II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/361

of 28 November 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 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.

([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).

(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 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,

([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).

([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).

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 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 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.

([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).

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 20 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 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

LIST OF ANNEXES

1. Annex I on category A and B diseases for which the use of vaccines shall be prohibited by Member States and on the use of certain veterinary medicinal products, other than vaccines, for prevention and control of category A and B diseases.
2. Annex II on the criteria for the use of a vaccine to prevent and control a category A disease in animals.
3. Annex III on the information to be included in the official vaccination plan.
4. Annex IV on the preliminary information to be provided to other Member States and the Commission prior to vaccination.
5. Annex V on the minimum records on vaccination.
6. Annex VI on the minimum information to be provided by the competent authority to other Member States and the Commission on the implementation of vaccination.
7. Annex VII on vaccination against foot and mouth disease (FMD).
8. Annex VIII on vaccination against infection with Rift Valley Fever virus (RVF).
9. Annex IX on vaccination against infection with lumpy skin disease virus (LSD).
10. Annex X on vaccination against infection with peste des petits ruminants virus (PPR).
11. Annex XI on vaccination against African horse sickness (AHS).
12. Annex XII on vaccination against classical swine fever (CSF).
13. Annex XIII on vaccination against highly pathogenic avian influenza (HPAI).
14. Annex XIV on vaccination against infection with Newcastle disease virus (NCD).

ANNEX I

PART 1

CATEGORY A DISEASES FOR WHICH THE USE OF VACCINES SHALL BE PROHIBITED BY MEMBER STATES

— Infection with Rinderpest virus

PART 2

CATEGORY B DISEASES FOR WHICH THE USE OF VACCINES SHALL BE PROHIBITED BY MEMBER STATES

— Infection with *Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis)*

PART 3

USE OF CERTAIN VETERINARY MEDICINAL PRODUCTS, OTHER THAN VACCINES, FOR PREVENTION AND CONTROL OF CATEGORY A AND B DISEASES

(Article 4)

Disease	Type of veterinary medicinal product	Conditions
Infection with *Brucella abortus, B. melitensis, B. suis*	Immunological veterinary medicinal products to diagnose the state of immunity of animals: brucelin	Their use shall be allowed only in accordance with Delegated Regulation (EU) 2020/688, Delegated Regulation (EU) 2020/689, Delegated Regulation (EU) 2020/686 and Regulation (EU) No 853/2004, or for export purposes
Infection with *Mycobacterium tuberculosis complex (M. bovis, M. caprae, M. tuberculosis)*	Immunological veterinary medicinal products to diagnose the state of immunity of animals: tuberculin	Their use shall be allowed only in accordance with Delegated Regulation (EU) 2020/688, Delegated Regulation (EU) 2020/689, Delegated Regulation (EU) 2020/686 and Regulation (EU) No 853/2004, or for export purposes

ANNEX II

Criteria for the use of a vaccine to prevent and control a category A disease in animals

PART 1

1. **Vaccination of kept animals**

1. Number of establishments where the category A disease has been confirmed or suspected;
2. Type of establishments where the category A disease has been confirmed or suspected;
3. Number of animals kept in the establishments where the category A disease has been confirmed or suspected;
4. Species affected and risk of disease spread to humans;
5. Presence of the disease in wild animals;
6. Density of animals of listed species in the areas where the disease is present;
7. Density of establishments keeping animals of listed species in the areas where the disease is present;
8. Origin of the outbreak(s);
9. Traceability and possibility to perform contact tracing;
10. Incidence slope of outbreaks;
11. Simulation models used to assess when and if vaccination is relevant, if such information is available;
12. Capacity of killing and killing and disposal schedule in establishments where animals are killed;
13. Movement of potentially infected animals or products out of the restricted zone established pursuant to Delegated Regulation (EU) 2020/687;
14. Rate of airborne or vector-borne spread of the disease agent from the establishments or area where the category A disease has been confirmed;
15. Effectiveness of other disease control measures taken and available resources to implement them;
16. Level of preparedness and capacity of the competent authorities and other personnel concerned;
17. Economic assessment: cost–benefit analysis;
18. Trade concerns: consequences on disease freedom status of the Member State concerned and trade restrictions likely to be imposed by third countries or territories as a consequence of vaccination.

2. **Vaccination of wild animals**

In addition to the criteria provided for in point 1, the following criteria shall be considered:

1. mortality in wild animals due to the category A disease;
2. knowledge of the population and ecological dynamics of the affected wild animals;
3. size of the affected area (where animals affected are found);
4. the risk of spread of the disease to additional listed species of wild animals or beyond the above area;
5. the risk of spread of the category A disease to kept animals or to humans;

6. the availability of vaccines and vaccination systems to distribute the vaccine among the target population;

7. the possibility to control the vaccination and to establish a surveillance system to detect the specific disease agent and to assess the effectiveness of vaccination.

