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COVER NOTE

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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) …/... of 28.11.2022 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(2022) 8457 final.

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EUROPEAN
COMMISSION

Brussels, 28.11.2022
C(2022) 8457 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 28.11.2022

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.

The rules laid down in this Regulation supplement Article 46 of Regulation (EU) 2016/429 by providing 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') and (b) ('category B diseases') of that Regulation in kept and wild terrestrial and aquatic animals ('animals').

More specifically, this Regulation lays down:

(a) restrictions on the use of certain immunological veterinary medicinal products and antimicrobials in animals for prevention and control of category A and B diseases:

(b) rules on the use of vaccines in animals for prevention and control of category A diseases and certain category B diseases;

(c) risk-mitigating measures to prevent the spread of category A diseases through vaccinated animals or products from such animals;

(d) rules on surveillance of category A diseases following the use of vaccines in terrestrial animals for their prevention and control.

This Regulation takes account of newly available scientific knowledge and the experience gained in the application of the existing Union rules in this domain. It also updates animal health rules in line with the new Union animal health policy framework and international standards. Thus, it offers more clarity, transparency and consistency in the requirements for the use of immunological veterinary medicinal products for disease prevention and control of category A and category B 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.

In addition, stakeholders' comments on the draft delegated Regulation were collected in the context of the Better Regulation feedback mechanism between 5 August 2022 and 2 September 2022. 26 feedbacks, were received in total, including opinions from the following stakeholders: European Forum of Farmed Animal Breeders (EFFAB), Swedish Poultry Meat Associatio- SPMA (SE), FESASS - Fédération Européenne pour la Santé Animale et la

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

Sécurité Sanitaire, Dominant Genetica (CZ)**,** Krajowa Rada Drobiarstwa - Izba Gospodarcza (PL), SYVOFA (FR), Le Syndicat National des Accouveurs (SNA) (FR), SYNALAF - Syndicat National des Labels Avicoles de France (FR), ELPHA- European Live Poultry and Hatching Egg Association, EPB- European Poultry Breeder Association, AVEC- The Voice of the European Poultry Meat, CEVA SANTE ANIMALE (FR), Federation of Veterinarians of Europe, AVINED (NL), ZDG - Der Zentralverband der Deutschen Geflügelwirtschaft e. V. (DE), Poultry Veterinary Study Group of EU (DE), AviAlter (ES), ERPA – European Rural Poultry Association, Dierenbescherming (NL), COPA and COGECA, Landbrug & Fødevarer (DK), Producentenorganisatie Varkenshouderij (Dutch pig producers organization (NL), BunyaVax BV (NL), Stichting Wageningen Research(NL), EURO FOIE GRASS, one EU citizen.

The main requests submitted and points made are the following:

– The request to make testing and surveillance after the vaccination against avian influenza less cumbersome or request for a modifications in the proposed approach;

– The request to change the type of vaccine to be used for some category A diseases;

– The request to ensure that vaccinated animals and products from vaccinated animals are accepted in the international trade and the removal of trade barriers;

– The request to involve stakeholders in the risk assessment before deciding for emergency vaccination;

– The request that the use of vaccination be a decision taken at EU level and not left for Member States to take. It should be noted that the responsibility for Member States to decide on the vaccination is provided for in the basic act;

– The acknowledgements for the delegated act which provides rules for vaccination and supports best vaccination practices;

– The request for possibilities to move animals and animal products from the vaccination zones.

Based on the feedback received, the Commission introduced certain changes in this Regulation, including changes and corrections to some articles and disease specific annexes. Regarding several comments on Highly Pathogenic Avian Influenza (HPAI), the Commission introduced several adjustments in the relevant annex, and had already launched a mandate to EFSA.

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) …/...

of 28.11.2022

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) 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 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

[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).

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) It is necessary to lay down rules supplementing the rules on disease awareness and preparedness set out in Chapter 2, Title I of Part III of Regulation (EU) 2016/429 for certain listed diseases, in particular the rules on the use of veterinary medicinal products for disease prevention and control. Those supplementing rules and the rules set out in Regulation (EU) 2016/429 are closely linked and should be applied in tandem.

