



# **CARTAGENA LAW**

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

**Hirosaki University**



# Definition of a "living modified organism" under the Cartagena Law

## An organism refers to

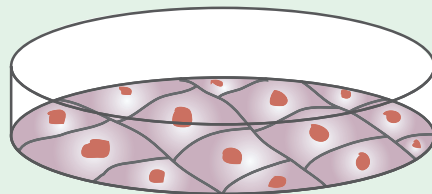
A single cell (excluding a single cell forming a cell colony) or a cell colony which has the capacity to transfer or replicate nucleic acid, viruses and viroids.

Animals, plants, mushrooms, parasites, fungi, bacteria, gametes, fertilized eggs and embryos, viruses, viroids

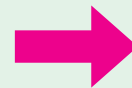
Not subject to regulation: human cells, cultured animal cells, tissue or organs, etc.

## Note

Modified cell culture



(Not subject to regulation)



Mouse featuring modified gene from cell culture



(Subject to regulation)



## Definition of a "living modified organism" under the Cartagena Law

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A single cell (excluding a single cell forming a cell colony) or a cell colony which has the capacity to transfer or replicate nucleic acid, viruses and viroids.

Animals, plants, mushrooms, parasites, fungi, bacteria, gametes, fertilized eggs and embryos, viruses, viroids

Not subject to regulation: human cells, cultured animal cells, tissue or organs, etc.

### A living modified organism refers to

An organism that possesses nucleic acid, or a replicated product thereof, obtained through use of 1) technologies for the processing of nucleic acid extracellularly or 2) technologies for the fusing of the cells of organisms belonging to different taxonomical families.



# Definition of "Use" in the Cartagena Law

## Definition of "Use"

- Provision as food, animal feed or experimental material
- Cultivation and other growth
- Processing, storage, transportation, and disposal
- Other acts subsidiary to these

## Types of use

- Type 1 use
  - Use without measures to prevent dispersal into the environment
  - Ex: Cultivation on a farm, transportation not in a closed container
- Type 2 use
  - Use with measures to prevent dispersal into the environment
  - Ex: Handling in laboratories, transportation in a closed container

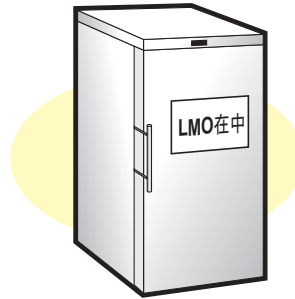


# Types of use covered by Type 2 Use

## Classification of use in the Research and Development Type 2 Ordinance



Experiments  
(including storage and transport  
during experiments)



Storage



Transport

All of these actions are covered  
by the regulations

Measures to prevent dispersal are stipulated  
for each of these actions



# Types of "Experiments" in Type 2 Use

Experiments

LMO experiments

Microorganism experiments

Large-scale culture experiments

Animal experiments

Plant experiments

Cell fusion experiments

Animal development experiments

Animal inoculation experiments

Plant development experiments

Plant inoculation experiments

Mushroom development experiments





# Experiments requiring institutional approval and experiments requiring ministerial confirmation

## ① Experiments requiring institutional approval

- **LMO experiments** for which required measures to prevent dispersal have already been stipulated by the Research and Development Type 2 Ordinance.

## ② Experiments requiring ministerial confirmation

- **LMO experiments** for which required measures to prevent dispersal have not been stipulated by the Research and Development Type 2 Ordinance, and that require obtaining advance confirmation from the minister of Education, Culture, Sports, Science and Technology.
- **Cell fusion experiments**



# Classification of measures that should be taken in order to prevent dispersal in experiments requiring institutional approval

## ① Classification of measures to prevent dispersal

- Microorganism experiments → P1-P3 level
- Large-scale culture experiments → LSC, LS1, LS2 level
- Animal experiments → P1A-P3A level, special breeding section
- Plant experiments → P1P-P3P level, special screened greenhouse