PART 2

SIMPLIFIED ASSESSMENT OF THE VACCINATION STRATEGY

1. Number of establishments where the category A disease has been confirmed or suspected;

2. Type of establishments where the category A disease has been confirmed or suspected;

3. Number of animals kept in the establishments where the category A disease has been confirmed or suspected;

4. Species affected;

5. Capacity of killing and killing and disposal schedule in establishments where animals are killed;

6. Rate of airborne or vector-borne spread of the disease agent from the establishments or area where the category A disease has been confirmed.

ANNEX III

Information to be included in the official vaccination plan

PART 1

1. **Kept animals**

(a) the description and the results of the assessment performed in accordance with Annex II, including the epidemiological situation and the relevant information used as a basis for the assessment;

(b) the main objectives and targets with the chosen vaccination strategy and the official vaccination plan;

(c) the detailed geographic description of the vaccination zone in which vaccination is to be carried out and the location of establishments keeping animals to be vaccinated, when available and applicable, including maps;

(d) where relevant, the detailed geographic description of the peri-vaccination zone surrounding the vaccination zone, and the location of establishments keeping animals of listed species, when available, including maps;

(e) the number of establishments keeping animals of listed species located in the vaccination zone and the number of establishments in which vaccination is to be carried out, if different;

(f) the estimated number of kept animals of listed species to be vaccinated, their categories and, when relevant, their age;

(g) intended final use of vaccinated animals and products;

(h) categories of animals exempted from vaccination and reasoning;

(i) the arrangements to administer the vaccine and the system to supervise the administration of the vaccine;

(j) the envisaged duration of the vaccination, from the start of the vaccination to the end of the surveillance carried out after vaccination;

(k) the summary of the characteristics of the vaccine, including the name of the product(s) and the name of the manufacturer(s), and routes of administration;

(l) indication if the vaccine is used in accordance with Article 110(2) of Regulation (EU) 2019/6;

(m) the details of the reinforced clinical and laboratory surveillance referred to in Article 9, point 1(c) and Article 10, point 2(b);

(n) the hygiene and biosecurity rules to be applied;

(o) the record keeping system on the vaccination;

(p) the restrictions on movements of vaccinated animals and products thereof and other risk-mitigating measures to control the potential spread of disease to be put in place and their duration in addition to those provided for in this Regulation;

(q) communication campaign to be put in place to inform operators and the public about the vaccination, including the safety for human consumption of products of animal origin from vaccinated animals of listed species;

(r) other matters deemed appropriate to the situation by the competent authority.

2. **Wild animals**

In case vaccination involves wild animals of listed species, the official vaccination plan shall include the information referred to in point 1, points (a), (b), (j), (k), (l), (m), (n), (o), (p) and (q), and the following information:

(a) the detailed geographic description of the vaccination zone and the peri-vaccination zone, where relevant;

(b) the estimated number of wild animals of listed species to be vaccinated;

(c) the measures to be adopted to avoid a high number of movements of wild animals;

(d) the vaccination periods or seasons where relevant;

(e) the vaccine delivery system.

PART 2

SIMPLIFIED INFORMATION TO BE INCLUDED IN THE OFFICIAL VACCINATION PLAN

(a) The description and the results of the assessment performed in accordance with Annex II, including the epidemiological situation and the relevant information used as a basis for the assessment;

(b) the main objectives and targets with the chosen vaccination strategy and the official vaccination plan;

(c) the number of establishments keeping animals of listed species to be vaccinated;

(d) the estimated number of kept animals of listed species to be vaccinated, their categories and, when relevant, their age;

(e) categories of animals exempted from vaccination and reasons for exempting them;

(f) the system to supervise the administration of the vaccine;

(g) the summary of the characteristics of the vaccine, including the name of the products and the name of the manufacturers;

ANNEX IV

Preliminary information to be provided to other Member States and the Commission prior to vaccination

The Member State intending to apply a vaccination against category A diseases shall provide the following information before starting the vaccination:

(a) brief reasoning to start the vaccination;

(b) chosen strategy and motivation;

(c) species of animals that will be vaccinated, specifying if wild animals will be included;

(d) estimated number of animals that will be vaccinated;

(e) estimated duration of the vaccination;

(f) type and commercial name of the vaccine applied, including the indication if the vaccine will be used in accordance with Article 110(2) of Regulation (EU) 2019/6;

(g) description of the estimated vaccination zone.

ANNEX V

Minimum records on vaccination

1. **Kept animals**

— Individual identification, where relevant in accordance with Regulation (EU) 2019/2035,

— species and category,

— Registration number of the establishment,

— number of vaccinated animals,

— number of vaccine doses administered,

— type and name of the vaccine,

— date of vaccination,

— date of killing (where applicable),

— date and method of disposal of the carcass (where applicable).

