TENTATIVE TRANSLATION

Kyoto University Regulations Regarding Safety Control of Recombinant DNA Experiments, etc.

March 29, 2021
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Contents

Chapter 1 General Provisions

Article 1 Purpose

Safety in connection with recombinant DNA experiments, etc. to be performed at Kyoto University (hereinafter referred to as the "University") shall comply with 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 of 2003; hereinafter referred to as the "Act"), of the Regulations Related to the 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 of 2003 of the 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; hereinafter referred to as the "Enforcement Regulations"), of the Ministerial Ordinance Providing Containment Measures to Be Taken in Type 2 Use of Living Modified Organisms for Research and Development (Ministerial Ordinance No. 1 of 2004 of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of the Environment; hereinafter referred to as the "Ministerial Ordinance for Type 2 Use") (hereinafter collectively referred to as the "Act, etc.)), and of these Regulations.

Article 2 Definitions

1. Terms used in these Regulations are defined below.
   (1) Recombinant DNA experiment: A gene recombination experiment and cell fusion experiment as specified in the Act, etc. and a gene recombination experiment using cells that do not grow into individuals under natural conditions as hosts.
   (2) Type 1 use, etc.: The use of genetically modified living organisms, etc. in a recombinant DNA experiment that is performed without fully taking containment measures.
   (3) Type 2 use, etc.: The use of genetically modified living organisms, etc. in a recombinant DNA experiment that is performed with containment measures.
   (4) Minister-approved experiment: A recombinant DNA experiment that necessitates prior approval of the competent minister for the Regulations Concerning Type 1 Use.
   (5) Minister-verified experiment: A recombinant DNA experiment that uses genetically modified living organisms, etc. listed in Appended Table 1 of the Ministerial Ordinance for Type 2 Use and that requires verification of its containment measure by the competent minister when using the genetically modified living organisms, etc. concerned in accordance with the provisions of Article 13 of the Act.(6) Institution-approved experiment: A recombinant DNA experiment for which Type 1 use, etc. is specified according to the provisory clause of Paragraph 1, Article 4 of the Act, for which any of the containment measures outlined in Article 12 of the Act is specified according to Article 5 of the Ministerial Ordinance for Type 2 Use.
2. Other than defined above, the terms used in these Regulations shall conform to those used in the Act, etc.

Chapter 2 Safety Control Systems

Article 3 Responsibilities of the President

The President shall be responsible for supervising the securement of safety in connection with recombinant DNA experiments to be performed at the University.

Article 4 Responsibilities of the Executive Vice President

The Executive Vice President for research standards (hereinafter referred to as the "relevant Vice President") shall be responsible for supporting the President regarding the securement of safety in connection with recombinant DNA experiments to be performed at the University.

Article 5 Committee

1. Kyoto University Recombinant DNA Experiment Safety Committee (hereinafter referred to as the "Committee") shall be organized within the University.
2. The Committee shall investigate and deliberate matters required to secure safety in connection with recombinant DNA experiments at the University.
3. The Committee shall be organized with the following members:
   (1) Several professors or associate professors in a research area pertaining to recombinant DNA experiments
   (2) Several professors or associate professors in a research area concerning natural sciences other than the area stated in item (1) above and professors or associate professors in a research area pertaining to humanities and social sciences
   (3) Director of the health management department of the Agency for Health, Safety and Environment
   (4) Director of the Research Promotion Department
   (5) Several other personnel considered necessary by the President
4. The members set forth in items (1), (2), and (5) of Paragraph 1 above shall be commissioned by the President.
5. The tenure of the members set forth in items (1), (2) and (5) of Paragraph 3 shall be two years, and these members may be recommissioned. However, the tenure of the member who succeeds any of the original members shall be the remaining months of the original tenure of the predecessor.
6. The Committee shall elect its president from among the members outlined in items (1) and (2) of Paragraph 3.
7. The president shall summon the members to a Committee meeting and serve as chairperson.
8. In the event that the chairperson is unable to perform the required duties due to incapacity, the person designated by the chairperson in advance shall act for the chairperson.
9. The Committee shall be authorized to request personnel other than the Committee members to attend a Committee meeting to hear their explanations or opinions whenever the Committee considers it necessary.
10. The Research Promotion Department shall be responsible for the administrative work of the Committee.
11. The Committee shall define any and all matters concerning its operation and management besides the matters specified in Paragraphs 1 to 10 above.

