Collaborative Campaigning for Food Sovereignty & Environmental Justice

September 7, 2021

Response to the consultation questionnaire on CFIA proposed guidance for determining whether a plant is subject to Part V of the *Seeds Regulations*

This document is in response to the CFIA (Canadian Food Inspection Agency) online public consultation questionnaire on the proposed guidance for determining whether a plant is subject to re: Part V of the *Seeds Regulations*.

We include a summary of our objection to the guidance and concerns over the consultation process followed by answers to the each of the questions in the consultation questionnaire, with references and the attached documents:

1. "Genome Editing in Food and Farming: Risks and Unexpected Consequences", Canadian Biotechnology Action Network, 2020.
2. CBAN's comments submitted to Health Canada re: Proposed new guidance for Novel Foods Regulations, May 11, 2021.
3. CBAN's comments submitted to Health Canada re: primer on gene editing, June 23, 2021.

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 across Canada: Canadian Organic Growers, Check Your Head, Council of Canadians, Ecology Action Centre (NS), Ecological Farmers Association of Ontario, GE Free BC Network, Greenpeace Canada, Growers or Organic Food Yukon, Inter Pares, National Farmers Union, No More GMOs Toronto, GMO-Free PEI, Organic Agriculture Protection Fund of SaskOrganics, Union Paysanne, SeedChange, Vigilance OGM. CBAN is a project on the shared platform of MakeWay Charitable Society.. **www.cban.ca**

Notes on terminology

Genetic engineering is commonly referred to as genetic modification (GM) by the Canadian public, in the Canadian media, and in the North American marketplace. In addition, French-speaking Canada uniformly refers to modification génétique. The term genetic modification is used to refer to genetic engineering in international agreements and in most national regulatory systems around the world.

However, the Canadian Food Inspection Agency and Health Canada historically use the term genetic modification to include multiple technologies including genetic engineering and conventional plant breeding. The Food and Drugs Act broadly defines "genetically modify" as "to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation" and CFIA further states that "Genetically engineered foods are one type of genetically modified foods."[1]

Yet we note that, in the consultation document "Draft guidance for determining whether a plant is subject to Part V of the *Seeds Regulations*," the CthemeIA does not use the terms genetic modification, genetic engineering, or biotechnology. The CFIA "Summary of the guidance for determining whether a plant is subject to Part V of the *Seeds Regulations*" makes one reference to genetic modification in the overview, "Over the past 25 years, the CFIA has assessed over 120 plant products for release into the environment. This has included plants developed using conventional breeding methods such as mutagenesis, as well as plants developed by inserting foreign DNA (genetically modified plants)." We are concerned here that there is a suggested narrowed definition of genetic modification (genetic engineering) to only those plants that have been developed by inserting foreign DNA. This usage
is not consistent with regulatory definitions, public usage, or the scientific literature.

Critically, we also note that, though the *Seeds Regulations* pertain to plants with "novel traits" the CFIA does not use the term Plants with Novel Traits or refer to novelty in the consultation documents.

The consultation documents do, however, explicitly refer to "gene editing" which is a collection of genetic engineering techniques that is widely called "genome editing" in the scientific literature.

Summary Objection

The Canadian Biotechnology Action Network (CBAN) is providing our answers to the CFIA's consultation questionnaire and stating our objection to the proposal to exempt genetically engineered seeds that have no foreign DNA from Part V of the *Seeds Regulations*. This regulatory exemption would allow product developers to sell some new genetically engineered seeds without a CFIA environmental safety assessment. Instead, many new genetically engineered plants would be assessed for environmental safety by the product developers themselves, with no government oversight. If this regulatory guidance is implemented as proposed, the result would be unregulated genetically engineered seeds sold and grown in Canada, some of which may go entirely unreported to the CFIA and public, including farmers.

The CFIA's implementation of the *Seeds Regulations* has already failed to prevent two of the four negative environmental outcomes that are outlined in the proposed guidance. This failure has both environmental and economic costs. The CFIA has failed to successfully regulate the confined release (field testing) and environmental release of genetically engineered crop plants for the protection

of biodiversity and farmer livelihoods. So far, the CFIA has allowed the field testing and commercial introduction of genetically engineered seeds resulting in the emergence and spread of herbicide-resistant weeds, increased herbicide use, the development of pests resistant to GM traits, and contamination and escape events that have affected farmers. This track-record of failure demands that the CFIA strengthen its regulation of genetically engineered seeds for environmental protection and warns of the potential environmental and economic impacts if product developers are left to self-regulate.

The proposed guidance could have profound environmental consequences, economic costs, and would negatively impact many farmers. The guidance would jeopardize environmental protection, threaten market stability and the livelihoods of some farmers, increase the costs and challenges for many organic farmers and for some food businesses, further diminish transparency for Canadians, and undermine public trust in both the food system and in regulation. The new regulatory guidance allowing for corporate self-regulation of many or most new genetically engineered seeds, would be an abdication of the CFIA's responsibility to protect the environment in the public interest to enhance "the health and well-being of Canada's people, environment and economy."

The regulatory guidance proposed is in conflict with CFIA's responsibility "to safeguard food safety, protect the health of plants and animals in Canada, and support market access both now and in the future."[2] The guidance would undermine the Government of Canada's work to support a healthier and more sustainable food system for Canadians and could undermine the policy goal to increase exports in the agriculture and agri-food sector. The guidance would undercut the description of the CFIA as "a science-based regulator."

The CFIA's Departmental Plan 2020-21 discussed this review of "the approval process for crops developed using biotechnology" however **the proposed guidance would actually remove CFIA's approval process for many new genetically engineered seeds and hand the entire process over to product developers instead**.

Concerns over the consultation process

Both the format and timing of the CFIA's consultation are problematic, and the pre-consultation process is incomplete, with a focus on consulting product developers.

The consultation questionnaire solicits answers on a limited set of questions that appear to assume that the proposed guidance is a foregone conclusion. While each question invites elaboration, the limitations of the questions raise concerns about the ability of the CFIA to consider detailed responses. We hope the CFIA is open to a full examination of the responses provided.

The timing of the consultation seriously compromises public engagement and the engagement of farmers in particular. Despite requests from both CBAN and the National Farmers Union for the CFIA to delay the consultation launch until after the 2021 farming season, the CFIA set the public consultation for May 24 - Sept 16. The timing of the consultation created significant obstacles for public outreach and participation, and for farmer participation in particular. In the context of the farming season (and what emerged as a particularly challenging season for many farmers because of drought and wildfires) and the second summer of the pandemic, the increased length of the consultation period (120 days versus 60 days) did not resolve timing concerns. We are disappointed that the CFIA decided not to wait for the end of the farming season in order to enable more robust

discussions in farming communities and **we are concerned that this decision reflects a dismissal of input from the public and a diminished consideration for the impacts of the proposed regulatory guidance on Canadian farmers**. We note that the consultation questionnaire has several questions directed to product developers and none directed to farmers who will be buying and using the seeds. We stress that Canadian farmers are the key stakeholders in relation to implementation of the *Seeds Regulations* and are key to CFIA upholding its mandate.

The pre-consultation process is also of concern because meetings were dominated by product developers or those organizations that represent them. The CFIA and Health Canada held many joint meetings and we note that the "experts" session of October 16, 2020 - "To seek expert input and perspectives on a list of scientific questions that have been identified by regulators and that are linked to the development of new regulatory guidance for novel foods, specific to plant breeding" – relied on **eight panelists, four of whom were from companies selling genetically engineered seeds**: two experts were from academia, two were research scientists from Agriculture and Agri-Food Canada, and four were from companies with genetically engineered seed sales: **Corteva, Bayer, Cibus and Calyxt** (where Corteva and Bayer together control approximately 41% of the global commercial seed market and 29% of the global agrochemicals market[3]). The expert session was attended by 15 employees from Health Canada, 18 from Agriculture and Agri-Food Canada and 20 from the CFIA which is a very high level of attendance to a meeting led by just a few experts, half of whom stand to profit from sales of related products. Furthermore, this meeting permitted five observers including three from the biotechnology and pesticide industry lobby group CropLife Canada whose members include the same four companies.

The 2020-21 Departmental Plan described that, "The health and safety of Canadians is the driving force behind the design and development of CFIA programs"[4] however the driving force behind this proposed guidance is the interests and demands of product developers. As articulated in the Plan, "**This review will focus on minimizing regulatory burden while improving the predictability and clarity of the regulatory system for both domestic and international stakeholders**. The changes will enable businesses to plan with greater confidence and, consequently, support investment and innovation in Canada."[5] [emphasis added] **The CFIA is prioritizing the demands of product developers over the need to protect the environment for the public good**. This focus on minimizing regulatory burden comes at the cost of protecting biodiversity and farmer livelihoods.

