

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

# Update and Overview

## Health Canada is proposing to remove regulation from some genetically engineered foods

Health Canada has launched a public consultation on a proposal to remove government oversight for some genetically engineered foods, particularly those produced through the new genetic engineering techniques of genome editing (also called gene editing). This proposal would allow some GMOs (genetically modified organisms) into our food system without any government safety assessments – these would be unregulated GMOs that the government may not even know exist.

Health Canada wants your opinion on proposals to:

1. Allow some genetically engineered foods onto the market without government safety assessments
2. Allow unregulated GMOs to go unreported to the government
3. Conduct lesser safety assessments for GMOs that are similar (“identical”) to previously approved GMOs

## Stop corporate self-regulation

**Demand mandatory, independent risk assessments for all genetically engineered foods.**

You can send your comments about the new proposals to Health Canada **until May 24**.

Comments can be submitted by email to Health Canada at [hc.bmh-bdm.sc@canada.ca](mailto:hc.bmh-bdm.sc@canada.ca)

Visit Health Canada's consultation website [www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding.html](http://www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding.html)

More information and analysis at [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions)

**Add your voice for the future of our food and democracy**

# Overview

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Health Canada has launched a public consultation on its proposal to remove government regulation of some genetically engineered (genetically modified or GM) foods.

If approved, the proposals would remove government oversight for some genetically engineered foods, allowing some GMOs (genetically modified organisms) into our food system without any government safety assessments – these would be unregulated GMOs that the government may not even know exist. These GMOs would be those that have no foreign DNA inserted and many are likely to be produced using the new genetic engineering techniques of genome editing, also called gene editing.

**Health Canada’s proposals threaten food safety and democracy.** Health Canada is proposing to abdicate its responsibility to ensure food safety and **set a precedent of corporate self-regulation** in the use of genetic engineering in our food system.

Government safety assessments already rely on confidential science submitted by product developers, but, if these new proposals go ahead, Health Canada will not even check this corporate science. **Allowing corporate self-regulation would be a significant move away from government oversight and review by independent government scientists.** Multinational biotechnology and pesticide corporations and their lobby group CropLife Canada have asked for these changes because seed companies want easier, faster regulations for genetic engineering and, in particular, the new genetic engineering techniques of gene editing.

Health Canada is proposing three changes:

**1. Allow some genetically engineered foods onto the market without government safety assessments:** Health Canada is proposing to exempt some genetically engineered foods from regulation. This means that some GMOs would be allowed onto the market without government safety assessments. Specifically, Health Canada is proposing to allow product developers to assess the safety of their own GMOs if there is no foreign DNA inserted. This proposal overlooks the potential consequences of unintended and

unexpected effects created by the process of genetic engineering, in this case, genome editing in particular (See CBAN’s report for discussion of the risks of genome editing [www.cban.ca/GenomeEditingReport](http://www.cban.ca/GenomeEditingReport) ). For more information and analysis see [www.cban.ca/NoExemptions/Proposal1](http://www.cban.ca/NoExemptions/Proposal1)

**2. Allow unregulated GMOs to go unreported to the government:** Health Canada proposes to set up a “Voluntary Transparency Initiative” that would not require, but would *encourage* private companies to voluntarily inform the government of any unregulated gene-edited GMOs that companies intend to put on the market. For more information and analysis see [www.cban.ca/NoExemptions/Proposal2](http://www.cban.ca/NoExemptions/Proposal2)

**3. Conduct weaker safety assessments for GMOs that are similar (“identical”) to previously approved GMOs:** Health Canada also wants to relax information requirements for the safety assessments of GM foods that have “identical” GM characteristics to those already approved. This proposal introduces “tiered” assessments that could mean “expedited service standards” (shorter timelines for a risk assessment) for some GMOs. More information and analysis on this proposal is forthcoming. Contact us if you have questions: [info@cban.ca](mailto:info@cban.ca)

If accepted, these changes would set a critical precedent to allow corporate self-regulation of genetically engineered organisms. **In fact, Health Canada’s consultation is the beginning of a multi-year process to “modernize” regulation for all GMOs, including GM seeds and GM animals.** This is an important opportunity to press for transparency and strong regulation.

