to use a part of the plant that has no history of safe use in the human diet.

This list narrowly emphasizes the most anticipated and obvious categories of potential food safety concerns that could result from a new genetically engineered characteristic, while **overlooking the range of potential unintended effects from the process of genetic engineering, including genome editing, that could raise safety concerns**.

Health Canada calls this "product-based" regulation. Rather than choosing to analyze both the characteristics of the product and the potential impacts of the process on the organism, these proposals further diminish "process-based" regulation that would ask additional safety questions and cast a wider net to look for potential problems.

Since all unintended changes that could result from the use of genetic engineering techniques need to be detected and evaluated, safety assessment would ideally consider both the product and the process. Instead, Health Canada proposes to ask product developers to examine the intended changes to the organism and the possible safety impacts that could be directly related to the new GM trait, but **not to screen for possible unintended and unexpected changes across the genome**. The public would be left to trust product developers to screen their own genetically engineered foods for possible unintended genetic errors and other unexpected effects that could pose a food safety risk.

Why is this a problem?

The assumption embedded in this proposal is that there would be no unintended effects from the process of genome editing, or that any such effects would have no impact on food safety. Health Canada has even concluded in their "primer" on genome editing in the consultation documents that, for the purposes of regulation, "the use of gene editing technologies does not present any unique safety concerns compared to other methods of plant breeding." Health Canada said the same about earlier genetic engineering techniques.[4]

However, the processes of engineering an organism, whether by first-generation genetic engineering or the new techniques of genome editing, can create genetic errors and result in unexpected consequences.[5] **These risks exist even when there is no foreign DNA present in the GMO**, because of possible damage that can happen during the genome editing process itself and because of possible impacts resulting from complex, poorly understood relationships within the organism's genome.

Some genetic errors caused by genome editing processes can be predicted, but others cannot. All unintended changes need to be detected, and then evaluated to see if they might affect food safety. Because these technologies are very new and the research is rapidly evolving, scientists are still discovering new information about how the genome editing techniques function in the genome and how to detect any unintended damage.

Sometimes, intended changes created by genome editing techniques are described as "mutations" because only very small parts of DNA are altered and no novel genes have been intentionally introduced. However, **even small changes in a DNA sequence can have big effects**, even if there is no foreign DNA inserted.[6] Such effects might not be detected right away and can appear after several generations.

The functioning of genes is coordinated by a complex regulatory network that is still poorly understood. This means that it is not possible to predict the nature and consequences of all the interactions between altered genetic material and other genes within an organism. For example, one small genetic change can impact an organism's ability to express or suppress other genes. This is why a full scientific evaluation of all GMOs is needed.

Documents from Health Canada show that an earlier proposal draft considered **the option to regulate all products of genome editing**: "All gene-edited plants would be considered novel (i.e., as substances with no history of safe use) due to scientific uncertainty and/or lack of regulator familiarity with these products." This option would maintain government regulation of all genetically engineered foods. However, the final proposal is essentially the opposite of this option.

Demand mandatory, independent safety assessments for all genetically engineered foods, including those produced by the new genome editing techniques.

What is Genome Editing?

Genome editing (also 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. Generally, genome editing 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's genome. Sometimes additional genetic material (a repair template) is inserted to direct the DNA changes that occur when the cell repairs itself. The most frequently used genome editing technique is CRISPR, but other techniques follow similar principles.

First-generation genetic engineering techniques insert genes, at random locations, to permanently become part of the host organism's genome, creating new DNA sequences that often confer a desired trait, such as herbicide tolerance. In contrast, with genome editing, the genetic material is inserted at a precise spot to makes changes to the genome, but the DNA does not necessarily have to become incorporated into the resulting GMO.

Genome editing is widely described as being precise because of its ability to target a specific site in the genome for change. However, this targeting is only one part of the engineering process. Many studies now show that genome editing techniques can be imprecise and create genetic errors, including:

- Unintended changes to genes that were not the target of the editing system. These are called "**off-target effects**." For example, the CRISPR-Cas9 system can make unintended edits to the host's DNA at additional sites to the target location.
- Unintended "**on-target effects**," which occur when a technique succeeds in making the intended change at the target location but also leads to other unexpected outcomes at the same location.
- Extensive **deletions and complex re-arrangements** of DNA.
- **Unexpected integration of foreign DNA** in the host organism during the genome editing process. For example, foreign DNA was unexpectedly found in genome-edited hornless cows.

An overview of the range of risks and unexpected consequences from genome editing is provided in CBAN's 2020 report "Genome Editing in Food and Farming: Risks and Unexpected Consequences." This report and an introduction document are posted at **www.cban.ca/GenomeEditingReport**

For further information and updates on genome editing see **www.cban.ca/gene-editing**

For updates relating to this consultation, more analysis and further action see **www.cban.ca/NoExemptions**

Demand mandatory, independent safety assessments for all genetically engineered foods, including those produced by the new genome editing techniques.

Submit your comments to Health Canada at hc.bmh-bdm.sc@canada.ca
Deadline for comments May 24, 2021

Please consider copying CBAN to your email so we can see your concerns: **info@cban.ca**

cban.ca/NoExemptions

Notes

1 The consultation documents are available upon request from Health Canada via the consultation webpage. The two documents are also posted online by CBAN.

2 For the briefing on Proposal #2: Allow unregulated GMOs to go unreported to the government (the "Voluntary Transparency Initiative") see www.cban.ca/NoExemptions/Proposal2

3 These proposals are updates to the Guidance on the Safety Assessment of Novel Foods, 2006.

4 Health Canada, The safety of genetically modified (GM) foods.

5 See CBAN's report "Genome Editing in Food and Farming: Risks and Unexpected Consequences"; or consult the list of studies posted by GMWatch "Gene editing: Unexpected outcomes and risks"

6 See for example: Kawall, K. Genome-edited *Camelina sativa* with a unique fatty acid content and its potential impact on ecosystems. *Environ Sci Eur* 33, 38 (2021).

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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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