Article 6 Responsibilities of the department head

1. The head of the department (hereinafter referred to as the "department head") shall be responsible for supervising the securement of safety in connection with recombinant DNA experiments to be performed at the department.
2. The department head shall determine necessary matters concerning the securement of the safety of experiments performed at the department concerned.

Article 7 Safety Chief

1. A department that performs recombinant DNA experiments shall appoint a recombinant DNA experiment safety chief (hereinafter referred to as the "Safety Chief") in the department.
2. The Safety Chief shall assist the department head in containment measures and securement of safety in connection with recombinant DNA experiments to be performed in the department concerned and shall provide guidance and advice to the personnel who perform recombinant DNA experiments.
3. The Safety Chief shall be appointed by the President on the basis of a request from the department head concerned.

Article 8 Experiments jointly performed by different departments

1. Notwithstanding the provision of Article 6, when different departments jointly perform recombinant DNA experiments, or when a department uses the facilities or equipment of another department to perform recombinant DNA experiments, the heads of the departments involved shall consult among themselves to appoint a department head to manage the securement of safety in connection with the performance of such experiments. In this case, the "department that performs recombinant DNA experiments" in Paragraph 1 of Article 7 and "recombinant DNA experiments to be performed in the department concerned" in Paragraph 2 of the same Article shall be deemed to be replaced with the "department whose head manages the securement of safety in connection with recombinant DNA experiments" and the "recombinant DNA experiments concerned," respectively.
2. When the heads of the concerned departments appoint a department head to manage recombinant DNA experiments in accordance with the provisions of the preceding paragraph, they must report the appointment to the President.

Article 9 Person responsible for the experiment

1. When a department performs recombinant DNA experiments, the department must appoint a person responsible for the experiments as the person responsible for implementing an experiment plan.
2. The person responsible for the experiments shall observe the Act, etc. and these Regulations in the development and implementation of an experiment plan and shall exercise appropriate supervision over recombinant DNA experiments.

Article 10 Experimenter

Each person engaged in recombinant DNA experiments (hereinafter referred to as an "experimenter") must observe the Act, etc. and these Regulations in the development and implementation of a recombinant DNA experiment plan, give necessary consideration to the securement of safety, and follow the instructions of the person responsible for the experiments.

Chapter 3 Experiment Plan Review and Related Items

Article 11 Minister-approved experiments

1. When performing a minister-approved experiment, the person responsible for the experiment must submit the specified application along with the Regulations Concerning Type 1 Use for the concerned minister-approved experiment and other related documents to the President via the department head to have it approved by the President.
2. Upon confirmation by the Committee concerning the documents submitted as specified in the preceding paragraph, the President shall determine whether or not to file an application for the approval of the Regulations Concerning Type 1 Use for the concerned minister-approved experiment to the competent minister.
3. Upon the confirmation specified in the preceding paragraph, the Committee may seek opinions from those who have specialized expertise related to the minister-approved experiment.
4. When the application specified in Paragraph 2 is approved by the competent minister, the President shall approve the performance of the minister-approved experiment in the concerned application.
5. Once determined whether or not to file an application to the competent minister as specified in Paragraph 2 or once the performance of the minister-approved experiment is approved as specified in the preceding paragraph, the President shall immediately notify the person responsible for the experiment via the department head.

Article 12 Institution-approved experiments and minister-verified experiments

1. When performing an institution-approved experiment or a minister-verified experiment, the person responsible for the experiments must submit the specified application to the President via the department head to have it approved by the President.
2. The President shall determine approval or nonapproval for the performance of institution-approved experiments after deliberation by the Committee.
3. The President shall determine whether or not to file an application for verification of containment measures for a minister-verified experiment to the competent minister after deliberation by the Committee.
4. Upon the deliberation specified in the preceding two paragraphs, the Committee may seek opinions from those who have specialized expertise in the concerned institution-approved experiment or minister-verified experiment.

