asta | american seed trade association

September 16, 2021

Plant Biosafety Office
Canadian Food Inspection Agency
PBO@inspection.gc.ca

To Whom This May Concern:

The American Seed Trade Association (ASTA) welcomes the initiatives by the Government of Canada to provide additional clarity on the interpretation of plants with novel traits, and novel food and feed derived from plants developed through breeding. We provided comments to the Proposed Changes to Health Canada Guidance on the interpretation of Division 28 of Part B of the *Food and Drug Regulations* and appreciate the opportunity to provide comments to the Canadian Food Inspection Agency (CFIA) draft guidance for determine whether a plant is subject to Part V of the *Seeds Regulations*.

Founded in 1883, 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.

While CFIA highlights the application of gene editing tools in plant breeding as impetus for the draft guidance, the "plants of novel trait" scope, as currently defined, is potentially applicable regardless of breeding tools used and potentially contrary to the assertion in the draft guidance that effectively all plants developed through conventional breeding would be exempted from Part V. Therefore, a clear and science-based scope of what would be consider plants with novel traits will be welcomed across the plant breeding community, and ASTA encourages CFIA to revise the guidance to accomplish that goal.

ASTA respectfully provides the following specific comments to the themes posed by CFIA in the questionnaire.

Determining when a plant qualifies for an exemption from Part V

ASTA supports CFIA's statements that "virtually all plants developed by conventional breeding techniques qualify for exemption from Part V" and that "gene editing techniques can introduce genetic changes that are comparable to conventional breeding outcomes, and will also qualify for an exemption."

Under the glossary of terms, we recommend revision to the explanation of the term "conventional breeding" to read, "breeding methods *including but not limited to*, the crossing and selection of plants,

marker-assisted breeding, cell and embryo fusions, and chemical or radiation-based mutagenesis." The suggested revision would clarify that conventional breeding is not limited to just the methods listed.

ASTA appreciates that CFIA included in the draft guidance a mechanism for plant breeders, at their discretion, to request an exemption opinion letter. ASTA suggests that including a time frame for CFIA to provide such a letter would provide predictability which may encourage its utilization. ASTA supports making opinion letters public as long as appropriate protections are in place for confidential business information.

Determining which plants are subject to Part V

In the current description of "foreign DNA", ASTA believes that "DNA that is not currently part of an organism" can be interpreted narrowly to preclude the introduction of DNA from sexually compatible species. Therefore, we recommend revising to the description of "foreign DNA" 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.

With regards to the four plant breeding outcomes that may negatively impact the environment, ASTA cautions that overly broad interpretation of the four outcomes may inadvertently capture plants developed through conventional breeding that are not intended to come within Part V. Therefore, ASTA supports the recommendations made by Seeds Canada to further refine the four outcomes. In addition, ASTA has the following comments after considering the four outcomes in concert with the five criteria the environmental safety assessment is based on, as outlined in Part V of the *Seeds Regulations*.

- *A trait that would make a plant more difficult to control by removing a management option*

  This outcome can be more precisely described if the intent is to guard against the potential for the plant to become a weed in an agricultural setting or become invasive, as well as the potential for gene introgression to sexually compatible wild species that alters their weediness or invasiveness. Losing a management option does not by itself render plants weedy or invasive.

- *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*

  ASTA recommends the addition of "known" so this category would read "a known toxin, allergen, or other known compounds..."

- *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*

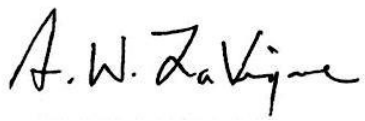
  Similarly, this category could be clarified by providing additional parameters to ensure that novelty is the key element of evaluation. This can be accomplished by stating that the plant, or its wild relative(s) inherently has invasive characteristics, and that gene introgression may be likely to occur to the wild relative(s) present in Canada. In the case of survivability, the

parameter can be narrowed so that the improvement must be beyond the range that has been observed in the plant species in Canada.

In closing, ASTA supports international regulatory alignment and compatibility to minimize trade barriers. With respect to seeds for planting, in 2020, U.S. and Canada bilateral 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. While the U.S. and Canadian regulatory agencies may have different regulatory triggers, the protection goals and regulatory assessment endpoints are compatible. In the process of clarifying and revising regulations, ASTA encourages open and frank bilateral conversations between the relevant U.S. and Canadian agencies to ensure regulatory alignment and compatibility to the fullest extent possible.

Thank you for the opportunity to provide comments.

Sincerely,



Andrew W. LaVigne

President & CEO