

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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POLICY

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Environment Ministry Finalizes Policy for Regulating Genome Editing

Report Categories:

Biotechnology and Other New Production Technologies

Agricultural Situation

Grain and Feed

Oilseeds and Products

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Report Highlights:

On February 8, 2019, Japan's Ministry of Environment released its final policy for the regulation of genome editing technologies. In its policy, the ministry established the conditions under which genome edited organisms will be not considered to be living modified organisms.

General Information:

As the final step in its development process (see, e.g., [JA8048](#), [JA8064](#) and [JA8075](#)), Japan's Ministry of Environment (MOE) released its final policy for the regulation of genome editing technologies (<https://www.env.go.jp/press/106439.html>, in Japanese) on February 8, 2019.

Regulatory Policy for Genome Editing Technology

In its policy, the MOE states that any genome edited organism in which there is inserted extracellularly processed nucleic acid will be considered to be a living modified organism (LMO) and is subject to the regulations of the "[Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms](#)" (Cartagena Act, in Japanese and English).

The MOE also provided specific conditions under which the Cartagena Act will not be applicable to the genome edited organism (conditions under which the organism will not be considered an LMO). In short, when an organism is not obtained by inserting nucleic acid that was processed extracellularly, the organism is not considered a living modified organism (LMO) as specified in the Cartagena Act. Also, if the organism is obtained by inserting nucleic acid that was processed extracellularly, the organism is not considered an LMO (as specified in the Cartagena Act) as long as the organism is confirmed to have no remnants of inserted nucleic acid or its replicated product.

The MOE identified three instances under which an organism would not be considered a living modified organism (LMO) under the Cartagena Act.

1. When an artificial nuclease composed only of protein is directly transferred into a cell, it will not be considered to be an LMO since it does not contain extracellularly processed nucleic acids. Also, when an artificial nuclease composed of protein and RNAs (nucleic acids), or artificial nuclease's mRNA (nucleic acids) is directly transferred into a cell, it will not be considered to be an LMO, as long as the transferred RNAs (nucleic acid) and/or its replicate is not integrated into the host's genome.
2. When artificial nuclease gene is integrated into a vector and the vector is transferred into a cell for transient expression, even though it uses a technology to process nucleic acid extracellularly, it will not be considered to be an LMO as long as the vector containing the artificial nuclease gene is not transferred or replicated into the host genome.
3. When extracellularly processed nucleic acids are integrated into the host genome, it will be considered to be an LMO. However, when the integrated gene(s) is eliminated through backcrossing with conventional cultivars, the finally obtained organism will not be considered to be an LMO (null segregant) since the finally obtained organism does not contain extracellularly processed nucleic acids or its replicates.

It is important to note that the organism transferred with extracellularly processed nucleic acids is regarded as an LMO, and regulated under the Cartagena Act, until it is confirmed that there are no remnants of inserted nucleic acids or its replicated products. If the finally obtained organism contains extracellularly processed nucleic acids and/or their replicates integrated into the host's genome, it will be considered to be an LMO.

The MOE has noted that organisms obtained through the use of technologies as follows will not be

considered LMOs:

- Technologies to induce mutation (chemical treatment, irradiation, protoplast culture, ion beam irradiation, etc.)
- Technologies to induce polyploidy (chemical treatment, pressure treatment, etc.)

Also, when only the nucleic acids of an organisms of the same taxonomic species as the host are used (self-cloning), or when only nucleic acids of an organism belonging to the species that exchange nucleic acids with the taxonomic species to which the host belongs under natural conditions are used (natural occurrence), it will not be considered an LMO. For Japan's formal definition of LMO, please visit "[Regulation related to the Enforcement of the Cartagena Law](#)" at Japan Biosafety Clearing House.

Provision and consultation of non-LMO genome edited organism

When any party is creating or importing and/or using or handling organisms obtained through genome editing technologies, the MOE requests the party to provide information to the Japanese regulatory authority before their use. The list of information the MOE requests is:

- a. Evidence indicating that the organism does not possess remnants of extracellularly processed nucleic acid or its replicated product, as stipulated in the Cartagena Act;
- b. Taxonomical species of the modified organism;
- c. Method of genome editing used for the modification;
- d. Modified gene and its functions;
- e. Change of traits added by the modification;
- f. Whether is a change of traits other than those described in "e" (describe the changes, if any);
- g. Usage/purpose of the organism; and,
- h. Discussion/rationale on biological diversity when the organism is used.

The MOE notes that some of the information reported from the party, mainly summaries of "b", "e", "g" and "h," will be posted to the website of the [Japan Biosafety Clearing House](#). Inquiries should be addressed to the relevant ministry corresponding to the use of the organism (note Attachment 1). Although the MOE announced the regulatory policy for genome editing technology, specifics on the practical process of product consultation for developers has not yet been established by the relevant ministries related to agriculture and food products. It is expected that the Ministry of Agriculture, Forestry and Fishery (for agricultural crops and animals) and the Ministry of Health, Labour and Welfare (for foods) will develop regulatory policies and consultation systems for each subject. The MOE has also provided the summary guideline in English (see note Attachment 1, also available on the [MOE's website](#)).

To Genome Editing Technologies Users

- Any organism that inserted extracellularly processed nucleic acid (including RNA) is regarded as a living modified organism (LMO), even those obtained using genome editing technologies, and is subject to the regulations stipulated in the Cartagena Act, in principle.
- Such organisms are subject to the Cartagena Act unless complete removal of the inserted nucleic acid (including RNA), or its replicated product, is confirmed.
- When using organisms obtained through genome editing technologies, please submit information to the competent government agencies (see back), even when the organism is not subject to the Cartagena Act.

