



Brussels, 30.7.2024
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COMMISSION DELEGATED REGULATION (EU) .../...

of 30.7.2024

**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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2016/429 of the European Parliament and of the Council¹ lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans. It provides, amongst other things, for the approval and recognition of the disease-free status of compartments for listed diseases, and for the protection of the disease-free status of such compartments compared to the rest of the territory of a Member State in the event of an outbreak of one or more of those listed diseases. A compartment in this case means an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status.

Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts supplementing the rules in that respect laid down in Article 37 of that Regulation.

The rules laid down in this Delegated Regulation supplement Article 37 of Regulation (EU) 2016/429 by providing for general rules for the approval of the disease-free status of compartments keeping terrestrial animals in the Member States, and specific requirements for the approval of the animal health status of compartments keeping poultry as regards highly pathogenic avian influenza and infection with Newcastle disease virus.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission had several meetings and exchanges with the Expert Group on animal health. The draft delegated regulation was also made available to the European Parliament and to the Council, with neither institution making any comments. Meetings were held with a range of stakeholders as part of the Animal Health Advisory Committee, in which the main elements of the draft delegated regulation were illustrated and discussed.

In addition, stakeholders' comments on the draft delegated regulation were collected in the context of the Better Regulation feedback mechanism during the period between 30 April 2024 and 28 May 2024. During that period the Commission received twelve feedbacks, five from EU citizens, four from business associations, one from non-governmental organisations, one from a company and one from a third country. The Commission has analysed the contributions and modified the draft to address better the qualifications of compartment manager and certain aspects of common biosecurity management scheme.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2016/429, and in particular Article 37(5) thereof.

¹ 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 ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>).

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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 Code² 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.

¹ 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 (‘Animal Health Law’) (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/>

- (5) Article 2 of Commission Implementing Regulation (EU) 2020/690³ 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.
- (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 diseases due 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

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).

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 Directive 2005/94/EC⁴, with regard to avian influenza. Compartments that had been approved in accordance with that Directive and Commission Regulation (EC) No 616/2009⁵, 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 Article 280(3) of Regulation (EU) 2016/429, and in Article 84(2), point (a), of Commission Delegated Regulation (EU) 2020/689⁶. Those compartments of the Member States that are recognised as being free from HPAI are listed in Annex XI to Commission Implementing Regulation (EU) 2021/620⁷. 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,

⁴ 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>).

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).

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;
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 1, 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 Commission 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 TERRESTRIAL 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) 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, 30.7.2024

For the Commission
The President
Ursula VON DER LEYEN