american seed trade association

August 12, 2021

Bio-Convergence Industry Division
Ministry of Trade, Industry and Energy
Government Complex-Sejong, 402, Hannuri-Daero, Sejong-si 30118
Republic of Korea
Tel: +(82) 44 203 4396
Fax: +(82) 44 203 4731
E-mail: kooku757@korea.kr

Re: G/SPS/N/KOR/723: Draft partial amendment of the Transboundary Movement, etc. of Living Modified Organisms Act

To Whom This May Concern:

The American Seed Trade Association (ASTA) appreciates the opportunity to provide comments to the recent announcement by the Ministry of Trade, Industry and Energy (MOTIE) to revise the Living Modified Organism Act (LMO Act).

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. Our 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.

Like plant breeders in the Republic of Korea and around the world, 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. In recent decades, with advances in the understanding of plant genomes, plant breeders have increasingly integrated genomic-enabled methods 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 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, based on the best available scientific evidence, and minimizes unnecessary trade barriers.

Consistent regulatory scope

Certain genome editing applications used in plant breeding are refinements of earlier mutation breeding methods. These applications result in enhanced specificity and precision of the genomic modification. Through genome editing applications, the DNA change can be induced at a very specific site in the genome, something that is not possible through chemical- or irradiation-induced mutation or cross breeding. Genome editing applications to direct a change to a characteristic or phenotype are guided by prior knowledge about the gene and gene

function, and adds a degree of precision in predicting the outcome of the changed variety or hybrid.

Given the similarity of certain applications of genome editing in plant breeding to conventional breeding, many governments have established policies that enable the exclusion of certain products from the scope of existing GMO/LMO regulations. These exclusions are mainly based on a process to determine when a product of genome editing is in the scope of regulations for "genetically modified organisms" or "living modified organisms", and when it is not and is to be treated the same as a conventional product. In doing so, these governments have taken into account the breadth of genome editing applications in plant breeding, specifically, to create genetic diversity through changes in endogenous gene sequences and functions that are, in principle, possible to create using conventional breeding methods, such as via spontaneous/induced mutagenesis, and cross-breeding.

Many of these governments, similar to the Republic of Korea, are Parties to the Cartagena Protocol on Biosafety, and have based their exclusions of certain genome edited products from GMO/LMO regulations on the interpretation of "novel combination of genetic material" part of the definition of LMO. Rather than changing legislation, the consensus approach thus far has been for governments to publish guidance or regulations that clarify the regulatory scope. The growing consensus among many governments, such as Argentina, Colombia, Brazil, and Japan, is that genetic changes introduced with the use of genome editing methods are not considered novel, or otherwise subject to regulation as GMO/LMO, if they are comparable to the genetic changes that are introduced with conventional breeding methods, or that can occur via spontaneous processes in nature. If the resulting genetic changes are not novel, the resulting organisms are not considered LMOs. The proposed LMO Act revision by MOTIE, where all genome edited organisms are considered LMOs, is inconsistent with this growing consensus.

Plant breeding innovations, such as genome editing, can be used to breed new varieties of crops that are comparable to those developed using conventional breeding methods and thus of comparable risk and safety profile. Consistent with World Trade Organization Sanitary and Phytosanitary Standards, these like-products should not be regulated differently, merely based on the process of development, when there is no novel risk.

Case by case consultation

The criteria in MOTIE's proposal regarding when certain products of genome editing would be exempted from the risk assessment and approval requirements for import, production, and use are aligned with the criteria used by other governments. In specific, when the product is:

(1) Developed without using any foreign gene[1], or

(2) Developed through a process where a foreign gene was introduced but removed from final product, or

(3) Comparable to those developed by conventional breeding[2]

These criteria would provide a robust framework for the government of South Korea to conduct the preliminary review to assess whether a product is excluded from the LMO risk assessment. However, we emphasize that the preliminary review is not a risk assessment. Therefore the information required to support a preliminary review should be confined to only information necessary and sufficient to make the determination of whether a product meets the exemption criteria. Further, we believe it is important that the preliminary review should be under the jurisdiction of agencies that have the relevant technical capacity, such as The Rural Development Administration, or have responsibility for food and feed safety, such as Ministry of Food and Drug Safety and Ministry for Agriculture, Food & Rural Affairs. Finally, ASTA requests MOTIE to reconsider using the term "new living modified organisms". This terminology is inconsistent with the

[1] By which a foreign gene is understood to be a gene derived from sexually incompatible species.

[2] By which conventional breeding is understood to be the improvement of plant varieties by modifying plant genomes using methods such as selective breeding, hybridization, marker-assisted selection, cell or embryo fusions, chemical or radiation induced mutagenesis, *in vitro* selection.

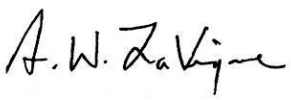
established policies of many governments, and could create unnecessary trade disruptions and public misconceptions. To align more closely with the approaches taken by other governments, MOTIE should refine its proposal by clarifying that when a product meets one of the above exemption criteria, it is not a LMO and thus excluded from the scope of the Living Modified Organisms Act.

ASTA supports alignment and consistency in regulatory scope, upholding and promoting science-based, and risk proportionate regulatory approaches internationally. ASTA members develop and produce new plant varieties and seeds not only for the U.S. marketplace, but also for an ever-growing number of countries worldwide, including the Republic of Korea. Additionally, the international plant breeding and seed production sector relies on the smooth movement of seeds across national borders for use in research and development, for parental seed and stock seed production, for counter-seasonal seed production and for processing and packaging of commercial seed. Further, a compatible, harmonized regulatory scope facilitates international trade of agricultural products, from grains to fresh produce, to prepared food.

In addition to smooth trade, seed production and movement, globally-harmonized and science based regulatory systems are important for broad international collaboration in plant science and plant breeding. As the world seeks solutions to foster a more sustainable global agriculture and food system in supporting a growing population and in response to climate change, continual innovation in plant breeding is crucial for both public and private entities. Regulatory requirements that are disproportionate to the level of risk and that introduce discriminatory handling of like-products can impede trade, innovation, and agricultural productivity beyond national borders, especially by limiting entry only to those entities and food crops that can afford the resources of time and money to navigate multiple regulatory systems. It is vital that governments enable the adoption of innovations in plant breeding, and do not implement additional, unnecessary barriers to market entry that disproportionately impede public sector researchers, small private sector entities, and innovation in fruit and vegetable crops.

ASTA respectfully requests that the government of the Republic of Korea, and MOTIE reconsider the proposed revision to the LMO Act in light of global harmonization and compatibility in regulatory scope.

Sincerely,



Andrew W. LaVigne
President & CEO