Health Canada Santé Canada

251 Sir Frederick Banting Driveway
Tunney's Pasture
Ottawa, Ontario K1A 0K9

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Lucy Sharatt
Coordinator
Canadian Biotechnology Action Network
coordinator@cban.ca

Dear Ms. Sharatt,

Thank you for your correspondence to the Prime Minister dated November 1, 2021, regarding Health Canada's proposed regulatory guidance of genetically engineered foods. A copy of your correspondence was forwarded to Health Canada's Food Directorate for reply.

The Government of Canada is committed to ensuring the safety of the Canadian food supply and the health and safety of Canadians. Under Health Canada's product-based regulatory system for novel foods (which may include genetically engineered foods), products are determined to be novel or not novel based on their characteristics, rather than by the specific technology used to develop that product. Health Canada has a mandate under Division 28, Part B of the *Food and Drug Regulations* (i.e., the *Novel Food Regulations*) to conduct a pre-market safety assessment on all novel foods prior to their sale in Canada.

Health Canada recognizes the desire for increased clarity, predictability, and transparency regarding the *Novel Food Regulations*, and in particular, the regulation of genetically engineered and gene-edited products of plant breeding. As you are aware, Health Canada recently developed new guidance pertaining to products of plant breeding. A public consultation for this guidance was conducted from March to May 2021. The proposed guidance is based on Health Canada's review of the independent scientific literature regarding gene-editing and plant breeding practices, and engagement with a variety of stakeholders, including plant developers, academic researchers, and non-governmental organizations. The Department has carefully reviewed all comments received about the guidance during the public consultation, and where relevant, revised the guidance.

Health Canada is also improving our transparency regarding foods derived from genetically engineered and gene-edit plants. As you are aware, the Department, under the *Food and Drug Regulations*, does not have a mandate to track or publicly disclose the status of genetically engineered or gene-edited foods in Canada. However, the Department publishes information related to the safety assessments of all novel foods, including novel genetically engineered foods or novel gene-edited foods. Health Canada maintains the *List of completed safety assessments of novel foods including genetically modified (GM) foods*. This list includes a technical summary of each assessment, including a detailed description of the supporting data for each product.

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As you know, under the current regulatory framework for novel foods, developers are already able to make their own determinations as to whether their products meet the definition of a novel food. Developers can also request a novelty determination from Health Canada whereby the Department can determine the novelty status of a product based on information provided by the requester (something that Health Canada will continue to do going forward). Until recently, the non-novel outcomes of these requests have not been publically disclosed. To increase the transparency, Health Canada is taking two actions.

The first will build on the work done in 2020, to publish a *List of non-novel determinations for food and food ingredients*. Moving forward, in all cases where a developer requests a novelty determination from Health Canada, a non-novel outcome will be disclosed on the Health Canada website.

The second will be to launch a new Transparency Initiative (TI). Using this process, the Department will publish information regarding non-novel gene-edited plant products that may be sold for food use in Canada, but for which no novelty determination was sought from Health Canada. Through this process, product developers can voluntarily provide Health Canada with a set of information regarding their non-novel product. This information will be published on the Department's website for public access. While the new transparency process is voluntary, it will increase transparency by providing a means by which the public can be informed about these products.

To facilitate access to this public information, Health Canada intends to develop a singular list for products of plant breeding to encompass non-novel determinations made by Health Canada and information received via the new TI process.

The creation of a singular list will provide a useful resource for Canadians who are interested in what products of plant breeding may be marketed in Canada. The Department will continue to publish our list of completed safety assessments for those products that are novel. Overall, the actions that Health Canada is taking will increase the transparency of the regulatory system.

Health Canada acknowledges the concerns raised by the Canadian Biotechnology Action Network (CBAN) regarding the potential for unintended genetic changes that can occur using gene editing technologies. The current scientific literature shows that while such unintended changes can occur through gene editing, the same changes can also occur using other plant breeding methods including those that are considered conventional breeding practices. Gene editing technologies do not create any unique risks to food safety compared to any other method of plant breeding. As such, foods derived from gene-edited plant products should be regulated like all other products of plant breeding as described in the new guidance (i.e., based on the characteristics of the product itself).

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Along with the publication of the new guidance, Health Canada intends to publish a "Scientific Opinion on the Regulation of Gene-edited Plant Products within the Context of the *Novel Food Regulations*". This opinion outlines the scientific argument to support this approach to the regulation of gene-edited plant products.

I hope that my comments are helpful in addressing your concerns.

Yours sincerely,

Karen McIntyre
Director General, Food Directorate
Health Products and Food Branch