(5) Since both terrestrial and aquatic animals may be affected by category A diseases listed in accordance with Article 5 of Regulation (EU) 2016/429, certain general rules laid down in this Regulation should cover terrestrial and aquatic animals. This would help Member States facing an imminent risk of spread of a category A disease in their territory to immediately react under a harmonised framework, if needed. This is particularly important for aquatic animals, since disease-specific rules for the use of vaccines against category A diseases can only be developed for terrestrial animals for the time being, due to lack of scientific knowledge, combined with lack of experience and of availability of vaccines against aquatic category A diseases.

(6) Listed diseases referred to in Article 5 of Regulation (EU) 2016/429 which are to be controlled in all Member States with the goal of eradicating them throughout the Union ('category B diseases') are subject to specific rules laid down in Article 9(1), point (b), of that Regulation. Therefore, it is necessary to harmonise the rules under which Member States may use certain veterinary medicinal products for that purpose. Such rules should aim to ensure the effective eradication of category B diseases without detection and diagnostic interferences caused by any veterinary medicinal product.

(7) For listed diseases referred to in Article 5 of Regulation (EU) 2016/429 which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed diseases concerned, as referred to in Article 9(1), point (c), of that Regulation (' category C diseases'), rules for the use of certain veterinary medicinal products, in particular for the use of vaccines in the context of eradication programmes are laid down in Commission Delegated Regulation (EU) 2020/689[3]. For listed diseases referred to in Article 5 of Regulation (EU) 2016/429 for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, as referred to in Article 9(1), point (d), of that Regulation ('category D diseases'), rules for the use of certain veterinary medicinal products for the movements of animals within the Union are laid

[3] 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).

down in Commission Delegated Regulation (EU) 2020/688[4]. Such rules should therefore not be replicated in this Regulation.

(8) In accordance with Article 46(3) of Regulation (EU) 2016/429, Member States are to take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health. It is necessary to facilitate the research and innovation as regards development of more effective and safer veterinary medicinal products to prevent and control listed diseases. Therefore, the rules laid down in this Regulation should not apply to the use of veterinary medicinal products for scientific studies or for the purpose of developing and testing them under controlled conditions to protect animal and public health, to avoid any unnecessary burden that may interfere in the development of new possibilities, considering the specific risk-mitigating conditions under which veterinary medicinal products are used in those circumstances.

(9) Regulation (EU) 2019/6 of the European Parliament and of the Council[5] lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. That Regulation lays down a definition of a veterinary medicinal product and definitions of certain categories of veterinary medicinal products. It also lays down conditions under which a competent authority may allow the use of an immunological veterinary medicinal product not authorised within the Union. The rules provided for in this Regulation should comply with those definitions as well as with the requirements laid down in Regulation (EU) 2019/6, for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. Furthermore, the rules provided for in this Regulation should only aim to lay down specific conditions for the appropriate use or prohibition of use of veterinary medicinal products to prevent and control category A diseases and certain category B diseases in the Union, irrespective of the products' origin, marketing authorisation or other characteristics.

(10) In accordance with Article 47 of Regulation (EU) 2016/429, the Commission may adopt rules when this is appropriate and necessary to prohibit the use of a certain veterinary medicinal product for a specific disease. Rinderpest has been recognised as a globally eradicated disease by the World Organisation for Animal Health (WOAH, founded as OIE) and all vaccinations against rinderpest have ceased throughout the world. Vaccination against rinderpest should therefore be prohibited by this Regulation.

(11) In addition, the currently available vaccines against infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis*, *Mycobacterium tuberculosis* and *Mycobacterium caprae*) (MTBC), do not confer full protection in vaccinated animals and compromise tuberculin skin tests or other immunological tests relying on the use of tuberculin, for the distinction between vaccinated and infected animals. As a result, use of these vaccines in kept animals of listed species may jeopardise current bovine

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[4] Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ, L 174, 3.6.2020, p. 140).

[5] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

tuberculosis control and eradication policies, since it may not be possible to distinguish between vaccinated and infected animals. Vaccination against MTBC, in kept animals of listed species, should therefore also be prohibited by this Regulation.

