

ANNEX II

APPROVAL OF ESTABLISHMENTS

CHAPTER I

GENERAL RULES

1. In order to be approved by the competent authority for the purposes of intra-Community trade, establishments must:
 - (a) satisfy the conditions as regards facilities and operation set out in Chapter II;
 - (b) apply and adhere to a disease surveillance programme approved by the competent central veterinary authority, taking into account the requirements of Chapter III;
 - (c) provide every facility for the carrying out of the operations listed in point (d);
 - (d) be subject to the supervision of the competent veterinary authority within the context of an organised form of animal health monitoring. Such monitoring shall include in particular:
 - at least one inspection visit per year by the official veterinarian, supplemented by checks to verify the application of hygiene measures and the operation of the establishment in accordance with the conditions in Chapter II,
 - the recording by the farmer of all the information necessary for the continuous monitoring of the health status of the establishment by the competent veterinary authority,
 - (e) contain only poultry.
2. The competent authority shall give each establishment which complies with the conditions laid down in point 1 a distinguishing number, which may be the same as that given pursuant to Regulation (EC) No 1234/2007.

CHAPTER II

FACILITIES AND OPERATION

- A. Pedigree breeding, breeding and rearing establishments
 1. Facilities
 - (a) The setting and layout of the facilities must be compatible with the type of production pursued, ensuring that the introduction of disease can be prevented or, if an outbreak occurs, that it can be controlled. If an establishment houses several species of poultry, there must be a clear separation between them.
 - (b) The facilities must provide good conditions of hygiene and allow health monitoring to be carried out.
 - (c) The equipment must be compatible with the type of production pursued, and allow cleansing and disinfection of the facilities and of vehicles for transporting poultry and eggs at the most suitable spot.

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2. Rearing

- (a) Rearing techniques must be based as far as possible on the ‘protected rearing’ principle and on the ‘all-in/all-out’ principle. Cleansing, disinfection and depopulation must be carried out between batches.
- (b) Pedigree-breeding, breeding and rearing establishments must house only poultry:
- from the establishment itself, and/or,
 - from other pedigree-breeding, breeding or rearing establishments in the Community approved in accordance with Article 6(a)(i), and/or,
 - imported from third countries in accordance with this Directive,
- (c) Hygiene rules must be drawn up by the management of the establishment; personnel must wear appropriate working clothing and visitors protective clothing.
- (d) Buildings, pens and equipment must be kept in good repair.
- (e) ^{F1}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 clean and disinfected packaging material.]
- (f) The farmer must notify the authorised veterinarian of any variation in production performance or any other sign suggesting the presence of a contagious poultry disease. As soon as disease is suspected, the authorised veterinarian must send the samples needed for making or confirming the diagnosis to an approved laboratory.
- (g) A flock history, register or data medium must be kept for each flock for at least two years after the disposal of the flock and must show:
- arrivals and departures,
 - production performance,
 - morbidity and mortality with causes,
 - any laboratory tests and the results thereof,
 - the place of origin of the poultry,
 - the destination of eggs,
- (h) Where a contagious poultry disease occurs, the results of laboratory tests must be communicated immediately to the authorised veterinarian.

Textual Amendments

F1 Substituted by [Commission Decision of 1 April 2011 amending Annexes II to IV to Council Directive 2009/158/EC on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs \(notified under document C\(2011\) 2068\) \(Text with EEA relevance\) \(2011/214/EU\)](#).

B. Hatcheries

1. Facilities

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- (a) A hatchery must be physically and operationally separate from rearing facilities. The layout must be such as to allow the various functional units listed below to be kept separate:
- egg storage and grading,
 - disinfection,
 - pre-incubation,
 - hatching,
 - preparation and packaging of goods for dispatch,
- (b) Buildings must be protected against birds coming from outside and rodents; floors and walls must be of hard-wearing, impervious and washable materials; natural or artificial lighting and air flow and temperature systems must be of an appropriate type; provision must be made for the hygienic evacuation of waste (eggs and chicks).
- (c) Equipment must have smooth and waterproof surfaces.
2. Operation
- (a) Operation must be based on a one-way circuit for eggs, mobile equipment and personnel.
- (b) Hatching eggs must be:
- from Community pedigree breeding or breeding establishments approved in accordance with Article 6(a)(i),
 - imported from third countries in accordance with this Directive,
- (c) Hygiene rules must be drawn up by the management of the establishment; personnel must wear appropriate working clothing and visitors protective clothing.
- (d) Buildings and equipment must be kept in good repair.
- (e) The following must be disinfected:
- [F]eggs, between the time of their arrival at the hatchery and the incubation process or at the time of their dispatch for trade within the Union or export to a third country, unless they have been previously disinfected at the breeding establishment of origin,
 - the incubators, regularly,
 - hatching equipment, after the hatching of each batch,
- (f) A programme of microbiological quality control must be used to assess the health status of the hatchery.
- (g) The farmer must notify the authorised veterinarian of any variation in production performance or any other sign suggesting the presence of a contagious poultry disease. As soon as contagious disease is suspected, the authorised veterinarian must send the samples needed for making or confirming the diagnosis to an approved laboratory and inform the competent veterinary authority, which shall decide on appropriate measures to be taken.
- (h) A flock history, register or data medium for the hatchery must be kept for at least two years showing, if possible by flock:
- the origin of the eggs and their arrival date,
 - hatching yields,
 - any abnormalities,

