Comments on Health Canada's

PROPOSED NEW GUIDANCE FOR NOVEL FOOD REGULATIONS FOCUSED ON PLANT BREEDING

Safe Food Matters Inc. is a Canadian non-profit corporation, founded in 2016, dedicated to safe food and a safe environment. We work to improve regulatory policies to better protect human health and the environment.

We are pleased to provide these comments on Health Canada's "Proposed New Guidance for Novel Food Regulations focused on Plant Breeding", and the two associated consultation documents:

a) The *Proposed Changes to Health Canada Guidance on the interpretation of "When is a food that was derived from a plant developed through breeding a "novel food"?*" (the "**Novel Foods Document**"); and

b) The *Proposed Health Canada Guidance on the pre-market assessment of foods derived from Retransformants* (the "**Retransformants Document**").

Our comments revolve around legal problems with the proposed new guidance.

Abdication of Regulatory Authority

Health Canada holds the legal authority to regulate for the health of Canadians and the safety of Canada's food supply. It holds the mandate to regulate. This authority can be characterized as legislative, not administrative. The law says that because it is a legislative authority, it cannot be abdicated or delegated. (In comparison, administrative functions **can** be delegated).

It is up to Health Canada to fulfill the role of regulator. Legal principles say it cannot leave gaps in the space where it should be regulating (abdicate its authority), nor can it transfer this regulatory legislative responsibility to anyone else (delegate its authority).

The proposed new guidance on novel foods as presented by Health Canada, if implemented, would amounts to an abdication of authority, because it would leave a big gap in the regulation. Health Canada's regulatory mandate is to determine whether a food is safe before it is sold, as stated by Health Canada itself in the beginning of the Novel Foods Document. The proposed guidance would allow all genetically edited foods that do not fit into narrow, prescribed tests to get a free pass and not be individually assessed for safety.

Health Canada, in effect, indicates that no individual Health Canada safety assessment is needed unless a genetically modified food falls into one of five categories:

1. Its genetic modifications alter an endogenous protein;

2. Its genetic modifications increase levels of an endogenous allergen, an endogenous toxin or an endogenous anti-nutrient beyond the documented range;

3. Its genetic modifications have an impact on key nutritional composition and/or metabolism;

4. Its genetic modifications change the food use of the plant; and

5. Its genetic modifications are the result of the insertion of foreign DNA.

The problem here is that the "five category" test is too narrow. Note that the focus is only on whether the genetic modification causes a particular result (such as change in nutrition or a protein, more of an allergen) or introduces foreign DNA (collectively, the "GM Results"). There is no examination of whether other changes or results can occur in the plant.

The result is that a whole range of gene-edited foods, those that do not show any of the GM Results (the "Other Foods"), would not be individually assessed for safety. It also means that, even with respect to those foods that do show the GM Results, other changes in the food are not assessed for risks, such as the creation of new proteins, or the exhibition of off-target effects or of on-target but unintended effects (the "Other Risks"). With respect to these foods, Health Canada is not fulfilling its mandate of determining whether these foods are safe.

The Safety of Gene-Edited Foods Has Not Been Well Characterized

Health Canada is of the view that foods that are part of the Other Foods or that show Other Risks do not need to be individually assessed, because they "do not add to our body of knowledge about their safety…. because their safety is already well characterized".

However, the safety of gene-edited foods has **not** been well characterized. The techniques of gene editing are new and evolving at a very rapid rate, with new techniques being introduced all the time. As Health Canada itself acknowledges in the "Primer", gene editing can introduce off target effects that alter the risk profile of gene-edited foods. It states:

> "Off-target edits are genetic changes that result from the gene editing tools working at genomic sites other than the intended edit site (Wolt et al. 2016). Off-target edits can introduce unintended characteristics, and alter the risk profile of the plant-derived foods (Wolt et al., 2016; Zhao and Wolt, 2017)."

Health Canada also in the Primer is not clear whether unintended characteristics pose higher risks; it leaves the question open. This means that the risk and safety analysis with respect to off-target edits cannot be described as "well characterized".

Gene editing introduces more than off-target edits and effects. It also introduces unintended on-target effects, which in turn can result in unexpected effects in the gene-edited plant. Please see this recent report on Gene Editing for further detail. The bottom line is that gene editing can result in unintended off-target and on-target effects, which cannot be known *a priori*. As such, the safety profile is not, and cannot be, "well characterized".

European regulatory authorities consider gene-edited organisms to be similar to organisms that have had a foreign gene inserted, and they require individual safety assessments for both. In 2018, the European Court of Justice reaffirmed that gene-edited organisms require the same regulatory scrutiny as other genetically modified organisms, and need to be individually assessed. Its reasons were that gene edited varieties were being produced at an increased rate and in new quantities, and that the effect of releases of such varieties may be irreversible such that protection of human health and the environment requires due attention be given to controlling releases. It endorsed the position of the

lower court that it is impossible to determine with certainty the existence and extent of the risks presented by the new techniques. Excerpts from the judgement are attached as Schedule 1.

