

Biosafety Regulations in Japan

Act on the Conservation and Sustainable Use
of Biological Diversity Through Regulations
on the Use of Living Modified Organisms

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地球のいのち、つないでいこう



生物多様性

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Nowadays, rapidly-developing gene-recombination technology is used for many kinds of research and industrial fields that support our life. Among these fields are agriculture, medicine, and industry. Recombinant DNA technology also holds possible alternatives that can provide solutions to global food problems and environmental concerns. However, on the other hand, when we use the recombinant DNA technology, we need to consider the effects on “biological diversity”* and the safety of food, feed, and medical supplies.

This brochure introduces the system in Japan to check beforehand whether the use of Living Modified Organisms affect biological diversity or not.

* There are around 30 million kinds of life that evolve by adapting to a variety of environments on the face of the earth. These life forms are connected with natural spaces such as forests, mountains and rivers. In addition, even in same species, different genes make different characteristics of shapes, colors, and behavior. These “characteristics” and “connections” are called “biological diversity.”

What are Living Modified Organisms (LMOs)?

The process of removing specific genes* from an organism and introducing them to another organism is known as “recombinant DNA technology.” The organisms into which the new characteristics have been incorporated with this technology are called “Living Modified Organisms (LMOs).”

Traditional breed improvements are not different from changing genes by hand. However, the recombinant DNA technology has features that make it possible to introduce “beyond species,” “in a short time,” “aimed characters for certainty.”

* Genes are blueprints for producing many kinds of proteins, and determine the shapes, colors, and behavior. Usually it is composed of the substance called DNA (RNA, in some viruses).

GMO or LMO?

Although organisms created by recombinant DNA technology are generally referred to as Genetically Modified Organisms (GMOs), the Cartagena Protocol uses the term “Living Modified Organisms (LMOs).” The term refers to “living” organisms obtained using modern biotechnology including cell fusion across taxonomic families.

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Conditions for the Use of Living Modified Organisms

Today, LMOs have been developed and used in many countries around the world.

For example, in the field of agriculture, genetically modified crops which

possess the abilities to specific chemical resist herbicides and agriculture pests, are created from soybean, maize, rapeseed, etc. The cultivated area of genetically modified crops is increasing every year.

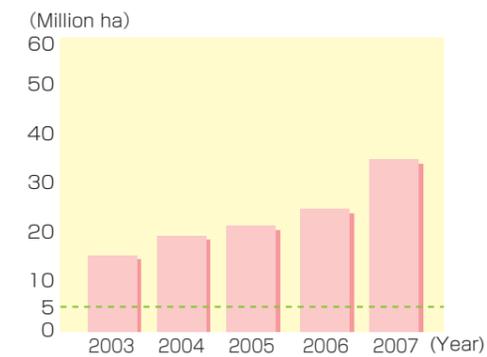
The Change of the Cultivation Area of Genetically Modified Crops

(Clive James, ISAAA2008)