**Take some time now to tell Health Canada you want mandatory, independent safety assessments of all genetically engineered foods.**

## How to comment

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**It is easy to comment, and your comments matter.** Your comments can be short and to-the-point because the proposals from Health Canada are straightforward (though they are written up in two documents that use some new and possibly confusing language). Your comments, in your own words, will be critically important.

Health Canada asks the public two questions (the other four questions are directed to product developers):

1. *“Does the guidance align with the goal of a regulatory approach that is based on the level of food safety risk posed by specific products of plant breeding?”* i.e. **Would the changes ensure food safety?**
2. *“Does the voluntary transparency initiative serve its purpose to inform Canadians what non-novel gene-edited products are on the market? Can we do more to achieve this objective?”* i.e. **Would the changes give you enough information about unregulated GMOs on the market and, if not, how can Health Canada provide more transparency?**

Your comments to Health Canada can answer these questions **and go beyond**, to express how you want decisions to be made about the use of genetic engineering in food and farming.

### If you only have 5 minutes, you can email today:

Email today if you want Health Canada to assess the safety of all genetically engineered foods, including those produced through the new genetic engineering techniques of genome editing (also called gene editing). Email [hc.bmh-bdm.sc@canada.ca](mailto:hc.bmh-bdm.sc@canada.ca) and please add CBAN to the BCC [info@cban.ca](mailto:info@cban.ca) so we can see your concerns.

You can react to the proposals, and can also go further and use this opportunity to tell Health Canada how you want genetic engineering treated by our government. Here are some points of concern that directly relate to the proposals:

- Health Canada should conduct mandatory, independent safety assessments for all genetically engineered foods, including those produced by the new genetic engineering techniques of gene editing.
- It is Health Canada’s responsibility to ensure the safety of all the food in our grocery stores.
- Health Canada should maintain regulatory authority over all genetically engineered foods, including those produced by the new genetic engineering techniques of gene editing.
- Health Canada’s regulators should check the science behind all genetically engineered foods to make sure that products are safe.
- Independent science, not corporate science, needs to be behind all safety assessments.
- Product developers should not be allowed to judge the safety of their own products without government checks.
- The government needs to provide transparency to consumers and farmers by requiring companies to report any new genetically engineered foods they put on the market, for a public list.
- Health Canada should establish mandatory labelling for genetically engineered foods, including those produced through gene editing. This would provide Canadians with information about which GM foods are on the market, and where they are in our grocery stores.

### » Email today or send more detailed comments

by May 24, 2021

Keep reading for more background. CBAN will also send detailed comments to Health Canada but it will take some time for us to put these together. For updates, subscribe to the CBAN E-news at [www.cban.ca/#subscribe](http://www.cban.ca/#subscribe)

# Background

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## What is happening?

- There are two consultation documents. The documents are available upon request from Health Canada or see [www.cban.ca/NoExemptions/ConsultationDocs](http://www.cban.ca/NoExemptions/ConsultationDocs)
- There are three proposals in this consultation. The consultation documents are 6 and 19 pages each but the actual proposals in them are short. For example, the proposal on gene editing is summarized on one page: Section 3 on page 5 of the document on “plant breeding.” See [www.cban.ca/NoExemptions/ConsultationDocs](http://www.cban.ca/NoExemptions/ConsultationDocs)
- CBAN will soon provide more detailed analysis of the proposals with more background information. Subscribe to the CBAN e-news at [www.cban.ca/#subscribe](http://www.cban.ca/#subscribe) for updates or stay tuned to [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions)
- The deadline to send your comment is May 24, 2021.

## Why is it happening?

- Multinational biotech and pesticide companies and their lobby group, CropLife Canada, have asked for these changes because companies want easier, faster regulations for the new genetic engineering techniques of gene editing in particular. See [www.cban.ca/NoExemptions/CorporateLobby](http://www.cban.ca/NoExemptions/CorporateLobby)

## What is at stake?

- **The role of government and the future of independent science:** The public cannot rely on product developers and corporate science to ensure product safety – independent, peer-reviewed science and independent government oversight is essential to safeguarding public health.

