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Bureau of Microbial Hazards
Food Directorate, Health Canada
251 Sir Frederick Banting Driveway
Ottawa, Ontario K1A 0K9
hc.bmh-bdm.sc@canada.ca

The American Seed Trade Association (ASTA) appreciates the opportunity to provide comments to the Proposed Changes to Health Canada Guidance on the interpretation of Division 28 of Part B of the *Food and Drug Regulations:* When is a food that was derived from a plant developed through breeding a "novel food"?

Founded in 1883, the American Seed Trade Association (ASTA) represents over 700 member companies involved in seed production and distribution, plant breeding, seed treatment and related industries in North America. ASTA members produce seed for row crops, vegetables, ornamentals, grasses, and cover crops, and for conventional, genetically engineered, and organic seed markets. ASTA's mission is to enhance the development and movement of quality seed worldwide.

ASTA members have been safely and reliably bringing seed improvements, such as improved taste, enhanced nutrition, higher germination, higher seed purity, and the latest innovations in disease and pest resistance, to the marketplace so that farmers have a wide array of planting choices. The enterprise of consistently developing and producing quality seeds is supported by a growing suite of breeding techniques and well-established best practices, such as quality management systems. In recent decades, with advances in the understanding of plant genomes, plant breeders have increasingly integrated genomic-enabled techniques and knowledge, such as marker assisted selection, into well-established procedures to improve breeding efficiency and efficacy.

Continual innovation in plant breeding is crucial for both the seed industry and the sustainability of the global agricultural and food system, particularly at a time of rapid growth in the global population and the challenges of climate change. A key factor that incentivizes and protects the continuation of seed innovation is a transparent, consistent regulatory approach that is risk proportionate and based on the best available scientific evidence.

ASTA supports international regulatory alignment and compatibility to minimize trade barriers. The United States and Canada boast the world's largest bilateral agricultural trade relationship. With respect to seeds for planting, in 2020 U.S. and Canada trade totaled over $600 million USD. In addition to bilateral trade of commercial seeds, the U.S. and Canada plant breeding and seed production sectors rely on the smooth movement of seeds across national borders for the development of foundation and breeder seed lines used in research and development, for parental seed and stock seed production, and for processing and packaging of commercial seed. To maintain the smooth integration of the U.S. and Canada seed industry and bilateral agricultural trade, alignment and consistency in regulatory scope bilaterally are vitally important.

Because the Canadian regulatory trigger is based on "novelty", the proposed guidance with enhanced clarity of what is not novel is impactful for foods derived from all types of plant breeding, including mutation breeding and gene editing. The successful implementation of clear and science-based

interpretation of novelty for food that was derived from a plant developed through breeding will be welcomed across the plant breeding community.

ASTA respectfully provides the following specific comments to key questions posed by Health Canada.

Does this new guidance improve clarity, helping plant developers and interested parties determine which plant-derived foods are, and are not, novel foods?

ASTA is pleased that the guidance acknowledges the longstanding safety record associated with plant breeding. Plant breeders have well-established screening and quality management processes to evaluate newly developed varieties for acceptable product performance, regardless of the plant breeding method employed.

ASTA supports the proposed five categories of foods that are not novel foods that require pre-market notification. We believe these five categories can use further refinement to improve clarity and avoid interpretation beyond the intended scope. ASTA offers the following recommendations:

1) *Food derived from plants with genetic modifications that do not alter an endogenous protein so that it now demonstrates significant homology with a known allergen or toxin relevant to human health.*

   ASTA recommends revising the language so that scope of this category is limited to endogenous proteins that do NOT demonstrate significant homology to known allergen or toxin prior to the genetic modification. Many plant scientists are developing plant varieties to minimize allergenicity or toxicity. This can be achieved either by decrease homology or more often by eliminating the expression of allergens or toxins. It is not clear how the five categories would apply to food derived from these plants.

