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Japan Discusses Genome Editing Technology

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Report Highlights:
On August 7, 2018, Japan's Ministry of Environment (MOE) committee met for the first time to discuss handling of genome editing technology under the Cartagena Protocol on Biosafety. Committee members agreed that "Site-directed nucleases-1" should not be regulated under the existing genetic engineering regulation. Other types of modification will be discussed in the coming months before the committee concludes its opinion by the end of October 2018.

General Information:
After internal discussions on the regulatory handling of genome editing technology, Japan's Ministry of Environment (MOE) held its first committee meeting for Japanese Fiscal Year (JFY) 2018 (April 2018 – March 2019) to discuss handling of genome editing technology under 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, Japan.

The meeting focused on the scope of genome editing products 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 (hereafter the Protocol).

Regarding nucleases used in genome editing technologies, the committee mentioned technologies using both protein-guided DNA-binding domain (e.g., ZFN, TALEN, etc.) and RNA-guided DNA-binding domain (e.g., CRISPR/Cas9). The discussion focused on how the technology would be used. The committee cited three categories for the application of genome editing technologies.

1. Site-directed nucleases-1 (SDN-1): After the intended site-specific cleavage of the DNA in the genome, random mutation (base substitution, insertion, or deletion) occurring for one or a few bases as a natural repair mechanism.
2. Site-directed nucleases-2 (SDN-2): Systematically induces mutation for one or a few bases by artificially synthesizing a short DNA fragment (template) that is homologous to the target base sequence and introducing it along with an artificial restriction enzyme at the time of cleaving.
3. Site-directed nucleases-3 (SDN-3): Forms a special DNA fragment at a specific domain on the genome by introducing a long DNA fragment containing a gene of several thousand base pairs not originating from compatible same or related varieties (transgene) in a form sandwiched by sequences homologous to the target sequence.

The committee agreed that SDN-1 should not be regulated under the regulation of genetic engineering. At the same time, a member commented that although SDN-1 is not regulated under the Protocol, there is a need to discuss how to ensure product safety.

The MOE committee meets next on Monday, August 20, 2018. The Ministry of Health, Labor and Welfare started internal discussion in spring of JFY2018. However, they have not held official committee meetings yet.