March 4, 2022

The Honourable Justin Trudeau
Prime Minister of Canada
CC: The Honourable Jean-Yves Duclos, Minister of Health;
The Honourable Marie-Claude Bibeau, Minister of Agriculture and Agri-Food;
Karen McIntyre, Director General, Food Directorate, Health Products and Food Branch, Health Canada.

RE: Proposed regulatory guidance on genetic engineering threatens the safety of the food supply and would result in a profound loss of transparency for Canadians

Dear Prime Minister,

We are writing to respond to a letter from Health Canada (January 27, 2022) that is a response to our correspondence to you, acknowledged on November 1, 2021, regarding Health Canada's proposed updated regulatory guidance on genetically engineered foods. We are writing to raise our concerns about the response provided by Health Canada, and to further clarify our view of the proposed regulatory guidance.

Health Canada's letter restates that "the Government of Canada is committed to ensuring the safety of the Canadian food supply and the health and safety of Canadians," however, the proposed regulatory guidance for *Novel Food Regulations* threatens both. Health Canada's response confirms our urgent request to re-evaluate the proposals, in order to ensure safety and transparency.

The increased clarity and predictability that Health Canada and the Canadian Food Inspection Agency are seeking via changes to guidance over novel food and seed regulation would come at the cost of transparency and government oversight. Clarity and predictability in implementing the Regulations could be achieved by updates to guidance that ensure all genetically engineered foods and seeds, including those with no foreign DNA, are regulated, rather than exempting many of them as is proposed (by defining them as non-novel). A direction that ensures government oversight over all genetically engineered products would future-proof the implementation of the Regulations: it would ensure this implementation is guided by the ever-evolving science and can respond to rapid new technology development.

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We ask you to consider the attached letter of November 17, 2021, signed by 105 groups in Canada, asking for transparency and government oversight of all genetically engineered foods and seeds.

We ask your government to take action to ensure that the Departments have regulatory authority over all genetically engineered products, including those with no foreign DNA; that all genetically engineered foods and seeds entering the market are regulated for safety and transparency.

Profound loss of transparency

Rather than "improving transparency" as stated by Health Canada in their letter, the proposed regulatory guidance would allow many (most or all) future genetically engineered products (those with no foreign DNA, produced via genome editing) to skip regulation (be defined as non-novel) and leave the federal government and the Canadian public without notification of all the genetically engineered products intended for commercialization. In an attempt to compensate for the loss of transparency created by exempting products from regulation, Health Canada proposes to encourage product developers to voluntarily notify Health Canada about unregulated genetically engineered foods, for public posting. This voluntary approach would mean that the federal government would be unable to provide any assurance to the public that the information posted is complete. This will result in a profound lack of transparency for Canadians. Only mandatory reporting requirements can ensure transparency.

The proposal to create a singular list of non-novel foods (combining those overseen by Health Canada with those products regulated by product developers and voluntarily disclosed to Health Canada) will not be, as Health Canada describes in their response, "a useful resource for Canadians who are interested in what products of plant breeding may be marketed in Canada." Firstly, Canadians are particularly interested in products of genetic engineering and this distinction is important for transparency. Centrally, Health Canada proposes that this list would rely on voluntary disclosures from product developers. This means that this public list will, in fact, be a useless resource: Canadians will have no way of determining whether the list is complete and will need to assume that it is not. The voluntary nature of the disclosure will render the list largely irrelevant and certainly not transparent. Furthermore, renaming the proposed voluntary notification system for unregulated product from the "Voluntary Transparency Initiative" to the "Transparency Initiative" does not make the system transparent.

Canadians place a high value on transparency in relation to genetically engineered foods, and many Canadians are interested in public information in relation to genetically engineered foods on the market. This is clearly shown through polls over twenty years that consistently find over 80% of Canadians want mandatory labelling of genetically engineered foods. It is clear that Canadians want the government to track and disclose the status of these foods on the market, and they want a useful, accessible resource to provide this information.

Health Canada has written to us that, "As you are aware, the Department, under the Foods and Drugs Regulations, does not have a mandate to track or publicly disclose the status of genetically engineered or gene-edited foods in Canada." We are very aware that the Department does not track or disclose the status of GM foods in Canada. Where this mandate is missing, it should be

created. In order for Health Canada and the CFIA to fulfill their mandates to ensure the safety of Canada's food supply, we argue that the Departments should, at a minimum, have the ability to track and publicly disclose all genetically engineered foods and seeds.

