

Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act)

The Cartagena Act was enacted in 2003 for the purpose of ensuring the smooth and proper implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) by devising measures to regulate the use of living modified organisms, in order to ensure biological diversity through international cooperation.

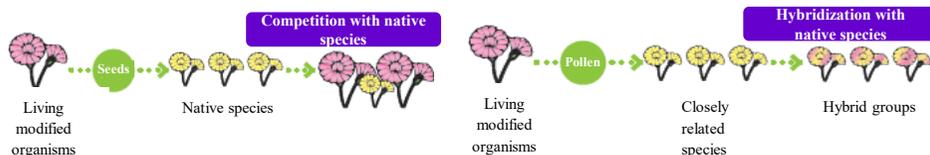
The Cartagena Protocol

- Under the Convention on Biological Diversity, the parties are required to implement the following measures to **prevent adverse effects of living modified organisms** (such as crops, microorganisms, viruses) **on biological diversity**.
 - Procedures for advance notification and consent for the import and export of living modified organisms
 - Assessment of risks posed by living modified organisms at the time of import, and managing those risks inside the parties
- Became effective in September 2003. Japan concluded the Protocol in November 2003.

Enactment of the Cartagena Act

- In order to implement the Cartagena Protocol in national law, the **Cartagena Act**, which establishes **a system, etc. of advance approval for the use, etc. of living modified organisms**, was promulgated in June 2003 and came into effect in February 2004.
- Adverse effects on biological diversity with regard to type-1 use of living modified organisms is assessed from the perspectives of competition with native species, hybridization with native species, and production of harmful substances.
- In order to implement the Nagoya-Kuala Lumpur Supplementary Protocol in national law, the Act was amended in April 2017. **It adds a provision requiring the "restoration" of biological diversity that has already been lost.**

(Reference) Examples of the adverse effect of living modified organisms on biological diversity



Measures concerning the use of living modified organisms

Before the use of living modified organisms, measures must be taken according to their usage

"Type 1 use of living modified organisms"
= Use of living modified organisms without taking containment measures to prevent dispersal into the environment

"Type 2 use of living modified organisms"
= Use of living modified organisms with containment measures to prevent dispersal into the environment

Any person who intends to make type-1 use of living modified organisms that have not been approved is **required to** establish regulations on use in advance, **attach a biological diversity risk assessment report and obtain approval from the competent minister** (Article 4).

<Competent ministers>

The Minister of the Environment and the competent ministers in charge of each field

- Research and development: Minister of Education, Culture, Sports, Science and Technology
- Alcoholic beverages production: Minister of Finance
- Pharmaceutical products, etc.: Minister of Health, Labour and Welfare
- Agriculture, forestry and fisheries: Minister of Agriculture, Forestry and Fisheries
- Mining and industry: Minister of Economy, Trade and Industry

If containment measures such as use format of facilities are specified by order of the competent ministry, the person who makes type-2 use of living modified organisms must take those measures (Article 12). If not, the person must take containment measures that have been confirmed in advance by the competent minister (Article 13)

<Competent ministers>

- Research and development: Minister of Education, Culture, Sports, Science and Technology
- Alcoholic beverages production: Minister of Finance
- Pharmaceutical products, etc.: Minister of Health, Labour and Welfare
- Agriculture, forestry and fisheries: Minister of Agriculture, Forestry and Fisheries
- Mining and industry: Minister of Economy, Trade and Industry

遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律 (カルタヘナ法)

国際的に協力して、生物の多様性の確保を図るため、遺伝子組換え生物等の規制に関する措置を講ずることにより、生物の多様性に関する条約のバイオセーフティに関するカルタヘナ議定書（カルタヘナ議定書）の的確かつ円滑な実施を確保することを目的に、平成15年に制定。

カルタヘナ議定書

- 生物多様性条約の下、**遺伝子組換え生物等**（例：農作物、微生物、ウイルス）による**生物多様性への悪影響を防止**するため締約国に対し、主に以下の措置の実施を求める。
 - ・ 遺伝子組換え生物等の輸出入に係る事前通告及び同意の手続
 - ・ 輸入時等における遺伝子組換え生物によるリスクの評価及び締約国内におけるリスクの管理
- 平成15年9月発効。我が国は平成15年11月に締結。

カルタヘナ法の制定

- カルタヘナ議定書を担保するため、**遺伝子組換え生物等使用等する場合の事前承認制度**等を規定する**カルタヘナ法**を平成15年6月公布、平成16年2月施行。
- 在来種との競合、在来種との交雑、有害物質の産生の観点から遺伝子組換え生物等による生物多様性への影響を評価。
- 名古屋・クアラルンプール補足議定書を担保するため、平成29年4月に改正。**現に損なった生物多様性の「復元」を命ずることを追加**。

[参考] 遺伝子組換え生物等による生物多様性への悪影響の例



遺伝子組換え生物等の使用等に係る措置

遺伝子組換え生物等の使用等に先立ち、使用形態に応じた措置を実施

「第一種使用等」
= 環境中への拡散防止措置を執らざりて行う使用等

「第二種使用等」
= 環境中への拡散防止措置を執りて行う使用等

新規の遺伝子組換え生物等の環境中での使用等をしようとする者等は事前に使用規程を定め、**生物多様性影響評価書を添付し、主務大臣の承認を受ける義務**（第4条）。

＜主務大臣＞
環境大臣及び分野ごとの主務大臣

- ・ 研究開発：文部科学大臣
- ・ 酒類製造：財務大臣
- ・ 医薬品等：厚生労働大臣
- ・ 農林水産：農林水産大臣
- ・ 鉱工業：経済産業大臣

施設の態様等拡散防止措置が主務省令で定められている場合は、当該措置をとる義務（第12条）。定められていない場合は、あらかじめ主務大臣の確認を受けた拡散防止措置を執る義務（第13条）。

＜主務大臣＞

- ・ 研究開発：文部科学大臣
- ・ 酒類製造：財務大臣
- ・ 医薬品等：厚生労働大臣
- ・ 農林水産：農林水産大臣
- ・ 鉱工業：経済産業大臣