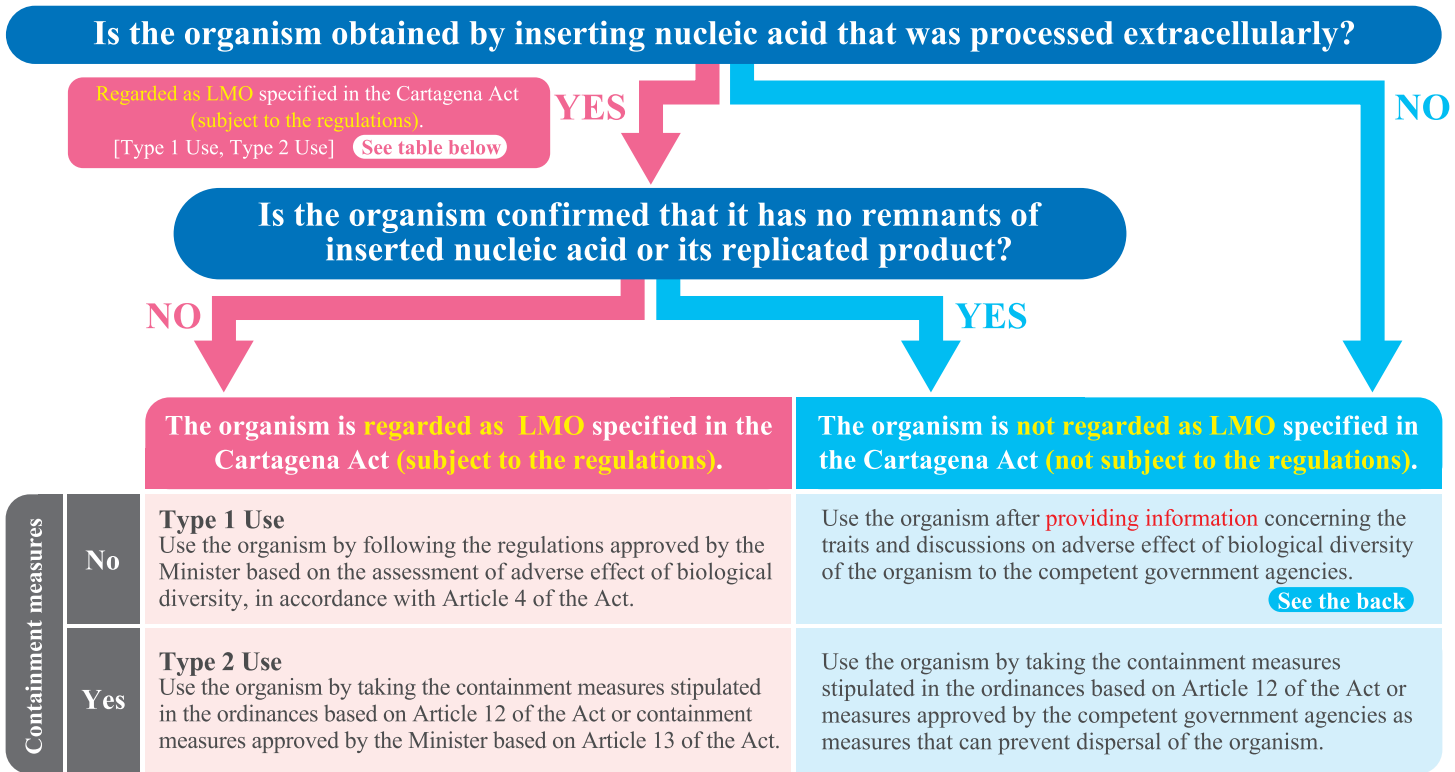


To Genome Editing Technologies Users

- 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.

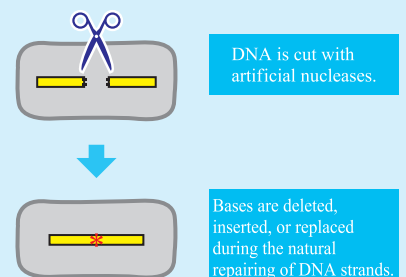
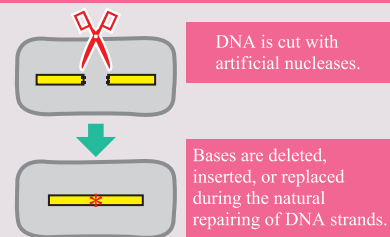
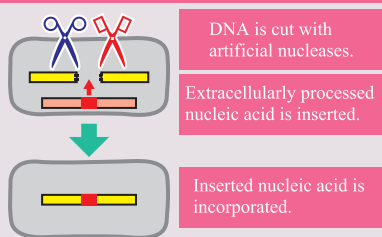
First, using the chart below, check the applicable regulations and laws pertaining to the organisms obtained.



Reference: genome-edited organisms and living modified organisms

Genome-edited organisms

Living modified organisms (subject to the Cartagena Act)



Note: The organism is not regarded as a living modified organism (LMO) if it is confirmed that it possesses no remnants of inserted nucleic acid or its replicated product.

Artificial nuclease lacking foreign nucleic acid

Artificial nuclease containing foreign nucleic acid



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 **e**. 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 **b**, **e**, **g** 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)