Jeopardizing safety and moving without science

In proposing to exempt genetically engineered foods and seeds with no foreign DNA from triggering government safety review, Health Canada and the CFIA are moving without science, rather than being guided by it. The proposed approach would move from case-by-case, product-by-product safety evaluations and, instead, would make broad assumptions about the safety of genetically engineered products that have no foreign DNA. This proposed approach rests on assumptions over the safety of all products developed with genome editing that have no foreign DNA, and/or faith in the ability of product developers to adequately assess safety issues and their willingness to report these to government. If the guidance is implemented as proposed, these assumptions will apply into the future, to an ever-increasing number and diversity of genetically engineered (genome-edited) foods and seeds, including those produced by genomic technologies that have not yet been developed. The new genetic engineering techniques of genome editing have no history of safe use. We argue that if Health Canada and the CFIA were guided by the science in drafting these guidance updates then the proposals would acknowledge that the science is constantly moving, just as new techniques are quickly being created. Government oversight in this rapidly-moving field is necessary to ensure safety now and into the future.

The advent of genome editing should trigger an update to regulatory guidance that ensures the regulation of all genome-edited products. Such guidance would be a forward-thinking, precautionary approach that would allow the government to be responsive to scientific developments and provide flexibility for future policy and regulatory responses. This approach to ensure government oversight would assure Canadians that there are, at least minimal, government checks over corporate science and/or that the government has the authority to undertake such independent checks and require information from developers about their products.

As discussed in our attached critique (June 23, 2021) of Health Canada's "A Primer on Gene editing technology in relation to Health Canada's product-based regulatory framework for Novel Foods" that was included in the 2021 public consultation documents, we argue that Health Canada has not provided a scientific rationale for the regulatory guidance proposals and the guidance does not reflect the current scientific knowledge regarding the use of genome editing. The proposed guidance does not reflect the global scientific literature and it does not recognize the constantly evolving nature of scientific inquiry on safety in this field of research. Even this January, a new paper (Monroe et al. 2022)[1] finds mutation bias in plants that confirms the profound difference between genome editing and conventional plant breeding where genome editing can access areas of the genome for change that are otherwise protected from mutation.

[1] Monroe, J.G., Srikant, T., Carbonell-Bejerano, P. et al. Mutation bias reflects natural selection in Arabidopsis thaliana. *Nature* 602, 101–105 (2022). https://doi.org/10.1038/s41586-021-04269-6

Additionally, we raise our concern over the use of terminology in Health Canada's letter which refers to "genetically engineered and gene-edited products" which may imply a difference between genetic engineering and gene editing (genome editing) despite the fact that gene edited products are genetically engineered: It is scientifically incorrect to make a distinction between gene editing and genetic engineering (genome editing tools such as CRISPR are tools of genetic engineering). This language raises concerns for us about Health Canada's use of the science and about how Health Canada will communicate the science to Canadians.

In summary

Implementation of the regulatory guidance as proposed would jeopardize food safety and result in a profound loss of transparency that would have economic and social consequences, including that it will: create uncertainty in the domestic and international markets, lead to the loss of some international customers, undermine the future of organic food and farming in Canada, and deepen public mistrust in the Canadian food system and government regulation.

We ask your government to take action to ensure that the Departments have regulatory authority over all genetically engineered products, including those with no foreign DNA; that all genetically engineered foods and seeds entering the market are regulated for safety and transparency.

Thank you for addressing this important and urgent issue.

Sincerely,

Lucy Sharratt
Coordinator

Attached documents:

1. Joint letter from 105 groups "Call for Transparency and Government Oversight of All Genetically Engineered Foods and Seeds: No Regulatory Exemptions," addressed to The Honourable Jean-Yves Duclos Minister of Health and The Honourable Marie-Claude Bibeau, Minister of Agriculture and Agri-Food, November 17, 2021. https://cban.ca/wp-content/uploads/105-Groups-Call-for-Transparency-GMOs-Nov-2021.pdf
2. CBAN's comments submitted to Health Canada re: primer on gene editing, June 23, 2021. https://cban.ca/wp-content/uploads/CBAN-comments-to-HC-consultation-on-gene-editing-primer-June-23-2021.pdf

The Canadian Biotechnology Action Network (CBAN) brings together 16 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN is a project on MakeWay's shared platform.

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