



April 7, 2022

To: The Honourable Steven Guilbeault, Minister of Environment and Climate Change
CC: The Honourable Marie-Claude Bibeau, Minister of Agriculture and Agri-Food

RE: CFIA proposals will jeopardize environmental safety and mean that CFIA regulation of genetically engineered seeds and trees is not CEPA-equivalent

Dear Minister Guilbeault,

Nature Canada and the Canadian Biotechnology Action Network (CBAN) are writing to express our serious concerns about the environmental risks of proposed changes to regulatory guidance on genetically engineered seeds (genetically modified organisms or GMOs), including genetically engineered (genetically modified or GM) trees. New proposals from the Canadian Food Inspection Agency will exempt many genetically engineered seeds from regulation.¹ The changes would apply to the regulation of genetically engineered seeds for agricultural use as well as the regulation of genetically engineered trees for cultivation and release into the wild.

The CFIA is proposing to exempt many new genetically engineered seeds, including genetically engineered trees, from regulation. Specifically, many GMOs with no foreign DNA, produced via techniques of genome editing, would not be subject to Part V of the *Seeds Regulations*. Instead, these GMOs will be allowed to enter the environment with no government environmental safety assessments and no mandatory notification to government. The environmental safety of these new GMOs will be determined by the product developers themselves and the developers will control all of the information about these new organisms. Product developers will not be required to provide any notice of environmental release.

We are concerned that the release of unregulated, unreported GMOs into the environment could have profound consequences.

We are writing to ask you to examine the implications of the proposed changes for the protection of the environment.

We argue that:

The new proposed guidance would mean that CFIA's regulation of genetically engineered seeds is not CEPA-equivalent.

- In particular, the proposed regulatory guidance would allow many new genome-edited seeds to be released into the environment without an independent government safety assessment, increasing the possibility of harm.
- The application of the proposed regulatory guidance to the regulation of genetically engineered trees is not appropriate and would pose serious, unprecedented risks to forest ecosystems.

In our view, the implementation of the proposed regulatory exemptions to Part V of the *Seeds Act* would be an abdication of CFIA's mandate and responsibilities to protect the environment in the public interest.²

Regulatory guidance changes will mean CFIA regulation is not CEPA-equivalent

The proposed guidance will create broad regulatory exemptions that will remove the CFIA from its role as independent regulator in relation to the environmental safety of many new genetically engineered seeds, specifically many genetically modified organisms that have no foreign DNA, produced using genome editing.

We argue that this guidance will mean that the CFIA's implementation of the *Seeds Regulations* would not be CEPA-equivalent, i.e. CFIA's regulation will not ensure the environmental safety of all genetically engineered seeds and will therefore not be a functioning alternative to regulating these products under the Canadian Environmental Protection Act.

The CFIA is responsible for ensuring the environmental safety all genetically engineered seed that is field tested and released in Canada but the new regulatory guidance will shift many safety assessments to product developers, with no government oversight. Product developers will assess the environmental safety of some of their own products and will own and control all the information relating to these unregulated GMOs.

Proposed regulatory exemptions will result in a loss of government regulatory authority over many new genetically modified organisms.³ This will include the loss of the CFIA's ability to require information from private companies about unregulated genetically engineered seeds released into the environment. In our view, the CFIA needs to retain this authority in order to ensure safety, ensure regulatory compliance, and provide necessary transparency to the Canadian public as well as to have the ability to trace and monitor all genetically engineered seeds and their possible impacts. The CFIA will be left with few or no mechanisms to address new relevant scientific findings or possible issues arising from unregulated, unreported products in the environment.

There is an inherent conflict of interest in product developers determining if regulations apply to their own products, and in determining their safety. There is no assurance that environmental safety assessments carried out by product developers would be sufficiently rigorous to discover possible important environmental risks or that developers would disclose such findings. Without government oversight, we will not know if companies have considered the necessary factors, or how fully. This proposed reliance on unseen, corporate environmental safety assessments is not science-based.⁴

The proposed regulatory exemptions will mean that the CFIA would no longer have access to the corporate science behind product developer safety determinations, would not verify the quality of any corporate data, and not act as an independent control on corporate science. This shift to corporate self-regulation is inconsistent with the role of CFIA in regulating for environmental safety.