Consultation Questionnaire

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)

#1 Not at all clear

In addition to proposing to exempt a range of genetically engineered seeds with no foreign DNA from Part V of the *Seeds Regulations*, the CFIA is proposing regulatory exemptions for genetically engineered seeds deemed to be "substantially equivalent" by product developers to previously approved seeds. This determination of "equivalent plants" for the purposes of regulatory exemption is not appropriate to CFIA's responsibilities to ensure that any field testing or environmental releases of genetically engineered seeds are safe. It is not clear how the exemptions for equivalent plants would work, particularly as product developers themselves would make these determinations.

1. Firstly, product developers should not be left to decide if their genetically engineered seeds qualify for a regulatory exemption. Product developers should not be in a position to determine if their genetically engineered seed is "substantially equivalent" to a previously approved product, and thus exempt from regulation and CFIA safety assessment.

2. Even the question of how *regulators* make use of substantial equivalence in decision-making is largely unknown. The determination of equivalency is opaque – it is not precise and it is overly flexible (it has "interpretive flexibility"[6]), and it is utilized in a regulatory process that is not open to public scrutiny and is based on confidential science.

3. Deciding if a genetically engineered seed is "substantially equivalent" to a previously approved seed is not an appropriate way to determine environmental safety. The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001) highlighted their concern about the use of substantial equivalence and concluded that, "The Panel finds the use of 'substantial equivalence' as a decision threshold tool to exempt GM agricultural products from rigorous scientific assessment to be scientifically unjustifiable and inconsistent with the precautionary regulation of the technology."[7] The Expert Panel was concerned that approvals may be based upon "unsubstantiated assumptions about the equivalence of the organisms, by analogy with conventional breeding."[8]

4. Of particular concern, the CFIA proposes allowing regulatory exemption based on a past authorization where "the underlying mechanism of action is substantially equivalent to the original trait." This proposed consideration for exemption focuses on the intended GM trait at the expense of examining potential unintended impacts resulting from the process of genome editing. The CFIA provides the example of reduced enzyme expression, to delay ripening, where the reduction of enzyme expression could be achieved through different biochemical processes. The CFIA is explicit that, "functionally equivalent mechanisms of action can be achieved using many approaches" even where the modification is the result of targeting entirely different processes and regions in the genome or achieved through a different genetic engineering

technique. As discussed in CBAN's attached report, such exclusion of considering the process is not supported by the science which shows potential off-target and other unexpected effects resulting from the process of genome editing.[9]

5. The proposal to exempt genetically engineered seeds deemed to be equivalent by developers to previously approved seeds would **significantly reduce the ability of the CFIA to monitor the use of genetic engineering and its impacts in the environment and marketplace, and would have a significant impact on current and future policy options**. For those few genetically engineered seeds that would still be assessed by the CFIA (subject to Part V) under this guidance, the CFIA proposes that, over time, fewer and fewer of them would be regulated. As regulatory exemptions "will increase as more products are authorized," more and more genetically engineered seeds will be released without government safety assessments, approval decisions and notifications to government. **The result in the long-term would be the widespread use of genetically engineered seeds with undetermined origins and unknown impacts**.

    - This future release of many unknown, unregulated genetically engineered seeds would **compromise or eliminate the ability of the CFIA to trace, monitor, and recall products**. It assumes no future need for such measures. It would leave little possibility for government to play a role in monitoring impacts, negative or positive. Instead, all **post-market environmental impact monitoring** of genetically engineered plants would be left to product developers and farmers. Analysis of economic costs or benefits would be left to non-governmental parties, with decreasing informational tools.
    - The CFIA is undertaking work in other areas to enhance transparency and traceability, for example to implement "full traceability systems (ie. boat-to-plane) in order to ensure consumers have the information they need to make informed choices."[10] However, with this guidance on genetically engineered seeds, the CFIA would **significantly hamper traceability and remove transparency, further impeding the ability of Canadians to make informed choices**.
    - Permitting ever-expanding regulatory exemptions over time, dominated by determinations made by product developers themselves, could **undermine the ability of the CFIA to apply new scientific findings and new policy priorities to regulating the release of genetically engineered seeds in the future**. Most techniques and applications of genome editing (that could be used to genetically engineer seeds such that they would have no foreign DNA) are still experimental - there is a range of genome editing techniques in development, and yet to be developed.

With this guidance, **the CFIA is proposing to divest itself from the work of conducting environmental safety assessments**. In 2000, the concepts of familiarity and substantial equivalence, as implemented in Canadian regulation of genetic engineering, were already critiqued as providing "a framework and rationale not for regulation, but for deregulation."[11] The proposed guidance would use substantial equivalence to facilitate further CFIA divestment from regulation and increased corporate self-regulation. This divestment would jeopardize the protection of biodiversity, farmer livelihoods and international trade, and it would result in a profound lack of transparency with both environmental and economic impacts, including undermining public trust.

However, the CFIA does not ask about the potential implications of these proposed exemptions for "equivalent plants." For example, the CFIA does not ask whether these exemptions are appropriate to meeting the CFIA's goal of "safeguarding food, animals and plants, which enhances the health and well-being of Canadians, the environment and Canada's economy." Instead, the CFIA's lead

consultation question appears to be directed at product developers, about their ability to use this part of the guidance (how clear it is to those proponents who will use it). This approach in the consultation questionnaire suggests that the CFIA sees the proposals as a foregone conclusion, with the primary purpose of meeting the needs of product developers.

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.

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

Not applicable.

The CFIA should conduct mandatory environmental safety assessments of all genetically engineered seeds in order to serve the Canadian public, protect the environment, and support farmer livelihoods. Instead, the CFIA proposes to exempt a wide range of new genetically engineered seeds from Part V of the *Seeds Regulations* and offers that product developers may, instead, request an "exemption opinion letter" from the CFIA to confirm regulatory status, to "help support compliance". **Government oversight of product safety should not be an option that product developers can choose voluntarily**.

This question is directed to product developers and asks whether the CFIA can be "useful" to the work of product developers by providing the option of a CFIA opinion on the regulatory status of a GMO. This question about how the CFIA can be "useful" to product developers raises concerns about the CFIA's priorities in designing the regulatory guidance. **The purpose of any CFIA product review and approval decision should be to ensure environmental protection and regulatory compliance in the service of this protection, not to provide a useful service to product developers**.

In the preamble to question 1.2.d., the CFIA describes the option for product developers to request an exemption opinion as "a service that the CFIA provides to help support compliance with Part V." However, in this consultation question, the CFIA asks if product developers would find receiving an exemption opinion letter "useful" to their work. **Ensuring regulatory compliance should be the priority, not providing a useful service to product developers**.

If regulatory compliance is the goal, offering to provide exemption opinion letters for those private companies that volunteer to ask for an opinion on regulatory status is not sufficient. The exemption

opinion letters would **not ensure compliance** with Part V of the *Seeds Regulations* - they would, at a minimum, "help support compliance" from those product developers that request opinions. The assumption is that product developers can successfully comply through their own environmental assessments, can responsibly and successfully determine if their GMO needs government environmental safety assessment, and/or can appropriately make use of the CFIA's offer of assistance via an opinion on regulatory status.

The optional exemption opinion letters would functionally replace CFIA environmental safety assessments for many new genetically engineered seeds (most or all of those that have no foreign DNA). Instead of proposing mandatory environmental safety assessments where all genetically engineered seeds, including those with no foreign DNA, are subject to Part V of the *Seeds Regulations*, the CFIA is proposing an optional exemption opinion that product developers could request if they determine that the letter would be "useful" to their work. **This proposed ad hoc (voluntary) structure of exemption opinion letters elevates the interests of product developers over those of environmental protection, the public, and farmers**. It elevates the role of product developers in safety determinations and removes the CFIA from a role in ensuring regulation compliance. In the context of the guidance proposals, **the optional exemption opinion letters would be what remains of CFIA-proponent communication in relation to most or all future genome-edited plants**.

By providing the option to request exemption opinion letters, **the CFIA is creating an on-demand service for product developers**. Product developers may use the CFIA letters for marketing and promotion purposes. In its question, the CFIA asks "whether there would be value in sharing information about products **at an early stage of development**" [emphasis added] which suggests that the CFIA anticipates requests for opinions about products that at an early stage in development (some of which may never be commercialized). This suggests that the CFIA acknowledges any listing of exemption opinions is unlikely to fully represent what is or could be commercially available. Further, it suggests that the CFIA recognizes that product developers may use the option of requesting a CFIA letter for the purpose of promoting theoretical products in order to, for example, attract investors. Health Canada acknowledged a similar potential problem in its guidance consultation documents when it said that its proposed Voluntary Transparency Initiative "is to be used for products ready for commercialization and not for theoretical products," while offering no mechanism to verify the commercial status of products.

In this question, the CFIA appears to cast doubt on the value of sharing information about the exemption opinion letters. Rather than construct this flawed voluntary system that would result in information of questionable (little) value, **the CFIA should ensure integrity and consistency by ensuring that all genetically engineered seeds are subject to Part V of the *Seeds Regulations***. The CFIA should not offer optional government oversight but should ensure mandatory government regulation of both confined and environmental release of all genetically engineered seeds.

