

COMMISSION REGULATION (EC) No 616/2009

of 13 July 2009

implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC ⁽¹⁾, and in particular Article 3, and Articles 34(4) and 63(1) thereof,

Whereas:

- (1) In 2004, the World Organisation for Animal Health (OIE) introduced the concept of compartmentalisation in the chapter on zoning and regionalisation of its Terrestrial Animal Health Code ⁽²⁾ (the Code).
- (2) The Code describes in Chapter 4.3 zoning and compartmentalisation as 'procedures implemented by a country under the provisions of this chapter with a view to defining subpopulations of distinct health status within its territory for the purpose of disease control and/or international trade.' Although spatial considerations and good management play important roles in the application of both concepts, zoning applies to an animal subpopulation defined primarily on a geographical basis (using natural, artificial or legal boundaries), whereas compartmentalisation applies to an animal subpopulation defined primarily by management and husbandry practices related to biosecurity.
- (3) In addition, Chapter 4.4 on the application of compartmentalisation provides a structured framework for the application and recognition of compartments within countries. A compartment may consist of several establishments and can be approved for a defined animal disease(s), based upon a detailed and documented biosecurity plan drawn up and implemented for the disease(s) concerned. The initial approval of a compartment should preferably take place in a disease-free country, territory or zone, before an outbreak of the specific disease(s) occurs.

This is particularly important in the case of highly contagious diseases, such as highly pathogenic avian influenza. In the event of an outbreak, compartmentalisation may be used to facilitate trade.

- (4) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on A new Animal Health Strategy for the European Union (2007 to 2013) where 'Prevention is better than cure' ⁽³⁾ (the new animal health strategy) provides direction for the development of an animal health policy for the period from 2007 to 2013. The new animal health strategy aims to put greater focus on precautionary measures, disease surveillance, controls and research, in order to reduce the incidence of animal disease and minimise the impact of outbreaks when they do occur.
- (5) Biosecurity plays an important role in the new animal health strategy. In addition, compartmentalisation would encourage farmers in the Community to apply biosecurity measures as compartmentalisation would facilitate safe trade and so present clear advantages for farmers while at the same time prevent animal diseases.
- (6) In that respect, this Regulation should lay down rules for the approval, suspension and withdrawal of approval of compartments in respect of avian influenza. Such rules should take the Code into account in the interests of a consistent approach to combating the spread of avian influenza while considering the distinct health status of approved compartments.
- (7) Directive 2005/94/EC sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and the minimum control measures and movement restrictions to be applied in the event of an outbreak of that disease in poultry or other captive birds. Certain of those measures are to be applied in poultry compartments or in other captive bird compartments, as defined in that Directive.
- (8) Directive 2005/94/EC provides a definition of poultry compartments and other captive birds' compartments and also provides that additional biosecurity measures may be applied in those compartments in order to prevent the spread of avian influenza.

⁽¹⁾ OJ L 10, 14.1.2006, p. 16.

⁽²⁾ http://www.oie.int/eng/normes/mcode/en_sommaire.htm (Terrestrial Animal Health Code 2008).

⁽³⁾ COM 539(2007) final.

- (9) Directive 2005/94/EC provides that Member States are to carry out surveillance programmes in order to detect the prevalence of infections with avian influenza virus subtypes H5 and H7 in different species of poultry. For that purpose, compulsory surveillance programmes for avian influenza are annually approved in Member States. The approval of compartments in a Member State should therefore be subject to the approval of the national surveillance programme of the concerned Member State.
- (10) Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC ⁽¹⁾, lays down diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of an outbreak of avian influenza. In the interests of consistency of Community legislation in this area, those procedures and methods should be followed in the framework of a compartment.
- (11) In order to facilitate the use of procedures by electronic means between Member States, and to ensure transparency and comprehensibility, it is important that information on the approved compartments, and on any granting, suspension or withdrawal of approval is made available in the most efficient way throughout the Community. The Member States should therefore establish Internet-based information pages containing such information and the Commission's website should display links to those pages.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

This Regulation lays down rules for approval by the Member States of poultry compartments, and other captive birds compartments, in relation to avian influenza (hereinafter referred to as compartments), and provides for additional preventive biosecurity measures to be implemented in such

compartments to grant them a distinct health status in relation to avian influenza.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

