

July 2021



# GUIDE

## TO THE PUBLIC CONSULTATION:



**THE CFIA'S PROPOSAL TO EXEMPT SOME GENETICALLY ENGINEERED (GENE EDITED) SEEDS FROM REGULATION**

## THE ISSUE

The CFIA's proposed new regulatory guidance would exempt many new genetically engineered seeds from government environmental risk assessment.

Public consultation DEADLINE: **September 16, 2021**

## SUMMARY

The Canadian Food Inspection Agency (CFIA) has launched a public consultation on a proposal to exempt many new genetically engineered (genetically modified or GM) plants from government regulation.

The proposal would allow private companies to sell some GMOs (genetically modified organisms) without government environmental risk assessments. Instead, many new genetically engineered plants would be **assessed for environmental safety by the product developers themselves, with no government oversight**. Specifically, the CFIA proposes to exempt genetically engineered seeds that have no foreign DNA, many of which would be produced with the new genetic engineering techniques of genome editing (also called gene

editing). **The result would be unregulated genetically engineered seeds sold and grown in Canada.** Farmers, consumers, and the CFIA itself, may not even know that some of these new genetically engineered seeds exist because there would be no requirement for companies to report the new unregulated GMOs to the government.

**The CFIA's proposal for corporate self-regulation could have profound environmental consequences and would negatively impact many farmers.**

The CFIA's proposal for GM seed regulation follows a similar proposal from Health Canada that would hand many GM food safety assessments over to product developers (see [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions)).

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



## CONCERNS

- » The release of genetically engineered (genetically modified or GM) plants can have many different impacts on the environment.

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- » Genetically engineered plants could pose environmental risks even if they have no foreign DNA (are gene edited). The CFIA is overlooking the potential for gene editing techniques to create genetic errors and result in unintended effects.

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- » The CFIA has already failed to prevent negative environmental outcomes from the use of genetically engineered herbicide-tolerant plants.

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- » It is a conflict of interest for product developers to assess the environmental safety of their own products.

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- » Allowing corporate self-regulation of new genetically engineered plants is an abdication of the CFIA's responsibility to protect the environment for the public good.

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- » Allowing the sale of some genetically engineered (gene-edited) seeds without any mandatory reporting to the government or disclosure to farmers could put some farmers at risk of unknowingly using GM seeds and could expand the GM contamination risk, threatening organic farm systems and the livelihoods of farmers who sell into GM-sensitive markets.

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- » Unregulated, unreported field tests of genetically engineered plants would increase GM contamination risks that could have environmental and economic impacts.

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- » The proposed changes are entirely inappropriate for the regulation of genetically engineered trees that pose serious environmental risks and complex challenges for risk assessment.

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- » The proposed changes would further undermine public trust in both the food system and government regulation.

## INTRODUCTION AND OVERVIEW

The Canadian Food Inspection Agency (CFIA) is asking you to “share your thoughts” about its **proposal to exempt many gene-edited (also called genome edited) genetically engineered seeds from regulation**. The CFIA has posted a consultation document and an online questionnaire with a deadline of September 16, 2021.

The CFIA is proposing new regulatory guidance “to clarify the requirements” for how the release of new seeds is regulated and **when government safety assessments are required**.

The CFIA is proposing that genetically engineered plants with no foreign DNA be exempt from regulation (be exempt from Part V of the *Seeds Regulations*). This would mean that many new seeds produced through the newer genetic engineering techniques of gene editing would not need to be approved by the CFIA before being released into the environment (to be grown on farms, for example). Instead, **product developers themselves would determine if their new genetically engineered gene-edited seeds are safe for the environment, with no government oversight**.

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## THE CFIA'S PROPOSAL

The CFIA proposes that genetically engineered plants can be **exempt from government regulation** (Part V of the *Seeds Regulations*) if they:

- 1) are not a new crop kind to Canada,
- 2) have no foreign DNA, and
- 3) if the product developer can conclude that the plant will not negatively impact the environment.

*"If not a new crop and no foreign DNA has been incorporated into the plant, the proponent [product developer] must then consider the plant's capacity to impact the environment."* [emphasis added]

**This is a proposal for corporate self-regulation where product developers would assess the environmental safety of releasing their genetically engineered plants.**

The CFIA proposes four environmental "outcomes" for companies to consider "where a plant would have the capacity to impact the environment." If product developers determine that their GM plants would not result in any of these four negative outcomes, then the CFIA proposes that they can release their GM seeds without asking for government assessment and approval. It would be up to the product developer, not the CFIA, to determine if there could be negative environmental impacts from genetically engineered plants that have no foreign DNA..

The CFIA also proposes that regulatory exemptions "will increase as more products are authorized." This means that as the CFIA approves more genetically engineered plants (those that still qualify for government assessments), "similar plants developed in the future" would be allowed without government safety assessments.

The proposed regulatory guidance would apply to GM crop plants as well as to GM plants for other purposes and in other contexts such as using GM trees in plantations or releasing **GM trees** into the wild (See below or [www.cban.ca/trees](http://www.cban.ca/trees) for information about the proposal to plant American chestnut trees in Canadian forests).