## ② Method for deciding levels of measures to prevent dispersal

In principle, these are decided taking into consideration the following points

- (1) The experimental classification of the recipient and donor organisms to be used
  - Microorganisms, fungi, parasites → Classified as Classes 1-4
  - Animals (including humans, excluding parasites), plants → Class 1
- (2) Usage method (type of experiment)
- (3) Presumed behavior of the living modified organism





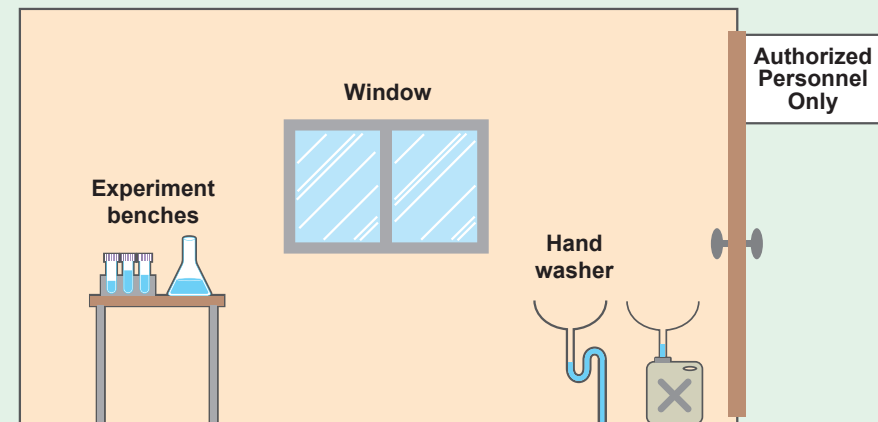
# Method for deciding the level of measures to prevent dispersal in microorganism experiments

Recipient/vector	Donor nucleic acid	Level of measures to prevent dispersal
(Unspecified)	(Unspecified)	Class where the recipient and donor organism are the same, or one is higher = Level of measures to prevent dispersal Class 2 → P2 level
Specially recognized recipient vector (B2)	(Unspecified)	The donor organism experimental taxonomy is Class 1, Class 2 → P1 level Class 3 → P2 level
(Unspecified)	This is a specified nucleic acid, and clear scientific knowledge assumes that this is not pathogenic or contagious towards mammals	The recipient is Class 1 → P1 level Class 2 → P2 level
Other than recognized recipient vector	This is pathogenic or contagious towards mammals, and there is clear scientific knowledge that assumes that its characteristic will increase its pathogenicity of recipient organisms towards mammals	When neither the recipient or donor organism is lower Class 1 → P2 level Class 2 → P3 level



