Osaka University Regulations on Genetic Modification Experiment Safety Management

(Purpose)

Article 1:

The purpose of these Regulations is to stipulate matters necessary for safety management of genetic modification experiments (“Experiments”) conducted at Osaka University (“University”) pursuant to 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), 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 (Ordinance 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 No. 1 of 2003) (“Enforcement Regulations”), and the Ministerial Ordinance Providing Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (Ordinance of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of the Environment No. 1 of 2004) (“Ministerial Ordinance”), and other applicable laws and regulations (“Applicable Laws”), thereby ensuring the safety of Experiments.

(Definitions)

Article 2:

1. The following terms as used herein shall have the meanings set forth below:
2. The term “Division” shall mean any of the Graduate School of Human Sciences, the Graduate School of Science, the Graduate School of Medicine, the Graduate School of Dentistry, the Graduate School of Pharmaceutical Sciences, the Graduate School of Engineering, the Graduate School of Engineering Science, the Graduate School of Information Science and Technology, the Graduate School of Frontier Biosciences, the Osaka University Hospital, the Research Institute for Microbial Diseases, the Institute of Scientific and Industrial Research, the Institute for Protein Research, the Research Center for Ultra-High Voltage Electron Microscopy, the International Center for Biotechnology, the Research Center for Solar Energy Chemistry, the Health and Counseling Center, the Immunology Frontier Research Center, the Institute for Radiation Sciences, the Center for Education in Liberal Arts and Sciences, the Co-Creation Bureau, the International College, and the Administration Bureau.
3. The term “Organism” shall mean a single cell or cell colony (“Cells”) having the capacity to transfer or replicate nucleic acid, and viruses and viroids, excluding:
4. Human cells
5. Cells (excluding individuals and gametes) that are capable of differentiation or have differentiated and which do not grow into individuals under natural conditions
6. The term “Living Modified Organism (LMO)” shall mean an organism that possesses a nucleic acid, or a replicated product thereof, obtained using the following technologies:
7. Technology for processing a nucleic acid extracellularly as stipulated in the Enforcement Regulations
8. Technology for fusing cells of organisms belonging to different taxonomical families as stipulated in the Enforcement Regulations
9. The term “Laboratory” shall mean a room where an Experiment is performed and containment measures are in place.
10. The term “Experimental Area” shall mean the Laboratory and other space demarcated from other areas for access control.

2. Terms not defined in the preceding Paragraph shall have the meanings used in the Applicable Laws.

(Obligations of President)  
Article 3:

The President shall supervise the safety of Experiments conducted at the University and perform the following duties:

1. To appoint members of the Osaka University Genetic Modification Experiment Safety Committee (“Committee”) and Genetic Modification Experiment Biosafety Officers (“Biosafety Officers”).
2. To establish internal regulations on the safety of Experiments following deliberations by the Committee.
3. To seek confirmation of the Minister of Education, Culture, Sports, Science and Technology for minister-reviewed experiments (experiments listed in the Attachment) following deliberation by the Committee and give approval to the experiments based on said confirmation.
4. To give approval to institution-reviewed experiments (experiments other than those listed in the Attachment) following deliberation by the Committee.
5. To work with the Committee and the relevant Biosafety Officer to investigate the situation and consequences of an accident that may happen relating to an Experiment upon receipt of a report thereof, and give instructions for improvement and other necessary actions.