1. 'biosecurity plan' means all the biosecurity measures being implemented at holding level;
2. 'common biosecurity management system' means:
 - (a) the common rules governing the functioning of a compartment; and
 - (b) the overall biosecurity measures implemented in all the holdings comprising the compartment in accordance with their biosecurity plans;
3. 'compartment manager' means the person formally responsible for the compartment, in particular in relation to Articles 3, 4 and 5, and including:
 - (a) supervising all actions carried out in the compartment relating to the common biosecurity management system, in particular for the implementation and monitoring of that system;
 - (b) supervising the implementation of the holdings' biosecurity plans by the poultry or other captive birds' owners or keepers; and
 - (c) liaising with the competent authority;
4. 'exit holding' means a holding from which poultry or other captive birds or their day-old chicks or hatching or table eggs (hereafter referred to as 'commodities'), are destined to be moved outside of the compartment;
5. 'supplier holding' means a holding from which the commodities are destined for an exit holding or any other holding within a compartment;
6. 'all involved parties' means compartment managers, business operators including food and feed business operators as defined in Article 3(3) and (6) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾, animal owners and keepers, pharmaceutical producers, or other industries delivering commodities to, or providing services for, the compartment.

⁽¹⁾ OJ L 237, 31.8.2006, p. 1.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

CHAPTER II

APPROVAL OF COMPARTMENTS

Article 3

Applications for the approval of compartments

1. Voluntary applications for the approval of compartments (hereinafter referred to as applications) shall be submitted to the competent authority by the compartment manager.
2. The application shall contain the following information:
 - (a) the name of the compartment manager, his or her qualifications and position, contact details and the address of the compartment;
 - (b) a detailed description of the compartment, as set out in Part 1 of the Annex;
 - (c) a description of the common biosecurity management system and of the biosecurity plans of the holdings comprising the compartment, as set out in Part 2 of the Annex;
 - (d) detailed information on the specific measures, criteria and requirements for disease surveillance, in particular specific protection and surveillance for avian influenza, as set out in Part 3 of the Annex.

Article 4

Granting approval of compartments

1. The initial approval of a compartment shall only be granted by the competent authority for compartments which are situated in the territory, or part of the territory of a Member State, where no restrictions apply in relation to avian influenza, pursuant to Community legislation.

The initial approval of a compartment shall only be granted in a Member State whose national surveillance programme in order to detect the prevalence of infections with avian influenza virus subtypes H5 and H7 in different species of poultry, has been approved.

2. Before granting approval for a compartment, the competent authority shall ensure that in the compartment:
 - (a) specific protection and surveillance for avian influenza has been carried out for a period of at least six months prior to the date of application, as required by Part 3 of the Annex (including at least one testing procedure as required in point 4 of Part 3 of the Annex), and the presence of avian influenza has not been detected in any of the holdings comprising the compartment during that period;

- (b) where appropriate, vaccination plans are carried out in accordance with Community legislation;
- (c) the information submitted in accordance with Article 3(2) is complete and accurate;
- (d) a common biosecurity management system, as set out in point 1 of Part 2 of the Annex, has been implemented and has shown to be sufficient to ensure a distinct health status with respect to avian influenza for the poultry or other captive birds population of the compartment;
- (e) an official on-site control has been carried out with favourable results with respect to points (a) to (d);

3. The compartment shall have only one name and be granted only one approval number.

4. The competent authority shall ensure that following the granting of approval of a compartment, it is listed without delay on the list of approved compartments on the Internet-based information page provided for in Article 9(1) with detailed information concerning the location of the holdings comprising the compartment and whether they are exit or supplier holdings (list of approved compartments).

CHAPTER III

CONDITIONS FOR THE RETENTION OF APPROVAL OF COMPARTMENTS

Article 5

Responsibilities and duties of the compartment manager

Following the grant of approval of a compartment, the compartment manager shall:

1. supervise and monitor the compartment in order to ensure that it continues to comply with the information submitted in accordance with Article 3(2) and the criteria and requirements set out in the Annex; in particular such information must be kept up-to-date and made available to the competent authority on request;
2. ensure that disease surveillance activities, in particular surveillance for avian influenza, are carried out according to the common biosecurity management system and each biosecurity plan of the holdings comprising the compartment and that:
 - (a) an early warning system is in place for the detection of the presence of avian influenza; and sampling and diagnostic tests are carried out in accordance with Decision 2006/437/EC and Part 3 of the Annex to this Regulation;

