

Ministerial Ordinance for Enforcement of the Act on Domestic Animal Infectious Diseases  
Control

(Ministry of Agriculture, Forestry and Fisheries Ordinance No. 35, 1953)

**Chapter I General Provisions**

(Pathogens of piroplasmosis, anaplasmosis and avian salmonellosis)

Article 1

The pathogens of piroplasmosis, anaplasmosis, and avian salmonellosis prescribed by the Ordinance of the Ministry of Agriculture, Forestry and Fisheries referred to in the table of Article 2 paragraph 1 of the Act on Domestic Animal Infectious Diseases Control (hereinafter referred to as "the Act") and the table of Article 1 of the Government Ordinance for Enforcement of the Act on Domestic Animal Infectious Diseases Control (Government Ordinance No. 235, 1953; hereafter referred to as "the Ordinance") shall be as listed in the following table:

Infectious disease	Pathogens
Piroplasmosis	<i>Babesia bigemina</i> , <i>Babesia bovis</i> , <i>Babesia equi</i> , <i>Babesia caballi</i> , <i>Theileria parva</i> , <i>Theileria annulata</i>
Anaplasmosis	<i>Anaplasma marginale</i>
Avian salmonellosis	<i>Salmonella enterica</i> (Only those whose serotype is <i>Salmonella gallinarum</i> and whose biotype is <i>Salmonella pullorum</i> or <i>Salmonella gallinarum</i> )

(Highly pathogenic Newcastle disease)

Article 1-2

Newcastle disease prescribed by the Ministerial Ordinance referred to in the table of Article 2 paragraph 1 of the Act and the table of Article 1 of the Government Ordinance shall be the following:

(1) Newcastle disease, whose ICPI (index indicating pathogenicity of a pathogen obtained in an intracerebral inoculation test; hereinafter referred to as the same) of the pathogen is 0.7 or more in one-day old chicks.

(2) Newcastle disease to which both of the following items are applied:

a. Of the 113rd to 116th amino acid residues of the F protein of the causative agent, three or more are estimated to be an arginine or a lysine residue.

b. The 117th amino acid residue of the F protein of the causative agent is estimated to be a phenylalanine residue.

(Animal infectious diseases requiring the development of Specific Domestic Animal Infectious Disease Quarantine Guidelines)

Article 1-3

The animal infectious diseases prescribed by the Ministerial Ordinance referred to in Article 3-2 paragraph 1 of the Act shall be rinderpest, contagious bovine pleuropneumonia, foot-and-mouth disease, bovine spongiform encephalopathy (which means the diseases concerning cattle out of transmissible spongiform encephalopathy listed in table 15 of Article 2 paragraph 1 of the Act), classical swine fever, African swine fever, highly pathogenic avian influenza, and low pathogenic avian influenza.

## **Chapter II Preventing the Outbreak of Livestock/Domestic Animal Infectious Diseases**

(Report on infectious diseases)

Article 2

The notifiable infectious diseases specified by the Ministerial Ordinance referred to in Article 4 paragraph 1 of the Act shall be the infectious diseases specified in the left column of the following table and contracted by the livestock specified in the corresponding line of the right column:

Kind of infectious disease	Kind of livestock
Bluetongue	Cattle, water buffalo, deer, sheep, goat
Akabane disease	Cattle, water buffalo, sheep, goat
Malignant catarrhal fever	Cattle, water buffalo, deer, sheep
Chuzan disease	Cattle, water buffalo, goat
Lumpy skin disease	Cattle, water buffalo
Bovine viral diarrhea / mucosal disease	Cattle, water buffalo
Infectious bovine rhinotracheitis	Cattle, water buffalo
Bovine leukemia	Cattle, water buffalo
Aino virus infection	Cattle, water buffalo
Ibaraki disease	Cattle, water buffalo
Bovine papular stomatitis	Cattle, water buffalo
Bovine ephemeral fever	Cattle, water buffalo
Melioidosis	Cattle, water buffalo, deer, horse, sheep, goat, pig, wild boar
Tetanus	Cattle, water buffalo, deer, horse
Blackleg	Cattle, water buffalo, deer, sheep, goat, pig, wild boar

Leptospirosis (caused by only <i>Leptospira pomona</i> , <i>Leptospira canicola</i> , <i>Leptospira icterohaemorrhagiae</i> , <i>Leptospira grippotyphosa</i> , <i>Leptospira hardjo</i> , <i>Leptospira autumnalis</i> and <i>Leptospira australis</i> )	Cattle, water buffalo, deer, pig, wild boar, dog
Salmonellosis (caused by only <i>Salmonella dublin</i> , <i>Salmonella enteritidis</i> , <i>Salmonella typhimurium</i> and <i>Salmonella choleraesuis</i> )	Cattle, water buffalo, deer, pig, wild boar, chicken, duck, quail, turkey
Bovine Campylobacteriosis	Cattle, water buffalo
Trypanosomiasis	Cattle, water buffalo, horse
Trichomoniasis	Cattle, water buffalo
Neosporosis	Cattle, water buffalo
Hypodermatitis	Cattle, water buffalo
Nipah virus infection	Horse, pig, wild boar
Equine influenza	Horse
Equine viral arteritis	Horse
Equine rhinopneumonitis	Horse
Equine morbillivirus pneumonia	Horse
Horse pox	Horse
Tularemia	Horse, sheep, pig, wild boar, rabbit
Contagious equine metritis	Horse
Equine paratyphoid	Horse
Epizootic lymphangitis	Horse
Contagious ecthyma	Deer, sheep, goat
Nairobi sheep disease	Sheep, goat
Sheep pox	Sheep
Maedi visna	Sheep
Contagious agalactia	Sheep, goat
Enzootic abortion of ewes	Sheep
Toxoplasmosis	Sheep, goat, pig, wild boar
Mange	Sheep
Goat pox	Goat
Caprine arthritis / encephalomyelitis	Goat
Contagious caprine pleuropneumonia	Goat
Aujeszky's disease	Pig, wild boar
Transmissible gastroenteritis	Pig, wild boar
Swine enteroviral encephalomyelitis	Pig, wild boar

Porcine reproductive / respiratory syndrome	Pig, wild boar
Swine vesicular exanthema	Pig, wild boar
Porcine epidemic diarrhea	Pig, wild boar
Atrophic rhinitis	Pig, wild boar
Swine erysipelas	Pig, wild boar
Swine dysentery	Pig, wild boar
Avian influenza	Chicken, duck, quail, turkey
Low pathogenic Newcastle disease	Chicken, duck, quail, turkey
Avian pox	Chicken, quail
Marek's disease	Chicken, quail
Infectious bronchitis	Chicken
Infectious laryngotracheitis	Chicken
Infectious bursal disease	Chicken
Avian leukosis	Chicken
Avian tuberculosis	Chicken, duck, quail, turkey
Avian Mycoplasmosis	Chicken, turkey
Leucocytozoonosis	Chicken
Duck hepatitis	Duck
Duck viral enteritis	Duck
Rabbit hemorrhagic disease	Rabbit
Myxomatosis	Rabbit
Varroosis	Honey bee
Chalkbrood	Honey bee
Acariosis	Honey bee
Nosemmosis	Honey bee

#### Article 2-2

Reports under the provision of Article 4 paragraph 1 of the Act shall be made in writing or verbally for the items listed below.

- (1) Name and address of notifier
- (2) Name and address of the owner of the livestock
- (3) Kind of notifiable infectious disease and whether confirmed or suspected case
- (4) Kind, sex and age (estimated age when unknown) of the livestock (including dead livestock)
- (5) Location of the livestock of the confirmed or suspected case or the carcass of those animals
- (6) Time and date of discovery of the disease and condition at the time of discovery

(7) Estimated date of disease onset

(8) Other items for reference

(Exception to obligation to report of infectious diseases)

### Article 3

The cases prescribed by the Ministerial Ordinance referred to in Article 4 paragraph 3 of the Act shall be the following:

(1) The cases in which a notifying holder (which means the notifying holder defined in Article 46-19 paragraph 2 of the Act; hereinafter referred to as the same) finds that the livestock kept in the facility for storage, use, sterilization and others (which mean sterilization and others specified in Article 46-11 paragraph 1 of the Act; hereinafter referred to as the same) of the pathogens of notifiable infectious diseases concerning the said holding notification and others (which mean the pathogens of notifiable infectious diseases and others specified in Article 46-19 paragraph 1 ; hereinafter referred to as the same) (hereinafter referred to as "handling facility for pathogens of notifiable infectious diseases and others) in order to use the said pathogens of the said notifiable infectious diseases and others has been affected or is suspected to have been affected with the notifiable infectious disease.

(2) The cases in which the livestock kept for the manufacture of biological preparations (only those for the notifiable infectious diseases) by a drug manufacturer/distributor or a drug manufacturer (hereinafter referred to as "licensed manufacturer etc.") approved under the provision of Article 12 paragraph 1 or Article 13 paragraph 1 of the Pharmaceutical Affairs Act (Act No. 145, 1960) (including the cases in which these provisions are applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act) who is not the notifier are found affected or suspected to be affected with a notifiable infectious disease.

(3) The cases in which the person who is nominated by the Minister of Agriculture, Forestry and Fisheries referred to in Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act (hereinafter referred to as "designated test institution") and who is not the notifying holder finds that the livestock kept for assay referred to in the same Article 43 paragraph 1 has been affected or is suspected to have been affected with a notifiable infectious disease.

(4) The cases in which the livestock kept for academic research by an academic research institution approved by the Minister of Agriculture, Forestry and Fisheries which is not a notifier are found to have affected or be suspected to have affected a notifiable infectious disease.

(Notification and report of outbreak of infectious diseases)

#### Article 4

The notification under the provision of Article 4 paragraph 4 of the Act concerning items to be reported referred to in Article 2-2 shall be made in writing or verbally without delay.

2. The report under the provision of Article 4 paragraph 4 of the Act shall be made by electronic communication, telephone or a method of similar nature without delay, and by the tenth of each month the situation throughout the previous month shall be provided in accordance with Form 1 of the Appendix.

(Report of new diseases)

#### Article 5

The report under the provision of Article 4-2 paragraph 1 of the Act concerning the items listed below shall be made in writing or verbally.

- (1) Name and address of the notifier
- (2) Name and address of the owner of the livestock
- (3) Disease condition or treatment results
- (4) Kind, sex and age (estimate age when unknown) of livestock (including dead livestock)
- (5) Location of livestock which have affected or are suspected to have affected with an emerging disease or their carcasses
- (6) Time and date of discovery of disease and condition at the time of discovery
- (7) Estimated date of disease onset
- (8) Additional items for reference

(Exception of obligation to report of new diseases)

#### Article 6

The cases specified by the Ministerial Ordinance referred to in Article 4-2 paragraph 2 of the Act shall be the cases in which livestock kept by a designated test organization for testing under Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act are found to have affected or be suspected to have affected a new disease.

(Notification and reports of outbreak of new diseases)

## Article 7

The notification under the provision of Article 4-2 paragraph 4 concerning items to be reported specified in Article 5 shall be conducted in writing or verbally without delay.

2. The report under the provision of Article 4-2 paragraph 4 shall be made without delay by electronic communication, telephone or a method of similar nature, and by the tenth of each month the situation throughout the previous month shall be provided in accordance with Form 2 of the Appendix.

(Public notification)

## Article 8

The public notification referred to in Article 4-2 paragraph 6 and Article 5 paragraph 2 of the Act (including cases where this is applied mutatis mutandis to Article 6 paragraph 2 of the Act) shall be implemented by the same method as the notice of provisions and posted at a prominent site in public.

(Inspection for determining the status of outbreak of monitored infectious disease and others)

## Article 9

The order given to prevent the outbreak of the monitored infectious disease under the provision of Article 5 paragraph 1 of the Act shall be given for the cases in which it is deemed necessary to do so by the governor of the prefecture, as well as for the cases in connection with brucellosis, tuberculosis, Johne's disease or equine infectious anemia at least every five years, while for the cases in connection with transmissible spongiform encephalopathy every year.

2. The inspection carried out in accordance with the order under the provision of the preceding paragraph (only that in connection with brucellosis, tuberculosis, Johne's disease transmissible spongiform encephalopathy or equine infectious anemia) shall be carried out by the method of inspection specified in the attached table 1. Of the said inspections, the inspections carried out at least every five years under the provision in the preceding paragraph shall target cattle listed from (1) to (4) kept within the district prescribed by the Minister of Agriculture, Forestry and Fisheries for brucellosis or tuberculosis, cattle listed from (1) to (4) that are designated by the governor of the prefecture for Johne's disease, and horses listed from (5) to (9) for equine infectious anemia, and the inspections for transmissible spongiform encephalopathy carried out every year under the provision in the preceding paragraph shall target the carcasses of livestock listed from (10) to (11) which are designated by the governor of the prefecture.

(1) Cows being used or to be used for milking.

- (2) Bulls being used or to be used for mating.
- (3) Cattle kept with the cattle referred to in (1) or (2) within the same facilities.
- (4) Other cattle designated by the Minister of Agriculture, Forestry and Fisheries or the governor of the prefecture.
- (5) Mares being used or to be used for breeding.
- (6) Stallions being used or to be used for mating.
- (7) Horses kept with a horse referred to in (5) and (6) within the same facilities.
- (8) Horses participating in a horse race under the Horse Racing Act (Act No. 158, 1948).
- (9) Other horses designated by the Minister of Agriculture, Forestry and Fisheries or the governor of the prefecture.
- (11) Carcasses of cattle that died at the age or estimated age of 24 months or more.
- (12) Carcasses of sheep or goat that died at the age or estimated age of 12 months or more.

Article 10

The order given to predict the outbreak of monitored infectious disease under the provision of Article 5 paragraph 1 of the Act shall be given for any kind of monitored infectious disease listed in the left column in the cases in the corresponding right column of the following table:

Kind of monitored infectious disease	Case of orders given
(1) Rinderpest, Contagious bovine pleuropneumonia, Foot-and-mouth disease, Rabies, Vesicular stomatitis, Rift Valley fever, Haemorrhagic septicaemia, Glanders, African horse sickness, Classical swine fever, African swine fever, Swine vesicular disease, Fowl cholera, Highly Pathogenic Avian Influenza, Low pathogenic avian influenza, Avian salmonellosis (only that caused by the pathogens specified in Article 1; hereinafter referred to as the same), Lumpy skin disease, Melioidosis, Trypanosomiasis, Trichomoniasis, Nipah virus infection, Equine viral arteritis, Equine morbillivirus pneumonia, Horse pox, Epizootic lymphangitis, Peste-des-petits-ruminant, Nairobi sheep disease, Sheep pox, Maedi visna, Infectious agalactia, Epidemic ovine abortion, Mange, Goat pox, Caprine infectious pleural pneumoni, Swine enteroviral encephalomyelitis, Swine vesicular exanthema, Duck hepatitis, Duck viral enteritis, Rabbit myxoma, <i>Acarapis woodi</i> infection, Nosema infection.	Case when the Minister of Agriculture Forestry and Fisheries recognizes that a monitored infectious disease listed in the left column is likely to break out and designates it.
(2) Infectious encephalitis, Bluetongue, Akabane disease, Chuzan disease, Aino virus infection, Ibaraki disease, Bovine ephemeral fever.	The following cases: (1) One month prior to the season when a vector carrying the



	<p>causative agent of the monitored infectious disease listed in the left column usually develops.</p> <p>(2) The season when a vector carrying the causative agent of the monitored infectious disease listed in the left column usually develops.</p> <p>(3) One month after the season when a vector carrying the causative agent of the monitored infectious disease listed in the left column usually develops.</p>
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2. The inspections carried out in accordance with the order under the provision of the preceding paragraph, for the monitored infectious diseases listed in (1) of the table of the same paragraph, shall be carried out targeting the livestock kept within the district prescribed by the governor of the prefecture for each kind of monitored infectious diseases, and for the monitored infectious diseases listed in (2) of the table of the same paragraph, targeting the livestock designated by the governor of the prefecture which are among those which did not pass the summer kept within the district prescribed by the governor of the prefecture for each kind of such monitored infectious diseases.

(Inspection for determining the status of outbreak of infectious diseases of animals other than livestock and others)

#### Article 11

The inspections described in Article 5 paragraph 3 of the Act shall be carried out for animals other than livestock which have affected or are suspected to have affected with the infectious disease listed in the left column of the table in Article 2 paragraph 1 of the Act and their carcasses, using the inspection method corresponding to the one specified in Table 1 of the Appendix for the infectious diseases listed in the column of category of Table 1 of the Appendix and using the usual method for the infectious diseases which are listed in the left column of the table in same Article and are not the infectious diseases listed in the column of category of Table 1 of the Appendix, by a prefectural government official engaged in matters concerning wild animals and an animal health inspector in close contact with each other, sharing information appropriately.

(Report)

#### Article 12

The report under the provision of Article 5 paragraph 4 of the Act shall be made in writing without delay.

(Indication of inspection, injection, dipping or medication)

#### Article 13

In accordance with the provisions of Article 7 of the Act (including cases where this is applied mutatis mutandis to Article 31 paragraph 2 of the Act), the kinds of livestock to be tagged with branding tattooing or other means, or their carcasses, tagging site, and the kind and style of the said tag shall be shown in the following table:

Kind of livestock or their carcasses	Site	Kind and style of tag
Cattle, water buffalo, deer, sheep, goat, pig and wild boar vaccinated against rinderpest or foot-and-mouth disease.	Right ear	Ear tag Form 6 of the Appendix
Cattle (excluding affected and suspected animals) listed in (1) to (4) of Article 9 paragraph 2 inspected for Brucellosis, Tuberculosis or Johne's disease.	Left ear	Ear tag Form 7 of the Appendix
Chicken (excluding affected and suspected animals) inspected for Avian salmonellosis	Left leg	Leg ring Form 8 of the Appendix
Cattle carcasses listed in Article 9 paragraph 2 (10) (excluding affected animals and suspected animals) and carcasses of sheep or goat listed in (11) in the same paragraph (excluding affected and suspected animals) inspected for transmissible spongiform encephalopathy, and other livestock (excluding honey bee and affected and suspected animals)	Site specified by the governor of the prefecture (excluding the ear for cattle and water buffalo)	Tag specified by the governor of the prefecture

(Format of certificates for inspection, injection and others)

#### Article 14

The forms of certificates under the provision of Article 8 of the Act (including cases where this is applied mutatis mutandis to Article 31 paragraph 2 of the Act) shall be in accordance with Form 9 and Form 10 of the Appendix.

(Installation of disinfection equipment)

#### Article 14-2

The installation of equipment specified in the provision of Article 8-2 paragraph 1 of the Act shall be carried out according to the following items:

(1) Near the doorway of the livestock barns and others specified in the next Article, equipment which is a boot bath, a disinfectant spray device, and other equivalent equipment and is used to disinfect the body of a person entering the such livestock barns and others and articles described in Article 14-6 brought into the such livestock barns and others shall be installed.

(2) Near the gateway of the premises including livestock barns and others specified in the next Article (excluding the premises of livestock barns and others described in Article 14-4), equipment which is a disinfectant spray device, a disinfection mat and equivalent equipment and is used to disinfect the vehicles entering the premises shall be installed.

(Facilities concerning obligation of installation of disinfection equipment)

#### Article 14-3

The facilities provided by the Ministerial Ordinance referred to in Article 8-2 paragraph 1 of the Act shall be a livestock barn and a hatchery (hereinafter referred to as “livestock barns and others”).

(Premises excluded from the obligation of installation of disinfection equipment)

#### Article 14-4

The premises provided by the Ministerial Ordinance referred to in Article 8-2 paragraph 1 of the Act shall be premises of livestock barns and others used for housing only.