In regards to the **utility of the exemption opinion letters for product developers**, in the consultation document the CFIA says that, "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." In this way, the letters are envisioned as **a tool to enable the expansion of regulatory exemptions into the future, led by product developers themselves** - to enable product developers to more successfully make their own safety determination without involving the CFIA. The cumulative exemption opinion letters would function as a (partial) guide to which GM seeds can be commercialized by product developers without government oversight (are not subject to Part V of the *Seeds Regulations*) or

may be expediated. The publication, however incomplete, of exemption opinion letters would thereby serve to pilot the CFIA project of divesting from regulation.

Additionally, because the opinions would be sought voluntarily and the list of opinions (published voluntarily or mandatorily) would not be verifiable as representing all of the opinions issued, the utility of this information to product developers is also limited.

Furthermore, **the CFIA does not describe the process and structure of CFIA exemption opinion determination**. The CFIA is proposing a new structure of limited product review that is not clear.

The proposed regulatory guidance would result in a profound loss of transparency for the public, including for farmers, with many important consequences. In this question, the CFIA is correct to say that the publication of "information about assessments and decision for authorized products…provides transparency…" This statement acknowledges the diminished transparency that would result from implementation of the proposal: allowing many new genetically engineered seeds onto the market with no CFIA assessment and no government decision to authorize, with no required reporting or provision of information to the CFIA. **The CFIA acknowledges the transparency that is provided by information about assessments and decisions for authorized products and then proposes to exempt more products from authorization and remove this associated transparency**.

If the CFIA exempts some genetically engineered seeds from Part V of the *Seeds Regulations* as proposed, many new genome-edited GMOs will be sold without a government approval decision and the CFIA will no longer have a list for the public of all the genetically engineered seeds that could be on the market. The CFIA does not monitor and maintain a list of genetically engineered seeds that are actually on the market, but if the guidance is implemented as proposed, the CFIA would not even be aware of all of the GM seeds that *could* be sold and planted in Canada. This missing information would have the following consequences:

- Uncertainty about which genetically engineered seeds are on the market would increase costs for farmers, food manufacturers and other businesses in the food sector.
- Uncertainty about what is on the market would threaten consumer confidence and undermine public trust.
- The CFIA would be entirely dependent on product developers for post-market monitoring of negative environmental outcomes for new GMOs that are on the market but not reported/ disclosed by product developers.
- The CFIA, the Minister of Agriculture and Agri-food, and Members of Parliament would not have an answer available to the question from Canadians of which genetically engineered seeds could be on the market. The answer will be: the government does not know.
- Allowing unregulated, unreported genetically engineered seeds to be planted, and allowing unreported GMO field tests, will heighten and expand GM contamination risks and their environmental and economic consequences.

The benefits *to the public* of information provided by product developers on a voluntary basis are not "similar" to the benefits of information required by the CFIA from product developers on a mandatory basis. The CFIA should maintain regulatory authority over all genetically engineered seeds including those with no foreign DNA, such that the CFIA has "a way to publish information" about these products.

The CFIA knows that there is strong public support for the publication of information about genetically engineered seeds. This has been made clear year after year, for twenty years, by consistent poll results that show over 80% of Canadians want mandatory labelling of genetically engineered foods[12] (for a range of reasons[13]). This demand for mandatory labelling would be most appropriately addressed by the Minister of Agriculture and Agri-food and implemented by the CFIA, as a label implemented for non-health reasons, for the primary purpose of providing transparency and enabling informed consumer choice.

All CFIA decisions should be public information. All CFIA decisions should be disclosed to Canadians in conformity with the Open and Transparent Agency Policy under which the CFIA is committed to making "more information available about its decisions and activities"[14]:

> *"The Government of Canada is making more data and information available to Canadians than ever before. Canadians are also being offered more opportunities to participate in discussions on government policies and priorities. The Canadian Food Inspection Agency (CFIA) plays a key role in protecting the health and safety of Canadians and is committed to greater transparency and openness."*[15]

The exemption of many genetically engineered plants with no foreign DNA from Part V of the *Seeds Regulations* would seriously compromise openness and transparency.

We ask the CFIA to re-evaluate their proposals, and consultation questions, with a reflection on the policy definitions of openness and transparency, prioritizing "programs and services" to protect the environment and provide accountability to the public:

> **Openness** *is being receptive to free exchange of information, communications, change and new ideas as part of seeking excellence and continual improvement in design and delivery of programs and services.*
>
> ***Transparency*** *is proactively providing relevant, accurate and timely information to the public to demonstrate accountability for delivery of programs and services, as part of supporting the right of Canadians to government records.*[16]

The CFIA states that, "increasing openness and transparency will enhance general public and foreign market trust in Canada's regulatory system."[17] However, the proposed regulatory guidance would achieve the opposite. The loss of transparency created by the guidance would undermine the trust of Canadians in the food system and in government regulation. If genetic engineering, including genome editing, continues to be regulated and labelled in other countries, and remains a subject of consumer concern resulting in differentiated markets, the proposed regulatory approach of non-transparency would undermine the ability of some markets and trading partners to trust in Canadian commodities.

With more openness and transparency, the CFIA says that, "Canadians will better understand how and why regulatory decisions are made and will be able to use this information to make well-informed choices for themselves, their families and their businesses."[18] However, the guidance would mean that Canadians would have even less information to assist informed choices. Farmers and food businesses would not necessarily be provided with information about whether or not their seeds are genetically engineered and Canadians would have even less information to help determine which genetically engineered foods are on the market.

Critically, the CFIA offers no parallel question directed to the public about the usefulness of information about which genetically engineered seeds are approved and/or on the market. This question suggests that CFIA is seeking to be "useful" to the work of product developers but is not considering the impacts on the public, including farmers.

We ask the CFIA to reject this guidance in favour of regulation that is "open by design," where the public and farmers are involved in guidance and regulatory review: "Open by design refers to strategies that are used to ensure that openness and transparency considerations are deliberately and thoughtfully hard-wired into the design phase of all CFIA programs and services, and integrated when improvements are made to existing ones."[19]

The proposed regulatory guidance amounts to a CFIA project to reduce government oversight and regulatory activities, to allow for corporate self-regulation. This approach to rely on corporate self-regulation is clear in the CFIA's articulation of one of the top listed expected benefits of openness and transparency where, "Providing more information on our regulatory activities will help Canadians and trading partners better understand **the efforts industry puts in place to keep them safe**."[20] [emphasis added] The guidance would reduce regulatory activities and diminish available information about genetically engineered seeds such that the Canadian public and trading partners would be asked to turn to product developers for assurances of safety.

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?

#1 Yes, very useful.

There should be no question about providing information on all CFIA decisions and all genetically engineered seeds to the public. This information is necessary for openness and transparency. If providing an exemption opinion letter to a product developer, the CFIA should make the letter itself public, with all information about the decision and the genetically engineered organism. All CFIA regulatory assessments and decisions should be public information and such information should be disclosed to the Canadian public for openness and transparency, not for the purpose of being useful to product developers, as suggested by this question.

However, we stress our objections, as discussed above in question 1.2.a, to the proposed offer of optional exemption opinions in place of mandatory government safety assessments. **There should be no voluntary processes and no optional exemption opinions offered**. Instead, all genetically engineered seeds should be subject to review by the CFIA. All genetically engineered seeds, including those that do not have foreign DNA, should be subject to Part V of the *Seed Regulations*, requiring mandatory CFIA assessments to investigate their potential negative impacts on the environment.

We also stress that the utility to the *public* of publishing information from the proposed exemption opinion letters is limited by the optional/voluntary nature of the requests for a CFIA opinion. Because the CFIA opinions are not mandatory, the publication of information would not be complete and would not therefore provide transparency. We refer you to our critique of Health Canada's proposed "Voluntary Transparency Initiative" on novel foods regarding the problems and contradictions created by information, whether published on a voluntary or mandatory basis, resulting from voluntary processes. Please see our attached May 11 comments to Health Canada.

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

All of the information proposed in this question should be released for the public along with the addition of the studies used by the product developer to conclude safety, not just a request for the developer's "rationale for exemption."

All genetically engineered seeds should be assessed for safe environmental release by the CFIA and, supplemented by mandatory product labelling, **as much information as possible about all CFIA decisions and all genetically engineered seeds should be posted on the CFIA website for the Canadian public, for use by consumers, farmers and food businesses**. The current interpretation of Confidential Business Information (CBI) already keeps the public from accessing the science behind regulatory decisions.[21] The CFIA's and Health Canada's interpretation of CBI means that the departments will not even publicly disclose which genetically engineered products are under government assessment for approval.[22] The Canadian Biotechnology Action Network has a long-standing request for an interpretation of CBI that would provide more transparency and allow for public engagement.[23]

It is important to be clear that the voluntary nature of the proposed "list of exempt plants" is **not adequate to provide transparency for the public**. Because it is not mandatory for all developers seek a CFIA opinion, the list would not be a full list of genetically engineered seeds that are exempt from regulation but would be a list of those GMOs where product developers sought and achieved confirmation from CFIA of regulatory exemption.