- (b) surveillance plans as set in point 4 of Part 3 of the Annex are updated in the case of the identification of an increased risk of the introduction of avian influenza;
 - (c) all avian influenza diagnostic tests are carried out in laboratories officially approved for that purpose by the competent authority; information on the surveillance and results are made available to the competent authority;
 - (d) any inconclusive or positive results of the surveillance in the compartment are immediately reported to the competent authority, so that the related samples can be sent for confirmation to the national reference laboratory or Community reference laboratory for avian influenza;
3. ensure that any vaccination applied is carried out according to the common biosecurity management system and each biosecurity plan of the holdings comprising the compartment and that vaccination plans and procedures are made available to the competent authority on request;
 4. organise regular internal or external audits to guarantee that all biosecurity measures, surveillance activities and the traceability system are effectively implemented in the compartment and keep the results of such audits, including those carried out in the framework of a quality assurance system, so that they are available to the competent authority on request;
 5. immediately inform the competent authority if:
 - (a) the compartment no longer complies with the information submitted in accordance with Article 3(2) or the criteria and requirements set out in the Annex;
 - (b) the common biosecurity management system or a biosecurity plan has been amended or adapted to the epidemiological situation, including when a holding is added or withdrawn from the compartment.

Article 6

Responsibilities and duties of the competent authority

1. The competent authority shall ensure that official on-site risk-based controls of compartments are carried out in order to verify whether they continue to comply with the information submitted in accordance with Article 3(2) and the criteria and requirements set out in the Annex (controls).
2. Controls shall be carried out at intervals based on:
 - (a) the epidemiological situation inside and outside of the compartment, in particular in relation to avian influenza;
 - (b) information concerning any amendments or adaptations to the common biosecurity management system or biosecurity

plans of the holdings comprising the compartment, as provided for in Article 5(5)(b).

3. The competent authority shall be responsible for any certification attesting that commodities come from an approved compartment.

CHAPTER IV

SUSPENSION OR WITHDRAWAL OF APPROVAL OF COMPARTMENTS

Article 7

Suspension of approval of compartments

1. If a control, or the epidemiological information related to the compartment shows that it no longer complies with the information submitted in accordance with Article 3(2), or the criteria and requirements set out in the Annex, the competent authority shall immediately suspend the approval of the compartment concerned and the compartment manager shall ensure that immediate action is taken to correct any such non-compliance.
2. Following the suspension of the approval of a compartment, the competent authority shall suspend any certification attesting that the commodities come from an approved compartment.
3. Where the approval of a compartment has been suspended, the competent authority shall not lift the suspension until it has verified that corrective action has been launched within 30 days of the date of the suspension and a subsequent control has been carried out with favourable results.

Article 8

Withdrawal of approval of compartments

1. The competent authority shall withdraw the approval of a compartment where, following suspension of the compartment in accordance with Article 7(1), the subsequent control in accordance with Article 7(3) demonstrates that:
 - (a) the compartment continues not to comply with the information submitted in accordance with Article 3(2) or the criteria and requirements set out in the Annex; or
 - (b) an outbreak of avian influenza occurred in the compartment.
2. Following the withdrawal of an approval of a compartment, the competent authority shall:
 - (a) stop any certification attesting that commodities come from an approved compartment;

(b) delete the name of the compartment from the list of approved compartments.

3. Following the deletion of the name of a compartment from the list of approved compartments, it may only be restored following a new application in accordance with Chapter II.

CHAPTER V

INTERNET-BASED INFORMATION PAGE AND FINAL PROVISIONS

Article 9

Internet-based information page

1. Member States shall:

(a) establish a list of approved compartments with the information required by Article 4(3) and (4);

(b) establish an Internet-based information page to make the list of approved compartments electronically available;

(c) communicate the Internet address of the Internet-based information pages to the Commission;

(d) keep their Internet-based information page updated to take into account without delay any new approvals or withdrawals of approval of compartments;

2. The Commission shall assist the Member States in making such information available to the public by providing the Internet address of its website which shall display national links to Internet-based information pages.

Article 10

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 October 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 July 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

CRITERIA AND REQUIREMENTS FOR COMPARTMENTS

PART 1

Description of the compartment as referred to in Article 3(2)(b)

The description of the compartment as referred to in Article 3(2)(b) shall be based on a site map(s) of the compartment showing its demarcations, indicating the precise location of all its components including the holdings and their premises, and all related functional units, such as feed processing or storage facilities, and other material storage facilities.

