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Japanese Health Ministry Continues Discussions on Genome Edited Food

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Report Highlights:
Japan's Ministry of Health, Labour and Welfare held its second and third public discussions on the handling of food products derived from genome editing technology on October 15 and November 19, 2018, respectively. The "Research Sub-Committee for Genetically Modified Food" (the Sub-Committee) continued its discussions with a focus on the risk of off-target mutation, the handling of food products being categorized as not-genetically engineered (GE), and the mechanisms and scope for voluntary notification for non-GE products. The Sub-Committee also invited representatives from six groups to present their views on genome editing technology. The Sub-Committee's next discussion is expected to be held on December 5, 2018.

General Information:
Building on the Japanese Ministry of Health, Labour and Welfare's (MHLW) first public discussion on the handling of food products derived from genome editing technology (see JA8077), the Sub-Committee met on October 15 and on November 19 to continue their discussions on key concerns.

In general, Sub-Committee members were of the following opinion:

- The regulatory discussion of genome editing technology should be focused on the food safety of a product derived from that technology rather than the technology itself.
- In terms of regulatory enforcement, members believed it is important to recognize that some products derived from genome editing technology cannot be scientifically or technically distinguished from the products that are naturally occurring or derived from traditional breeding.
- Members argued it is important to be aware that off-target mutation occurs naturally. Furthermore, off-target mutation by the use of genome editing technology (CRISPR-Cas9) is not necessarily any more frequent than what takes place in naturally occurring processes.
- The confirmation of the absence of foreign genes in final products is important. If this cannot be done, then the products will be considered genetically engineered (GE).
- It is important to confirm that the products will not produce new and/or additional allergenic substances because of genome editing. Confirmation methods need to be determined after consideration of the feasibility of the method as well as global movements.
- The inert components and metabolites in crops vary significantly by cultivars, time, location, etc. Therefore, the study for the effects of genome editing technology on components and metabolites should be focused only on those components and metabolites that the genome edit intended to change.
- Non-GE genome edited products should be "registered" with the authorities. However, the contents of a "registration" require further discussion.

After the briefing by MHLW regulators, representatives from six organizations were invited to present their opinions and concerns:

1. Mr. Yoshiharu Kumagai, the Director General, Council for Biotechnology Information Japan
    - Plant products derived from genome editing technology should not be regulated as products from traditional breeding techniques are not regulated. Furthermore, unintended mutation is far less frequent in genome editing technology when compared with mutation breeding (e.g., radiation breeding) which are not considered or regulated as GE.
    - Plant products of self-cloning and natural occurrence produced by genome editing technology should be exempted from GE regulations, as the microorganisms of self-cloning and natural occurrence are already exempted from GE regulations.
    - The contents of any "report" to be required for non-GE products with genome editing technology shall not be an excessive burden for developers.

2. Dr. Takeshi Izawa, Board Member for Access and Benefit Sharing/Living Modified Organisms,

Japanese Society of Breeding (also Professor, Laboratory Plant Breeding and Genetics, Faculty of agriculture, The University of Tokyo)

- Plant breeding has a history of 10,000 years to have changed and edited genes. Although traditional breeding led to a large number of genetic changes in plants, the selection process allows us to choose useful traits for humans.
- Genome editing technology will allow us to make more precise breeding with less unintentional mutation which will speed up of the breeding process and the breeding of crops with poliploidy.
- It is important to have access to genome editing technology for agricultural crops to be able to address the global challenge we face - one billion people suffering from hunger and two billion suffering from malnutrition.

3. Ms. Mutsuko Nimura, Japanese Consumers' Co-operative Union
    - Consumers are concerned about the safety of new technology, its rapid development, and are uncertain about the potential for the commingling of products in the distribution channel.
    - The technology itself has to be evaluated and the technology application (i.e., products) should be regulated.
    - Consumers need more information and the opportunity to participate in the risk communication process for genome editing technology.

4. Ms. Hiroko Yoshimori, Co-Chair, The Forum for Seeds, Foods and Human
    - MHLW should provide a hearing opportunity to collect views from a wider array of stakeholders including, but not limited to, marketers, retailers and growers.
    - The relevant authority has to conduct increased risk communication with consumers before making policy decisions because some consumers might not be able to express their views via a public comment period, as it requires a higher level of scientific and technical knowledge to file comments.
    - By educating people that some products derived from genome editing technology might not be distinguishable from products derived through traditional breeding, the authority may not require a specific label or traceability. The technology at present has not matured enough for commercial application.

5. Dr. Keisuke Amagasa, Co-Chair, Consumer Union of Japan
    - A number of researchers and reports identify safety concerns (e.g., related to allergenicity and toxicity) with products derived from genome editing technology. Therefore, strict safety reviews should be required.
    - The public understanding of genome editing technology is extremely limited. Therefore, the government should not rush into a policy decision on genome editing technology.
    - As a number of new breeding technologies are under development, there is a limited ability to regulate all technologies under Japan's Food Sanitation Act. The government should discuss revisions to the current laws before discussing a policy for genome editing technology.

6. Ms. Maki Morita, Chair, Food Communication Compass
    - Discussion on food safety needs to be transparent and sufficient as the general public

does not have enough recognition of genome editing technology.
- What constitutes adequate data requirements for non-GE products from genome editing technology should be fully discussed.
- A system to ensure the registration of non-GE products derived from genome editing technology is necessary.

After the presentations, members of the Sub-Committee addressed what they perceived to be certain misunderstandings and misrepresentations of genome editing technology by some of the six speakers (e.g., citing information from retracted scientific articles and misinterpreting research results).

The Sub-Committee's next discussion is expected to be held on December 5, 2018.