# Microorganism experiment P1

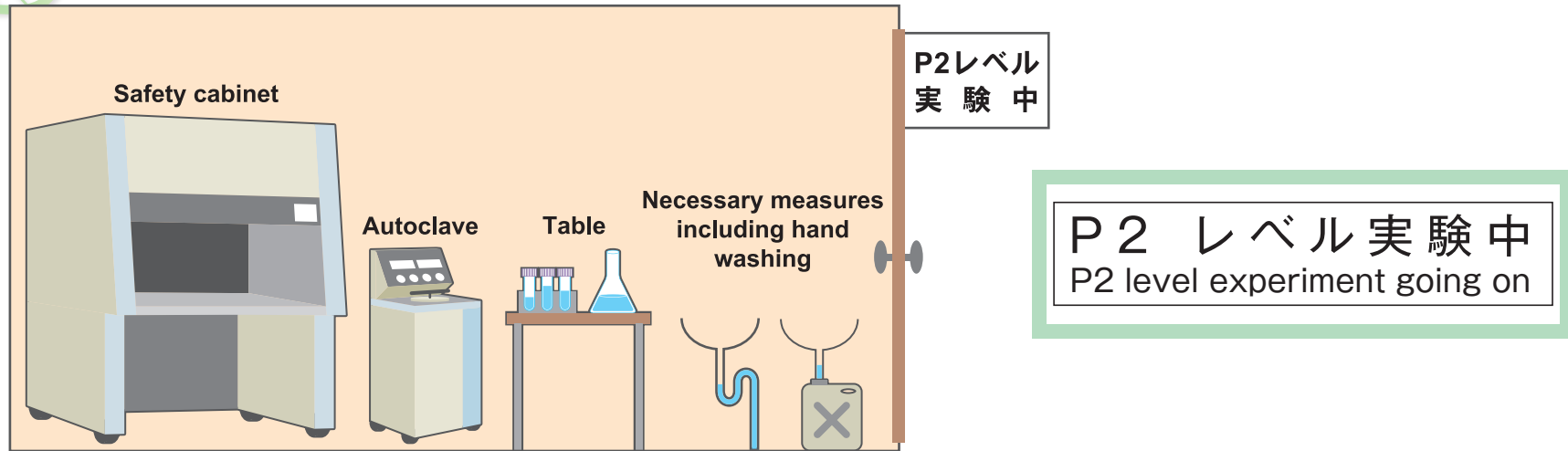
- (1) Laboratory for ordinary organisms
- (2) Restricted entry to other than involved parties
- (3) Laboratory doors must be kept closed
- (4) Laboratory windows must be kept closed
- (5) Production of aerosol must be minimized
- (6) Ensure hand washing in order to prevent LMOs sticking to or infecting persons  
(hand washing after experiments, wearing of protective equipment, prohibition on eating and drinking)
- (7) Inactivation of LMOs  
(inactivation of experiment benches, contaminated equipment, instruments, implements, and waste products)



関係者以外立ち入り禁止  
Authorized Personnel Only



# Microorganism experiment P2



- (1) Adhere to P1 level requirements
- (2) Install a biological safety cabinet in laboratories for operations that produce aerosol (inactivate after usage)
- (3) Install an autoclave in buildings containing laboratories
- (4) Post "P2 Level experiment going on" on doors and on storage equipment
- (5) When multiple P1 (A, P) level experiments are being carried out at the same time, establish clear areas for each experiment, or put in place P2 (A, P) level measures to prevent dispersal.



# Measures to prevent dispersal in animal experiments

## P1A level measures to prevent dispersal

In addition to adhering to P1 level requirements, the following measures (A measures) are also required:

- (1) An ordinary animal breeding room
- (2) Installation of equipments on laboratory doors and windows to prevent escape
- (3) Installation of equipment to collect feces if these contain LMOs
- (4) Post "Modified animal being bred" on doors
- (5) Identification of modified animals by the type of introduced modified nucleic acid, or by the type of LMOs carried by modified animal.



## P2A level measures to prevent dispersal

In addition to P1A level requirements, P2 level measures to prevent dispersal are necessary. Post "Modified animal being bred (P2)" on doors.



# Example of measures to prevent dispersal in animal experiments

## Measures to prevent dispersal

Ex: Installation of barrier panels in the doorways to prevent mice escaping  
Usage of isolator racks when breeding

## Post on laboratory doors

P1A level: "Modified animal being bred"

P2A level: "Modified animal being bred (P2)"



組換え動物等飼育中  
Modified animal being bred

組換え動物等飼育中 (P2)  
Modified animal being bred (P2)

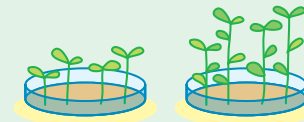


# Measures to prevent dispersal in plant experiments

## P1P level measures to prevent dispersal

In addition to adhering to P1 level requirements, the following measures (P measures) are also required:

- (1) An ordinary plant culture room
- (2) Exhaust system capable of minimizing the quantities of pollen from modified plants contained in the exhaust from the laboratory (for operations that scatter pollen)
- (3) Post "Modified plant being cultured" on doors.