(12) Some Member States currently allow the regular precautionary use of vaccines against Newcastle disease, for purposes other than responding to an outbreak. In addition, there are uses of vaccines against Newcastle disease as a requirement for movements, within the Union and for entry into the Union from third countries or territories. These uses have proven to be safe and effective in preventing the disease since there have not been outbreaks of Newcastle disease linked to the use of vaccines for such purposes. Therefore, the general prohibitions and restrictions for the use of vaccines against category A diseases laid down in this Regulation should not apply to such use of vaccines against Newcastle disease in those contexts.

(13) Moreover, some other veterinary medicinal products, such as hyper-immune sera, antimicrobials and some immunological veterinary medicinal products may, if used for the prevention and control of certain animal diseases, mask the presence of these diseases that may spread unnoticed in animal populations. This may hamper the early detection of the disease, and negatively affect its rapid eradication. This is in particular relevant for category A and B diseases, for which an immediate or timely eradication is essential. Therefore, it is appropriate to lay down certain restrictions for such veterinary medicinal products in this Regulation preventing their use in listed species for category A and B diseases.

(14) The competent authority of each Member State should be responsible for implementing disease prevention and control measures for category A diseases in terrestrial and aquatic animals. Vaccination may be a useful measure that may help prevent, control and eradicate some of category A diseases. Considering the pathogenic potential of these diseases and the potential risk of their spreading, derived from the use of vaccines, it is necessary that vaccines administered against such type of diseases are used under the control of the competent authority and only when disease control measures need to be put in place to prevent and control the spread of the disease. Furthermore, in order to ensure an effective eradication and a consistent application of all disease control measures, vaccination should be implemented in a structured manner according to an official vaccination plan. An official vaccination plan should include detailed information about the measures set out in it. The minimum information to be included in those official vaccination plans should be provided for in this Regulation.

(15) Given that vaccination may be an appropriate tool in some circumstances to control or eradicate a category A disease, while not in others, and that its use may sometimes have negative impacts (e.g. on trade), the competent authority should carry out a prior risk assessment before applying vaccination. Criteria for such assessment should be provided for in this Regulation.

(16) To ensure a coordinated EU approach, Member States should provide the Commission and the other Member States with a set of preliminary information before they apply vaccination against a category A disease. The Commission should review that information from Member States in accordance with Article 71 of Regulation (EU) 2016/429.

(17) Article 69 of Regulation (EU) 2016/429 provides for the possibility that the competent authority of a Member State uses emergency vaccination where relevant for the effective control of a listed disease in kept animals. To do that, the competent

authority should develop an official vaccination plan for its implementation and establish vaccination zones taking into account certain requirements. This Regulation should therefore lay down those requirements for emergency vaccination, the use of vaccines and the establishment of vaccination zones.

(18) The competent authority may implement such emergency vaccination in affected establishments or in not affected establishments as provided for in Commission Delegated Regulation (EU) 2020/687[6]. Such establishments will normally be located in restriction zones, however they may also be placed outside such zones. Different emergency vaccination strategies should be applied to those situations. Vaccination implemented in affected establishments where vaccinated animals will be killed is considered as emergency suppressive vaccination. Emergency vaccination may also take place to prevent the spread of the disease in animal populations at risk of infection that are kept in establishments where the disease has not been suspected or confirmed in accordance with Delegated Regulation (EU) 2020/687. In such cases, the animals may be killed or kept alive under special conditions. Emergency vaccination may also be used in wild terrestrial animals when the risk of spreading of the disease in kept or wild terrestrial animal populations requires so. This Regulation should therefore develop those strategies and provide for the rules for their implementation, and for record keeping and reporting obligations that apply in all those circumstances.

(19) To prevent the spread of a category A disease or to avoid potential losses and the need to apply drastic disease control measures, Member States may decide to use preventive vaccination against a category A disease in its absence in a country or a zone. To this effect, specific rules should be laid down in this Regulation.

(20) Although vaccination has proved its capacity to help with prevention, control and eradication of several diseases, it may however, depending on the disease and type of vaccine used, mask in certain circumstances an underlying infection and affect the reliability of disease surveillance. Therefore, when vaccination is implemented, certain accompanying risk mitigation measures should be taken for the movement of vaccinated animals and their products.

