

Nara Institute of Science and Technology, National University Corporation
Genetically Modified Organism Safety Management Regulations

April 1, 2004
Regulations No. 41

Article 1 (Purpose)

These Regulations specify the safety management for genetic recombination experiments (hereinafter referred to as “Experiments”) and genetically modified organisms at the Nara Institute of Science and Technology (hereinafter referred to as “NAIST”), in addition to the provisions of the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97, 2003; hereinafter referred to as the “Act”), the Ordinance for Enforcement of the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Ministerial Ordinance No. 1, 2003, Ministry of Finance; the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; the Ministry of Agriculture, Forestry and Fisheries; the Ministry of Economy, Trade and Industry; and the Ministry of the Environment), and other applicable laws and regulations.

Article 2 (Definitions)

As used in these Regulations, the terms below shall be defined as follows:

- (1) “Departments” refers to the Graduate School of Science and Technology, the Research and Education Center for Genetic Information and the Center for Digital Green-innovation.
- (2) “Experiment Workers” refers to the persons who engage in conducting Experiments, and
- (3) “Experiment Manager” refers to one of the Experiment Workers responsible for the performance of each individual experimental protocol.

Article 3 (Genetically modified organism director)

1. A genetically modified organism director (hereinafter referred to as the “Director”) shall be assigned to oversee the safety assurance of Experiments and genetically modified organisms at NAIST.
2. The Director shall be appointed by the President from among the safety chiefs.

Article 4 (Genetically modified organism safety chiefs)

1. Several genetically modified organism safety chiefs (hereinafter referred to

as “Safety Chiefs”) shall be assigned to assist the Director.

2. Safety Chiefs shall be appointed from among the professors and associate professors of NAIST, who have an intimate knowledge of the applicable laws and regulations and NAIST Regulations and have knowledge and high-level proficiency of technology to prevent impact on biodiversity and biological disaster from genetically modified organism use, as well as other related knowledge and technology.

3. Safety Chiefs shall be appointed by the President based on the recommendation of the General Safety and Health Manager.

4. Safety Officers shall perform the following duties in the relevant Departments:

(1) Provide the Experiment Manager with guidance and advice on performing Experiments,

(2) Provide guidance and advice on education and training implemented by the Experiment Manager, in accordance with the policy of the Committee under Article 7 hereof,

(3) Take the necessary precautions for experiment worker’s health care,

(4) Duties related to facility and equipment management and maintenance,

(5) Provide the Experiment Manager with guidance and advice on measures in case of emergency and accidents, and

(6) Implementation other requirements.

Article 5 (Experiment Manager)

1. When Experiments shall be performed, an Experiment Manager must be assigned for each individual experimental protocol.

2. The Experiment Manager shall be appointed from among NAIST faculty Experiment Workers who have intimate knowledge of the applicable laws and regulations and University Regulations and have knowledge and proficiency in technology to prevent biodiversity impact and biological accidents from genetically modified organism use, as well as other related knowledge and technology.

3. The Experiment Manager shall be responsible for the safe performance of relevant Experiments.

4. The Experiment Manager shall perform the following duties:

(1) Design experimental protocol and apply for confirmation of containment measures for genetically modified organism use,

(2) Conduct proper management and supervision, in close contact with the relevant Safety Chief, when performing Experiments,

(3) Plan and implement Experiment Worker education and training,

(4) Record and maintain records of the name, quantity, and delivery destination (research institute and Experiment Manager), when transporting samples

- and waste containing genetically modified organisms,
- (5) Prepare and maintain records of storage of samples and waste containing genetically modified organisms, and
 - (6) Implement other requirements.

Article 6 (Experiment Workers)

1. Experiment Workers must be familiar with and proficient in using standard experimental methods and the operation methods specific to the Experiments and related microorganism experimental methods.
2. Experiment Workers must, when performing Experiments, have sufficient awareness and necessary consideration for safety assurance to prevent biodiversity impact and biological accidents from genetically modified organism use, and follow the instructions of the Experiment Manager.