Sufficient information must be included in the application in order to provide a detailed description of the compartment, in particular:

1. Information on the infrastructural factors and their contribution to an epidemiological separation between the poultry and other captive birds in the compartment and animal populations with a different health status, including:
 - (a) a description of the type of activity and the commodities produced in the compartment, including the total capacities of the premises and the number of poultry or other captive birds present;
 - (b) a flow chart clearly indicating in detail all activities carried out in the compartment, and the responsibilities, roles and interrelations of all involved parties;
 - (c) a description of the functional interactions between the holdings comprising the compartment, including a diagram of all premises showing their links to one another;
 - (d) a description of the animal and animal product transport means, their usual routes, and cleaning and parking places.
2. Information on the epidemiological status regarding avian influenza and on the risk factors including the following elements:
 - (a) the epidemiological history of the holdings comprising the compartment, and in particular their health status and any information in relation to avian influenza;
 - (b) the movements into, out of, or within the compartment (inputs, outputs), such as movements of persons, commodities, other animals, products of animal origin or other products in contact with animals, transport vehicles, equipment, animal feed, water supply and drainage;
 - (c) the presence of other poultry and other captive birds holdings in the vicinity of the compartment, including density (such as breeding or fattening farms, backyard farms, markets, collection centres, slaughterhouses, zoos);
 - (d) the environmental risk factors such as waterways, wildlife resting and mixing places (including migratory routes of wild birds), the presence of rodents, the historical presence of the avian influenza agent in the environment;
 - (e) the risk factors and potential pathways for the entry into and spread of avian influenza within the compartment in accordance with Community legislation and/or standards and guidelines of the World Organisation for Animal Health (OIE);
 - (f) the early warning system in place to inform the competent authority of findings of any risk factors and potential pathways as referred to in point (e).

PART 2

Description of the common biosecurity management system and of the biosecurity plans, as referred to in Article 3(2)(c)

1. The common biosecurity management system shall include at least the following elements:
 - (a) good animal hygiene practices;
 - (b) a traceability system for all movements between the holdings comprising the compartment and for all inputs and outputs; the traceability system must be continuously documented and be available to the competent authority at all times;

- (c) a common plan of hazard analysis and critical control points (HACCP plan);
 - (d) the biosecurity plan(s) of the holdings comprising the compartment and an evaluation of their effectiveness in accordance with a defined level of risk.
2. The biosecurity plans of the holdings under the common biosecurity management system shall include at least the following elements:
- (a) a documented implementation system of a staff hygiene plan, including general and specific hygienic practices, general and specific training for permanent and temporary staff and the procedure for control of that hygiene plan, including a rule that staff must (i) not personally keep poultry or other birds nor (ii) have close contact with poultry or other birds other than those of the compartment for a period of at least 72 hours before entering the holding; a shorter period may be required in case of urgent need of specific staff, but it must in no event be less than 24 hours and the procedure mitigating the risk must be described in the biosecurity plan;
 - (b) products and personnel flows, described on a diagram of all the premises of the holding with colour coded levels of biosecurity; there must be a hygiene barrier with a changing zone, including where appropriate showers, with separated clean and dirty areas at all entry points to the premises;
 - (c) a plan regulating the movements of any person entering or leaving the holding, distinguishing authorised and non-authorised persons or visitors, including a description of the physical barriers (such as hedges, fences, or any other barrier that clearly defines the perimeters of the premises of the holding), signs, locked gates and entrances to buildings; external visitors (including auditors or inspectors) must be required not to have had any contact with poultry or other birds for a period of at least 72 hours before entering the holding; a longer period may be required depending on risk factors (such as visitors coming from a protection or surveillance zone); a shorter period may be required for the official veterinarians or in case of urgent need of external specific intervention (such as a consultant or veterinarian), but it must in no event be less than 24 hours and the procedure mitigating the risk must be described in the biosecurity plan;
 - (d) a plan regulating and recording the movements of vehicles into, out of or between the holdings, including private and delivery vehicles (such as for feed, animals, or other supplies); a record of all vehicle movements must be available;
 - (e) an animal and product traceability system, enabling the tracing of all movements into, out of or between the holdings (inputs, outputs);
 - (f) a protocol to prevent contamination, including contamination through the supply, transportation, storage, delivery and disposal of:
 - (i) packing materials (such as the use of new or disinfected packing materials);
 - (ii) bedding materials (such as an appropriate storage quarantine time or a disinfection of bedding materials);
 - (iii) feed (such as the use of enclosed systems of feed);
 - (iv) water (such as an internal water treatment system);
 - (v) animal by-products such as carcasses, manure, dirty/cracked eggs or dead in shell eggs;
 - (g) a cleaning and disinfection plan of the holding, its equipment and of materials used; a specific protocol on vehicle cleansing and disinfection must be available;
 - (h) a pest control plan, including rodents and other wild animals, providing for physical barriers and measures in case of findings of their activity;

