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COMMISSION DELEGATED REGULATION (EU) 2024/2623

of 30 July 2024

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (the 'Animal Health Law') ([1]), and in particular Article 37(5) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases referred to in Article 5 thereof, including rules on disease notification and reporting, surveillance, eradication programmes and disease-free status. In particular, Article 37(1) of that Regulation allows Member States to apply to the Commission for the recognition of disease-free status of compartments for listed diseases referred to in Article 9(1), point (a), thereof (category A diseases).

(2) The compartmentalisation approach provided for in Regulation (EU) 2016/429 is in line with the international standards of the World Organisation for Animal Health ('WOAH'), and in particular Chapters 4.4. and 4.5. of the Terrestrial Animal Health Code ([2]) respectively on zoning and compartmentalisation, and on the application of compartmentalisation, which are meant to be used as a basis by WOAH Members for their regulations on animal disease prevention and control.

(3) While general rules for recognition of the disease-free status of compartments keeping terrestrial animals for category A diseases are laid down in Article 37(1) of Regulation (EU) 2016/429, this Regulation should lay down supplementing rules for the approval by the competent authority of the disease-free status of such compartments.

(4) For such approval by the competent authority of the disease-free status for category A diseases of compartments keeping terrestrial animals, the rules laid down in this Regulation should include general requirements for such compartments, as well as rules on the responsibilities and duties of the compartment manager, requirements for a common biosecurity management system, and detailed requirements and procedures for the approval of such compartments by the competent authority, including compartments which are located in the territory of more than one Member State.

(5) Article 2 of Commission Implementing Regulation (EU) 2020/690 ([3]) provides that the listed diseases for which the disease-free status of compartments may be established, in accordance with Article 37(4), point (b), of Regulation (EU) 2016/429, are set out in Annex II to that Implementing Regulation). Specific requirements for the approval by the competent authority of the disease-free status for those category A diseases should be laid down in this Regulation.

([1]) OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/oj.
([2]) https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/.
([3]) Commission Implementing Regulation (EU) 2020/690 of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established (OJ L 174, 3.6.2020, p. 341, ELI: http://data.europa.eu/eli/reg_impl/2020/690/oj).

(6) To prevent the introduction and spread of category A diseases in a compartment keeping terrestrial animals, and for the control of those category A diseases in the Union, detailed requirements should be laid down in this Regulation concerning specific surveillance and strict biosecurity provisions. The rules laid down in this Regulation should also provide that certain establishments, such as those keeping free-range animals or establishment for assembly operations, which even when they have strict biosecurity measures in place still inherently pose a heightened risk for the spread of diseasesdue to frequent movements and mixing of animals of different categories or a different health status, cannot be part of a compartment for the purposes of the approval of disease-free status for category A diseases.

(7) Establishing and maintaining specific disease-free compartments for category A diseases is demanding, as when they are established, operators must ensure that the animal population is protected and its distinct health status is preserved in all situations, even and especially where there is a restricted zone for the category A disease in the vicinity of the compartment. Therefore, the strictest biosecurity measures should apply to all components of the compartments, which can only be achieved through a common biosecurity management system. Such a system requires strict management and therefore each compartment operator should appoint for that purpose a compartment manager with defined tasks and responsibilities.

(8) Operators applying to the competent authority for approval of the disease-free status for category A diseases of compartments keeping terrestrial animals should be aware of the requirements and procedures for such applications. It is therefore necessary to lay down such requirements and procedures in this Regulation.

(9) An application for approval of the disease-free status for a category A disease of a compartment keeping terrestrial animals should not be allowed, while the compartment or a part thereof is located in a restricted zone for that category A disease, due to the difficulty to establish, maintain and verify effective biosecurity plans when outbreaks of that category A disease are occurring in the vicinity of the compartment.

(10) Articles 94 to 100 of Regulation (EU) 2016/429 lay down general rules and procedures for the approval of certain types of establishments, notably those referred to in Article 94(1), point (e), thereof, which includes compartments. This Regulation should lay down certain detailed procedures for the competent authority for the approval, suspension, and withdrawal of the disease-free status for category A diseases of compartments keeping terrestrial animals. This is due to the complexity and specificity of biosecurity management measures for compartments and the differences in terms of animal disease risk between breaches in the biosecurity measures and the actual occurrence in the compartment of the category A disease(s) for which it has been granted disease-free status.