(Disinfection method)

#### Article 14-5

The disinfection specified in the provision of Article 8-2 paragraph 2 and 3 of the Act when a

pharmaceutical agent specified in Article 2 paragraph 1 of the Pharmaceutical Affairs Act is used, shall be subject to the package insert of the agent or the dosage and administration and other precautions described on the containers or packages under the provision of Article 52 of the same Act and to the instruction of an animal health inspector or a veterinarian when a disinfectant other than such pharmaceutical agent is used.

(Articles under obligation of disinfection)

#### Article 14-6

The articles provided by the Ministerial Ordinance referred to in Article 8-2 paragraph 2 of the Act shall be the articles which a person entering livestock barns and others used or that might have been used in a farming related facility, etc. (livestock barns and others and their premises, a facility where gathering livestock is held and its premises, and other facilities and places related to farming; hereinafter referred to as the same) outside the premises of the such livestock barns and others before entering such livestock barns and others and are directly used for the livestock raised in such livestock barns and others.

(Public notification)

#### Article 15

The order under the provisions of Article 9 or Article 30 of the Act shall be given by public notification (when not more than 10 people are given the said order, the order form for such people shall be issued in accordance with Form 11 of the Appendix) concerning the items listed in Article 5 paragraph 2 (1), (2) and (4), and the disinfecting, cleaning or extermination of mice, insects and others, and the such implementing methods by 10 days prior to the date of implementation. However, in urgent circumstances, this period may be shortened to 3 days prior to the implementation date in cases referred to in Article 9 of the Act and one day prior to the implementation date in cases referred to in Article 30.

2. The provisions in Article 8 shall be applied mutatis mutandis to the public notification mentioned in the preceding paragraph.

(Passage restriction or blocking)

#### Article 15-2

The items specified by the Ministerial Ordinance in Article 3 paragraph 2 and Article 5 paragraph 3 of the Ordinance shall be the following:

(1) Areas subject to restriction or blocking of a passage.

(2) The period and details of the restriction for the passage restriction.

(3) The period for the passage blocking.

(Designated bone, meat, hide, hair and others)

#### Article 16

The bone, meat, hide, hair and others designated by the Minister of Agriculture, Forestry and Fisheries referred to in Article 11 of the Act shall be the following:

(1) Imported bone, meat, hide, hair and others.

(2) The bone, meat, hide, hair and others derived from affected or suspected animals of haemorrhagic septicaemia or swine vesicular disease or the carcasses of those animals, or affected or suspected animals of classical swine fever or their carcasses.

(Equipment and manufacturing methods at rendering plants)

#### Article 17

The standards for equipment specified by Ministerial Ordinance in Article 11 of the Act shall be the following:

(1) A raw material storage area, rendering room, waste pit, liquid waste pit, product storage area and staff room are provided and each of them is segregated.

(2) A considerable distance between the locations of the raw material storage and product storage areas is kept with the floor of the building laid with material through which liquid waste does not permeate to the outside, and facilities that keep out dogs, cats and other animals are provided.

(3) A rendering room with its floor laid with material through which liquid waste does not permeate, including the installation of liquid waste ditches inside, the separation of the entrance for raw materials and the exit for products, and necessary facilities for incinerating and disinfecting within or adjacent to the room.

(4) The waste pit and liquid waste pit are isolated from the raw material storage area, product storage area, rendering room, and staff room, and built with material through which waste or others do not permeate.

(5) Necessary facilities for disinfecting people and clothes are provided at the entrances/exits of the staff room and rendering room.

2. The standards for methods specified by Ministerial Ordinance in Article 11 of the Act shall be the following:

(1) The raw material storage area shall be disinfected without delay, when bone, meat, hide, hair and others are taken out of the area for rendering.

(2) The product storage area shall be disinfected before rendered articles (including unfinished products) are put in the said product storage.

(3) The bone, meat, hide, hair and others shall be taken into the rendering area through the entrance, rendered through rendering process without contamination by the causative agent of the specified disease or the monitored infectious disease, and taken out of the rendering room through the exit exclusive for products.

(4) As for imported bone, meat, hide, hair and others, the pathogens of rinderpest, contagious bovine pleuropneumonia, foot-and-mouth disease and haemorrhagic septicaemia for those derived from cattle, water buffalo or deer or their carcasses, the causative agent of glanders for those derived from horse or the carcasses of horse, the pathogens of rinderpest, foot-and-mouth disease and hemorrhagic septicaemia for those derived from sheep, goat or their carcasses, the pathogens of rinderpest, foot-and-mouth disease, haemorrhagic septicaemia, classical swine fever, African swine fever and swine vesicular disease for those derived from pig, wild boar or their carcasses, shall be completely inactivated during the rendering process.

(5) As for the bone, meat, hide, hair and others derived from affected or suspected animals, or their carcasses of haemorrhagic septicaemia or swine vesicular disease, or suspected animals or their carcasses of classical swine fever, the pathogens of these monitored infectious diseases shall be completely inactivated during the rendering process.

(6) Staff shall wear work clothes and boots exclusively for use in the rendering room and disinfect them after work.

(7) Filth in the waste pit shall be incinerated or disinfected, and any water in the liquid waste pit shall be drained after disinfection.

(Designated livestock/domestic animal gathering facilities)

## Article 18

The events designated by the Minister of Agriculture, Forestry and Fisheries referred to in Article 12 paragraph 1 of the Act shall mean the following:

(1) Horse racing, which is held based on the Horse Racing Act.

(2) Livestock markets under the provision of Article 2 paragraph 3 of the Livestock Transaction Act (Act No. 123, 1956) and other facilities for trading livestock which open annually or for not less than 100 days.

(3) Competitive exhibitions and exhibitions which gather cattle, water buffalo, deer, horse, sheep, goat, pig, wild boar, chicken, duck, quail or turkey and other events which display these livestock or their abilities from areas of other prefectures (other sub-divisions of the prefecture in the case of Hokkaido).

## Article 19

The equipment necessary for preventing the outbreak of the specified diseases or the monitored infectious diseases referred to in Article 12 paragraph 1 of the Act shall comply with the following standards:

(1) A livestock/domestic animal veterinary clinic, isolation station, and waste pit shall be provided.

(2) The livestock/domestic animal veterinary clinic shall be provided with equipment needed for inspections, and have the structure to provide the adequate disposal of waste and disinfection.

(3) The isolation station shall be located in a place away from any place which keeps healthy livestock, rivers or roads, and have the structure to prevent the spreading of the pathogens of the specified diseases or the monitored infectious diseases.

(4) The waste pit shall be located in a place away from any place which keeps healthy livestock, have the structure to prevent the spreading and outflow of sewage and to keep insects and others from going out or coming in, and to allow adequate waste disposal and disinfection to be made.

(Report and notification of the status of implementation of inspections and others)

## Article 20

As for the measures taken to prevent the outbreak of the specified diseases or the monitored infectious diseases within the previous month, the governor of the prefecture shall compile the status and results of the implementation and then report them in accordance with Form 12 of the Appendix to the Minister of Agriculture, Forestry and Fisheries by the tenth of every month.

2. As for the measures taken to prevent the outbreak of the specified diseases or the monitored infectious diseases within the previous year, the governor of the prefecture shall compile the status and results of the implementation and then report them in accordance with Form 13 of the Appendix to the Minister of Agriculture, Forestry and Fisheries by January 31st of every year.

3. The governor of the prefecture, when he/she orders the owner of livestock to undergo the inspection by an animal health inspector specified by Article 4-2 paragraph 3 or 5, or Article 5 paragraph 1 of the Act or the injection, dipping or medication by an animal health inspector under Article 6 paragraph 1 of the Act, or to carry out the method of disinfecting, cleaning or extermination of mice, insects and others under the provision of Article 9 of the Act, shall notify, without delay, the status of the implementation to the relevant governors of the prefectures.

(Standards of rearing hygiene management)

## Article 21

The Standards of Rearing Hygiene Management in Article 12-3 paragraph 1 of the Act shall be specified in the right column of Table 2 of the Appendix for each kind of the livestock listed in the left column of the same table.

(Periodic report)

#### Article 21-2

As for the report specified in Article 12-4 paragraph 1 of the Act, by which every farm (which means a place including livestock barns and other facilities for rearing livestock; hereinafter referred to as the same), the owner of cattle, water buffalo, deer, horse, sheep, goat, pig and wild boar by April 15 of every year and any owner of chicken, duck, quail pheasant, ostrich, guinea fowl, and turkey by June 15 of every year shall submit a report in accordance with Form 14 of the Appendix with the following documents:

(1) A ground plan of the farm describing the locations of a health management area (which means an area required for health management for rearing of livestock to prevent entering pathogens into a farm; hereinafter referred to as the same) and doorway of the area and the places where disinfection equipment required to prevent the outbreak of the specified diseases or the monitored infectious diseases is installed.

(2) Document describing measures taken to prevent an unnecessary persons from entering the health management area and to minimize possibilities of a person entering the health management area contacting the reared livestock.

(3) Document describing the kinds of disinfection equipment required to prevent the outbreak of the specified diseases or the monitored infectious diseases, which is installed near the doorway of the health management area and livestock barns and others.

(4) Document describing the rearing density of livestock for each livestock barn.

(5) Document describing the following items concerning the status of securing the land for burying:

a. Address of the land for burying

b. In case the land for burying is not self-owned, name or title of the owner of the land and the contact details on the use of such land.

c. Area of the land for burying and its status of use

d. Distance between the farm and the land for burying

e. Presence or absence of an explanation concerning the implementation of burying to residents neighboring the land for burying and other related parties and the acceptance of the said explanation by the said relevant people

f. Other items to be referred to in order to appropriately and promptly implement the burying

(6) In case where the preparatory action is taken for incineration or rendering, document describing the following items concerning the status of such preparation:

a. Name and address of the facility for incinerating or the rendering plant

b. Distance between the farm and the facility for incinerating or the rendering plant



c. Presence or absence of an explanation concerning the implementation of incinerating and rendering to residents neighboring the facility of incinerating or the rendering plant and other related parties and the acceptance of the said explanation by the said relevant people.

(7) Document describing the status of efforts to secure land for burying, a facility for incinerating or a rendering plant, when it is not secured.

(8) Document describing the name and title of the attending veterinarian or the name of the attending care facility, according to the category of the livestock listed in the following a to e, as for the owner having the livestock whose number is not less than those specified in the following a to e (hereinafter referred to as “large-scale owner”):

a. Cattle (limited to those of the age of four months or more): 200 (3000 for the following cattle)

1) Fattening cattle (limited to males of dairy breed (species listed in Article 3 paragraph 2 (8) to (10) of the Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle (No. 72 of the Ministerial Ordinance, 2003; hereinafter referred to as the same) and cross-bred cattle (species listed in the same paragraph (11); hereinafter referred to as the same)) whose age is less than 17 months.

2) Other cattle under 24 months of age.

b. Water buffalo and horse: 200

c. Deer, sheep, goat, pig and wild boar: 3000

d. Chicken and quail: 100,000

e. Duck, pheasant, ostrich, guinea fowl, and turkey: 10,000

(9) A copy of the document specifying that a large-scale owner (excluding owners of horse), when his/her staff finds the specific symptoms (those described in Article 13-2, paragraph 1, hereinafter referred to as the same), shall immediately notify such finding to the livestock hygiene service center.

(Items to be reported)

### Article 21-3

The items prescribed by the Ministerial Ordinance referred to in Article 12-4 paragraph 1 of the Act shall be the following (limited to the items listed in (1), as for the owner rearing the following number of the livestock: One for cattle, water buffalo and horse; less than 6 for deer, sheep, goat, pig and wild boar; less than 100 for chicken, duck, quail, pheasant, guinea fowl and turkey; less than 10 for ostrich):

(1) Kind and number of livestock reared

(2) Number of livestock barns and others

(3) Status of compliance with the Standards of Rearing Hygiene Management referred to in Article 12-3 paragraph 1 of the Act and the status of implementation of measures to comply with the said Standards of Rearing Hygiene Management

(Notice)

#### Article 21-4

The notice under the provision of Article 12-4 paragraph 2 of the Act shall be made in writing concerning each of the items listed in the previous Article.

### **Chapter III Preventing the Spread of Domestic Animal Infectious Diseases**

(Report of affected animals and others)

#### Article 22

The report under the provision of Article 13 paragraph 1 of the Act shall be made in writing or verbally for the following items:

- (1) Name and address of the notifier
- (2) Name and address of the owner
- (3) Kind of the animal infectious disease and category of affected animal or suspected animal
- (4) Kind, sex and age (estimated age when unknown) of livestock (including dead livestock)
- (5) Location of affected or suspected animals or the carcasses of these animals
- (6) Time and date of discovery of disease onset and condition at the time of discovery
- (7) Estimated date of disease onset
- (8) Other items for reference

(Exception to report of affected animals and others)

#### Article 23

The cases prescribed by the Ministerial Ordinance referred to in Article 13 paragraph 3 of the Act shall be the following:

- (1) Cases in which the person having permission (which means those specified in Article 46-5 paragraph 1 (2); hereinafter referred to as the same) found livestock kept in the handling facility (which means facilities for handling specified in paragraph 2 (4) of the same Article; hereinafter referred to as the same) to use the pathogens of the animal infectious diseases for such permission to have become affected or suspected animals as a result of the said use.
- (2) Cases in which the notifier found livestock kept in the handling facility for use the pathogens of the notifiable infectious diseases for reporting to have become affected or suspected animals as a result of the said use.
- (3) Cases in which a licensed manufacturer, etc. (excluding a person having permission and a notifier;

hereinafter referred to as the same) found livestock kept in the facility for the testing and manufacture of biological products (only those for the animal infectious diseases; the same in Article 26-2 (3), Article 29 (3), Article 31 (3) and Article 33 (3)) to have become affected or suspected animals as a result of the said testing and manufacturing.

(4) Cases in which the designated test institution (excluding a person having permission and a notifier; hereinafter referred to as the same) found livestock kept for inspection specified in Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act to have become affected or suspected animals as a result of the said inspection.

(5) Cases in which an academic research institution designated by the Minister of Agriculture, Forestry and Fisheries (excluding a person having permission and a notifier; hereinafter referred to as the same) found livestock kept in the facility for academic research to have become affected or suspected animals as a result of the said academic research.

(Public notification of outbreak of affected animals and others)

#### Article 24

The public notification under the provisions of Article 13 paragraph 4 of the Act shall be given for the following items for respective kinds of animal infectious diseases and livestock:

- (1) Category and number of affected animals or suspected animals
- (2) Location or district of outbreak
- (3) Date of onset
- (4) Other items for reference

2. The provision of Article 8 shall be applied mutatis mutandis to the public notification referred to in the preceding paragraph.

(Notification and report of outbreak of affected animals and others)

#### Article 25

The notification under the provision of Article 13 paragraph 4 of the Act (excluding those concerning the relevant governors of the prefectures) shall be conducted for each item of Article 22 by telegraph, telephone or a method of similar nature for the livestock listed in the following (1) and (2), and by post or a method of similar nature for the livestock listed in the following (3):

- (1) Affected or suspected animals of rinderpest, contagious bovine pleuropneumonia, foot-and-mouth disease, infectious encephalitis, vesicular stomatitis, Rift Valley fever, haemorrhagic septicaemia,

glanders, African horse sickness, classical swine fever, African swine fever, swine vesicular disease, fowl cholera, highly pathogenic avian influenza, low pathogenic avian influenza, or Newcastle disease (limited to those listed in each item of Article 1-2)

(2) affected or suspected animals of a new-onset other than the affected animals and suspected animals specified in the preceding item.

(3) Affected or suspected animals other than the affected or suspected animals specified in the preceding two items.

2. By the tenth of each month, the relevant governors of the prefectures under the provisions of Article 13 paragraph 4 of the Act shall be notified of the condition during the previous month in accordance with Form 15 of the Appendix, and when there has been a report under the provision of Article 13 paragraph 1 of the Act concerning livestock referred to in (1) and (2) of the previous paragraph, the report shall be delivered by telegraph, telephone or method of similar nature.

3. The report under the provision of Article 13 paragraph 4 of the Act shall be made without delay by telegraphic communication, telephone or method of similar nature, and by the tenth of every month the situation during the previous month shall be reported in accordance with Form 15 in the Appendix.

(Report of livestock with the symptoms designated by the Minister of Agriculture, Forestry and Fisheries)

#### Article 26

The Report under the provision of Article 13-2 paragraph 1 of the Act shall be made verbally for the following items:

- (1) Name or title and address of the notifier
- (2) Name or title and address of the owner
- (3) Details of the specific symptoms
- (4) Kind, sex and age (estimated age when unknown) of the said livestock (including dead livestock)
- (5) Location of the said livestock or their carcasses
- (6) Time and date of discovery
- (7) Conditions of other livestock in the same farm at the discovery
- (8) Other items for reference

(Exception to obligation of report of livestock with the symptoms designated by the Minister of Agriculture, Forestry and Fisheries)

#### Article 26-2

The cases prescribed by the Ministerial Ordinance referred to in Article 13-2 paragraph 3 of the Act shall be the following:

(1) Cases in which the person having permission found livestock kept in the handling facility to use the pathogens of the animal infectious diseases for the said permission to have the specific symptoms as a result of the said use.

(2) Cases in which the notifier found livestock kept in the handling facility of the pathogens of the notifiable infectious diseases to use the pathogens of notifiable infectious disease for the said notification to have the specific symptoms as a result of the said use.

(3) Cases in which a licensed manufacturer, etc. found livestock kept in the facility for the testing and manufacture of biological products to have the specific symptoms as a result of the said testing and manufacturing.

(4) Cases in which the designated assay institution found livestock kept for assay specified in Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act to have the specific symptoms as a result of the said assay.

(5) Cases in which the academic research institution designated by the Minister of Agriculture, Forestry and Fisheries found livestock kept in the facility for academic research to have the specific symptoms as a result of the said academic research.

(Reports concerning specific symptoms)

#### Article 26-3

The report under the provision of Article 13-2 paragraph 4 of the Act shall be conducted for each item of Article 26 by telegraph, telephone or a method of similar nature.

(Requirement of sample collection and submission submitting of samples)

#### Article 26-4

The requirement prescribed by the Ministerial Ordinance referred to in Article 13-2 paragraph 4 of the Act shall be the cases in which the livestock with the specific symptoms have been found in multiple stalls (a space which is a part of a livestock barn and is surrounded with a barrier to house animals; hereinafter referred to as the same) (in multiple nearby stalls when a domestic animal is reared in a stall).

(Notice of affected animals and others)

#### Article 26-5

The notice under the provision of Article 13-2 paragraph 5 and 7 of the Act shall be conducted for the results of the judgment under the provision of Article 13-2 paragraph 5 by telegraph, telephone or a method of similar nature.

(Public notification of affected animals and others)

#### Article 26-6

The public notification under the provision of Article 13-2 paragraph 8 of the Act shall be conducted for the following items for respective animal infectious diseases and the animal species:

- (1) Category and number of affected and suspected animals
- (2) Location or district of affected and suspected animals or their carcasses
- (3) Time and date of judgment
- (4) Other items for reference

2. The provision of Article 8 shall be applied mutatis mutandis to the public notification referred to in the preceding paragraph.

(Notification of affected animals and others)

#### Article 27

The notification under the provision of Article 13-2 paragraph 8 of the Act shall be conducted for respective items of Article 26, name of animal infectious diseases, and distinction between affected and suspected animals by telegraph, telephone or a method of similar nature for the livestock listed in the following (1) and (2), and by post or a method of similar nature for the livestock listed in the following (3):

- (1) Affected or suspected animals with an animal infectious disease specified in Article 25 paragraph 1.
- (2) Affected or suspected animals of a new-onset of disease other than the affected and suspected animals specified in the preceding item.
- (3) Affected or suspected animals other than the affected and suspected animals specified in the preceding two items.