- (i) a HACCP plan relating to avian influenza, developed following the seven steps (namely hazards analysis, list of the critical control points (CCP), critical limits, monitoring procedures, corrective actions, verification and recordings), and which shall include at least the following elements:
- (i) data on the production of poultry or other captive birds and other data in relation to defined periods (morbidity and mortality history, details of medications used, birds hatched, data relating to animal feed and water consumption);
 - (ii) information relating to the clinical checks and sampling plans for active and passive surveillance and screening analyses (frequencies, methods, results);
 - (iii) a register of visitors to the holding, in sufficient detail to be able to trace and contact any visitor;
 - (iv) information concerning any vaccination programmes applied, including the type of vaccine used and the frequency and dates of administration;
 - (v) detailed information records on the corrective actions performed and the related critical control points not complied with.

All involved parties shall be fully aware of and follow the rules of the HACCP plan, which is the management tool of the compartment that guarantees biosecurity measures and management practices.

The HACCP plan shall take into consideration the list of hazards and pathways which must be identified in advance. It shall be adaptable to the level of risk and include described actions to be taken in the case of increased risk, such as frequency of sampling.

3. Corrective actions and updates

The common biosecurity management system and the biosecurity plans shall describe whether a particular breach is to be considered as a minor or major breach, and the corrective actions to be taken.

The biosecurity plans shall be updated according to the level of risk, in particular where an outbreak of avian influenza is officially suspected or confirmed in the Member State or in the region or zone in which the compartment is situated (such as placing restrictions on vehicles, materials, animals and/or personnel movements, or implementing additional disinfection procedures).

PART 3

Specific protection and surveillance for avian influenza

1. An adequate physical bird proofing system shall be in place to prevent contact with wild birds and to prevent any contamination of feed, water and litter. The direct environment of the holdings shall not be attractive for wild birds.
2. Control of inputs and outputs
 - (a) The diagram referred to in point (1)(a) of Part 1 shall indicate the location of all types of poultry or other captive birds, including the pure line breeders, the great-grandparents, grandparents, parents and production animals, as well as flocks, hatcheries, rearing sites, laying sites, trial sites, egg stores and all places where eggs or birds are kept; it shall indicate the flows of commodities between those locations.
 - (b) A detailed protocol shall regulate the movements of poultry or other captive birds, their eggs and other related products; poultry or other captive birds, their eggs and other related products entering any holding on the compartment must come from a holding having the same health status as regards avian influenza and/or be checked to ensure that they present no risk of introduction of avian influenza.
 - (c) Poultry or other captive birds and hatching eggs moved into or within the compartment shall be identified in such a way that their history can be audited; flocks and/or eggs shall have the proper documented identification.
 - (d) In the case of a multi-age site, a written protocol shall regulate the addition and removal of poultry or other captive birds, including the washing and disinfection of catching crates.

3. The same compartment cannot comprise holdings of poultry and holdings of other captive birds. The same holding cannot comprise different poultry species, except for hatcheries.
 4. In the compartment, the surveillance plan under the responsibility of the compartment manager shall include continuous active surveillance that shall be carried out on 20 blood samples taken at random from poultry, or other captive birds, of the same production unit for serological testing for avian influenza:
 - (a) at least every six months during the production period where no outbreaks of highly pathogenic avian influenza (HPAI) in poultry or other captive birds, have been confirmed during the preceding six months in the territory of the Member State;
 - (b) at least every three months where an outbreak of HPAI in poultry or other captive birds, has been confirmed during the preceding six months in the territory of the Member State;
 - (c) when the compartment is located within an area under movement restrictions due to an outbreak of avian influenza pursuant to Community legislation, within one week following the date of the outbreak and at least every 21 days; in addition, and without prejudice to any specific provisions of Community legislation, the surveillance plan shall be updated and include enhanced clinical surveillance and active virological surveillance, carried out within one week following the date of the outbreak and at least every 21 days thereafter, on:
 - (i) a sample of 20 tracheal/oropharyngeal swabs and 20 cloacal swabs taken at random from poultry or other captive birds of the same production unit; and
 - (ii) samples taken on five sick or dead birds if found.
 5. The early warning system provided for in Article 5(2)(a) must be based upon a written protocol which specifies the reporting procedures. It shall, in particular, be adapted to the different species of poultry or other captive birds and their respective susceptibility to avian influenza, and it shall:
 - (a) prescribe action levels, such as mortality equal or higher to a defined threshold, significant drops in feed and/or water consumption and/or in egg production, behavioural changes or other relevant indicators;
 - (b) describe the actions to be taken;
 - (c) include a list of the responsible personnel to be notified.
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