(21) After the completion of emergency protective vaccination an exit strategy should enable Member States to demonstrate the absence of infection and to recover the health status they had prior to the outbreaks of the relevant category A disease and the use of vaccination. Such exit strategy should consist of a specific reinforced clinical and laboratory surveillance during the pre-defined recovery period for each specific category A disease.

(22) Specific conditions for each category A disease should be set out for implementing vaccination as regards the type of vaccines used, the size of the vaccination zones, the targeted animal populations, disease surveillance, movement restrictions for animals and their products, and recovery periods. This is the case for diseases for which sufficient experience and data are available from the application of rules in place, before the entry into application of Regulation (EU) 2016/429, from recent European Food Safety Authority (EFSA) opinions or from the relevant chapters of the WOAH Terrestrial Animal Health Code and WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. For diseases for which sufficient experience and data are not

[6] Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

available, disease specific measures cannot be provided for the moment. For those diseases general rules of this Regulation should apply,

HAS ADOPTED THIS REGULATION:

Part I
General provisions

Article 1
Subject matter and scope

1. This Regulation supplements the rules laid down in Regulation (EU) 2016/429 on the use within the Union of veterinary medicinal products with regard to prevention and control of the listed diseases referred to in Article 9(1), points (a) and (b), of Regulation (EU) 2016/429 in kept and wild terrestrial and aquatic animals ('animals'). In particular, it lays down:

   (a) prohibitions and restrictions on the use of certain veterinary medicinal products in animals for prevention and control of category A and B diseases;

   (b) rules on the use of vaccines in animals for prevention and control of category A and certain category B diseases;

   (c) risk-mitigating measures to prevent the spread of category A diseases through vaccinated animals or products from such animals;

   (d) rules on surveillance of category A diseases following the use of vaccines in terrestrial animals for their prevention and control.

2. This Regulation does not apply to the use of the veterinary medicinal products referred to in paragraph 1 for scientific studies or for the purposes of developing and testing them, as referred to in Article 46(3) of Regulation (EU) 2016/429.

Article 2
Definitions

1. For the purposes of this Regulation the following definitions apply:

   (a) '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;

   (b) 'category B disease' means a listed disease which must be controlled in all Member States with the goal of eradicating it throughout the Union, as referred to in Article 9(1), point (b), of Regulation (EU) 2016/429;

   (c) 'emergency suppressive vaccination' means a vaccination strategy implemented by the competent authority in kept terrestrial animals for the prevention and control of category A diseases in accordance with Article 7(1), point (a)(i);

   (d) 'emergency protective vaccination' means a vaccination strategy implemented by the competent authority in kept terrestrial animals for the prevention and control of category A diseases in accordance with Article 7(1), point (a)(ii);

(e) ‘emergency vaccination in wild terrestrial animals’ means a vaccination strategy implemented by the competent authority in wild terrestrial animals for the prevention and control of category A diseases in accordance with Article 7(1), point (a)(iii);

(f) ‘preventive vaccination’ means a vaccination strategy implemented by the competent authority for the prevention and control of category A diseases in accordance with Article 7(1), point (b);

(g) ‘vaccination zone’ means a zone in which a vaccine is administered to listed species to prevent and control category A diseases;

(h) ‘peri-vaccination zone’ means a zone, surrounding the vaccination zone, where vaccination for the purpose of preventing and controlling category A diseases is not allowed and where reinforced surveillance is implemented to detect those diseases.

(i) ‘confirmed outbreak’ means an outbreak confirmed in accordance with Article 9(2), (3) and (4) of Delegated Regulation (EU) 2020/689;

(j) ‘recovery period’ means the necessary period of time required for a vaccination zone to recover the animal health status prior to the implementation of vaccination against a category A disease, by demonstrating absence of the category A disease after emergency protective vaccination against the disease has been carried out;

(k) ‘protection zone’ means a protection zone as established on the basis of Article 21(1), point (a), of Delegated Regulation (EU) 2020/687;

(l) 'surveillance zone' means a surveillance zone as established on the basis of Article 21(1), point (b), of Delegated Regulation (EU) 2020/687;

(m) ‘bovine animal’ means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;

(n) ‘ovine animal’ means an animal of the species of ungulates belonging to the genus Ovis and the offspring of crossings of those species;

(o) ‘caprine animal’ means an animal of the species of ungulates belonging to the genus Capra and the offspring of crossings of those species;

(p) ‘camelid animal’ means an animal of the species of ungulates belonging to the family Camelidae listed in Annex III to Regulation (EU) 2016/429;

(q) ‘porcine animal’ means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;

(r) ‘equine animal’ as an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species; ‘

(s) ‘day-old chicks’ means all poultry less than 72 hours old.