The CFIA says that the goals of the new regulatory guidance proposals are "**decreasing regulatory burden**, providing clarity for developers, and maintaining Canada's standards for safety, while allowing Canadians to benefit from improved crops." [emphasis added] **The CFIA is prioritizing the demands of product developers over the need to protect the environment for the public good.**

This public consultation follows a similar consultation from Health Canada (which closed on May 24, 2021, with a report to the public expected in late August). The proposals would not change the regulations themselves but would change the "regulatory guidance" —the interpretation of the regulations, guiding how departments implement them. This is part of a multi-year process to "modernize" the regulation of all GMOs, including GM animals. The consultation is an important opportunity to press for strong regulation to protect the environment and support farmers. The CFIA has an online questionnaire for your feedback. Deadline: Sept. 16, 2021.

**Take some time now to tell the CFIA that you want mandatory, independent environmental assessments of all genetically engineered plants ►**

# GUIDE TO THE CFIA'S QUESTIONNAIRE

The CFIA is asking you to “share your thoughts” by filling out an online questionnaire. There are 11 questions organized in three short sections (four online pages). Most questions have a numbered scale (1-7) where you can rate how much you agree or disagree, and **each question gives you an opportunity to write your own comments.**

**Below, we provide the CFIA's questions along with some bullet points of analysis that you could consider when answering.**

The questionnaire doesn't ask for any personal information such as your name or contact, however, in your answers you could tell the CFIA who you are. For example, “As a farmer...” “As a member of the public...” voter, parent, etc.

The questionnaire needs to be filled out online at: [https://ca1se.voxco.com/SE/93/CFIA\\_guidance\\_directrices\\_de\\_IACIA/?&lang=en](https://ca1se.voxco.com/SE/93/CFIA_guidance_directrices_de_IACIA/?&lang=en) However, the CFIA will also accept your answers in an emailed document. If you want to write your comments in a file, email it to [cfia.pbo-pbo.acia@canada.ca](mailto:cfia.pbo-pbo.acia@canada.ca) (Please consider copying [info@cban.ca](mailto:info@cban.ca) so CBAN can also read your comments).

The CFIA consultation page is <https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/eng/1619740964754/1619741042405>

The  
**questionnaire**  
will take around  
15 minutes  
to answer.

**Follow our  
guide ►**

For more information on genome editing see CBAN's introduction or report at [www.cban.ca/GenomeEditingReport](http://www.cban.ca/GenomeEditingReport)

For more information on the environmental impacts of GMOs see CBAN's report “Are GM Crops Better for the Environment?” [www.gmo inquiry.ca/environment](http://www.gmo inquiry.ca/environment)

For more information on the consultations, more analysis, and to check for updates see [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions)

For email updates on this consultation, subscribe to the CBAN e-news [www.cban.ca/#Subscribe](http://www.cban.ca/#Subscribe)

Public consultation DEADLINE: **September 16, 2021**

## QUESTIONNAIRE

### CFIA guidance for determining whether a plant is subject to Part V of the *Seeds Regulations*



The CFIA is seeking your feedback on the proposed guidance for determining whether a plant is subject to Part V of the *Seeds Regulations*.

Feedback will help the CFIA finalize guidance that considers the needs of industry and Canadians, and that is reflective of Canada's science-based approach of adapting to innovation while protecting health and safety.



The CFIA proposes to exempt some genetically engineered plants from government regulation (from Part V of the *Seeds Regulations*). If implemented, this would allow companies to sell many new GMOs without government environmental risk assessments. Instead, many GM plants would be assessed for environmental safety by the product developers themselves, with no government oversight. Specifically, the CFIA proposes to exempt genetically engineered seeds that have no foreign DNA, many of which would be produced with the new genetic engineering techniques of genome editing (also called **gene editing**).

### Theme 1: Determining when a plant qualifies for an exemption from Part V



1.1 How clear is the guidance on how exemptions for equivalent plants would work? (See Draft Guidance, Section 2, Exemptions from Part V)

#### ***Section 2, Exemptions from Part V***

##### ***2.1 Statement on conventional breeding and gene editing***

*Virtually all plants developed by conventional breeding techniques qualify for an exemption from Part V, on the basis of being substantially equivalent to the lines they are derived from. Similarly, genetic changes that do not include foreign DNA will, for the most part, resemble conventional breeding outcomes, and will also qualify for an exemption. The CFIA recognizes that gene editing techniques can introduce genetic changes that are comparable to conventional breeding outcomes, and will also qualify for an exemption.*

*Plants derived from populations that have been previously grown in Canada qualify for an exemption, provided that they do not present new risks to the environment. Plants previously grown in Canada include those that were present prior to 1996 when Part V came into force, as well as those that were authorized after 1996.*

## **2.2 Exemptions will increase as more products are authorized**

*Part V allows for subsequent plant lines to be exempted once an original event has been authorized in that species. Authorization decisions are listed on the CFIA's website. A plant will qualify for an exemption based on a past authorization if:*

- *the original authorization was issued without risk management conditions*
- *the subsequent plant does not contain foreign DNA*
- *the underlying mechanism of action is substantially equivalent to the original trait, and*
- *the trait does not result in one of the environmental impact outcomes listed in Section 3.3*

*Proponents can view the list of authorization decisions and exemption opinions as available. Proponents can use this information to identify if their plant is substantially equivalent and would qualify for an exemption from Part V. This exemption builds on the safety record of plant breeding, and allows for improved plant varieties to be continually developed.*



Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.

