

ANNEX I

REQUIREMENTS FOR GRANTING APPROVAL OF ESTABLISHMENTS AS REFERRED TO IN CHAPTERS 2, 3 AND 4 OF TITLE I OF PART II

PART 1

Requirements for granting approval of establishments for assembly operations of ungulates referred to in Article 5

1. The requirements in relation to isolation and biosecurity measures of establishments for assembly operations of ungulates, as referred to in Article 5, shall be the following:
 - (a) appropriate isolation facilities for the ungulates must be available;
 - (b) at any given time, the establishment must only accommodate the same category of ungulates of the same species and health status;
 - (c) an appropriate system must be in place to ensure the collection of waste water;
 - (d) the areas where the ungulates are kept and any passageways, and material and equipment that comes into contact with them must be cleaned and disinfected after the removal of each batch of ungulates, and where necessary before the introduction of any new batch of ungulates, in accordance with established operational procedures;
 - (e) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new batch of ungulates in the facilities where ungulates are kept.
2. The requirements in relation to facilities and equipment of establishments for assembly operations of ungulates, as referred to in Article 5, shall be the following:
 - (a) suitable equipment and facilities must be available for the purpose of loading and unloading ungulates;
 - (b) adequate housing of a suitable standard for the ungulates must be available and constructed in such a way that contact with livestock outside and direct communication with isolation accommodation are prevented, and that inspection and any necessary treatment can be easily carried out;
 - (c) an appropriate storage area must be available for bedding material, fodder, litter and manure;
 - (d) the areas where those animals are kept and the passageways, floors, walls, ramps and all other material or equipment that comes into contact with them can be readily cleaned and disinfected;
 - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport used for the ungulates.
3. The requirements in relation to the personnel of establishments for assembly operations of ungulates, as referred to in Article 5, shall be the following:
 - (a) they must possess the appropriate ability and knowledge, and have received specific training, or have acquired the equivalent practical experience in:

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- (i) the handling of, and if necessary the administration of appropriate care to, the ungulates kept on the establishment;
 - (ii) the disinfection and hygiene techniques needed to prevent the spread of transmissible diseases.
- 4. The requirements in relation to the supervision by the competent authority of establishments for assembly operations of ungulates, as referred to in Article 5, shall be the following:
 - (a) the operator must provide the official veterinarian with the possibility to use an office for
 - (i) supervising the assembly operations of ungulates;
 - (ii) inspecting the establishment for compliance with the requirements laid down in points 1, 2 and 3;
 - (iii) providing animal health certification of ungulates;
 - (b) the operator must ensure that assistance is provided on request from the official veterinarian to carry out the supervision duties referred to in 4(a)(i).

PART 2

Requirements for granting approval of establishments for assembly operations of poultry referred to in Article 6

- 1. The requirements in relation to the isolation and other biosecurity measures of establishments for assembly operations of poultry, as referred to in Article 6, shall be the following:
 - (a) appropriate isolation facilities for the poultry must be available;
 - (b) at any given time the establishment must only accommodate the same category of poultry of the same species and health status;
 - (c) an appropriate system must be in place to ensure the collection of waste water;
 - (d) the areas where the poultry are kept and any passageways, and the material and equipment that comes into contact with them must be cleaned and disinfected after the removal of each batch of poultry, and where necessary before the introduction of any new batch of poultry, in accordance with established operational procedures;
 - (e) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new batch of poultry in the facilities where poultry are kept;
 - (f) visitors must wear protective clothing and the personnel must wear appropriate working clothing and act in accordance with the hygiene rules drawn up by the operator.
- 2. The requirements in relation to facilities and equipment of establishments for assembly operations of poultry, as referred to in Article 6, shall be the following:
 - (a) the establishment must only house poultry;

