

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary - Public

Date: 9/25/2018

GAIN Report Number: J8075

Japan

Post: Tokyo

Environment Ministry Proposes Policy for Regulating Genome Editing

Report Categories:

Biotechnology and Other New Production Technologies

Approved By:

Christopher Riker

Prepared By:

Tomohiro Kurai and Suguru Sato

Report Highlights:

On August 29, 2018, the “Advisory Panel on Genetically Modified Organisms” of Japan’s Ministry of Environment held its second meeting to review recommendations made by the expert committee on the handling of genome editing technology under the Cartagena Protocol. The advisory panel concluded that any living organism with foreign nucleotide(s) remained in the host genome should be regulated regardless of whether the foreign nucleotide(s) is detectable. As a result, only “Site-directed nucleases-1” will fall outside the scope of existing regulations on genetically engineered organisms in Japan. This proposal has been made available for public comment until October 19, 2018.

General Information:

Japan's advisory panel of Genetically Modified Organisms¹ (hereafter "the Panel") held its second meeting on August 30 to determine the scope of genome editing techniques based on the conclusions of the expert committee meeting held on August 7th and 20th (see [JA8048](#) and [JA8064](#) for details).

Although the expert committee discussed the scope of genome editing technology and its regulatory handling based on product with consideration of applied technology, the Panel recognized the difficulty of technology-based control. Accordingly, the Panel decided to regulate on a product basis.

The Panel focused on what products should be exempted from the current regulations. The committee confirmed that any product not categorized as genetically engineered under the Cartagena Protocol, such as null segregant, is exempted from the current regulations. However, the Panel emphasized that until removal or absence of foreign nucleotides from the final product is confirmed, the product should be treated as biologically engineered and subject to regulation. Similarly, genome editing without the introduction of any foreign nucleotide (e.g. deletions or self-cloning) will not be regulated. Furthermore, genome editing with introduction of foreign nucleotide(s) derived from species which could naturally and/or conventionally cross with the host organism (e.g. natural occurrence) also fall outside of the Cartagena Protocol and will not be regulated.

The Panel also concluded that any biologically engineered product regardless of detectability and length of foreign nucleotide(s) falls under the scope of the Cartagena Protocol and, in turn, should be regulated.

Unlike the case of modified organisms regulated under the Cartagena Protocol, the current Japanese law does not require users to submit information on "non-genetically modified organisms" to the regulatory agency. However, the Panel recommended the Japanese Ministry of the Environment (MOE) mandate developers/users submit the following information if the organisms are treated with genome editing technology:

- a) Information that the organism has no remaining nucleic acid and/or its replicate which are synthesized outside of host cells as defined in the Cartagena Protocol (Supporting scientific evidence required);
- b) Taxonomic/species information of the engineered organism;
- c) The method being used in genome editing;
- d) Information on the edited gene and its function;
- e) Phenotypical change obtained by the edit;
- f) Presence (or non-presence) of other modifications other than (e). (Detailed information if it does);
- g) Purpose (use) for the edited organism; and,

¹ Japan uses the term "genetically modified organisms (GMO)" in its regulations when referring to genetically engineered organisms.

h) Assessment of the potential impact on biodiversity.

This information requirement provision will be exempted if the engineered organism is used with containment measures defined by the regulatory agency based on Article 12 of the Cartagena Protocol. The MOE will make some of the provided information (e.g. (b), (e), (g) and (h)) publically available on the website of the “Japan Biosafety Clearing House” on an annual basis.

The MOE has established a public comment period until October 19, 2018, for these conclusions (see <https://www.env.go.jp/press/105960.html> {only in Japanese}) so that it can complete its review by the end of calendar year 2018. Comments are to be written in Japanese and submitted by email via text format (not in html) and without file attachment(s) to bch@env.go.jp, or by fax to 03-3581-7090 (+81-3-3581-7090 from outside Japan). Interested parties are requested to include the following in their submission:

- The following subject line:
“「ゲノム編集技術の利用により得られた生物のカルタヘナ法上の整理及び取扱方針について(案)」に対する意見”
- Name of applicant
- Address
- Phone number
- Fax number
- Comment (and reference if applicable)

The MOE has stated it does not intend to revise the current law. Instead, it will notify the public of its final decision via ministerial notification published on its website. Accordingly, there will be no WTO notification on this issue.

Annex 1: Flow chart for Determining the Japanese Regulation for Biologically Engineered Living Organisms with Genome Edited Technology