## P2P level measures to prevent dispersal

In addition to P1P level requirements, P2 level measures to prevent dispersal are necessary. Post "Modified plant being cultured (P2)" on doors.

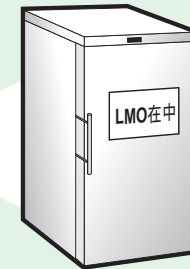


# Storage and transport in LMO experiments

**Measures to prevent dispersal identical to those used in experiments are required**

## Storage

- Laboratories used for the storage of LMOs are to have their windows and doors closed at all times.
- Doors into P2 or P3 level laboratories and storage equipment are to post signs in accordance with the level of their measures to prevent dispersal.



## Transport

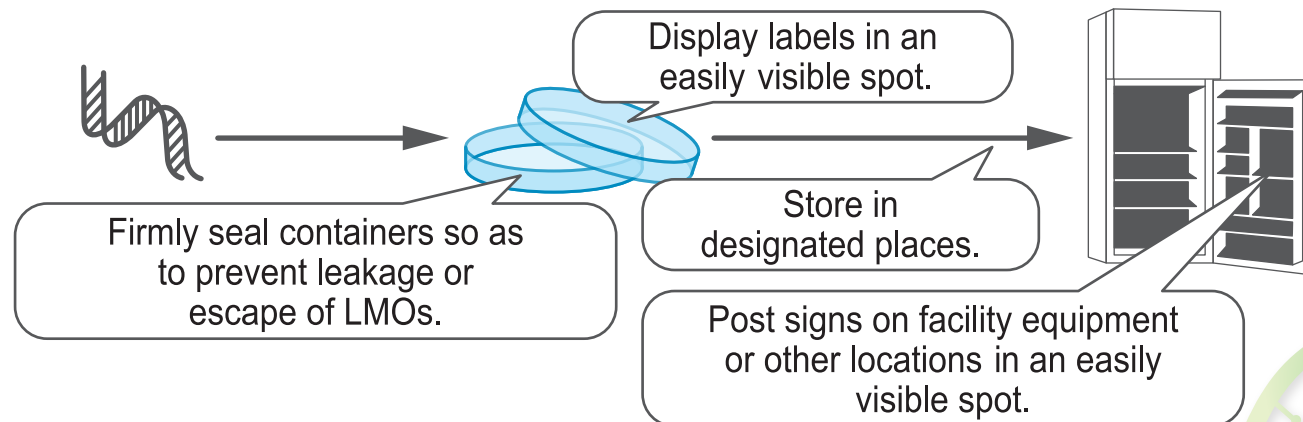
- When modified organisms are removed from the laboratory, these are to be contained within containers with a structure that prevents leakage, escape, or other dispersal.





# Measures to prevent dispersal in storage

- (1) Putting LMOs into containers with a structure that prevents leakage, escape, or other dispersal
- (2) Indication in an easily visible spot on the container that it contains LMOs
- (3) Storage of the container in a specified place
- (4) Indication in an easily visible spot on the refrigerator or other storage equipment that it contains LMOs

