

RE: Primary Roles of CFIA Regulation - The Need to Regulate Gene Edited Seeds

Submitted from the Canadian Biotechnology Action Network, July 25, 2022.

Regulatory exemptions for some gene-edited seeds could have profound negative environmental and economic consequences. The following are fundamental, primary needs from regulatory guidance updates and/or regulatory change in order to secure basic government oversight and transparency, to allow for a precautionary approach in the public interest:

1. All field tests of genetically engineered (GE, including all gene edited) plants need to be regulated i.e. regulatory exemptions cannot apply to field testing of any GE seeds.

- Field tests need to be a fundamental part of environmental safety assessment. Even if trials are designed to test other questions, such as performance, they can reveal unseen/unexpected environmental issues. **The question of environmental risk/novelty cannot be understood to be settled until long-term field tests are completed.**
- Unknown, undisclosed field tests put the environment and farmers at greater risk. Though specific field test locations are currently not disclosed to the public, CFIA knows and discloses which GE/novel plants and traits are tested, by whom, and in which province. If a company has determined their GE plant to be non-novel for the purposes of field testing but then requests an opinion from the CFIA or otherwise discovers that their plant is novel, the field tests will have been unregulated/uncontained and could present a concrete environmental and economic risk. **Environmental containment of all GE crops in field testing is a necessary precaution.**

2. Guidance updates cannot be applied to GE trees. There needs to be a moratorium on the release of GE trees until CFIA can address the specific needs of this regulation.

- CFIA cannot apply regulatory exemptions to any gene edited forest trees (those trees not cultivated for food in orchards, but grown for timber and paper products for example.).
- CFIA needs to regulate all GE trees, in line with the UN CBD COP 9 Decision IX/5.
- CFIA must specifically examine its regulation of GE trees. No GE trees can be approved or exempted from regulation until this regulation is reviewed to address the particular challenges of environmental risks, and of risk assessment, posed by GE trees.
- The question of releasing GE trees exposes the limits of current CFIA assessment criteria that excludes socio-economic considerations. The prospect of GE tree release exposes the need for public engagement, and consultation with First Nations in particular.

3. Guidance updates should ensure mandatory public reporting of all genetically engineered seeds such that no gene edited seeds are released unidentified.

- **For the federal government:** CFIA needs to ensure mandatory notification to the government of the release of any and all genetically engineered seed including all of those produced via gene editing techniques.
 - CFIA needs to know which GE seeds could be/are released such that the federal government has a basic ability to track and recall products, if necessary/desired.
 - The ability to track would provide the federal government with tools to assess the benefits to the economy of gene edited crops. Without knowledge of which gene edited products may be/are being sold, there is nothing but guesswork in front of the federal government and public about the role of gene editing in the economy and society.

- Future regulation and policy options would be constrained by a lack of information if gene edited seeds are sold and grown without notification to CFIA.
- **For the environment:** The ability to track gene edited seeds is necessary to enable the possibility of long-term, independent monitoring or investigation of environmental impacts, including the complexity of interactions between multiple gene-edited plants.
- **For farmers:** CFIA needs to mandate notification in order to provide farmers with information about which gene edited products could be on the market. Farmers need this information for a number of economic and social reasons, including to protect their organic certification and markets. Organic farmers clearly need all gene edited seeds - as prohibited in the Canada Organic Standards - identified such that their purchase can be avoided and farmers can take steps to minimize GM contamination threats.
- **For consumers:** There will be no tools remaining for Canadians to choose not to buy gene edited foods if CFIA does not implement mandatory notification. This lack of choice in the market will be complete if organic or other non-GM food production is not viable in the future due to contamination facilitated by the same lack of notification. Mandatory labelling of all GE foods is consistently supported by a vast majority of Canadians polled.

4. CFIA needs to develop its own Scientific Opinion on the question of exempting some GE seeds from Part V (further to developing this Opinion, please see below).

- Health Canada's Scientific Opinion was developed in regard to health risk. It is missing critical analysis and questions relating to environmental safety.

Proposal: CFIA should regulate all gene edited seeds for a set timeframe / amount and scope of products to test CFIA assumptions about knowledge of gene editing i.e., regulate to support an evidence-based assessment of regulatory exemptions as currently proposed.

Whereas:

- There is no history of safe use of gene editing in food and farming.
- CFIA has almost no experience assessing gene edited products, and CFIA's experience assessing transgenic organisms is limited to a few traits and crop types.
- The techniques of gene editing are new and much is continually being discovered about their use including issues relevant to risk assessment such as mechanisms resulting in unintended effects, and how to detect and evaluate such effects.
- There is a need for the development of scientific protocols to assess the environmental and food safety of gene edited foods and crops.
- Mistakes made now could be costly to Canada's environment and economy. It is valuable to invest at the front-end of regulation to protect the public interest by preventing multiple unknown harms.
- Maintaining regulatory authority over all gene edited seeds provides tools necessary to enable a wider range of future regulation and policy options (future-proof regulation).

Therefore: Rather than exempting some gene edited seeds at this early stage in the development of these genetic engineering techniques, **CFIA should regulate in order to test assumptions about knowledge of gene editing.** CFIA should catalogue its conclusions and assumptions about gene editing, as begun in Health Canada's Scientific Opinion, and then test them through verification and validation via CFIA environmental safety assessments.