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- any laboratory tests and the results thereof,
 - details of any vaccination programmes,
 - the number and the destination of incubated eggs which have not hatched,
 - the destination of day-old chicks,
- (i) Where a contagious poultry disease occurs, the results of laboratory tests must be communicated immediately to the authorised veterinarian.

[^{F1}CHAPTER III

DISEASE SURVEILLANCE PROGRAMME

Without prejudice to health measures and to Articles 16 and 17, disease surveillance programmes must, as a minimum, comprise surveillance of the infections and species listed in Sections A to D.

- A. *Salmonella Pullorum*⁽¹⁾, *Salmonella Gallinarum*⁽²⁾ and *Salmonella arizonae*⁽³⁾ infections
1. Species concerned
 - (a) *Salmonella Pullorum* and *Salmonella Gallinarum*: fowls, turkeys, guinea fowls, quails, pheasants, partridges and ducks.
 - (b) *Salmonella arizonae*: turkeys.
 2. Disease surveillance programme
 - (a) Serological and/or bacteriological tests must be used to determine whether an infection is present⁽⁴⁾.
 - (b) Samples for testing must be taken, as appropriate, from blood, embryos that fail to hatch (namely embryos dead-in-shell), second grade chicks, meconium, post mortem tissues, especially liver, spleen, ovary/oviduct and ileo-caecal junction⁽⁵⁾.
 - (c) Direct enrichment in Selenite-cysteine broth for faecal/meconium and intestinal samples is to be used. Non-selective pre-enrichment followed by selective enrichment in soya based Rappaport-Vassiliadis (RVS) broth or Müller-Kauffmann Tetrathionate-novobiocin broth (MKTTn) may be used for samples (such as embryos dead-in-shell) where competing flora is expected to be minimal^{(6), (7)}.
 - (d) When blood samples are taken from a flock for serological testing for *Salmonella Pullorum* and *Salmonella Gallinarum* or *Salmonella arizonae*, the prevalence of infection in the Member State concerned and its past incidence in the establishment must be allowed for in determining the number of samples to be taken. However, a statistically valid number of samples for serological and/or bacteriological testing to detect infection must always be taken.
 - (e) Flocks must be inspected during each laying period at the best time for detecting the disease in question.
 - (f) Samples for bacteriological testing must not be taken from poultry or eggs that have been treated with antimicrobial medicinal products during the 2 to 3 weeks prior to testing.

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- (g) Detection techniques must be capable of differentiating serological responses to *Salmonella Pullorum* and *Salmonella Gallinarum* infection from serological responses due to the use of *Salmonella* Enteritidis vaccine, where this vaccine is used⁽⁸⁾. Such vaccination must therefore not be used if serological monitoring is to be used. If vaccination has been used, bacteriological testing must be used, but the confirmation method used must be capable of differentiating live vaccinal strains from field strains.
- B. *Mycoplasma gallisepticum* and *Mycoplasma meleagridis* infections
1. Species concerned
- (a) *Mycoplasma gallisepticum*: fowls and turkeys.
- (b) *Mycoplasma meleagridis*: turkeys.
2. Disease surveillance programme
- (a) The presence of infection must be tested by validated serological and/or bacteriological and/or molecular tests. The presence of air sacculitis lesions in day-old chicks and turkey poults suggests that a *Mycoplasma* infection is present and must be investigated.
- (b) Samples for testing for the presence of *Mycoplasma* infection must be taken, as appropriate, from blood, day-old chicks and turkey poults, sperm, or swabs taken from the trachea, the choanae, cloaca or air sacs and in particular for the detection of *Mycoplasma meleagridis* samples must be taken from oviduct and penis of turkeys.
- (c) Tests for detecting *Mycoplasma gallisepticum* or *Mycoplasma meleagridis* must be performed on a representative sample in order to allow continuous surveillance of the infection during rearing and laying, namely just before the start of laying and every 3 months thereafter.
- C. Results and measures to be taken

If there are no reactors, the test must be deemed to be negative. Otherwise, the flock must be deemed to be suspect and the measures set out in Chapter IV must be applied to it.