Not at all clear

1 2 3 4 5 6 7 Unsure

Please provide additional information on your response:

- There should be no exemptions from the regulations for any genetically engineered plants. Instead, all genetically engineered plants including those that do not have foreign DNA (new gene edited plants), need to be assessed by the CFIA for their potential environmental risks.
- The use of the new genetic engineering techniques of gene editing should trigger regulation. Gene editing can create genetic errors and result in unintended effects in the resulting GMO. Gene editing has no history of safe use.
- Product developers should not be left to decide if their genetically engineered plants qualify for exemptions.
- The CFIA should conduct a full environmental risk assessment of each genetically engineered plant before they are introduced even if those genetically engineered plants appear to resemble previously approved plants.

For CBAN's responses to statements on genome editing see our two comment documents to Health Canada at [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions) or our introduction to genome editing at [www.cban.ca/GenomeEditingReport](http://www.cban.ca/GenomeEditingReport)

- Deciding if a GMO is “substantially equivalent” to previously approved plant is not an adequate way to determine environmental safety.
- Product developers should not be allowed to decide if their GMO is “substantially equivalent” as this could easily be a path to avoiding a CFIA environmental assessment.
- As science advances, we will learn more about the effects of gene editing. New science could shed new light on past approvals.



**1.2 CFIA publishes information about assessments and decisions for authorized products. This information provides transparency, helps to ensure consistency in decision-making, and adds efficiencies to decisions about equivalent products.**

Similar benefits could come from publishing information about CFIA’s opinions for exempt products. However, this is balanced against the *Privacy Act*, and whether there is value in sharing information about products at an early stage of development. CFIA doesn’t currently have a way to publish information about products that are exempt from Part V: this is protected information and can’t be shared without the consent of the developer. CFIA is interested in learning whether there is support for publishing this type of information, and if so, what should be published and when.



If the CFIA exempts some GM plants from the regulations as proposed, many GMOs will be sold without a government approval decision and the CFIA will no longer have a list for the public of all the GM seeds could be on the market.

The CFIA is offering that product developers can request an “exemption opinion” if they want an official opinion about whether or not their GM seed is exempt from the regulations or needs a government assessment. Seeking an “exemption opinion letter” would be voluntary.



**1.2.a If you are a plant developer, would it be useful to your work to receive an exemption opinion letter?**



Please use a scale of 1 to 7 where 1 is not at all useful and 7 is very useful.

(unless you are a plant developer)

1 2 3 4 5 6 7 Unsure

Please provide additional information on your response:

- The purpose of any CFIA assessment should not be to provide a service to product developers. Instead, the CFIA should conduct mandatory environmental safety assessments of all genetically engineered plants, to serve the Canadian public and the goals of environmental protection.
- The CFIA should not offer voluntary “exemption opinion letters” as a marketing tool for product developers but should conduct mandatory full environmental assessments for all genetically engineered plants.



**1.2.b. When providing an exemption opinion letter, the CFIA could make certain information about the opinion public. For example, this could include the plant species, a summary of the trait(s) and how they function, and the rationale for the opinion. Some information could be made available within the bounds of the Privacy Act, while sharing other information would require the consent of the plant developer.**

**Would it be useful to make information in CFIA’s exemption opinions publicly available?**



Please use a scale of 1 to 7 where 1 is not at all useful and 7 is very useful.

Yes

1 2 3 4 5 6  7 Unsure

Please provide additional information on your response:

- All CFIA regulatory decisions should be made public.
- All CFIA decisions and assessments should be disclosed to Canadians for public transparency, not for the purpose of being useful to product developers.
- There should be no voluntary exemption opinions offered. Instead, all genetically engineered seeds, including all those that do not have foreign DNA, should be subject to mandatory CFIA assessments to investigate their potential negative impact on the environment.
- There should be no exemptions from the regulations for any genetically engineered products.



**1.2.c What information should be included in any list of exempt plants? Please select all that apply.**

- Developer name
- Product name/identifier
- Plant species

- Trait(s) (high-level description)
- Method of trait development
- Rationale for exemption
- Antecedent line(s) (if applicable where a previous authorization was cited) Intended use: Food/ Feed/ Environment  
Regulatory status: Food/ Feed/ Environment
- Access to the opinion letter as-written
- Other, please specify



Click all.

- All genetically engineered plants should be assessed by the CFIA and as much information as possible about the decisions and the new GMOs should be posted on the CFIA website.



**1.2.d. No developer is required to seek an opinion from CFIA for plants that are exempt from Part V. The CFIA has no authority to require information from a developer if the plant is not subject to Part V. For this reason, requesting an opinion from the CFIA is voluntary. This is a service that the CFIA provides to help support compliance with Part V.**

**While the exemption opinion itself is optional, consenting to publish the opinion could be made a mandatory requirement. All opinions issued by the CFIA would be published. However, not all developers will seek an opinion, and mandatory publication could serve as a disincentive to participation.**

**If a plant developer requests that CFIA provides an opinion, should it be mandatory or voluntary that CFIA publishes the opinion in a public list of exemption opinions**



- Voluntary
- Mandatory
- Unsure

Please provide additional information on your response:

- The CFIA should secure the authority to require information from private companies about all genetically engineered plants that could be on the market by ensuring that they are all subject to the regulations. There should be no exemptions for any genetically engineered products, even those that have no foreign DNA (produced by gene editing).
- Requiring mandatory CFIA assessments of all genetically engineered plants, including those developed using gene editing, will ensure that the CFIA has the authority to provide necessary transparency to the public.
- The CFIA should require all genetically engineered plants to be submitted to the CFIA for a full safety assessment.
- The CFIA should not provide product developers with confidential letters and confidential decisions. All information should be published for the public on a mandatory basis.
- Product developers should not be allowed to decide whether information about a CFIA decision should be public or not. The CFIA should ensure that all information about CFIA evaluations is made public.

