

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.



Brussels, **XXX**
PLAN/1113/2023 CIS
(POOL/G2/2023/1113/1113-EN
CIS.docx)
[...] (2023) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

**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)

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2016/429 of the European Parliament and of the Council ¹ 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 recognition of the disease-free status of compartments for major animal diseases, and for the protection of the disease-free status of such compartments compared to the rest of the territory of the Member State in the event of an outbreak of one or more of 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 on that field laid down in that Regulation.

The rules laid down in this Regulation supplement Article of 37 Regulation (EU) 2016/429 by providing for general rules for the approval of compartments for terrestrial animals in the Member States, and specific rules and conditions for the recognition of the animal health status of compartments for poultry only, 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 (E00930). The draft delegated Regulation was also made available to the European Parliament and 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 [xx month] 2024 [to be supplemented].

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>).

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

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 the 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 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 granting disease-free status to compartments keeping terrestrial animals for category A diseases are laid down in Article 37(1) of Regulation (EU) 2016/429, detailed requirements should be laid down in this Regulation concerning detailed requirements and rules for the approval by the competent authority of compartments keeping terrestrial animals, and specific requirements for granting disease-free status to compartments for those listed diseases of terrestrial animals that are referred to in Article 2 of Commission Implementing Regulation (EU) 2020/690 that determines for which listed diseases the disease-free status of compartments may

¹ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases (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/>

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

be established³. These diseases are highly pathogenic avian influenza and infection with Newcastle disease virus.

- (4) For the approval of compartments keeping terrestrial animals by the competent authority, the rules laid down in this Regulation should not only include general requirements for granting disease-free status to the compartments, but also the responsibilities and duties of the compartment manager, requirements for a common biosecurity management system, detailed rules for the approval by the competent authority as well as certain rules for compartments which are located in the territory of more than one Member State.
- (5) In addition, to cover all the measures that prevent introduction and spread of category A diseases in a compartment keeping terrestrial animals, and to ensure the safe use of approved compartments for the control of those 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 the establishments that cannot have strict biosecurity measures in place cannot be part of a compartment.
- (6) Establishing and maintaining specific disease-free compartments 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 when the disease might be present in the area surrounding the compartment. Therefore, the strictest biosecurity measures should apply to the compartments with the same level in all their components, which can only be achieved through a common biosecurity management system. Such a system requires strict management and therefore each compartment should appoint for that purpose a responsible person, a compartment manager with defined tasks and responsibilities as provided for in this Regulation.
- (7) Operators applying to the competent authority for the approval of the disease-free status of compartments with respect to category A diseases of terrestrial animals should be aware of the procedure for such applications. It is therefore necessary to lay down such rules in this Regulation.
- (8) Although 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 described in Article 94(1), point (e), thereof, which include compartments, certain detailed procedures for the competent authority to approve, suspend and withdraw the disease-free status of compartments should be laid down in this Regulation. This is due to the impossibility to establish, maintain and verify effective biosecurity plans when the disease from which the compartment is expected to be free is still occurring in the area surrounding the compartment, as well as to the differences in terms of animal disease risk between breaches in those biosecurity plans and the actual occurrence of the disease of concern in the compartment.

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),

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

- (9) Compartments granted disease-free status for highly pathogenic avian influenza and infection with Newcastle disease virus in poultry 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 introduction into the compartment of each of the two diseases. Such specific technical and detailed requirements should be laid down in this Regulation.
- (10) This Regulation should lay down rules on the approval of the disease-free status of compartments of terrestrial animals, which 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 repealed Directive 2005/94/EC⁴, with regard to avian influenza. Compartments that had been approved in accordance with that Directive and the repealed Commission Regulation (EC) No 616/2009⁵ have been deemed to still have an approved disease-free status for highly pathogenic avian influenza, on the basis of Article 280(3) of Regulation (EU) 2016/429, and of Article 84(2), point (a), of Commission Delegated Regulation (EU) 2020/689⁶. These compartments have been listed as such in Commission Implementing Regulation (EU) 2021/620⁷, and should have their disease-free status maintained for the time necessary to re-apply in accordance with this Regulation. Therefore, appropriate transitional rules should be laid down to ensure a smooth transition for the existing recognised poultry compartments that are listed in Annex XI of 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).

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

HAS ADOPTED THIS REGULATION:

Chapter I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation supplements the rules as regards the requirements for the recognition of disease-free status of compartments keeping terrestrial animals for listed diseases referred to in Article 9(1), point (a), of Regulation (EU) 2016/429 ('category A diseases') and for the approval of such compartments by the competent authority.
2. Chapter II of this Regulation lays down the following requirements and rules for the recognition of the disease-free status of compartments keeping terrestrial animals referred to in Article 37(1) of Regulation (EU) 2016/429:
 - (i) general requirements for granting disease-free status to compartments keeping terrestrial animals for category A diseases;
 - (ii) responsibilities and duties of the compartment manager;
 - (iii) common biosecurity management system for those compartments;
 - (iv) detailed rules for the approval by the competent authority of the disease-free status of those compartments, including for cross-border compartments.
3. Chapter III of this Regulation lays down specific conditions and requirements for the recognition of disease-free status of compartments from 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) 'category A disease' means a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in Article 9(1), point (a), of Regulation (EU) 2016/429;
- (2) '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;
- (3) '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, and the functional relations between all the compartment components; it includes the overall biosecurity measures implemented in the establishments, in accordance with their biosecurity plans;
- (4) 'compartment manager' means a person formally responsible for the compartment and its common biosecurity management system;