5. When the application specified in Paragraph 3 is verified by the competent minister, the President shall approve the performance of the minister-verified experiment in the concerned application.
6. Once determined whether or not to approve the performance of the experiment as specified in Paragraph 2, determined whether or not to file an application to the competent minister as specified in Paragraph 3, or received a notification on the results for the application from the competent minister, the President shall immediately notify the results via the department head to the person responsible for the concerned institution-approved experiment or minister-verified experiment.

Article 13 Changes in the experiment plan

1. When making changes (excluding minor changes) to an experiment plan of an institution-approved experiment or a minister-verified experiment that is approved to be performed, the provisions in Article 12 shall be applied mutatis mutandis.
2. When making minor changes to an experiment plan of an institution-approved experiment or a minister-verified experiment, the provisions in Paragraph 1 of Article 12 shall be applied mutatis mutandis.
3. When changes were confirmed as minor changes in the case specified in the preceding paragraph, the President shall determine the approval of the changes.

Article 14 Measures taken for violation of the Regulations

1. If any recombinant DNA experiment is performed in violation of the Act. etc. or these Regulations, the Committee shall suggest a restriction on or suspension of the experiment concerned or other necessary measures to the President.
2. When a suggestion is received on a recombinant DNA experiment specified in Paragraph 1 from the Committee, the President may order a restriction on or suspension of the experiment concerned or other necessary measures to the head of the department where the recombinant DNA experiment concerned is to be performed.
3. When ordered by the competent minister to take necessary measures regarding a recombinant DNA experiment based on the provisions of the Act, etc., the President shall order a restriction on or suspension of the experiment concerned or other necessary measures to the head of the department where the recombinant DNA experiment concerned is to be performed.

Chapter 4 Measures for Management, Maintenance and Securement of Safety of Experiment Facilities, etc.

Article 15 Compliance with the Regulations Concerning Type 1 Use

When performing a minister-approved experiment, the person responsible for the experiment as well as the experimenters must comply with the Regulations Concerning Type 1 Use pertaining to the concerned experiment.

Article 16 Management and maintenance of experiment facilities, etc.

1. For the experiment facilities used for the Type 2 use, etc. (hereinafter referred to as the “experiment facilities”), etc., the department heads must take containment measures specified in Article 5 of the Ministerial Ordinance for Type 2 Use or containment measures verified by the competent minister and strive to manage the measures to secure safety.
2. When Type 2 use, etc. is performed, the person responsible for the experiments must have the experimenters take containment measures specified in Article 5 of the Ministerial Ordinance for Type 2 Use or take containment measures verified by the competent minister to secure safety.
3. The person responsible for the experiments must inspect the experiment facilities, etc. periodically and on an as-necessary basis to maintain their conformity to the containment measures specified in Article 5 of the Ministerial Ordinance for Type 2 Use or conformity to containment measures verified by the competent minister. Safety cabinets, however, must be inspected at intervals of no longer than 1 year, and the results of inspections must be recorded.
4. When Type 2 use, etc. is performed, the person responsible for the experiments and experimenters must take containment measures specified in Article 5 of the Ministerial Ordinance for Type 2 Use or take containment measures verified by the competent minister.

Article 17 Investigation, inspection, and report concerning securement of safety

1. Each department head shall instruct its safety chief to investigate and inspect necessary matters concerning the securement of safety in recombinant DNA experiments periodically and on an as-necessary basis. In this case, the department head shall inform the person responsible for the recombinant DNA experiment concerned of such investigation and inspection in advance.
2. The Committee shall be authorized to request a report from the person responsible for the experiments or the department head regarding the securement of safety pertaining to recombinant DNA experiments whenever the Committee considers it necessary.

Article 18 Handling of samples

The person responsible for the experiments and experimenters must verify that the nucleic acid donors, vectors, hosts, etc. used in the recombinant DNA experiments comply with the conditions outlined in the containment measures specified in the Act, etc. before and during the experiment, and they must appropriately handle the samples used in the experiments according to the level of containment measures specified in the Act, etc.

Article 19 Recording of experiments

The person responsible for the experiments shall keep a detailed record of recombinant DNA experiments performed and other necessary information.