Article 7 (Genetically modified organism safety management committee)

1. In order to ensure safe Experiment performance and to prevent biodiversity impact and biological accidents from genetically modified organism use at NAIST, the Genetically Modified Organism Safety Management Committee (hereinafter referred to as the "Committee") shall be established.
2. The Committee shall discuss and review the safe Experiment performance and safety management to prevent biodiversity impact and biological accidents from genetically modified organisms use.
3. The Committee may, as necessary, provide the Director, Safety Chiefs, and Experiment Managers with guidance on safe Experiment performance and genetically modified organism safety management.
4. Other requirements for the Committee shall be specified separately.

Article 8 (Experiment application, review, and reporting)

1. Experiments may not be performed unless confirmation is obtained from the President for containment measures (hereinafter referred to as "Containment Measures") to be taken in connection with the Type 2 Use of genetically modified organisms through separately specified procedures.
2. In the case of Experiments in which genetically modified organisms are created or imported for Type 1 Use, or for any use for which there are no provisions on Containment Measures to be taken when performing gene recombination experiments as provided for in the ordinances (hereinafter referred to as the "Ordinances") and in which containment measures to be taken in connection with Type 2 Use of genetically modified organisms are stipulated, specific regulations on Type 1 Use must be established in advance for each type of genetically modified organism and for which confirmation must

be obtained from the Minister of Education, Culture, Sports, Science and Technology.

3. The Experiment Manager must submit an application (hereinafter referred to as the "Application") through the relevant Safety Chief for confirmation from the President for the Containment Measures of the planned experimental protocol to be implemented.

4. Applications under the preceding paragraph shall be made on an as-needed basis; provided, however, that if the relevant Experiment is subject to Grants-in-Aid for scientific research and requires confirmation for Containment Measures from the Minister of Education, Culture, Sports, Science and Technology, such Application shall be submitted by the subscription deadline to the Grants-in-Aid for scientific research of NAIST, and any other Application shall be submitted by the grant application deadline for the Grants-in-Aid for scientific research of NAIST.

5. The Experiment Manager must, if he or she intends to alter experimental protocol, submit an Application for the altering to the President through the relevant Safety Chief.

6. The President shall, upon Application under the provisions of Paragraph 3 hereof or the preceding paragraph, decide whether to grant approval of the Containment Measures for the Experiment after review by the Commission and shall notify the applicant of the decision. In such a case, for Experiments that require confirmation from the Minister of Education, Culture, Sports, Science and Technology, prior confirmation shall be obtained from the Minister.

7. The purpose of the review by the Commission under the preceding paragraph shall be to examine whether the description and methods of the Experiment, Containment Measures, facilities and equipment for the Experiment, and the Experiment Worker's knowledge and technology related to the Experiment meet the standards required by applicable laws and regulations.

8. The Experiment Manager must, upon completion or suspension or non-performing of the approved Experiment, notify the President of that completion, suspension, or non-performing.

9. The Experiment Manager must report in writing to the Safety Chief the performance progress of the relevant Experiment at the end of each fiscal year.

10. Forms for application, review, and report for Experiments shall be prescribed separately.

Article 9 (Medical examinations and health care)

1. Experiment Workers must undergo medical examinations conducted by NAIST in accordance with applicable laws and regulations.

2. The President shall notify Experiment Workers of the medical examination results under the preceding paragraph through the Department heads.
3. Experiment Workers must always try to maintain their health, and if they are ill or develop a severe or long-term illness, notify the President of this through the Experiment Manager or Safety Chief. Persons other than Experiment Workers, who come to know such fact, shall follow the same procedures.