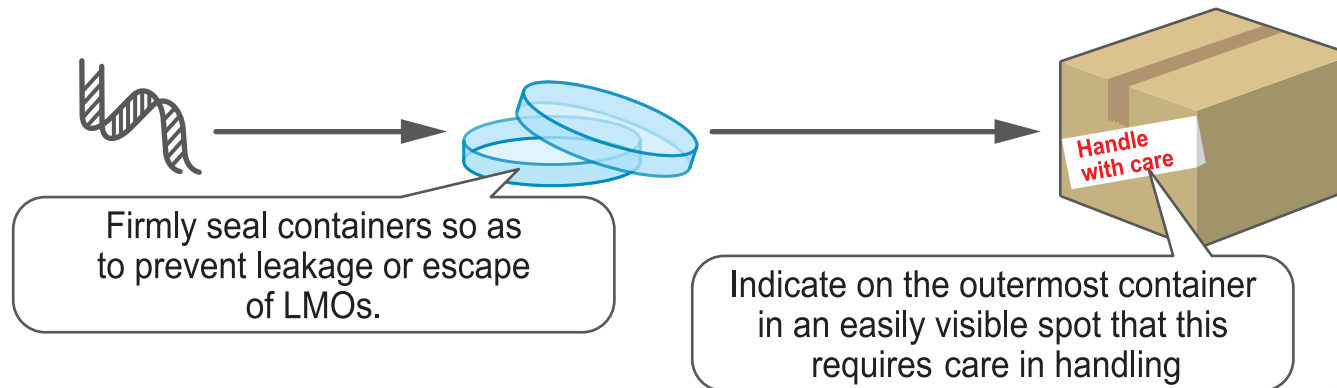






# Measures to prevent dispersal in transport

- (1) Put into containers with a structure that prevents leakage, escape, or other dispersal of LMOs
- (2) Indicate on the outermost container in an easily visible spot that this requires care in handling





# Transfer of LMOs (domestic)

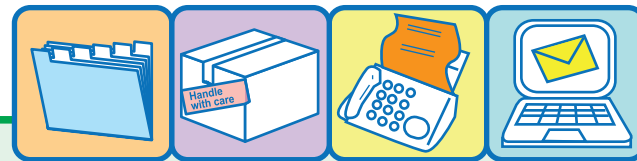
## Details of provided information (Type 2 Use)

- That Type 2 Use of a living modified organism is being made
- The name of the recipient and of the modified nucleic acid (indicate if this does not have a name, or if this is unclear)
- If used while exempted from the ministerial approval, then indicate to this effect
- Name of the organization, name and contact details of the responsible person



## Method for providing information

Issuance of documents, display on the LMO container, FAX, or email (Telephone or other verbal communication is not permitted)





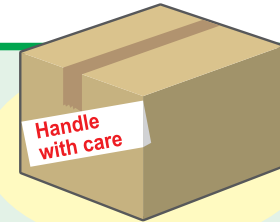
# Measures for Export

## Notification for Export

If suitable containment measures are taken at the other party's laboratory, then no particular measures are necessary.

## Display for Export

Display items in the specified format on the LMO or on its packaging, container, or consignment invoice.



As containment measures in the importing country, use the format as specified in the ordinance, and detail the following;

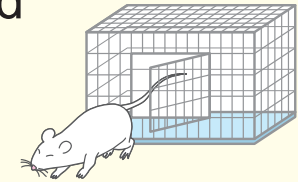
- (1) Name of the living modified organism, and its international identification number
- (2) Requirements as regards safe handling, storage, transport, and use
- (3) Names, addresses, and telephone or fax number of the exporter and importer, and contact person



# Measures in the Event of Accidents

## An accident refers to the following

- When there is a reason to believe that containment measures have been compromised and that LMO has leaked or escaped
- When a modified mouse or mice have been discovered outside of the containment section
- When there are holes in the glass of an isolated greenhouse



## Required measures

- (1) When containment measures stipulated by law or such measures as confirmed by the minister of Education, Culture, Sports, Science and Technology cannot be carried out, emergency measures are to be taken immediately.
- (2) The minister of Education, Culture, Sports, Science and Technology is to be promptly notified and provided with an overview explaining the accident and the measures taken to address it.



# Penalties

1. If in violation of ordinances as regards measures from the Minister of Education, Culture, Sports, Science and Technology  
---- Prison of up to 1 year, fine of up to 1,000,000yen (or both)
2. A person who makes Type 1 Use without obtaining approval  
---- Prison of up to 6 months, fine of up to 500,000yen (or both)
3. A person who makes Type 2 Use without receiving confirmation  
---- Fine of up to 500,000yen
4. A person who fails to provide information, or provides false information  
---- Fine of up to 500,000yen
5. If items are exported without the required display  
---- Fine of up to 500,000yen



etc.