2. **Wild animals**

— Regions or zones where wild animals are vaccinated,

— vaccine delivery system,

— period of vaccination,

— type and name of the vaccine,

— number of vaccine doses distributed,

— methods to monitor vaccination effectiveness and methods of disease surveillance in vaccinated zones.

ANNEX VI

Minimum information to be provided by the competent authority to other Member States and the Commission on the implementation of vaccination

1. **Minimum information to be provided in the reports**

	Emergency vaccination strategy			Preventive vaccination strategy
	Suppressive vaccination	Protective vaccination	In wild animals	
Description of vaccination and peri-vaccination zones	WHERE APPLICABLE	YES	YES	WHERE APPLICABLE
Total number of establishments and total number of establishments in each vaccination zone (where applicable)	YES	YES	NO	YES
Total number of animals to be vaccinated, (by species) and total number of animals in each vaccination zone (where applicable).	YES	YES	NO	YES
Total number of vaccinated establishments (in each vaccination zone where applicable)	YES	YES	NO	YES
Total number of vaccinated animals, by species, (in each vaccination zone, where applicable)	YES	YES	NO	YES
Total number of doses administered or distributed	YES	YES	YES	YES
Expected date for completing the vaccination	NO	YES	YES	YES
Total number of vaccinated animals killed.	YES	WHERE APPLICABLE	NO	NO
Dates of killing of the vaccinated animals (suppressive vaccination) or expected date of completion of killing (protective vaccination, where applicable)	YES	WHERE APPLICABLE	NO	NO

2. **Time points and minimum frequency to submit the reports**

<table>
<tr><th colspan="3">Emergency vaccination strategy</th><th rowspan="2">Preventive vaccination</th></tr>
<tr><th>Suppressive vaccination</th><th>Protective vaccination</th><th>In wild animals</th></tr>
<tr><td rowspan="2">Within 7 days from the end of the administration of the vaccine to all animals included in the official vaccination plan</td><td>At least once every two weeks for the first month of vaccination and once a month for the rest of the duration of the vaccination for one-year or shorter vaccination campaigns</td><td>At least once a month for one-year or shorter vaccination campaigns</td><td rowspan="2">Once a year</td></tr>
<tr><td>At least once at the end of the annual vaccination for multi-year vaccination campaigns</td><td>At least every 6 months for multi-year vaccination campaigns</td></tr>
</table>

ANNEX VII

Foot and mouth disease (FMD)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF FMD

1. Type of vaccine to be used or prioritised: Inactivated vaccines (live attenuated vaccines shall not be used).

2. Size of the peri-vaccination zone: The peri-vaccination zone shall be of at least 10 km width from the perimeters of the vaccination zone.

3. Minimum coverage: to be adapted according to the circulating strain, the effectiveness of biosecurity in establishments situated in the vaccination zone and animal density. As a baseline, vaccine coverage should aim for at least 80 % of establishments in the vaccination zone and for 80 % of the targeted animals per each species kept in each of those establishments selected for the application of vaccination.

4. Targeted animals/species: Listed species in accordance with Implementing Regulation (EU) 2018/1882.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF FMD

The following clinical and laboratory surveillance shall be implemented in the vaccination zone to identify establishments keeping animals of listed species that had contact with the FMD virus without showing clinical signs of the disease during the period starting not earlier than 30 days after the completion of emergency protective vaccination. This surveillance shall include:

1. a clinical examination of one of the following types:

   (a) clinical examination of all animals of listed species kept in all establishments in the vaccination zone;

   (b) clinical examination targeted at particular species likely to exhibit clear clinical signs, if the competent authority decides so, based on the positive outcome of a risk assessment;

2. laboratory examination in line with the following conditions:

   (a) for antibodies against non-structural proteins of the FMD virus carried out on samples taken from vaccinated animals of listed species and their non-vaccinated offspring in all establishments in the vaccination zone;

   (b) to detect infection with the FMD virus, either by an assay for antibodies against non-structural proteins of the FMD virus, or by another approved method, carried out on samples collected in accordance with Annex I to Delegated Regulation (EU) 2020/687 from all establishments in the vaccination zone in which vaccination was not carried out;

   (c) carried out for each establishment tested under point (a) according to a sample size that shall be calculated to detect a within-establishment animal prevalence of 5 % or less, with a 95 % confidence, in both vaccinated and non-vaccinated animals;

   (d) where the competent authority uses in addition sentinel animals introduced in affected establishments as part of their repopulation, the conditions for repopulation of affected establishments provided for in Delegated Regulation (EU) 2020/687 shall be taken into account.

