EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Commission Delegated Regulation (EU) 2023/361 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

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')[1] lays down rules on transmissible animal diseases. In particular, Chapter 2 of Part III thereof lays down the rules for the use of veterinary medicinal products for disease prevention and control.

The Animal Health Law empowers the Commission to adopt delegated acts supplementing the rules on that field laid down in that Regulation.

Commission Delegated Regulation (EU) 2023/361 of 28.11.2022 supplements Regulation (EU) 2016/429 as regards rules on the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases. It provides among others for detailed and specific rules on the use in the Union of veterinary medicinal products with regard to prevention and control of the listed diseases referred to in Article 9(1)(a) ('category A diseases') of Regulation (EU) 2016/429 in kept and wild terrestrial animals.

This Regulation updates the rules in Commission Delegated Regulation (EU) 2023/361, taking account of newly available scientific knowledge and the experience gained in the application of those rules. It offers new possibilities in, and add clarity and consistency in the requirements for, the use of immunological veterinary medicinal products for disease prevention and control of category A diseases.

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. A number of meetings were held with a range of stakeholders as part of the Animal Health Advisory Committee, in which the main elements of the draft act were illustrated and discussed.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2016/429, and in particular Article 47(1) thereof.

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(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 ('Animal Health Law')[1], and in particular Article 47(1) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases that are transmissible to animals or to humans, including rules on disease awareness, preparedness and control. In particular, Regulation (EU) 2016/429 lays down disease-specific rules for the prevention and control of diseases referred to in its Article 5. Regulation (EU) 2016/429 also provides that those disease-specific rules apply to species and groups of animal species that pose a considerable risk for the spread of specific diseases and that are listed as such in Commission Implementing Regulation (EU) 2018/1882[2].

(2) In accordance with Article 46 of Regulation (EU) 2016/429, Member States may take appropriate and necessary measures concerning the use of veterinary medicinal products for listed diseases to ensure the most efficient prevention and control of those diseases. Certain veterinary medicinal products may interfere in the detection and diagnosis of diseases, and therefore in their prevention and control. This is particularly relevant for those listed diseases that are subject to stricter prevention and control measures in accordance with Regulation (EU) 2016/429. It is necessary to identify the veterinary medicinal products for which supplementing rules need to be developed pursuant to Article 47 of that Regulation and to establish restrictions or prohibitions to their use to ensure safe and effective prevention and control of certain listed diseases.

(3) Implementing Regulation (EU) 2018/1882 lays down the definitions of category A, B, C, D and E diseases, relying on disease prevention and control rules set out in Article

[1] OJ L 84, 31.3.2016, p. 1.

[2] Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases, (OJ L 308, 4.12.2018, p. 21).

9(1) of Regulation (EU) 2016/429. Listed diseases referred to in Article 5 of Regulation (EU) 2016/429 that do not normally occur in the Union and for which immediate eradication measures are to be taken as soon as they are detected ('category A diseases') are subject to specific rules laid down in Article 9(1), point (a), of that Regulation. With a view to prevent the potentially devastating effects of category A diseases on animal health in the Union, it is necessary to harmonise the rules under which Member States may use veterinary medicinal products for the prevention and control of those diseases. Such rules should aim to ensure effective prevention of category A diseases and their immediate eradication in the case of an outbreak, as well as to prevent that the use of the veterinary medicinal products poses a risk for the spread of those diseases.

(4) Commission Delegated Regulation (EU) 2023/361[3] supplements Regulation (EU) 2016/429 as regards rules on the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases. It provides among others for detailed and specific rules on the use in the Union of veterinary medicinal products with regard to prevention and control of the listed diseases referred to in Article 9(1)(a) ('category A diseases') of Regulation (EU) 2016/429 in kept and wild terrestrial animals.

(5) Delegated Regulation (EU) 2023/361 lays down specific conditions for each category A disease for which sufficient experience and data were available at the time of its adoption. For diseases for which sufficient experience and data were not available at the time of its adoption, disease specific measures could not be provided. For some of those diseases [ASF, PPR, SPGP…], recent European Food Safety Authority (EFSA) opinions or the relevant chapters of the WOAH Terrestrial Animal Health Code and WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, have provided sufficient experience and additional data that allow to lay down specific conditions, which should be added to that Regulation.

(6) For CSF and HPAI [and …], recent experience and scientific data, including an EFSA opinion on HPAI [add reference], provided sufficient data to amend and update the specific conditions for those diseases.

(7) During the reviewing of Delegated Regulation (EU) 2023/361, some parts of the text were considered unclear and they should be amended for clarity and consistency [between the articles and the annexes].

(8) After the completion of emergency protective vaccination an exit strategy should enable Member States to demonstrate the absence of infection before the restrictions to movements of animals and their products may be lifted. Such exit strategy should consist of a specific reinforced clinical and laboratory surveillance during a pre-defined waiting period for each specific category A disease. Since there is no free status for category A diseases, this waiting period cannot be called 'recovery period' and the term should be modified to 'waiting period', in the definition, in the articles and in the annexes.