Article 10 (Performing Experiments)

Experiment workers must, when performing Experiments, adhere to the following procedures:

- (1) Experiments shall be performed in a laboratory in compliance with applicable laws and regulations.
- (2) Experiments shall be performed in accordance with a confirmed and approved protocol for Containment Measures.
- (3) During the performance of Experiments, a sign shall be put according to the level of Containment Measures required by applicable laws and regulations, and no persons other than Experiment Workers shall enter the laboratory.
- (4) When Experiments are performed, experimental records shall be prepared and maintained for each case.
- (5) Nucleic acid donor, hosts, and vectors, etc., used in Experiments shall meet the requirements for Containment Measures required by applicable laws and regulations.
- (6) Storage and transport of samples and waste containing genetically modified organisms shall be performed in accordance with applicable laws and regulations.
- (7) Disposal of items contaminated by genetically modified organisms shall be carried out after killing all genetically modified organisms with the appropriate treatment methods.
- (8) Experimental equipment contaminated by genetically modified organisms shall be sterilized or disinfected prior to cleaning, reusing, or removal from the laboratory.
- (9) Experiments shall be performed in accordance with the separately provided manual.

Article 11 (Facility and equipment management and maintenance)

Safety Officers must manage and maintain facilities and equipment of the relevant Departments in accordance with the following provisions:

- (1) Placing necessary signs and labels on facilities and equipment as required by applicable laws and regulations, and
- (2) Conducting inspections of the facilities as necessary to check that facilities

meet the requirements under applicable laws and regulations, and providing the Experiment Manager with guidance so that the facilities will always meet the requirements under applicable laws and regulations.

Article 12 (Education and training)

The President and the Experiment Manager must, under the guidance and advice of the relevant Safety Chief, provide Experiment Workers with education and training on the matters specified by applicable laws and regulations.

Article 13 (Importing genetically modified organisms)

1. In the case when there is a high likelihood genetically modified organisms that may be considered to give rise to adverse effects on biodiversity are imported without knowledge of that fact, in view of the production area or other circumstances or other similar cases, a person who intends to import the genetically modified organisms specified above must notify the Minister of Education, Culture, Sports, Science and Technology through the President to that effect on each occasion.

2. Notification under the preceding paragraph must be made in accordance with applicable laws and regulations.

Article 14 (Exporting genetically modified organisms)

In the case of the exporting of genetically modified organisms that are used for intentional introduction into the environment, notification with the prescribed form must be submitted in accordance with the provisions of the Act, which must be attached to the genetically modified organisms to be exported, after obtaining the President's approval.

Article 15 (Provision of information)

If genetically modified organisms for Type 2 Use are transferred, supplied, or entrusted, the following information must be provided in accordance with the method specified by the Act, such as by issuing a document or labelling on the genetically modified organisms or their package or container:

- (1) The fact that the genetically modified organisms are for Type 2 Use,
- (2) The name of the genetically modified organism host or parent organism and the name of nucleic acid or its replicated product obtained by using the technologies specified by law (or the fact that the name is unknown, if they have no name), and
- (3) The name and address of the transferor.

Article 16 (Emergency and accident measures)

1. If a biological disaster shall occur due to accidents or genetically modified organisms may leak or escape the facilities due to earthquake, fire, and other disasters, the Experiment Manager must implement emergency measures and immediately notify the President, Safety Chief, and the Director and take appropriate precautions under the guidance of the Safety Chief.
2. Upon the occurrence of any of the events described in the preceding paragraph, the Director shall promptly submit a document describing the situation and measures implemented to the President.

Article 17 (Corrective measures)

The President shall, if he or she considers safe Experiment performance or genetically modified organism safety management is not properly secured in accordance with applicable laws and regulation, University Regulations, and manuals, implement corrective measures, such as re-education, guidance for improvement, and Experiment suspension, and other necessary measures according to the situation.

Article 18 (Miscellaneous provisions)

In addition to the provisions of these Regulations, requirements concerning Experiment and genetically modified organism safety assurance shall be separately specified by the Committee.

Supplementary provisions

These Regulations shall come into effect on April 1, 2004.

Supplementary provisions

These Regulations shall come into effect on April 1, 2007.

Supplementary provisions

These Regulations shall come into effect on April 1, 2012.

Supplementary provisions

These Regulations shall come into effect on September 20, 2016.

Supplementary provisions

These Regulations shall come into effect on April 1, 2018.

Supplementary provisions

These Regulations shall come into effect on January 1, 2021.