2) *Foods derived from plants with genetic modifications that do not increase levels of an endogenous allergen, an endogenous toxin, or an endogenous anti-nutrient beyond the documented range.*

   To be consistent with category 1, ASTA recommends the addition of "known" before and addition of "relevant to human health" after the terms "endogenous allergen" and "endogenous toxin." Further, this category erroneously implies that any expression outside the documented range results in increased risk to food safety. The importance is that expression remain at safe levels, which may be outside the documented range.

3) *Foods derived from plants with genetic modifications that do not have an impact on key nutritional composition and/or metabolism.*

   ASTA notes that the documentation of expression levels is not equally available for all plant species. The two resources cited by the guidance are limited mostly to row crops. While the guidance allows for the developers own experience as acceptable sources of information with regards to range of expression levels, developers of the same plant crop may have different experiences and may come to different conclusions regarding whether the new expression level is within range.

Generally, unless a food is documented to be the primary source of key nutrient(s), change in key nutrient(s) in one particular food is unlikely to change nutritional availability from a whole diet perspective. The modern human diet is constantly changing due to a variety of factors, such as changing availability and accessibility of a food, and changing food trends. All these factors may impact the prevalence of under-consumption or over-consumption. It is beyond the responsibility of, and difficult for developers to predict how food derived from a new plant variety may lead to alterations in consumption patterns.

4) *Foods derived from plants with genetic modifications that do not change the food use of the plant.*

ASTA reiterates that changes in consumption patterns are not under the control or within the responsibility of the plant developer. The non-novel food status of a product should not be tied to level of consumption. For example, seedless varieties of fruit crops have historically been considered not novel; however, these varieties likely increased consumption. Further, under consumption or over consumption of a particular plant derived food do not necessarily lead to food safety concerns. This category would benefit from articulating the scope of change in food use where it would be considered a novel food, for example, plant species that has no history of being in the food supply.

5) *Foods derived from plants with genetic modifications that are not the result of the insertion of foreign DNA.*

ASTA seeks confirmation that the intent of this category is to ensure that there are no foreign DNA *contained* in the final plant product. As written, resultant of insertion of foreign DNA could be interpreted to include the use of transient expression of foreign DNA in a breeding intermediary. For example, in the case of the FasTrack system used in fruit trees breeding, where intermediate breeding stock contains a transgene for early flowering, but only the improved seedlings that *do not contain* the transgene would be used in commercial production.[1] In this example, fruit from commercially orchards would not contain any foreign DNA, and under this category, should not be considered novel. ASTA recommends revision of the text to reflect the intent more clearly.

In addition, ASTA recommends revision to footnote 4 to reflect the prevailing understanding among regulatory entities around the world that "foreign DNA" refers to DNA that is not a part of the organism's gene pool of sexually compatible plant species.

Is it clear that plant developers and interested parties can consult with Health Canada to help make this determination?

ASTA appreciates that Health Canada has a voluntary process for developers to request a novelty determination. To provide more predictability to the process, ASTA suggests that the guidance includes a time frame for Health Canada to complete the determination process. The timeliness of the novelty determination process would impact the extent that plant developers would use it.

[1] Scorza, Ralph & Dardick, Chris & Callahan, Ann & Srinivasan, Chinnathambi & Dejong, Theodore & Harper, Jay & Raines, Doug & Castro, Sarah. (2012). 'Fastrack'—A Revolutionary Approach to Long-generation Cycle Specialty Crop Breeding.

Does the guidance reference the most useful and appropriate resources for plant characterization? Are there alternative or additional resources you would recommend?

ASTA has developed the following resources to support broad understand of the plant breeding practices, available at www.betterseed.org.[2]

- Common Practices of Plant Breeders
- The Guide to Seed Quality Management
- Guide to Evaluation of Genome Edited Plants

In addition, we recommend Glenn, K.C., Alsop, B., Bell, E., Goley, M., Jenkinson, J., Liu, B., Martin, C., Parrott, W., Souder, C., Sparks, O., Urquhart, W., Ward, J.M. and Vicini, J.L. (2017), Bringing New Plant Varieties to Market: Plant Breeding and Selection Practices Advance Beneficial Characteristics while Minimizing Unintended Changes. Crop Science, 57: 2906-2921. https://doi.org/10.2135/cropsci2017.03.0199

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?

