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Review Process Confirmed for GE Food Derived from Genome Editing

Report Categories:

Biotechnology and Other New Production Technologies

Biotechnology - GE Plants and Animals

Agricultural Situation

Grain and Feed

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Report Highlights:

The Food Safety Commission (FSC) of the Government of Japan (GOJ) held its 187th Genetically Modified Foods Expert Committee to discuss procedures for the safety review of genetically engineered (GE) foods derived from genome editing technology. The Committee concluded the review process will remain the same as for existing GE products.

General Information:

The GOJ has released regulatory policies for genome edited products for food ([JA9050](#)) and environmental ([JA9024](#)) safety. The policies articulate that if a product contains “foreign genes” (food) or “extracellularly process nucleic acid” (environment), the product will be considered GE. The GOJ has announced that it will finalize the policies and guidelines in Japanese Fiscal Year (JFY) 2019 (between April 1, 2019 – March 31, 2020, but the process could be completed as early as summer 2019).

In order to ensure clarity, the FSC met to confirm the GOJ’s position regarding when a scientific review is required for GE¹ foods derived from genome editing² technology. In its 187th Genetically Modified Foods Expert Committee meeting on May 20, 2019, committee members confirmed that:

- The safety review for GE food products derived from genome edited technology will remain the same as for existing GE products.
- Safety review standards will be based on existing safety assessment standards for GE foods (without a requirement for additional data).
- The FSC’s current “[Standards for the Safety Assessment of Genetically Modified Foods \(Seed Plants\)](#)” says “{w}herever possible, it should be demonstrated that the insertion does not cause any alterations in the nucleotide sequences of the host genes.” Therefore, it is reasonable to conclude that the safety confirmation procedures, such as those for the confirmation of unintended leftover foreign genes, off-target mutation, etc. can be conducted with information already provided by developers under the current information and data requirements.
- Also, “[Consideration to the Lineage in the Safety Review of Genetically Engineered Plants](#)” (in Japanese only and decided in the Genetically Modified Foods Expert Committee of April 23, 2018) will be maintained during the review of GE food products derived from genome edited technology.

¹ The FSC defines genetic engineering, or recombinant DNA techniques, as a “{t}echnique whereby recombinant DNA molecules prepared by cleavage and recombination of DNA using enzymes or other methods are transferred to living cells for proliferation (the term refers to the techniques that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection). See http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf (in English).

² Japan’s Ministry of Health, Labor, and Welfare defines genome editing is, in general, as a group of technologies that allow not only the introduction of foreign genes but also the modification of genome, such as gene deletion, DNA substitution, etc., to the targeted certain loci in the genome. So far, it has been mostly used to induce the loss of specific gene function. See <https://www.mhlw.go.jp/content/11121000/000494346.pdf> (in Japanese).