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- (b) an appropriate storage area must be available for bedding material, feed, litter and manure;
 - (c) the poultry must not come into contact with rodents and with birds coming from outside the establishment;
 - (d) the areas where those animals are kept and the passageways, floors, walls, ramps and all other material or equipment that comes into contact with them must be readily cleaned and disinfected;
 - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport used for the poultry;
 - (f) the establishment must have good conditions of hygiene and allow health monitoring to be carried out.
3. The requirements in relation to the personnel of establishments for assembly operations of poultry, as referred to in Article 6, shall be the following:
- (a) they possess the appropriate ability and knowledge, and have received specific training, or have acquired the equivalent practical experience in:
 - (i) the handling of, and if necessary the administration of appropriate care to, the poultry kept on the establishment;
 - (ii) the disinfection and hygiene techniques needed to prevent the spread of transmissible diseases.
4. The requirements in relation to supervision by the competent authority of establishments for assembly operations of poultry, as referred to in Article 6, shall be the following:
- (a) the operator must provide the official veterinarian with the possibility to use an office for:
 - (i) supervising the assembly operations of poultry;
 - (ii) inspecting the establishment for compliance with the requirements laid down in points 1, 2 and 3;
 - (iii) providing animal health certification of poultry;
 - (b) the operator must ensure that assistance is provided on request from the official veterinarian to carry out the supervision duties referred to in 4(a)(i).

PART 3

Requirements for granting approval of hatcheries referred to in Article 7

1. The requirements in relation to biosecurity measures of hatcheries, as referred to in Article 7, shall be the following:
- (a) hatching eggs of poultry must come either from approved establishments keeping breeding poultry or from other approved hatcheries of poultry;

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- (b) eggs must be cleaned and disinfected, between the time of their arrival at the hatchery and the incubation process or at the time of their dispatch unless they have been previously disinfected on the establishment of origin;
 - (c) the following must be cleaned and disinfected:
 - (i) the incubators and equipment after hatching;
 - (ii) the packaging materials after each use, unless they are disposable to be destroyed after first use;
 - (d) an appropriate system must be in place to ensure the collection of waste water;
 - (e) protective clothing is provided for visitors working;
 - (f) appropriate working clothing and the code of conduct with hygiene rules must be provided to personnel.
2. The requirements in relation to the surveillance of hatcheries, as referred to in Article 7, shall be the following:
- (a) the operator must implement a microbiological quality control programme in accordance with Part 1 of Annex II;
 - (b) the operator of the hatchery must ensure that arrangements are in place with the operator of the establishment keeping the poultry, where the hatching eggs are originating for sampling to be carried in the hatchery for testing for the disease agents referred to in the disease surveillance programme referred to in Part 2 of Annex II, in order to complete that programme.
3. The requirements in relation to the facilities and equipment of hatcheries, as referred to in Article 7, shall be the following:
- (a) hatcheries must be physically and operationally separated from facilities keeping poultry or any other birds;
 - (b) the following functional units and equipment must be kept separate:
 - (i) egg storage and grading;
 - (ii) egg disinfection;
 - (iii) pre-incubation;
 - (iv) incubation for hatching;
 - (v) sexing and vaccination of day-old chicks;
 - (vi) packaging of hatching eggs and day-old chicks for dispatch;
 - (c) day-old chicks or hatching eggs kept at the hatchery must not come into contact with rodents and with birds outside the hatchery;
 - (d) operations must be based on a one-way circuit for hatching eggs, mobile equipment and personnel;
 - (e) appropriate natural or artificial lighting, air flow and temperature systems must be available;

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- (f) it must be possible to readily clean and disinfect the floors, walls and all other material or equipment at the hatchery;
 - (g) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport used for the day-old chicks and hatching eggs.
4. The requirements in relation to the personnel in contact with hatching eggs and day-old chicks, as referred to in Article 7, shall be the following:
- (a) the personnel must possess the appropriate ability and knowledge, and have for that purpose received specific training, or have acquired the equivalent practical experience in the disinfection and hygiene techniques needed to prevent the spread of transmissible diseases.
5. The requirements in relation to supervision by the competent authority of hatcheries, as referred to in Article 7, shall be the following:
- (a) the operator must provide the official veterinarian with the possibility to use an office for
 - (i) inspecting the hatchery for compliance with the requirements laid down in points 1 to 4;
 - (ii) providing animal health certification of hatching eggs and day-old chicks;
 - (b) the operator must ensure that assistance is provided on request from the official veterinarian to carry out the supervision duties referred to in 5(a)(i).