(11) The listed diseases for which the disease-free status of compartments may be established in accordance with Article 37 of Regulation (EU) 2016/429 are set out in Annex II to Implementing Regulation (EU) 2020/690 and include highly pathogenic avian influenza (HPAI) and infection with Newcastle disease virus (NDV). Compartments keeping poultry (poultry compartments) granted disease-free status for HPAI and NDV should fulfil several specific requirements, notably a detailed description of the poultry compartment, a targeted common biosecurity management system, and protection and surveillance systems tailored to address the risk of the introduction into the poultry compartment of those two category A diseases. Such specific technical and detailed requirements should be laid down in this Regulation.

(12) The rules laid down in this Regulation for the approval of the disease-free status for category A diseases of compartments keeping terrestrial animals differ from the rules in force before the date of application of Regulation (EU) 2016/429. In the case of terrestrial animals, the use of poultry compartments was permitted under Council Directive 2005/94/EC ([4]), with regard to avian influenza. Compartments that had been approved in accordance with that Directive and Commission Regulation (EC) No 616/2009 ([5]), which have both now been repealed, are deemed to still have an approved disease-free status for HPAI, on the basis of the transitional provisions laid down in

([4]) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16, ELI: http://data.europa.eu/eli/dir/2005/94/oj).

([5]) 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 (OJ L 181, 14.7.2009, p. 16, ELI: http://data.europa.eu/eli/reg/2009/616/oj).

Article 280(3) of Regulation (EU) 2016/429, and in Article 84(2), point (a), of Commission Delegated Regulation (EU) 2020/689 ([6]). Those compartments of the Member States that are recognised as being free from HPAI are listed in Annex XI to Commission Implementing Regulation (EU) 2021/620 ([7]). That disease-free status should be maintained for the time necessary for operators to apply for approval of the disease-free status for compartments in accordance with this Regulation. Therefore, appropriate transitional rules should be laid down to ensure a smooth transition for the existing recognised disease-free status of poultry compartments that are listed in Annex XI to Implementing Regulation (EU) 2021/620,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules supplementing those laid down in Article 37(1) of Regulation (EU) 2016/429 as regards the requirements and procedures for the approval by the competent authority of the disease-free status, for listed diseases referred to in Article 9(1), point (a), of that Regulation (category A diseases), of compartments keeping terrestrial animals.

2. Chapter II of this Regulation lays down the following requirements and procedures for the approval of the disease-free status of compartments keeping terrestrial animals referred to in Article 37(1) of Regulation (EU) 2016/429:

(a) general requirements for granting disease-free status to such compartments;

(b) responsibilities and duties of the operators and the compartment managers of such compartments;

(c) common biosecurity management systems for such compartments;

(d) procedures for the approval by the competent authority of the disease-free status of such compartments, including for compartments that are located in the territory of more than one Member State.

3. Chapter III of this Regulation lays down specific requirements for the approval of the disease-free status of compartments keeping terrestrial animals as regards the category A diseases listed in Annex II to Implementing Regulation (EU) 2020/690 for the relevant listed species and categories of animals.

Article 2

Definitions

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

(1) 'biosecurity plan' means a plan that identifies potential pathways for the introduction and spread of disease in an establishment, and describes the biosecurity to be applied to mitigate the risks of specific disease introduction and spread;

([6]) Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211, ELI: http://data.europa.eu/eli/reg_del/2020/689/oj).

([7]) Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases (OJ L 131, 16.4.2021, p. 78, ELI: http://data.europa.eu/eli/reg_impl/2021/620/oj).

(2) 'common biosecurity management system' means the common rules governing the functioning of a compartment designed to ensure the disease-free status of all establishments forming part of it; it includes the functional relations between all the compartment components and the overall biosecurity measures implemented in the establishments, in accordance with their biosecurity plans;

(3) 'compartment manager' means an appointed person responsible for the common biosecurity management system of the compartment;

(4) 'compartment component' means any establishment forming part of the compartment or any premises, food or feed business, animal by-products establishments or other plants belonging to the compartment;

(5) 'all involved parties' means the operator of the compartment, the compartment manager and food and feed business operators, animal professionals, transporters, veterinarians, pharmaceutical producers or retailers, or operators of other industries providing services for, delivering animals, products or other commodities to, or receiving animals, products or other commodities from, the compartment;

(6) 'early warning system' means a system for the timely detection, reporting and communication of the occurrence, incursion or emergence of category A diseases.