PART 3

SPECIFIC CONDITIONS FOR THE PROHIBITION OF MOVEMENTS OF ANIMALS AND PRODUCTS AND FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13, IN VACCINATION ZONES WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF FMD IS CARRIED OUT

1. Animals and products subject to prohibition of movements: vaccinated animals and products thereof, destined to be moved to other Member States, until the end of the recovery period laid down in PART 4:

   (a) animals of listed species from establishments located in the vaccination zone;

   (b) fresh meat, raw milk and colostrum obtained from vaccinated animals;

   (c) dairy products and colostrum-based products produced from milk and colostrum obtained from vaccinated animals;

2. Germinal products subject to prohibitions of collection: semen for artificial insemination from donor animals of listed species kept in approved germinal product establishments located in the vaccination zone, until the end of the recovery period laid down in Part 4.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).

3.1. From the start of the emergency protective vaccination until at least 30 days have elapsed following its completion, the following may be authorised:

   (a) movements for slaughter of kept animals of listed species from establishments located in the vaccination zone to a slaughterhouse located within or as close as possible to the vaccination zone, within the same Member State, under the same conditions as those laid down in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 29(1) and (2) of Delegated Regulation (EU) 2020/687;

   (b) movements of fresh meat and raw milk obtained from vaccinated animals under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (6) and (7) and Article 33(1), point (a), and Article 33(2) of Delegated Regulation (EU) 2020/687;

   (c) movements of dairy products produced from milk obtained from vaccinated animals if they have undergone an effective treatment for FMD in accordance with Annex VII to Delegated Regulation (EU) 2020/687 and only if during the production process, storage and transport they have been separated from products not eligible for dispatch outside the vaccination zone pursuant to this Regulation;

   (d) collection of semen for artificial insemination from donor animals of listed species kept in approved germinal product establishments located in the vaccination zone for the production of frozen semen, under the following conditions:

      (i) it is ensured that the semen collected during this period is stored separately for at least 30 days;

      (ii) prior to dispatch of the semen, either:

         — the donor animal has not been vaccinated and the same conditions as those set out in Article 32, points (b) and (c), of Delegated Regulation (EU) 2020/687 are fulfilled, or

         — the donor animal has been vaccinated following a negative result to a laboratory examination for the detection of antibodies against the FMD virus carried out prior to vaccination, and

            — a negative result has been achieved in a laboratory examination for the detection of either virus or viral genome, or in an approved test for the detection of antibodies against non-structural proteins of the FMD virus, carried out at the end of the quarantine period for the semen on samples taken from all animals of listed species present at that time in the approved germinal product establishment, and

— the semen complies with the conditions set out in Part 5, Chapter I, point 3, of Annex II to Delegated Regulation (EU) 2020/686.

3.2. During the period starting not earlier than 30 days after the completion of emergency protective vaccination until completion of the specific surveillance provided for in Part 2 of this Annex, the following may be authorised:

(a) movements for slaughter of kept animals of listed species kept in the vaccination zone to a slaughterhouse located within or outside the vaccination zone but within the same Member State, under the same conditions as those provided for in Article 24 and Article 28(5) of Delegated Regulation (EU) 2020/687;

(b) movements of fresh meat, excluding offal, obtained from vaccinated ungulates of listed species, other than porcine animals, if the fresh meat:

— complies with the same conditions as those set out in Article 28(6) of Delegated Regulation (EU) 2020/687,

— has been de-boned and the main accessible lymph nodes have been removed,

— is, or has been obtained from, carcasses that have been subjected to a maturation process at a temperature of more than 2 °C for at least 24 hours and the pH value recorded in the middle of the *Longissimus dorsi* muscle was less than 6,0;

(c) movements of fresh meat obtained from ungulates of listed species, other than porcine animals, kept and slaughtered outside the vaccination zone;

(d) movements of fresh meat, excluding offal, obtained from vaccinated porcine animals slaughtered in this period, if the fresh meat was produced under the conditions provided for in Article 24, Article 28(2), (3), (4), (6) and (7) and Article 33(1), point (a), and Article 33(2) of Delegated Regulation (EU) 2020/687;

(e) movements of raw milk obtained from vaccinated animals under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (6) and (7) and Article 33(1), point (a), and Article 33(2), point (b), of Delegated Regulation (EU) 2020/687;

(f) movements of dairy products obtained from vaccinated animals if those dairy products have undergone an effective treatment against FMD in accordance with Annex VII to Delegated Regulation (EU) 2020/687 and only if during the production process, storage and transport have been separated from products not eligible for dispatch outside the vaccination zone pursuant to this Regulation.

(g) collection of semen for artificial insemination from donor animals of listed species kept in approved germinal product establishments located in the vaccination zone under the conditions set out in point 3.1, subpoint (d).