(Exception to obligation of culling)

#### Article 28

The cases prescribed by the Ministerial Ordinance referred to in the proviso of Article 16 paragraph 1 of the Act shall be those cases in which the said livestock fall under any of the following:

(1) Livestock that are kept in the handling facility of the pathogens of animal infectious diseases to use the pathogens of animal infectious diseases for the said permission by the person having permission and that are identified as the livestock listed in each item of Article 16 paragraph 1 of the Act as a result of the said use.

(2) Livestock that are kept in the handling facility of the pathogens of notifiable infectious diseases to use the pathogens of notifiable infectious diseases for the said permission by the notifier and that are identified as the livestock listed in each item of Article 16 paragraph 1 of the Act as a result of the said use.

(3) Livestock that are kept in the facility for the purpose of testing and manufacturing of vaccines against rinderpest, classical swine fever, highly pathogenic avian influenza, or low pathogenic avian influenza, or in vitro diagnostics specified in Article 2 paragraph 13 of the Pharmaceutical Affairs Act and that are identified as affected or suspected animals with rinderpest, classical swine fever, highly pathogenic avian influenza, or low pathogenic avian influenza as a result of the said testing or manufacturing.

(4) Livestock that are kept for the inspection specified in Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act by the designated test institution and that are identified as affected or suspected animals with rinderpest, classical swine fever, highly pathogenic avian influenza, or low pathogenic avian influenza as a result of the said inspection.

(5) Livestock that are kept by the academic research institution designated by the Minister of Agriculture, Forestry and Fisheries in its facility for the purpose of academic research and that are identified as affected or suspected animals listed in each item of Article 16 paragraph 1 of the Act as a result of the said academic research.

(6) Livestock which are diagnosed under the provisions of Article 20 paragraph 2 of the Act

(7) Livestock that are found to be suspected animals specified in Article 16 paragraph 1 (2) of the Act by the animal health inspector during the inspection specified in Article 40 of the Act and that are sent back to the exporting country of the said livestock because it is admitted that they are rare animals and there are other special circumstances (limited to those that are able to be kept by the method without possibility of spreading of the pathogens until they are sent back to the said exporting country and that are able to be sent back to the said exporting country).

(Exception to notification of culling)

## Article 29

The cases prescribed by the Ministerial Ordinance referred to in Article 18 of the Act shall be the following:

(1) Cases where the person having permission culls the livestock that are kept in the handling facility of

the pathogens of animal infectious diseases to use those agents for permission and that are identified as affected or suspected animals as a result of the said use, in the said facilities.

(2) Cases where the notifier, culls livestock that are kept in the handling facility of the pathogens of the notifiable infectious diseases to use those agents for notification and that are identified as affected or suspected animals as a result of the said use within the said handling facility of the pathogens of notifiable infectious diseases.

(3) Cases where a licensed manufacturer and others culls livestock that are kept within the facilities for the testing or manufacturing of biological products and that are identified as affected or suspected animals as a result of the said testing and manufacturing.

(4) Cases where the designated assay institution culls livestock that are kept for assay under the provision of Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act and that are identified as affected or suspected animals as a result of the said assay.

(5) Cases where the academic research institution designated by the Minister of Agriculture, Forestry and Fisheries, within the said facilities, culls livestock that are kept for the said academic research and that are identified as affected or suspected animals as a result of the said academic research.

(Standards for incineration, burial and others)

#### Article 30

The standards prescribed by the Ministerial Ordinance concerning the incineration and burial referred to in Article 21 paragraph 1 of the Act, the incineration, burial and disinfection referred to in Article 23 paragraph 1 of the Act, and disinfection referred to in Article 25 paragraph 1 of the Act shall be shown in Table 3 of the Appendix. However, the standards for the incineration and disinfection referred to in Article 23 paragraph 1 of the Act concerning articles contaminated or suspected to have been contaminated with the pathogens of fowlbrood shall be shown in the Appended Table 4.

(Exception to obligation of incineration of contaminated articles and others)

#### Article 31

The articles prescribed by the Ministerial Ordinance referred to in the proviso of Article 23 paragraph 1 shall be the following:

(1) Articles that the person having permission uses in order to use the pathogens of the animal infectious diseases for the said permission and that are within the handling facility.

(2) Articles that the notifier uses in order to use the pathogens of notifiable infectious diseases for the said notification and that are within the handling facility of the pathogens of the notifiable infectious



diseases.

(3) Articles that a licensed manufacturer and others use for testing or manufacturing of biological products and that are within its facilities.

(4) Articles that the designated assay institution uses for test under the provision of Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act.

(5) Articles that an academic research institution designated by the Minister of Agriculture, Forestry and Fisheries uses for its academic research and that are within the facilities of the institution.

(6) Clothes of the person who contacted or could have contacted with the pathogens of animal infectious diseases.

(Period of ban on excavation)

### Article 32

The period prescribed by the Ministerial Ordinance referred to in Article 24 of the Act shall be 20 years for the cases of anthrax and fowlbrood and 3 years for the cases of other animal infectious diseases.

(Exception to obligation of disinfection of livestock barns and others)

### Article 33

The facilities prescribed by the Ministerial Ordinance referred to in the proviso of Article 25 paragraph 1 shall be the following:

(1) Handling facilities where livestock identified as affected or suspected animals as a result of using the pathogens of animal infectious diseases for permission by the person having permission or the carcasses of the said animals were located.

(2) Handling facilities of the pathogens of notifiable infectious disease where the livestock identified as affected or suspected animals as a result of using the pathogens of the notifiable infectious disease for report by the notifier or the carcasses of the said animals were located.

(3) Facilities where livestock identified as affected or suspected animals as a result of testing or manufacturing of biological products by a licensed manufacturer and others, or the carcasses of the said animals were located.

(4) Facilities where livestock identified as affected or suspected animals as a result of assay referred to in Article 43 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act by the designated assay institution, or the carcasses of the said animals were located.

(5) Facilities where livestock identified as affected or suspected animals as a result of the academic

research by the academic research institution designated by the Minister of Agriculture, Forestry and Fisheries, or the carcasses of the said animals were located.

(Installation of disinfection equipment)

#### Article 33-2

The installation of equipment under the provision of Article 25 paragraph 4 and Article 26 paragraph 4 of the Act shall be performed according to the following:

(1) Near the doorways of livestock barns and others to be disinfected (which means those specified in Article 25 paragraph 1 of the Act; hereinafter referred to as the same) or storerooms and others to be disinfected (meaning those specified in Article 26 paragraph 1 of the Act; hereinafter referred to as the same), equipment, including a boot bath, a disinfectant spray device and other equivalent equipment, which is used to disinfect the body of a person going out of the said livestock barns and others or the said storerooms and others shall be installed.

(2) Near the gateway of the premises of livestock barns and others to be disinfected or storerooms and others to be disinfected (excluding the premises of livestock barns and others to be disinfected or storerooms and others to be disinfected described in the next Article), equipment, including a disinfectant spray device and equivalent equipment, which is used to disinfect the vehicles going out of the said premises shall be installed.

(Premises excluded from obligation of installation of disinfection equipment)

#### Article 33-3

The premises prescribed by the Ministerial Ordinance referred to in Article 25 paragraph 4 and Article 26 paragraph 4 of the Act shall be premises of livestock barns and others to be disinfected or storerooms and others to be disinfected used for housing only.

(Disinfection method)

#### Article 33-4

The disinfection prescribed in the provision of Article 25 paragraph 6, Article 26 paragraph 6, and Article 28 paragraph 2 of the Act shall be carried out on the animal infectious diseases listed in the left column in the Appended Table 5, using the equipment specified in the middle column and respective disinfectants specified in the right column. In this case when a pharmaceutical agent referred to in Article

2 paragraph 1 of the Pharmaceutical Affairs Act is used for the disinfection, the package insert of the agent or the dosage and administration and other precautions described on the package shall be followed and when a disinfectant other than the said pharmaceutical agent is used, the instruction of an animal health inspector shall be followed.

(Special exception during navigation)

#### Article 34

The measures referred to in Article 27 of the Act shall be carried out by the owner of the said livestock, articles or facilities if he/she is aboard a ship, or by the captain (if there is any person who acts for the captain, that person. This is the same in paragraph 2 of the following Article) of the ship if the owner is not aboard.

#### Article 35

In the case of Article 27 of the Act, the whole carcass of a livestock/domestic animal shall be wrapped in straw matting or other material of a similar nature soaked in disinfectant, and the articles or facilities shall be disinfected in accordance with the standards for disinfection referred to in the Appended Table 3.

2. The carcasses of livestock or articles may be thrown overboard outside the territorial waters of Japan instead of the measures in the preceding paragraph. However, in the event the captain of the said ship throws overboard articles (except bedding and other articles of a similar nature used for transport of the said livestock), he/she shall obtain the consent of the owner of the said articles beforehand.

(Disinfection equipment)

#### Article 36

The equipment prescribed by Ministerial Ordinance referred to in Article 28-2 paragraph 1 of the Act shall be:

- (1) Boot bath
- (2) Disinfectant spray device
- (3) Equipment equivalent to preceding two items

(Disinfection method)

#### Article 37

Any person who passes through the place installed with the equipment referred to in Article 28-2 paragraph 1 of the Act by the governor of the prefecture shall undergo disinfection of the body and the vehicle to be passed through the place using the said equipment in order to ensure an adequate effect of disinfection on the said pathogens of the animal infectious diseases, according to the instructions of staff of the said prefecture or the person commissioned to do the clerical work on disinfection using the said equipment by the said governor of the prefecture.

(Indication of the disinfection equipment installed location)

#### Article 38

The indication prescribed by the Ministerial Ordinance referred to in Article 28-2 paragraph 3 of the Act shall be easy to read and to understand that the location is installed with disinfection equipment required for preventing spreading of the animal infectious diseases under the provision of paragraph 1 of the same Article and that the person passing through the location shall undergo disinfection of the body and the vehicle to be passed through the location using the said equipment.

(Tagging of affected animals and others)

#### Article 39

The kinds of livestock which may be tagged with branding, tattooing or other means of tagging, the site to be tagged, and the kind and form of tag thereof under the provision of Article 29 shall be shown in the following table:

Kind of livestock	Site	Kind and form of the tag
Cattle that are listed in Article 9 paragraph 2 (1) to (4) and which are affected with brucellosis, tuberculosis or Johne's disease.	Left ear	Ear tag Form 16 of the Appendix
Cattle that are listed in Article 9 paragraph 2(1) to (4) and which are suspected animals of brucellosis, tuberculosis or Johne's disease.	Left ear	Ear tag Form 17 of the Appendix
Affected animals of Equine infectious anemia	Left buttock	Brand Form 18 of the Appendix
Other affected or suspected animals or the designated livestock in Article 17-2 paragraph 1 (hereinafter referred to as "designated livestock")	Site determined by the governor of the prefecture (excluding the ear for cattle and	Tag determined by the governor of the prefecture

	water buffalo)	
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(Methods of inspection and others)

#### Article 40

The methods prescribed by the Ministerial Ordinance referred to in Article 31 paragraph 1 of the Act shall be shown in the Appended Table 1 for the animal infectious diseases listed in the Appended Table 1 and the usual methods shall be used for other animal infectious diseases.

(Notification)

#### Article 41

When the governor of the prefecture establishes regulations under the provisions of Article 32 through 34 of the Act, or when he/she implements an important measure based on these regulations, he/she shall without delay report that effect to the Minister of Agriculture, Forestry and Fisheries, and notify the relevant governors of the prefectures of that effect.

(Restriction of outward movement of livestock and others)

#### Article 41-2

When prohibiting or restricting outward movement under the provision of Article 32 paragraph 2 of the Act, the Minister of Agriculture, Forestry and Fisheries shall notify the following items and post the notification in a place easily visible by the public:

- (1) Details of the prohibition or restriction
- (2) Period of the prohibition or restriction
- (3) District targeted for the prohibition or restriction
- (4) Livestock, their carcasses, and article targeted for the prohibition or restriction

2. When prohibiting or restricting outward movement under the provision of Article 32 paragraph 2 of the Act, the Minister of Agriculture, Forestry and Fisheries shall notify the relevant governors of the prefectures of that effect.

(Report)

#### Article 42

The governor of the prefecture shall, by the tenth of each month, summarize the situation and the results of measures taken to prevent spreading of the animal infectious diseases during the previous month, and report the summary to the Minister of Agriculture, Forestry and Fisheries in accordance with Form 12 of the Appendix.

2. The governor of the prefecture shall, by January 31, summarize the situation and the results of measures taken to prevent spreading of animal infectious diseases during the previous year, and report the summary to the Minister of Agriculture, Forestry and Fisheries in accordance with Form 13 and 19 of the Appendix.

#### **Chapter IV Export and Import Quarantine and Others**

(Prohibition of Importation)

##### Article 43

The articles listed in the middle column of the following table, which were shipped from or via the places listed in the corresponding line of the left column of the following table (including islands belonging to the said places) shall be those designated by the Minister of Agriculture, Forestry and Fisheries, being shipped from or via the places prescribed by the Ministerial Ordinance in Article 36, paragraph 1 (1) of the Act:

Region	Articles	Remarks (Monitored infectious disease to be targeted)
1. Singapore, Romania, Slovenia, Croatia, and Bosnia-Herzegovina	<p>1. Carcasses of cloven-hoofed animals and their containers and packing.</p> <p>2. Meat of cloven-hoofed animals (exclusions: those attached with a certificate issued by the government authorities of an exporting region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that they have been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing monitored infectious diseases or the facilities designated by the</p>	Rinderpest, foot-and-mouth disease, African swine fever

	<p>government authorities of an exporting country that conforms to the standards prescribed by the Minister of Agriculture, Forestry and Fisheries; those attached with a certificate issued by the government authorities of an exporting region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that they were imported from a region other than the regions listed in the left column of this table (hereinafter referred to as "non-restricted region") without transiting through any other regions with the attachment of a certificate issued by the government authorities of the non-restricted region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that they have been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries, and that they were stored in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries; and those attached with a certificate issued by the government authorities of an exporting region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that they have been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing monitored infectious diseases or the facilities designated by the government authorities of an exporting country that conforms to the standards prescribed by the Minister of Agriculture, Forestry and Fisheries, and which was imported without transiting through the regions other than the said non-restricted region) and their containers and packing.</p> <p>3. Organs of cloven-hoofed animals (exclusions: those that are the digestive tract, uterus and bladder (hereinafter referred to as "heat-treated digestive tract and others") attached with a certificate issued by the government authorities of an exporting country or a person designated</p>	
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	<p>by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries and organs other than digestive tract, uterus and bladder and others attached with a certificate issued by the government authorities of an export country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries as being fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases or in the facilities designated by the government authorities of the exporting country that conforms to the standards prescribed by the Ministry of Agriculture, Forestry and Fisheries; casing) and their containers and packing.</p> <p>4. Straw from grain (excluding that which has been processed or prepared for use for other than feed) and forage for feeding (excluding that attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the article has been disinfected in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases and which is imported without going through any region other than the said region).</p>	
<p>2. Regions except: Singapore, Finland, Sweden, Norway, Poland, Hungary, Czech Republic, Romania, Slovenia,</p>	<p>1. Cloven-hoofed animals, bedding for their transport and other articles of a similar nature</p> <p>1-2. Semen, embryo and unfertilized eggs of cloven-hoofed animals and their containers and packing</p>	



<p>Croatia, Bosnia and Herzegovina, Germany, Denmark, Italy (except Sardinia Island), San Marino, Liechtenstein, Swiss, The Netherlands, Belgium, France, Austria, U.K. (limited to Great Britain and Northern Ireland), Spain, Portugal, Ireland, Iceland, Brazil (limited to the state of Santa Catarina, Canada, U.S.A. (limited to American continent, Hawaiian Islands and Guam), Mexico, Belize, Guatemala, Honduras, El Salvador, Nicaragua, Costa Rica, Panama, The Dominican Republic, Chile, Northern Mariana, New Zealand, Vanuats, New Caledonia, and Australia</p>	<p>2. The carcasses of cloven-hoofed animals and their containers and packing.</p> <p>3. Meat of cloven-hoofed animals (exclusion: that attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases; those attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been imported into the said listed region from the said non-restricted region without going through other regions with a certificate issued by the government authorities of the country of the non-restricted region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries and that it has been stored in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries as being fitted with the equipment necessary for the prevention of an outbreak of monitored infectious diseases and which are imported without going through any region other than the said regions; and that attached with a certificate issued by the government authorities of the country of the non-restricted region or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been imported from the said region into the said non-restricted region without going through any other</p>	
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	<p>region with a certificate issued by the government authorities of an exporting country or a person by the Minister of Agriculture, Forestry and Fisheries stating that the item had been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries as being fitted with the equipment necessary for the prevention of an outbreak of monitored infectious diseases) and its containers and packing.</p> <p>4. The organs of cloven-hoofed animals (exclusion: heat-treated digestive tract and others; and organs other than digestive tract, uterus and bladder that are attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases and which has been imported without going through any region other than the said regions; and casing) and their containers and packing.</p> <p>5. Sausages, ham and bacon using the meat and organs of cloven-hoofed animals as the raw material (exclusion: those which are attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been heat-treated in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases; and ham that is made from pork attached with a certificate</p>	
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	<p>issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the item has been treated and stored in accordance with the standards designated by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries and additionally noted by animal quarantine officer that the item has been treated and stored in accordance with the standards designated by the Minister of Agriculture, Forestry and Fisheries and which is imported without going through other region than the said region.) and their containers and packing.</p> <p>6. Straw from grain (excluding that which has been processed or prepared for use other than feed) and forage for feeding (excluding that attached with a certificate issued by the government authorities of an exporting country or a person designated by the Minister of Agriculture, Forestry and Fisheries stating that the article has been disinfected in accordance with the standards prescribed by the Minister of Agriculture, Forestry and Fisheries in the facilities designated by the Minister of Agriculture, Forestry and Fisheries to be fitted with the necessary equipment for preventing an outbreak of monitored infectious diseases and which is imported without going through any region other than the said region).</p>	
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Article 44

As for the import of articles listed in each item in Article 36 paragraph 1 of the Act (hereinafter, referred to as "prohibited articles"), any person intending to gain permission in the proviso in this paragraph 1 shall submit an application in accordance with Form 20 of the Appendix to the Minister of Agriculture, Forestry and Fisheries

2. When giving permission referred to in the preceding paragraph, the Minister of Agriculture, Forestry and Fisheries shall issue the said applicant with the import permit certificate in accordance with Form 21 of the Appendix for a prohibited article or an animal.

3. Any person issued with the import permit certificate referred to in the preceding paragraph shall send it to a consignor and have the consignor ship the said prohibited article attached with or together with the said import permit certificate.

(Notification of the importation of pathogens)

#### Article 44-2

The notification under the provision of Article 36-2 paragraph 1 of the Act shall be made in writing in accordance with the Appended Form 21-2 by the date a ship or aircraft carrying pathogens of the infectious diseases of livestock for the said report gets into port or lands.

