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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) ... /... amending and correcting 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

Delegations will find attached document C(2026) 1412 final.

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

of 6.3.2026

amending and correcting 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') 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.

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

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amending and correcting 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)

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)(b) and (c) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2023/361² 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.
- (2) Article 2 of Delegated Regulation (EU) 2023/361 set out definitions of terms used in that Regulation, including that of 'recovery period'. 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 an exit strategy should consist of a specific reinforced clinical and laboratory surveillance during a pre-defined waiting period for each specific category A disease. There is no free status for category A diseases in EU rules, so the term 'recovery period', which refers to the recovery of a free status, should be replaced by 'waiting period'. The definition thereof should be updated and Article 2 amended accordingly, as well as the title and point (1) of Article 16.
- (3) Moreover, the relevant disease-specific Annexes should describe in their Parts 4 respective conditions for this waiting period and not refer to animal health status,

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

² 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 (OJ L 52, 20.2.2023, p. 1, ELI: http://data.europa.eu/eli/reg_del/2023/361/oj).

including status granted by WOA. Therefore, all the disease-specific annexes should be amended accordingly to include this conceptual change.

- (4) Article 4 of Delegated Regulation (EU) 2023/361 lists the veterinary medicinal products prohibited for the prevention and control of category A and B diseases. Part 3 of Annex I lists the diseases for which some specific type of veterinary medicinal products allowed, and the conditions for their use; both the type and the use should comply with this Part 3 of Annex I, and it should be clearly stated in Article 4.
- (5) Article 7 of Delegated Regulation (EU) 2023/361 sets up vaccination strategies for prevention and control of Category A diseases and distinguishes between emergency and preventive vaccination strategies. Return of experience from vaccination plans applied in the field show that emergency protective vaccination may be applied when outbreaks of a listed disease occur in zones where preventive vaccination against that disease is already implemented. In order to avoid misunderstanding, implementation of emergency protective vaccination should be clarified in Article 7, and some explanatory text should be introduced to explain that preventive vaccination plan may continue to be implemented in a restricted zone, unless the competent authority decides to apply emergency vaccination.
- (6) During the review of Delegated Regulation (EU) 2023/361, Article 13 was considered unclear and should be amended for clarity: paragraphs 1 to 4 should not lay down in the detail which animals or products are prohibited and may be moved, and should clearly refer to the relevant parts of the annexes for the details, and paragraph 6 should be clarified to explain better the restrictions in accordance with paragraphs 1 to 5 of that Article, which apply simultaneously with the restricted zones in accordance with Delegated Regulation (EU) 2020/687.
- (7) During the review of Delegated Regulation (EU) 2023/361, it was noted that for clarity, Article 14(2)(a) should include a reference to the Article 13(1) that lists the animals and products subject to prohibition.
- (8) Delegated Regulation (EU) 2023/361 lays down specific conditions, in the respective disease-specific annexes, for each category A disease based on the experience and data that 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.
- (9) For Foot-and-Mouth Disease (FMD), recent outbreaks provided information relevant to the difficulties to use protective vaccination and the necessity to clarify in annex VII that all animals of listed species were concerned by prohibition, how surveillance was to be implemented and according which conditions derogations to prohibition could be granted.
- (10) For Lumpy Skin Disease (LSD), recent field experience and scientific data provided further information and evidence that should be taken into account in annex IX for the conditions related to the vaccination zones, and the related restrictions and waiting period before their lifting.
- (11) For Classical Swine Fever (CSF), up-to-date available scientific data should be used to update the conditions for vaccination of domestic pigs in annex XII and lay down specific conditions for vaccination of wild pigs in a new annex.
- (12) For Highly Pathogenic Avian Influenza (HPAI), recent experience of field implementation of vaccination of poultry, as well as scientific data on vaccination, risk-mitigation and surveillance, including a European Food Safety Authority (EFSA)

scientific opinion , provided sufficient information to amend and update the specific conditions in annex XIII for restrictions, derogations, and surveillance, notably when preventive vaccination is applied.

- (13) For African Swine Fever (ASF), although currently no effective and safe vaccine is available, in view of recent EFSA reports and updated scientific data on vaccines included in the WOAHP Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, new annexes should be added to describe the conditions for use of such vaccines, once available, respectively in domestic and in wild pigs.
- (14) For Sheep Pox and Goat Pox (SPGP), the scientific justifications for the modification of the relevant chapters of the WOAHP Terrestrial Animal Health Code have provided sufficient data to lay down specific conditions in a new annex.
- (15) For consistency between the articles and the Annexes, the numbering should be amended due to additions or deletions of points, and to the addition of new Annexes.
- (16) Finally, editorial errors in Article 3(2) should be corrected,

HAS ADOPTED THIS REGULATION:

Article 1
Amendments

Delegated Regulation (EU) 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 the absence of the category A disease after emergency protective vaccination against the disease has been carried out in a vaccination zone;’
2. In Article 4, the introductory 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.’
3. 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:
 - 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;
 - equine animals subject to the derogation provided for in point 1 of Annex III to Delegated Regulation (EU) 2020/687;’
4. 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 decides to apply an emergency vaccination to respond to the increased risk.’