- **The role of the public in decision-making:** Consumers and farmers should have input into decisions over the use of new technologies in our food system like genetic engineering, including to assess the question of need and the potential social and economic impacts.
- **The future of food and farming:** The new genetic engineering techniques of genome editing are powerful and could be used to produce many new patented GM foods, plants, and animals.
- **Food safety:** Safety issues could be missed if assessments of genetically engineered foods do not consider the potential unexpected impacts resulting from the process of genetic engineering, and if these assessments are carried out by product developers instead of independent government regulators.

## Decoding Health Canada’s language:

- **“Regulatory guidance”:** The proposals are not changes to regulations, but would change the “guidance” document which interprets the regulations and instructs regulators on how to assess GMOs for food safety.
- **“Plant breeding”:** The biotech industry and Health Canada often refer to the new genetic engineering techniques of gene editing as “breeding” methods, but this is not accurate or appropriate. Unlike breeding methods, genetic engineering techniques (including gene editing techniques) intervene directly in the genome to make changes.
- **“Genetic modification”:** The term “genetic modification” is commonly used interchangeably with “genetic engineering,” to refer to the new laboratory techniques of directly intervening in the genome of organisms to make changes. However, Health Canada uses the term “genetic modification” to refer to a broad category that includes conventional plant breeding as well as genetic engineering.

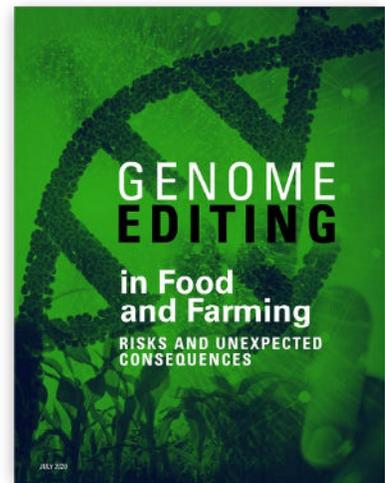
- **“Biotechnology”**: In the proposals, Health Canada does not use the term “genetic engineering” at all but instead uses the broader term “biotechnology.”
- **“Pre-market notification”**: When Health Canada refers to pre-market notification, they are referring to the process where product developers submit information on their GMO to regulators for safety assessment.
- **“Retransformants”**: This is not a common term, but Health Canada uses it for the purposes of regulation, to refer to plants that have been genetically engineered with the identical sequence of DNA as a previously-authorized plant of the same or similar species, to create the same GM trait.

For information on how genetically engineered foods are regulated in Canada, see CBAN’s report “Are GM Foods and Crops Well Regulated?”

[www.gmoinquiry.ca/regulation](http://www.gmoinquiry.ca/regulation)

Genome editing techniques (also called gene editing) are a type of genetic engineering, resulting in the creation of genetically modified organisms (GMOs).

Genome editing can be imprecise, causing unexpected and unpredictable effects.



[www.cban.ca/GenomeEditingReport](http://www.cban.ca/GenomeEditingReport)



[cban.ca](http://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](mailto:coordinator@cban.ca) | 902 209 4906

## 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?’”<sup>1</sup>

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

### 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.**

the government (See CBAN Briefing on Proposal #2<sup>2</sup>). 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.<sup>3</sup>):

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.<sup>4</sup>

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.<sup>5</sup> **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.<sup>6</sup> 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 make 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](http://www.cban.ca/GenomeEditingReport)

**For further information and updates** on genome editing see [www.cban.ca/gene-editing](http://www.cban.ca/gene-editing)

**For updates** relating to this consultation, more analysis and further action see [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions)

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Deadline for comments May 24, 2021

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[cban.ca/NoExemptions](http://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](http://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).



[cban.ca](http://cban.ca)

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

### Proposal #2:

### Allow unregulated GMOs to go unreported to the government (the "Voluntary Transparency Initiative")

This proposal is to create a "Voluntary Transparency Initiative" whereby Health Canada would encourage product developers to voluntarily report their unregulated gene-edited GMOs to the department, for a public list called the "List of Non-Novel Gene-Edited Plants for Food Use." The proposal is outlined in Section 6 (pages 8-9) 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"?"