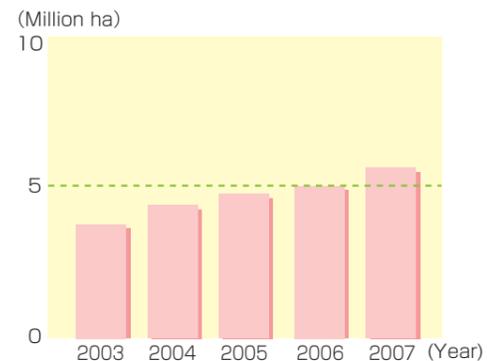
Soybean



Maize

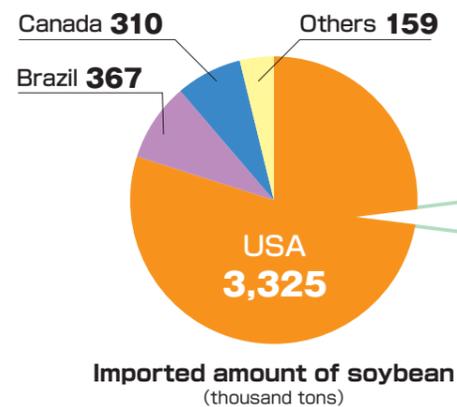


Rapeseed

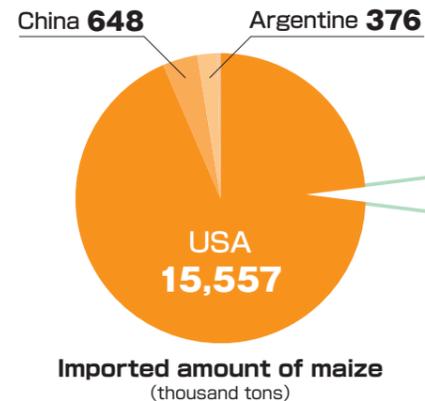


Japan's Import Volume by Individual Countries

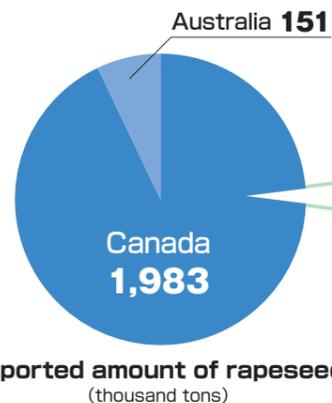
* including both of genetically modified and non- genetic modified (Trade statistics of Japan, ISAAA2007)



Imported amount of soybean (thousand tons)



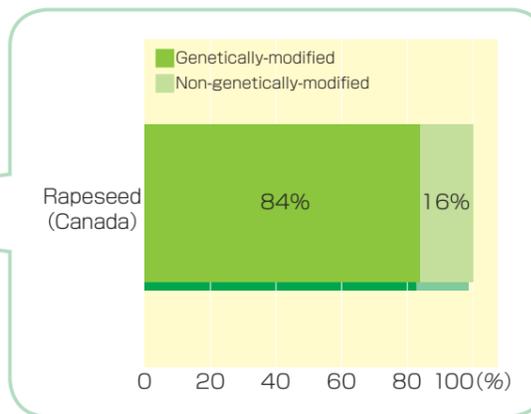
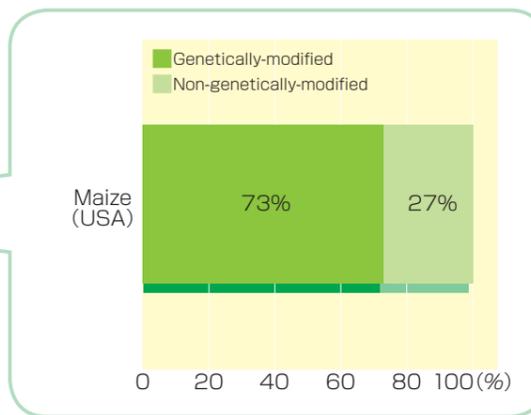
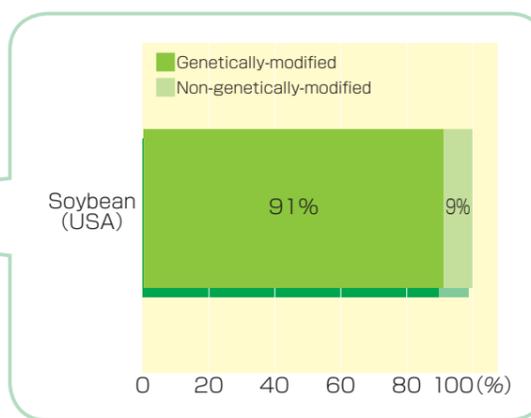
Imported amount of maize (thousand tons)



Imported amount of rapeseed (thousand tons)

The Cultivated Area's Percentage of Genetically Modified Crops in Japan's Import Trading Partner

(NASS 2007)



In the U.S. and Canada, (main import trading partners of Japan for soybean, maize, and rapeseed), the percentage of the cultivated area of genetically modified crops is high, and it leads to a high percentage of genetically modified crops in Japan's import trading by these countries. (Graphs do not show the actual percentage of imported genetically modified crops.) These genetically modified crops are mostly used for oil and feed.

Additionally, various LMOs are developed and used in Japan.

