

Responding to Health Canada's Public Relations on GMO regulation

On May 18, 2022, Health Canada published new regulatory guidance that will allow companies to sell some foods from gene-edited plants (genetically modified organisms or GMOs) without any government safety assessments or mandatory notification to government.

At the same time, [Health Canada published a webpage](#) to explain the changes to the public, in the form of responses to five key concerns. However, **Health Canada's responses to the concerns are not clear and some can be misleading**. Here, the Canadian Biotechnology Action Network (CBAN) directly reacts to Health Canada's responses.

CBAN has published extensively on the regulation of gene editing: www.cban.ca/NoExemptions/Publications

Updates and background: www.cban.ca/NoExemptions



[Health Canada's "Response to concerns about the new guidance on Novel Food Regulations, products of plant breeding"](#)

Canadians have expressed a number of concerns regarding the regulation of these products, including those developed using gene editing technologies and other methods of genetic modification. Here are the department's responses to these concerns.

[Response from the Canadian Biotechnology Action Network \(CBAN\)](#)

[105 groups together called](#) for transparency and government oversight over all genetically engineered foods and seeds. Thousands of Canadians wrote letters and participated in Health Canada's consultation to express their concerns.

Concern #1

Health Canada is no longer regulating or conducting safety assessments for foods produced from genetically modified (GM) plants unless they contain foreign DNA.



Health Canada's response #1

Health Canada will continue to regulate and conduct [safety assessments](#) for all novel foods prior to their use in the Canadian food supply.

The *Novel Food Regulations* are product-based. The regulatory status of a product is based on the characteristics of that product. It's not based on the process by which the product is developed. This regulatory approach is scientifically supported, as it's the characteristics of a product, like whether it contains an allergen or a toxin, that determine if it's safe to eat.

The new guidance doesn't change this approach. The guidance identifies 5 categories of characteristics that a plant may have that would require a safety assessment before its use in the Canadian food supply. The presence of foreign DNA is only 1 of these categories. Under the new guidance, the department considers any foods produced from plants [having any of the identified characteristics as "novel foods,"](#) regardless of whether a plant has been developed using:

- conventional breeding
- gene editing
- other methods of genetic modification



CBAN's response #1

Health Canada will not regulate and conduct safety assessments for some gene-edited GM foods.

Health Canada has decided that foods from gene-edited plants that have no foreign DNA are not **"novel foods"** unless companies find a food safety problem. Therefore, Health Canada **will not** regulate and conduct safety assessments for those gene-edited GM foods. Health Canada will **exempt** genetically modified plants that have no foreign DNA from the *Novel Food Regulations*.

Yes, the new guidance identifies five categories of characteristics that a plant must have to require a Health Canada safety assessment and the presence of foreign DNA is one of these categories. This means that **product developers themselves will decide** whether their products fit these categories. **Without any government checks, product developers are asked to determine:**

- if their GM food has any foreign DNA;
- if they are not introducing a significant change to how we use this plant in our diet;
- if their GM food meets these three limited safety criteria:
 - the gene editing does not change a protein so that it looks similar to a known allergen or toxin,
 - the gene editing does not significantly increase levels of allergens, toxins, or anti-nutrients that are already known to be in the plant,
 - the gene editing does not impact key nutritional composition or metabolism.

This is **corporate self-regulation** where, if there is no foreign DNA in the GMO, product developers will decide by themselves if their product is safe enough to enter the market.



Concern #2

Health Canada is allowing industry developers to decide for themselves if foods produced from GM plants are regulated under the *Novel Food Regulations*.

Health Canada's response #2

All food producers are responsible for ensuring they comply with the provisions of the Food and Drugs Act and its regulations. This responsibility includes determining if their products meet the definition of a "novel food" and submitting a notification for pre-market assessment to Health Canada prior to sale in Canada. Health Canada's new guidance doesn't change this responsibility.

Health Canada will continue to encourage developers to [request a novelty determination](#) in cases where they're unsure of the regulatory status of their products.

CBAN's response #2

All food producers are responsible for deciding whether their own products are safe or if they need to be submitted for a safety assessment by Health Canada regulators.

If companies want to ask Health Canada for an opinion on whether their product needs to be regulated (is considered "novel"), they can ask for one, but it is not required.



Concern #3

There's a lack of transparency about the presence of foods produced from GM plants in the Canadian food supply.

Health Canada's response #3

Health Canada recognizes that transparency regarding foods produced from GM organisms is important to people in Canada. The department publishes [technical and plain language summaries](#) for every novel food safety assessment, including for those produced from GM organisms (GMOs). Health Canada will continue to publish these summaries for all novel foods.

The department acknowledges that certain products of plant breeding don't meet the definition of a "novel food." This can include foods produced from specific GM plants, depending on the characteristics expressed by those plants.

Health Canada doesn't have the regulatory authority to require notification of products that are not novel. However, the department has sought ways to increase transparency around non-novel products. Currently, Health Canada maintains a [list of products](#) for which the producer has sought confirmation regarding the novelty status.

Given the high degree of interest in products of gene editing, Health Canada has also introduced a new transparency initiative. This initiative will help people in Canada access information about non-novel, gene-edited products of plant breeding. Health Canada will maintain and publish a [list of every non-novel product of plant breeding](#) submitted to the department. While this initiative is voluntary, it increases transparency regarding these non-novel products where previously none existed.