## Theme 2: Determining which plants are subject to Part V



For plants that are not new and do not contain foreign DNA, the developer must consider whether the plant has the capacity to impact the environment.



Under these proposals, if a plant is not a new crop kind and has no foreign DNA, **product developers themselves would decide if their GM plant could negatively impact the environment.**

The CFIA proposes that **genetically engineered plants would only be regulated if:**

- 1 They are a new crop kind in Canada (a crop never grown here before),
- 2 Have foreign DNA, or,
- 3 Could negatively impact the environment.

**The CFIA lists four environmental “outcomes” or impacts that companies should consider** in order to determine if their GM plants could negatively impact the environment.



**2.1 The guidance states that when a plant is considered to be a new crop kind in Canada, it is subject to Part V. Is this information clear?**



Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.

Yes, it is very clear

1 2 3 4 5 6  7 Unsure

Please provide additional information on your response:

(An example of a new crop kind, never grown in Canada, might be cassava, papaya or mango.)



**2.2 The guidance states that when a plant has foreign DNA, it is subject to Part V. Is this information clear? Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.**



Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.

Yes, it is very clear

1 2 3 4 5 6  7 Unsure

- This information is clear because it is overly simplistic. Risk issues raised by GMOs are not limited to the presence or absence of foreign DNA, but also arise from unexpected and unpredictable effects from the process of genetic engineering.
- Even small changes in a DNA sequence can have significant effects, even if there is no foreign DNA present in the resulting GMO.
- The process of gene editing can create genetic errors and result in unintended consequences that need to be investigated. Gene editing has no history of safe use.
- Exempting genetically engineered plants that have no foreign DNA could leave many gene-edited seeds unregulated and some may even be sold without any notification to the government, public, or even to farmers.
- All genetically engineered plants, including seeds that have no foreign DNA, should be subject to Part V of the *Seeds Regulations* and undergo mandatory, government environmental safety assessments.
- The CFIA should not give product developers the responsibility to assess the risks of their own gene-edited plants because they have a profit incentive to downplay any negative impacts. Private companies may not fully look for evidence of negative impacts on the environment.



2.3 The guidance lists 4 outcomes that could negatively impact the environment. Are these 4 outcomes an appropriate way to define when a plant is subject to Part V?

1. *Make a plant more difficult to control,*
2. *Introduce or enhance a toxin, allergen, or other compound that would negatively affect plants, animals, or microbes,*
3. *Improve the survival of plants in natural environments to a degree that ecosystems would be disrupted, or*
4. *Enhance a plant pest (such as a fungal disease)*



Please use a scale of 1 to 7 where 1 is not at all appropriate and 7 is very appropriate.

Not at all appropriate.

1 2 3 4 5 6 7 Unsure

- It is not appropriate for product developers to decide the environmental safety of their own genetically engineered seeds, this is a job for independent government regulators.
- There is no assurance that GMO environmental safety assessments carried out by product developers would discover or disclose important environmental outcomes. Research clearly shows that industry-funded studies tend to produce results that are favourable to the funder.
- The four proposed outcomes are not adequate to ensure that biodiversity is protected. The proposed outcomes are too limited and could easily miss wider impacts. For example, the CFIA needs to consider how the on-farm use of a GM crop plant could affect the environment, not just the isolated impact of the new or enhanced GM trait itself. Such outcomes should include:
  - Impact of GM crop use on herbicide use and the related impacts on biodiversity
  - Impact on soil health, fertility and soil structure
  - Climate change impacts such as increased demand for greenhouse-gas emitting synthetic nitrogen fertilizers
  - Long term and systemic impacts need to be assessed.
- The precautionary principle should guide regulation because of the uncertainty and complexity involved in assessing all the potential environmental impacts of releasing a GMO.
- The proposed outcomes are entirely inappropriate for assessing the environmental risks of releasing genetically engineered trees. The federal government should prohibit the release of any genetically engineered trees, including gene-edited trees that do not have foreign DNA.



**2.4 How clear are the 4 outcomes in the guidance and examples? Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.**



Please use a scale of 1 to 7 where 1 is not at all clear and 7 is very clear.

Not at all clear

1 2 3 4 5 6 7 Unsure

Please provide additional information on your response:

- The outcomes are too limited to evaluate the possible long term and system-wide ecological consequences of using genetically engineered plants.
- It is evident that the outcomes are not clear because the CFIA itself has already failed to successfully prevent negative impacts on the environment relating to the first outcome. For example, the CFIA approved herbicide-tolerant traits in the major crops of soy, canola and corn despite knowing that the widespread use of herbicide-tolerant crops was likely to 1) increase the use of herbicides that could have environmental and human health consequences and 2) lead to the emergence and spread of herbicide resistant weeds, creating new management problems for farmers. The CFIA did not prevent these outcomes that are currently unfolding in Canada.