(Committee)  
Article 4:

1. The Committee shall be established within the University to ensure the safety of Experiments.
2. The Committee members shall have advanced knowledge and skills in relevant fields as well as the ability to make judgment from a broad perspective. Thus the Committee shall consist of:
3. The Biosafety Officer of each Division
4. A few professors and/or associate professors who have experience in conducting Experiments as researchers
5. A few professors and/or associate professors in natural sciences other than those stated in the preceding two Items
6. A few professors and/or associate professors in humanities and social sciences
7. A few professors and/or associate professors in medical sciences
8. A person selected from among academic staff of the Genome Information Research Center of the Research Institute for Microbial Diseases
9. The Director of the Health and Counseling Center
10. A person selected from among staff of the Department of Safety and Hygiene
11. A person selected from among staff of the Department of Facilities
12. A few persons deemed necessary by the President in addition to those stated in the preceding Items
13. The Committee members shall be appointed by the President.
14. The Committee members stated in Items (2) to (5) of Paragraph 2 of this Article shall be appointed based on the recommendation by the Committee.
15. The Committee members stated in the preceding Paragraph and in Items (6), (8), (9) and (10) of Paragraph 2 of this Article shall serve a term of two (2) years and may be reappointed.
16. The Committee shall conduct inspection and deliberation on the following matters upon request of the President and give advice or recommendation to the President thereon:
17. The propriety of Experiment plans and methods to be used therein
18. Facilities and equipment to be used in Experiments
19. Knowledge and skills of persons engaged in Experiments
20. Education, training and health management of persons engaged in Experiments
21. Actions to be taken in case of danger or accident and improvement measures
22. Communications and coordination within the University
23. Other matters necessary for the safety of Experiments
24. In addition to performing the duties stated in the preceding Paragraph, the Committee may request Biosafety Officers and Principal Investigators to report on the safety of Experiments or give guidance or advice to them thereon as necessary.
25. The Committee shall meet every two (2) months in principle.
26. The Committee shall have a Chairperson who shall be elected by mutual vote from among the Committee members.
27. The Chairperson shall serve a term of two (2) years and may be reappointed.
28. The Chairperson shall convene and preside over Committee meetings.
29. The Committee may allow non-member(s) to attend a Committee meeting and present opinions when deemed necessary by the Chairperson. However, non-member(s) cannot participate in decision-making.
30. The Committee shall have a Vice Chairperson, who shall be appointed by the Chairperson from among the Committee members.
31. The Vice Chairperson shall assist the Chairperson, and in the event of the inability of the Chairperson to act, shall perform the duties of the Chairperson.
32. The administrative work relating to the Committee shall be carried out by the Research Promotion Division of the Department of Research Promotion.
33. Matters relating to the administration of the Committee not specified in the preceding Paragraphs shall be set forth separately.

(Obligations of Division Directors)

Article 5:

Directors of the Divisions (“Division Directors”) shall oversee the following matters in their respective Divisions, provided that an Executive Director in charge of facilities shall serve as the Division Director for the Administration Bureau:

1. Safety of Experiments
2. Health checkups
3. Education and training

(Biosafety Officers)

Article 6:

1. Each Division shall have one (1) Biosafety Officer as an assistant to the Division Director, provided that the Graduate School of Medicine shall have two (2) Biosafety Officers.
2. Professors or associate professors who are familiar with the Applicable Laws and have advanced knowledge and skills, including those necessary for prevention of biohazards, shall serve as Biosafety Officers.
3. Biosafety Officers shall be appointed in the name of the President and the President shall allow each Division Director to name a Biosafety Officer at their own discretion for his or her Division.
4. When a Division Director has named a Biosafety Officer at his or her discretion pursuant to the preceding Paragraph, the Division Director shall notify the President thereof.
5. Biosafety Officers shall perform the following duties:
6. To make sure that Experiments are conducted appropriately in compliance with Applicable Laws.
7. To certify the competence of persons engaged in Experiments.
8. To give guidance and advice on implementation of Experiments to Principal Investigators.
9. To take measures necessary for safeguarding the health of persons engaged in Experiments.
10. To give guidance and advice on education and training to be provided by Principal Investigators in line with the policies of the Committee.
11. To give guidance and advice on management and maintenance of facilities and equipment used for Experiments to Principal Investigators.
12. To give guidance and advice on actions to be taken in case of danger or accident to Principal Investigators.
13. To perform other necessary duties.