First, using the chart below, check the applicable regulations and laws pertaining to the organisms obtained.

Is the organism obtained by inserting nucleic acid that was processed extracellularly?

Regarded as LMO specified in the Cartagena Act (subject to the regulations).
[Type 1 Use, Type 2 Use] See table below

YES

NO

Is the organism confirmed that it has no remnants of inserted nucleic acid or its replicated product?

NO

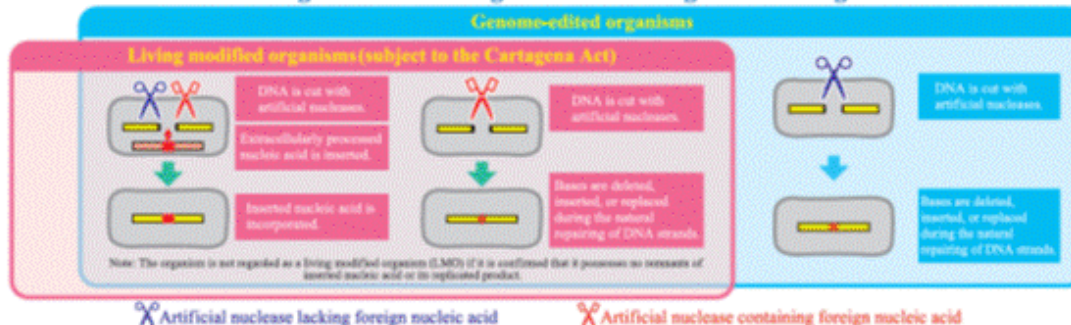
YES

The organism is regarded as LMO specified in the Cartagena Act (subject to the regulations).

The organism is not regarded as LMO specified in the Cartagena Act (not subject to the regulations).

Containment measures	The organism is regarded as LMO specified in the Cartagena Act (subject to the regulations).		The organism is not regarded as LMO specified in the Cartagena Act (not subject to the regulations).	
	No	Type 1 Use Use the organism by following the regulations approved by the Minister based on the assessment of adverse effect of biological diversity, in accordance with Article 4 of the Act.		Use the organism after providing information concerning the traits and discussions on adverse effect of biological diversity of the organism to the competent government agencies. See the back
Yes	Type 2 Use Use the organism by taking the containment measures stipulated in the ordinances based on Article 12 of the Act or containment measures approved by the Minister based on Article 13 of the Act.		Use the organism by taking the containment measures stipulated in the ordinances based on Article 12 of the Act or measures approved by the competent government agencies as measures that can prevent dispersal of the organism.	

Reference: genome-edited organisms and living modified organisms



Ministry of the Environment

Please provide information concerning organisms obtained through genome editing technologies.

The Ministry of the Environment and competent government agencies are compiling knowledge about and learning about conditions concerning the influence of organisms obtained through genome editing technologies on biological diversity.

When creating or importing and/or using or handling* organisms obtained through genome editing technologies, you are requested to **provide information** before their use, to the competent government agencies regarding the following items, even if it is confirmed that the organisms are not regarded as LMOs.

When the country which users would like to export implements import regulations other than this information providing, please follow the regulations.

* Using or handling: Activities including using, cultivating or raising/growing, processing, storing, transporting, and disposing of, as well as other activities that accompany these activities to provide food, animal feed, or for other related purpose.

Please provide information on the following items.

- a The fact that the organism does not possess remnants of extracellularly processed nucleic acid or its replicated product, as stipulated in the Cartagena Act (including bases of decision)
- b Taxonomical species of the modified organism
- c Method of genome editing used for the modification
- d Modified gene and its functions
- e Change of traits added by the modification
- f Whether there is a change of traits other than those described in c. Please describe the changes, if any.
- g Usage of the organism
- h Discussion on possible influences on biological diversity when the organism is used.

◆ Part of the information provided (mainly a, b, c and h) will be posted on the Japan Biosafety Clearing House (J-BCH) Website (<http://www.biodic.go.jp/bch/>).

◆ When a question arises concerning possible influence on biological diversity, or when it is deemed necessary due to the species involved, the competent government agencies may request the user to provide additional information that is needed and may take necessary measures.



J-BCH
Website

Please send inquiries to:

Competent government agencies	Applicable organisms	Phone number
Ministry of the Environment / Office for Alien Species Management, Wildlife Division, Nature Conservation Bureau	All organisms	03-5521-8344
Ministry of Agriculture, Forestry and Fisheries / Plant Products Safety Division, Food Safety and Consumer Affairs Bureau	Agriculture and forestry products, veterinary medicine, etc.	03-6744-2102
Ministry of Economy, Trade and Industry / Commerce and Service Industry Policy Group, Bio-Industry Division	Organisms used in the manufacturing processes of industrial products, etc.	03-3501-8625
Ministry of Health, Labour and Welfare / Health Science Division	Organisms used for medical products and gene therapy, etc.	03-3595-2171
Ministry of Education, Culture, Sports, Science and Technology / Office for Bioethics and Biosafety/Life Sciences Division/Research Promotion Bureau	Organisms used for experiments in research, etc.	03-6734-4113
National Tax Agency / Director (Analysis and Brewing Technology), Taxation Department	Organisms used for the production of alcoholic beverages	03-3581-4161

Inquiries regarding safety assessment of genetically modified foods: Ministry of Health, Labour and Welfare (phone (operator): 03-5253-1111)
Inquiries on labeling of food products: Consumer Affairs Agency (phone (operator): 03-3507-8800)