CHAPTER II

REQUIREMENTS AND PROCEDURES FOR THE APPROVAL OF DISEASE-FREE STATUS FOR CATEGORY A DISEASES OF COMPARTMENTS KEEPING TERRESTRIAL ANIMALS

Article 3

Requirements for granting disease-free status for category A diseases to compartments keeping terrestrial animals

1. Operators that apply to the competent authority for approval of the disease-free status for a category A disease of a compartment keeping terrestrial animals shall ensure that:

(a) the surveillance in the compartment for the category A disease complies with:

  (i) the requirements on the design of surveillance laid down in Article 3(1) of Delegated Regulation (EU) 2020/689;

  (ii) the specific surveillance requirements laid down in Chapter III of this Regulation;

(b) the biosecurity measures in place in the compartment comply with:

  (i) the requirements laid down in Article 10 of Regulation (EU) 2016/429;

  (ii) the specific biosecurity requirements laid down in Chapter III of this Regulation;

(c) establishments forming part of the compartment:

  (i) are approved in accordance with Article 94(1), points (b) to (e), of Regulation (EU) 2016/429; and

  (ii) comply with Article 97(1) of Regulation (EU) 2016/429;

(d) establishments forming part of the compartment are not:

  (i) establishments keeping:

    — free-range animals;

    — more than one animal species in the same epidemiological unit;

  (ii) establishments for assembly operations, markets, exhibition places, fairs, animal shelters, confined establishments, zoos, and wildlife sanctuaries.

2. Operators that apply to the competent authority for approval of the disease-free status for a category A disease of a compartment keeping terrestrial animals shall appoint an appropriately qualified compartment manager who shall ensure:

(a) compliance with the requirements set out in Part I of Annex I;

(b) that all establishments forming part of the compartment, as well as all other compartment components, are managed under a common biosecurity management system, which complies with the requirements set out in Part II of Annex I;

(c) that all involved parties comply with the requirements of the common biosecurity management system.

Article 4

Applications for approval of disease-free status for category A diseases of compartments keeping terrestrial animals

1. Operators applying to the competent authority for approval of the disease-free status for a category A disease of a compartment keeping terrestrial animals shall submit an application for approval to the competent authority that contains the following information:

(a) the information required by Article 96(1) of Regulation (EU) 2016/429 for establishments;

(b) the information referred to in Part III of Annex I to this Regulation.

2. Operators of compartments keeping terrestrial animals shall not submit an application for approval of the disease-free status of a compartment for a category A disease, provided for in paragraph 1, while the compartment or any component thereof is situated in a restricted zone for the category A disease.

Article 5

Granting approval of disease-free status for a category A disease of a compartment keeping terrestrial animals

1. The competent authority shall only grant approval of a disease-free status for a category A disease of a compartment keeping terrestrial animals subject to compliance with the following conditions:

(a) none of the compartment components are situated in a restricted zone or restricted zones for the category A disease;

(b) the information required in accordance with Article 96(1) of Regulation (EU) 2016/429 and referred to in Part II of Annex I to this Regulation, regarding disease surveillance demonstrating the absence of the category A disease, is complete, up-to-date and accurate;

(c) the compartment manager has checked that the common biosecurity management system is in place and is sufficient to ensure a distinct health status, through documented internal and external audits referred to in Part I, point (d), of Annex I;

(d) the procedure for granting approval by the competent authority laid down in Article 99 of Regulation (EU) 2016/429 has been completed, including an on-site inspection by the competent authority or a delegated body to verify compliance with the requirements laid down in Article 3 of this Regulation, and the requirements laid down in points (a), (b) and (c) of this paragraph.

2. Where at least one component of the compartment is situated in the territory of another Member State, the competent authority to which the application was submitted shall liaise with the competent authority of the other Member State to ensure verification of compliance with the conditions referred to in paragraph 1, point (d).

3. The competent authority shall:

(a) keep registers of approved compartments and their approval files in accordance with the procedure laid down in Article 101 of Regulation (EU) 2016/429;

(b) report to the Commission without delay of any modifications in the components or the animal health status of compartments already recognised by the Commission.

Article 6

Review, suspension and withdrawal of approval of disease-free status of compartments keeping terrestrial animals

1. The competent authority shall check that the compartment continues to comply with the conditions for approval, as laid down in Article 5(1), point (d), at appropriate intervals based on the assessment of the epidemiological situation in the area where the compartment components are situated and based on documents and information received from the compartment manager as set out in Part I, points (f) and (g), of Annex I.