The proposed guidance is a positive step in aligning Health Canada's regulatory approach with its safety objectives. ASTA's specific recommendations provided within this letter would improve clarity and refine the scope of what food would be considered not novel.

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?

ASTA and our members recognize that for some non-novel plant products, for example, plant varieties developed using technologies such as genome editing, there may be stakeholders in the agricultural and food system who would like more information. We believe that information sharing mechanisms should be achieved independently of regulations focused on safety and risk assessment, and therefore should not impede the science-based approach of the regulatory system. In support of stakeholder engagement and information sharing, ASTA developed, *Best Practices: Seed Industry Information Sharing for Products of Gene Editing.*[3] One of the principles articulated in this document is that "developers will inform regulatory authorities about their products that are intended to be commercialized and are exempt from pre-market regulatory reviews under current biotechnology regulations." ASTA and our members are committed to continuing to proactively engage with the stakeholder community on how newer plant breeding technologies are used and the standard practices of plant breeding that Health Canada recognizes as the basis for providing a safe food supply.

[2] https://www.betterseed.org/the-issues/innovation-and-policy/

[3] https://www.betterseed.org/wp-content/uploads/ASTA-Best-Practices-Information-Sharing-for-Products-of-Gene-Editing_final.pdf

ASTA would like to better understand the implementation of the Voluntary Transparency Initiative for products derived from a specific set of technologies. For example, how can the implementation avoid a product-by-product, event-by-event approach that is common for transgenic plant products? A single vegetable seed company may have breeding programs in 20 different crops and can introduce hundreds of new commercial varieties every year. Field crop seed companies often work in multiple species and collectively will commercialize hundreds of hybrids and varieties in the U.S. market every year. Many of these varieties may share common gene edited characteristics. Notification can be by crop-characteristic-mode of action. This approach would be consistent with Health Canada's product based regulatory policy and the approach taken by United States Department of Agriculture Biotechnology Regulatory Service in determining regulatory status.

Since building public trust is a stated goal of the Voluntary Transparency Initiative, ASTA believes that information provided in the notification should be information that the public would find relevant and useful. We note that the implementation of the Voluntary Transparency Initiative should also mitigate the misperceptions that all notified products are in the food supply. "Ready for commercialization" and "commercialization" have different meaning and may not align with the product being in the food supply.

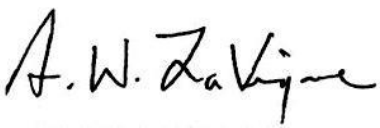
ASTA suggests that information needed for notification relevant to the public may not be the same as what Health Canada may need from developers to support a "determination of concurrence with the non-novel status." ASTA cautions that confirmation of regulatory status does not becomes a de facto regulatory hurdle that involves significant resources dedicated to information and data gathering. Further, we ask Health Canada to provide more clarity on how it would determine concurrence of non-novel status, and how non-concurrence would be handled.

Comments on Annex 2

In general, Annex 2 provides a comprehensive and concise overview of gene editing as a plant breeding tool. However, ASTA disagrees with the assertion that "the off-target edit sites are more likely to inadvertently impact secondary biological processes when compared to random sources of unintentional characteristics that have been previously analyzed." There is no scientific literature or plausible rationale that support such claim. The scientific consensus is clear that off target modifications from gene editing are significantly lower than that occurring with other commonly used breeding tools and concurs with Health Canada's conclusion that "the use of gene editing technologies does not present any unique safety concerns compared to other methods of plant breeding." ASTA recommends Health Canada reviews this claim and remove it from the guidance if there is no supportive scientific evidence.

In closing, ASTA supports Health Canada in continuing its efforts toward the development of a clear, risk-proportionate, progressive regulatory approach that would incentivize innovation. ASTA appreciates the opportunity to provide comments.

Sincerely,



Andrew W. LaVigne
President & CEO