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

Mandatory

The CFIA should ensure that all information about CFIA evaluations and related decisions and processes is made public.

Furthermore, all genetically engineered seeds, including those with no foreign DNA, should be subject to Part V of the *Seeds Regulations* and, hence, all developers should be required to seek CFIA approval for release of genetically engineered seeds. **This mandatory approval request would ensure compliance with Part V and provide CFIA with the authority to require information on all genetically engineered seeds**. It would also eliminate product developer uncertainty as to how to determine regulatory status/safety, by placing this responsibility with the regulator.

In this question, the CFIA identifies an important consequence of the proposal to exempt some genetically engineered plants from Part V: the inability of the CFIA to require information from a developer ("The CFIA has no authority to require information from a developer if the plant is not subject to Part V"). **The CFIA should never allow product developers to decide what information should be available to the Canadian public**. Product developers should not be allowed to decide whether information about a CFIA decision should be public or not.

The CFIA also identifies the problem that mandatory publication of the exemption opinion letters "could serve as a disincentive" for product developers to participate. This concern exposes **the further weakness in this proposal in relation to ensuring compliance**. Compliance with the regulations cannot rely on product developers opting to participate in a voluntary process, and one that is less attractive to product developers if the information is made public. The CFIA should not be in a position to incentivise developer cooperation. Having identified this problem, the CFIA can resolve it by requiring that all genetically engineered products be submitted for review/be subject to Part V.

The structure of optional exemption opinion letters allows for a process led by product developers.

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.

The CFIA should secure its authority to require information from private companies about all genetically engineered seeds that could be on the market by ensuring that they are all subject to Part V of the *Seeds Regulations*. There should be no exemptions for any genetically engineered

products, even those that have no foreign DNA. Requiring mandatory CFIA assessments of all genetically engineered seeds, including those developed using genome editing, will ensure that the CFIA has the authority to provide necessary transparency to the public.

Theme 2: Determining which plants are subject to Part V

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?

#7 Very clear

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.

#7 Very clear

This information is clear because it is simple - and overly simplistic. **Risk issues raised by genetic engineering are not limited to the presence or absence of foreign DNA**, but also arise from unexpected and unpredictable effects from the processes of genetic engineering including genome editing processes.

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. The process of genome editing can create genetic errors and result in unintended consequences that need to be investigated. Even small changes in a DNA sequence can have significant effects, even if there is no foreign DNA present in the resulting GMO. Genome editing has no history of safe use.

As discussed in our 2020 report “Genome Editing in Food and Farming: Risks and Unexpected Consequences” (Please find this report attached) and as outlined in our second consultation submission to Health Canada of July 23, 2021 critiquing the primer (Please find this also attached), many studies now show that **genome editing techniques can be imprecise and create genetic errors**, including:

- Off-target effects - Unintended changes to genes that were not the target of the editing system.
- 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.

The science supports mandatory government safety assessments for genetically engineered seeds: All genetically engineered seeds, including seeds that have no foreign DNA, should be subject to Part V of the *Seeds Regulations* and undergo mandatory, government environmental safety assessments.

In contrast, **the proposed approach to allow for corporate self-regulation of GMOs is not science-based**. The proposed reliance on unseen, corporate environmental safety assessments is not science-based. As discussed in 2001 by the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology, "In the judgment of the Expert Panel, the more regulatory agencies limit free access to the data upon which their decisions are based, the more compromised becomes the claim that the regulatory process is "science based". This is due to a simple but well-understood requirement of the scientific method itself — that it be an open, completely transparent enterprise in which any and all aspects of scientific research are open to full review by scientific peers."[24] The proposed exemptions would mean that the CFIA would no longer have access to the corporate science behind product development and developer study of safety, would not verify the quality of data that is not already peer-reviewed, and not act as an independent control on corporate science. Environmental safety assessments should, however, rest on independent science and science-based regulation. The field testing and introduction of genetically engineered seeds requires the independent oversight of government regulators.

The CFIA summarizes the regulatory guidance: "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." The CFIA should not give product developers the responsibility to assess the risks of their own genome-edited plants because they have a profit incentive to downplay or underestimate negative impacts. Private companies may not fully look for evidence of negative impacts on the environment. Allowing product developers to assess the safety of some genetically engineered seeds is a shift to corporate self-regulation that jeopardizes biodiversity protection, and further undermines Canada's claim to science-based regulation and the claim of the CFIA that it is a "science-based regulator."

This exemption of genetically engineered plants that have no foreign DNA would leave many genome-edited seeds unregulated and some may even be released without notification to the government, pubic, or even to farmers. The resultant profound lack of transparency could enhance and multiply environmental risks and could also have significant social and economic consequences.

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 Not at all appropriate.

Overview

Assessing the proposed 4 negative environmental outcomes is not adequate to ensure that biodiversity is protected. The proposed outcomes are limited and are likely to miss ecosystem-wide and long-term impacts. They are trait-focused and do not examine the full environmental and economic impacts of the potential use of genetically engineered plants.

The 4 proposed outcomes focus on the impact of the intended genetically engineered 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** in the organism that can result from the process of genome 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.[25] Unintended traits in commercialized GM crops are common[26] and genomic irregularities have also been found.[27]

Of particular concern, the CFIA does not fully consider how the **use** of a GM plant could affect the environment, but instead focusses on the isolated impact of the new or enhanced GM trait itself.

The CFIA itself has already failed to successfully prevent these negative outcomes. It has approved herbicide-tolerant and insect resistant traits knowing that their use would result in herbicide resistant weeds and insects resistant to Bt, and off-loading the management of these environmental outcomes to corporate stewardship plans which in turn off-load management to farmers, at their own cost. 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, with economic and environmental consequences. In fact, these two GM traits - herbicide tolerance and insect resistance - dominate those that have been approved by the CFIA (by our calculation, 117 of 139 approved events are herbicide tolerant and/or insect resistant – and all currently grown LMOs in Canada have herbicide tolerant traits). **These observed negative environmental outcomes in Canada demonstrate both the risks of releasing genetically engineered seeds and the inability of the CFIA to successfully consider these outcomes**.

Outcomes that need to be considered should include:

- The impact of GM crop use on herbicide use and the related impacts on biodiversity
- Impacts 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 carefully assessed. Biological, ecological and social systems are interrelated and interdependent. Understanding how the release of GMOs affects all of these systems is complex, particularly because there may be a time lag between the release of a GMO into the environment and any observable impacts.[28] **The precautionary principle should guide regulation because of the uncertainty and complexity involved in assessing all the potential environmental impacts of releasing a genetically engineered seed**.

The proposed outcomes are also 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 genome-edited trees that do not have foreign DNA.

Critically, 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.[29] There is no guarantee that product

developers will submit all of the studies they have conducted – studies that provide evidence of harm can be omitted. In assessing the outcomes, the CFIA (in Appendix 2 of the consultations document) suggests 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**.

"We are dealing with highly complex, variable and interdependent systems that do not lend themselves to simple cause-and-effect explanations or isolated experimentation. In fact, complexity and irresolvable uncertainty are now recognised principles of ecosystems-based management."

– Katherine Barrett, 2001[30]

The 4 outcomes are not sufficient for the environmental risk assessment of genetically engineered seeds and each has its own limitations:

Outcome 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 negative outcome in its assessment of genetically engineered seeds. This failure suggests that the CFIA should strengthen and improve its assessments rather than hand risk evaluations over to product developers.

CFIA's inability to prevent outcome #1 regarding herbicide tolerant traits:

To explain outcome #1 in the consultation documents, the CFIA uses the example of herbicide-tolerant (Ht) crop plants, saying, "Herbicide tolerance traits make a plant more difficult to control than its conventional susceptible counterparts, and the associated use of herbicides increases the selection pressure for herbicide tolerant weeds." Yet the CFIA has approved many Ht traits such that these exact outcomes are now evident, with both environmental and economic consequences.

Despite clear early warnings that the use of Ht crops would lead to the evolution and spread of more herbicide-resistant weeds[31] and that Ht volunteer plants would be hard to control, CFIA approvals have allowed for widespread use. Now, in these consultation documents, the CFIA explains the need to assess this outcome, without having done so itself. CFIA's use of this example is confusing in the proposed regulatory guidance and not at all clear because it **contradicts the CFIA's own regulation of herbicide tolerant traits**. The use of this example suggests that the CFIA does not view the current negative impacts of using herbicide tolerant crop plants as a consequence of its own failure to assess and prevent this outcome, or that the CFIA dismisses these impacts as inconsequential or manageable (or not its responsibility but a problem for companies and farmers to deal with).