Article 20 Report of completion or suspension of experiments

The person responsible for the experiment must submit the specified report to the President via the department head when any recombinant DNA experiment is completed or suspended.

Article 21 Storage

1. The person responsible for the experiments must take the containment measures specified in Article 6 of the Ministerial Ordinance for Type 2 Use for the storage of genetically modified living organisms, etc. and waste.
2. The person responsible for the experiments must prepare and safekeep storage records. However, with regard to the records for genetically modified living organisms, etc. and waste that require containment measures of level P2 or lower levels, the implementation records of the experiments may be used in place of them.

Article 22 Waste disposal, etc.

1. The person responsible for the experiments or a person who receives instructions from the person responsible for the experiments must thoroughly disinfect or sterilize the substances, etc. concerned before disposal in order to dispose of substances, etc. contaminated by genetically modified living organisms, etc.
2. The person responsible for the experiment must appropriately dispose of the genetically modified living organisms, etc. concerned when any recombinant DNA experiment is completed or suspended (including the cases where suspension of the experiments was ordered based on the provisions in Paragraph 2 or Paragraph 3 of Article 14).

Chapter 5 Application, Approval, and Information Provision Regarding Transfer and Receipt

Article 23 Procedures for transfer and receipt

1. When the person responsible for the experiments conducts the transfer or provision of genetically modified living organisms, etc. (hereinafter referred to as “transfer, etc.”) (including the relocation of genetically modified living organisms, etc. to enable the person responsible for the experiments concerned to continue the experiments at another university, etc.), as well as when the person responsible for the experiments conducts the reception or acquisition of genetically modified living organisms, etc., (hereinafter referred to as “receipt, etc.”), they must submit the specified application to the President via the department head to have it approved by the President.
2. When approving transfer, etc. of genetically modified living organisms, etc., the President must receive approval from the head of the organization of the researchers, etc. receiving the transfer, etc.
3. When determined whether or not to approve transfer, etc. or receipt, etc. of genetically modified living organisms, etc., the President shall notify the approval or nonapproval to the person responsible for the experiments pertaining to the concerned application via the department head.

Article 24 Information provision concerning transfer, etc.

When the person responsible for the experiments conducts the transfer, etc. of genetically modified living organisms, etc. or entrusts any person to use genetically modified living organisms, etc. with the approval of the President, as specified in Paragraph 1 of Article 23, the person responsible for the experiments must submit the specified information provision sheet to the person receiving the transfer, etc. or who is entrusted to use the genetically modified living organisms, etc.

Article 25 Notification concerning import

1. When, based on the conditions of the place of production or other circumstances, there is a high possibility to import genetically modified living organisms, etc. without knowing that the use of such genetically modified living organisms, etc. could cause an impact on biodiversity or in other similar cases that are designated by the competent minister, the person responsible for the experiments must submit the specified application to the President via the department head to have it approved by the President.
2. The President shall determine approval or nonapproval for the application in the preceding paragraph after deliberation by the Committee.
3. Once determined whether or not to approve the application as specified in the preceding paragraph, the President shall immediately notify the person responsible for the experiments who submitted the application via the department head of the results.

Article 26 Transportation

1. When transporting genetically modified living organisms, etc. or their waste out of the experiment facilities, the person responsible for the experiments or a person who receives instructions for transportation from the person responsible for the experiments must take containment measures specified in Article 7 of the Ministerial Ordinance for Type 2 Use and clearly mark on the carrying containers to be used the fact that the living organisms concerned are genetically modified living organisms, etc.; the details thereof; the institution from which the gene-recombined living organisms, etc. will be carried out; the genetically modified living organisms, etc.; the institution to which the genetically modified living organisms, etc. will be forwarded; and the telephone numbers, etc. of the personnel responsible at these institutions and, if necessary, must attach a document describing how to respond to an accident if one should occur.
2. Whenever genetically modified living organisms, etc. and waste are to be transported out of an experiment facility, the person responsible for the experiments shall make and keep a record of the names and quantities of the genetically modified living organisms, etc. to be transported, the name of the institution to which the genetically modified living organisms, etc. will be forwarded, and the name of the person responsible at the institution. However, with regard to the records for genetically modified living organisms, etc. that require containment measures of level P2 or lower levels, the implementation records of the experiments may be used in place of them.
3. When carrying genetically modified living organisms, etc. to be used at level LSC or LS1 or for special containment measures and waste out of a mass culture experiment area in a mass culture experiment, these genetically modified living organisms, etc. and waste shall be handled in the same manner as those requiring containment measures of level P2 or lower levels. However, when the substances to be carried out are genetically modified living organisms, etc. to be used at level LS2 or higher levels and waste, these genetically modified living organisms, etc. and waste shall be handled in the same manner as those requiring containment measures of level P3 or higher levels.
4. Transportation of infectious genetically modified living organisms, etc. shall be conducted as required by Paragraph 3 as well as by, depending on the pathogen, Kyoto University Regulations for the Management of Pathogens, etc. (Notification No. 20 of 2011) and Guidance on Regulations for the Transport of Infectious Substances published by the WHO.

