

ANNEX II

Conditions governing approval of breeding establishments in the third country of origin as provided for in Article 4

CHAPTER 1

Approval of breeding establishments

In order to be granted approval as provided for in Article 4, a breeding establishment shall comply with the conditions set out in this Chapter.

- (1) The breeding establishment must be clearly demarcated and separated from its surroundings or the animals confined and located so as not to pose a health risk to animal holdings whose health status might be jeopardised.
- (2) It must have adequate means for catching, confining and isolating animals and have available adequate approved quarantine facilities and approved procedures for animals coming from establishments that have not been approved.
- (3) The person responsible for the breeding establishment must have adequate experience in the breeding of birds.
- (4) The breeding establishment must be free of avian influenza, Newcastle disease and *Chlamydoiphila psittaci*; in order for it to be declared free from those diseases, the competent authority shall assess the records on the animal health status kept for at least the previous three years before the date of the application for approval and the results of the clinical and laboratory tests carried out on the animals therein. However, new breeding establishments shall only be approved on the results of the clinical and laboratory tests carried out on the animals in such establishments.
- (5) It must keep up-to-date records indicating:
 - (a) the number and identity (age, sex, species and individual identification number where practical) of the animals of each species present in the breeding establishment;
 - (b) the number and identity (age, sex, species and individual identification number where practical) of animals arriving in the breeding establishment or leaving it, together with information on their origin or destination, the transport from or to the breeding establishment and the animals health status;
 - (c) the results of blood tests or any other diagnostic procedures;
 - (d) cases of disease and, where appropriate, the treatment administered;
 - (e) the results of the post-mortem examinations on animals that have died in the breeding establishment, including still-born animals;
 - (f) observations made during any isolation or quarantine period.
- (6) The breeding establishment must either have an arrangement with a competent laboratory to perform post-mortem examinations, or have one or more appropriate premises where such examinations may be performed by a competent person under the authority of the approved veterinarian.
- (7) The breeding establishment must either have suitable arrangements or on-site facilities for the appropriate disposal of the bodies of animals which die of a disease or are euthanised.
- (8) The breeding establishment must secure, by contract or legal instrument, the services of a veterinarian approved by and under the control of the competent authority of the exporting third country, who:
 - (a) shall ensure that appropriate disease surveillance and control measures in relation to the disease situation of the country concerned are approved by the competent authority and applied in the breeding establishment. Such measures shall include:
 - (i) an annual disease surveillance plan including appropriate zoonoses control of the animals;
 - (ii) clinical, laboratory and post-mortem testing of animals suspected to be affected by transmissible diseases;
 - (iii) vaccination of susceptible animals against infectious diseases as appropriate, in conformity with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE);
 - (b) shall ensure that any suspect deaths or the presence of any other symptoms suggesting that animals have contracted avian influenza, Newcastle disease or *Chlamydoiphila psittaci* is notified without delay to the competent authority of the third country;
 - (c) shall ensure that animals entering the breeding establishment have been isolated as necessary, and in accordance with the requirements of this Regulation and the instructions, if any, given by the competent authority;

- (d) shall be responsible for the day to day compliance with the animal health requirements of this Regulation and of Union legislation on welfare of animals during transport.
- (9) If the breeding establishment breeds animals intended for laboratories carrying out experiments, the general care and accommodation of such animals must be in conformity with the requirements of Article 33 of Directive 2010/63/EU of the European Parliament and of the Council ⁽¹⁾.

CHAPTER 2

Maintaining the approval of breeding establishments

Breeding establishments shall only remain approved as such if they comply with the conditions set out in this Chapter.

- (1) The premises are under the control of an official veterinarian from the competent authority, who shall:
- ensure that the conditions set out in this Regulation are met;
 - visit the premises of the breeding establishment at least once per year;
 - audit the activity of the approved veterinarian and the implementation of the annual disease surveillance plan;
 - verify that the results of the clinical, post-mortem and laboratory tests on the animals have revealed no occurrence of avian influenza, Newcastle disease or *Chlamydophila psittaci*.
- (2) Only animals coming from another approved breeding establishment are introduced into the breeding establishment, in accordance with the conditions set out in this Regulation.
- (3) The breeding establishment shall keep the records referred to in point 5 of Chapter 1 following the date of approval, for a period of at least 10 years.

CHAPTER 3

Quarantine of birds introduced from other sources than approved breeding establishments

By way of derogation from point 2 of Chapter 2, birds introduced from sources other than approved breeding establishments, may be introduced in a breeding establishment after approval for such an introduction is given by the competent authority, provided that such animals undergo quarantine in accordance with the instructions given by the competent authority before being added to the collection. The quarantine period must be at least 30 days.

CHAPTER 4

Suspending, withdrawing or regranting approval of breeding establishments

The procedures for partly or completely suspending, withdrawing or regranting approval of breeding establishments shall comply with the conditions set out in this Chapter.

- (1) Where the competent authority finds that a breeding establishment no longer complies with the conditions set out in Chapters 1 and 2, or there has been a change of use so that it is no longer used exclusively for the breeding of birds, it shall suspend or withdraw the approval of such establishment.
- (2) Where the competent authority has received notification of the suspicion of avian influenza, Newcastle disease or *Chlamydophila psittaci*, it shall suspend the approval of the breeding establishment, until the suspicion has been officially ruled out. It shall ensure that the measures necessary to confirm or rule out the suspicion and to avoid any spread of disease are taken, in accordance with the requirements of Union legislation governing measures to be taken against the disease in question and on trade in animals.
- (3) Where the suspected disease is confirmed, the competent authority may only approve the breeding establishment again in accordance with Chapter 1 following:
- the eradication of the disease and the source of infection in the breeding establishment;
 - the suitable cleaning and disinfection of the breeding establishment;
 - the fulfilling of the conditions laid down in Chapter 1, with the exception of point 4.
- (4) The competent authority shall immediately inform the Commission of the suspension, withdrawal or regranting of approval of any breeding establishment.