2. The person intending to notify as specified in the preceding paragraph using the electronic data processing system (which means the electronic data processing system prescribed in Article 3, paragraph 1 of the Act on Use of Information and Communications Technology in Administrative Procedure (Act No. 151, 2002); the same in Article 47-3 paragraph 2, Article 49 paragraph 2, Article 51 paragraph 1, Article 51-2 paragraph 2, Article 52 paragraph 2, and Article 54 paragraph 2) is not subject to Article 3 paragraph 3 of the Ordinance for Enforcement of the Act on Use of Information and Communications Technology in Administrative Procedure pertaining to Laws and Regulations Under the Ministry of Agriculture, Forestry and Fisheries of Japan (Ministry of Agriculture, Forestry and Fisheries Ordinance No. 21, 2003)

(Designated quarantine items)

#### Article 45

The designated quarantine items referred to in Article 37 paragraph 1 of the Act shall be the following:

(1). The following animals and their carcasses:

a. Cloven-hoofed animals and horse

b. Chicken, quail, pheasant, ostrich, guinea fowl and turkey, and Anseriformes including duck, goose and other birds of Anseriformes (hereinafter referred to as “ducks”) (excluding one day-old chicks of these animals meeting the conditions prescribed by the Minister of Agriculture, Forestry and Fisheries which are to be exported in status quo without being moved outside the area of the seaport or airport into which they were imported in compliance with the directions of the animal quarantine officer).

c. Dog (excluding those meeting the conditions prescribed by the Minister of Agriculture, Forestry and Fisheries which are to be exported in status quo without being moved outside the area of the seaport or airport into which they were imported in compliance with the directions of the animal quarantine officer).

d. Rabbit (excluding those meeting the conditions prescribed by the Minister of Agriculture, Forestry and Fisheries which are to be exported in status quo without being moved outside the area of the seaport or airport into which they were imported in compliance with the directions of the animal quarantine officer).

e. Honey bee (excluding those meeting the conditions prescribed by the Minister of Agriculture, Forestry and Fisheries which are to be exported in status quo without being moved outside the area of the seaport or airport into which they were imported in compliance with the directions of animal quarantine officer).

(2) Eggs of chicken, quail, pheasant, ostrich, guinea fowl, turkey and duck

(3) Bones, meat, fat, blood, hide, hair, feathers, horns, hooves, tendons and internal organs of any animal in (1).

(4) Raw milk, semen, fertilized eggs, unfertilized eggs, feces and urine of any animal in (1).

(5) Bone meal, meat meal, meal and bone meal, blood meal, hide meal, feather meal, powdered hooves and, powdered horns and powdered organs of any animal in (1).

(6) Sausages, ham and bacon made from any item in (3).

(7) Straw of grains (excluding that processed or prepared for purposes other than feeding) and forage for feeding that have been sent from regions (including islands belonging to these regions) listed in the left column of the table in Article 43 or transited through the regions.

(8) Those imported with permission under the proviso of Article 36 paragraph 1 of the Act.

(Straw of grains supplied for other than feeding)

#### Article 45-2

Those prescribed by the Ministerial Ordinance as straw of grains for use other than feeding referred to in Article 37 paragraph 1 (2) of the Acts shall be those processed or prepared for use other than feeding.

(Exemption of attachment of inspection certificate for importation)

#### Article 46

Cases prescribed by the Minister of Agriculture, Forestry and Fisheries referred to in Article 37 paragraph 2 (1) of the Act shall be the cases of importation from a country in which it is recognized that the attachment of an inspection certificate or its copy prescribed in Article 37 paragraph 1 is particularly difficult.

2. The country prescribed by the Ministerial Ordinance referred to in Article 37 paragraph 2 (2) of the Act means Australia.

(Place of import)

Article 47

The seaports or airports prescribed by the Ministerial Ordinance referred to in Article 38 of the Act are listed in the right column of the following table with designated quarantine items in the corresponding line of the left column:

Kind of designated quarantine item	Seaport, airport
Those prescribed in Article 45 (1) (excusing assistance dogs prescribed in Article 2 paragraph 1 of the Act on Assistance Dogs for Physically Disabled Persons (Act No. 49, 2002, and which a disabled person are accompanied by) and Article 45 (2) (only those unshelled)	Tomakomai Port, Keihin Port, Nagoya Port, Hanshin Port, Kanmon Port, Hakata Port, Kagoshima Port, Naha Port, Shin-Chitose Airport, Narita International Airport, Tokyo International Airport, Chubu International Airport, Kansai International Airport, Kitakyushu Airport, Fukuoka Airport, Kagoshima Airport, Naha Airport
Those prescribed in Article 45 (2) (excluding those unshelled), meat, fat, blood, tendons and organs in Article 45 (3), and those prescribed in Article 45 (6)	Kushiro Port, Ishikariwan Port, Tomakomai Port, Otaru Port, Muroran Port, Sendai-Shiogama Port, Akita Port, Sakata Port, Onahama Port, Chiba Port, Keihin Port, Niigata Port, Naoetsu Port, Fushiki-Toyama Port, Kanazawa Port, Shimizu Port, Nagoya Port, Yokkaichi Port, Hanshin Port, Himeji Port, Wakayama-Shimotsu Port, Sakai Port, Hamada Port, Fukuyama Port, Hiroshima Port, Kanmon Port, Tokushima-Komatsushima Port, Takamatsu Port, Matsuyama Port, Kochi Port, Hakata Port, Imari Port, Nagasaki Port, Oita Port, Hosojima Port, Kagoshima Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Akita Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai International Airport, Miho Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Miyazaki Airport, Kagoshima Airport, Naha Airport

<p>Hide, hair, feathers, horns and hooves referred to in Article 45 (3), and bone meal, meat and bone meal, blood meal, leather meal, feather meal, hoot and bone meal and viscera meal, referred to in Article 45 (5)</p>	<p>Tomakomai Port, Otaru Port, Muroran Port, Hachinohe Port, Ishinomaki Port, Sendai Shiogama Port, Akita Port, Sakata Port, Onahama Port, Kashima Port, Chiba Port, Keihin Port, Niigata Port, Fushiki-Toyama Port, Kanazawa Port, Shimizu Port, Nagoya Port, Yokkaichi Port, Hanshin Port, Wakayama-Shimotsu Port, Sakai Port, Mizushima Port, Hiroshima Port, Kanmon Port, Tokushima-Komatsushima Port, Takamatsu Port, Matsuyama Port, Hakata Port, Imari Port, Nagasaki Port, Oita Port, Hosojima Port, Shibushi Port, Kagoshima Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai International Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Kagoshima Airport, Naha Airport</p>
<p>Bone referred to in Article 45 (3) and bone meal referred to in Article 45 (5) (excluding raw bone meal passing through a sieve of mesh size 840 micrometers)</p>	<p>Tomakomai Port, Otaru Port, Muroran Port, Hachinohe Port, Ishinomaki Port, Sendai-Shiogama Port, Sakata Port, Onahama Port, Kashima Port, Chiba Port, Keihin Port, Niigata Port, Fushiki-Toyama Port, Kanazawa Port, Shimizu Port, Nagoya Port, Yokkaichi Port, Hanshin Port, Wakayama-Shimotsu Port, Sakai Port, Mizushima Port, Kanmon Port, Tokushima-Komatsushima Port, Takamatsu Port, Matsuyama Port, Kochi Port, Hakata Port, Imari Port, Oita Port, Hosojima Port, Shibushi Port, Kagoshima Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai</p>

	International Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Kagoshima Airport, Naha Airport
Raw bone meal passing through a sieve of mesh size 840 microns.	Kagoshima Port
Those prescribed in Article 45 (4)	<p>Otaru Port, Muroran Port, Ishinomaki Port, Sendai-Shiogama Port, Akita Port, Kashima Port, Chiba Port, Keihin Port, Niigata Port, Fushiki-Toyama Port, Kanazawa Port, Shimizu Port, Nagoya Port, Yokkaichi Port, Hanshin Port, Wakayama-Shimotsu Port, Sakai Port, Mizushima Port, Kanmon Port, Tokushima-Komatsushima Port, Takamatsu Port, Matsuyama Port, Hakata Port, Imari Port, Kagoshima Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai International Airport, Miho Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Miyazaki Airport, Kagoshima Airport, Naha Airport</p> <p>Those prescribed in Article 45 (7)</p> <p>Tomakomai Port, Otaru Port, Hachinohe Port, Sendai-Shiogama Port, Akita Port, Sakata Port, Hitachinaka Port, Kashima Port, Keihin Port, Niigata Port, Fushiki-Toyama Port, Kanazawa Port, Mikawa Port, Nagoya Port, Yokkaichi Port, Maizuru Port, Hanshin Port, Sakai Port, Hamada Port, Mizushima Port, Fukuyama Port, Hiroshima Port, Kanmon Port, Tokushima-Komatsushima</p>



	<p>Port, Imabari Port, Kochi Port, Hakata Port, Karatsu Port, Imari Port, Kumamoto Port, Yatsushiro Port, Hosojima Port, Shibushi Port, Sendai Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Akita Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai International Airport, Miho Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Miyazaki Airport, Kagoshima Airport, Naha Airport</p>
<p>Those prescribed in Article 45 (8)</p>	<p>Keihin Port, Nagoya Port, Hanshin Port, Kanmon Port, Naha Port, Asahikawa Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Akita Airport, Fukushima Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Chubu International Airport, Kansai International Airport, Miho Airport, Okayama Airport, Hiroshima Airport, Takamatsu Airport, Matsuyama Airport, Kitakyushu Airport, Fukuoka Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Miyazaki Airport, Kagoshima Airport, Naha Airport</p>
<p>Assistance dogs prescribed in Article 2 paragraph 1 of the Act on Assistance Dogs for Physically Disabled Persons that are of the dogs described in Article 45 (1) c and which a disabled person is accompanied by, and designated quarantine items listed in Article 45 (2) to (8) which are imported as baggage</p>	<p>Wakkanai Port, Tomakomai Port, Otaru Port, Keihin Port, Niigata Port, Shimizu Port, Nagoya Port, Yokkaichi Port, Hanshin Port, Sakai Port, Hiroshima Port, Kanmon Port, Tokushima-Komatsushima Port, Takamatsu Port, Hakata Port, Nagasaki Port, Hitakatsu Port, Izuhara Port, Kagoshima Port, Naha Port, Ishigaki Port, Asahikawa Airport, Kushiro Airport, Obihiro Airport, Shin-Chitose Airport, Hakodate Airport, Aomori Airport, Sendai Airport, Akita</p>

	Airport, Hanamaki Airport, Yamagata Airport, Shonai Airport, Fukushima Airport, Hyakuri Airport, Narita International Airport, Tokyo International Airport, Niigata Airport, Toyama Airport, Komatsu Airport, Shizuoka Airport, Nagoya Airport, Chubu International Airport, Kansai International Airport, Kobe Airport, Tottori Airport, Miho Airport, Okayama Airport, Izumo Airport, Hiroshima Airport, Yamaguchi-Ube Airport, Tokushima Airport, Takamatsu Airport, Matsuyama Airport, Kochi Airport, Kitakyushu Airport, Fukuoka Airport, Saga Airport, Nagasaki Airport, Kumamoto Airport, Oita Airport, Miyazaki Airport, Kagoshima Airport, Naha Airport, New-Ishigaki Airport
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(Report on animal importation)

Article 47-2

The designated quarantine animals under Article 38-2 paragraph 1, designated by the Minister of Agriculture, Forestry and Fisheries shall be the following:

- (1) Cloven-hoofed animals and horse
- (2) Chicken, quail, pheasant, ostrich, guinea fowl, turkey and duck
- (3) Dog

Article 47-3

The notification under the provision of Article 38-2 paragraph 1 shall be submitted in writing in accordance with Form 21-3 of the Appendix for animals listed in (1) of the preceding Article between 120 days to 90 days before the scheduled date of a ship entering a seaport or an aircraft landing at an airport prescribed in Article 47 and for animals listed in (2) of the preceding Article between 70 days to 40 days before the scheduled date of a ship entering a seaport or an aircraft landing at an airport prescribed in Article 47, and in accordance with Form 21-4 of the Appendix for animals listed in (3) of the preceding Article by 40 days before the scheduled date of a ship entering a seaport or an aircraft landing at an airport prescribed in Article 47. However, this shall not apply when the chief of Animal Quarantine Service deems it difficult to do so under special circumstances.

2. For a person intending to make a report specified in the preceding Article using the electronic data

processing system, Article 44-2 paragraph 2 of the Act shall be applied mutatis mutandis.

#### Article 47-4

The items prescribed by the Ministerial Ordinance referred to in Article 38-2 paragraph 1 of the Act shall be the following:

- (1) Name and address of the consignee and consignor, and the name of the representative if the consignee and/or consignor is a corporation.
- (2) Sex, age and place of production of any animal that is intended to be imported.
- (3) Scheduled place, date and name of ship or aircraft of loading for any animal intending to be imported.
- (4) Other items for reference

#### Article 47-5

The cases prescribed by the Ministerial Ordinance referred to in Article 38-2 paragraph 1 of the Act shall be the cases of importation that have been approved as referred to in the proviso of Article 36 paragraph 1 of the Act.

(Quarantine signal)

#### Article 48

Regarding the quarantine signal referred to in Article 39 paragraph 1 of the Act, during the day a flag in accordance with Form 22 in the Appendix shall be hoisted at the front of the masthead, and during the night two white lights below a single red light shall be hung at the same spot.

(Prior notification of import inspection)

#### Article 49

When the animal quarantine officer receives an import inspection application form in accordance with Form 23 of the Appendix from the person intending to import the designated quarantine items (excluding that transported as postal matter), the animal quarantine officer shall notify the said person of the inspection place and date beforehand.

2. For the person intending to make a report under the provision of Article 40 paragraph 1 of the Act using the electronic information processing system, the provisions of Article 44-2 paragraph 2 shall be applied mutatis mutandis.

(Quarantine period for inspection)

Article 50

Inspection referred to in Article 40 paragraph 1 or 2 or Article 45 of the Act shall be carried out under quarantine, and the quarantine period shall be shown in the right column of the following table for each kind of animals (excluding the animals listed in the left column in the table in the next paragraph) in the corresponding line of the left column of the following table. However, when the government authorities of an importing country require a longer quarantine period for the animals to be imported than those shown in the table, the said quarantine period shall be applied:

Kind of animals	Quarantine period at the time of importation or exportation
(1) Cloven-hoofed animals	15 days (7 days in the case of exportation )
(2) Horse	10 days (5 days in the case of exportation)
(3) Chicken, quail, pheasant, ostrich, guinea fowl, turkey and duck	10 days (14 days in the case of one day-old chicks and 2 days in the case of exportation)
(4) Dog	Time as long as deemed by the animal quarantine officer, and within 12 hours
(5) Animals other than those in the preceding items	1 day

2. The quarantine period for the animals listed in the left column in the table in the preceding paragraph which fall under the category of the animals (excluding livestock listed in each item of Article 16 paragraph 1 of the Act and livestock which are ordered to be killed under the provisions of Article 17 paragraph 1) in the left column in the next table shall be shown in the right column in the same table. However, when the said quarantine period is within the period specified in the right column in the table in the preceding paragraph (when the said period is shortened under the provision of the next paragraph, the said shorten period) for the kind of animals listed in the left column in the same table, the said quarantine period is applied.

Animal	Quarantine period at the time of importation or exportation
(1) Animals affected with infectious diseases of livestock (limited to infectious diseases by the pathogens of monitored infectious diseases in cases of importation; hereinafter the same in this table)	Period until the possibility of spreading the pathogens of infectious diseases of livestock disappears
(2) Animals suspected to be affected with	Period until the suspicion that the animals are

infectious diseases of livestock	affected with infectious diseases of livestock disappears
(3) Animals likely to be affected with infectious diseases of livestock	Period until the possibility that the animals are affected with infectious diseases of livestock disappears
(4) Animals which had been kept with animals suspected to be affected with infectious diseases of livestock	Period until the suspicion that the animals suspected to be affected with infectious diseases of livestock disappears

3. The quarantine period in the preceding paragraph 1 in cases of importation may be extended up to 30 days for animals in (1) in the table in paragraph 1, up to 20 days for animals in (2) and (3) of the same table and up to 10 days for animals in (5) of the same table if an inspection certificate or its copy specified in Article 37 paragraph 2 (1) of the Act is not attached and if deemed it appropriate to do so by the animal quarantine officer depending on the status of the control of endemic animal disease of the exporting country, may be reduced up to 7 days for animals in (1) of the same table, 5 days for animals in (2) of the same table, and 5 days for animals in (1) to (3) of the same table if they are transported into a slaughterhouse designated by the animal quarantine officer in accordance with the methods and routes prescribed by the animal quarantine officer and slaughtered at the said slaughterhouse.

4. The quarantine period referred to in (2) in the table in paragraph 1 in the case of export of an animal imported for the purpose of entering a horse race prescribed in Article 57 paragraph 1 of the Ministerial Ordinance for Enforcement of the Horse Racing Act (Ministry of Agriculture, Forestry and Fisheries Ordinance No. 55, 1954), (including cases where this applies mutatis mutandis under the provision of Article 58 of the same regulation), may be reduced to a time period being within one day and deemed to be necessary by the animal quarantine officer, if the animal quarantine officer deems it appropriate to do so depending on the rearing management from importation and exportation of the said animal. However, this shall not apply to cases in which the government of an importing country requires a longer quarantine period for importation than the said period.

5. The quarantine period referred to in item 3 of the table in paragraph 1 in the case of export of one day-old chicks mentioned in the same item may be reduced to a time period being within one day and deemed to be necessary by the animal quarantine officer, if the animal quarantine officer finds that infectious disease of the said chicks has not broken out at their production site within three months before inspection referred to in Article 45 of the Act concerning the said day-old chicks. However, this shall not apply to cases in which the government of an importing country requires a longer quarantine period for importation than the said period.

(Instruction of import inspection using the electronic information processing system)

#### Article 50-2

As for the application of the provisions of Article 6 paragraph 3 of the Ordinance for Enforcement of the Act on Use of Information and Communications Technology in Administrative Procedure pertaining to Laws and Regulations under the Ministry of Agriculture, Forestry and Fisheries of Japan when the instructions under Article 40 paragraph 4 of the Act are given using the electronic data processing system (which means the electronic data processing system prescribed in Article 4, paragraph 1 of the Act on the Use of Information and Communications Technology in Administrative Procedure; the same in the next Article paragraph 2, Article 54 paragraph 3, Article 55 paragraph 2, and Article 56), the description in the paragraph stating “enter, electronically sign on the information about the said item, along with a digital certificate of the said electronic signature listed in each item of Article 3 paragraph 3” shall be replaced with “enter”.

(Import Quarantine Certificate and others)

#### Article 51

The form of the import quarantine certificate referred to in Article 44 paragraph 1 and 2 of the Act shall be Form 24 of the Appendix. However, when issuance of an import quarantine certificate is requested from the person having notified under the provision of Article 40 paragraph 1 of the Act using the electronic information processing system, the animal quarantine officer shall describe the verification of completion of the inspection under the provision of Article 40 paragraph 1 and paragraph 2 of the Act, sign and place a seal on the said certificate with the items to be listed in Form 23 of the Appendix, which were input by the said person to his/her computer (including an input-output unit, hereinafter referred to as the same) and were output by the computer of the animal quarantine service.

2. When the notification of the certification is made using the electronic information processing system instead of the issuance of a import quarantine certificate under the provisions of Article 44 paragraph 1 and 2 of the Act, the contents of the notification shall verify that the inspection under the provisions of Article 40 paragraph 1 and paragraph 2 of the Act has been completed.

3. In the cases in the preceding paragraph, the provision of the preceding Article applies *mutatis mutandis*.

4. The kinds and places of designated quarantine articles that must be tagged or marked with a brand, tattoo and other tags or marks under the provision of Article 44 paragraph 1 of the Act, and the kinds and forms of the said tags or marks shall be shown in the following table. However, the label listed in the

table shall be used as the marks for mail containing a designated quarantine item when it is difficult to stamp on the item because of the size or condition of the container or packaging of the said item.