For example:

- Flowers with color that cannot get under the conventional technology, such as blue roses
- Recombinant viruses to use for cancer treatment
- Microbes which produce reagents or medicines, such as insulin, used for the treatment of diabetes

* The main genetically modified crops are soybean, maize, cotton, and rapeseed, and these four items occupy almost all of cultivated area of genetically modified crops.

What is the Cartagena Protocol?

The Cartagena Protocol is what set the rule to control international transfers of LMOs based on “The Convention on Biological Diversity,” which aims at conservation and sustainable use of biological diversity on the earth. (Medicine for human beings is excluded from this rule.)

The outline is,

- Exporter or exporting country of LMOs that are used for intentional introduction into the environment, for example cultivation, have to announce their partners in advance. Importing countries assess the effect of the LMOs on biological diversity and then decide whether or not they approve the importation based on AIA procedure.
- In regards to the genetically modified crops for the use as food, feed, or for processing, the AIA procedure is not required. However, when domestic utilization is decided, the information must be shared through BCH (Information System).
- It also provides for rules about handling, packing and identification of exporting LMOs.

AIA procedure



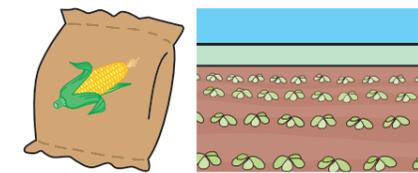
What is the Cartagena Act * ?

* Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of LMOs.

Cartagena Act is the law that regulates the use of LMOs, to ensure the precise and smooth implementation of the Cartagena Protocol on the Biosafety to Convention on Biological Diversity. This act provides for rules to assess the effect of LMOs on biological diversity in advance and also the way to appropriately use LMOs.

The Cartagena Act separates uses into two types and uses different approaches for evaluating each type.

Use under the open system



Type 1 Use: Uses for conveyance and cultivation for food, feed etc. Approved only when the LMOs are judged not to cause adverse effects on biological diversity.

Use under the closed system



Type 2 Use: Uses in laboratories, factories etc. Possible uses are those with containment measures to prevent to dispersal of LMOs in the environment.

For the remainder, the act provides the systems which examine import of non-approved LMOs, and the ways to provide the information to partners in exports.