2. The competent authority shall suspend or withdraw approval of disease-free status of compartments keeping terrestrial animals in accordance with the rules laid down in Article 100 of Regulation (EU) 2016/429 and Article 82 of Delegated Regulation (EU) 2020/689.

3. When the competent authority suspends the approval of the disease-free status of a compartment keeping terrestrial animals because it no longer complies with the information submitted in accordance with Article 5(1), points (b) and (c), the compartment approval shall be restored once corrective actions have been verified as effective by the competent authority.

4. The competent authority shall withdraw the approval of disease-free status of a compartment keeping terrestrial animals in the case of an outbreak, within a component of that compartment, of the category A disease for which the disease-free status was granted.

5. When the approval of the disease-free status of a compartment has been withdrawn as provided for in paragraph 4 of this Article, the disease-free status may only be restored following a new application in accordance with Article 4.

CHAPTER III

SPECIFIC REQUIREMENTS FOR THE APPROVAL OF THE DISEASE-FREE STATUS OF COMPARTMENTS KEEPING TERRESTIAL ANIMALS AS REGARDS CATEGORY A DISEASES LISTED IN ANNEX II TO IMPLEMENTING REGULATION (EU) 2020/690

Article 7

Specific requirements related to category A diseases listed in Annex II to Implementing Regulation (EU) 2020/690 for compartments of the relevant listed species and categories of terrestrial animals

1. In addition to the information referred to in Part III of Annex I, applications for approval of disease-free status for highly pathogenic avian influenza (HPAI) of poultry compartments shall contain the following:

(a) a detailed description of the poultry compartment, as set out in Part I, Section 1, of Annex II;

(b) a detailed description of the common biosecurity management system of the poultry compartment, as set out in Part I, Section 2, of Annex II;

(c) a detailed description of the protection and surveillance measures, as set out in Part II, Section 1, of Annex II.

2. In addition to the information referred to in Part III of Annex I, applications for the approval of the disease-free status for infection with Newcastle disease virus (NDV) for poultry compartments shall contain the following:

(a) a detailed description of the poultry compartment, as set out in Part I, Section 1, of Annex II;

(b) a detailed description of the common biosecurity management system of the poultry compartment, as set out in Part I, Section 2, of Annex II;

(c) a detailed description of the protection and surveillance measures, as set out in Part II, Section 2, of Annex II.

CHAPTER IV

TRANSITIONAL AND FINAL PROVISIONS

Article 8

Transitional provisions

Poultry compartments that have been approved in relation to avian influenza in accordance with Regulation (EC) No 616/2009 and that are listed as free from HPAI in Annex XI to Implementing Regulation (EU) 2021/620, shall continue to have their disease-free status with respect to HPAI maintained after the date of entry into force of this Regulation.

Operators of those poultry compartments shall apply for approval of disease-free status for HPAI in accordance with Article 4 of this Regulation within a period of 12 months from that date, or the competent authority shall withdraw their approval at the end of that period.

Article 9

Entry into force

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

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

Done at Brussels, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

REQUIREMENTS FOR THE APPROVAL OF DISEASE-FREE STATUS FOR CATEGORY A DISEASES OF COMPARTMENTS KEEPING TERRESTRIAL ANIMALS

PART I

COMPARTMENT MANAGER

The compartment manager referred to in Article 3(2) shall:

(a) supervise and monitor the activities of the compartment in relation to its health status;

(b) compile the necessary documentation for the application by the operator for approval of the disease-free status of the compartment as referred to in Article 4;

(c) ensure that the compartment complies with the following requirements:

  (i) the common biosecurity management system is in place, which includes each biosecurity plan of the establishments forming part of the compartment;

  (ii) movements of animal and animal products into, within and out of the compartment can be traced;

  (iii) surveillance (including a surveillance plan, an early warning system, sampling schemes, and adaptation of the surveillance plan to the risk of introduction of disease and to the analysis of laboratory results) demonstrates the continuous absence of the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

  (iv) training maintains the necessary competences of the personnel of the compartment for the implementation of the biosecurity measures;

  (v) communication is carried out for the awareness of all involved parties to the risk of introduction of the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

(d) ensure regular internal audits by trained personnel, and at least once a year external audits by a contracted third party, to verify compliance with the requirements listed in point (c);

(e) be responsible for validating or refusing the reports of the audits referred to in point (d);

(f) keep the reports of the audits referred to in point (e) available to the competent authority;

(g) ensure that immediate action is taken to correct any non-compliance with the requirements listed in point (c) revealed by the audits referred to in point (d) or by official controls, and keep records of the corrective actions and the verification of their implementation and effectiveness;

(h) keep disease surveillance and biosecurity information and documentation up-to-date, and make them available to the competent authority on request;

(i) inform the competent authority of animal health events, functioning problems, biosecurity breaches, modifications of establishments or of biosecurity or surveillance plans, or any other matter that might affect the approval of the compartment.