Kinds of designated quarantine items	Place	Kinds and forms of tags and marks
Cattle	Left horn or left front hoof	Branding: Form 25 of the Appendix
Horse	Left front hoof	Branding: Form 26 of the Appendix
Designated quarantine items other than animals	Suitable place on the container or packaging	Stamp: Form 27 of the Appendix
Postal matter containing a designated quarantine item	Suitable place on the container or packaging	Stamp and Label : Form 28 of the Appendix and label

(Application for export inspection)

#### Article 51-2

Any person intending to export cloven-hoofed animals and horses and the semen of these animals shall submit an export inspection application referred to in paragraph 1 of the next Article to the chief of Animal Quarantine Service by 90 days prior to the export (when it is accepted that a special circumstance makes the submission difficult, by a date designated by the he chief of Animal Quarantine Service).

2. For the person intending to submit an export inspection application referred to in paragraph 1 of the next Article using the electronic information processing system, the provisions of Article 44-2 paragraph 2 shall be applied mutatis mutandis.

(Prior notification of export inspection)

#### Article 52

When an export inspection application in accordance with the Form 29 of the Appendix from any person intending to export an article listed in each item in Article 45 paragraph 1 of the Act is submitted to the animal quarantine officer, the animal quarantine officer shall notify the person beforehand of the place and date of the inspection.

2. For the person intending to submit an export inspection application referred to in the preceding paragraph using the electronic information processing system, the provisions of Article 44-2 paragraph 2 shall be applied mutatis mutandis.

(Designation of export articles)

#### Article 53

Articles designated by the Minister of Agriculture, Forestry and Fisheries specified in Article 45 paragraph 1 (2) of the Act shall be those listed in (1) to (6) of Article 45.

(Export quarantine certificate)

#### Article 54

The form of an export quarantine certificate referred to in Article 45 paragraph 3 of the Act shall be Form 30 of the Appendix. However, when the government of an importing country requires an export quarantine certificate different from this form for importation, the required form shall be used.

2. When issuance of an import quarantine certificate is requested from the person who has submitted the export inspection application referred to in Article 52 paragraph 1 using the electronic information processing system, regardless of the provision in the above paragraph, the animal quarantine officer shall describe the verification of completion of the inspection under the provision of Article 45 paragraph 1 of the Act, sign and place a seal on the said certificate with the items to be listed in Form 29 of the Appendix, which were input by the said person to his/her computer (including an input-output unit, hereinafter referred to as the same) and were output by the computer of the animal quarantine service.

3. When the certification is notified using the electronic information processing system instead of the issuance of an export quarantine certificate under the provisions of Article 45 paragraph 3 of the Act, the contents of the said notification shall certify that the inspection under paragraph 1 of the same Article has been completed.

4. In the cases in the preceding paragraph, the provision of Article 50-2 applies mutatis mutandis.

(Measures based on inspection)

#### Article 55

For the application of the provisions of Article 13, 39, and 62, when measures are carried out on the basis of the inspection referred to in Article 46 paragraph 1 of the Act, "the governor of the prefecture" in Article 13 and Article 39 and "animal health inspector, .....except animal health inspector" in Article 62 shall be replaced with "the Director General of the Animal Quarantine Service" and "animal quarantine



officer", respectively.

2. When the measures on the basis of the inspection referred to in Article 46 paragraph 1 of the Act (limited to the measures under Article 6 paragraph 1, Article 14, 16, 17, 19 to 21, 23, 25, 26 and 31 paragraph 1 of the Act applied by the reading of terms under the provision of Article 46 paragraph 1 of the Act when the inspection referred to in Article 40 paragraph 1 or 2 is carried out and measures under Article 25 and 26 of the Act applied by the reading of terms under the provision of Article 46 paragraph 1 of the Act when the inspection under the provision of Article 41 of the Act is carried out) is notified using the electronic information processing system, the provision of Article 50-2 applies *mutatis mutandis*.

#### Article 56

When isolation or disinfection is ordered under the provisions of Article 46 paragraph 2 and 3 of the Act or when the animal quarantine officer is ordered to carry out isolation, injection, dipping, medication or disinfection, the owner of the animals and other articles to be subject to the measures shall be notified of that effects in writing or verbally, or using the electronic information processing system (limited to the cases in which the person who made the report referred to in the provision of Article 40 paragraph 1 of the Act using an electronic information processing system is ordered to conduct isolation or disinfection).

2. When the notification in the preceding paragraph is conducted using the electronic information processing system, the provision of Article 50-2 applies *mutatis mutandis*.

### **Chapter V: Measures for possession of the pathogens**

(Definition of terms)

#### Article 56-2

In this chapter, the meanings of the terms listed in the following items shall be as prescribed respectively in those items:

(1) Management area:

An area which needs to be restricted from access of people by the means such as locking in order to safely manage the pathogens of the monitored infectious diseases specified in Article 46-21 paragraph 1 of the Act (hereinafter referred to as “pathogens of monitored infectious diseases”) in a business facility for handling the pathogens of monitored infectious diseases.

(2) Storage cabinet:

A cabinet to store the pathogens of monitored infectious diseases.

(3) Laboratory:

A room in which the pathogens of monitored infectious diseases are used (excluding the testing room referred to in the next item or those within the manufacturing facility referred to in item 6).

(4) Testing room:

A room in which when an institution conducting the test for the pathogens of infectious diseases of livestock possesses the pathogens of monitored infectious diseases for its business, a test is carried out using the said pathogens of monitored infectious diseases.

(5) Laboratory without using animals:

A laboratory in which the pathogens of monitored infectious diseases are not used on animals.

(6) Manufacturing facility:

A facility in which storage, use, the sterilization and others (hereinafter referred to as “handling”) of the pathogens of monitored infectious diseases are conducted in order to manufacture the pharmaceutical products specified in Article 2 paragraph 1 of the Pharmaceutical Affairs Act or the drugs targeted for clinical trials referred to in Article 2 paragraph 16 (including implementation of studies aiming to collect the materials on results of clinical studies out of those to be submitted under the provision of Article 14 paragraph 3 of the same Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act (including the cases for which Article 14 paragraph 9 and Article 19-2 paragraph 5 applied by the reading of terms under the provision of Article 83 paragraph 1 is applied mutatis mutandis).

(7) Laboratory and others:

A laboratory, testing room, and the manufacturing facility.

(8) Biological safety cabinet:

A device for using the pathogens of monitored infectious agents, meeting the standards of the biohazard class II cabinet specified in the Japanese Industrial Standards K 3800 (biohazard class II cabinet: hereinafter referred to as “JIS K 3800”) or having an equivalent performance.

(9) Class III cabinet:

A cabinet that suits to the basic structure of the biohazard class III cabinet specified in the JIS K 3800, out of all biological safety cabinets.

(10) HEPA filter:

A filter for air supply and exhaust, which has the performance specified in the Japanese Industrial

Standards Z 8122(contamination control term)-4114 or equal to or more than that, when the test is conducted using the test method specified in the Japanese Industrial Standards B 9927 (performance test method for air filters for clean rooms).

(11) Housing facility:

A facility in which the animals are kept when the pathogens of monitored infectious agents are used on the said animals.

(12) Isolator:

A device that prevents the pathogens of monitored infectious diseases from spreading from the inside to the outside with negative pressure maintained, and air from which is discharged through a HEPA filter.

(13) Equipment for the sterilization and others

Equipment for the sterilization and others of the pathogens of monitored infectious diseases used in the laboratory and others or contaminated articles by those pathogens.

(14) Handling and others:

Handling and management and other works associated with them which the person having permission specified in Article 46-17 paragraph 1 of the Act or the person possessing the pathogens of monitored infectious diseases or his/her employees perform.

(15) Pathogens worker:

The person who performs handling and others and enters the laboratory and others.

(16) Protective equipment:

Personal protective equipment including a cap, gloves, glasses and a mask, which a user of the pathogens of monitored infectious diseases puts on to prevent himself/herself from being exposed to the said pathogens.

(17) Primary container:

Containers, including a plastic bottle and a test tube, which the pathogens of monitored infectious diseases are directly put into.

(18) Secondary container:

Containers, including a metal or reinforced-plastic container, which protect the primary containers.

(19) Inner container:

The whole article associated with the primary and secondary containers, which is required to transfer the pathogens of monitored infectious diseases.

(20) Outer container:

A fiber board container and other containers, which protect the inner container.

(Pathogens of domestic animal infectious diseases)

Article 56-3

The pathogens prescribed in the Ministerial Ordinance in the text of Article 46-5 paragraph 1 of the Act shall be the following:

(1) Morbillivirus, Rinderpest virus (excluding L, BA-YS, and RBOK strains) (Synonym: Rinderpest virus)

(2) Mycoplasma mycoides (limited to the SC strains of Mycoplasma mycoides subsp. mycoides) (Synonym: Mycoplasma mycoides)

(3) Aphthovirus, foot-and-mouth disease virus (Synonym: foot-and-mouth disease virus)

(4) Orbivirus, African horse sickness virus (Synonym: African horse sickness virus)

(5) Morbillivirus, peste-des-petits-ruminants virus (Synonym: peste-des-petits-ruminants virus)

(6) Pestivirus, classical swine fever virus (Synonym: classical swine fever virus)

(7) Asfivirus, African swine fever virus (Synonym: African swine fever virus)

(8) Influenzavirus A, influenzavirus A (limited to those apply to one of the following requirements (excluding the pathogens listed in Article 56-27 (16)) (Synonym: highly pathogenic avian influenza virus)

a. The IVPI (a pathogenicity index of a pathogens obtained in an intravenous inoculation test) in 6-week-old chickens is greater than 1.2.

b. The mortality of 4-8 week-old chickens inoculated intravenously with the virus is at least 75%.

c. Viruses with serosubtype H5 or H7 which has multiple basic amino acids at the cleavage site of the haemagglutinin molecule (HA0) and the said amino acid motif is estimated to be similar to that of the pathogens identified as that referred to in this item.

(9) Influenzavirus A, influenzavirus A (limited to those whose serosubtype is H5 or H7 and which are isolated from animals other than human beings (excluding the pathogens referred to in the preceding item, the following pathogens, and the pathogens listed Article 56-27 (16)). (Synonym: low pathogenic avian influenza virus)

a. A/chicken/Mexico/232/94/CPA (H5N2)

b. A-H5N9 TW68 Bio

c. A/duck/Hokkaido/Vac-1/04 (H5N1)

d. A/duck/Hokkaido/Vac-2/04 (H7N7)

e. A/duck/Hokkaido/Vac-3/2007 (H5N1)

f. A/common magpie/Hong Kong/5052/2007 (H5N1) (SIRG-166615)

- g. A/turkey/Turkey/1/2005 (H5N1) (NIBRG-23)
- h. rg A/bar-headed goose/Qinghai lake/1a/05[R] 6+2 (163222)
- i. rg A/whooper swan/Mongolia/244/05[R] 6+2 (163243)

(Permission for possession of the pathogens of animal infectious diseases)

#### Article 56-4

Permission referred to in the text of Article 46-5 paragraph 1 of the Act shall be obtained for each business facility.

(Standards of possession by the person having the obligation of the sterilization and transfer)

#### Article 56-5

The possession of the pathogens of domestic animal infectious diseases specified in Article 46-5 paragraph 1 (1) shall comply with the following standards:

- (1) The pathogens of domestic animal infectious diseases are put in a closed container and the container is placed in the storage facility.
- (2) During the said possession, unless absolutely necessary, the measures, including reliable locking, shall be taken to prevent the pathogens of domestic animal infectious diseases from being taken out from the storage cabinet.
- (3) In the sterilization and others, the person shall perform the said activities or delegate them to others in compliance with the standards specified in Article 56-25 paragraph 4, as to the category listed in the following a to c, within 7 days from the date specified in the following a to c. The transfer shall be conducted as to the categories listed in the following a to c from the date specified in the following a to c without delay:
  - a. When the person having permission does not need to possess the pathogens of animal infectious disease for the permission anymore: The date when the possession has become unnecessary.
  - b. When the person having permission referred to in the text of Article 46-5 paragraph 1 of the Act gets the permission revoked, or the validity of the permission is lost: The date when the permission was cancelled or the validity was lost.
  - c. When a test institution of animal infectious diseases (excluding those having permission) possesses the pathogens of animal infectious diseases for its business: The date when the said possession has been started.

(Application for permission of possession)

#### Article 56-6

The submission of the application referred to in Article 46-5 paragraph 2 of the Act shall be performed in the application form in accordance with Form 31 of the Appendix along with the following documents:

- (1) For a corporation, a certificate of registered matters of the corporation.
- (2) Document describing the scheduled time of start of the possession.
- (3) A written oath that the person intending to obtain the permission referred to in the text of Article 46-5 paragraph 1 of the Act does not apply to the person referred to in each item of Article 46-6 paragraph 2.
- (4) Any plan of the inside and outside of the business facility centering on the handling facility, with scale and orientation.
- (5) A ground plan of the handling facility describing the floor plan, equipment, use and doorway of the room for handling the pathogens of domestic animal infectious diseases, the management area, the places to be marked using Form 32 of the Appendix, with scale and orientation.
- (6) An elevation plan of the facility describing the main parts for handling the pathogens of domestic animal infectious diseases with scale (excluding the cases in which the ground plan in the preceding item includes all such main parts).
- (7) Other documents stating that the handling facility concerning the said submission of the application applies to the technical standards referred to in Article 46-6 paragraph 1 (2) of the Act.

(Products concerning the permission of possession)

#### Article 56-7

The products prescribed by the Ministerial Ordinance referred to in Article 46-6 paragraph 1 (1) of the Act (including the case where it applies *mutatis mutandis* to Article 46-8 paragraph 4 of the Act) shall be test reagents.

(Standards of the handling facility of the pathogens of animal infectious diseases with intensive management)

#### Article 56-8

Out of the technical standards prescribed by the Ministerial Ordinance referred to in Article 46-6 paragraph 1 (2) of the Act (including the case where it applies *mutatis mutandis* to Article 46-8 paragraph 4 of the Act), those concerning the handling facility for the pathogens listed in Article 56-3 (1), (3), and (7) (hereinafter referred to as “pathogens of animal infectious diseases with intensive management”) shall be the following:

- (1) The management area shall be set up in the said handling facility.
- (2) The storage cabinet of the pathogens of animal infectious diseases with intensive management shall be located within the laboratory and others, and equipment or a device to close the storage cabinet such as a lock shall be attached.

(3) The laboratory and others of the pathogens of animal infectious diseases with intensive management shall be the following:

a. The structures of parts which are likely to be contaminated with the pathogens of animal infectious diseases with intensive management, including walls, floors and ceilings, shall be easy to disinfect their surfaces.

b. The biological safety cabinet is placed within the laboratory and others (in the manufacturing facility, the measures for prevent the pathogens of animal infectious diseases with intensive management from spreading from the said facility shall be taken). However, the following cases are excluded:

1) The cases in which the use of the pathogens of animal infectious diseases with intensive management is not associated with the occurrence of aerosols.

2) The cases in which when the pathogens of animal infectious diseases with intensive management are used on animals, the animals are too big to be kept in the biological safety cabinet.

c. In the laboratory and others, the anteroom only for the laboratory and others is attached in accordance with the following:

1) The structure of the anteroom in which the access to the laboratory and others shall be usually allowed only through the anteroom and a shower room referred to in 2) and the doorway of the said anteroom shall not face directly to the outside.

2) A shower room shall be placed in the anteroom, and the said shower room shall have an interlock or airtight double doors with the function equivalent to the interlock.

3) Drainage equipment with a function for the sterilization and others of wastewater contaminated or suspected to be contaminated with the pathogens of animal infectious diseases with intensive management from the said anteroom shall be equipped in the anteroom.

d. Air supply, air exhaust, and drainage equipment shall be placed in the laboratory and others in accordance with the following:

1) The air supply equipment shall have the structure in which the air is supplied to the laboratory and others through one or more HEPA filters.

2) The air exhaust equipment shall have the structure in which the air is exhausted from the laboratory and others through one or more HEPA filters.

3) The drainage equipment shall have the function to sterilize, etc. of wastewater contaminated or suspected to be contaminated with the pathogens of animal infectious diseases with intensive management from the said anteroom.

e. Equipment or a device to close such as a lock shall be attached in the laboratory and others.

f. The structure may maintain negative pressure inside of the laboratory and others.

(4) The pathogens of animal infectious diseases with intensive management are used on animals in the laboratory and others as follows:

a. The housing facility shall be placed inside the said laboratory and others, as well as inside the isolator or near the outlet of the air exhaust equipment. In these cases, when the housing facility is placed near the outlet of the air exhaust equipment, "one or more" described in the preceding item b, 2) shall be "two or more".

b. An incinerator or equipment having the function equal to or more than that of the incinerator shall be placed in the said handling facility.

(5) Equipment of sterilization and others of the pathogens of the animal infectious diseases with intensive management shall be placed inside the laboratory and others.

(6) The said handling facility shall be attached with standby power supply equipment for emergencies.

(7) The said handling facility shall have a system for checking its operation status and a person constantly observing the said operation status shall be in place.

(8) The said handling facility shall be regularly inspected one or more times a year to maintain the function applying to the standards referred to in each of the preceding items.

(Standards of the handling facility of the pathogens of the animal infectious diseases requiring management)

#### Article 56-9

Out of the technical standards prescribed by the Ministerial Ordinance referred to in Article 46-6 paragraph 1 (2) of the Act (including the cases where it applies mutatis mutandis to Article 46-8 paragraph 4 of the Act), those concerning the handling facility for the pathogens of animal infectious diseases other than the pathogens of animal infectious diseases with intensive management (hereinafter referred to as “pathogens of animal infectious diseases requiring management”) mean the following:

(1) The management area shall be set up in the said handling facility.

(2) The storage cabinet of the pathogens of animal infectious diseases requiring management shall be located within the laboratory and others (when the storage facility in which measures to restrict access such as a lock are taken, within the said storage facility), and equipment or a device to close the storage cabinet such as a lock shall be attached.

(3) The laboratory and others of the pathogens of animal infectious diseases requiring management shall be the following:

a. The surfaces of structures of parts which are likely to be contaminated with the pathogens of animal infectious diseases requiring management, including walls, floors and ceilings, shall be easy to disinfect.

b. The biological safety cabinet is placed within the laboratory and others (in the manufacturing facility, the measures shall be taken to prevent the pathogens of animal infectious diseases requiring management from spreading from the said facility). However, the following cases are excluded:

1) The cases in which the use of the pathogens of animal infectious diseases requiring management is not associated with the occurrence of aerosols.

2) The cases in which when the pathogens of animal infectious diseases requiring management are used on animals, the animals are too big to be kept in the biological safety cabinet.

c. In the laboratory and others (excluding a laboratory without using animals), the anteroom only for the laboratory and others is attached in accordance with the following:

1) The structure of the anteroom in which the access to the laboratory and others shall be usually allowed



only through the anteroom and the doorway of the said anteroom shall not face directly to the outside.

2) The doorway of the anteroom shall have an interlock or airtight double doors with the function equivalent to the interlock.

d. Air exhaust equipment shall be placed in the laboratory and others (excluding a laboratory without using animals) in accordance with the following, provided, however, that this shall not apply when only a class III cabinet is placed inside the said laboratory and others:

1) The air exhaust equipment shall have the structure in which air is constantly controlled to flow from the doorway of the laboratory and others.

2) The air exhaust equipment shall have the structure in which the air is exhausted from the laboratory and others through one or more HEPA filters.

3) The air exhaust equipment shall have a device checking the status of its operation.

e. The laboratory and others shall have foot- or elbow-operated or automatic equipment for hand washing, provided, however, that this shall not apply when measures equivalent to or more effective than the said equipment, are taken.

f. The laboratory and others shall have equipment or a device to close it such as a lock.

g. The laboratory and others shall have the structure which allows them to be completely closed in order to decontamination with the pathogens of the animal infectious disease requiring management.