**2.5 Are there any additional outcomes of concern to the environment that should be included?**



Yes, please specify:

- The CFIA needs to evaluate if the use of a new GMO would negatively impact the transition we need to sustainable agriculture.
- The CFIA needs to evaluate if the use of a new GMO would negatively impact our climate as well as biodiversity. The environmental impacts of a GM plant can only be fully evaluated by investigating how it will be used.
- Many unintended traits created by genetic engineering have already been observed in GM plants on the market. Some unintended traits, such as yield drag or loss of disease resistance, could negatively impact sustainability by encouraging the use of more farm inputs such as pesticides, fuel or fertilizer.
- The CFIA should assess the GM contamination risks for organic farmers and other ecological farmers who provide important environmental services and are needed to meet biodiversity and climate targets.

- The CFIA has a duty, particularly in the face of the current biodiversity and climate crises, to ensure that the use of new genetic engineering techniques in farming does not increase the use of natural resources and inputs such as synthetic fertilizers and pesticides because these degrade air, soil, and water quality and cause large-scale biodiversity loss.

## Theme 3: Overall impressions of the draft guidance



### 3.1 Overall, does proposed guidance make understanding whether a plant is subject to Part V more predictable?



Please use a scale of 1 to 7 where 1 is not predictable at all and 7 is very predictable.

Not at all predictable

1 2 3 4 5 6 7 Unsure

Please provide additional information on your response:

- The goal of the regulations is to protect the environment and biological diversity, not ensure predictability for product developers.
- Exempting many new GMOs from the regulations would lead to a lack of transparency and a high level of uncertainty for the public, and could lead to market instability. For example, Canadian farmers may not know whether newly introduced varieties are genetically engineered seeds.



### 3.2 Please identify any further suggestions, areas for improvements, impacts of the guidance on your work, or provide any additional comments you may wish to communicate.



- This proposed regulatory guidance is a pathway for accelerating environmental harm at a time when we need to take every step to protect biodiversity and stop the climate crisis.
- The CFIA has, according to its own criteria (outcomes), already failed to adequately assess the environmental safety of genetically engineered plants. For example, the use of herbicide-tolerant plants has resulted in the emergence and spread of herbicide-resistant weeds, and the use of insect-resistant (Bt) plants is leading to the development of insect resistance to Bt.
- There is an inherent conflict of interest in product developers determining whether regulations apply to their own products, and determining the environmental safety of their own products.

- Allowing some unidentified (unregulated and unreported) genetically engineered seeds onto the market and into our fields will increase contamination risks that could have negative impacts on many farmers, particularly organic farmers who farm according to the Canada Organic Standards that prohibits the use of genetically engineered seeds and synthetic pesticides. Canada's plan to address climate change needs to support certified organic and other low-input farming.
- The proposed guidance could leave farmers without information about whether a seed variety is gene edited or not. There could be serious economic costs to all farmers and the Canadian economy if even a few farmers inadvertently contaminate export shipments to GM-sensitive markets because of this lack of transparency. Farmers' livelihoods should not be put at risk.
- All field tests of genetically engineered plants need to be regulated by the CFIA to ensure mandatory containment practices limit contamination and so that the government has a record of field test locations and the GM test plants. This information will be critical if unexpected effects are discovered later and/or contamination occurs that has environmental or economic impacts.
- The CFIA is not equipped to assess the environmental risks of planting genetically engineered trees in plantations or in the wild. The environmental risks of genetically engineered trees are enhanced by many factors including the fact that trees are long-lived organisms, with pollen that can travel long distances.
- The CFIA has no expertise in forest ecology or in examining the release of GMOs into the wild and the existing *Seeds Regulations* are already dangerously inappropriate tools for assessing the risks of releasing genetically engineered trees.
- There should be no regulatory exemptions for gene-edited trees. Instead, the federal government should prohibit the release of all genetically engineered trees.
- We are facing dangerous biodiversity and climate crises that demand a fuller and more holistic evaluation of the environmental, social and economic impacts of using GMOs.

## BACKGROUND

We are facing global biodiversity and climate crises that make evaluating the full environmental risks of releasing new genetically modified organisms (GMOs) more important than ever. Carefully assessing the potential environmental impacts of using GM plants is particularly critical because **these are living organisms that, once released into the environment, may be difficult or impossible to control or recall.**<sup>1</sup> Because many of the ecological systems we need for our survival are already under great stress and are dangerously vulnerable, any new mistakes we make could have significant impacts.

It is paramount that we use a precautionary approach to evaluate the risks of releasing GMOs with a focus on reversing the processes that are driving our current biodiversity and climate crises. Our regulatory system needs to support the transition to sustainable low-input farming, led by agroecological practice and small-scale farmers.<sup>2</sup> Environmental safety assessments cannot be left to the companies that will profit from the sale of GM seeds and any associated products such as herbicides.

