

## Domestic Animal Infectious Diseases Control Regulations of Kyoto University

Enacted on June 25, 2013 (Order No.46)

Revised on:

March 31, 2015 (Order No.31)

September 20, 2018 (Order No. 61)

March 31, 2020 (Order No. 23)

September 29, 2020 (Order No. 58)

### (Objective)

Article 1. The purpose of these regulations is to set forth matters necessary for safety control of pathogens of domestic animal infectious diseases or notifiable infectious diseases (hereinafter referred to collectively as “monitored infectious disease pathogens”) that are handled at Kyoto University (hereinafter referred to as “KU”) under the Act on Domestic Animal Infectious Diseases Control (Act No. 166 of 1951, hereinafter referred to as the “Act”) and other applicable laws, thereby preventing the outbreak and spread of domestic animal infectious diseases or notifiable infectious diseases (hereinafter referred to collectively as “monitored infectious diseases”).

### (Definitions)

Article 2. For the purpose of these regulations, the terms below shall have the following meanings.

- (1) “Domestic animal infectious disease pathogens” refers to pathogens as defined in Article 56-3 of the Ordinances for Enforcement of the Act on Domestic Animal Infectious Diseases Control (Ordinance of the Ministry of Agriculture and Forestry No. 35 of 1951, hereinafter referred to as the “Ordinance”).
- (2) “Notifiable infectious disease pathogens” refers to pathogens as defined in Article 56-27 of the Ordinance.
- (3) “Sterilization (sterilize)” refers to sterilization or detoxification of monitored infectious disease pathogens.
- (4) “Divisions” refers to facilities as defined in Chapter 3, sections 7 through 11 of the Regulations for the Organization of National University Corporation, Kyoto University (Order No. 1 of 2004), including, but not limited to, graduate schools, attached research institutes, Kyoto University Library, Kyoto University Hospital, and centers (all organizations as defined in paragraph 1 of Article 47 thereof, excluding Library Network).

### (Duties of the President)

Article 3.

1. The President of KU shall oversee possession, handling, and management of monitored infectious disease pathogens at KU and take overall responsibility for prevention of the outbreak and spread of monitored infectious diseases.
2. The President of KU shall, as a holder of monitored infectious disease pathogens, file an application for approval and notification concerning possession of monitored infectious disease pathogens pursuant to the Act.

(Duties of Heads of Divisions)

Article 4. Heads of Divisions shall oversee possession, handling, and management of monitored infectious disease pathogens at their respective Divisions and take responsibility for prevention of the outbreak and spread of monitored infectious diseases.

(Possession of Domestic Animal Infectious Disease Pathogens)

Article 5.

1. Heads of Divisions shall notify the President beforehand if they intend to possess domestic animal infectious disease pathogens. However, this shall not apply when the situation falls under the provisory clause to paragraph 1 of Article 46-5 of the Act.
2. Domestic animal infectious disease pathogens may be possessed only after the Minister of Agriculture, Forestry and Fisheries (hereinafter referred to as "MAFF") has granted permission pursuant to the provisions of paragraph 1 of Article 46-5 of the Act.
3. Heads of Divisions possessing domestic animal infectious disease pathogens shall notify the President beforehand if they intend to alter the types of such pathogens, the purpose and method of their possession, or the location, structure, and equipment of facilities in which they are preserved, used, or sterilized (hereinafter referred to as "handling facilities").
4. Alterations in the preceding paragraph may be effected only after the MAFF has granted permission pursuant to the provisions of paragraph 1 of Article 46-8 of the Act. However, this shall not apply when such alterations are negligible according to the Ordinance.
5. Heads of Divisions possessing domestic animal infectious disease pathogens that have made alterations to the names and/or addresses of their respective Divisions shall immediately notify the President of the same.

(Possession of Notifiable Infectious Disease Pathogens)

Article 6.

1. Heads of Divisions that intend to possess notifiable infectious disease pathogens shall notify the President prior to the day on which possession of such pathogens will commence. However, this

shall not apply when the situation falls under the provisory clause to paragraph 1 of Article 46-19 of the Act.

2. Heads of Divisions possessing notifiable infectious disease pathogens shall immediately notify the President when they have altered matters concerning notification of such pathogens or have ceased to possess such pathogens.

(Import of Monitored Infectious Disease Pathogens, etc.)

Article 7.

1. Heads of Divisions shall notify the President if they intend to import monitored infectious disease pathogens or domestic animal infectious disease pathogens other than those that are already known (hereinafter referred to as the “monitored infectious disease pathogens, etc.”) prior to the day on which transportation of such pathogens will commence.

2. Monitored infectious disease pathogens, etc. may be imported only after the MAFF has granted permission pursuant to the provisory clause to paragraph 1 of Article 36 of the Act.

3. Heads of Divisions shall notify the President if they intend to import domestic animal infectious disease pathogens that are already known but are not included under monitored infectious disease pathogens (hereinafter in this paragraph referred to as “pathogens other than those of monitored infectious diseases”) prior to the day on which transportation of pathogens other than those of monitored infectious diseases will commence.

(Restriction of Transfer and Acceptance of Domestic Animal Infectious Disease Pathogens)

Article 8. Domestic animal infectious disease pathogens shall not be transferred or accepted except when any of the items within paragraph 10 of Article 46 of the Act apply.