Herbicide tolerant seeds are designed for use with specific herbicide products and are marketed together as a cropping system. Yet the CFIA has assessed individual herbicide tolerant traits without fully considering the impacts of the cropping system including the impacts of its potential widespread use: now widely used in multiple, major commercial crops, including crops used in rotation (soy and canola, corn and soy). Without engaging in an overall assessment of the potential impacts of Ht cropping systems, the CFIA's incremental product-by-product approval of Ht traits in genetically

engineered crops over the past twenty years **has led to a predominance of Ht cropping systems in corn, canola, soy and sugarbeet production in Canada. All of the genetically engineered crops currently grown commercially in Canada have herbicide tolerant traits**[32] and this now includes all insect-resistant (Bt) corn varieties.[33] Even in 2013, with ample evidence available, and over the objections of farmers across Canada, the CFIA allowed variety registration of genetically engineered glyphosate-tolerant alfalfa.[34]

The first genetically engineered crops approved by the CFIA, in 1995, were herbicide tolerant (to glyphosate, glufosinate, or imidazolinone). Herbicide-tolerant crops were introduced with the promise of creating a more efficient system for herbicide application, and hence reducing herbicide use. While this was true for many farmers in the first few years, this trend quickly reversed.[35] Herbicide sales (kilograms [kg] active ingredients) in Canada increased by 189% during the first two decades of genetically engineered herbicide-tolerant crops (1994-2018).[36] The use of glyphosate tripled in Canada between 2005 and 2011.[37] As of 2018 (the most recent Health Canada sales report), glyphosate is the top herbicide ingredient sold in Canada (>25 million kg), followed by glufosinate-ammonium, Bromoxynil, MCPA, and 2,4-D (>1,000,000 kg each).[38]

Just four years after their introduction, glyphosate-resistant weeds emerged affecting GM glyphosate-tolerant crops.[39] Glyphosate-resistant weeds are now found in five Canadian provinces: Four in Ontario (Common ragweed, Common waterhemp, Giant ragweed, and Horseweed); glyphosate-resistant kochia is spreading across Manitoba, Saskatchewan and Alberta; and the first glyphosate-resistant weed (Birdsrape mustard) was found in Quebec in 2017. Herbicide tolerant volunteer plants are also a major agronomic problem. For example, volunteer glyphosate-resistant canola is a limiting factor in soybean expansion in Saskatchewan.[40]

Most of these Ht crops are glyphosate-tolerant, and glyphosate resistant weeds are now environmental and agronomic challenges in five provinces. Product developers themselves acknowledge the emergence of this problem in the field, widely advertising herbicide products to control glyphosate-resistant weeds. Despite the emergence of glyphosate resistant weeds, the CFIA continued to approve glyphosate-tolerant crops. The CFIA has, since 2001, also permitted biotechnology companies to respond to glyphosate-tolerant weeds by "stacking" multiple herbicide tolerant traits together in one genetically engineered seed so that the GM crop plant can survive being sprayed by many different herbicides.[41] As a specific response to glyphosate-resistant weeds, companies have also developed and are marketing new seeds that are genetically engineered to be tolerant to the older, more toxic herbicides 2,4-D and dicamba. The CFIA has approved many of these new herbicide-tolerant seeds: In 2012, the CFIA approved the first dicamba-tolerant and 2,4-D-tolerant crops (marketed in 2017 and 2018); in 2020, the CFIA approved Bayer's corn MON 87429 that is tolerant to four herbicides including both 2,4-D and dicamba; and, in April 2021, the CFIA approved Bayer's dicamba-tolerant canola MON94100. These decisions show that the **CFIA has not yet assessed the observable and documented post-market impacts of Ht cropping systems and is not assessing outcome #1 successfully in relation to new requests to approve herbicide tolerant traits**.

In 2012, the Environmental Commissioner of Ontario noted that the adoption of genetically engineered crops had resulted in "a huge increase in the application of glyphosate to agricultural soils"[42] and expressed concern over the impacts of herbicide-tolerant weeds and the long-term sustainability of the partnership of genetically engineered crops and glyphosate-based herbicides. That same year, CBAN, Équiterre, Nature Québec, the Canadian Association of Physicians for the Environment, Prevent Cancer Now, and Vigilance OGM, raised concerns that the approval of 2,4-D-tolerant crops would lead to further increases in herbicide use, with more toxic pesticides in the environment and our food.[43] The Environmental Commissioner of Ontario stated, "If these new

GM plants are approved in Canada, Ontario may see a lot more 2,4-D applied to agricultural fields in years to come."[44] Analysis of US Environmental Protection Agency data shows that the use of dicamba in the US has increased dramatically since the widespread introduction of dicamba-tolerant soy and cotton in 2017.[45] This increased use of 2,4-D- and dicamba-tolerant crops is predicted to lead to more weeds becoming resistant to herbicides with these modes of action.[46] Twenty-three weeds around the world are already resistant to 2,4-D, including two in Canada.[47] According to Canadian scientists Hugh Beckie and Linda Hall (2014), "Cultivars with stacked-HR [HT] traits (e.g., glyphosate, glufosinate, dicamba or 2,4-D) will provide a short-term respite from HR weeds, but will perpetuate the chemical treadmill and selection of multiple-HR weeds."[48]

In 2019, CBAN and Prevent Cancer Now requested a systematic review of the environmental, health, agronomic and economic impacts of the use of herbicide tolerant crops in Canada, and the development of an appropriate response to the failure of Ht cropping systems.[49] We recommended that the process of this review "include consultation with farmers and weed scientists, and experts in human and environmental health, and lead to the development of a national pesticide-reduction strategy, bringing us closer to building resilient, sustainable agriculture in the face of climate change." This request was submitted to the CFIA as part of comments responding to Monsanto's request for approval of corn MON 87429 which is genetically engineered to tolerate the herbicides dicamba, 2,4-D/quizalofop, and glufosinate, and to have male sterility inducible by glyphosate. The CFIA has since approved MON 87429 which is the first genetically engineered plant with tolerance to both dicamba and 2,4-D. **The seed itself illustrates the failure of herbicide-tolerant cropping systems (glyphosate-tolerant crops in particular) and its approval demonstrates CFIA's continued failure to successfully consider and prevent this negative outcome**.

The CFIA has not addressed this building evidence and critique such that the resultant outcomes are multiplying and becoming a more serious environmental and economic challenge. For example, Shyam et al (2021) say that the evidence of multiple resistance in Palmer amaranth in the US raises "serious questions on the effectiveness of stacked resistance traits in crops, such as 2,4- D + glyphosate + glufosinate or dicamba + glyphosate resistance in corn and beans."[50]

In Decision Documents that summarize approvals of Ht plants, the CFIA has identified their evaluation of corporate "herbicide tolerance stewardship plans" as the means to address the issues of increased selection pressure for herbicide resistant weed populations and the appearance of Ht volunteers. These plans have clearly not succeeded. Corporate stewardship plans were not adequate to prevent the spread and development of glyphosate resistant weeds and will not be an adequate strategy to manage the risks associated with the use of crops that are tolerant to dicamba and/or 2,4-D. The onus for implementing the stewardship plans was placed on farmers.

Farmers face the increasing costs of managing herbicide resistant weeds and volunteer Ht plants. These impacts were made clear when, in 2010, Monsanto began offering rebates to farmers to buy more than one herbiclde as a strategy prevent further spread of glyphosate-resistant weeds.[51] In 2018, DowDupont warned that weeds with resistance to multiple herbicides may prevent some farmers from growing certain crops altogether.[52] As discussed by Beckie et al. (2019), "An increasing number of growers are now facing the prospect of changing crops or crop rotations to manage their HR weeds with remaining effective herbicides."[53]

The promise of Ht technology was to decrease herbicide use. Monsanto's promise was that, "with the Roundup-resistant crops farmers will be able to target application more precisely and thus may use less herbicide overall."[54] Instead, over time, the use of glyphosate-tolerant crops has increased the use of glyphosate.[55] This overuse of glyphosate has driven the wide-spread development of

glyphosate-resistant weeds, increasing the quantity and diversity of pesticide modes of action needed to control them. **This increased use of pesticides in food production has serious negative environmental and human health consequences**. However, the CFIA's toxicity considerations are limited to the evaluating the toxicity of the new, intended genetically engineered trait (please see our comments below regarding outcome #2).

The extent to which the environmental impacts of potential changes in herbicide use are assessed by the CFIA in GE product evaluations appears to be limited. For example, the Notice of Submission information on MON 87429 (tolerant to both 2,4-D and glyphosate) outlines that Monsanto submitted information (confidential business information) describing "Examination for potential weediness; Examination of seed yield; Examination of phenotypic characteristics; Examination of seed dormancy and germination; Examination of the response to biotic and abiotic stressors; Examination of plant pest potential."[56] (The Decision Document summarizing CFIA's August 26, 2020 decision to approve MON 87429 is not yet posted for public examination.[57] Please see our letter of June 10, 2021 requesting the timely release of Decision Documents.[58]) These criteria do not include explicit assessment of changes in pesticide use and related impacts. The extent of consideration of pesticide use impacts is unknown because the regulatory decision-making process is confidential and is based on confidential business information submitted by the company. While consideration of herbicide-tolerant volunteers and the development of herbicide resistant weeds is mentioned in CFIA summaries of past Decision Documents, no in-depth analysis or long-term, systematic evaluation appears to be undertaken. Certainly, the observed negative outcome shows that the CFIA's assessment has failed.