- D. In the case of holdings which consist of two or more separate production units, the competent veterinary authority may derogate from the measures set out in point 3(b) of Chapter IV required for restoring of approval as regards healthy production units on a holding where the infection is present provided that the authorised veterinarian has confirmed that the structure and size of those production units and the operations carried out there are such that the production units provide completely separate facilities for housing, keeping and feeding, so that the disease in question cannot spread from one production unit to another.

CHAPTER IV

CRITERIA FOR SUSPENDING OR WITHDRAWING APPROVAL OF AN ESTABLISHMENT

1. Approval granted to an establishment must be suspended:
- (a) when the conditions laid down in Chapter II are no longer met;
- (b) until an investigation appropriate to the disease has been completed,

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if:

- an outbreak of avian influenza or Newcastle disease is suspected at the establishment,
- the establishment has received poultry or hatching eggs from an establishment with a suspected or confirmed outbreak of avian influenza or Newcastle disease,
- contact liable to transmit the infection has occurred between the establishment and the site of an outbreak of avian influenza or Newcastle disease;

(c) until such time as new tests are performed, if the results of surveillance carried out in accordance with the conditions laid down in Chapters II and III for infection by *Salmonella Pullorum*, *Salmonella Gallinarum*, *Salmonella arizonae*, *Mycoplasma gallisepticum* or *Mycoplasma meleagridis* give cause to suspect an outbreak;

(d) until completion of the appropriate measures required by the official veterinarian, if the establishment is found not to conform with the requirements of point 1(a), (b) and (c) of Chapter I.

2. Approval must be withdrawn if:

- (a) an outbreak of avian influenza or Newcastle disease is confirmed on the establishment;
- (b) a second test of an appropriate type confirms an outbreak of infection by *Salmonella Pullorum*, *Salmonella Gallinarum*, *Salmonella arizonae*, *Mycoplasma gallisepticum* or *Mycoplasma meleagridis*;
- (c) after a second notice served by the official veterinarian on the person responsible for the establishment, action to bring the establishment into line with the requirements of point 1(a), (b) and (c) of Chapter I, has not been taken.

3. Conditions for restoring approval if:

- (a) approval has been withdrawn because of an outbreak of avian influenza or Newcastle disease, it may be restored 21 days after cleansing and disinfection if sanitary slaughter has been carried out;
- (b) approval has been withdrawn because of an outbreak caused by:
 - *Salmonella Pullorum* and *Salmonella Gallinarum*, or *Salmonella arizonae*, it may be restored after negative results have been recorded in two tests performed with an interval of at least 21 days on the establishment following sanitary slaughter of the infected flock and after disinfection for which the effectiveness has been verified by suitable tests on dried surfaces,
 - *Mycoplasma gallisepticum* or *Mycoplasma meleagridis*, it may be restored either after negative results have been recorded in two tests performed on the entire flock with an interval of at least 60 days or after negative results have been recorded in two tests performed with an interval of at least 21 days on the establishment after disinfection following sanitary slaughter of the entire infected flock.]

- (1) ^{F1} *Salmonella* Pullorum means *Salmonella enterica* subspecies *enterica* serovar Gallinarum biochemical variant (biovar) Pullorum.]
- (2) ^{F1} *Salmonella* Gallinarum means *Salmonella enterica* subspecies *enterica* serovar Gallinarum biochemical variant (biovar) Gallinarum.]
- (3) ^{F1} *Salmonella arizonae* means *Salmonella enterica* subspecies *arizonae* serogroup K (O18) arizonae.]
- (4) ^{F1} [Note that serological testing in avian species other than fowls may sometimes result in an unacceptable proportion of false-positive reactions.]
- (5) ^{F1} [Note that environmental samples are generally not suitable for reliable detection of *Salmonella pullorum* and *Salmonella gallinarum*, but are suitable for *Salmonella arizonae*.]]
- (6) ^{F1} [Note that direct plating of aseptically collected tissues on to a minimally selective agar, such as MacConkey agar, is also useful for diagnosis.]
- (7) ^{F1} [*Salmonella pullorum* and *Salmonella gallinarum* do not readily grow in the modified semi-solid Rappaport Vassiliadis (MSRV) medium that is used for monitoring of zoonotic *Salmonella* spp. in the Union, but it is suitable for *Salmonella arizonae*.]]
- (8) ^{F1} [Note that there is currently no test that can differentiate between the response to *Salmonella* Pullorum and *Salmonella* Gallinarum infection and vaccination for this serotype.]

Textual Amendments

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