PART 4

Requirements for granting approval of establishments keeping poultry referred to in Article 8

1. The requirements in relation to biosecurity measures of establishments keeping poultry, as referred to in Article 8, shall be the following:
- (a) the hatching eggs must be:
 - (i) collected at frequent intervals, at least daily and as soon as possible after laying;
 - (ii) cleaned and disinfected as soon as possible, unless disinfection takes place at a hatchery in the same Member State;
 - (iii) placed either in new or in cleaned and disinfected packaging material;
 - (b) if an establishment houses poultry species of the orders *Galliformes* and *Anseriformes* at the same time, a clear separation must be made between them;
 - (c) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new flock of poultry in the facilities where poultry is kept;
 - (d) visitors must wear protective clothing and the personnel must wear appropriate working clothing and act in accordance with the hygiene rules drawn up by the operator;

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- (e) an appropriate system must be in place to ensure the collection of waste water.
2. The requirements in relation to surveillance of establishments keeping poultry, as referred to in Article 8, shall be the following:
- (a) the operator must apply and adhere to a disease surveillance programme referred to in Part 2 of Annex II;
 - (b) the operator of the establishment must ensure that arrangements are in place with the operator of the hatchery where the hatching eggs are destined for sampling to be carried in the hatchery for testing for the disease agents referred to in the disease surveillance programme referred to in Part 2 of Annex II, in order to complete of that programme.
3. The requirements in relation to the facilities and equipment of establishments keeping poultry, as referred to in Article 8, shall be the following:
- (a) the setting and layout must be compatible with the type of production pursued;
 - (b) the establishment must house only poultry:
 - (i) from the establishment itself;
 - or
 - (ii) from other approved establishments keeping poultry;
 - or
 - (iii) from approved hatcheries of poultry;
 - or
 - (iv) which entered into the Union from authorised third countries and territories;
 - (c) the poultry must be prevented from coming into contact with rodents and with birds coming from outside;
 - (d) the facilities must provide good conditions of hygiene and allow health monitoring to be carried out;
 - (e) it must be possible to readily clean and disinfect the floors, walls and all other material or equipment at the establishment;
 - (f) the establishment must have appropriate equipment, compatible with the type of production pursued, which is available for the cleaning and disinfection of facilities, equipment and means of transport at the most suitable spot in the establishment.

PART 5

Requirements for granting approval of assembly centres of dogs, cats and ferrets and of animal shelters for those animals referred to respectively in Articles 10 and 11

1. The requirements in relation to isolation and other biosecurity measures of assembly centres of dogs, cats and ferrets, as referred to in Article 10, shall be the following:
- (a) they must only admit dogs, cats and ferrets coming from registered establishments keeping those animals;

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- (b) appropriate isolation facilities for the dogs, cats and ferrets must be available;
 - (c) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new batch of dogs, cats and ferrets in the facilities keeping such animals;
 - (d) appropriate system must be in place to ensure the collection of waste water.
2. The requirements in relation to isolation and other biosecurity measures of animal shelters for dogs, cats and ferrets, as referred to in Article 11, shall be the following:
- (a) appropriate isolation facilities for the dogs, cats and ferrets must be available;
 - (b) the areas where the cats, dogs and ferrets are kept and any passageways, and material and equipment that comes into contact with them must be cleaned and disinfected after the removal of each batch of those animals, and where necessary before the introduction of any new batch of such animals, in accordance with established operational procedures;
 - (c) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new batch of dogs, cats and ferrets in the facilities where those animals are kept;
 - (d) appropriate system must be in place to ensure the collection of waste water.
3. The requirements in relation to facilities and equipment of assembly centres of dogs, cats and ferrets, and animal shelters for those animals, as referred to respectively in Articles 10 and 11, shall be the following:
- (a) adequate housing of a suitable standard for those animals must be available and must be constructed in such a way that contact with animals from the outside is prevented and there is no direct communication with the isolation accommodation, and inspections and any necessary treatments can be easily carried out;
 - (b) the areas where those animals are kept and any passageways, floors, walls and all other material or equipment that comes into contact with them can be readily cleaned and disinfected;
 - (c) appropriate storage areas must be available respectively for bedding material, litter, manure and petfood;
 - (d) appropriate equipment must be available for the cleaning and disinfection of facilities, implements and means of transport.