History of the Cartagena Protocol

International Movement

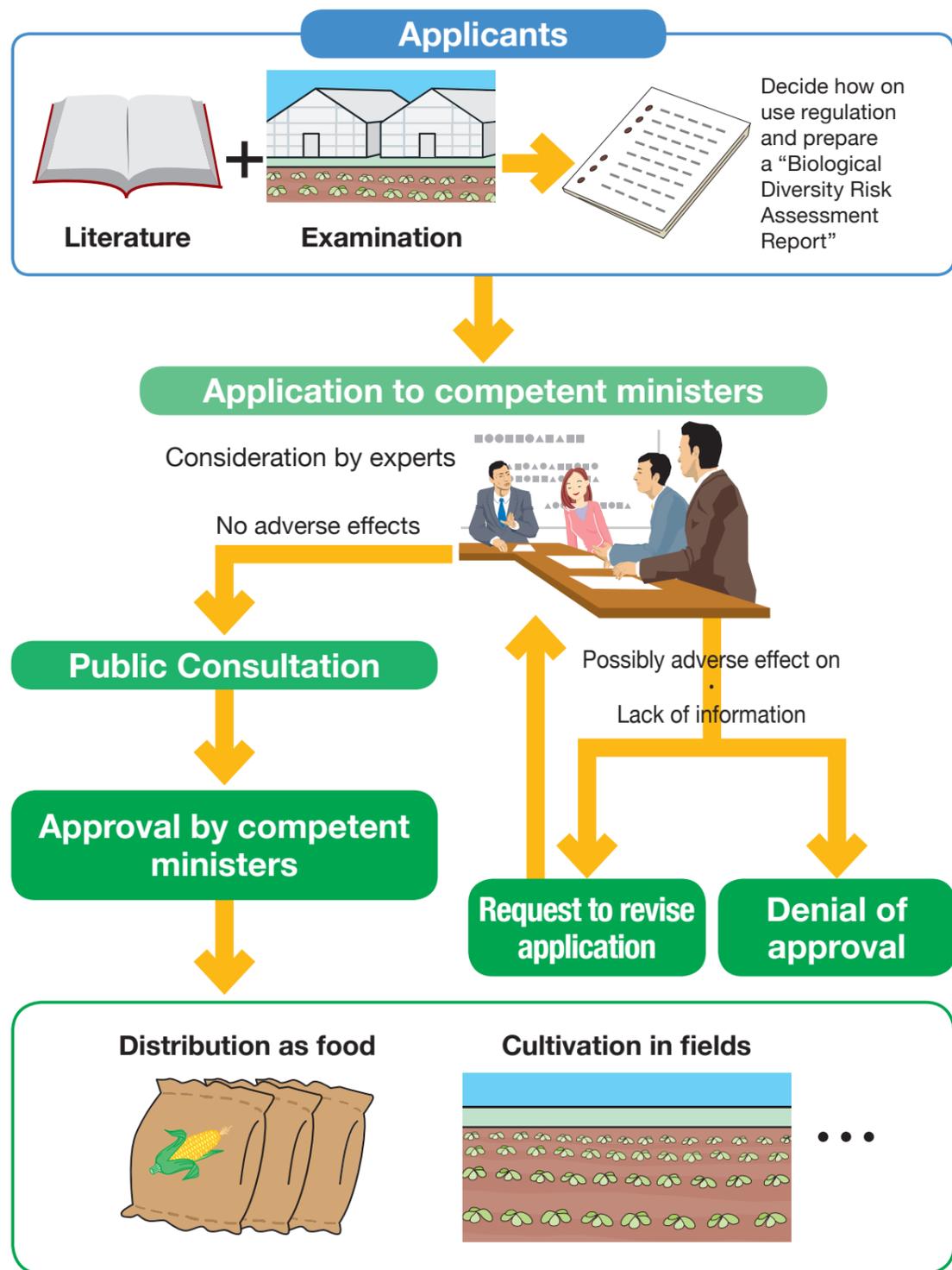
- December 1993 Convention on Biological Diversity enters into force
- November 1995 Second Conference of the Parties (Decide to start the negotiation to develop protocol on biosafety)
- January 2000 Adoption of Cartagena Protocol
- September 2003 Cartagena Protocol enters into force

Movement in Japan

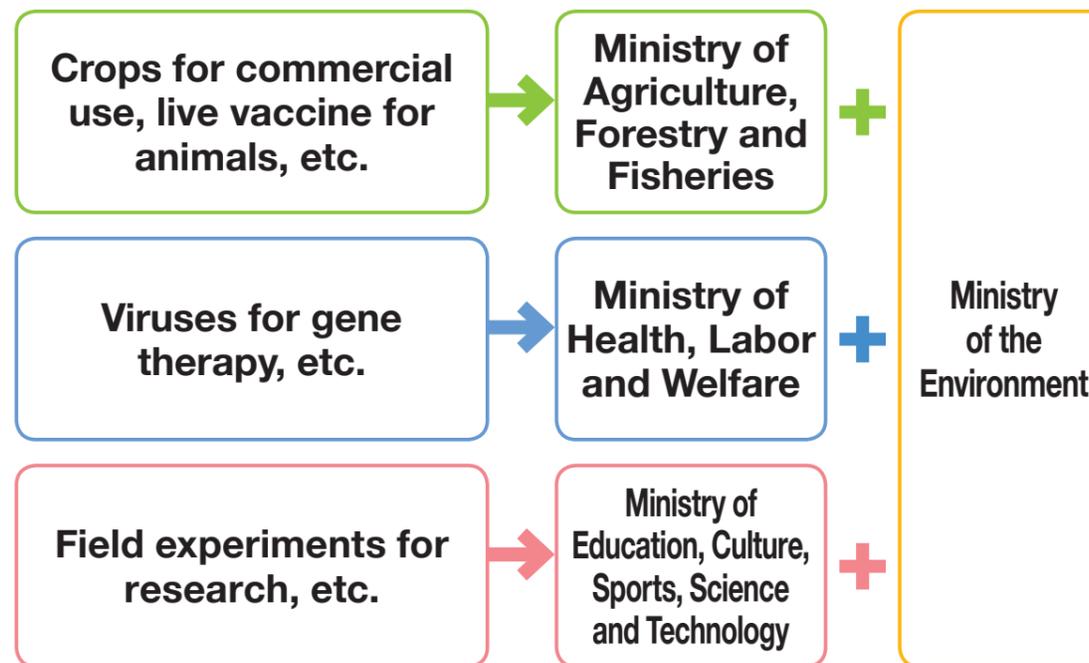
- February 2004 Cartagena Act becomes effective and the Cartagena Protocol enters into force in Japan.