3.3. After the completion of the specific surveillance provided for in Part 2 of this Annex and until the end of the recovery period provided for in Part 4 of this Annex, the following may be authorised:

(a) movements for slaughter of animals of listed species kept in the vaccination zone to a slaughterhouse located within or out of the vaccination zone, but within the same Member State, under the same conditions as those set out in Article 24 and Article 28(5) of Delegated Regulation (EU) 2020/687;

(b) movements of unvaccinated animals of listed species in accordance with the following provisions:

(i) within 24 hours preceding loading, all animals of listed species on the establishment have been subjected to clinical examination and have not shown clinical signs of FMD,

(ii) the animals have completed a standstill on the establishment of origin of at least 30 days during which no animal of listed species has been introduced into the establishment,

(iii) the animals intended for transport were either individually subjected, with negative results, to tests for the detection of antibodies against the FMD virus at the end of the isolation period, or a serological survey was completed on that establishment irrespective of the species concerned;

(iv) the animals were not exposed to any source of infection during their transportation from the establishment of origin to the place of destination, that shall be located in the same Member State;

(c) movements of non-vaccinated calves, offspring of vaccinated cows to:

(i) an establishment within the vaccination zone of the same health status as the establishment of origin;

(ii) a slaughterhouse for immediate slaughter;

(iii) an establishment designated by the competent authority, from which the offspring are to be sent directly to a slaughterhouse;

(iv) any establishment, after having obtained a negative result in a serological test for the detection of antibody against the FMD virus carried out on a sample of blood taken prior to dispatch from the establishment of origin;

(d) movements of fresh meat, meat products, raw milk, dairy products in accordance with point 3.2, points (b) to (f);

(e) collection of semen in accordance with point 3.1, point (d)

PART 4

RECOVERY PERIODS FOR FMD FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery 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 (EU) 2020/687	Clinical and laboratory
The relevant recommendations in the FMD Chapter, 30th edition 2022, of the WOAH Terrestrial Animal Health Code are met	

ANNEX VIII

Infection with Rift valley fever virus (RVF)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF RVF

1. Size of the vaccination zone: 50 km radius around affected establishments or ring vaccination between 20 and 50 km.

2. Size of the peri-vaccination zone: No specific rules.

3. Type of vaccine to be used or prioritised: Inactivated vaccines. Live attenuated vaccines may only be used in endemic areas.

4. Minimum coverage: No specific rules.

5. Targeted animals/species: Animals of listed species in accordance with Implementing Regulation (EU) 2018/1882 kept in the vaccination zone, including at least bovine, ovine, caprine and camelid animals.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF RVF

Passive surveillance: in the vaccination and peri-vaccination zones, enhanced passive surveillance on abortions, stillbirths and neonatal mortality during summer and autumn (during the peak of and end of the vector season).

PART 3

SPECIFIC CONDITIONS FOR THE PROHIBITION OF MOVEMENTS OF ANIMALS AND PRODUCTS AND FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13, IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF RVF IS CARRIED OUT

1. Animals and products subject to prohibition of movements: vaccinated animals and products thereof, including semen, embryos and oocytes destined to be moved to other Member States.

2. Germinal products subject to prohibition of collection: semen, oocytes and embryo from animals of listed species.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b). Movements that may be authorised.

   Movements of vaccinated animals and products thereof, including semen, embryos and oocytes to another Member State for which the competent authority of the Member State of destination grants a specific authorisation for entry of each consignment of vaccinated animals or products thereof. This authorisation may be based on the results of laboratory examinations.

PART 4

RECOVERY PERIODS FOR RVF

No additional disease-specific requirements

ANNEX IX

Infection with lumpy skin disease virus (LSD)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF LSD

1. Types of vaccination zones:

1.1. Vaccination zone I: vaccination zone where emergency protective vaccination is implemented in areas where LSD has not been confirmed;

1.2. Vaccination zone II: vaccination zone where emergency protective vaccination is implemented in areas where outbreaks of LSD have been confirmed.

2. Size of vaccination zone II: Vaccination zone II shall cover at least the areas included in the protection, surveillance and further restricted zones established after the confirmation of that disease in accordance with Article 21 of Delegated Regulation (EU) 2020/687.

3. Size of the peri-vaccination zone: At least 20 km width from the perimeters of the vaccination zones I and II.

4. Type of vaccine to be used or prioritised: to prioritise the use of homologous vaccines.

5. Minimum coverage: vaccine coverage of at least 95 % of the establishments keeping bovine animals representing at least 75 % of the bovine animals population of the vaccination zone.

6. Targeted animals/species: All bovine animals and their offspring kept in the vaccination zone.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF LSD

No additional disease-specific requirements

PART 3

SPECIFIC CONDITIONS FOR THE PROHIBITION OF MOVEMENTS OF ANIMALS AND PRODUCTS AND FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13, IN VACCINATION ZONES WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF LSD IS CARRIED OUT

1. Animals and products subject to prohibition of movements from establishments located in vaccination zones I and II, until the end of the recovery period laid down in Part 4:

   (a) bovine animals;

   (b) germinal products from bovine animals;

   (c) unprocessed animal by-products from bovine animals other than milk, colostrum, dairy products and colostrum-based products intended for animal feed.

2. Germinal products subject to prohibition of collection: none.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b). Movements that may be authorised.