2. In addition to the definitions laid down in paragraph 1, the definitions of ‘veterinary medicinal product’, ‘immunological veterinary medicinal product’ and ‘antimicrobial’ set out in Article 4(1), (5) and (12) of Regulation (EU) 2019/6 shall apply.

Article 3

Prohibitions and restrictions on the use of vaccines in animals for the prevention and control of category A and certain category B diseases

1. Member States may allow the use of vaccines in animals for the prevention and control of category A diseases, except for the diseases listed in Part 1 of Annex I, only under the control of the competent authority and if they are used:

   (a) as a part of the official measures put in place by the competent authority for prevention and control of those diseases;

   (b) under the conditions laid down in this Regulation.

2. The conditions for the use of vaccines against category A diseases, laid down in the first subparagraph, 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, that the Member States may allow outside the official disease prevention and control measures referred to in paragraph 1 for purposes other than responding to an outbreak.

3. Member States may allow the use of vaccines in animals for prevention and control of category B diseases, except for the diseases listed in Part 2 of Annex I, in those listed species for which the corresponding diseases have been classified as category B.

Article 4

Prohibitions and restrictions on the use of certain veterinary medicinal products, other than vaccines, in animals, for the prevention and control of category A and B diseases

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 use complies with the conditions set out therein:

(a) immunological veterinary medicinal products to diagnose the state of immunity of animals;

(b) hyper-immune serum;

(c) inactivated immunological veterinary medicinal products, as referred to in Article 2(3) of Regulation (EU) 2019/6;

(d) antimicrobials.

Part II
Rules on the use of vaccines for the prevention and control of category A diseases in animals

Chapter 1
Preconditions

Article 5

Preconditions for the use of vaccines for the prevention and control of category A diseases in terrestrial and aquatic animals

1. The competent authority may decide on the use of vaccines in animals to prevent and control category A diseases, in accordance with Article 3(1), provided that:

   (a) it has carried out an assessment to support this decision considering at least the criteria set out in Part 1 of Annex II, in addition to the criteria provided for in Article 46(2) of Regulation (EU) 2016/429;

   (b) the vaccines are used in accordance with an official vaccination plan which fulfils the requirements laid down in Article 6.

2. The competent authority may carry out the assessment referred to in paragraph 1, point (a), following the simplified rules provided for in Part 2 of Annex II when implementing the vaccination strategy referred to in Article 7(1), point (a)(i).

Article 6

Official vaccination plan for the prevention and control of category A diseases in terrestrial and aquatic animals, and information obligations for the Member States

1. The official vaccination plan referred to in Article 5(1), point (b), shall:

   (a) detail, at least, the information and measures set out in Part 1 of Annex III;

   (b) be implemented under the control of the competent authority and only for the strictly necessary period of time.

2. The competent authority may include in the official vaccination plan referred to in Article 5(1), point (b), the simplified information provided for in Part 2 of Annex III, when implementing the vaccination strategy referred to in Article 7(1), point (a)(i).

3. The competent authority shall keep up to date, amend or supplement the official vaccination plan referred to in Article 5(1), point (b), taking into account the evolution of its implementation and the evolution of the epidemiological situation of the disease.

4. Member States shall provide the other Member States and the Commission with:

   (a) at least the preliminary information set out in Annex IV, at the latest two days before starting the vaccination;

   (b) the official vaccination plan and its amendments and updates, as soon as possible and at the latest two weeks after starting the vaccination or implementing the amendments or updates of the official vaccination plan.

5. The Commission shall, in accordance with Article 71 of Regulation (EU) 2016/429, review the national measures referred to in paragraph 2 of that Article, as laid in the official vaccination plan, and act in accordance with that Article.