The Ht cropping systems rely on patented genetically engineered seeds along with accompanying herbicides. Until 2016, the global market for genetically engineered crops was dominated by six companies – Monsanto, Dupont, Syngenta, Dow, Bayer and BASF – that, together, controlled around 75% of the global pesticide market and 62% of the global commercial seed market. After a series of mergers, **three companies - Bayer, Corteva and Syngenta - now control approximately half of both the global agrochemical and seed markets**. This unprecedented level of corporate consolidation in the markets has increased the economic and political power of companies seeking to market herbicide-tolerant crops and herbicides. The CFIA should consider this market context in its regulation of genetically engineered seeds in order to fully assess the potential impacts of product introductions and to ensure that new regulatory guidance is not vulnerable to manipulation by such powerful corporate interests, with so much to gain from product commercialization. Instead, as discussed in our summary concern over the consultation process, the CFIA consulted experts from two of these three dominant companies and designed this regulatory guidance in close communication with the lobby group CropLife Canada that represents these same companies (including discussing CropLife Canada communications strategies[59]).

The implications of CFIA approvals clearly go beyond the impacts of the individual traits assessed, to the wider implications of using genetically engineered plants and cropping systems - for wild and agricultural ecosystems as well as for farmer livelihood, corporate market power, our farm economy and food security. Most recently, for example, in the context of herbicide resistance in Palmer amaranth in the US, and upon the discovery of the evolution of six-way resistance in a single Palmer amaranth population, Shyam et al (2021) said, "Weed resistance to herbicides, especially multiple-herbicide resistance, poses a serious threat to global food production."[60] Regulations and regulatory guidance should be built to assess these critical questions.

"The vision for the future of HR weed management globally should center on reduced herbicide dependency, especially glyphosate."

– Beckie et al., 2019[61]

Outcome 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

The potential for toxins expressed by GM (Bt) insect-resistant crops to negatively impact non-target organisms such as butterflies and bees as well as soil organisms continue to be investigated. Most recently, for example, damage was discovered to the gut of an important beneficial insect feeding on an insect targeted by Bt Cry proteins.[62] Negative impacts of Bt corn residue on aquatic organisms (in streams near farms, for example) were discovered in 2007[63] and laboratory tests show various toxicity.[64] GM Bt toxins are distinct from natural Bt toxins, with differences that are important because they typically cause GM Bt proteins to be more toxic and to be active against many more species than natural forms of Bt toxins.[65] The real-world impacts of using Bt crops still need study yet, despite the indications and unknowns, the CFIA continues to approve Bt traits and is permitting companies to "stack" multiple Bt traits/toxins together in one seed, leading to questions about possible interactions or combinatorial effects.[66]

More broadly, the focus on the environmental toxicity of the intended trait is missing an assessment of the impacts of any potential unintended traits resulting from the genetic engineering process as well as a full examination of the potential toxicity resulting from the proposed or anticipated use of the GM seed. For example, the expanded use of glyphosate and/or other herbicides with the use of Ht crops and the related toxicity questions appear to be unaddressed. The toxicity of increased herbicide use and the potential synergism among multiple herbicides, as well as the risks of tank mixes used to control resistant weeds, were not considered. The toxicity of increased pesticide use, potential synergism among multiple herbicides, and bio-effects beyond killing target pests need to be captured in regulation.

Outcome 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 with a genetically engineered seed is not an issue. **However, many potential indirect environmental impacts of GM contamination have already been overlooked**. For example, the CFIA approved use of the glyphosate tolerant trait in alfalfa despite the prospect of glyphosate-tolerant volunteers and the ability of this trait to increase the plant's survivability in areas proximate to farms.[67] Genetically engineered "Roundup Ready" alfalfa was reasonably expected (anticipated by farmers[68] and Canadian academics[69]) to spread into unmanaged areas (not wild ecosystems) such as ditches and through feral alfalfa populations, presenting an acute and particularly consequential contamination threat to organic farms and other ecological farming systems (as well as to producers of alfalfa for export markets).[70] These consequences would have a negative impact on farming systems that provide important ecosystem services and enhance the ability to transition to sustainable agriculture in Canada. Furthermore, farmer organizations made it clear that industry proposed "co-existence" plans to manage the risk would not work.[71]

In 2013, two Ontario farmers requested a provincial environmental assessment of genetically engineered alfalfa.[72] While Ontario's Minister of Environment denied the request because a provincial

review would "overlap with existing federal regulation,"[73] the Environmental Commissioner of Ontario responded that, "Provincial ministries should be able to rely on the review process of one of its federal counterparts. However, the applicants raised several valid issues that clearly fall outside **the scope of the narrow federal safety assessment**. Issues related to sustainable and organic agriculture, increased herbicide use, and related social and economic effects play no role in the federal approval process for GE crops."[74][emphasis added]

The CFIA approved genetically engineered alfalfa (in 2005) and allowed for variety registration (in 2013) despite the known contamination risk and the clear concerns and broad opposition from both conventional and organic farm organizations across Canada.[75] Farm organizations continue to ask for its deregistration in order to remove this risk.[76]

Outcome 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.[77]

CFIA's inability to prevent outcome #4 regarding insect-resistant (Bt) traits:

Insect resistance (Bt) is the other lead genetically engineered trait approved by the CFIA and in commercial use. The CFIA decided that the Bt trait was for safe environmental release in corn (18 events) as well as in potato and soy, however, the use of Bt corn has begun to lead to the development of Bt-resistant insects in Canada, as observed in Nova Scotia[78] and Ontario[79] and as already seen in other countries.[80] The development of insect pests with resistance to the Bt toxins in genetically engineered plants means that farmers are losing the use of some Bt traits as management tools. In 2021, Government of Ontario experts, for example, are recommending crop rotation as the remaining pest management tool for farmers to control corn rootworm in that province.[81]

This development of insect resistance was predicted by the CFIA and the industry, and the onus and costs of preventing this resistance was placed on individual farmers. For example, the Corn Pest Coalition says, "Ultimately, resistance evolution is inevitable. Resistance management strategies are developed to delay the evolution of resistance and prolong the lifespan of pest management tools."[82] In 1998, the Corn Pest Coalition developed a management plan to "reduce and delay the development" of resistant populations of European Corn Rootworm.[83] This plan was approved by the CFIA and focused on guidelines for farmers to provide non-Bt refugia at 20% of the crop. In the US, 20% for corn was also decided, despite the recommendation of 50% from the Environmental Protection Agency's Scientific Advisory Panel.[84] As early as 1997, such management plans were critiqued as ecologically implausible.[85]

The CFIA approved the refugia requirements but handed implementation to farmers, and monitoring and enforcement over to companies. The CFIA said, "There is a risk that the viability of the technology

will diminish as the proportion of planted Bt transgenic crops increases in Canada. To prevent or delay the onset of resistance in the European corn borer (ECB) and corn rootworm (CRW) populations, the Canadian Food Inspection Agency (CFIA) requires each registrant of Bt corn to implement an insect resistant management (IRM) strategy with producers."[86] CFIA inspectors conducted insect resistant plan monitoring across Ontario, Quebec and Manitoba in 2008 to "get an overall picture of the IRM compliance rates…The purpose of IRM inspections is to improve IRM compliance to ensure the long term sustainability of the Bt corn technology."[87] In 2009, refugia compliance in Canada's cornfields was down to 61% from 81% in 2005.[88] By 2010, Monsanto said it would give corn growers one warning to keep refugia at 20%.[89] In 2011, the US Environmental Protection Agency stated that Monsanto's strategy for monitoring resistance in the US was "inadequate and likely to miss early resistance events."[90] By 2013 refugia compliance levels in Canada were high because of the new option of "Refuge in the Bag" where non-Bt corn seed was mixed in the bag of Bt seed, at a lower 5%. This reduction of refugia size from 20% to 5% was justified by the development of plants that produce two or more Bt toxins to kill the same pests. The theory was that the two different proteins could work on the same pest in two different ways and thus reduce the probability of resistance developing. According to Monsanto, the stacking of multiple Bt genes, or modes of action, "provide additional protection and effectively reduce the likelihood of insect resistance developing."[91]

The CFIA's policy of allowing companies to stack GM traits together allowed for the 2010 introduction of Monsanto's "SmartStax" corn that has six Bt toxins (and two herbicide-tolerant traits). The CFIA did not assess the impacts of stacking the traits except that it "evaluated the potential impact on and risk to the environment of using a 5 per cent structured non-Bt refuge strategy for this product" in 2009 and 2011 and concluded that "the use of this refuge strategy for a time-limited period poses minimal risk to the environment."[92] The CFIA was explicit about the need to delay insect resistance, saying that this Bt corn "is expected to be more effective in delaying the development of resistant insects than cultivation of the individual single event Bt corn products with their respective structured refuge strategies." The CFIA then placed the onus on monitoring and management to product developers: "However, continued diligence on the part of technology developers, federal and provincial government representatives, public sector researchers and growers is required to ensure the continued stewardship of Bt corn products in support of sustainable agricultural practices in the long term" and "the proponents are required to conduct additional field evaluations, including further research on the effect of the blended product on European corn borer."