It is submitted that Health Canada must conduct individual safety assessments for all gene-edited foods, whether they fit into the "five categories" or not, so as to fulfill its regulatory mandate.

Improper Delegation of Authority

The proposed guidance on Novel Foods, as it relates to the decision-making on whether a food is a "novel food", also amounts to an improper delegation of authority. It is a delegation of authority for deciding whether a food is novel from Health Canada to the corporate plant developer, and also by extension the decision on whether the food is safe. It is improper because it is delegation of a power that the law says must be exercised by the regulator.

Health Canada is clearly of the view that the corporate plant developer is better positioned to make the decision. This is evident from all of Section 2.2 of the Novel Food Document, wherein Health Canada makes statements to the effect plant developers have the knowledge of the product and so can assess the safety. For example: "Plant developers are experts in their plant variety and the plant species in relation to its use in food, and related food safety".

Undue Reliance on Plant Developer Safety Determinations

Moreover, Health Canada in the Novel Food Document itself in effect says that the plant developers have shown that the gene-edited foods are safe. Health Canada does not conduct its own analysis, but instead relies on the knowledge of the plant developers and their consideration of food safety. This is evident from the statements: "It is well established that:

"plant developers are current in their knowledge of how the intended characteristic(s) may affect the expression of other characteristics, and **how this may affect food safety**" (emphasis added);

"plant developers consider whether there are **possible risks to food safety** linked to the new characteristics that they have or plan to introduce in the plant." (emphasis added)

"throughout the plant development process, any plants with characteristics that can negatively affect **food safety** are noted and discarded" (emphasis added)

"following commercialization, plant developers carefully observe their plant varieties for characteristics **that can negatively affect food safety** in relation to the plant variety they are working with." (emphasis added)

Health Canada even refers to these points as "conclusions" and that the plant developer's "plant variety development, as well as the post-commercialization variety stewardship, is of high quality and of sufficient rigor to adequately support the conclusion" that gene edited products are safe.

In other words, Health Canada is in effect saying that the plant developer has the knowledge, and looks at safety, so the gene edited foods are safe.

Problems with Relying on the Plant Developer

The problem with both the delegation of authority to the plant developer and the undue reliance on the knowledge of the plant developer is that the plant developer is not motivated by safety considerations. The motivation of a plant developer that is a business enterprise, by definition and by legal mandate, is the "best interests of the corporation", which generally translates as profit. The boards of directors of corporations have a fiduciary duty to act in this best interest.

Profits, made in a legal fashion, in most instances take precedence over everything else, including safety. Safety comes into play when it is legally mandated, or when the corporation considers that safety concerns will likely attract a liability that can be proven, and that the corporation cannot afford. Such safety concerns are few and far between; especially in the world of (unlabelled) gene editing where cause and effect are difficult to prove.

The result is that Health Canada, in the proposed guidance, delegates the decision making on novelty and safety to private enterprises that have little, or no, incentive to assess safety. The delegated decision making will not provide assurances that the regulatory mandate of Health Canada is fulfilled, which mandate requires ensuring a food is safe before it is sold.

It is worth considering whether plant developers will accept the transfer of responsibility for the safety of gene edited foods in situations where concerns about safety arise. Their "best interests" would be to absolve themselves of all such responsibility.

Regulatory Negligence

The proposed guidance also exposes Health Canada to claims of regulatory negligence. To establish negligence, it must be shown that the negligent party had a duty to care for the harmed party. It is likely Health Canada has a duty of care to Canadians to ensure the safety of their food supply, established by the principles set out in the legislation that governs Health Canada. This duty would be breached by a failure to ensure the safety of the food supply, and damages would arise from those Canadians hurt by unsafe food.

Different aspects of the proposed guidance might constitute a breach of the duty of care. One might be by Health Canada allowing plant developers, who are not motivated by safety, to make decisions on what is a novel food and on safety, as discussed.

Another breach might be the failure of Health Canada to establish a mandatory reporting and tracking system for gene-edited foods. To ensure safety of the food supply, there must be the ability to track the foods and know where they come from and what they are made of. This is particularly the case with gene-edited foods since unintentional effects may show up years into the future. However, there is no such system proposed by in Health Canada's proposed guidance.

Health Canada does attempt to put in place some kind of transparency with the *Voluntary Transparency Initiative*, but this would likely not be an adequate or reliable reporting and tracking system. The obvious problem is that the initiative is "voluntary", and so there is no assurance whatsoever of participation by product developers. This problem is exacerbated by the fact that the "best interests" of the corporate product developer is to **not** disclose information that might lead to liability unless such disclosure is legally mandated.

Retransformants Document

There are at least two concerns with the rationale presented in the Retransformants Document. Retransformants are described in the Retransformants Document as new plants that have been inserted with a sequence of DNA that is identical to that of a previously assessed genetically modified plant. It is worth noting that the DNA sequence is identical, but the plants are not. Health Canada assumes, without scientific basis, that different plants will be affected by inserted DNA sequence in an identical fashion, even thought the DNA of the non-assessed plant is different than the previously assessed plant.