Critically, exempting some genetically engineered seed from regulation based on the absence of foreign DNA is not science-based.⁵ We argue that an assumption of safety is not scientifically justified. The science clearly shows that the process of genome editing can create genetic errors and result in unintended consequences that need to be investigated for their possible environmental risks.⁶ Many studies show and continue to discover that genome editing techniques can be imprecise and create genetic errors including off-target effects and extensive deletions and complex re-arrangements of DNA.⁷ The processes of genome editing have no history of safe use.

Furthermore, we argue that the CFIA has already failed to apply its own criteria to adequately assessing the environmental risks of releasing genetically engineered seeds.⁸ CFIA approvals of seeds with GM herbicide-tolerant and insect-resistant traits have allowed for the evolution and spread of more herbicide-resistance weeds and insects developing resistance.⁹ The CFIA appears not to have engaged in a process to evaluate these observed outcomes nor to assess the ability of its regulation to account for such possible systemic and long-term impacts.

Regulatory guidance changes would apply to genetically engineered trees

The CFIA's proposals for the regulation of genetically modified seeds will also apply to GM forest trees. This means that some genetically engineered trees could be exempt from regulation. Such exemptions would pose significant, long-term environmental risks. In our view, the application of this guidance to the regulation of trees in particular shows that the CFIA's regulation is not CEPA-equivalent.

The release of GM trees could have serious unpredictable and irreversible environmental consequences that demand a precautionary approach, as reaffirmed by the UN Convention on Biological Diversity (CBD).¹⁰ 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.¹¹

The *Seeds Regulations* are inappropriate and inadequate for assessing the risks of releasing genetically engineered trees. Now, the CFIA proposes four environmental consequences or “outcomes” to be assessed that are not appropriate for regulating the field testing and environmental release of genetically engineered trees and, in particular, genetically engineered forest trees. This is also contrary to the CBD’s decision that urges Parties to “further engage to develop risk-assessment criteria specifically for genetically modified trees.”¹²

Additionally, the CFIA is not equipped to assess the environmental risks of cultivating genetically engineered forest trees in plantations or releasing them into the wild. The CFIA has already applied the *Seeds Regulations* to the assessment and approval of a genetically engineered apple tree for cultivation in an agricultural context but the CFIA has no experience with forest trees nor the context of wild forest ecosystems. CFIA regulators have little or no expertise in tree biology or forest ecology, and have no experience examining the purposeful release of GMOs into the wild.

This issue needs to be urgently addressed because product developers have already asked the US government to allow the release of a genetically engineered American chestnut tree into the wild, and say they will also ask Canadian regulators to approve its release.¹³ This request to purposefully release a GM tree into the forests of Canada and the US poses unique and unknown risks to our forest ecosystems.¹⁴ If approved, the GM 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.

In conclusion

Our concerns over the CFIA’s regulation of GM seeds are enhanced by the fact that what the CFIA calls the “receiving environment” for release of new GMOs is already under tremendous stress. The biodiversity and climate crises require a more careful consideration of risks before releasing new genetically engineered seeds and trees.

In November 2021, 105 groups wrote together to ask the Minister of Health and the Minister of Agriculture and Agri-Food to ensure transparency and government oversight of all genetically engineered foods and seeds.¹⁵

We ask you to help ensure that government regulators can continue doing their important work as independent assessors of environmental risk, and have the regulatory infrastructure to provide government oversight. CFIA regulators should assess the environmental safety of all genetically engineered seeds, including all genome-edited seeds and trees.

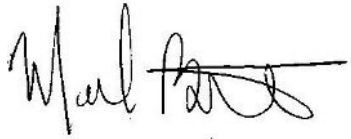
We argue that there should be no regulatory exemptions for any genetically engineered products field tested or released into the environment. However, if the proposed regulatory guidance is implemented, it should not be applied to genetically engineered trees. We argue that a precautionary approach requires, instead, that the federal government prohibit the field testing and release of all genetically engineered trees.

We ask that you work with the Minister of Agriculture and Agri-Food to ensure that the CFIA has regulatory authority over all genetically engineered seeds, including all those with no foreign DNA, to ensure safety and provide transparency.

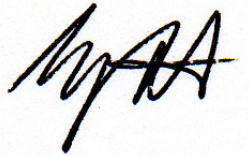
Thank you for your attention to this critical and urgent matter.