(Principal Investigators)  
Article 7:

1. A Principal Investigator shall be appointed for each Experiment plan prior to conducting the Experiment.
2. Academic staff of the University who are familiar with the Applicable Laws and have advanced knowledge and skills, including those necessary for prevention of biohazards, shall serve as Principal Investigators.
3. Principal Investigators shall be responsible for the safe implementation of the relevant Experiment plan.
4. Each Principal Investigator shall perform the following duties:
5. To develop an Experiment plan and apply for approval therefor.
6. To manage and oversee the implementation of the Experiment plan in close cooperation with the Biosafety Officer.
7. To plan for and provide education and training for persons engaged in Experiments.
8. Each time samples containing an LMO are to be transported, to keep a record of the names and quantities of the samples, and the destination (the name of the research institution to which said samples are to be transported, and the name of the Principal Investigator in charge) and maintain the record.
9. To keep a record of samples containing an LMO in storage and maintain the record.
10. To perform other necessary duties.

(Persons Engaged in Experiments)

Article 8:

1. In planning and conducting Experiments, persons engaged in Experiments shall be fully aware of the necessity of ensuring the safety thereof under the Applicable Laws and take appropriate measures. Persons engaged in Experiments shall also master the standard technique for handling the organism to be used in the Experiments, the operation method unique to the Experiments, and other relevant experimental methods prior to conducting the Experiments.
2. Persons engaged in Experiments shall follow the instructions given by the Principal Investigator when conducting the Experiments.

(Health Checkups)

Article 9:

1. Division Directors shall require persons engaged in Experiments to receive health checkups as stipulated in separate regulations and shall take measures necessary for safeguarding their health following the guidance of the Committee.
2. Persons engaged in Experiments that require P3- or higher level (including P3A-level and P3P-level) containment measures shall have their blood sampled before and during the Experiments. Said blood sampling during the Experiments shall be done once a year.
3. The results of the health checkups of persons engaged in Experiments and the blood serum sampled pursuant to the preceding Paragraph shall be kept in storage at the Health and Counseling Center for the period of five (5) years after termination of said Experiments and after blood sampling respectively.
4. Persons engaged in Experiments shall take care of their health at all times and if any health problem arises or severe or prolonged illness develops, shall report to the President thereon through the relevant Division Director.
5. Upon occurrence of any of the following events or receipt of a report pursuant to the preceding Paragraph, Division Directors shall immediately investigate the situation and take necessary measures:
6. A Person engaged in Experiments has accidentally ingested or inhaled an LMO.
7. A Person engaged in Experiments has had his or her skin contaminated by an LMO and could not remove the contamination, or the contamination may cause an infection.
8. A person engaged in Experiments is present in a Laboratory or Experimental Area that was heavily contaminated by an LMO.

(Management and Maintenance of Experimental Facilities and Equipment)  
Article 10:

Principal Investigators shall be responsible for management and maintenance of experimental facilities and equipment by taking the following measures:

1. Putting up specified signs at experimental facilities and equipment pursuant to the Applicable Laws.
2. Inspecting experimental facilities that require P3- or higher level (including P3A-level and P3P-level) containment measures periodically in accordance with the frequency of use thereof following the guidance and advice of the Biosafety Officer to ensure said facilities satisfy conditions under the Applicable Laws.
3. Inspecting biosafety cabinets used for Experiments following the guidance and advice of the Biosafety Officer under separate regulations.
4. Putting up signs at experimental facilities during Experiments to indicate the level of the containment measures taken therein, excluding P1-level, pursuant to the Ministerial Ordinance and to prevent anyone unaware of the nature of the Experiment from entering the facilities.