Chapter 2
Rules on the implementation of vaccination in terrestrial animals and entry into force

SECTION 1
VACCINATION STRATEGIES AND RELATED DISEASE SURVEILLANCE

Article 7
Vaccination strategies for the prevention and control of category A diseases in terrestrial animals

1. The competent authority may implement the following vaccination strategies to prevent and control category A diseases in terrestrial animals, in accordance with Article 3(1):

   (a) emergency vaccination, as referred to in Article 69 of Regulation (EU) 2016/429, may be any of the following:

      (i) emergency suppressive vaccination, implemented in response to an outbreak of a category A disease to control its spread and limited to kept terrestrial animals that are to be killed in accordance with Articles 12(1), point (a), and 18(1), point (b), of Delegated Regulation (EU) 2020/687 but are subject to the derogation provided for in Article 12(4), point (b), of that Regulation;

      (ii) emergency protective vaccination, implemented in response to an outbreak of a category A disease, which is 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 zone thereof;

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

      (iii) emergency vaccination in wild terrestrial animals, implemented in response to an outbreak of a category A disease;

   (b) preventive vaccination, where a vaccine against a category A disease is administered to terrestrial animals in non-affected geographic areas for preventive purposes other than the cases covered by emergency protective vaccination.

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 geographic zones and at different time points throughout an outbreak, and may vary the strategies applied according to the zone, 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).

Article 8

Rules for the implementation of emergency suppressive vaccination

When implementing emergency suppressive vaccination, as referred to in Article 7(1), point (a)(i), the competent authority shall:

(a) vaccinate the animals subject to the derogation provided for in Article 12(4), point (b), of Delegated Regulation (EU) 2020/687 without delay after the confirmation of the relevant outbreak(s);

(b) order and supervise the killing of all vaccinated animals as soon as possible, in accordance with the rules laid down in either Article 12(1), point (a), or Article 12(4), point (a), of Delegated Regulation (EU) 2020/687 and under the biosecurity measures provided for in Articles 12(1), point (c), and Article 12(2) of that Delegated Regulation.

Article 9

Rules for the implementation of emergency protective vaccination and emergency vaccination in wild animals

1. When implementing emergency protective vaccination, as referred to in Article 7(1), point (a)(ii), and emergency vaccination in wild animals, as referred to in Article 7(1), point (a)(iii), the competent authority shall:

   (a) specify the type of vaccine to be used or prioritised, the minimum vaccine coverage and the targeted animals/species;

   (b) establish geographically:

      (i) a vaccination zone, in which vaccination is carried out, in order to prevent spreading of the category A disease from affected areas to non-affected areas;

      (ii) a peri-vaccination zone, surrounding the vaccination zone, in which vaccination is not allowed, covering a distance width from the perimeters of the vaccination zone;

   (c) implement reinforced clinical and laboratory surveillance in the vaccination and peri-vaccination zones referred to in point (b):

      (i) to assess vaccination effectiveness in the vaccination zone;

      (ii) to detect any possible new outbreak of the disease in the vaccination and peri-vaccination zones;

      (iii) in accordance with Annex I to Delegated Regulation (EU) 2020/687 as regards the sampling procedures, diagnostic methods and transport of samples;

      (iv) selecting the diagnostic methods depending on the type of vaccine administered.

2. 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 and when implementing emergency vaccination in wild animals.

3. Where vaccination zones or peri-vaccination zones as provided for in paragraph 1, point (b), are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing them.

4. Where disease-specific conditions are laid down in Parts 1 and 2 of Annexes VII to XIV, the competent authority shall implement the measures laid down in paragraph 1 in accordance with those conditions.

Article 10
Rules for the implementation of preventive vaccination

1. Preventive vaccination may only be implemented for the prevention of category A diseases for which specific conditions for preventive vaccination are laid down in Part 5 of Annexes VII to XIV, and shall be implemented in accordance with those conditions.

2. When implementing preventive vaccination, as referred to in Article 7(1), point (b), the competent authority shall:

   (a) specify the type of vaccine to be used or prioritised;

   (b) implement reinforced clinical and laboratory surveillance

   in accordance with the relevant disease-specific conditions laid down in Part 5 of Annexes VII to XIV, where provided.