We are available to meet with you to discuss these issues further at any time.

Sincerely,



Mark Butler
Senior Advisor
Nature Canada



Lucy Sharratt
Coordinator
Canadian Biotechnology Action Network

Contact:

Lucy Sharratt
coordinator@cban.ca 902 209 4906

¹ Canadian Food Inspection Agency (2021) Draft guidance for determining whether a plant is subject to Part V of the Seeds Regulations. Accessed March 31, 2022. <https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/draft-guidance/eng/1619540046303/1619540212691>

² Canadian Biotechnology Action Network (2021) letter to Dr. Siddika Mithani, President, Canadian Food Inspection Agency, Abdication of the CFIA's responsibilities via proposed Seeds Regulations guidance proposals, November 2. <https://cban.ca/wp-content/uploads/CBAN-letter-to-CFIA-president-Nov-2-2021-on-regulatory-guidance-GMOs.pdf>

³ Canadian Biotechnology Action Network (2021) Response to the consultation questionnaire on CFIA proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations. September 17. <https://cban.ca/wp-content/uploads/CBAN-response-CFIA-consultation-questionnaire-2021.pdf>

⁴ Canadian Biotechnology Action Network (2021) Comments #1 submitted to Bureau of Microbial Hazards, Food Directorate, Health Canada RE: Consultation: Proposed new guidance pieces for the Novel Foods Regulations, focused on plant breeding. May 11. <https://cban.ca/wp-content/uploads/CBAN-comments-to-HC-regulatory-guidance-May-11-2021.pdf>

⁵ Canadian Biotechnology Action Network (2021) Comments #2 submitted by the Canadian Biotechnology Action Network to Bureau of Microbial Hazards, Food Directorate, Health Canada RE: Consultation: Proposed new guidance pieces for the Novel Foods Regulations, focused on plant breeding. Response to "A Primer on Gene editing technology in relation to Health Canada's product-based regulatory framework for Novel Foods, June 23. <https://cban.ca/wp-content/uploads/CBAN-comments-to-HC-consultation-on-gene-editing-primer-June-23-2021.pdf>

⁶ See Canadian Biotechnology Action Network (2020) Genome Editing in Food and Farming: Risks and Unexpected Consequences. www.cban.ca/GenomeEditingReport2020

⁷ Testbiotech and the Canadian Biotechnology Action Network (2022) "Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks" March. www.cban.ca/NewGERisksReport

⁸ Canadian Biotechnology Action Network (2021) Response to the consultation questionnaire on CFIA proposed guidance for determining whether a plant is subject to Part V of the Seeds Regulations. September 17. See pages 15-23. <https://cban.ca/wp-content/uploads/CBAN-response-CFIA-consultation-questionnaire-2021.pdf>

⁹ Ibid. Pages 17-23.

¹⁰ United Nations Convention on Biological Diversity (2008) COP 9 Decision IX/5 Forest biodiversity. <http://www.cbd.int/decision/cop/?id=11648>

¹¹ Ricarda A. Steinbrecher with Antje Lorch (2008) Genetically Engineered Trees & Risk Assessment: An overview of risk assessment and risk management issues. Federation of German Scientists. https://www.econexus.info/files/GE-Tree_FGS_2008.pdf

¹² United Nations Convention on Biological Diversity (2008) COP 9 Decision IX/5 Forest biodiversity. <http://www.cbd.int/decision/cop/?id=11648>

¹³ William A. Powell (2020) Petition for determination of Nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*). January 17. <https://www.aphis.usda.gov/brs/aphisdocs/19-309-01p.pdf>

¹⁴ The Campaign to STOP GE Trees, Biofuelwatch and Global Justice Ecology Project (2019) Biotechnology for Forest Health? The test case of the genetically engineered American chestnut. April. <https://stopgetrees.org/wp-content/uploads/2019/04/biotechnology-for-forest-health-test-case-american-chestnut-report-WEB-1.pdf>

¹⁵ Joint letter from 105 groups (2021) Call for Transparency and Government Oversight of All Genetically Engineered Foods and Seeds: No Regulatory Exemptions. November 17. www.cban.ca/NoExemptions/OpenLetterSigned