(4) When the pathogens of animal infectious disease requiring management are used on animals in the laboratory and others, the following shall be followed:

a. The housing facility shall be placed within the said laboratory and others, as well as be placed within the isolator or near the outlet of the air exhaust equipment.

b. An incinerator shall be placed in the said handling facility, provided, however, that this shall not apply when the equivalent or more effective measures are taken.

c. A shower room shall be placed in the anteroom of the said laboratory and others, provided, however, that this shall not apply when all of the following apply:

1) In the cases where special clothes (a person entering the said laboratory and others puts on special clothes over his or her clothes) are double layered for work.

2) In the cases where the housing facility is placed within the isolator or the biological safety cabinet.

3) In the cases where the pathogens of animal infectious diseases requiring management are used on animals inside the isolator or the biological safety cabinet.

(5) Equipment of sterilization and others of the pathogens of the animal infectious diseases requiring management shall be placed inside of the laboratory and others.

(6) The laboratory and others (excluding a laboratory without using animals) shall have a standby power equipment for emergencies in the said handling facility, provided, however, that this shall not apply when the air supply equipment having the structure in which air is supplied through a HEPA filter to the said laboratory and others is provided.

(7) The said handling facility shall be regularly inspected one or more times a year to maintain the function applying to the standards referred to in each preceding item.

2. To the handling facility of the pathogens listed Article 56-3 (9) in which the said pathogens are not used on animals, the provisions of (3) c, d and g and (6) in the preceding paragraph are not applied. When the provision of (5) of the same paragraph is applied, “laboratory and others” described on (5) shall be replaced with “the said handling facility”.

3. For the handling facility of the pathogens listed Article 56-3 (9) (only those which have been found not to apply to any of the requirements listed in Article 56-3 (8)), in which the said pathogens are used on animals other than birds, the provisions of paragraph 1 (3) c and g, (4), and (6) are not applied to. When the provisions of the same paragraph (3) d and (5) are applied, “is placed” described paragraph 1 (3) d and “laboratory and others” in the same paragraph (5) shall be replaced with “is placed or the housing facility is placed within the isolator” and “the said handling facility”, respectively.

4. For the handling facility referred to in the preceding paragraph, which applies to the following requirements, the provisions of paragraph 1 (3) c, d, and g, (4), and (6) do not apply, and when the provision of the same paragraph (5) applies, “laboratory and others” described on (5) shall be replaced with “the said handling facility”.

(1) The housing facility shall be placed inside the isolator or the biological safety cabinet.

(2) The pathogens of animal infectious diseases requiring management are used on birds inside the isolator or the biological safety cabinet.

(Permit for Possession)

#### Article 56-10

The items prescribed by the Ministerial Ordinance referred to in Article 46-7 paragraph 1 shall be the following and the form of the permit referred to in the same paragraph (herein after referred to as “permit”) shall be Form 33 of the Appendix.

(1) Name and address, and the name of the representative for a corporation.

(2) Purpose and methods of possession

(3) Name and address of the handling facility

(4) Conditions of permission prescribed by the text of Article 46-5 paragraph 1 referred to in the provision of Article 46-6 paragraph 3

2. When the permit is spoiled or lost, the person having permission may be reissued his/her permit by submitting the application in accordance with Form 34 of the Appendix or the said permit when it is spoiled to the Minister of Agriculture, Forestry and Fisheries.

3 The person having permission shall immediately return his/her permit (in the case in item 3, the permit

found by the person) to the Minister of Agriculture, Forestry and Fisheries in the following cases:

- (1) When the person has accomplished or lost his/her purpose.
- (2) When the permission in the text in Article 46-5 paragraph 1 of the Act has been cancelled.
- (3) When the lost permit has been found after the permit was reissued prescribed by the provision of the preceding paragraph.

(Application for permission of changes in the permission items)

#### Article 56-11

For the application of changes in the permission items referred to in the provision in the text of Article 46-8 paragraph 1, the application in accordance with Form 35 of the Appendix shall be submitted to the Minister of Agriculture, Forestry and Fisheries with the following documents:

- (1) Document describing the scheduled time of the changes.
- (2) Documents on the changes referred to in Article 56-6 (4) to (7).
- (3) When construction work is performed, the document including the scheduled period of the construction work and the measures for prevention and the spread of the outbreak of the animal infectious diseases caused by the pathogens of animal infectious diseases during the said construction work.

2. The person having permission intending to obtain the permission referred to in the text of Article 46-8 paragraph 1 of the Act, when he/she apply for the permission, shall submit the permit to the Minister of Agriculture, Forestry and Fisheries and be issued the permit including the changed items.

(Minor changes without permission for changes in the permission items)

#### Article 56-12

The minor changes prescribed by the Ministerial Ordinance referred to in the proviso of Article 46-8 paragraph 1 of the Act shall be the following:

- (1) Abolishment of the handling facility (limited to those are not associated with the sterilization and transfer of the pathogens of animal infectious diseases prescribed by Article 46-11 paragraph 2 of the Act (hereinafter referred to as “sterilization and transfer”)).
- (2) Changes in the method of possession
- (3) Changes in the management area and expansion of equipment (limited to that without a construction work)

(Reporting of minor changes in the permission items)

#### Article 56-13

As for the reporting prescribed by the provision of Article 46-8 paragraph 2 of the Act, the reporting document in accordance with Form 36 of the Appendix with the documents listed in Article 56-11 paragraph 1(1) and (2) shall be submitted to the Ministry of Agriculture, Forestry and Fisheries.

(Report of changes of name and others)

#### Article 56-14

For the report prescribed by the provision of Article 46-8 paragraph 3 of the Act, the reporting document in accordance with Form 37 of the Appendix shall be submitted to the Ministry of Agriculture, Forestry and Fisheries along with the following documents:

- (1) When the name of the corporation is changed, a certificate of registered matters of the corporation after changes.
- (2) When the name is changed, a written oath that the person holding the changed permission does not apply to the person referred to in each item of Article 46-6 paragraph 2 of the Act (excluding item 8).
- (3) When the name of the representative of a corporation is changed, a written oath that the representative after the change does not apply to the person prescribed by Article 46-6 paragraph 2 (8) of the Act.

(Restriction of transfer)

#### Article 56-15

The transfer of the pathogens of animal infectious diseases prescribed by Article 46-10 (2) shall require the report of the sterilization and transfer prescribed by Article 46-11 paragraph 2 of the Act.

(Report of the sterilization and transfer)

#### Article 56-16

The report of the sterilization and transfer prescribed by Article 46-11 paragraph 2 of the Act shall be conducted within 3 days from the date prescribed by each item in accordance with Form 38 of the Appendix according to the categories referred to in each of the following items:

- (1) When the person having permission no longer needs to possess the pathogens of animal infectious disease for the permission: The date when the possession has become unnecessary.

(2) When the person having permission referred to in the text of Article 46-5 paragraph 1 of the Act revoked, or the validity of the permission is lost: The date when the permission was cancelled or the validity was lost.

(3) When a test institution of animal infectious diseases (excluding those having permission) possesses the pathogens of animal infectious diseases for its business: The date when the said possession has been started.

2. The items prescribed in the Ministerial Ordinance referred to in Article 46-11 paragraph 2 of the Act shall be the following:

(1) Name and address, and the name of the representative for a corporation.

(2) Scheduled date of the sterilization and transfer.

(3) In the case of transfer, name and address of the business facility to receive the transfer.

(Entries of the order on measures)

#### Article 56-17

The order prescribed by Article 46-11 paragraph 4 of the Act shall be conducted by issuing of the order including the following items:

(1) Contents of the measures to be taken

(2) Date of the order and deadline for implementation

(3) Reasons for the order

(Provisions for preventing the outbreak of animal infectious diseases)

#### Article 56-18

The preparation of the provisions for preventing the outbreak of animal infectious diseases prescribed by Article 46-12 paragraph 1 of the Act shall be conducted by determining concerning the following items:

(1) The duties and organization of the pathogens handling supervisor and those working in handling and management of the pathogens of animal infectious diseases

(2) The restriction of the person who works in handling of the pathogens of animal infectious diseases and enters the laboratory and others.

(3) The maintenance and management of the handling facility.

(4) The storage, use, transport, and the sterilization and transfer of the pathogens of animal infectious diseases.

(5) The restriction of receipt, delivery, movement of the pathogens of animal infectious diseases.

(6) The education and training required to prevent the outbreak and the spread of animal infectious

diseases caused by the pathogens of animal infectious diseases.

(7) The record and storage prescribed by Article 46-15 of the Act.

(8) The management of information on handling of the pathogen of animal infectious diseases.

(9) The measures to be taken in the cases of accidents, including theft and disappearance of the pathogens of animal infectious diseases.

(10) The emergency measures in the event of a disaster.

(11) Other items required for preventing the outbreak and the spread of animal infectious diseases caused by the pathogens of animal infectious diseases.

2. The report prescribed by Article 46-12 paragraph 1 of the Act shall be conducted in accordance with Form 39 of the Appendix

3. The report prescribed by Article 46-12 paragraph 2 of the Act shall be conducted in accordance with Form 40 of the Appendix, with the changed provisions of preventing the outbreak of animal infectious diseases.

(Requirements of the pathogens handling supervisor)

#### Article 56-19

The requirements prescribed by the Ministerial Ordinance referred to in Article 46-13 paragraph 1 of the Act shall be that the pathogens handling supervisor is selected from those listed in the following, who have sufficient knowledge and experience on handling of the pathogens of animal infectious diseases:

(1) Veterinarian

(2) Medical doctor

(3) Dentist

(4) Pharmacist

(5) Clinical laboratory technician

(6) Person who completed and graduated the course of biology or agriculture or a program equivalent to the two in a university in accordance with the School Education Act (Act No. 26, 1947) or an education institution having the course corresponding to a university or a graduate school referred to in Article 104 paragraph 4 (2) of the same Act.

(Reporting of selection of the pathogens handling supervisor and others)

#### Article 56-20

The report of the selection and removal of the pathogens handling supervisor prescribed by Article 46-13 of the Act paragraph 2 shall be conducted in accordance with Form 41 of the Appendix.

(Education and training)

Article 56-21

The education and training referred to in Article 46-14 of the Act shall be conducted for people entering the management area (for the handling facilities of the pathogens of the animal infectious diseases requiring management or the pathogens of notifiable infectious disease, the laboratory and others; hereinafter referred to as “management area and others”) and the workers in operations including handling in accordance with the following:

(1) The education and training for the pathogens workers (excluding the education and training referred to in the next item) shall be conducted before first entering the management area and others and at intervals of less than three years after the entering those places.

(2) The education and training for the pathogens workers who enter the management area of the handling facility of the pathogens of the animal infectious diseases with intensive management to master handling and management of the said pathogens shall be conducted after first entering the said management area.

(3) The education and training for the pathogens workers who do not enter the management area and others shall be conducted before starting activities including handling and at intervals of less than three years after starting those activities.

(4) The education and training for the person prescribed by the preceding three items shall be conducted for the following items (as for the person prescribed by the previous item, excluding the following a):

a. Characteristics of the pathogens of animal infectious diseases.

b. Management of the pathogens of animal infectious diseases.

c. Laws and ordinances concerning prevention of the outbreak and the spread of animal infectious diseases caused by the pathogens of animal infectious diseases.

d. Provisions of prevention of the outbreak of animal infectious diseases.

(5) The education and training for the person referred to in items 1 to 3 shall be conducted for requirements to prevent the outbreak and the spread of animal infectious diseases caused by the pathogens of animal infectious diseases in the handling facility which the said person enters.

2. Regardless of the provisions in the preceding paragraph, for the person recognized as having knowledge and skills concerning item a to d in (4) of the previous paragraph or all or part of contents of (5) of the same paragraph, the education and training on the said items or contents may be omitted.

(record)

Article 56-22

The items which shall be recorded in the books to be kept by the person having permission prescribed by Article 46-15 paragraph 1 of the Act shall be the following:

- (1) Kinds and quantities of the pathogens of animal infectious diseases for receipt or delivery.
- (2) Date of receipt or delivery of the pathogens of animal infectious diseases.
- (3) Method or place for storage of the pathogens of animal infectious diseases.
- (4) Kind of the pathogens of animal infectious diseases to be used.
- (5) Date of use of the pathogens of animal infectious diseases.
- (6) Kind of the pathogens of animal infectious diseases for the sterilization and transfer.
- (7) Date of the sterilization and transfer of the pathogens of animal infectious diseases.
- (8) Method or place for sterilization and others of the pathogens of animal infectious diseases.
- (9) Name of the person who received or delivered the pathogens of animal infectious diseases.
- (10) Name of the person who used the pathogens of animal infectious diseases.
- (11) Name of the person who conducted sterilization and others of the pathogens of animal infectious diseases.
- (12) Name of the person who entered the management area for the pathogens of the animal infectious diseases with intensive management.
- (13) Date of entering the management area for the pathogens of the animal infectious diseases with intensive management.
- (14) Implementation date and items of the education and training on the management area for the pathogens of the animal infectious diseases with intensive management, and name of the person who received the said education and training.
- (15) Implementation date of inspection of the handling facility, the results of the inspection, contents of the measures thereof and name of the person who conducted the inspection.

2. When the details listed in each item of the preceding paragraph are recorded in a file in a computer or a magnetic disk (including those capable of certainly recording of certain items by an equivalent manner) and clearly printed on paper using a computer and other devices where appropriate, the said record may be replaced by registering it in the book.

3. The person having permission shall annually close the books in Article 46-15 paragraph 1 of the Act.

4. The storage of the books prescribed by Article 46-15 paragraph 2 of the Act shall be conducted for one year after closing the book specified in the preceding paragraph.

(Standards of storage of the pathogens of animal infectious diseases)

Article 56-23



Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act, those concerning storage of the pathogens of the animal infectious diseases with intensive management shall be the following:

- (1) The pathogens of the animal infectious diseases with intensive management shall be put in a tightly closed container and the container shall be placed in the storage cabinet.
- (2) Unless absolutely necessary, the measure to prevent the pathogens of the animal infectious diseases with intensive management from being taken out, including that the storage cabinet is certainly locked during the storage of the pathogens of the animal infectious diseases with intensive management shall be taken.
- (3) The doorway of the anteroom of the laboratory and others of the pathogens of the animal infectious diseases with intensive management shall have a sign in accordance with Form 32 of the Appendix.

2. Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act, those concerning the storage of the pathogens of the animal infectious diseases requiring management shall be the following:

- (1) The pathogens of the animal infectious diseases requiring management shall be put in a tightly closed container and the container shall be placed in the storage cabinet.
- (2) Unless absolutely necessary, the measure to prevent the pathogens of the animal infectious diseases requiring management from being taken out, including checking that the storage cabinet is certainly locked during the storage of the pathogens of the animal infectious diseases requiring management shall be taken.
- (3) The doorway of the storage facility of the pathogens of the animal infectious diseases requiring management (when the pathogens of the animal infectious diseases requiring management are stored within the laboratory and others, the anteroom of the said laboratory and others (in the case of a laboratory without using animals, the said laboratory without using animals)), shall have a sign in accordance with Form 32 of the Appendix.

3. As regards the application of the provision of item 3 of the preceding paragraph for the handling facility referred to in Article 56-9 paragraph 2 to 4, “the anteroom of the laboratory and others (for a laboratory without using animals, the said laboratory without using animals)” shall be replaced with “the laboratory and others”.

(Standards of the use of the pathogens of animal infectious diseases)

Article 56-24

Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17

paragraph 1 of the Act, those concerning the use of the pathogens of the animal infectious diseases with intensive management shall be the following:

(1) When entering the laboratory and others, special clothes (all clothes which the person entering the laboratory and others wears) and protective equipment shall be put on in the anteroom.

(2) Work shall be carried out wearing clothes and protective equipment in the laboratory and others.

(3) When the pathogens of the animal infectious diseases with intensive management are used, except for the following cases, the use shall be conducted in the biological safety cabinet placed inside of the laboratory and others (excluding the manufacturing facility).

a. The case in which the said use is not associated with the occurrence of aerosols.

b. The case in which when the pathogens of animal infectious diseases with intensive management are used on animals, the animals are too big to be kept in the biological safety cabinet.

(4) Eating and drinking, smoking, and makeup are prohibited in the working area in the laboratory and others.

(5) When going out of the laboratory and others, the clothes and the protective equipment shall be removed. Except when they are taken out into the said laboratory and others, the said clothes and the protective equipment shall not be taken out of the said anteroom before the sterilization and transfer by equipment for sterilization and others.

(6) When going out of the laboratory and others, contamination with the pathogens of animal infectious diseases with intensive management on the body surface shall be removed in the shower room and placed in the anteroom.

(7) The exhaust air from the laboratory and others shall be sterilized and others through the air exhaust equipment.

(8) The wastewater contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases with intensive management from the laboratory and other and their anterooms shall be sterilized and others through the drainage equipment or equipment for sterilization and others.

(9) When articles contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases with intensive management are taken out of the laboratory and others, except when clothes and the protective equipment are taken out to the anteroom of the said laboratory and others, the said articles shall be sterilized through equipment for the sterilization and others.

(10) The person who used the pathogens of animal infectious diseases with intensive management in the laboratory and others shall not contact with animals which are susceptible to the said pathogens of animal infectious diseases with intensive management outside the management area, for 7 days after the date of use.

(11) Animals not related to the work in the laboratory and others shall not be brought to the said laboratory and others.

(12) When the pathogens of animal infectious diseases with intensive management are used on animals in the laboratory and others, the following shall be followed:

a. When entering the laboratory and others, aside from the permission referred to in item 14, the

permission of the pathogens handling supervisor shall be obtained.

b. Unless absolutely necessary, the animals on which the pathogens of animal infectious diseases with intensive management were used, shall not be taken out of the said laboratory and others.

c. When carcasses of the animals on which the pathogens of animal infectious diseases with intensive management were used are taken out of the said laboratory and others, the said carcasses shall be sterilized by the equipment for the sterilization and others, and the said carcass which was taken out shall be incinerated in the incinerator placed in the handling facility or by equipment equivalent to the incinerator, provided, however, that this shall not apply when the said carcasses with the pathogens of animal infectious diseases with intensive management removed are used for academic research.

d. For the clothes and the protective equipment and the housing facility, contamination caused with the pathogens of animal infectious diseases with intensive management shall be removed before cleaning.

e. The measures required to prevent arthropods and rodents from entering shall be taken.

(13) The doorway of the anteroom of the laboratory and others shall have a sign in accordance with Form 32 of the Appendix.

(14) The person who does not obtain the permissions from the person having permission and from the pathogens handling supervisor in advance shall be prohibited to enter the management area and when a person other than the pathogens workers obtains these permissions and enters the said management area, the person shall be made to follow the instructions of the pathogens handling supervisor.

2. Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act, those concerning the use of the pathogens of the animal infectious diseases requiring management in the handling facility of the pathogens of the animal infectious diseases requiring management (excluding the handling facilities referred to in Article 56-9 paragraph 2-4) shall be the following:

(1) When entering the laboratory and others (excluding the laboratory without using animals), the special clothes (clothes which a person entering the laboratory and others wears over his/her clothes (as for the laboratory and others where the pathogens of the animal infectious diseases requiring management are used on animals, all clothes which the person entering the said laboratory and others are wearing), hereinafter referred to as the same in this paragraph) and the protective equipment shall be put on in the anteroom.

(2) The work shall be carried out wearing clothes and the protective equipment in the laboratory and others.