However, when insects resistant to one toxin are exposed to these crops, they may develop resistance to the second toxin even faster.[93] Planting crops with multiple Bt toxins may speed up resistance, instead of slowing it down. Laboratory studies indicate that, for instance, that rootworm resistant to the toxins in Monsanto's Bt corn (Cry3Bb1) may also be resistant to those in Syngenta's Bt corn (mCry3a).[94] A meta-analysis led by the University of Arizona in 2015 found that in about half of the cases, the actual efficacy of the multiple toxins against pests did not live up to expectations.[95] Resistance to one toxin often caused cross-resistance to another toxin.

The first principle of insect resistant management is to "Use pest management tools judiciously, not prophylactically"[96] however Bt crops are often, unavoidably, used prophylacticly as they are planted in anticipation of a pest problem that may not yet be reliably predicted. Furthermore, with the marketing of stacked products, some corn hybrids may only be available with multiple Bt modes of action, where not all the Bt traits may be relevant in that particular season.

In the US, the problem of insect resistance to Bt toxins has evolved far enough that, in 2020, the US Environmental Protection Agency proposed a national phase-out of single Bt traits and "non-functional Pyramids" of Bt traits in corn and cotton to "improve Lepidopteran resistance management."[97]

Limited Outcomes and Assessment

CFIA's inability to regulate genetically engineered trees

Critically, these 4 outcomes are not appropriate for the regulation of the field testing and environmental release of genetically engineered trees and, in particular, genetically engineered forest 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.[98]

The CFIA has applied the *Seeds Regulations* to the approval of a genetically engineered apple tree – the non-browning "Arctic" Apple – for cultivation in an agricultural context but the CFIA has no experience with the context of forest trees and wild forest ecosystems.

This issue needs to be urgently addressed because university researchers have already asked the US government to allow the release of a genetically engineered blight-resistant American chestnut tree into the wild,[99] and they say they will also ask the Canadian government to approve its release.[100] The request to purposefully release a GM American chestnut tree into the forests of Canada and the US poses unique and unknown risks to our forest ecosystems. 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**.

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[101] and the US biotech company ArborGen has developed a cold-tolerant GE eucalyptus tree.[102] 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[103]). **This case of the GE lobolly pine in the US shows what can happen when government departments narrow their environmental assessments and exempt some GMOs from regulation**.

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.[104] 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**.[105] These trees could therefore be planted anywhere in the US, without public knowledge or access to information about them.[106] The same unregulated release of a GM tree could happen in Canada if these CFIA proposals are implemented because the regulatory guidance would set up a limited scope for environmental assessment, particularly for genome-edited trees that have no foreign DNA.

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 way to prevent the escape of genetic material from genetically engineered trees is to prohibit the release of GM trees into the open environment.[107]

- 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.

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.

#7 Not at all clear

The four outcomes are not clear.

It is evident that the 4 outcomes are not clear because, as discussed in our response to the above question 2.3, the CFIA itself has already failed to prevent 2 of the 4 outcomes - outcomes that are relevant to *all* of the GM plants currently grown in Canada. 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 and does not therefore provide a clear, working example in its own assessment practice to illustrate how the outcomes are to be understood and considered**. In our view, this leads to extreme confusion about the outcomes, in particular #1 and #4 - what they mean, how seriously they are considered by the CFIA, and how seriously the CFIA is suggesting that product developers consider them in the case of those genetically engineered seeds that are proposed to be exempt from Part V of the *Seeds Regulations*.

The four outcomes are too limited to evaluate the possible long term and system-wide ecological consequences of using genetically engineered plants, and they do not address related economic and social consequences. The focus is on the intended GM trait without an adequate elaboration of how to assess the relationship between the trait and its "receiving environment", with little direction on how to assess the relevant factors of projected or possible use in the field.

The 4 outcomes are listed to help "clarify" the guidance so that companies understand how to assess the regulatory status and safety of their products for themselves. Product developers should not be in a position to self-regulate. **Simplifying the environmental assessment criteria risks simplifying the assessment such that it is not rigorous**.

Furthermore, as discussed, it is not at all clear how these outcomes would be applied to the regulation of the release of genetically engineered trees and, in particular, genetically engineered forest trees.

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

The CFIA has a duty, particularly in the face of **the current biodiversity and climate crises**, to carefully assess the long-term, real-world impacts of the use of new genetic engineering in farming. The organisms and ecosystems that could be negatively affected by the release of genetically engineered seeds are more vulnerable than ever, facing multiple threats simultaneously. The "receiving environment" is already under stress and this reality requires even more careful consideration before allowing field testing or release of new GM plants, using the precautionary principle as a guide.

- The CFIA should ensure that the use of genetically engineered seeds 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. For example, some unintended traits, such as yield drag or loss of disease resistance, could negatively impact sustainability by encouraging the use of more inputs such as pesticides, fuel or fertilizer.[108]
- The role of GMOs in farm practices that impact biodiversity lneeds to be examined. For example, the use of herbicides on herbicide-tolerant crops (glyphosate in particular) reduces weed diversity in and around fields, which in turn reduces habitat and food sources for insects and other animals. In the case of the Monarch butterfly, this impact has had a serious impact on an already-stressed species.[109]
- The CFIA cannot narrow the focus of risk assessment to an exclusive attention to the impacts of the intended GM trait. As discussed in Wilson (2021), the high level of unintended traits found, even in highly-selected commercial genetically engineered plants, suggests that developers and regulators are not fully controlling for unintended effects.[110]
- The CFIA needs to evaluate if the use of a new GMO would negatively impact **the transition we need to sustainable agriculture**. This may, for example, require more careful examination for unintended traits and their consequences as well as the risks of GM contamination and its consequences, with the assistance of farmers in assessments.

Gene flow is not just an issue for ecosystems but also for agricultural systems with important environmental and economic implications. The CFIA should assess the **GM contamination risks** for organic farmers and other ecological farmers who provide important environmental services needed to meet biodiversity and climate targets. The economic consequences of GM contamination and escape incidents in Canada thus far have included the temporary or permanent loss of export markets, lower crop prices in the short or long-term, the loss of access to grow a particular crop, and the loss of some farm-saved seed.[111]

Widespread GM canola contamination in Canada has meant that most organic farmers have lost the option of growing canola.

- GM flax contamination temporarily shut down export markets and lowered crop prices. It shifted Canada's market for conventional flax to a lower priced one.
- The discovery of a few GM wheat plants temporarily shut two export markets to Canadian wheat.
- GM alfalfa commercialization in Canada poses an immediate contamination threat to organic farming systems and other farm operations.

New and proposed GMOs may pose significant risks of escape and/or serious consequences if escape occurs. Furthermore, some proposed GMOs such as the GM American chestnut tree, are specifically designed to be released into the wild, to deliberately cross with wild populations.

Uncertainty about some impacts of release is likely to 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. This uncertainly, particularly in the context of the climate and biodiversity crises, demands the CFIA make use of **the precautionary principle as a guide in decision making**.

The CFIA's approval of genetically engineered traits has supported continued chemical intensive agriculture that has a number of serious environmental and human health impacts, and is not sustainable in the long-term.[112] The approval of patented genetically engineered seeds has increased the profits and power of the largest seed and agrochemical companies in the world such that there is unprecedented market consolidation.[113] These outcomes, post-market, now need to be assessed to ensure lessons are learned and that the policy priorities for biodiversity protection, climate change mitigation, food security and farmer livelihood are built in to the regulatory system.

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?

#1 Not at all predictable

The goal of the CFIA's regulation of genetically engineered seeds is to protect the environment and biological diversity, not ensure predictability for product developers. **In seeking predictability for developers, the regulatory goals of environmental protection are compromised**.

A predictable regulatory system is one where all genetically engineered seeds are subject to Part V of the *Seeds Regulations*. Knowing that all genetically engineered seeds will be regulated is arguably more predictable for product developers than creating exemptions that apply to those that have no foreign DNA but still require assessment by developers to determine their regulatory status/ environmental risk.