3.1. Movements of bovine animals from vaccination zone I:

Movements of consignments of bovine animals may be authorised from establishments located in vaccination zone I to:

   (a) vaccination zones I or II of the same or another Member State provided that all of the following conditions are fulfilled:

      (i) the bovine animals in the consignment must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;

(ii) all the other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on the date of dispatch;

(iii) the bovine animals in the consignment must have been kept in their establishment of origin since birth or for a continuous period of at least 28 days prior to the date of dispatch; and

— 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,

— if necessary, a laboratory examination was carried out, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;

(b) any destination, in the same Member State or in other Member States, if, in addition to the conditions laid down in point (a) (ii) and (iii), all of the following conditions are fulfilled:

(i) the bovine animals in the consignment must have been vaccinated against LSD at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on the date of dispatch;

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

(iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against LSD at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within the immunity period induced by maternal immunity;

(c) any destination, in other Member States or territories in third countries, if, in addition to the conditions laid down in point (a), the following conditions are fulfilled:

(i) the animals must comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of LSD required by the competent authority of the Member State of origin and approved by the competent authority of the Member States of passage and destination, prior to the date of dispatch;

(ii) there must 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; and

(iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against LSD at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within the immunity period induced by maternal immunity.

3.2. Movements of bovine animals from vaccination zone II:

Movements of consignments of bovine animals may be authorised from establishments located in vaccination zone II to:

(a) any destination, in the same Member State and other Member States, provided that all of the following conditions are fulfilled:

(i) the bovine animals in the consignment shall comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of LSD required by the competent authority of the Member State of origin and approved by the competent authority of the Member States of passage and destination, prior to the date of dispatch;

(ii) the bovine animals in the consignment must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;

(iii) all other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date;

(iv) the following examinations were carried out:

— a clinical examination, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments,

— if necessary, a laboratory examination, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;

(v) the bovine animals must have been resident since birth, or for a period of at least 28 days prior to the date of dispatch, in an establishment where, within a radius of at least 20 km, no outbreak of LSD has been confirmed during the three months prior to the date of dispatch;

(vi) all bovine animals in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against LSD, at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within the immunity period induced by maternal immunity;

(b) any destination located within another vaccination zone II of the same Member State, provided that all of the following conditions are fulfilled:

(i) all other bovine animals kept in the establishment of origin of such consignments must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date; and

(ii) the bovine animals must have been vaccinated against LSD at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or are unvaccinated offspring less than four months old, born to dams vaccinated at least 28 days prior to parturition that remained within the immunity period according to the vaccine manufacturer on the date of parturition, and may be moved to another establishment.

3.3. Movements of consignments of bovine animals from vaccination zones I and II to a slaughterhouse outside those zones:

Movements of consignments of bovine animals may be authorised from vaccination zones I and II to a slaughterhouse outside of those zones, located in the territory of the same Member State, provided that the bovine animals are moved for the purposes of immediate slaughter in compliance with the general conditions laid down in Article 28(2) to (5) and Article 28(7) of Delegated Regulation (EU) 2020/687.

3.4. Movements of consignments of semen, oocytes and embryos of bovine animals from vaccination zones I and II:

3.4.1. Movements of consignments of semen, oocytes and embryos of bovine animals may be authorised from approved germinal product establishments or other establishments located in vaccination zone I to:

(a) vaccination zones I or II of the same Member State provided that all of the following conditions are fulfilled:

(i) the donor animals were either:

— vaccinated and revaccinated against LSD according to the manufacturer's instructions of the vaccine used, and the first vaccination must have been administered at least 60 days prior to the date of collection of the semen, oocytes or embryo, or

— subjected, with negative results, to a serological test to detect specific antibodies against LSD virus on the day of the collection and at least 28 days after the period of collection as regards semen or on the day of collection as regards embryos and oocytes;

(ii) the donor animals were kept, during the 60 days prior to the date of collection of the semen, oocytes or embryos, in an artificial insemination centre or other appropriate establishment where, within a radius of at least 20 km, no outbreak of LSD has been confirmed during the three months prior to the date of collection of the semen, oocytes or embryos;

(iii) the donor animals were clinically checked 28 days prior to the date of collection, as well as throughout the entire collection period, and did not show any clinical symptoms of LSD;

(b) any destination located in another vaccination zone I or II of another Member State, provided that, in addition to the conditions laid down in point (a), all of the following conditions are fulfilled:

(i) the donor animals were subjected, with negative results, to a polymerase chain reaction (PCR) test to detect LSD conducted on blood samples collected at the commencement of collection of the semen and at least every 14 days thereafter during the semen collection period or on the day of collection for embryos and oocytes;

(ii) the semen was subjected, with negative results, to a PCR test to detect LSD;

(c) any destination located in the same or another Member State or, in case of a vaccination zone I, to a third country provided that, in addition to the conditions laid down in point (a), the donor animals comply with any other appropriate animal health guarantees, based on a positive outcome of a risk assessment of the impact of such dispatch and of the measures against the spread of LSD, required by the competent authority of the Member State of the establishment of origin and approved by the competent authorities of the Member States of the places of passage and of destination, prior to the dispatch of such semen, oocytes or embryos.