Health Canada in the Retransformant Document also says the information requirements are "tiered in a way that is commensurate with the level of risk associated with these plant-derived food products". Here Health Canada is, in effect, putting the cart ahead of the horse. It is deciding how much information is required on safety for a Retransformant based on the determination by Health Canada of the level of risk associated with the Retransformant; but it cannot know the level of risk until it has obtained information on the Retransformant and assessed the safety.

Health Canada justifies this tiered approach by indicating it has "extensive experience" with certain characteristics and uses because it has evaluated 140 genetically modified plant varieties. However, as discussed above, genetic modification can result in unintended and/or unexamined effects that no level of experience can mitigate or foresee.

The assumption made by Health Canada that plants with different DNA will behave in the same fashion when inserted with an identical DNA sequence, and the pre-judgement of the "level of risk" posed by a Retransformant, are both factors that weigh against any assurance that Health Canada is ensuring the safety of the food supply of Canadians. No assessment, no assurance.

Response to Consultation Questions:

Apart from submitting the above comments, Safe Food Matters would like to respond to two questions posed in the consultation. The remaining questions were clearly aimed at assisting plant developers in utilizing the guidance, and consequently Safe Food Matters is not in a position to respond to them.

1. One of the questions asked in the Consultation was:

"Does the guidance align with the goal of a regulatory approach that is based on the level of food safety risk posed by specific products of plant breeding?"

Based on the above comments, it is the submission of Safe Food Matters Inc. that the proposed guidance does **not** align with a regulatory approach that is based on the level of food safety risk posed by the products of plant breeding.

Safe Food Matters if of the view that the level of food safety risk is likely high. Risk is the quotient of hazard x exposure. The proposed guidance allows for complete exposure of all Canadians through their diet to the products of gene editing that do not meet the five criteria, without individual safety (hazard) assessments having been conducted. This means the hazard of the particular foods is not known, and the exposure is high.

As discussed in the comments presented, this is a particularly critical issue in these times when new and increased numbers of gene editing techniques are being promulgated by product developers, the

working and effects of which have not been examined for unintended edits or effects, or for unintended effects associated with intended edits.

As discussed above, it is the legal mandate of Health Canada to regulate for the safety of the Canadian food supply. The proposed guidance amounts to an abdication and/or an improper delegation of this mandate and authority and may also qualify as an example of regulatory negligence.

2. A second question asked was:

"Does the voluntary transparency initiative serve its purpose to inform Canadians what non-Novel gene-edited products are on the market? Can we do more to achieve this objective?"

It is the submission of Safe Food Matters that the voluntary transparency initiative does not and likely will not inform Canadians what non-Novel gene-edited products are on the market. The reason is, as explained, that product developers will likely not be motivated to participate in the voluntary transparency initiative because participation does not align with the "best interests" of the developer.

Health Canada can do more to achieve this objective. Good corporate actors will obey the law, but other corporate actors will obey the law only if they know the law will be enforced. If a law is not enforced, and this fact is known, then the "best interests" of the enterprise might lean toward taking a risk in not obeying the legal mandate. Thus the only way to achieve the objective is to legally mandate the transparency, and then to enforce it.

Schedule 1

Excerpts from the Judgement of the Court of Justice of the European Union:

> "According to the referring court, the conventional *in vivo* mutagenesis methods were used for several decades without creating identified risks for the environment or health. By contrast, since the adoption of Directive 2001/18, new varieties, in particular those resistant to herbicides, have been obtained through random mutagenesis techniques applied *in vitro* to plant cells and **through directed mutagenesis techniques/methods applying new genetic engineering techniques**, such as oligonucleotide-directed mutagenesis or directed nuclease mutagenesis. **It is, in the view of the referring court, impossible to determine with certainty the existence and extent of the risks presented by those new herbicide-resistant varieties** [produced by directed gene editing] for the environment and human and animal health, the only risk assessments thus far being carried out in the context of the marketing authorisation procedure for the plant protection products to which those varieties have been made resistant."
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> "The referring court considers that those risks are in part similar to those that might result from seeds produced by transgenesis [introduction of a foreign gene]. As regards, in particular, the mutations obtained by the new directed mutagenesis techniques [directed gene editing], the direct modification of the genome that they involve **would result in the same effects as the introduction of a foreign gene**, specific to transgenesis. In addition, **since the development of the new techniques of mutagenesis allows the production of modifications of the genetic heritage to increase at a rate out of all proportion to the modifications likely to occur naturally or randomly, the possibility of harm occurring as a result of unintentional modifications of the genome or of the properties of the plant thus obtained would be increased**."
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> "[T]he direct modification of the genetic material of an organism through mutagenesis [gene editing] makes it possible to obtain the same effects as the introduction of a foreign gene into that organism [genetic modification] and, secondly, that the development of those new [gene editing] techniques/methods makes it possible to produce genetically modified varieties **at a rate and in quantities quite unlike** those resulting from the application of conventional methods of random mutagenesis."
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> "[L]living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects of such releases on the environment may be irreversible. In the same vein, recital 5 of that directive states that the protection of human health and the environment requires that due attention be given to controlling risks from such releases". (emphasis added)