Critically, exempting many new GMOs from the regulations would also remove a level of certainty (predictability) for Canadian consumers, farmers and food businesses. For example, Canadian farmers may not know if newly introduced varieties are genetically engineered, and food businesses may not have the certainty they need about ingredients in the supply chain. The regulatory exemptions would lead to a profound lack of transparency and a high level of uncertainty for the public, which could lead to market instability domestically and internationally.

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.

The proposed guidance is contrary to the aim of the *Seeds Regulations*. The CFIA says, in discussing the purpose and scope of the guidance, that, *"Part V of the Seeds Regulations provides* ***a mechanism to verify that the release of new plants does not have a negative impact on the Canadian environment or human health****. This directive provides guidance to assist proponents in determining whether a plant is subject to Part V."* [emphasis added] CBAN asks: How does Part V of the *Seeds Regulations* provide "a mechanism to verify" safety if product developers undertake assessments themselves with no government oversight? **Rather than a verification system, the proposed regulatory guidance would function as an exemption mechanism**.

The proposals would empty out Part V of the *Seeds Regulations*. The guidance would remove government verification of safety by exempting whole classes of genetically engineered seeds from regulation. The guidance would thereby empty the *Seeds Regulations* and the CFIA of its ability to regulate to ensure safe confined and environmental release. In these proposals, the CFIA is providing guidance to product developers on how to assess their own products and avoid government assessment (verification) of environmental safety. **This guidance would mean that the CFIA's implementation of the Seeds Act is not CEPA-equivalent (equivalent to the Canadian Environmental Protection Act)**.

Implementing the proposed guidance would be an abdication of CFIA's responsibility to protect the environment in the public interest, to enhance "the health and well-being of Canada's people, environment and economy." 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. 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's track-record of failure in the regulation of genetically engineered seeds highlights the need for stronger, more rigorous and careful regulation. According to its own proposed outcomes in assessment, the CFIA has already failed to adequately assess the environmental safety of genetically engineered seeds and prevent negative outcomes. The majority of genetically engineered seeds permitted onto the market in Canada are now linked to the negative outcomes of herbicide-resistant weeds and increased herbicide use as well as with evolving pest-resistance. These current outcomes require investigation, to strengthen government regulation to protect biodiversity, farmer livelihood and the public interest.

We ask the CFIA to consider that the problems with the proposed guidance require more than "suggestions" and "areas for improvements." **The regulatory guidance must be rejected in full. Instead, all genetically engineered seeds should be subject to Part 5 of the *Seeds Regulations*** and the CFIA should maintain its role as active regulator of new technologies in agriculture for environmental protection in the public interest. The Canadian Biotechnology Action Network has brought forward multiple recommendations and requests to the CFIA for improved regulation of genetically engineered seeds for over a decade. Our recommendations for regulatory change follow on from the recommendations of the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology[114] and are rooted in the following principles that need to be embedded in the regulation of genetically engineered seeds:

PRINCIPLES IN REGULATION

Transparency

All government assessments and decisions about genetically engineered seeds must be disclosed to the public. There is a strong public demand for information about the regulatory processes and the science behind regulatory decisions, as well as about the genetically engineered products themselves. Disclosing such information serves the public interest and is necessary to support the food and farm economy, including to maintain international trade. Many farmers in Canada need transparency about GMO field trial locations and GM seeds on the market, and Canadian consumers want to know which genetically engineered foods are in the grocery store. The proposed guidance would result in a deeper lack of transparency and further undermine public trust.

"From the time its Transparency Agenda was first initiated in 2011, transparency and openness have been key considerations underpinning the CFIA's values. The Agency will continue to expand its existing transparency and openness practices and take on new ones to meet growing public expectations."

– CFIA, Openness and Transparency Framework 2019-2022[115]

Independent science and science-based regulation

Allowing product developers to assess the safety of many new genetically engineered seeds is a shift to corporate self-regulation that would further undermine Canada's claim to science-based regulation and CFIA's claim to being a "science-based regulator". All safety assessments of genetically engineered seeds should rest on independent science rather than on confidential corporate science which, in the proposed guidance, would not even be verified by government regulators and would therefore only be assumed to be "sound science." All genetically engineered seeds require government science-based safety assessments and the independent oversight of government regulators for environmental and food safety.

"The claim that the assessment of biotechnology risks is 'science-based' is only as valid as the independence, objectivity and quality of the science employed."

— Royal Society of Canada's Expert Panel on the Future of Food Biotechnology, 2011[116]

Support sustainable agriculture

Allowing some unidentified (unregulated and unreported) genetically engineered seeds onto the market and into our fields will increase the GMO contamination risks that could have negative impacts on many farmers, particularly organic farmers who farm according to the Canada Organic Standards that prohibit the use of genetically engineered seeds and synthetic pesticides. Canada's plan to protect biodiversity and address climate change needs to support certified organic farming, other ecological farming and low-input farming, and include a pesticide-reduction plan as part of a national transition to sustainable agriculture.

"Governments can support a rapid spread of lower-input, sustainable farming by involving farmers as both stakeholders and allies in Canada's climate change efforts."

— Farmers for Climate Solutions

Support farmer livelihoods

The proposed guidance could leave Canada's farmers without information about whether a seed variety is genetically engineered or not. There could be serious economic costs for 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.

"Before approving any more GM crops, the government must revamp its process so that it conducts a full assessment of the environmental, economic and social impacts based on public research and input from a cross-section of farmers and Canadians, rather than simply relying on information provided by the seed companies seeking regulatory approval for their products."

— Jan Slomp, National Farmers Union President and Alberta dairy farmer, 2014[117]

Precautionary Principle

The precautionary principle should be the foundation of the regulation of genetically modified organisms, in particular because once released into our environment, GMOs can be difficult or impossible to control or recall. We now also face urgent biodiversity and climate crises that demand a fuller and more holistic evaluation of the environmental, social and economic impacts of using GMOs. The precautionary principle not only advises us to take action to anticipate and prevent harm even when we do not have conclusive evidence about causes, but it also advises us to evaluate our need for new technologies, particularly in relation to other available technologies or alternatives.

"When it comes to human and environmental safety there should be clear evidence of the absence of risks; the mere absence of evidence is not enough."

— Conrad Brunk, Co-chair of the 2001 Royal Society of Canada Expert Panel on the Future of Food Biotechnology[118]

Prioritize the protection of forest and other wild ecosystems

The *Seeds Regulations* are inappropriate and inadequate for assessing the risks of releasing genetically engineered trees. Furthermore, the CFIA is not equipped to assess the environmental risks of planting genetically engineered forest trees in plantations or in the wild. The CFIA has no expertise in forest ecology and has no experience in examining the release of GMOs into 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 UN Convention on Biological Diversity reaffirmed "the need to take a precautionary approach when addressing the issue of genetically modified trees".[119] There should be no regulatory exemptions for genome-edited trees. Instead, the federal government should **prohibit the release of all genetically engineered trees**.

"We do not have confidence that scientists in biotechnology labs can outsmart millions of years of evolution, nor understand and anticipate all of the intricacies, shifting dynamics or interactions that make up ecology and evolution"

– Rachel Smolker, BiofuelWatch, 2015[120]

Key Recommendations

The CFIA should **retain regulatory authority over all genetically engineered seeds**, including those produced through genome editing. The CFIA should assess the environmental safety of all genetically engineered seeds and not leave any assessments to product developers.

- **Genome editing should trigger regulation and safety assessmen**t. The use of genome editing should be defined as a novelty trigger, replacing the proposed definition of foreign DNA as a novelty trait. The processes of genome editing have no history of safe use in our food system and evidence clearly shows that genome editing processes can create a range of unintended effects that need to be detected and evaluated. The CFIA should choose precaution in the regulation of genome-edited foods. At a minimum, all new genetically engineered products, including those of genome editing, should be assessed for safety by regulators and tracked by our government.

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.

Farmers should be consulted in the CFIA assessment of genetically engineered seeds, to assist in identifying environmental and economic risks. As requested in 2009-2011 via debate over Private Members Bill C-474,[121] the *Seeds Regulations* should be amended to require that an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted.

As requested in 2019 by CBAN and Prevent Cancer Now, CBAN asks the federal government to:

- Initiate a broad a systematic assessment of the uses and impacts of herbicide-tolerant crops and associated pesticides in Canada;
- Reform GM plant/animal assessments to include long-term, systematic environmental impacts and related human health impacts, and economic impacts;
- Establish a system to monitor which GM crops and animals are on the market, including through the mandatory labelling of all GM foods;
- Mandate the Pest Management Regulatory Agency to track and publish annually, pesticide use nationally, on a regional scale;
- Mandate Statistics Canada to track plantings of all GM crops and production of GM animals, including where and how much of each GM crop/trait is planted;
- Develop a national strategy for pesticide reduction;
- Work with farmers and their organisations as well as with civil society organisations to develop a strategy for a just transition to sustainable agriculture (agroecology).

CBAN further requests that the federal government **prohibit the confined and environmental release of genetically engineered trees**.

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