5. Article 13 is replaced by the following:

‘Article 13

Risk-mitigating measures in the vaccination zone when implementing emergency protective vaccination and emergency vaccination in wild animals

1. When implementing emergency protective vaccination the competent authority shall prohibit:
 - (a) the movements of animals and products thereof laid down in Part 3, point 1, of Annexes VII to XVIII;
 - (b) the collection of germinal products from animals laid down in Part 3, point 2, of Annexes VII to XVIII;(c) in the absence of disease-specific conditions laid down in Part 3, of Annexes VII to XVIII, movements of:
 - (i) vaccinated animals from the establishment where they were vaccinated;
 - (ii) products from vaccinated animals from the production and/or processing establishments.
2. By way of derogation from paragraph 1, point (a), the competent authority may allow movements of animals, either:
 - (a) if they are subject to compulsory killing after vaccination, in accordance with the official vaccination plan referred to in Article 5(1), point (b), and they are moved to be killed at the nearest suitable place;or
 - (b) if 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 conditions laid down in Part 3, point 3, of Annexes VII to XVIII.
3. By way of derogation from paragraph 1, point (a), the competent authority may allow movements of products of animals from the production and/or processing establishment in accordance with the conditions laid down in Part 3, point 3, of Annexes VII to XVIII.
4. By way of derogation from paragraph 1, point (b), the competent authority may allow the collection of germinal products in accordance with the conditions laid down in Part 3, point (3), of Annexes VII to XVIII.

5. When implementing emergency vaccination in wild animals the competent authority shall apply in the vaccination zone the disease-specific restrictions and other risk-mitigating measures set out in Part 3 of Annexes VII to XVIII for the relevant disease, where provided specifically for emergency vaccination in wild animals.
6. In vaccination zones situated in a restricted zone in accordance with Delegated Regulation (EU) 2020/687, the restrictions and other risk-mitigating measures provided for in paragraphs 1 and 5 shall apply in addition to the measures applicable to:
 - (a) protection and surveillance zones and further restricted zones where applicable, established in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687 in the event of an outbreak of a category A disease in kept terrestrial animals, until they are lifted in accordance with Articles 39 and 55 of that Regulation;
 - (b) infected zones established in accordance with Article 63(1) of Delegated Regulation (EU) 2020/687 in the event of an outbreak of a category A disease in wild animals, until they are lifted in accordance with Article 67 of that Regulation;
 - (c) restricted zones established under emergency measures provided for in Articles 71, 257 and 258 of Regulation (EU) 2016/429, and any rules adopted pursuant to Article 71(3) and Article 259 of that Regulation until those measures are lifted.
7. The measures referred to in paragraphs 1 and 5 shall continue to apply after the measures referred to in paragraph 6 have been lifted.’
6. In Article 14(2), point (a) is replaced by the following:

‘(a) they are not included in the list of animals and products, referred to in Article 13(1), points (a) and (b);’
7. In the title of Section 2 and in the title and in point (1) of Article 16, ‘recovery’ is replaced by ‘waiting’.
8. In Article 9(4), in Article 10(1), in Article 10(2), in Article 14(2), in Article 16(1) and in point (a)(i) of Article 16(2), ‘XIV’ is replaced by ‘XVIII’.
9. Annexes VIII, X, XI and XIV to Delegated Regulation (EU) 2023/361 are amended in accordance with Part 1 of the Annex to this Regulation.
10. Annexes VII, IX, XII and XIII to Delegated Regulation (EU) 2023/361 are replaced by the text set out in Part 2 of the Annex to this Regulation.
11. New Annexes XV, XVI, XVII and XVIII are added to Delegated Regulation (EU) 2023/361 in accordance with Part 3 of the Annex to this Regulation.
12. The List of Annexes to Delegated Regulation (EU) 2023/361 is replaced by the text set out in Part 4 of the Annex to this Regulation.

Article 2
Correction

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

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

- ‘2. The conditions for the use of vaccines against category A diseases 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.’

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, 6.3.2026

For the Commission
The President
Ursula VON DER LEYEN