* The Cartagena Protocol is named after the location of the Conference of the Parties which was held in Cartagena, Colombia, where the protocol was discussed in 1999.

From Application to Approval of Type 1 Use



Related ministries and the Ministry of the Environment (MOE) jointly manages Type 1 Use cases, depending on the LMOs' purpose and use. MOE is in charge of Type 1 Use in all fields because MOE need to decide whether the uses in open system affect biological diversity or not.



The following examples illustrate which ministries are in charge of Type 2 Uses:

- Improvements to crops in equipment, development of live vaccines for animals, etc. :
..... **Ministry of Agriculture, Forestry and Fisheries**
- Viruses for gene therapy, etc. :
..... **Ministry of Health Labor and Welfare**
- Uses in the experiments of gene recombination in University, etc. :
..... **Ministry of Education, Culture, Sports, Science and Technology**
- Uses in the process of production of industrial enzymes, etc. :
..... **Ministry of Economy, Trade and Industry**
- Yeast used in the production of alcoholic beverages, etc. :
..... **National Tax Agency**

Assessment of Effects on Biological Diversity

For Type 1 Use, applicants submit a biological diversity risk assessment report which evaluates the extent to which LMOs may affect biological diversity. Experts then review this assessment (see page 7).

In cases involving genetically modified crops, for example, a comprehensive

evaluation of the crop's effects on biological diversity is performed. If there is a native species that could be affected, the evaluation examines what the possible effects are and to what extent the species will be affected.

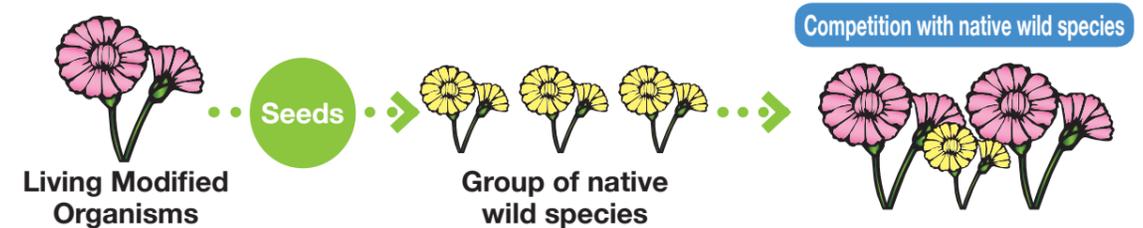
The influence of competition on native wild species by Living Modified Organisms

1

The points of view for assessment

Concern that the LMOs will compete native wild species for resources, including nutrients, sunlight and habitat etc., as well as the possibility of the LMOs becoming invasive:

- When compared with native species, does the LMO have morphological or developmental differences, such as plant height, seed production, germination rate, etc.?
- If so, do these differences affect native species?



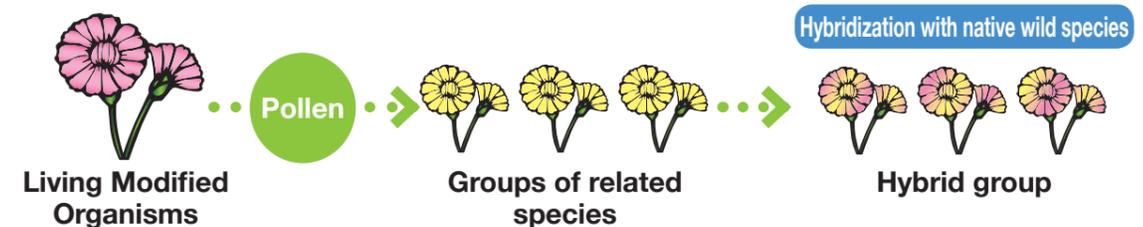
The influence of Living Modified Organisms hybridizing with native wild species

2

The points of view for assessment

Concern that hybridization with the LMOs will affect the native wild species populations:

- Is hybridization with native wild species possible?
- If so, to what degree will hybridization occur?
- Will hybrid varieties behave differently than native species?