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

- (5) ‘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;
- (6) ‘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;
- (7) ‘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

GENERAL REQUIREMENTS AND PROCEDURES FOR THE APPROVAL OF DISEASE-FREE STATUS OF COMPARTMENTS KEEPING TERRESTRIAL ANIMALS

Article 3

General requirements for compartments keeping terrestrial animals for category A diseases

Operators of compartments keeping terrestrial animals wishing to apply for a disease-free status in accordance with Article 37(1) of Regulation (EU) 2016/429 shall ensure that all the following requirements are complied with:

- (a) the surveillance for the disease(s) complies with the requirements on the design of surveillance laid down in Article 3(1) of Delegated Regulation (EU) 2020/689, and specific surveillance requirements laid down in Chapter III of this Regulation;
- (b) the biosecurity measures implemented in the compartment comply with the requirements laid down in Article 10 of Regulation (EU) 2016/429, and the specific biosecurity requirements laid down in Chapter III of this Regulation;
- (c) establishments forming part of the compartment are approved in accordance with Article 94(1), points (b) to (e), 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;
- (e) the compartment is managed by a compartment manager who has responsibility over all the compartment components;
- (f) the compartment manager ensures compliance of the compartment with the requirements set out in Part I of Annex I to this Regulation;

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

- (g) the compartment manager ensures 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 III of Annex I to this Regulation;
- (g) the compartment manager ensures that all involved parties comply with the requirements of the common biosecurity management system.

Article 4

Application for the approval of a disease-free compartment keeping terrestrial animals

1. Operators applying to the competent authority for the approval of the disease-free status of a compartment keeping terrestrial animals for one or more category A disease(s) in accordance with Article 37(1) of Regulation (EU) 2016/429, shall submit an application for approval to the competent authority.
2. Operators shall only submit the application referred to in paragraph 1 while no compartment component is situated in a restricted zone for the disease(s) concerned.
3. The application referred to in paragraph 1 of this Article shall contain:
 - (a) the information required by Article 96(1) of Regulation (EU) 2016/429 for establishments; and
 - (b) the information referred to in Part II of Annex I to this Regulation.

Article 5

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

1. The competent authority shall only grant approval of a disease-free status for a compartment keeping terrestrial animals for one or more category A disease(s):
 - (a) when all the compartment components are not situated in a restricted zone or restricted zones for the disease(s) concerned;
 - (b) if 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 the disease surveillance demonstrating the absence of disease, is complete and accurate;
 - (c) if verification that the common biosecurity management system has been in place and has shown to be sufficient to ensure a distinct health status, through documented internal and external audits referred to in Part I point (d) of Annex I to this Regulation;
 - (d) in accordance with the procedure for granting approval by the competent authority laid down in Article 99 of Regulation (EU) 2016/429 including an on-site inspection by the competent authority or a delegated body to verify the compliance with the requirements laid down in Article 3 of this Regulation and effective implementation of the requirements laid down in points (a), (b) and (c) of this paragraph, with favourable results.

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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 as referred to in paragraph 1, point (d).
3. The competent authority shall keep registers of approved compartments and their approval dossiers in accordance with the procedure laid down in Article 101 of Regulation (EU) 2016/429, and report to the Commission without delay of any changes in 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 review the maintenance of the compliance of the conditions for the approval of compartments keeping terrestrial animals, by subsequent inspections as provided for in Article 7(1), point (d), of this Regulation, with a frequency based on the assessment of the epidemiological situation and on information received from the compartment manager as set out in Part I, point (g), of Annex I to this Regulation, which shall be at least once every calendar year.
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 a compartment keeping terrestrial animals because it no longer complies with the information submitted in accordance with Article 5 (1), points (b) and (c) of this Regulation, the compartment approval shall be restored without a formal application as referred to in Article 4 of this regulation, once corrective actions have been verified as effective by the competent authority.
4. The competent authority shall withdraw the disease-free status of a compartment keeping terrestrial animals in the case of an outbreak, within a component of that compartment, of the disease for which the disease-free status has been granted.
5. Following the deletion from the list of approved compartments, the withdrawn approval of that compartment shall only be restored following a new application for approval in accordance with Article 4.

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Chapter III

SPECIFIC REQUIREMENTS

Article 7

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

1. In addition to the information referred to in Part II of Annex I to this Regulation, applications for the approval of a disease-free status for highly pathogenic avian influenza ('HPAI') for compartments of poultry 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 II of Annex I to this Regulation, applications for the approval of a disease-free status for infection with Newcastle disease virus ('NDV') for compartments of poultry 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 10

Poultry compartments that have been approved with respect to avian influenza in accordance with Regulation (EC) 616/2009 and 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 entry into force of this Regulation. Operators of these compartments shall reapply in accordance with Article 4 of this Regulation within a period of 12 months from the date of entry into force of this Regulation, or the compartments shall be delisted by the competent authority.

Article 11

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

This draft has not been adopted or endorsed by the Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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

Done at Brussels,

*For the Commission
The President
Ursula VON DER LEYEN*

DRAFT