[3] Commission Delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 as regards rules on the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases

(10)

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) ~~2020/687~~2023/361 is amended as follows:

1. In Article 2(1), point (j) is replaced by the following:

'(j) 'waiting period' means the necessary period of time required to demonstrate absence of the category A disease after emergency protective vaccination against the disease has been carried out in a vaccination zone;'

2. In Article 2(1), a new point (t) is added as follows:

'(t) 'flock' means all poultry or captive birds of the same health status kept in the same enclosure and constituting a single epidemiological unit; for in-housed poultry, this means all birds sharing the same airspace.'

~~2~~3. In Article 3, paragraph 2 is replaced by the following:

'2. The conditions for the use of vaccines against category A diseases, laid down in paragraph 1, shall not apply to certain uses of vaccines against infection with Newcastle disease virus, notably to routine precautionary use or to use in the framework of trade, which the Member States may allow irrespectively of the official disease prevention and control measures referred to in paragraph 1, for purposes other than responding to an outbreak;'

~~3~~4. In Article 4, the introduction sentence is replaced by the following:

'Member States shall prohibit the use of the following veterinary medicinal products in animals for the prevention and control of category A and B diseases unless they are used for the prevention and control of the diseases listed in Part 3 of Annex I and their type and use comply with the conditions set out therein:'

~~4~~5. In Article 7(1), point (a)(ii) is replaced by the following:

'(ii) emergency protective vaccination, implemented in response to an outbreak of a category A disease, and carried out in any of the following cases:

– on terrestrial animals at risk of infection that are kept in establishments located in affected Member States or zones thereof, in which category A diseases have not been confirmed nor are suspected in accordance with Article 6(1) and Article 11 of Delegated Regulation (EU) 2020/687;

– in response to a change in the risk of introduction of a category A disease in a non-affected Member State or area thereof;

– on equine animals subject to the derogation provided for in point 1 of Annex III to Delegated Regulation (EU) 2020/687;'

~~5~~6. In Article 7, paragraph 2 is replaced by the following:

'2. The competent authority may implement the strategies referred to in paragraph 1 simultaneously or consecutively in different kept and wild terrestrial animal

populations, in different zones and geographic areas and at different time points throughout an outbreak, and may vary the strategies applied according to the zone or area, species affected or other defining characteristics. In such cases, the competent authority shall include all the strategies applied simultaneously or consecutively in the official vaccination plan after the assessment referred to in Article 5(1), point (a).

When an area where preventive vaccination in accordance with paragraph 1, point (b) is implemented becomes affected by the relevant category A disease and falls under a restricted zone established in accordance with Article 21 of Delegated Regulation (EU) 2020/687, the preventive vaccination plan may continue to be implemented unless the competent authority decide to apply an emergency vaccination to respond to the increased risk.'

~~6~~7. In Article 9(1), point (b)(i) is replaced by the following:

'(i) a vaccination zone, in which vaccination is carried out;'

~~7~~8. In Article 9, paragraph 2 is replaced by the following:

'By way of derogation from paragraph 1, point (b)(ii), the competent authority may decide not to establish the peri-vaccination zone, when implementing emergency protective vaccination in zones where the relevant category A disease has not been suspected or confirmed, or when the whole country is a vaccinated zone, or when implementing emergency vaccination in wild animals,

~~8~~9. In Article 13, the introduction sentence in paragraph 2 is replaced by the following:

'2. By way of derogation from paragraph 1, points (a) and (c), the competent authority may allow movements of vaccinated animals from the establishment where they were vaccinated if:'

~~9~~10. In Article 13(2), point (b) is replaced by the following:

'(b) they are not subject to compulsory killing after vaccination, in accordance with the official vaccination plan referred to in Article 5(1), point (b), and they comply with the relevant conditions and the competent authority has authorised their movement in accordance with the conditions laid down in Part 3, point 3, of Annexes VII to XVIII.'

1~~0~~1. In Article 13, paragraph 3 is replaced by the following:

'3. By way of derogation from paragraph 1, point (a), the competent authority may allow movements of products from vaccinated animals from the production and/or processing establishment if the competent authority has authorised their movement in accordance with the conditions laid down in Part 3, point 3, of Annexes VII to XVIII.'