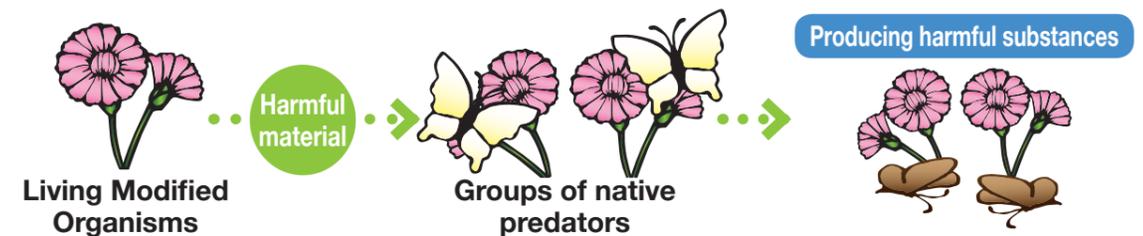
The influence of Living Modified Organisms which produces harmful substances

3

The points of view for assessment

Concern that the LMOs will produce substances harmful to the surrounding environment including other plants or insects:

- Does the LMO produce harmful substances?
- If so, are there insects which will eat the LMOs producing the substance?
- Will the LMO affect soil microorganisms?



Hybridization with Japanese Wild Species

In Japan, there are no native wild species that can cross with rice, maize or rapeseed. On the other hand, there are native Japanese wild species that can cross with soybeans, and also roses, for example wild soybean (*Glycine soja*) for soybeans, wild rose (*Rosa multiflora*) for roses.

Especially for those species, it is required to examine carefully if recombinant genes spread into groups of Japanese wild species or not.

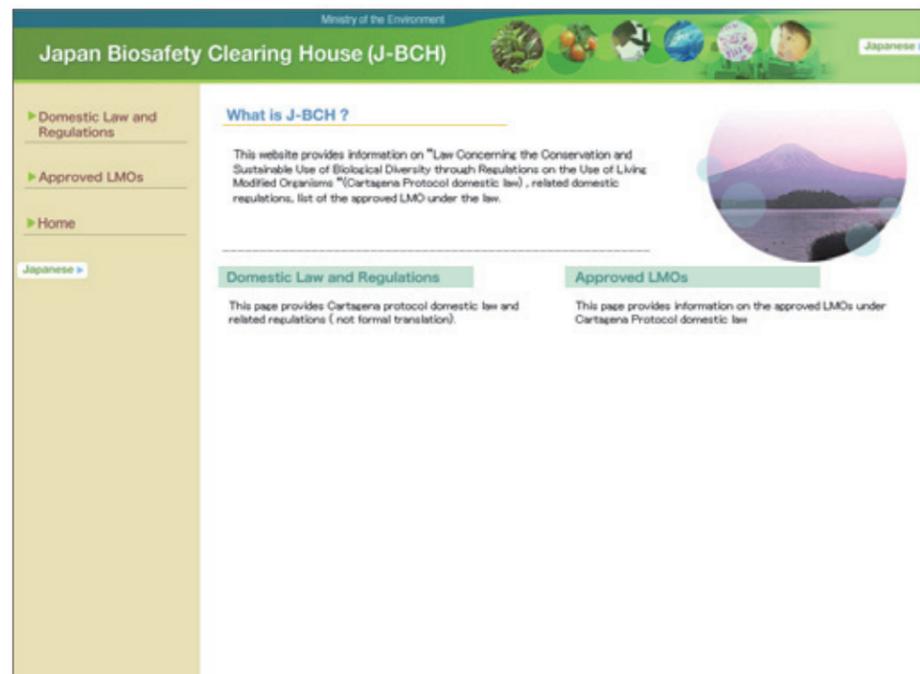


Wild soybean

Publications Concerning the Cartagena Act

The information about the Cartagena Act is shown to the public at the website of the Japan Biosafety Clearing-House (J-BCH).

http://www.bch.biodic.go.jp/english/e_index.html



The front page of JBH's website

- Cartagena Protocol: full text and summary of the Cartagena Act
- Biological Diversity Risk Assessment Report on Approved LMOs-Expert Opinions
- Results of Public Comments (Japanese only)

Latest information is posted.