(Education and Training)

Article 11:

Principal Investigators shall provide education and training on the following matters to persons engaged in Experiments following the guidance and advice of the Biosafety Officers at least once a year under the Applicable Laws:

1. Techniques for safe handling of organisms according to the degree of risk
2. Knowledge and skills for containment measures
3. Knowledge of the degree of risk of the Experiment to be conducted
4. Knowledge of measures to be taken upon occurrence of an accident (including considerations to be made when taking chemical measures, such as sterilization, to cope with accidental leakage of a culture fluid containing an LMO during a large-scale cultivation experiment)

(Measures to be Taken in Case of Danger or Accident)

Article 12:

1. In the event that a breakage or other accident occurs at a facility that requires containment measures but the action to contain LMOs stipulated in the Ministerial Ordinance cannot be taken, then the relevant Principal Investigator shall take temporary emergency measures, while immediately notifying the Biosafety Officer, the Division Director, the Chairperson of the Committee, and the Head of the Research Promotion Division of the situation and taking appropriate measures to cope therewith following the guidance and advice of the Biosafety Officer.
2. The relevant Division Director shall investigate the situation stated in the preceding Paragraph and take appropriate measures after consulting the Biosafety Officer.
3. Upon occurrence of the event stated in Paragraph 1 of this Article, the relevant Division Director shall submit documents describing the situation thereof and measures taken therefor to the Minister of Education, Culture, Sports, Science and Technology, the Minister of the Environment, and the President without delay.

(Compliance with Local Ordinances)  
Article 13:

For Experiments to be conducted at facilities located in Suita City or Ibaraki City, notifications concerning said facilities shall be submitted under Suita City’s ordinance on ensuring the safety and wellbeing of citizens against risks that may be caused by genetic modification facilities, pathogen handling facilities and radioisotope handling facilities (Suita City Ordinance No. 29 of 1994) or Ibaraki City’s ordinance on preserving the living environment (Ibaraki City Ordinance No. 35 of 2008), as well as under these Regulations.

(Miscellaneous Provision)

Article 14:

Matters concerning the implementation of Experiments not specified herein shall be set forth separately.

Supplementary Provision

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

2. Osaka University Regulations on DNA Modification Experiment Safety Management (dated October 17, 1979) shall be abolished.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2005.

Supplementary Provision

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

Supplementary Provision

These Regulations as amended shall come into effect on October 1, 2007.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2008.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2009.

Supplementary Provision

These Regulations as amended shall come into effect on April 21, 2009.

Supplementary Provision

These Regulations as amended shall come into effect on December 9, 2009.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2011.

Supplementary Provision

These Regulations as amended shall come into effect on April 27, 2012.

Supplementary Provision

These Regulations as amended shall come into effect on June 1, 2012.

Supplementary Provision

(Date of enforcement)

1. These Regulations as amended shall come into effect on December 1, 2013.

(Partial amendment of Osaka University Regulations on Genetic Modification Experiments)

2. Osaka University Regulations on Genetic Modification Experiments (dated April 1, 2004) shall be amended in part as follows.

　The description “Article 13” in Article 1 shall be read as “Article 14.”

Supplementary Provision

These Regulations as amended shall come into effect on August 1, 2014.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2015.

Supplementary Provision

These Regulations as amended shall come into effect on May 1, 2015.

Supplementary Provision

These Regulations as amended shall come into effect on July 1, 2015.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2016.

Supplementary Provision

These Regulations as amended shall come into effect on September 1, 2016.

Supplementary Provision

These Regulations as amended shall come into effect on February 1, 2017.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2017.

Supplementary Provision

These Regulations as amended shall come into effect on August 26, 2017.

Supplementary Provision

These Regulations as amended shall come into effect on January 1, 2018.

