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Health Ministry Begins Discussion of Genome Edited Foods

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Report Highlights:
On September 19, 2018, the "Research Sub-Committee for Genetically Modified Food" of Japan's Ministry of Health, Labour and Welfare held its first public discussion on the handling of food products derived from genome editing technology. The Sub-Committee concluded that product that does not contain a foreign gene should be exempted from the regulation of genetically engineered food. The discussion is expected to continue through Japanese Fiscal Year 2018 and conclude by the end of March 2019.

General Information:
The Ministry of Health, Labour and Welfare (MHLW) oversees a "Pharmaceutical Affairs and Food Sanitation Council" whose responsibility is to formulate policies related to pharmaceutical and food safety issues. Under that Council, a "Research Committee for Newly Developed Food" operates to review regulatory changes and issues (e.g., revising the safety review process for highly purified products from genetic engineering). Beneath that Committee is the "Research Sub-Committee for Genetically Modified Food" (the Sub-Committee) which develops science-based recommendations on the regulation of food related to genetic engineering.

The Sub-Committee held its first public discussion on the handling of food products derived from genome editing technology on September 19, 2018. The Sub-Committee was comprised of nine academic scientists with one advisor, and chaired by Dr. Kazunari Kondo.

The Sub-Committee members are:

- Dr. Keiko Asakura, Associate Professor, Department of Environmental and Occupational Health, School of Medicine, Toho university
- Dr. Yumiko Okada, Division of Biomedical Food Research, National Institute of Health Sciences
- Dr. Yoshihiro Ozeki, Professor, Division of Biotechnology and Life Science, Tokyo University of Agriculture and Technology
- Dr. Kazunari Kondo (Chair), Director, Division of Biochemistry, National Institute of Health Sciences
- Dr. Yasuto Kondo, Deputy Director for Allergy Center, Fujita Health University
- Dr. Yutaka Tabei, Director, Genetically Modified Organism Research Center, National Institute of Agrobiological Sciences
- Dr. Harushi Nakajima, Professor, Department of Agricultural Chemistry, Meiji University
- Dr. Hiroyuki Nagoya, Research Center for Aquatic Breeding, National Research Institute of Aquaculture, Japan Fisheries Research and Education Agency
- Dr. Kichiro Matsumoto, Executive Board Member, Japan Medical Association

The Sub-Committee's Advisor is:

- Dr. Akira Onishi, Professor, Laboratory of Animal Reproduction, Department of Animal Science and Resources, Nihon University

The meeting began by reviewing genome edited technology in the history of selection and breeding in agriculture. Examples discussed included, but were not limited to, natural point mutation in japonica rice for seed shattering, artificial mutations in eggplant for parthenocarpic trait, etc. Participants also presented on the classification of genome editing technology (e.g., site directed nucleases – 1, 2 and 3), as well as on products currently in the research and development phase in domestic (Japanese) research institutes – e.g., feed rice with high-yield trait and potato without inert toxic substances. The discussion ultimately focused on two issues:

1. The regulatory position/classification of foods and agricultural products obtained by genome

editing technology in Food Sanitation Act, with a focus on gene changes, breeding processes (such as the removal of inserted DNA molecules), organism types, etc. by comparison with those obtained via conventional breeding techniques and recombinant DNA techniques; and,

2. Detection methods for foods and agricultural products obtained by genome editing technology.

The Sub-Committee discussed the risk of off-target and unintended mutation by using genome editing technology, however, plant breeding experts pointed out that the mutations consistently occur during natural reproduction and traditional breeding processes. The Sub-Committee also emphasized the importance of practical detection method to be available for products being regulated. As a result, the Sub-Committee agreed that product would be regulated as genetically engineered (GE) only when it contains a "foreign" gene(s). At the same time, the Sub-Committee agreed that developers shall report technical information on their products to the regulatory authority, even if the product is exempted from current GE regulations.

MHLW plans to hold have a few more meetings of the "Research Sub-Commission for Genetically Modified Food" in October and November 2018, and will then summarize the expert opinion of the participants for the "Research Committee for Newly Developed Food" (the Committee). The Committee will then review the opinion from the Sub-Committee by January 2019, and this review will be followed by a public comment period in February 2019. By the end of March 2019, the "Pharmaceutical Affairs and Food Sanitation Council" plans to formally clarify the policy for handling of foods obtained by using genome editing technology under the Food Sanitation Act and establish MHLW's official position (guidance on how to implement the policy will come later).