The United States appreciates the opportunity to comment on Food Standards Australia New Zealand's (FSANZ) Proposal "Definitions for gene technology and new breeding techniques" (P1055). The United States encourages science- and risk-based policy approaches for innovative technologies and their products. Newer methods, including genome editing, can be used to develop enhanced crops at a faster rate, allowing farmers and consumers to access these products and their benefits more quickly. We commend FSANZ for looking ahead to future use of genetic technologies and implementing a risk-based regulatory approach that provides predictable pathways for new products to enter markets.

Currently, U.S. regulatory agencies are considering how to most effectively develop policy approaches for genome-edited products, basing their considerations on science- and risk-based policy approaches and the nearly three decades of regulatory experience on the evaluation and safe use of products of biotechnology. In light of this experience, the United States has prepared several high-level comments, as well as specific questions regarding this proposal. We welcome the opportunity to discuss and collaborate on these policy issues in order to achieve our individual and shared objectives, while enabling the use and commercialization of biotechnology.

General Comments

The United States commends FSANZ's efforts to reduce regulatory gaps and create a risk-proportionate system to enable food products of "New Breeding Techniques (NBTs)" to reach the market. The USDA Animal and Plant Health Inspection Service (APHIS) has determined that certain products of genetic engineering that could have otherwise been produced through conventional breeding are exempt from its regulatory review process for plant pests. Likewise, the United States Environmental Protection Agency (US EPA) has proposed to exempt certain plant-incorporated protectants (PIPs) that are created in plants using biotechnology as long as their pesticidal substances are found in plants that are sexually compatible with the recipient plant and meet the US EPA's proposed exemption criteria, ensuring their safety. FDA intends to publish draft guidance regarding food from genome edited plant varieties explaining how the FDA's current regulatory policy for foods derived from new plant varieties applies to foods produced using genome editing. We appreciate that, in reviewing its definitions, FSANZ compared regulatory developments around the world regarding genetically engineered crops, particularly the products of genome editing.

The United States emphasizes the importance of FSANZ's effort to develop a clear definition of "food produced using gene technology" that takes into account the continued development of new technologies, recognizes the potential positive benefits of new technologies, and maintains a science-based, and risk-proportionate regulatory approach.

Specific comments and questions

Exclusion criteria throughout the proposal refer to "novel DNA" but this term is not defined. Would products that have small changes to the genome that have not been observed in nature in the species or a closely related species be considered to contain "novel DNA?" Depending on how this concept is interpreted, a wider variety of products may be captured under the new

definitions than is intended. We encourage FSANZ to clarify what it means when referring to "novel DNA."

The presence of "novel DNA" in a refined product may not indicate the presence of a novel protein, especially in cases where a non-coding region has been altered, and may not present additional risk to food safety. Does the presence of "novel DNA" simply act as a trigger for regulatory review? In circumstances where the product characteristics do not differ from a conventional product but "novel DNA" is present, would a full regulatory review process be necessary to evaluate the product?

Additionally, the text on Pg. 16 and in Table 1 refer to proposed exclusion criteria for refined products: "Refined ingredients where novel DNA **and** novel protein is present in the food for sale" (bold emphasis ours). However, on Pg. 27 the exclusion criteria for refined products is written as: "For the exclusion of GM-derived food additives and processing aids, the only relevant consideration is whether novel DNA **or** novel protein is absent from the food for sale" (bold emphasis ours). The United States suggests 'or' should be used as the appropriate operator, as is written on Pg. 27, for text on Pg. 16 and in Table 1 to prevent confusion in understanding the exclusion criteria.

The United States thanks FSANZ for your consideration and the opportunity to provide feedback. We also encourage FSANZ to notify through the WTO the proposed changes to its definitions. We welcome and look forward to continued engagement on these issues and others in the coming months.