Supplementary Provision

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

Attachment (Article 3)

1. Experiments using microorganisms with an LMO that falls under any of the categories (a) to (h) below:
2. An LMO in which the recipient organism or the nucleic acid donor does not fall under any of the categories shown in the right columns of the Table in Article 3 of the Ministerial Ordinance (excluding LMOs in which an authorized recipient organism–vector system is used and the nucleic acid donor is a living organism [including a human] other than viruses and viroids, where the donor nucleic acid is an identified nucleic acid which can be inferred from scientific data not to be associated with pathogenicity and transmissivity in mammals)
3. An LMO in which the recipient organism or the nucleic acid donor is classified into Class 4 of the experiment classification
4. An LMO in which the recipient organism is classified into Class 3 of the experiment classification
5. An LMO in which an authorized recipient organism–vector system is not used and the nucleic acid donor is classified into Class 3 of the experiment classification, where the donor nucleic acid is either unidentified or is identified and associated with pathogenicity or transmissivity in mammals, and it can be inferred from scientific data that the pathogenicity of the recipient organism in mammals can increase drastically due to its property
6. An LMO (excluding viruses and viroids) in which the recipient organism is classified into Class 2 of the experiment classification and the donor nucleic acid contains a drug-resistance gene (limited to those which imparts a property that makes an infectious disease attributable to the LMO difficult to be treated if mammals are infected therewith)
7. A LMO that is a virus or a viroid capable of self-proliferating and transmitting an infection that keeps propagating with the use (excluding those designated by the Minister of Education, Culture, Sports, Science and Technology)
8. An LMO containing a donor nucleic acid with a gene for a proteinaceous toxin with a lethal dose to mammals no greater than 100 μg per kilogram of body weight (excluding LMOs involved in an authorized recipient organism–vector system where the recipient organism is E. coli and the donor nucleic acid contains a gene for a proteinaceous toxin with a lethal dose to mammals exceeding 100 μg per kilogram of body weight)
9. Other LMOs designated by the Minister of Education, Culture, Sports, Science and Technology
10. Large-scale cultivation experiments involving an LMO that falls under any of the categories (a) to (e) below:
11. An LMO that falls under any of the categories (a) to (g) stated in Paragraph 1 above
12. An LMO in which an authorized recipient organism–vector system is not used and the recipient organism or nucleic acid donor is classified into Class 2 of the experiment classification, where the donor nucleic acid is associated with pathogenicity or transmissivity in mammals and it can be inferred from scientific data that the pathogenicity of the recipient organism in mammals can increase drastically due to its property
13. An LMO in which a specific authorized recipient organism–vector system is not used and the nucleic acid donor is classified into Class 3 of the experiment classification (excluding the one specified in Item (e) of Paragraph 1 above)
14. Any of the LMOs listed in Items (a) to (c) of Paragraph 2 of Article 5 of the Ministerial Ordinance, where the use thereof requires LSC level containment measures as stated in Table 3 of the Ministerial Ordinance
15. Other LMOs designated by the Minister of Education, Culture, Sports, Science and Technology
16. Animal experiments involving an LMO that falls under any of the categories (a) to (d) below:
17. An LMO that falls under any of the categories (a) to (g) stated in Paragraph 1 above
18. An LMO whose recipient organism is an animal in which the donor nucleic acid contains a gene that provides the recipient organism with a receptor (limited to the one not present in an organism belonging to the same taxonomic species as the recipient organism) that results in infection by a microorganism with pathogenicity towards mammals
19. Any of the LMOs listed in Items (a) to (c) in Paragraph 3 of Article 5 of the Ministerial Ordinance, where the use thereof requires containment measures of a special breeding section as stated in Table 4 of the Ministerial Ordinance
20. Other LMOs designated by the Minister of Education, Culture, Sports, Science and Technology
21. Plant experiments involving an LMO that falls under any of the categories (a) to (c) below:
22. An LMO that falls under any of the categories (a) to (g) stated in Paragraph 1 above
23. Any of the LMOs listed in Items (a) to (c) in Paragraph 4 of Article 5 of the Ministerial Ordinance, where the use thereof requires containment measures of a special screened greenhouse as stated in Table 5 of the Ministerial Ordinance
24. Other LMOs designated by the Minister of Education, Culture, Sports, Science and Technology