(Sterilization)

Article 9.

1. Heads of Divisions possessing domestic animal infectious disease pathogens shall sterilize or transfer such pathogens when it becomes unnecessary to possess them.

2. Heads of Divisions possessing domestic animal infectious disease pathogens shall immediately notify the President when they sterilize or transfer such pathogens as described in the preceding paragraph.

(Preparation, etc. of Domestic Animal Infectious Disease Outbreak Prevention Regulations)

Article 10.

1. When Heads of Divisions intend to possess domestic animal infectious disease pathogens, they shall prepare regulations for prevention of the outbreak of domestic animal infectious diseases and

notify the President of such preparation prior to the commencement of possession in order to prevent the outbreak and spread of domestic animal infectious diseases by such pathogens.

2. Heads of Divisions possessing domestic animal infectious disease pathogens shall immediately notify the President when the regulations for prevention of the outbreak of domestic animal infectious diseases as prescribed in the preceding paragraph have been altered.

(Nomination of Domestic Animal Infectious Disease Pathogens Protection Supervisors)

Article 11.

1. Domestic Animal Infectious Disease Pathogens Protection Supervisors (hereinafter referred to as "Protection Supervisors") shall be nominated at Divisions possessing domestic animal infectious disease pathogens.

2. Protection Supervisors shall be nominated by the head of each Division from among those who have sufficient knowledge and experience of handling domestic animal infectious disease pathogens and meet any of the requirements listed in Article 56-19 of the Ordinance.

3. Heads of Divisions shall immediately notify the President when they have nominated or dismissed Protection Supervisors pursuant to the provisions of the preceding paragraph.

(Duties of Protection Supervisors)

Article 12.

1. Protection Supervisors shall supervise prevention of the outbreak and spread of domestic animal infectious diseases by domestic animal infectious disease pathogens at their respective Divisions.

2. Heads of Divisions possessing domestic animal infectious disease pathogens shall respect Protection Supervisors' opinions on prevention of the outbreak and spread of domestic animal infectious diseases by such pathogens.

3. Those who enter handling facilities shall follow the instructions of Protection Supervisors in order to ensure that applicable laws and university regulations are enforced.

(Training)

Article 13. Divisions possessing domestic animal infectious disease pathogens shall make regulations for prevention of the outbreak of domestic animal infectious diseases known to those who enter handling facilities as prescribed in the provisions of paragraph 1, Article 56-21 of the Ordinance and provide necessary training in order to prevent the outbreak and spread of domestic animal infectious diseases by such pathogens.

(Register Obligations)

Article 14.

1. Divisions possessing monitored infectious disease pathogens shall provide registers as specified by the Ordinance pursuant to the provisions of Article 46-15 of the Act and enter matters concerning their preservation, use, and sterilization and any other matters necessary for prevention of the outbreak and spread of monitored infectious diseases by such pathogens.
2. Heads of Divisions possessing monitored infectious disease pathogens shall preserve the registers of the preceding paragraph as stipulated by the Ordinance.

(Standards of Facilities)

Article 15. Divisions possessing monitored infectious disease pathogens shall, pursuant to the provisions of Article 46-16 of the Act, maintain the locations, structures, and equipment of facilities where such pathogens are preserved, used, and sterilized so that they meet the technical standards established by the Ordinance.

(Standards of Preservation)

Article 16. Divisions possessing monitored infectious disease pathogens shall, pursuant to the provisions of Article 46-17 of the Act, take measures necessary for prevention of the outbreak and spread of monitored infectious diseases by such pathogens in accordance with the technical standards established by the Ordinance, if they intend to preserve, use, transport (excluding transport by marine vessel or aircraft), or sterilize such pathogens.

(Emergency Measures in Disasters)

Article 17. If the outbreak or spread of monitored infectious diseases from monitored infectious disease pathogens has occurred or threatens to occur as a result of earthquake, fire, or other disaster, Divisions possessing such pathogens shall, in accordance with the provisions of paragraph 1 of Article 46-18 of the Act and the Ordinance, immediately take emergency measures and report to the President on the situation and measures thus taken without delay.

(Divisional Expert Committees)

Article 18.

1. Divisional Expert Committees shall be established under Divisions possessing monitored infectious disease pathogens in order to investigate and review the safety management of such pathogens at those Divisions.
2. Heads of relevant Divisions shall determine all necessary matters concerning the Divisional Expert Committees.

(Duties of Faculty and Staff Members and Students)

Article 19. Faculty and staff members and students shall comply with all applicable laws and university regulations concerning the handling of monitored infectious disease pathogens.

(Administrative Work)

Article 20. Administrative work for the management of monitored infectious disease pathogens shall be processed by the divisions possessing such pathogens and by the Research Promotion Department.

(Miscellaneous)

Article 21. The KU Executive Vice-President for Research Standards shall determine matters necessary for the management of monitored infectious disease pathogens other than those stipulated herein.

Supplementary Provisions

These regulations shall be effective from June 25, 2013.

(Interim supplementary provisions are omitted)

Supplementary Provisions (Order No. 61, 2018)

These regulations shall be effective from September 20, 2018, and apply from April 1, 2018.

Supplementary Provisions (Order No. 23, 2020)

These regulations shall be effective from April 1, 2020.

Supplementary Provisions (Order No. 58, 2020)

These regulations shall be effective from October 1, 2020.