#### CONCERNS:

- **There is no transparency if information is only voluntarily disclosed.**
- **Some unregulated genetically engineered foods may be put on the market without notification to the government, or public.**
- **Health Canada will have surrendered regulatory authority over some genetically engineered foods and not therefore be able to require companies to provide information about these GMOs.**
- **Undermine public trust in the food system and Health Canada's regulation.**

Health Canada is proposing to exempt some genetically engineered (commonly called genetically modified or GM) foods from regulation and, in so doing, surrender regulatory authority over these genetically modified organisms (GMOs). In the absence of regulatory authority, Health Canada is proposing what it calls a "Voluntary Transparency Initiative" where the government would **"encourage" product developers to voluntarily report the existence of any unregulated genome-**

**edited (gene-edited) GMOs.** Health Canada would then post this information online as a **“List of Non-Novel Gene-Edited Plants for Food Use.”**

Health Canada says, “The goal of this initiative is to provide Canadians with a clearer understanding of the gene-edited products in the Canadian market with the goal of enhancing public trust in these products and the regulatory system”, and one of the two questions Health Canada asks the public in the consultation is: “Does the voluntary transparency initiative serve its purpose to inform Canadians what non-Novel gene-edited products are on the market? Can we do more to achieve this objective?”

“Health Canada recognizes the need for greater transparency surrounding gene-edited plants as many of these plants will not be considered Novel, and thus **they will not undergo pre-market safety assessment** prior to entering the Canadian food supply. To increase transparency regarding gene-edited plant varieties that are present in the Canadian food supply, this guidance describes a Voluntary Transparency Initiative whereby **plant developers are encouraged to inform Health Canada** of any non-novel gene-edited plant variety that they have developed for commercial use.” (emphasis added)

Currently, Health Canada lists which GMOs (“novel foods”) it has approved for sale. The “Voluntary Transparency Initiative” is proposed to address the problem that, because Health Canada now proposes to exempt some GMOs from regulation and allow companies to forgo government safety assessment, Health Canada’s list of approved GMOs would no longer be a list of all the GMOs that could possibly be on the market. Note: **The federal government does not track which GMOs are actually on the market.**

However, with this proposed initiative, **Consumers, farmers, and the federal government itself, will not necessarily be made aware of all the new unregulated gene-edited GMOs** because the “Voluntary Transparency Initiative” would only result in a list of those unregulated gene-edited GMOs that product developers decide to disclose.

**This initiative would not result in a list of gene-edited foods on the market – at most, it would result in a list of some unregulated gene-edited GMOs that *could* be on the market:**

- Because the proposed mechanism is voluntary, not mandatory, the list of unregulated gene-edited GMOs **may not be complete and is not therefore transparent.** There would be no way for the public, or Health Canada, to know if the list names all of the unregulated GMOs that could be on the market: the public would be left to assume that the list is partial.
- **The market status of listed unregulated GMOs would remain unknown.** Health Canada’s list would be a list of some unregulated GMOs that *companies say they intend to commercialize.* Health Canada says that, “this voluntary system is to be used for products ready for commercialization and not for theoretical products” and that it will encourage product developers to provide information at least 90 calendar days prior to commercialization. It would be difficult, however for the public to verify that corporate notifications of new unregulated gene-edited GMOs are not just posted to promote theoretical products, to attract investors for example. Additionally, there are many reasons why a product intended for commercialization may not ultimately be sold. For example, many genetically engineered foods currently listed by Health Canada as approved for use are not actually sold in Canada, including GM tomatoes, GM flax and GM potatoes (see [www.cban.ca/gmfoods](http://www.cban.ca/gmfoods)).

Health Canada says, “there is great interest from and benefit for regulators, plant developers, and the public in greater transparency regarding all products developed using these technologies that are present in the Canadian food supply.” In fact, for over twenty years, polls have consistently shown that over 80% of Canadians want mandatory labelling of genetically engineered foods.<sup>2</sup>

However, rather than establish mandatory labelling for genetically engineered foods, Canada published the standard for “Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering” in 2004.<sup>3</sup> The example of this voluntary labelling standard illustrates the lack of utility in asking private companies to voluntarily disclose genetically engineered foods to the public. To our knowledge, no company has ever used this standard to voluntarily identify any genetically engineered food on the market.

## 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 a history of poll results see [www.cban.ca/labelling](http://www.cban.ca/labelling)
- 3 For background see CBAN's report “[Are GM Foods Better for Consumers?](#)”

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