PART II

COMMON BIOSECURITY MANAGEMENT SYSTEM OF A COMPARTMENT

The common biosecurity management system of a compartment as referred to in Article 3(2), point (b), shall include at least the following elements:

(a) a description of the general animal health and biosecurity measures applied as provided for in Article 10 of Regulation (EU) 2016/429, which shall include at least the following:

  (i) written procedures for good animal husbandry;

  (ii) physical protection measures of all establishments forming part of the compartment and other compartment components, adapted to their situation and their relations with one another;

(iii) general measures applied to minimise the risk of the introduction and spread of diseases, adapted to the species and categories of kept terrestrial animals, to the products and to the type of production;

(iv) specific management measures to avoid the entry, establishment and spread into, within and from the compartment, of the category A disease(s) for which an application for approval of disease-free status of the compartment has been made;

(b) a plan for equipment and human resources allocated to biosecurity management, including a training plan for the animal professionals and other personnel of the compartment to have the necessary knowledge of animal health, especially in relation with the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

(c) awareness activities, which shall include all involved parties;

(d) a documented implementation system of a plan for staff hygiene, including general and specific hygienic practices, general and specific training for permanent and temporary staff and the procedure for control of that hygiene plan;

(e) a risk analysis for each of the category A diseases for which an application for approval of the disease-free status of the compartment has been made, and the related terrestrial animal species and categories, which shall be documented and available to the competent authority, and shall:

(i) include the identification of the agents of those category A diseases, the assessment of the risk of their entry, establishment and spread in the compartment, the measures to reduce the risk, and the risk communication among all involved parties;

(ii) consider internal and external risks; the risks shall be regularly re-assessed, especially external risks when outbreaks of one or more of those category A diseases occur in the Member State where compartment components are located;

(iii) take into consideration identified pathways and risk factors related to those category A diseases;

(iv) propose risk management options that are adaptable to the level of risk and describe actions to be taken in the case of increased risk, such as an enhanced level of confinement or a higher frequency of sampling;

(f) a traceability system able to follow the movements of the animals of the compartment during all stages of their life within the compartment, and document all the movements of these animals and their products between the establishments forming part of the compartment, as well as their place of origin when entering the compartment and their destination when leaving the compartment;

(g) a documentation system for all inputs and outputs of goods and services from and to each compartment component;

(h) the specific biosecurity plans of the establishments forming part of the compartment, with an evaluation of their implementation and effectiveness against the category A disease(s) for which the application for approval of the disease-free status has been made; the biosecurity plans shall be updated taking account of the assessed risks referred to in point (e), shall indicate whether vaccination against the category A disease(s) for which the application for approval of the disease-free status has been made is carried out or not, with a description of the related vaccination schemes, and shall include emergency plans to respond to major biosecurity breaches, including suspicions or cases of category A disease(s) for which the application for approval of the disease-free status has been made;

(i) a plan regulating and recording the movements of any person entering or leaving the establishments forming part of the compartment, distinguishing authorised and non-authorised persons or visitors, including a description of the physical barriers that clearly define the perimeters of the premises of those establishments, and of signs, locked gates and entrances to buildings; external visitors, including auditors or inspectors, must not have had any contact with animals susceptible to the category A disease(s) for which an application for approval of the disease-free status has been made, for a defined period of time before entering one of those establishments;

(j) a plan regulating and recording the movements of any vehicles into, out of or between the establishments forming part of the compartment, including private and delivery vehicles for animals, feed, equipment or other supplies;

(k) a description of all critical points and possible breaches in biosecurity, and whether a particular breach is to be considered as a minor or major breach;

(l) a description of the corrective actions to be taken, and the measures to assess the implementation of the corrective actions;

(m) the procedures to inform the competent authority of animal health events, functioning problems, biosecurity breaches, modifications of compartment components or plans, or any other matter that might affect the approval of the disease-free status of the compartment.