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Carefully assessing the potential environmental impacts of using GM plants is particularly critical because these are living organisms that, once released into the environment, may be difficult or impossible to control or recall

## The Canadian Food Inspection Agency (CFIA)

*“The Canadian Food Inspection Agency is dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada’s people, environment and economy.”*

Under the authority of the Minister of Agriculture and Agri-Food, the CFIA regulates field tests (“confined release”) and the environmental release (“unconfined release”) of genetically modified plants. Under the Seeds Act and Seeds Regulations, the CFIA is responsible for ensuring the environmental safety of growing GM crop plants on farms as well as the safety of releasing other GM plants into the environment, including the use of GM trees in plantations and releasing GM trees or other GM plants into the wild.

For information on Canada’s GMO regulatory system see CBAN’s report [www.gmoenquiry.ca/regulation](http://www.gmoenquiry.ca/regulation)

# ASSESSING THE ENVIRONMENTAL IMPACTS

## The CFIA's proposed "4 outcomes"

The CFIA lists four considerations (what they call "outcomes") that companies should use to determine if their GM plants could negatively impact the environment. The CFIA asks the public if these proposed outcomes are appropriate. The four outcomes are focused on the impact of the intended GM trait:

### 1. *A trait that would make a plant more difficult to control by removing a management option*

**The CFIA has already failed to successfully consider and prevent this outcome.** The CFIA has approved GM traits that have led to plants and pests that are more difficult to control and have resulted in the loss of management options for farmers.

- **HERBICIDE RESISTANT WEEDS:** To explain what this first outcome means, the CFIA uses the example of herbicide-tolerant (Ht) plants that could lead to hard-to-control crop plants (the plant itself becomes a weed) and to the evolution and spread of herbicide resistant weeds, removing the management option for farmers of using certain herbicides. Despite clear warnings that Ht crops would lead to herbicide-resistant weeds,<sup>3</sup> the CFIA approved many Ht traits in the major commercial crops of corn, canola and soy, such that **100% of all the GM crops grown commercially in Canada have herbicide tolerant traits** (some also have insect resistant traits).<sup>4</sup> Most of these GM crops are glyphosate-tolerant and glyphosate resistant weeds are now spreading in five provinces. Product developers themselves have acknowledged this outcome and have developed GM crops tolerant to the older, more toxic herbicides

2,4-D and dicamba as a response.<sup>5</sup> The CFIA has approved many of these new herbicide-tolerant crops - and also allowed companies to "stack" multiple herbicide-tolerant traits together in one GM seed<sup>6</sup> - despite the same anticipated outcome.

*Herbicide sales in Canada have increased by 243% since the CFIA's first approval of a GM herbicide-tolerant plant (1994-2017).<sup>7</sup>*

- **PESTS RESISTANT TO BT:** Insect resistance (Bt) is the other major GM trait in commercial use and these crops are leading to the development of Bt resistant insects in Canada (in Nova Scotia and Ontario),<sup>8</sup> as already seen in other countries. The development of insect pests with resistance to the Bt toxins in GM plants means that farmers are losing the use of these GM crops and Bt such that government experts are recommending crop rotation as the remaining tool to manage the pests.<sup>9</sup>

### 2. *A trait that introduces or enhances a toxin, allergen, or other compound that could reasonably be expected to have a negative impact on non-target organisms in the environment*

Concerns that the toxins expressed by GM (Bt) insect-resistant crops could have negative impacts on non-target organisms such as butterflies and bees, and on soil organisms continue to be investigated. Negative impacts of Bt corn residue on aquatic organisms (in streams near farms, for example) were discovered in 2007<sup>10</sup> and while laboratory tests show various toxicity,<sup>11</sup> the real-world impacts of Bt crops on bees and other pollinators for example, still need to be studied. Despite the unknowns, the CFIA is permitting companies to "stack" multiple Bt traits/toxins together in one seed, leading to new questions about possible interactions or combinatorial effects.<sup>12</sup>

### ***3. A trait that could reasonably be expected to improve the survival of plants in unmanaged ecosystems to such a degree that other species or ecotypes are displaced***

With many of the major crop kinds in Canada, such as corn, canola and soy, the potential direct disruption to wild ecosystems from contamination is not an issue, however, many **potential indirect environmental impacts of GM contamination have already been overlooked**. For example, the herbicide (glyphosate) tolerant trait in GM “Roundup Ready” alfalfa increases its survivability in fields and areas proximate to farms.<sup>13</sup> GM alfalfa was reasonably expected to spread into unmanaged areas (not wild ecosystems) such as ditches and through feral alfalfa populations, presenting an acute and particularly consequential GM contamination threat to organic and other ecological farming systems.<sup>14</sup> The CFIA approved GM alfalfa despite this contamination risk, and farm organizations continue to ask for its deregistration.<sup>15</sup>

### ***4. A trait that could reasonably be expected to result in the creation or enhancement of a plant pest or a reservoir for a plant pest***

It is not just the intended trait that may create or enhance a plant pest. Unintended traits in a GMO such as increased susceptibility to plant diseases could be triggered in response to environmental stresses, such as drought or extreme heat. Such unintended traits need to be looked for and examined for their potential environmental impacts, and their impacts on farmers’ costs. There is an inherent conflict of interest in allowing companies to assess the susceptibility of their GMO to pests, and in leaving plant pest issues to be managed on-farm, because many developers also sell pest control products such as fungicides and other pesticides.<sup>16</sup>

These four proposed considerations or “outcomes” focus on the impact of the intended GM traits (defined as phenotypic characteristics

conferred to the plant by specific genetic changes) with **no mention of investigating to discover and assess any possible genomic irregularities or unintended traits** that can result from the process of gene editing or other genetic engineering techniques. Unexpected traits and impacts may not be observed immediately but could be a product of gene-environment interactions. For example, an unintended trait may only become apparent during times of stress such as drought. Unintended changes in the plant can have a negative impact on sustainability, for example GM crops with decreased yield may result in more fertilizer use.<sup>17</sup> Unintended traits in commercialized GM crops are common<sup>18</sup> and genomic irregularities have also been found.<sup>19</sup>

In their consultation document (Appendix 2), the CFIA says that companies should consider the characteristics of the plant, the trait(s), and the receiving environment, as well as the interactions between all three of these. This is very broad and vague suggestion and, **without government oversight, we will not know if companies have considered these factors, or how fully**.