National Contact

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Q&A for Cartagena Act

Q1 I am concerned about the safety of using LMOs.

A1 The Cartagena Act ensures safety through the conservation of biological diversity. As you can see from the figure below, domestic regulations in Japan only allow for those uses which have been confirmed safe.

Genetically modified foods, for example, are subject to regulation by the Japan Agricultural Standards (JAS) Act and the Food Sanitation Act.

Food Safety
〈Food Sanitation Act〉

Ministry of Health, Labor
and Welfare; Food Safety
Commission of the
Cabinet Office

Feed Safety
〈Feed Safety Law〉

Ministry of Agriculture,
Forestry and Fisheries;
Food Safety Commission
of the Cabinet Office

Medicine Safety
〈Pharmaceutical Affairs Act〉

Ministry of Agriculture,
Forestry and Fisheries;
Ministry of Health, Labor
and Welfare

They conduct scientific consideration for each utilization purpose, and confirm their safety.

Q2 I would like to know detailed information about risk assessment for each approved LMOs.

A2 Please go to the website of J-BCH mentioned in page 11 of this brochure (http://www.bch.biodic.go.jp/english/e_index.html) and look at the risk assessment report used for evaluation.

Q3 Are there any instances in which a genetically modified crop which is resistant to chemical herbicides has become an escaped weed? Also, if the resistant gene moves into weeds, increasing the number of weeds that cannot be killed using chemical herbicides, what will be done?

A3 Most cultivated crops cannot grow without humans weeding, watering and fertilizing them. Approved herbicide-tolerant crops are evaluated on the basis that their tolerance will not increase their fecundity or vitality. In addition, herbicide-tolerant crops show resistance only to particular chemical herbicides. It is hard to think that these particular chemical herbicides are disseminated widely and continuously in natural environment. Therefore, they have been evaluated that they do not have any more advantages than other plants.

In addition, it is impossible for the recombinant gene to move into weeds of other species with which the LMOs cannot cross-pollinate.

Q4 I have heard that a survey conducted by the Ministry of the Environment found a hybrid between genetically modified rapeseed and another species which propagated itself in the environment.

A4 These genetically modified rapeseeds were evaluated under the laws established by the Cartagena Act and were found to pose no threat to biological diversity even if hybridization occurs. As such, these rapeseeds were approved for agricultural cultivation in Japan.

The seed that Ministry of the Environment found is supposedly the hybrid that is from genetically modified rapeseeds (*Brassica napus*) and another species of rapeseed (*Brassica rapa*). "*B.rapa*" are originally introduced from other countries. They are not native of Japan. Therefore, this hybridization itself is not considered as adverse effect on biological diversity in Japan.

Q5 I have heard that there are genetically modified fluorescent fishes. Is it possible to keep them as pets in Japan?

A5 In some countries, there are cases of feeding "fluorescent fish" (medaka, or zebra danio) into which genes that produce fluorescent proteins are introduced from jelly fish, etc. However, in Japan, it is not approved by the Cartagena Act at the present day, March 2010. Therefore, in Japan, it is impossible to feed them without containment measures, such as keeping them in a laboratory.



Genetically modified zebra danio
©Japan Wildlife Research Center

Q6 What countermeasures will be taken if unexpected adverse effects on biological diversity arise?

A6 In those cases when adverse effects on biological diversity are found, applicant must quickly take necessary steps in conformity to a stated plan about emergency measures submitted on application. Additionally, the competent minister must change or abolish Type 1 Use regulation and to make users stop using it or to take necessary measures in these cases.