PART III

DESCRIPTION OF A COMPARTMENT

In addition to the information required by Article 96(1) of Regulation (EU) 2016/429 for establishments, applications for approval of disease-free status as referred to in Article 4 of this Regulation shall include the following information:

(a) the name of the compartment manager, the compartment manager's qualifications and position, contact details and the address of the compartment;

(b) a detailed description of the compartment including all its components, including the following:

  (i) site map(s) showing the compartment demarcations and the precise location of all the establishments forming part of the compartment and other compartment components;

  (ii) a flow chart clearly indicating in detail all activities carried out in the compartment, and the responsibilities, roles and interrelations of all involved parties;

  (iii) the functional interactions between the establishments forming part of the compartment, and between those establishments and other compartment components, including a diagram of all premises showing their links to one another;

  (iv) the means of transport for terrestrial animals and products belonging to the compartment, their usual routes, and cleaning and parking places;

(c) a description of the common biosecurity management system;

(d) the biosecurity plans of all the establishments forming part of the compartment;

(e) the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made, and detailed information on the specific measures, criteria and requirements for risk-based disease surveillance intended to demonstrate the disease-free status of the compartment;

(f) results of the surveillance demonstrating the absence of the category A disease(s) referred to in point (e) for a period of at least the preceding six months prior to the date of the application for approval of the disease-free status.

ANNEX II

SPECIFIC REQUIREMENTS FOR THE APPROVAL OF DISEASE-FREE STATUS FOR HPAI OR NDV OF POULTRY COMPARTMENTS

PART I

SECTION 1

Detailed description of the poultry compartment to be included in the application

1. The description of the compartment as provided for in Part III of Annex I shall contain details of the types of poultry establishments forming part of the compartment, as well as of the feed processing or feed storage facilities, other material storage facilities, slaughterhouses and processing plants and any other plants that may contain poultry, poultry products and poultry by-products.

2. In addition, the application for approval of the disease-free status of a poultry compartment shall include at least the following:

(a) information on the infrastructural and functional factors and their contribution to an epidemiological separation between the poultry in the compartment and animal populations with a different health status, which must include a description of the type of activity and the products or other commodities produced in the compartment, including the total capacities of the compartment;

(b) information on the epidemiological aspects and the risk factors regarding HPAI or NDV, including at least the following elements:

(i) the health status of the establishments forming part of the poultry compartment for the preceding 12 months, and in particular any information in relation to HPAI or NDV;

(ii) the allowed movements into, out of, or within the poultry compartment (inputs and outputs), of persons, products or other commodities, birds or bird products or other animals, products of animal origin or other products in contact with animals, transport vehicles, equipment, animal feed, water supply and drainage;

(iii) poultry or captive birds establishments outside the poultry compartment that may affect the health status of the poultry compartment because of their proximity to one or more of the compartment components; the risk factors shall also be evaluated in relation with the type of those establishments, including non-commercial establishments, markets, assembly centres, slaughterhouses, zoos or other premises containing captive birds;

(iv) the environmental risk factors such as waterways, wildlife resting and mixing places, including migratory routes of wild birds, the presence of rodents or other pests, and the occurrence in the preceding 12 months of HPAI or NDV in the vicinity of any of the poultry compartment components;

(v) the specific risk factors and pathways for the entry and spread of HPAI or NDV in the poultry compartment;

(c) information on the early warning system in place to detect HPAI or NDV and to inform the competent authority of findings of risk factors and pathways as referred to in point (b).

SECTION 2

Common biosecurity management system of a poultry compartment

1. In addition to the elements set out in Part II of Annex I, under the common biosecurity management system, the specific biosecurity plans of each of the poultry establishments forming part of a poultry compartment shall include at least the following:

(a) a rule that the personnel of the poultry compartment shall:

(i) not personally keep poultry or captive birds;

(ii) not have close contact with birds other than those of the poultry compartment for a period of at least 72 hours before entering an establishment; however, a shorter period may be required in the case of the urgent need of specific staff, but it shall in no event be less than 24 hours and the procedure mitigating the risk shall be described in the biosecurity plan;

