Date: 8/22/2018
GAIN Report Number: JA8064

Japan

Post: Tokyo

Japan Holds Second Meeting to Discuss Genome Editing Technology

Report Categories:
Biotechnology and Other New Production Technologies
Approved By:
Christopher Riker
Prepared By:
Suguru Sato

Report Highlights:
On August 20, 2018, Japan's Ministry of Environment (MOE) held its second technical meeting to discuss the handling of genome editing technology under the Cartagena Protocol on Biosafety. The MOE members of the "Expert Meeting of Genome Editing Techniques" agreed that as long as a product does not contain nucleic acids from a foreign source, it should not be regulated under the existing genetic engineering regulations in Japan. The MOE plans to have an "Advisory Panel on GMOs" meeting in the near-term which will include legal experts to discuss the acceptability of the conclusion from this technical committee meeting.

General Information:

After internal discussions on the regulatory handling of genome editing technology, Japan's Ministry of Environment (MOE) held its first "Expert Meeting of Genome Editing Techniques" for Japanese Fiscal Year (JFY) 2018 (April 2018 – March 2019) to discuss the handling of genome editing technology under the Cartagena Protocol on Biosafety. The committee consisted of 12 academic experts and was chaired by Dr. Ryo Osawa, a professor at the University of Tsukuba in Japan. For additional information on this meeting, see JA8048.

On August 20th, Japan held its second "Expert Meeting of Genome Editing Techniques" where the committee continued to discuss two issues:

1) The scope of genome editing technologies which could potentially be regulated under the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" known as the Cartagena Protocol on Biosafety (the Cartagena Protocol), and

2) The handling of technologies which would be out of scope of the Protocol as the result of discussion of Issue 1).

The committee concluded that the products from genome edit technology which do not contain "foreign nucleic acids and/or its copies" will not be categorized as genetically engineered (GE) under the Cartagena Protocol (e.g., null segregant). Similarly, the modification of the genome and the introduction of genes which could occur naturally and/or conventional cross breeding won't be regulated as GE either (e.g., self-cloning and natural occurrence).

The table below summarizes the draft conclusion proposed by the committee in the second meeting on August 20, 2018.

Table 1. (Draft) The Handling of Living Organisms Obtained through Genome Editing Technologies under the Protocol

<table>
<tr><td></td><td>SDN-1, etc.</td><td colspan="2">SDN-1, SDN-2, SDN-3, etc.</td></tr>
<tr><td></td><td>Host organism does not contain nucleic acids modified outside of the host cell</td><td colspan="2">Nucleic acids modified outside of the (host) cell were transferred to the host</td></tr>
<tr><td rowspan="3">Confined environment</td><td rowspan="3">When used with containment measures, no request for information from the applicants</td><td colspan="2">Type 2 use: The use of living modified organisms (LMOs, therefore not limited to plants) with containment measures</td></tr>
<tr><td>No remaining and/or replicate of nucleic acids modified in the extracellular space are in the final product</td><td>Remaining and/or replicate of nucleic acids modified in the extracellular space are in the final product</td></tr>
<tr><td>When used with containment measures, no request for information from the applicants</td><td>Type 2 use: The use of living modified organisms (LMOs, therefore not limited to plants) with containment measures</td></tr>
<tr><td>Open environment</td><td>Request for product information, including the assessment of the potential impact on biodiversity</td><td>Request for product information, including the assessment of the potential impact on biodiversity</td><td>Type 1 use: Conduct an assessment of the impact on biodiversity</td></tr>
</table>

	LMOs considered to be regulated under the Cartagena Protocol (genetically engineered)
	Organisms out of scope of the Cartagena Protocol. The relevant ministry will request information on the organism

For the organisms that fall outside of the Cartagena Protocol, the committee drafted a list of information the regulatory agency may wish to obtain:

(a) Information of the organism that has no remaining nucleic acid and/or its replicate which are modified extracellularly as defined in the Protocol;
(b) Taxonomic/species information of the target organism;
(c) The method being used in genome editing;
(d) Information on the edited gene and its function;
(e) Phonotypical change obtained by the edit;
(f) Presence (or non-presence) of other modifications other than (e);
(g) Purpose (use) for the edited organism; and,
(h) Assessment of the potential impact on biodiversity.

This proposal covers all organisms, not only agricultural crops but also microorganisms, products in the research and development (R&D) process and others. However, there is no detailed information on the depth and scope of information the regulator may seek. FAS/Tokyo expects each regulatory agency will provide guidance language as Japan's regulatory environment develops (example: guidance from the

Ministry of Health, Labor and Welfare for microorganisms in R&D for pharmaceutical use, the Ministry of Agriculture, Forestry and Fisheries for agricultural crops under the Cartagena Protocol, etc.).

The MOE plans to have another meeting, known as an "Advisory Panel on GMOs,"[1] in the near-term which will validate the conclusions of the "Expert Meeting of Genome Editing Techniques." The members of the Advisory Panel on GMOs would also include legal experts in addition to technical experts to determine the acceptability of the proposed regulatory handling of genome editing technology.

[1] This panel may include some of the members of the Committee on the "Expert Meeting of Genome Editing Techniques," as well as other non-governmental experts.