3.4.2. Movements of consignments of semen, oocytes and embryos of bovine animals, may be authorised from approved germinal product establishments or other establishments located in a vaccination zone II to any destination located in another vaccination zone II of the same Member State.

3.5. Movements of consignments of unprocessed animal by-products from bovine animals from vaccination zones I:

Movements of consignments of unprocessed animal by-products from bovine animals may be authorised from establishments located in a vaccination zone I to:

(a) any destination located in the same Member State or to any destination located in vaccination zones I or II of another Member State;

(b) in the case of consignments of hides and skins, any destination located in any area of the same or another Member State or third country provided that one of the following conditions is fulfilled:

(i) the treated hides and skins have been subjected to one of the treatments referred to in point 28(b) to (e) of Annex I to Commission Regulation (EU) No 142/2011 ([1]); or

(ii) the treated hides and skin have been subjected to one of the treatments set out in Section XIV, Chapter I, point (4)(b)(ii), of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council ([2]), and have undergone all precautions to avoid recontamination with pathogenic agents after treatment.

([1]) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

([2]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

3.6. Movements of consignments of unprocessed animal by-products from bovine animals from vaccination zones II:

Movements of consignments of unprocessed animal by-products from bovine animals may be authorised from establishments located in a vaccination zone II to:

(a) in the case of unprocessed animal by-products other than hides and skins, any destination located in the same Member State or any destination located in vaccination zones I or II of another Member State provided that the unprocessed animal by-products are dispatched under the official supervision of the competent authorities for processing or disposal in a plant approved in accordance with Article 24 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([3]);

(b) in the case of hides and skins of bovine animals:

(i) any destination located in a vaccination zone II of the same or another Member State provided that they are untreated raw hides and skins destined for human consumption or untreated hides and skins not intended for human consumption dispatched under the official supervision of the competent authorities for processing or disposal in a plant approved in accordance with Article 24 of Regulation (EC) No 1069/2009;

(ii) any destination located in the same or another Member State provided that the conditions laid down in point 3.5(b), are fulfilled;

(c) in the case of colostrum, milk and dairy products, any destination located in any area of the same or another Member State provided that they have been subjected to a risk-mitigating treatment for LSD, as set out in Annex VII to Delegated Regulation (EU) 2020/687.

3.7. Conditions related to the means of transport used for the movement of consignments of bovine animals and unprocessed animal by-products from vaccination zones I and II outside of those zones when granting relevant derogations:

(a) in the case of transport of bovine animals, the means of transport:

(i) comply with the requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and

(ii) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authority of the Member State;

(b) only include bovine animals or unprocessed animal by-products or untreated hides and skins of the same health status.

PART 4

RECOVERY PERIODS FOR LSD FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to demonstrate the absence of occurrence of LSD
14 months after the slaughter or killing of the last case, or after the last vaccination if emergency protective vaccination has been used (in vaccination zone II), whichever occurred last, and during which period clinical and laboratory surveillance has demonstrated no occurrence of LSD	Clinical and laboratory (virological and serological)
26 months after the slaughter or killing of the last case, or after the last vaccination if emergency protective vaccination has been used (in vaccination zone II), whichever occurred last, and during which period clinical surveillance alone has demonstrated no occurrence of LSD	Clinical
8 months after the last vaccination if emergency protective vaccination has been used (in vaccination zone I), and during which period clinical and laboratory surveillance has demonstrated no occurrence of LSD	Clinical and laboratory (virological and serological)

([3]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

ANNEX X

Infection with peste des petits ruminants virus (PPR)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF PPR

1. Size of the vaccination zone: No specific conditions.

2. Size of the peri-vaccination zone: No specific conditions.

3. Type of vaccine to be used or prioritised: No specific conditions

4. Minimum coverage: No specific conditions.

5. Targeted animals/species: Animals of listed species in accordance with Implementing Regulation (EU) 2018/1882 kept in the vaccination zone, including at least ovine and caprine animals.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF PPR

Passive surveillance: in the vaccination and peri-vaccination zones, enhanced passive surveillance for PPR signs and symptoms as well as for increased mortality in small ruminants.

PART 3

SPECIFIC CONDITIONS FOR THE PROHIBITION OF MOVEMENTS OF ANIMALS AND PRODUCTS AND FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13, IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF PPR IS CARRIED OUT

1. Animals and products subject to prohibition of movements until the end of the recovery period laid down in PART 4

   The same animals and products, located in the vaccination zones, as those subject to restrictions in establishments located in protection and surveillance zones established in the event of an outbreak of PPR provided for in Article 27 of Delegated Regulation (EU) 2020/687 and with the same restrictions.