Chapter 6 Education, Training, and Health Management

Article 27 Education and training

1. Before performing recombinant DNA experiments, the person responsible for the experiments must educate and train for securing the safety of those who will be engaged in the experiments concerned.
2. The education and training specified in the preceding paragraph shall be conducted in connection with each of the following items:
   (1) Knowledge about the degree of risk of the experiment to be performed

(2) Knowledge and skills about containment measures
(3) Skills in safely handling microorganisms according to the degree of risk
(4) Knowledge in responding to accidents
(5) Other necessary knowledge and skills about the securement of safety in the experiment to be performed

3. The person responsible for the experiments may ask the safety chief of the department for cooperation in conducting education and training described in the preceding paragraph.

Article 28 Health management

1. The Director-General of the Agency for Health, Safety and Environment (hereinafter referred to as the "Director-General of the Agency") must instruct all personnel engaged in experiments to have the medical checkups specified in the Kyoto University Regulations Regarding Safety and Health Control (Notification No. 8 of 2007).
2. When any person engaged in experiments handles genetically modified living organisms, etc. that are infectious, the Director-General of the Agency shall contemplate measures of prophylactic treatment and shall prepare antibiotics, vaccines, blood sera, etc. as needed before the experiment.
3. If there is a risk of infection with genetically modified living organisms, etc. of experimenters within a laboratory or mass culture experiment area, the Director-General of the Agency shall immediately conduct medical checkups for the personnel working there and take appropriate measures.
4. The Director-General shall separately determine specific items of the medical checkup specified in the preceding paragraph.

Chapter 7 Measures at the Time of Emergency

Article 29 Measures at the time of emergency

1. In the case of the occurrence of any of the following events, the person responsible for the experiments and experimenters must immediately report the event to the head and the safety chief of the department concerned and take first-aid measures to secure safety.
   (1) For Type 1 use, etc., when it is incapable of complying with the Regulations Concerning Type 1 Use and there is a risk of impact on biodiversity.
   (2) For Type 2 use, etc., when it is not possible to take the containment measures specified by the Act, etc. or take the containment measures verified by the competent minister as a result of damage on the facilities, etc. or any other accident.
   (3) When any experiment facility is seriously contaminated by genetically modified living organisms, etc. or genetically modified living organisms, etc. leak out or may leak out of the experiment facility as a result of an earthquake, fire, or other disaster.
   (4) When personnel are contaminated or may be contaminated by genetically modified living organisms, etc.
2. Upon receipt of a report of an event as specified in the preceding paragraph, the head and the safety chief of the department concerned must immediately take necessary measures in cooperation with the Committee, and the department head concerned must report the situation to the President.
3. Upon receipt of the report of an event described in item (1) or (2) of Paragraph 1, the President must immediately report the details of the accident and the summary of the measures taken to the competent minister.

Chapter 8 Miscellaneous Provisions

Article 30 Compliance with other laws, etc.

When the experiment to be performed is subject to any law, notification, or regulation other than the Act, etc., the person responsible for the experiments and the experimenters must comply with the applicable laws, etc.

Article 31 Miscellaneous Provisions

The responsible Executive Director shall determine the matters necessary for the enforcement of these Regulations besides the provisions hereof.

Supplementary Provision

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