PART 6

Requirements for granting approval of control posts referred to in Article 12

1. The requirements in relation to isolation and other biosecurity measures of control posts, as referred to in Article 12, shall be the following:
- (a) control posts must be located, designed, constructed and operated in such a way as to ensure sufficient biosecurity to prevent the spread of listed or emerging diseases to other establishments and between consecutive consignments of animals passing through these premises;

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- (b) control post must be constructed, equipped and operated in such a way as to ensure that cleaning and disinfection procedures can be readily carried out; a means of transport wash must be provided on-the-spot;
 - (c) control posts must have suitable facilities for the separate isolation of animals suspected of being infected with an animal disease;
 - (d) appropriate sanitary breaks must be taken between two consecutive consignments of animals and if appropriate adapted depending on whether the animals come from a similar region, zone or compartment with the same health status; in particular, there must be no animals present in the control posts for a period of at least 24 hours after a maximum period of 6 days' use and after cleansing and disinfecting operations have been completed, and prior to the arrival of any new consignment of animals;
 - (e) before accepting animals, operators of control posts must:
 - (i) have started the cleansing and disinfection operations within a period of 24 hours following the departure of all animals previously held there;
 - (ii) ensure that no animals enter the control posts until the cleansing and disinfection operations are completed to the satisfaction of the official veterinarian.
2. The requirements in relation to facilities and equipment of control posts, as referred to in Article 12, shall be the following:
- (a) they must be cleansed and disinfected before and after each use, as required by the official veterinarian;
 - (b) equipment that comes into contact with the animals present on the control posts must be exclusively dedicated to the premises concerned unless it has been subject to a cleaning and disinfection procedure after coming in contact with the animals or their faeces or urine; in particular, the operator of the control post must provide clean equipment and protective clothes, which must be kept exclusively for the use of any persons entering the control post, and suitable equipment must be made available for cleansing and disinfecting those items;
 - (c) litter must be removed when a consignment of animals is moved from an enclosure and, after the cleansing and disinfecting operations, must be replaced by fresh bedding;
 - (d) fodder, litter, faeces and urine must not be collected from the premises unless they have been subject to an appropriate treatment in order to avoid the spread of animal diseases;
 - (e) they must have suitable facilities for holding, inspecting, examining the animals, whenever necessary;
 - (f) an appropriate storage area must be available for bedding material, feed, fodder, litter and manure;
 - (g) an appropriate system must be in place to ensure the collection of waste water.

PART 7

Requirements for granting approval of environmentally isolated production establishments of bumble bees referred to in Article 13

1. The requirements in relation to biosecurity and surveillance measures of environmentally isolated production establishments for bumble bees, as referred to in Article 13, shall be the following:
 - (a) the operator must ensure, verify and record by internal controls that the entry into the establishment of small hive beetles is prevented and their presence within the establishment is detectable.
2. The requirements in relation to facilities and equipment of environmentally isolated production establishments for bumble bees, as referred to in Article 13, shall be the following:
 - (a) the production of bumble bees must be isolated from all the associated activities of the establishment and must be conducted in flying insect-proof facilities;
 - (b) the bumble bees must be kept isolated within that building throughout the whole production;
 - (c) the storage and handling of pollen within facilities must be isolated from the bumble bees throughout the whole production of bumble bees until it is fed to them.