(3) When the pathogens of the animal infectious diseases requiring management are used, except for the following cases, the use shall be conducted in the biological safety cabinet placed inside of the laboratory and others (excluding the manufacturing facility):

a. The cases in which the said use is not associated with the occurrence of aerosols.

b. The cases in which when the pathogens of animal infectious diseases requiring management are used on animals, the animals are too big to be kept in the biological safety cabinet.

(4) Eating and drinking, smoking, and makeup are prohibited in the working area in the laboratory and others.

(5) When going out of the laboratory and others, the following measures shall be taken:

a. For the laboratory and others (excluding the laboratory without using animals), the clothes and the protective equipment shall be removed. Except when they are taken out into the said laboratory and others, the said clothes and the protective equipment shall not be taken out of the said anteroom before the sterilization and transfer by equipment for sterilization and others.

b. For the laboratory without using animals, the clothes and the protective equipment shall be removed and not be taken out of the said laboratory without using animals before the sterilization and transfer by equipment for sterilization and others.

(6) When going out of the laboratory and others, hands shall be washed by equipment for hand washing, provided, however, that this shall not apply when measures equivalent to or more effective than the said equipment are taken.

(7) The exhaust air from the laboratory and others (excluding the laboratory without using animals) shall be sterilized and others through the air exhaust equipment.

(8) The wastewater contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases requiring management from the laboratory and others and their anterooms (for the laboratory without using animals, the said laboratory without using animal) shall be sterilized and others through equipment for the sterilization and others.

(9) When articles contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases requiring management are taken out of the laboratory and others, the following measures shall be taken:

a. For the laboratory and others (excluding the laboratory without using animals), except when clothes and the protective equipment are taken out to the anteroom of the said laboratory and others, these articles shall be sterilized through equipment for the sterilization and others.

b. As for the laboratory without using animals, the said articles shall be sterilized through equipment for the sterilization and others.

(10) Animals not related to the work in the laboratory and others shall not be brought to the said laboratory and others.

(11) When the pathogens of animal infectious diseases requiring management are used on animals in the laboratory and others, the following shall be followed:

a. When entering the laboratory and others, the permission of the pathogens handling supervisor shall be obtained.

b. Unless absolutely necessary, the animals on which the pathogens of animal infectious diseases requiring management were used shall not be taken out of the said laboratory and others.

c. When carcasses of the animals for which the pathogens of animal infectious diseases requiring management were used are taken out of the said laboratory and others, the said carcasses shall be sterilized by equipment for sterilization and other, and the said carcass which was taken out shall be incinerated in the incinerator placed in the handling facility or by taking the measures being equivalent to

or more effective than this incineration, provided, however, that this shall not apply when the said carcasses with the pathogens of animal infectious diseases requiring management removed are used for academic research.

d. When going out of the laboratory and others, contamination with the pathogens of animal infectious diseases requiring management on the body surface shall be removed in the shower room and placed in the anteroom, provided, however, that this shall not apply when all of Article 56-9 paragraph 1 (4) c, 1) to 3) applies.

e. As for the clothes and the protective equipment and the housing facility, contamination caused with the pathogens of animal infectious diseases with intensive management shall be removed before cleaning.

e. The measures required to prevent arthropods and rodents from entering shall be taken.

(12) The doorway of the anteroom of the laboratory and others (as for the laboratory without using animals, the said laboratory without using animals) shall have a sign in accordance with Form 32 of the Appendix.

(13) The measures to prevent people from entering the management area unless absolutely necessary shall be taken, and a person other than the pathogens workers shall be made to follow the instructions of the pathogens workers, when entering.

3. Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act, those concerning the use of the pathogens of animal infectious diseases requiring management in the handling facilities referred to in Article 56-9 paragraph 2-4 shall be the following:

(1) The work shall be carried out wearing the clothes (clothes which a person entering the laboratory and others wears over his/her clothes; hereinafter referred to as the same in this paragraph) and the protective equipment in the laboratory and others.

(2) When the pathogens of the animal infectious diseases requiring management are used, except for the following cases, the use shall be conducted in the biological safety cabinet placed inside of the laboratory and others (excluding manufacturing facilities):

a. The cases in which the said use is not associated with the occurrence of aerosols.

b. The cases in which when the pathogens of animal infectious diseases requiring management are used on animals, the animals are too big to be kept in the biological safety cabinet.

(3) Eating and drinking, smoking, and makeup are prohibited in the working area in the laboratory and others.

(4) When going out of the laboratory and others, the clothes and the protective equipment shall be removed and the said clothes and the protective equipment shall not be taken out of the said laboratory and others before the sterilization and transfer by equipment for the sterilization and others.

(5) When going out of the laboratory and others, hands shall be washed by equipment for hand washing, provided, however, that this shall not apply when the measures being equivalent or more effective than the said equipment are taken.

(6) When in the handling facility referred to in Article 56-9 paragraph 3 the air exhaust equipment

referred to in paragraph 1 (3) d of the same Article is placed in the laboratory and others, the exhaust from the said laboratory and others shall be sterilized through the said air exhaust equipment.

(7) The wastewater contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases requiring management from the laboratory and others, except when it is sterilized and others in the said laboratory and others, shall be taken out of the said laboratory and others by putting it into a closable container and sterilized and others through equipment of the sterilization and others placed in the handling facility.

(8) The articles contaminated or suspected to have been contaminated with the pathogens of animal infectious diseases requiring management, except when it is sterilized and others in the said laboratory and others, shall be taken out of the laboratory by putting it into a closable container and be sterilized and others through equipment of the sterilization and others placed in the handling facility.

(9) Animals not related to the work in the laboratory and others shall not be brought to the said laboratory and others.

(10) When the pathogens of animal infectious diseases requiring management are used on animals in the laboratory and others, the following shall be followed:

a. When entering the laboratory and others, the permission of the pathogens handling supervisor shall be obtained.

b. The windows of the said laboratory and others shall be closed and prevented from being broken.

c. Unless absolutely necessary, the animals on which the pathogens of animal infectious diseases requiring management were used shall not be taken out of the said laboratory and others.

d. When carcasses of the animals on which the pathogens of animal infectious diseases requiring management were used are taken out of the said laboratory and others, except when they are sterilized and others in the said laboratory and others, the said carcasses shall be put into a closable container and sterilized by equipment for the sterilization and others and incinerated or subject to the measures equivalent to or more effective than incineration, provided, however, that this shall not apply when the said carcasses with the pathogens of animal infectious diseases requiring management removed are used for academic research.

e. As for the clothes and the protective equipment and the housing facility, contamination caused with the pathogens of animal infectious diseases with intensive management shall be removed before cleaning.

e. The measures required to prevent arthropods and rodents from entering shall be taken.

(11) The doorway of the laboratory and others shall have a sign in accordance with Form 32 of the Appendix.

(12) The measures to prevent people from entering the management area shall be taken unless absolutely necessary, and a person other than the pathogens workers, when entering, shall follow the instructions of the pathogens workers.

(Standards of the transport and the sterilization and others of the pathogens of monitored infectious diseases)

Article 56-25

Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act (including the cases where this applies mutatis mutandis by the reading of terms under the provision of Article 46-20 paragraph 2 of the Act), those concerning the transport of the pathogens of the monitored infectious diseases shall be the following:

(1) To transport the pathogens of monitored infectious diseases, they shall be put in a container (which means the aggregate of the inner and the outer containers and the package; hereinafter referred to as the same in this paragraph).

(2) The container referred to in the preceding item shall apply to the following standards:

- a. It is easy and safe to handle the container.
- b. The measures such as attachment of tear-proof seals to prevent from being opened unless absolutely necessary shall be taken.
- c. It is of adequate strength and water-proof to prevent the contents from leaking.
- d. There is no possibility of the occurrence of cracks, damage, and others caused by changes in temperature and internal pressure, vibration, and others expected during transport.
- e. The primary container shall be closed by the appropriate method.
- f. The secondary container shall be closed by the appropriate method and tolerant to internal gauge pressure of not less than 95 kPa and temperature changes from -40 to 55 degrees C.
- g. The outer container shall be a cuboid, and each side of at least one face of the cuboid shall be 10 cm and more.
- h. When the container, of which the inner container holds water or a mixture of water and antifreeze instead of a pathogens of a monitored infectious disease in the proportion of 98 percent or more of the volume of the said inner container, is kept under the conditions in the right column in the following table according to each the material of inner container in the left column and the material of the outer container in the middle column, and then is immediately dropped from a height of 9 meters on a hard, smooth horizontal plane in order to cause maximum damage, there shall be no leakage of the contents or no damage likely to impair the safety of transport in the said container.

Material of inner container	Material of outer container	Condition
Plastic	Plastic	Condition 1
Plastic	Fiber board (cardboard)	Conditions 1 and 2
Plastic	Others	Condition 1
Others	Plastic	Condition 1
Others	Fiber board (cardboard)	Condition 2

Remarks:

(1) "Condition 1" in this table means that the container is kept at a temperature of -18 degrees C or below for 24 hours (in the case of addition of dry ice, for 4 hours or until that the said dry ice is

completely vaporized, whichever is longer).

(2) "Condition 2" in this table means the container is immersed in precipitation of at least approximately 50 mm per hour for an hour and more.

i. When the container, of which the inner container holds water or a mixture of water and antifreeze instead of a pathogens of a monitored infectious disease in the proportion of 98 percent or more of the volume of the said inner container, is kept under the following conditions, there shall be no leakage of the contents or no damage likely to impair the safety of transport in the said container.

1) As for the said container with the total mass of 7 kg or under, a steel round bar with the mass of 7 kg, diameter of 3.8 cm or less, and tip radius of 0.6 cm or less is dropped from a height of 1 m on the said container in order to cause maximum damage.

2) As for the said container with the total mass of over 7 kg, the said container is dropped on a steel round bar, with diameter of 3.8 cm or less, length of 20 cm and top radius of 0.6 cm or less, fixed vertically on a hard horizontal plane in order to cause maximum damage on the said container.

j. When the two or more primary containers are put in the secondary container, each primary container is individually or separately packaged in order for both the primary containers not to contact each other.

k. The pathogens of monitored infectious diseases and other articles (excluding the articles required for transport of the said the pathogens of monitored infectious diseases) shall not be put in the same outer container.

l. When absorber or packing is used in transport of liquid substances, the amount of the said absorber or packing shall be set to absorb the total amount of the said liquid substances.

m. In the cases of transport under a temperature equal to or higher than the ambient temperature, the primary container shall be glass, metal, or plastic.

n. When ice is put in the outer container during transport, a support shall be placed in order to maintain the secondary container in place even if the said ice melts and the measures to prevent leakage of water shall be taken in the said outer container.

o. When dry ice is put in the outer container during transport, a support shall be placed in order to maintain the secondary container in place even if the said dry ice vaporizes and the measures to emit the gas of vaporized dry ice shall be taken in the said outer container.

p. When liquid nitrogen is used, the primary container shall be made of plastic, and the primary and the secondary containers shall be resistant to the temperature of liquid nitrogen.

q. When freeze-dried substances are transported, the primary container may be a flame sealed glass ampule or a rubber-capped glass bottle with a metal seal.

r. The outer container shall include a list of the contents.

3. The surface of the container on which the following measures shall be taken:

a. Label in accordance with Form 42 shall be described by the method which makes it difficult to disappear.



- b. Mark in accordance with Form 43 shall be attached in a manner readily viewable.
- c. When the liquid pathogens of monitor infectious diseases are put in the container, its surface shall be marked with in b and a mark in accordance with Form 44 on the two opposing sides in a manner readily viewable.
- d. The following items shall be indicated in a manner readily viewable:
- 1) Name or title and address of the consignee and the consignor.
  - 2) Name or title and phone number of the responsible person.
  - 3) “Infectious Substances (infectious to animals)” and “UN2900” (in the case of transport of the pathogens infectious to humans, “Infectious Substances (infectious to humans)” and “UN2814).
  - (4) The stowage of containers containing the pathogens of monitor infectious diseases in vehicle and others shall be conducted not to compromise the safety by moving, falling, plunging and others during transport.
  - (5) The person who transports the pathogens of the animal infectious diseases with intensive management shall take the following measures:
    - a. Carry the document in which the consigner entered the items listed in item 3, d 1) to 3) and other items for reference.
    - b. Carry the document containing the handling method of the pathogens of animal infectious diseases with intensive management and consideration during transport of the said pathogens, including measures to be taken in an accident, and others.
    - c. Carry sodium hypochlorite solution with an effective chlorine concentration of not less than 0.1% or any other equivalent or more effective solution required in accidents.

2. The provisions of (2), b, g to i, k, n, r, (3), and (5) in the previous paragraph do not apply to the transport of the pathogens of animal infectious diseases within the business facility.

3. To transport of the pathogens of notifiable diseases and others within the business facility, the provision of paragraph 1 (2) (excluding a, c, and d), (3), and (5) do not apply. In the application of the provisions of (1) in the same paragraph, “a container (which means the aggregate of the inner and the outer containers and package; hereinafter referred to as the same in this paragraph)” shall be replaced with “a closable container”.

4. Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act (including the case where this applies mutatis mutandis by the reading of terms under the provision of Article 46-20 paragraph 2 of the Act), those concerning the sterilization and others of the pathogens of the notifiable diseases and others shall be the following:

(1) The sterilization and others shall be conducted by autoclaving under the condition at 121 degrees C or more for 15 minutes or more or any other equivalent or more effective conditions, or by any other equivalent or more effective methods.

(2) Wastewater shall be sterilized or others by autoclaving under the condition at 121 degrees C or more for 15 minutes or more or any other equivalent or more effective conditions or by any other equivalent or more effective methods.

(Emergency measures in the event of a disaster)

#### Article 56-26

The emergency measures to be taken under the provision of Article 46-18 paragraph 1 of the Act (including the case where this applies mutatis mutandis by the reading of terms under the provision of Article 46-20 paragraph 2 of the Act) shall be conducted in accordance with the following:

(1) The pathogens of monitored infectious diseases shall be transferred to a safe place where appropriate, and the surrounding area of the site with the pathogens of monitored infectious diseases shall be roped off, or marked and others, and the measures to prevent unauthorized people from entering the site by placing guards.

(2) The other measures necessary to prevent the outbreak and the spread of infectious diseases of livestock caused with the pathogens of monitored infectious diseases shall be taken.

2. The reporting prescribed in Article 46-18 paragraph 2 of the Act (including the case where this applies mutatis mutandis by the reading of terms under the provision of Article 46-20 paragraph 2 of the Act) shall be in accordance with Form 45 of the Appendix.

(Pathogens of notifiable infectious diseases and others)

#### Article 56-27

The pathogens prescribed in the Ministerial Ordinance referred to in the text of Article 46-19 paragraph 1 of the Act shall be the following:

(1) Morbillivirus, Rinderpest virus (limited to L, BA-YS, and RBOK strains) (Synonym: Rinderpest virus)

(2) Vesicular virus, vesicular stomatitis Alagoas virus (Synonym: Vesicular stomatitis virus)

(3) Vesicular virus, vesicular stomatitis Indiana virus (Synonym: Vesicular stomatitis virus)

(4) Vesicular virus, vesicular stomatitis New Jersey virus (Synonym: Vesicular stomatitis virus)

(5) Pasteurella multocida (limited to those of which capsular antigen type is B or E and somatic antigen type is Heddleston type 2 or 2.5) (Synonym: Pasteurella multocida)

(6) Brucella ovis (Synonym: Brucellosis bacteria)

(7) Mycobacterium bovis (Synonym: Tuberculosis bacteria)

(8) Mycobacterium caprae (Synonym: Tuberculosis bacteria)

(9) Lentivirus equine infectious anemia virus (Synonym: Equine infectious anemia virus)

(10) Enterovirus swine vesicular disease virus (Synonym: Swine vesicular disease virus)

(11) Influenzavirus A, influenzavirus A (limited to the pathogens listed in Article 56-3 (9) a to i) (Synonym: low pathogenic avian influenza virus)

(12) Avulavirus, Newcastle disease virus (limited to those applying to any of the following requirements)

(Synonym: Newcastle disease virus)

a. ICPI is 0.7 or more in one-day-old chicks.

b. All of the following shall be applied:

1) Of the 113rd to 116th amino acid residues of the F protein, three or more are estimated to be an arginine residue or a lysine residue.

2) The 117th amino acid residue of the F protein is estimated to be a phenylalanine residue.

(13) *Salmonella enterica* (limited to those whose serotype is *Salmonella gallinarum* and biotype is *Salmonella pullorum* or *Salmonella gallinarum*) (Synonym: Avian salmonella infectious bacteria)

(14) Macavirus, Alcelaphine herpes virus 1 (Synonym: Malignant catarrhal fever virus)

(15) Macavirus, Ovine herpes virus 2 (Synonym: Malignant catarrhal fever virus)

(16) Influenzavirus A, influenza virus A (limited to those whose serotype is H3N8 or H7N7 and which are separated from horse) (Synonym: Equine influenza virus)

(17) Vesivirus, Vesicular exanthema of swine virus (Synonym: Vesicular exanthema of swine virus)

(Report of the possession of the pathogens of notifiable infectious diseases and others)

#### Article 56-28

The report referred to in the text of Article 46-19 paragraph 1 of the Act shall be conducted by the reporting form in accordance with Form 46 of the Appendix along with the following documents for each business facility:

(1) For a corporation, a certificate of registered matters of the corporation.

(2) A sketch of the inside and outside of the business facility centering on the handling facility of the pathogens of notifiable infectious diseases and others, with scale and orientation.

(3) A ground plan describing a floor plan, equipment, use and doorway of the room for handling pathogens of notifiable infectious diseases and others, the management area, the places to be marked using Form 32 of the Appendix, scale and orientation of the handling facility of the pathogens of notifiable infectious diseases and others.

(4) An elevation with scale of the main part for handling the pathogens of notifiable infectious diseases and others of the handling facility of the pathogens of notifiable infectious diseases and others (excluding the cases in which the ground plan in the preceding item includes all of main parts).

(5) Other documents stating that the handling facility of the pathogens of notifiable infectious diseases and others concerning the said report applies to the technical standards referred to in Article 46-16 paragraph 1 of the Act applied mutatis mutandis by the reading of terms referred to in the provision of Article 46-20 paragraph 1 of the Act.

2. The items prescribed by the Ministerial Ordinance referred to in the text of Article 46-19 paragraph 1

of the Act shall be the following:

- (1) Name or title and address, and the name of the representative for a corporation.
- (2) Date of the start of possession.
- (3) Location, structure, and equipment of the handling facility of the pathogens of notifiable infectious diseases and others.

(Standards of possession of the pathogens of notifiable infectious diseases and others by a test institution of infectious diseases of livestock)

#### Article 56-29

The possession of the pathogens of notifiable infectious diseases and others prescribed in Article 46-19 paragraph 1 (1) of the Act shall be conducted in accordance with the following standards:

- (1) The pathogens of animal infectious diseases are put in a closed container and the container is placed in the storage facility.
- (2) During the said possession, unless absolutely necessary, the measures including reliable locking to prevent the pathogens of notifiable infectious diseases and others from being taken out from the storage cabinet shall be taken .
- (3) In the sterilization and others, the person shall perform the said activities or delegates them to others in compliance with the standards prescribed in Article 56-25 paragraph 4, within 10 days from the date of the start of possession. The transfer shall be conducted at the date of the start of possession without delay.

(Changes on report of possession and report of non-possession)

#### Article 56-30

The changes and report of non-possession prescribed in Article 46-19 paragraph 2 of the Act shall be conducted by the report form in accordance with Form 47 of the Appendix, and in the case of reporting the changes the documents listed in Article 56-28 paragraph 1 (2) to (5) shall be attached.