⁽¹⁾ OJ L 276, 20.10.2010, p. 33.

ANNEX IV

Minimum conditions for approved quarantine facilities and centres for birds as referred to in article 6

Approved quarantine facilities and centres shall comply with the conditions set out in Chapters 1 and 2.

CHAPTER 1

Construction and equipment of quarantine facilities or centres

- (1) The quarantine facility or centre must be a separate building or buildings which are separated from other poultry holdings and other bird holdings by a distance specified by the competent authority based on a risk assessment which takes into account the epidemiology of avian influenza and Newcastle disease. Entry/exit doors must be lockable with signs indicating: 'QUARANTINE — No admission for unauthorised persons'.
- (2) Each quarantine unit of the quarantine centre must occupy a separate airspace.
- (3) The quarantine facility or centre must be bird, fly and vermin proof and sealable so as to permit fumigation.
- (4) The approved quarantine facility and each unit of an approved quarantine centre must be equipped with hand washing facilities.
- (5) Entry and exit doors to the approved quarantine facility and to each unit of an approved quarantine centre must be double door systems.
- (6) Hygiene barriers must be installed at all entrances/exits to the approved quarantine facility and the different units of an approved quarantine centre.
- (7) All equipment must be constructed in such a way that it can be cleaned and disinfected.
- (8) The feed store must be bird and rodent proof and must be protected against insects.
- (9) A container must be available to store litter and must be bird and rodent proof.
- (10) A refrigerator and/or freezer must be provided for holding carcasses.

CHAPTER 2

Management requirements

- (1) Approved quarantine facilities and centres must:
 - (a) have an efficient control system so as to ensure adequate surveillance of the animals;
 - (b) be under the control and responsibility of the official veterinarian;
 - (c) be cleaned and disinfected in accordance with a programme approved by the competent authority after which there shall be an appropriate resting period; the disinfectants used must be approved for that purpose by the competent authority.
- (2) For each consignment of birds quarantined:
 - (a) the approved quarantine facility or unit of an approved quarantine centre must be cleaned and disinfected and then be kept free of birds for at least seven days before the imported birds are introduced;
 - (b) the consignment of birds must come from a single approved breeding establishment in the third country of origin and be introduced over a period of not more than 48 hours;
 - (c) the quarantine period must start when the last bird is introduced;
 - (d) the approved quarantine facility or unit of an approved quarantine centre must be emptied of birds, cleaned and disinfected at the end of the quarantine period.
- (3) Precautions shall be taken to prevent cross-contamination between incoming and outgoing consignments.
- (4) Unauthorised persons shall not enter the approved quarantine facility or centre.
- (5) Persons entering the approved quarantine facility or centre must wear protective clothing including footwear.

- (6) No contacts between personnel shall take place, which may cause contamination between approved quarantine facilities or units of approved quarantine centres.
- (7) Appropriate equipment shall be available for cleaning and disinfection.
- (8) If identification by microchipping is used, an appropriate microchip reader shall be available at the approved quarantine facility or centre.
- (9) Cleaning and disinfection of the cages or crates used for the transport must be carried out at the approved quarantine facility or centre unless they are destroyed. If reused, they must be made of a material that allows effective cleaning and disinfection. The cages and crates must be destroyed in such a way so as to avoid spread of disease causing agents.
- (10) Litter and waste material shall be collected regularly, stored in the litter container and subsequently treated in such a way as to avoid spread of disease-causing agents.
- (11) Carcasses of birds must be examined in an official laboratory designated by the competent authority.
- (12) The necessary analyses and treatments of birds must be carried out in consultation with and under the control of the official veterinarian.
- (13) The official veterinarian must be informed of diseases and death of birds and/or sentinel birds during the quarantine.
- (14) The person in charge of the approved quarantine facility or centre must keep a record of:
 - (a) the date, number and species of birds entering and leaving for each consignment;
 - (b) copies of the animal health certificates and the Common Veterinary Entry Documents accompanying the imported birds;
 - (c) individual identification numbers of the imported birds, and in case of identification by microchip the details of the type of microchip and the reader used shall be recorded;
 - (d) if in the quarantine facility or centre sentinel birds are used, the number and placing of the sentinel birds in the quarantine facility or centre;
 - (e) any significant observation: cases of illness and number of deaths on a daily basis;
 - (f) dates and results of testing;
 - (g) types and dates of treatment;
 - (h) persons entering and leaving the quarantine facility or centre.
- (15) The records referred to in point 14 shall to be kept for at least 10 years.

CHAPTER 3

Suspending, withdrawing or regranting approval of quarantine facilities and centres

The procedures for partly or completely suspending, withdrawing or regranting approval of quarantine facilities and centres shall comply with the conditions set out in this Chapter.

- (1) Where the competent authority finds that a quarantine facility or centre no longer complies with the conditions set out in Chapters 1 and 2, or there has been a change of use which is no longer covered by Article 3(e) and (f), it shall inform the Commission of this fact. Such quarantine facilities or centres shall not be used for imports in accordance with this Regulation.
- (2) Approval shall only be regranting to a quarantine facility or centre when the conditions laid down in Chapters 1 and 2 are again fulfilled.