(b) a rule that external visitors, including auditors or inspectors, must not have had any contact with birds for a period of at least 48 hours before entering the establishment; however, a longer period may be required depending on risk factors, especially for visitors coming from a restricted zone; and a shorter period may be required for official veterinarians or in the case of urgent need of external specific intervention, such as a consultant or veterinarian, in which case the procedure mitigating the risk shall be described in the biosecurity plan;

(c) the flows of products and personnel, described on a diagram of all the premises of the establishment with colour-coded levels of biosecurity; there shall be hygiene barriers with changing zones, including where appropriate showers, with separated clean and dirty areas at all entry points to the premises;

(d) specific procedures to prevent contamination of poultry, including contamination through the supply, transportation, storage, delivery and disposal of:

(i) packing materials, including at least the use of new or disinfected packing materials;

(ii) bedding materials, including at least an appropriate storage quarantine time or a disinfection of bedding materials;

(iii) feed, including the use of enclosed systems of feed;

(iv) water, including an internal water treatment system;

(v) animal by-products, including appropriate disposal of carcases, eggs containing dead embryos and manure;

(e) a cleaning and disinfection plan of the establishment, including equipment and materials used; a specific protocol for vehicle cleaning and disinfection shall be available;

(f) a pest control plan, including rodents and other wild animals, providing for physical barriers and measures in the case of findings of their activity;

(g) a critical control points plan, relating to HPAI or NDV, which shall include at least the following elements, ongoing and for the preceding six months:

(i) data on the production, data on morbidity and mortality, details of medications used, and 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, including frequencies, methods and results;

(iii) a register of visitors to the establishment, 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 related critical control points not complied with, and the corrective actions performed.

2. The specific biosecurity plans of the establishments forming part of a poultry compartment shall be updated in accordance with Part II, point (h), of Annex I, in particular where an outbreak of HPAI or NDV is officially suspected or confirmed in the Member State or in the area where one or more of the compartment components are situated.

PART II

SECTION 1

Specific protection and surveillance measures for HPAI

1. All the establishments forming part of the poultry compartment shall be approved in accordance with Article 3(1), point (c)(i), of this Regulation, and comply with the requirements for granting approval of hatcheries laid down in Article 7 of Commission Delegated Regulation (EU) 2019/2035 [1] or the requirements for granting approval of establishments keeping poultry laid down in Article 8 thereof. In addition, the following requirements shall be complied with:

(a) the diagram referred to in Part III, point (b)(iii), of Annex I to this Regulation shall indicate the location of the establishments keeping all types of poultry, as well as hatcheries, rearing sites, laying sites, trial sites, egg stores and all places where eggs or poultry are kept; it shall indicate the flows of products and other commodities between those locations;

(b) a detailed procedure shall regulate the movements of poultry, their eggs and other related products; poultry, their eggs and other related products entering any establishment forming part of the poultry compartment shall come from an establishment having a disease-free status as regards HPAI and be checked to ensure that they present no risk of introduction of HPAI;

(c) poultry and hatching eggs moved into or within the poultry compartment shall be identified in such a way that they can be traced, and be accompanied with the proper documented identification;

(d) in the case of a multi-age site or in other cases where poultry are added at different times of the life span of poultry, a written procedure shall describe the addition and removal of poultry, including the cleaning and disinfection of catching crates and reusable transport boxes.

2. The surveillance referred to in Part I, point (c)(iii), of Annex I, shall be established under the responsibility of the compartment manager, and shall include continuous passive and active surveillance to demonstrate the absence of infection in all establishments forming part of the poultry compartment. In addition, the following requirements shall be complied with:

(a) the passive surveillance shall contain clinical indicators and describe related follow-up investigations, including sampling for laboratory testing;

(b) the active surveillance shall contain testing carried out on a defined number of samples taken from birds of each establishment, or epidemiological unit if more than one per establishment, providing at least a 95 % level of confidence to detect the infection at a target prevalence rate of 5 %:

  (i) at least every six months during the production period, where no outbreaks of HPAI in poultry or other captive birds, have been confirmed during the preceding six months in the territory of the Member State;

  (ii) 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;

  (iii) when any component of the poultry compartment is located within a restricted zone due to an outbreak of HPAI, within one week following the date of the outbreak and at least every 28 days thereafter; in addition, the surveillance shall be updated to include daily clinical examination as well as samples taken weekly on a representative number of birds sick or found dead, for molecular virological testing.

[1] Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115, ELI: http://data.europa.eu/eli/reg_del/2019/2035/oj).