1~~1~~2. In Article 13, the introduction sentence in paragraph 6 is replaced by the following:

'In vaccination zones situated in a restricted zone in accordance with Delegated Regulation (EU) 2020/687, ~~T~~the restrictions and other risk-mitigating measures provided for in paragraphs 1 and 5 shall apply ~~in the vaccination zones if they are situated in a restricted zone in accordance with Delegated Regulation (EU) 2020/687,~~ in addition to the measures applicable to:'

13. In Article 14(2), point (a) is replaced by the following:

'(a) they are not included in the list of animals and products subject to prohibitions of movements, referred to in Article 13 (1) points (a) and (b);'

1~~4~~2. the title of Article 16 is replaced by the following:

'Waiting periods after emergency protective vaccination'

1~~5~~3. In Article 16, paragraph 1 is replaced by the following:

'1. After the completion of emergency protective vaccination the competent authority shall respect the relevant disease-specific waiting periods provided for in Part 4 of Annexes VII to XVIII, during which Articles 13 to 15 apply and clinical and/or laboratory surveillance demonstrating the absence of infection with the relevant pathogen is conducted in the vaccination and peri-vaccination zones.'

14. In Annex VII, Part 4 is replaced by the following:

'The competent authority shall maintain in the vaccination zone the conditions provided for in part 3 of this Annex until:

Waiting period	Type of surveillance to demonstrate the absence of occurrence of FMD
3 months after the last remaining vaccinated animal in the vaccination zone has been killed or slaughtered, excluding animals referred to in Article 13(2) of Regulation 2020/687	Clinical and laboratory

15. In Annex VIII, Part 1 , paragraph (1) is replaced by the following text:

' 1. Size of the vaccination zone: No specific rules. '

1~~5~~6. In Annex IX, Part 1, paragraph (1), the following point (1.3.~~2~~) is added after ~~paragraph (1),~~ point (1.2):

'1.3.~~2.~~ A Vaccination zone II or part thereof~~,~~, may be converted to a Vaccination zone I provided that all of the following requirements are fulfilled, during a period of at least 14 months :

a. There have been no outbreaks of LSD;

b. Clinical and laboratory (virological and serological) surveillance was carried out for LSD, with negative results;

c. LSD vaccination is implemented, in line with the approved vaccination plan.'

1~~6~~7. In Annex IX, Part 3, paragraph (3.1), the following point (d) is added after point (c):

'(d) any destination located within the same vaccination zone I, provided that all of the following conditions are fulfilled:

(i) the competent authority has ceased all LSD vaccination in the vaccination zone I and has inaugurated a waiting period, in line with Article 16, during which clinical and laboratory (virological and serological) surveillance is carried out for LSD;

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(ii) LSD vaccination has been implemented, in line with the approved vaccination plan, up until the date of inauguration of the waiting period;

(iii) there have been no confirmed outbreaks of LSD within a radius of at least 20 km around the establishment of origin of such consignments for a period of at least three months prior to the date of dispatch;

(iv) a clinical examination was carried out, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;

(v) the competent authority has informed the Commission and the Member States about the cease of LSD vaccination and the inauguration of the waiting period, at least thirty days before the start date of the waiting period.'

18. In Annex IX, part 4, the following sentence is added before the table:

'The competent authority shall maintain in the vaccination zone the conditions provided for in part 3 of this Annex until:'

19. In Annex X, Part 1, paragraph (4) is replaced by the following text:

' 4. Minimum coverage: Vaccine coverage should be at least 95% of the establishments in the vaccination zone representing at least 80% of the targeted animals in the vaccination zone.'

20. In Annex X, part 4, the following sentence is added before the table:

'The competent authority shall maintain in the vaccination zone the conditions provided for in part 3 of this Annex until:'

21. In Annex XI, Part 4 is replaced by the following:

'The competent authority shall maintain in the vaccination zone the conditions provided for in part 3 of this Annex until:

Waiting period	Type of surveillance to be implemented during the waiting period
12 months, since the last animal was vaccinated and 2 years since the last outbreak	Clinical and serological

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~~18~~22. Annex XII is replaced by Annex I to this Regulation;

23. Annex XIII is replaced by Annex II to this Regulation;

~~19~~24. A new Annex XV is added as Annex II to Regulation;

~~20~~25. A new Annex XVI is added by Annex IV~~II~~ to this Regulation;

~~21~~26. A new Annex XVII is added as Annex ~~I~~V to this Regulation;

~~22~~27. A new Annex XVIII is added as Annex VI to this Regulation.

Article 2

Delegated Regulation (EU) 2023/361 is corrected as follows:

1. In Article 9(4), Article 10, (1) and (2), points (a), (b) and (c) of Article 13(1), point (b)(ii) of Article 13(2) , point (b) of Article 13(3), point (b) of Article 13(4), Article 13(5), Article 14(2), Article 16(1) and point (a)(i) of Article 16(2), 'XIV' is replaced by 'XVIII'';
2. In Annexes VII to XI and in Annex XIV, the word 'recovery' is replaced by the word 'waiting';

~~2.~~3.The List of Annexes is replaced by Annex VII to this Regulation.

Article 3
Entry into force

This Regulation shall enter into force twenty days 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,

For the Commission
The President
Ursula VON DER LEYEN

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