PART 8

Requirements for granting approval of quarantine establishments for kept terrestrial animals other than primates referred to in Article 14

1. The requirements in relation to quarantine, isolation and other biosecurity measures of quarantine establishments for kept terrestrial animals other than primates, as referred to in Article 14, shall be the following:
 - (a) each unit of the quarantine establishment must:
 - (i) be located at a secure distance from surrounding establishments or other places where animals are kept to avoid transmission of contagious animal diseases between resident and quarantined animals;
 - (ii) start the required quarantine period when the last animal of the batch is introduced into the quarantine establishment;
 - (iii) be emptied of animals, cleaned and disinfected at the end of the quarantine period for the last batch and then be kept free of animals for a period of at least seven days before a batch of animals that has entered into the Union from third countries and territories is introduced into the quarantine establishment;
 - (b) litter must be removed when a consignment of animals is moved from an enclosure, and it must be replaced by fresh bedding, after the cleansing and disinfecting operations have been completed;

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- (c) fodder, litter, faeces and urine must not be collected from the premises unless they have been subject to an appropriate treatment in order to avoid the spread of animal diseases;
 - (d) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of animals;
 - (e) animals released from the quarantine establishment must comply with Union requirements for movements of kept terrestrial animals between Member States.
2. The requirements in relation to surveillance and control measures of quarantine establishments for kept terrestrial animals other than primates, as referred to in Article 14, shall be the following:
- (a) the disease surveillance plan must include appropriate zoonoses control of the animals, and must be implemented and updated according to the number and species of the animals present in the establishment and to the epidemiological situation in and around the establishment as regards listed and emerging diseases;
 - (b) animals suspected of being infected or contaminated by listed or emerging disease agents must be subject to clinical, laboratory or post-mortem testing;
 - (c) the vaccination and treatment of susceptible animals against transmissible animal diseases must be carried out as appropriate;
 - (d) where ordered by the competent authority, sentinel animals must be used for the early detection of possible disease.
3. The requirements in relation to facilities and equipment of quarantine establishments for kept terrestrial animals other than primates, as referred to in Article 14, shall be the following:
- (a) the establishments must be clearly demarcated and the access of animals and humans to animal facilities must be controlled;
 - (b) there must be sufficiently large premises at the disposal of the staff responsible for carrying out veterinary checks, including changing rooms, showers and toilets;
 - (c) adequate means for catching, confining, where necessary restraining and isolating animals must be available;
 - (d) equipment and facilities for cleaning and disinfecting must be available;
 - (e) the part of the establishment where the animals are kept must be:
 - (i) where ordered by the competent authority to address specific animal health risks, insect-proof with HEPA filter air inlet and outlet, internal vector control, double door access and operating procedures;
 - (ii) in the case of captive birds, bird, fly and vermin proof;
 - (iii) sealable so as to permit fumigation;
 - (iv) of a suitable standard and so constructed that contact with animals outside is prevented and that inspections and any necessary treatment can be easily carried out;
 - (v) constructed in such way that floors, walls and all other material or equipment can be readily cleaned and disinfected.

PART 9

Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16

1. The requirements in relation to quarantine, isolation and biosecurity measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following:
 - (a) they must only admit kept terrestrial animals which have been subject to a quarantine period appropriate to diseases relevant to the species, where those animals coming from establishment other than a confined establishment;
 - (b) they must only admit primates complying with the rules as strict as those referred to in Article 6.12.4 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), Edition 2018;
 - (c) where necessary, adequate facilities to quarantine kept terrestrial animals introduced from other establishments must be available.
2. The requirements in relation to surveillance and control measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following:
 - (a) the disease surveillance plan must include appropriate zoonoses control of the kept terrestrial animals, and must be implemented and updated according to the number and species of the kept terrestrial animals present in the establishment and to the epidemiological situation in and around the establishment as regards listed and emerging diseases;
 - (b) kept terrestrial animals suspected of being infected or contaminated by listed or emerging disease agents must be subject to clinical, laboratory or post-mortem testing;
 - (c) the vaccination and treatment of susceptible kept terrestrial animals against transmissible diseases must be carried out as appropriate.
3. The requirements in relation to facilities and equipment of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following:
 - (a) the establishments must be clearly demarcated and the access of animals and humans to animal facilities must be controlled;
 - (b) adequate means for catching, confining, where necessary restraining and isolating animals are available;
 - (c) animal accommodation areas shall be of a suitable standard and constructed in such way that
 - (i) contact with animals on the outside is prevented and that inspection and any necessary treatment can be easily carried out;
 - (ii) floors, walls and all other material or equipment can be readily cleaned and disinfected.

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