## **Environmental Impacts of GMOs in Canada**

### **Increased Herbicide Use**

All of the genetically engineered crops currently grown commercially in Canada have herbicide tolerant traits (some also have insect resistant traits). This means that all the GM seeds on the market are designed to be used with particular herbicides. The widespread use of GM herbicide-tolerant corn, canola, soy and sugar beet in Canada has meant that large areas of cropland are repeatedly sprayed with the same herbicide, mostly glyphosate-based herbicides. This has led to the (predicted) emergence and spread of herbicide-resistant weeds and glyphosate-resistant weeds in particular.

- Glyphosate-resistant weeds emerged in GM glyphosate-tolerant crops just four years after their introduction<sup>20</sup> and yet the CFIA continued to approve glyphosate-tolerant crops and other herbicide-tolerant crops.
- The CFIA has permitted biotechnology companies to respond to glyphosate-tolerant weeds by “stacking” multiple herbicide tolerant traits together in one seed so that the GM plant can survive being sprayed by many different herbicides.<sup>21</sup>
- The CFIA has approved new GM crop plants that have been genetically engineered to be tolerant to the older herbicides 2,4-D and dicamba, to kill glyphosate-resistant weeds. These GM crops are likely to further increase the herbicide load in the environment and lead to even more herbicide-resistant weeds.<sup>22</sup>

## Impacts on the “receiving environment”

The organisms and ecosystems that could be negatively affected by the release of GMOs are more vulnerable than ever, facing multiple threats simultaneously. The “receiving environment” is already under stress.

- The use of herbicides on herbicide-tolerant crops reduces weed diversity in and around fields, which in turn reduces habitat and food sources for insects and other animals. For example, the negative impact of increased glyphosate use on important Monarch butterfly habitat in the US is well documented.<sup>23</sup>
- Uncertainty about some impacts will likely remain because of the complexity of interactions between organisms and the receiving environment, including the farm, and some impacts may be difficult to rule out. For example, studies in the lab have indicated that the toxin in GM insect-resistant (Bt) plants can have negative impacts on non-target insects including pollinators and on soil and aquatic organisms, however definitive impacts in real-world conditions are difficult to assess.

- GM contamination threatens the production of non-GM crops, and organic crops in particular. Expanding GM contamination is a threat to the future of organic and other ecological farming systems in Canada. This is one reason why farmers in Canada protested the approval of GM herbicide tolerant alfalfa.

## Impacts on sustainable agriculture

- Genetically engineered crops perpetuate a model of intensive chemical agriculture that has a number of serious environmental impacts and is not sustainable in the long-term.<sup>24</sup>
- The approval of patented GM herbicide-tolerant and insect-resistant (Bt) plants has increased the profits and power of the largest seed and agrochemical (pesticide) companies in the world.<sup>25</sup> The economic and political power of these companies increases the costs for all farmers including raising seed prices, with fewer choices for seed and other inputs.<sup>26</sup>
- The use of genetically engineered crop plants, particularly those such as alfalfa that can easily spread, threatens the future for organic farmers who farm according to the Canada Organic Standards that prohibits the use of GM seed and other GMOs.

### For more information and discussion:

CBAN report (2015) “Are GM Crops Better for the Environment?”  
[www.gmo inquiry.ca/environment](http://www.gmo inquiry.ca/environment)

CBAN report (2015) “Are GM Crops Better for Farmers?”  
[www.gmo inquiry.ca/farmers](http://www.gmo inquiry.ca/farmers)

CBAN report (2019) “GM Contamination in Canada: The failure to contain living modified organisms: Incidents and impacts”  
[www.cban.ca/ContaminationReport2019](http://www.cban.ca/ContaminationReport2019)



## Environmental Risks of Genetically Engineered Trees

*The regulation of genetically engineered trees currently falls to the CFIA under the authority of the Minister of Agriculture and Agri-Food. However, the CFIA is not equipped to assess the environmental risks and the Seeds Regulations are an inappropriate tool to regulate genetically engineered trees. **The federal government should prohibit the release of genetically engineered trees.***

The release of genetically engineered trees could have serious unpredictable and irreversible environmental consequences. Genetically engineered trees pose an even greater risk of unwanted spread than GM crop plants because trees live for decades, have so many nearby wild relatives, and their pollen can travel hundreds of kilometres.<sup>27</sup>