Article 11
Record-keeping and reporting obligations for emergency and preventive vaccination

1. When implementing emergency and preventive vaccination the competent authority shall ensure that at least the information detailed in Annex V on the vaccination is recorded.

2. The competent authority shall provide the other Member States and the Commission with a report on the implementation of the vaccination that includes at least the relevant information detailed in point 1 of Annex VI at the time points and minimum frequency provided for in point 2 of that Annex.

SECTION 2
RISK MITIGATION MEASURES , CERTIFICATION REQUIREMENTS AND RECOVERY PERIODS

Article 12
Biosafety rules for emergency and preventive vaccination

1. When implementing emergency or preventive vaccination the competent authority shall ensure that the following tasks are under the supervision of an official veterinarian:

   (a) distribution and administration of the vaccine;

(b) returning of any residual quantities of the vaccine to the point of distribution or to any other designated point with a record on the vaccinated establishments, the number of vaccinated animals and the number of doses used.

2. During the administration of the vaccine and the return of residual quantities of the product, the competent authority shall put in place all the necessary measures to avoid the possible spread of disease agents.

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 XIV;

(b) the collection of the following germinal products from animals of listed species, laid down in Part 3, point 2, of Annexes VII to XIV:

(i) semen;

(ii) oocytes;

(iii) embryos;

(c) in the absence of disease-specific conditions laid down in Part 3, of Annexes VII to XIV, 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 vaccinated animals from the establishment where they were vaccinated if:

(a) 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) 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 are either:

(i) not subject to prohibitions of movements;

or

(ii) they are subject to prohibitions of movements but 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 XIV.

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:

(a) they are not subject to prohibitions of movements;

or

(b) the competent authority has authorised their movement in accordance with the conditions laid down in Part 3, point 3, of Annexes VII to XIV.

4. By way of derogation from paragraph 1, point (b), the competent authority may allow the collection of the germinal products listed therein if:

(a) they are not subject to prohibition of collection;

or

(b) the competent authority has authorised their collection in accordance with the conditions laid down in Part 3, point (3), of Annexes VII to XIV.

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 XIV for the relevant disease, where provided specifically for emergency vaccination in wild animals.

6. The restrictions and other risk-mitigating measures provided for in paragraphs 1 and 5 shall apply in the vaccination zones 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.

Article 14

Risk-mitigating measures when implementing preventive vaccination

1. When implementing preventive vaccination the competent authority shall prohibit the movement of vaccinated animals from the establishment where they were vaccinated and the movement of products from vaccinated animals from the production and/or processing establishment.

2. By way of derogation from paragraph 1, the competent authority may allow movements of vaccinated animals and products thereof from the establishment where they were vaccinated or where they were produced and/or processed if:

(a) they are not included in the list of animals and products subject to prohibitions of movements;

(b) they are subject to prohibitions of movements but they comply with the relevant conditions and the competent authority has authorised their movement;

in accordance with the conditions laid down in Part 5 of Annexes VII to XIV, where provided.

Article 15
Certification requirements for movements of kept animals and products thereof from vaccination zones

Operators shall move animals and products , to which measures provided for in Article 13(1) apply, within a Member State or from one Member State to another Member State, only if the animals and products to be moved comply with the relevant conditions provided for in Article 13 and are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with:

(a) Article 149(1) of Regulation (EU) 2016/429 for kept terrestrial animals;

(b) Article 161(4) of Regulation (EU) 2016/429 for germinal products;

(c) Article 167(3) of Regulation (EU) 2016/429 for products of animal origin;

(d) Article 22(5) and (6) of Delegated Regulation (EU) 2020/687 for animal by-products;

Article 16
Recovery periods after emergency protective vaccination

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

2. The surveillance referred to in paragraph 1 shall be implemented:

(a) in accordance with:

(i) the disease-specific conditions set out in Part 4 of Annexes VII to XIV;

(ii) Annex I to Delegated Regulation (EU) 2020/687, as regards the sampling procedures, diagnostic methods and transport of samples;

(b) taking into account the type of vaccine administered.

SECTION 3
FINAL PROVISIONS

Article 17
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, 28.11.2022

For the Commission
The President
Ursula VON DER LEYEN