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Health Ministry Proposes Draft Genome Edited Food Policy

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Report Highlights:
On December 5, 2018, Japan's Ministry of Health, Labour and Welfare (MHLW) held its fourth public discussion on the handling of food products derived from genome editing technology. The "Research Sub-Committee for Genetically Modified Food" (the Sub-Committee) reviewed previous discussions and proposed a general policy for the handling of genome edited foods. MHLW is expected to establish a domestic public comment period in the near future.

General Information:
After multiple discussions by scientific experts and a hearing from six interested parties (see JA8077 and JA8106), the Sub-Committee met on December 5, 2018, to propose a draft policy for the handling of genome edited foods:

1. **Handling of Foods Derived from Genome Edited Technology**

- The foods derived from genome editing technology that contain transgenic genes and/or fragments of transgenic genes are considered as (the foods derived from) recombinant DNA technology and required to undergo a safety review under the current standards and regulations.

- When there are no transgenic genes and/or fragments of transgenic genes in the final product, the genome edited foods will not be considered to be foods derived from recombinant DNA technology, as long as, the DNA double-strand break induced by engineered restriction enzyme and following repair (i.e., mutation) is:

  a) base-pair deletion;
  b) substitution;
  c) naturally occurring gene deletion; and/or,
  d) concomitant insertion (mutation) of one to several base pairs

  Also, as these mutations can occur during the natural process of repairing a break site and in traditional breeding technology, neither of which falls into recombinant DNA technology, it is appropriate to handle it differently from genetically engineered (GE) foods.

- In addition to confirming that food from genome editing is as safe as the food obtained by conventional breeding technologies, for the understanding and monitoring of the spread of the technology in the market, it is reasonable to request information from developers on their developed food. Some of this information should be published for public understanding, while respecting the need to protect certain elements that constitute proprietary information.

- The degree of mutation in non-GE genome edited foods is not to exceed the range of mutation by conventional breeding technology (such as natural mutation and induced mutation). Also, the information will facilitate Japan's ability to monitor technological adoption in the market. Furthermore, non-GE genome edited food products are not be distinguishable from the product derived from conventional breeding technology. Therefore, there is no legal mandate for the submission of product information by developers.

  However, it has been proposed to request developers to provide certain product outline information (which will be shared with the Sub-Committee) which will be released to the public (extending necessary protections to business proprietary information). The

information developers should provide includes:

a) Crop type, cultivar name, how to use/eat and the purpose of use;
b) The method and content of genome editing (target gene, function and altered function of the target gene, phenotypic change, etc.);
c) Information confirming that there has been no manufacture of allergenic substances or increases in pre-existing toxic substances observed in DNA mutation (including off-target);
d) Information confirming the absence of transgenic gene(s) and fragments of transgenic gene(s) in the product; and,
e) With regard to the modified metabolic pathway, information on major components (e.g., nutritional components, etc.).

- In addition to determining the applicability of the non-GE classification (by confirming the absence of transgenic gene and fragments of transgenic gene(s)), it is necessary for developers to confirm the presence of off-target mutation in the regions of high probability of off-target mutation by using search tools (e.g., GGgenome). If off-target mutation is confirmed in the regions of target or there is a high probability of off-target mutation, developers need to confirm there is no production of new protein(s) with allergenicity and/or toxicity by frameshift mutation.

- If a developer cannot make a clear decision on the applicability of the non-GE classification and/or absence of allergenic substance production due to the sequence condition, they should hold a consultation with MHLW. Based on the result of consultation on the applicability to the non-GE classification and/or absence of allergenic substance production, the product may need to be subjected to a safety review as a GE product.

- A consultation mechanism for the safety of foods derived from genome editing technology needs to be established for developers.

- Regarding the handling of transgenic DNA technology (including self-cloning and natural-occurring), it should be further evaluated as technology develops and knowledge is accumulated. Also, the issue needs to be discussed consistent with MHLW's policies of recombinant DNA and genome editing technologies.

2. Handling of Food Additives Derived From Genome Edited Organisms

- Additives manufactured from genome edited organisms and whose technology is considered recombinant DNA technology need to go through the safety review process under the GE regulations and standards.

- Additives manufactured from genomic edited organisms and whose technology applied is <u>not</u> considered recombinant DNA technology are subjected to the MHLW reporting requirements specific to food additive substances. Regarding the highly purified additives derived from genome edited organisms, reporting information may not be

necessary because the highly purified additives from genetically modified organisms have expedited approval processes already.

- Based on the current practice for the handling of additives with recombinant DNA technology, it is not necessary to report information on additives from genome edited microorganisms which fall under the self-cloning and natural occurrence.

3. Risk Communications Need to Continue for the Public

- The risk communication for all breeding technologies, including genome editing and recombinant DNA, as well as its food safety, needs to be continued to increase consumers understanding.

4. Refinements Should be Considered as Technology Develops

- As genome editing technology and detection methods are expected to develop continuously, the food safety aspect of genome editing technology needs to continue to be monitored.

- A survey of how genome editing technology is handled in other countries needs to be conducted from a food safety perspective. When new scientific knowledge and/or concerns in relation to food safety emerge, Japan's policy has to be reviewed as needed.

Next Steps

After finalizing the proposal by reflecting comments and opinion from the Sub-Committee in the fourth meeting, MHLW held a meeting of the "Research Committee for Newly Developed Food (the Research Committee)" on December 18, 2018, to review and potentially validate the conclusions of the Sub-Committee. However, as the presented policy is still under development, the details herein are subject to change depending on the results of the Research Committee's review and draft recommendation expected sometime in January 2019.

It is also expected that MHLW will hold a domestic public comment period in the near future.