(c) The samples shall be sent to a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council ([2]) by the competent authority to carry out the tests, taking into account the vaccination status of the birds and the types of vaccines used.

3. The early warning system referred to in Section 1, point 2(c), of Part I, shall be based upon a written protocol that specifies the reporting procedures. It shall be adapted to the species of poultry present in the compartment and their susceptibility to HPAI, and it shall:

(a) prescribe action levels based on results and defined thresholds of the passive and active surveillance described in point 2;

(b) describe the actions to be taken;

(c) include a list of the responsible personnel to be notified.

4. Documentation referred to in Part I, point (h), of Annex I shall:

(a) be retained for a minimum period of three years;

(b) contain the results of the disease surveillance, which shall be reported to the competent authority:

(i) every three months when an outbreak of HPAI in poultry or captive birds has been confirmed during the preceding six months in the territory of the Member State;

(ii) every 28 days when any compartment component is located within a restricted zone due to an outbreak of HPAI.

SECTION 2

Specific protection and surveillance measures for NDV

1. All the establishments forming part of the poultry compartment shall be approved in accordance with Article 3(1), point (c), of this Regulation and comply with the requirements for granting approval of hatcheries laid down in Article 7 of Delegated Regulation (EU) 2019/2035 or the requirements for granting approval of establishments keeping poultry laid down in Article 8, thereof. In addition:

(a) the diagram referred to in Part III, point (b)(iii), of Annex I to this Regulation, shall indicate the location of the establishments keeping all types of poultry, as well as hatcheries, rearing sites, laying sites, trial sites, egg stores and all places where eggs or poultry are kept; it shall indicate the flows of products and other commodities between those locations;

(b) a detailed procedure shall regulate the movements of poultry, their eggs and other related products; poultry, their eggs and other related products entering any establishment forming part of the poultry compartment shall come from an establishment where there are no outbreaks or restrictions due to outbreaks of NDV and be checked to ensure that they present no risk of introduction of NDV;

(c) poultry and hatching eggs moved into or within the poultry compartment shall be identified in such a way that they can be traced, and be accompanied with the proper documented identification;

(d) in the case of a multi-age site or in other cases where poultry are added at different times of the life span of poultry, a written procedure shall describe the addition and removal of poultry, including the cleaning and disinfection of catching crates and reusable transport boxes.

([2]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj).

2. The surveillance referred to in Part I, point (c)(iii), of Annex I shall be established under the responsibility of the compartment manager and shall include continuous passive and active surveillance to demonstrate absence of infection in all establishments forming part of the poultry compartment:

(a) the passive surveillance shall contain clinical indicators and describe related follow-up investigation, including sampling for laboratory testing;

(b) the active surveillance shall contain testing carried out on a defined number of samples taken from birds of each establishment, or epidemiological unit if more than one per establishment, providing at least a 95 % level of confidence to detect the infection at a target prevalence rate of 5 %:

  (i) at least every six months during the production period, where no outbreaks of NDV in poultry or other captive birds, have been confirmed during the preceding six months in the territory of the Member State;

  (ii) at least every three months where an outbreak of NDV in poultry or other captive birds, has been confirmed during the preceding six months in the territory of the Member State;

  (iii) when any component of the poultry compartment is located within a restricted zone due to an outbreak of NDV within one week following the date of the outbreak and at least every 28 days thereafter; in addition, the surveillance shall be updated to include daily clinical examination as well as samples taken weekly on a representative number of birds sick or found dead for molecular virological testing;

(c) the samples shall be sent to a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 by the competent authority to carry out the tests, taking into account the vaccination status of the birds and the types of vaccines used.

3. The early warning system referred to in Section 1, point 2(c), of Part I, shall be based upon a written protocol that specifies the reporting procedures. It shall be adapted to the species of poultry present in the poultry compartment and their susceptibility to NDV, and it shall:

(a) prescribe action levels, based on results and defined thresholds of the passive and active surveillance described in point 2;

(b) describe the actions to be taken;

(c) include a list of the responsible personnel to be notified.

4. Documentation referred to in Part I, point (h), of Annex I shall:

(a) be retained for a minimum period of three years;

(b) contain the results of the disease surveillance, which shall be reported to the competent authority:

  (i) every three months when an outbreak of NDV in poultry or captive birds, has been confirmed during the preceding six months in the territory of the Member State;

  (ii) every 28 days when any compartment component is located within a restricted zone due to an outbreak of NDV.