(Record)

#### Article 56-31

The items which shall be recorded in the books to be kept by a notifier prescribed Article 46-15 paragraph 1 applied mutatis mutandis by the reading of terms under the provision of Article 46-20 paragraph 1 of the Act shall be the following:

- (1) Kinds and quantities of the pathogens of notifiable infectious diseases and others for receipt or

delivery.

- (2) Date of receipt or delivery of the pathogens of notifiable infectious diseases and others.
- (3) Method or place for storage of the pathogens of notifiable infectious diseases and others.
- (4) Kind of the pathogens of notifiable infectious diseases and others to be used.
- (5) Date of use of the pathogens of notifiable infectious diseases and others.
- (6) Kind of the pathogens of notifiable infectious diseases and others for the sterilization and transfer.
- (7) Date of the sterilization and transfer of the pathogens of notifiable infectious diseases and others.
- (8) Method or place for the sterilization and others of the pathogens of notifiable infectious diseases and others.
- (9) Name of the person who received or delivered the pathogens of notifiable infectious diseases and others.
- (10) Name of the person who used the pathogens of notifiable infectious diseases and others.
- (11) Name of the person who conducted the sterilization and others of the pathogens of notifiable infectious diseases and others.
- (12) Implementation date of inspection of the handling facility of the pathogens of notifiable infectious diseases and others, the results of the inspection, contents of the measures thereof and name of the person who conducted the inspection.

2. To the books in the preceding paragraph, the provision of Article 56-22 paragraph 2 to 4 shall apply *mutatis mutandis*.

(Standards of the handling facility of the pathogens of notifiable infectious diseases and others)

#### Article 56-32

Out of the technical standards prescribed in the Ministerial Ordinance concerning the handling facility of the pathogens of notifiable infectious diseases and others referred to in Article 46-16 paragraph 1 of the Act applied *mutatis mutandis* by the reading of terms under the provision of Article 46-20 paragraph 1 of the Act shall be the following:

- (1) The management area shall be set up in the said handling facility of the pathogens of notifiable infectious diseases and others.
- (2) A storage cabinet of the pathogens of notifiable infectious diseases and others shall be located within the laboratory and others (when the storage facility in which measures to restrict access such as a lock are taken, within the said storage facility), and equipment or a device to close the storage cabinet such as a lock shall be attached.
- (3) The laboratory and others of the pathogens of notifiable infectious diseases and others shall be the following:
  - a. The surface structures of parts which are likely to be contaminated with the pathogens of notifiable

infectious diseases, including walls, floors and ceilings, shall be easy to disinfect.

b. The biological safety cabinet shall be placed within the laboratory and others (in the manufacturing facility, the measures for prevent the pathogens of notifiable infectious diseases and others from spreading from the said facility shall be taken). However, the following cases are excluded:

1) The cases in which the use of the pathogens of notifiable infectious diseases and others is not associated with the occurrence of aerosols.

2) The cases in which when the pathogens of notifiable infectious diseases and others are used on animals, the animals are too big to be kept in the biological safety cabinet.

c. The laboratory and others shall have foot- or elbow-operated or automatic equipment for hand washing, provided, however, that this shall not apply when the measures equivalent to or more effective than the said equipment are taken.

d. The laboratory and others shall have equipment or a device to close it such as a lock.

(4) When the pathogens of notifiable infectious diseases and others are used on animals in the laboratory and others, the following shall be followed:

a. The housing facility shall be placed within the said laboratory and others.

b. In the laboratories and others of the pathogens listed in Article 56-27 (1) to (4), (6) to (8), (10) to (12), and (16) and (17), air exhaust equipment shall be placed or the housing facility shall be placed in the isolator, in accordance with the following:

1) The air exhaust equipment shall have the structure in which air is constantly controlled to flow from the doorway to the inside.

2) The air exhaust equipment shall have the structure in which the air is exhausted from the laboratory and others through one or more HEPA filters.

3) The air exhaust equipment shall have a device checking the status of its operation.

(5) Equipment of the sterilization and others of the pathogens of notifiable infectious diseases and others shall be placed inside of the said handling facility of the pathogens of notifiable infectious diseases and others.

(6) The said handling facility of pathogens of notifiable infectious diseases and others shall be regularly inspected one or more times a year to maintain the functions to meet the standards referred to in each of the preceding items.

2. The provisions of the preceding paragraph shall not be applied to the facility handling the pathogens listed in Article 56-3 (9) a to i which handles only the said pathogens and does not use the said pathogens for animals.

(Standards of the storage and the use of the pathogens of notifiable infectious diseases)

Article 56-33

Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17

paragraph 1 of the Act applied mutatis mutandis by the reading of terms under Article 46-20 paragraph 2 of the Act, those concerning storage of the pathogens of notifiable infectious diseases shall be the following:

- (1) The pathogens of notifiable infectious diseases shall be put in a tightly closed container and the container shall be placed in the storage cabinet.
- (2) Unless absolutely necessary, the measure preventing the pathogens of notifiable infectious diseases from being taken out, including that the storage cabinet is certainly locked during the storage of the pathogens of notifiable infectious diseases shall be taken.
- (3) The doorway of the storage facility of the pathogens of notifiable infectious diseases (when the pathogens of notifiable infectious diseases are stored in the laboratory and others, the said laboratory and others) shall have a sign in accordance with Form 32 of the Appendix.

2. Out of the technical standards prescribed in the Ministerial Ordinance referred to in Article 46-17 paragraph 1 of the Act applied with modifications by the reading of terms under Article 46-20 paragraph 2 of the Act, those concerning use of the pathogens of notifiable infectious diseases shall be the following:

- (1) The special clothes (clothes which a person entering the laboratory and others wears over his/her clothes; hereinafter referred to as the same in this paragraph) and the protective equipment shall be put on to work in the laboratory and others.
- (2) When the pathogens of notifiable infectious diseases are used, except for the following cases, the use shall be conducted in the biological safety cabinet placed inside of the laboratory and others (excluding the manufacturing facility):
  - a. The cases in which the said use is not associated with the occurrence of aerosols.
  - b. The cases in which when the pathogens of notifiable infectious diseases are used on animals, the animals are too big to be kept in the biological safety cabinet.
- (3) The doors of the laboratory and others shall be closed when the pathogens of notifiable infectious diseases are used.
- (4) Eating and drinking, smoking, and makeup are prohibited in the working area in the laboratory and others.
- (5) When going out of the laboratory and others, the clothes and the protective equipment shall be removed.
- (6) When going out of the laboratory and others, hands shall be washed by equipment for hand washing, provided, however, that this shall not apply when the measures equivalent to or more effective than the said equipment are taken.
- (7) The wastewater contaminated or suspected to have been contaminated with the pathogens of notifiable infectious diseases from the laboratory and others, except when it is sterilized and others in the said laboratory and others, shall be taken out of the said laboratory and others by putting it into a closable

container and sterilized and others through equipment of the sterilization and others placed in the handling facility of the pathogens of notifiable infectious diseases.

(8) The articles contaminated or suspected to have been contaminated with the pathogens of notifiable infectious diseases, except when it is sterilized and others in the said laboratory and others, shall be taken out of the laboratory by putting it into a closable container and sterilized and others through equipment of the sterilization and others placed in the handling facility of the pathogens of notifiable infectious diseases.

(9) Animals not related to the work in the laboratory and others shall not be brought to the said laboratory and others.

(10) When the pathogens of notifiable infectious diseases are used on animals in the laboratory and others, the following shall be followed:

a. When entering the laboratory and others, the permission of the pathogens handling supervisor shall be obtained.

b. The windows of the said laboratory and others shall be closed and prevented from being broken.

c. In the case when the laboratory and other referred to in paragraph 1 (4) b in the preceding Article has the air exhaust equipment in the same item b, the exhaust from the said laboratory and other shall be sterilized and others by the said air exhaust equipment.

d. Unless absolutely necessary, the animals on which the pathogens of notifiable infectious diseases were used shall not be taken out of the said laboratory and others.

e. When carcasses of the animals on which the pathogens of notifiable infectious diseases were used are taken out of the said laboratory and others, except when they are sterilized and others in the said laboratory and others, the said carcasses shall be put into a closable container and sterilized and others by the equipment placed in the handling facility of the pathogens of notifiable infectious diseases and incinerated or subject to the measures equivalent to or more effective than incineration, provided, however, that this shall not apply when the said carcasses with the pathogens of notifiable infectious diseases removed are used for academic research.

f. For the clothes, the protective equipment, and the housing facility, contamination caused with the pathogens of notifiable infectious diseases shall be removed before cleaning.

g. The measures required to prevent arthropods and rodents from entering shall be taken.

(11) The doorway of the laboratory and others shall have a sign in accordance with Form 32 of the Appendix.

(12) The measures to prevent people from entering the laboratory and others unless absolutely necessary shall be taken, and a person other than the pathogens workers shall be made to follow the instructions of the pathogens workers, when entering.

3. The previous two paragraphs shall not apply to the facilities referred to in paragraph 2 in the preceding Article.

(Pathogens excluded from application)



#### Article 56-34

The pathogens prescribed by the Ministerial Ordinance referred to in Article 46-22 (1) of the Act shall be the following:

- (1) Morbillivirus, Rinderpest virus (limited to LA and Ako strains)
- (2) *Mycoplasma mycoides* (limited to V strain of SC strain of *Mycoplasma mycoides* subsp. *mycoides*)
- (3) Pestivirus, classical swine fever virus (limited to GPE- strain)
- (4) *Mycobacterium bovis* (limited to bacille Calmette-Guerin strain)
- (5) The pathogens contained in biological preparations (limited to the biological preparations referred to in Article 213 (4) of the Regulations for veterinary drug (Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 107, 2004)
- (6) The pathogens which were considered to be inappropriate for the application of the provisions of Article 46-5 to Article 46-21 of the Act and notified to the public by the Minister of Agriculture, Forestry and Fisheries, including the pathogens used for the manufacturing in meeting urgent needs of manufacturing of biological preparation.

(Pathogens not excluded from application)

#### Article 56-35

The pathogens prescribed by the Ministerial Ordinance referred to in Article 46-22 (2) of the Act shall be following:

- (1) The pathogens listed in Article 56-3 (8) whose serosubtype is H2N2, H5N1 or H7N7 (excluding the pathogens of infections including novel influenza specified in Article 6 paragraph 7 of the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases (No. 114, 1998) (hereinafter referred to as “infections including novel influenza”))
- (2) The pathogens listed in Article 56-3 (9) whose serosubtype is H5N1 or H7N7 (excluding the pathogens of infections including novel influenza)
- (3) The pathogens listed in Article 56-3 (9) c to i.
- (4) The pathogens listed in Article 56-27 (16) whose serosubtype is H7N7 (excluding the pathogens of infections including novel influenza)

### **Chapter VI Miscellaneous Provisions**

(Designation of biological preparations for animal use)

#### Article 57

The biological preparations for animal use referred to in Article 50 of the Act that are designated by the Minister of Agriculture, Forestry and Fisheries shall be the following:

(1) The biological preparations for animal use which are not included in the Japanese Pharmacopoeia and which are not approved by Article 14 paragraph 1 or Article 19-2 paragraph 1 of the Pharmaceutical Affairs Act applied by the reading of terms under the provision of Article 83 paragraph 1 of the same Act (limited to those to be used on cattle, water buffalo, deer, horse, sheep, goat, pig, wild boar, chicken, duck, quail, pheasant, ostrich, guinea fowl, turkey, dog, rabbit and honey bee).

(2) Vaccines against rinderpest, contagious bovine pleuropneumonia, foot and mouth disease, classical swine fever, and highly pathogenic avian influenza, tuberculin, mallein, and johnin

(Certificate)

Article 57-2

The form of the certificate referred to in Article 51 paragraph 3 of the Act shall be Form 48 of the Appendix.

(Report)

Article 58

The requirement of the reports on Article 52 paragraph 1 and 2 shall be conducted by issuing a written request including the following items. However, when the governor of the prefecture requires the report referred to in paragraph 1 of the same article of 50 people or more, the written request may be replaced with that of the following items and the scope of the people required to make a report are notified and posted in a place easily visible by the public.

(1) Purpose of implementation.

(2) Items to be reported.

(3) Due date of the report.

(4) Other items required

(Identity cards)

Article 59

The form of the identity cards referred to in Article 54 of the Act shall be Form 49 of the Appendix

(Person for non- delivery or return of allowances and special allowances)

## Article 60

The person prescribed by the Ministerial Ordinance in the provisos of Article 58 paragraph 1 and paragraph 2 of the Act (hereinafter referred to as “the person for abatement”) shall be the owners having the animals or the articles listed in each item of paragraph 1 of the same Article or the livestock or the articles listed in each item of paragraph 2 of the same Article (hereinafter referred to as “animals and others”) (hereinafter referred to as “person for the abatement”) and apply to any of the following:

(1) In comprehensive consideration of the following status and others of the owner of the said animal and others, the person who is deemed to fail to take measures to prevent the outbreak or the spread of the disease causing the delivery of the said allowance or special allowance (hereinafter referred to as “causative disease”).

a. Status of hygiene management on rearing the livestock.

b. Status of implementation of early notification on the causative disease to the prefectures.

c. Status of the cooperation to the measures taken to prevent spreading the causative disease by of the governor of the prefecture, animal health inspectors, or the mayor of the city, town or village.

(2) The owner of the said animals and others in the case when there is another person who manages the said animals and others other than the owner of the said animals and others (excluding forwarding agents who are entrusted with the transportation of said livestock, articles or facilities by railways, tramways, automobiles, ships or aircraft; hereinafter “manager”) and the said manager applies to the person listed in the preceding item.

(Method of non-delivery or return of allowances and special allowances)

## Article 61

When the owner of the animals and others is discovered to be the person subject to the abatement before the delivery of the allowance or special allowance, the national government shall not deliver all or a part of the allowance or special allowance to be delivered, and when the said person is discovered to be the person for the abatement after the delivery of the allowance or special allowance, the nation shall make the said person return all or a part of the delivered allowance or special allowance.

2. In the preceding paragraph, the amount of the allowance or special allowance which is not delivered or is returned shall be the amount of the allowance or special allowance to be delivered multiplied by the abatement rate.

3. The abatement rate in the preceding paragraph shall be determined by the Minister of Agriculture, Forestry and Fisheries in comprehensive consideration of the status and others listed in (1) a to c of the preceding Article of the person for the abatement (when the person has the manager, the said manager).

4. To determine the abatement rate in paragraph 2, the Minister of Agriculture, Forestry and Fisheries shall listen to the opinions of one or more person having an academic background in prevention of infectious diseases of livestock, person having an academic background in livestock industry, and person having an academic background in law respectively.

(Appraiser)

#### Article 62

The appraiser referred to in Article 58 paragraph 5 of the Act and Article 10 paragraph 3 of the Government Ordinance shall be selected from one or more from each of animal health inspectors, local government officials doing the clerical work on livestock industry other than an animal health inspector, and persons having experience in livestock industry other than a local government official.

(Calculation method of the amount for delivery)

#### Article 63

The amount calculated in accordance with the Ministerial Ordinance referred to in Article 9 of the Government Ordinance, according to the category in each of the following items, shall be the amount specified for each of the said items:

(1) Livestock: The total amount of the following amounts (as for the amount other than the decreased amount of sales, limited to those is judged to be usually needed):

a. Decreased amount of sales and increased amounts of feed cost and transportation cost (limited to those caused by the said special movement control and others) concerning the livestock reared within the target area of the said special movement control and others which are restricted to be shipped because of the said special movement control out of the livestock reared in the period of the prohibition, suspension or restriction (hereinafter referred to as “special movement control and others”) prescribed by Article 32 to 34 of the Act (excluding those reared by the person who did not comply with the said special movement control and others; hereinafter referred to as “target livestock”).

b. Decreased amount of sales and increased amounts of feed cost and transportation cost (limited to those caused by the said special movement control and others) concerning the target livestock reared outside the target area of the said special movement control and others which were unable to be shipped to the scheduled destination (which means the destination to which the said target livestock were scheduled to be shipped before the period of the said special movement control; hereinafter referred to as the same in this item) because of the said special movement control and others and then shipped to another destination instead of the said scheduled destination.

c. Decreased amount of sales and increased amounts of feed cost (limited to those caused by the said

special movement control and others) concerning the target livestock reared outside the target area of the said special movement control and others which were not able to be shipped to the scheduled destination because of the said special movement control and others, also those unable to be shipped to another destination instead of the said scheduled destination by unavoidable circumstances, and then were shipped to the said scheduled destination after the period of the said special movement control and others or were unavoidably disposed.

(2) Carcasses of livestock: The total amount of the following amounts (limited to those is judged to be usually needed):

a. Actual cost of transportation cost to the facilities for incineration and others (which means an incineration facility, a burial facility, or a rendering plant; hereinafter referred to as the same) and incineration cost, burial cost, or rendering cost concerning the carcasses of the target livestock which were difficult to distribute or continuously rear to be unavoidably disposed because of the said special movement control and others.

b. Increased amount of transportation cost and rendering cost (limited to those caused by the said special movement control and others) concerning the carcasses of the target livestock (excluding those apply to the carcasses referred in a) which were unable to be rendered in the regular rendering plant because of the special movement control and others and then were rendered in another rendering plant instead of the said rendering plant.

(3) Articles (which mean raw milk, semen for artificial insemination of livestock prescribed in the provision of Article 4 paragraph 1 of the Act on Improvement and Increased Production of Livestock (Act No. 209, 1950), fertilized eggs and eggs of livestock prescribed the provision of Article 11-2 paragraph 5 of the same Act; hereinafter referred to as the same in this item): The total amount of the following amounts (as for the amount other than the decreased amount of sales, limited to those is judged to be usually needed):

a. Decreased amount of sales, increased amount of transportation cost (limited to those caused by the said special movement control and others), and actual cost of storage expenses and cargo handling expense concerning the articles, which are out of the articles produced from the target livestock/domestic animal (hereinafter referred to as “target articles”) which were produced within the target area of the special movement control and others and which was restricted to be shipped because of the said special movement control and others.

b. Decreased amount of sales and increased amount of transportation cost (limited to those caused by the said special movement control and others) and actual cost of storage expenses and cargo handling expense concerning the target articles produced in outside the target area of the said special movement control and others which were unable to be shipped to the scheduled destination (which means the destination to which the said target articles were scheduled to be shipped before the period of the said special movement control; hereinafter referred to as the same in this item) because of the said special movement control and others and then shipped to another destination instead of the said scheduled destination.

c. Decreased amount of sales and increased amount of transportation cost (limited to those caused by the

said special movement control and others) and actual cost of storage expenses and cargo handling expense concerning the target articles produced outside the target area of the said special movement control and others which were unable to be shipped to the scheduled destination because of the said special movement control and others, also those unable to be shipped to another destination instead of the said scheduled destination by unavoidable circumstances, and then were shipped to the said scheduled destination after the period of the said special movement control and others or were unavoidably disposed.

d. Actual cost of transportation cost to the facilities for incineration and others, and incineration cost, burial cost, or rendering cost concerning the target articles which were difficult to distribute to be unavoidably disposed.

(Losses Subject to Compensation)

#### Article 64

The amounts of the costs prescribed by the Ministerial Ordinance referred to in Article 10 paragraph 4 of the Government Ordinance shall be the costs required to rear the said designated livestock, including the feed cost required from the date of the order specified in Article 17-2 paragraph 5 to the date when the said designated livestock were killed.

(Application to Managers)

#### Article 65

The provisions concerning the owners of livestock, articles or facilities in this Ministerial Ordinance shall apply to the person other than the owners who manage the said livestock, articles or facilities (excluding forwarding agents who are entrusted with the transportation of said livestock, articles or facilities by railways, tramways, automobiles, ships or aircraft).