Furthermore, the Minister of Health has received letters from industry developers indicating their commitment to participate fully in this process. These letters are available on the [openness and transparency page](#).

CBAN's response #3

Health Canada says it recognizes that "transparency regarding foods produced from GM organisms is important to people in Canada," but it does not ensure this transparency.

Yes, Health Canada publishes summaries for every novel food safety assessment it conducts - but the new regulatory guidance means that **not all GM foods will be defined as novel and, therefore, not all will be assessed by Health Canada**. This means that Health Canada will not publish summaries about every gene-edited food that could be on the market. The federal government is not requiring companies to provide public notification of these new unregulated GM foods.

Health Canada could have defined all gene-edited foods as novel which would have made sure they are all regulated, but it did not do this. Instead, Health Canada decided to narrow the definition of what is "novel" and thereby **surrender its regulatory authority** over those gene-edited foods deemed "non-novel". This means Health Canada cannot require companies to provide information about these unregulated gene-edited foods.

In the absence of its ability to require information, Health Canada is asking companies to **voluntarily** notify the government and public about new unregulated GMOs.

The Minister of Health has decided to rely on biotechnology companies to voluntarily notify the government of new gene-edited foods that could come to market. In fact, the Minister has decided to accept commitments directly from biotechnology lobby groups and companies. **The Minister has decided to be dependent on the voluntary cooperation of product developers, instead of securing regulatory authority over them.**



Concern #4

In developing the new guidance, Health Canada hasn't considered the current scientific literature regarding the safety of gene editing technologies and their use to develop new products of plant breeding.

Health Canada's response #4

Health Canada considered all of the available scientific literature regarding the use of gene editing technologies in plant breeding, as well as expert opinions, including those from:

- industry
- academia
- government

There's a consensus that the use of gene editing technologies doesn't present any unique safety concerns compared to other more conventional methods of plant breeding. As such, Health Canada should regulate [gene-edited products of plant breeding in the same manner as all other products of plant breeding](#) as described in the new guidance.

Health Canada has also published a [scientific opinion on the regulation of gene-edited plant products within the context of the Novel Food Regulations](#). The scientific opinion acknowledges that unintended genetic changes can occur in plants when using gene editing technologies. However, both the scientific literature and opinions from experts in the field of plant breeding confirm that these changes aren't unique to gene editing and can occur through all methods of plant breeding. Furthermore, these changes can be removed from a plant through standard plant breeding practices. One of the main conclusions of this opinion is that gene-edited plants are just as safe as their conventionally bred counterparts.

CBAN's response #4

CBAN has written three documents discussing the science that Health Canada should consider:

- [Genome Editing in Food and Farming: Risks and Unexpected Consequences](#), 2020
- [CBAN comments on Health Canada's primer on gene editing](#), 2021
- [Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks](#), 2022

CBAN sent these reports to the department. Health Canada responded and does not agree that all of these findings and concerns are relevant.

There is no consensus about the food safety of using genetic engineering and no consensus about the safety of using gene editing. There is active, ongoing scientific inquiry into the safety questions, and many gene editing techniques are still being developed.

Gene editing is genetic engineering, not plant breeding. Gene editing can introduce unique changes and risks. Regulating gene-edited foods in the same way as products of plant breeding, and handing assessments over to product developers, is **not science-based regulation**.

Health Canada's scientific opinion "acknowledges that unintended genetic changes can occur in plants when using gene editing technologies." However, Health Canada assumes that companies will carefully look for, find, and remove these unintended changes in their GM plants "through standard plant breeding practices." Health Canada assumes that product developers can be trusted to assess the safety of their own products.

CBAN disagrees with Health Canada's scientific opinion.



Concern #5

Health Canada developed the new guidance in a manner that wasn't transparent and Canadians weren't properly consulted.

Health Canada's response #5

Given the high degree of interest in genetically modified foods, Health Canada undertook the development of its new guidance in an open and transparent manner. Since the department announced its intent to develop the new guidance, summaries of all meetings with stakeholders have been available through the [openness and transparency page](#) for this project. This includes all documents shared and all correspondence with stakeholders on this topic. Health Canada accepted all invitations from stakeholders to present and discuss the development of the new guidance. Health Canada also reached out to groups with special interest in GMOs to discuss the new guidance.

Health Canada undertook a [60-day public consultation](#) on the proposed new guidance from March to May 2021. The department received and reviewed over 4,600 comments. This included reviewing any new scientific information submitted. Evidence-based comments are reflected in the new guidance.

Health Canada also accepted feedback submitted after the close of the consultation period and provided additional time when requested to ensure that all stakeholders had the opportunity to provide comments. We published a summary of the comments received in a ["What we heard" report](#).

CBAN's response #5

Health Canada undertook some of the last stages in the development of guidance in an open and transparent way, after [years of discussions with the biotechnology industry](#).

Health Canada undertook a 60-day public consultation in 2021 and published a summary of the consultation comments in a "What we heard" report - but **Health Canada did not take action to address the concerns it heard from the public.**



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.

cban.ca/NoExemptions