University researchers have already asked the US government to allow the release of a genetically engineered blight-resistant American chestnut tree **into the wild**, and they say they will also ask the Canadian government to approve its release.<sup>28</sup> **The request to purposefully release a GE American chestnut tree into the forests of Canada and the US poses unique and unknown risks to our forest ecosystems.** If approved, the GE American chestnut would be the first-ever genetically engineered forest tree planted in the wild in North America, and **the first-ever genetically engineered plant released with the purpose to spread freely through wild ecosystems.**

Companies have already invested in genetically engineering trees for **industrial plantations**. For example, Brazil has already approved the use of a high-yielding GM eucalyptus trees in plantations<sup>29</sup> and the US biotech company ArborGen has developed a cold-tolerant GE eucalyptus tree.<sup>30</sup> In fact, US government regulations already mean that the first genetically engineered forest tree in the US, a loblolly pine, can legally be released without any government or public oversight (ArborGen has since said they have no immediate plans to release it<sup>31</sup>). **This case of the GE**

### **loblolly pine in the US shows what can happen when government departments narrow their environmental assessments and exempt some GMOs from regulation.**

Fundamentally, it may not actually possible to fully assess the risks of releasing GM trees because we do not know what will happen in highly complex forest ecosystems, subject to climate change, over the long life-span of GM trees and multiple generations. If GM trees are released, it will be difficult, or impossible, to track or reverse their spread over time. The impacts on forest ecosystems are unknown and cannot be known until they are observed in the wild over decades and centuries. The release of genetically engineered trees into the wild can accurately be described be a large-scale, open-air experiment.

The Canadian Biotechnology Action Network, with groups across the world, has reached the conclusion that the only reliable method of preventing the escape of genetic material from genetically engineered trees is to prohibit the release of GM trees into the open environment.<sup>35</sup>

- The CFIA should ensure that, if the proposed regulatory guidance is implemented, it is not applied to genetically engineered trees.
- The federal government should prohibit the release of genetically engineered trees.

For more information see [www.cban.ca/trees](http://www.cban.ca/trees)

## CASE STUDY

### **Unregulated GM trees**

In the US, the limited scope of GMO environmental assessments meant that, in 2015, the US Department of Agriculture (USDA) decided that a genetically engineered loblolly pine, developed by the company ArborGen, was outside their mandate for review and could be released without any government oversight.<sup>32</sup> The USDA issued a letter confirming that the company could pursue unregulated commercial cultivation of the loblolly pine, genetically engineered for altered wood composition. That decision was based on the USDA's narrow interpretation that regulation of GM plants is only necessary when "plant pests" are utilized in the process of introducing genetic material, which was not the case with this GM pine. This means that, **by default, the company is free to commercially distribute the GM pine trees without any government environmental safety review or government oversight.**<sup>33</sup> These trees could be planted anywhere in the US, without public knowledge or access to information about them.<sup>34</sup> The same unregulated release of a GM tree could happen in Canada if the CFIA proposals are implemented because the regulatory guidance would set up a limited scope for environmental assessment, particularly for gene-edited trees that have no foreign DNA.

# What is Genome Editing?

**Genome editing, also called gene editing, is a collection of new genetic engineering techniques** to alter the genetic material (usually DNA) of plants, animals, and other organisms. The 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, which then 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 foreign 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.

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

- 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.

**For an overview of the range of risks and unexpected consequences from genome editing** see CBAN’s 2020 report “Genome Editing in Food and Farming: Risks and Unexpected Consequences.” The report and an “Introduction to Genome Editing” 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)

# THE BIG PICTURE

## What is happening?

- The Canadian Food Inspection Agency's proposal for corporate-self regulation of some GMOs follows a similar proposal from Health Canada. These consultations are part a multi-year process to "modernize" regulation for all GMOs, including GM animals.

## Why is it happening?

- The Canadian Food Inspection Agency (CFIA) has launched a public consultation on a proposal to exempt many genetically engineered seeds from Part V of the Seeds Regulations, so that many new GM (gene-edited) plants would not be subject to government environmental safety assessments.
- The deadline to answer the questionnaire is Sept 16, 2021.
- **The CFIA's proposal follows a similar proposal from Health Canada** to exempt many foods from genetically engineered plants from mandatory government safety assessments. See [www.cban.ca/NoExemptions](http://www.cban.ca/NoExemptions) for CBAN's responses to Health Canada and actions you can take.
- These consultations are part a multi-year process to "modernize" regulation for all GMOs, including GM animals.

## What is at stake?

- » **ENVIRONMENTAL PROTECTION:** Because we face dangerous global biodiversity and climate crises, every decision we make now is even more consequential and we have little room to make new mistakes. Significant environmental impacts of using GMOs could be missed if assessments are handed over to the product developers who will profit from their sale.
- » **THE ROLE OF GOVERNMENT AND THE FUTURE OF INDEPENDENT SCIENCE:** Independent, peer-reviewed science and independent government oversight are essential to safeguarding public health. The public cannot rely on product developers and corporate science to ensure product safety.
- » **THE ROLE OF THE PUBLIC IN DECISION-MAKING:** Consumers and farmers should have input into decisions regarding the use of new technologies like genetic engineering in our food system, including to assess the question of need for the technology 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. Farmers need to know that the seeds they are buying are safe for the environment and for human consumption, and are acceptable to their customers in Canada and other countries.

## ENDNOTES

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**Collaborative Campaigning for Food Sovereignty & Environmental Justice**

**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](https://cban.ca/NoExemptions)**