2. Germinal products subject to prohibition of collection: semen, oocytes and embryos from animals of listed species, until the end of the recovery period.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b). Movements that may be authorised.

3.1. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone, under the same general conditions as those provided for in Article 43 of Delegated Regulation (EU) 2020/687, and only in the cases covered by and under the same specific conditions as those provided for in Articles 44, 45, 48, 49, 51 and 53 of that Regulation in relation to the surveillance zone.

3.2. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone, provided that those establishments do not keep vaccinated animals any more.

3.3. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone after 2 years have elapsed from cessation of vaccination.

PART 4

RECOVERY PERIODS FOR PPR FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to demonstrate the absence of occurrence of PPR
6 months after the slaughter or killing of the last case and of all vaccinated animals if emergency protective vaccination has been used, and during which period clinical and laboratory surveillance has demonstrated no occurrence of PPR	Clinical and laboratory (virological and serological)
24 months after the slaughter or killing of the last case, or after the last vaccination if emergency protective vaccination has been used, whichever occurred last, and during which period clinical and laboratory surveillance has demonstrated no occurrence of PPR	Clinical and laboratory (virological and serological)

ANNEX XI

African horse sickness (AHS)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF AHS

1. Type of vaccine to be used or prioritised: Monovalent vaccines or, if monovalent vaccines are not available, polyvalent vaccines with the least possible number of valences authorised by the competent authority.

2. Size of the vaccination zone: infected establishments subject to the derogation provided for in Annex III to Delegated Regulation (EU) 2020/687 and establishments located within a 20 km radius around the infected establishments (included in the protection zone). A vaccination zone may cover the entire protection zone. Any vaccination in the surveillance zone is prohibited.

3. Size of the peri-vaccination zone: No specific conditions

4. Minimum coverage: No specific conditions

5. Targeted animals/species: all equine animals in the vaccination zone, in accordance with the instruction of the vaccine manufacturer/the marketing authorisation.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF AHS

Clinical and laboratory surveillance shall be carried out in the vaccination zone. This surveillance shall include at least:

1. a clinical examination of equine animals every 3 to 7 days, or each day in the case of severe clinical cases, since such cases may need to be euthanised because of animal welfare reasons;

2. a laboratory surveillance of equine animals (testing should be carried out on samples taken at intervals of 3 to 7 days as the minimum time required to capture the minimum incubation period after which an infected animal may test positive), and the diagnostic protocol shall be set up according to the vaccine used (a serological surveillance, in case a DIVA vaccine is used, or a virological surveillance). The surveillance is necessary to detect the AHS virus types circulating to ensure that all circulating serotypes are included in the official vaccination plan;

3. a surveillance of Culicoides.

PART 3

SPECIFIC CONDITIONS FOR THE PROHIBITION OF MOVEMENTS OF ANIMALS AND PRODUCTS AND FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13, IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF AHS IS CARRIED OUT

1. Animals and products subject to prohibition of movements

   Equine animals and germinal products thereof from the vaccination zone until the end of the recovery period.

2. Germinal products subject to prohibition of collection: none.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).

1. The equine animal to be moved from the establishment where it was kept at the time when the vaccination was carried out, was vaccinated more than 40 days prior to movement;

2. The animal referred to in point (1):

(a) has undergone a prior identity check and clinical examination as referred to in Article 91(1), point (a), of Delegated Regulation (EU) 2020/688;

(b) showed no clinical symptoms of AHS on the day of the clinical examination;

(c) is identified by way of a transponder and a record of vaccination against AHS is kept in its single lifetime document and in the computer database referred to in Article 109(1), point (d), of Regulation (EU) 2016/429;

(d) is kept in a vector protected establishment as defined in Article 2(18) of Delegated Regulation (EU) 2020/689 for a period of at least 14 days prior to movement and is subjected to an agent identification test for AHS, at the end of this period, with a negative result, or is kept in a vector protected establishment for at least 40 days prior to movement;

(e) is protected from the attack of vectors.

PART 4

RECOVERY PERIODS FOR AHS FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to be implemented during the recovery period
12 months, since the last animal was vaccinated and 2 years since the last outbreak	Clinical and serological
The relevant recommendations in the AHS Chapter, 30th edition 2022, of the WOAH Terrestrial Animal Health Code	

ANNEX XII

Classical swine fever (CSF)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF

1. Size of the vaccination zone: No specific conditions.

2. Size of the peri-vaccination zone: No specific conditions.

3. Type of vaccine to be used or prioritised: Live attenuated vaccines shall be prioritised. Other vaccines may be used only for duly justified reasons.

4. Minimum coverage: No specific conditions.

5. Targeted animals/species: Animals of listed species, in accordance with Implementing Regulation (EU) 2018/1882, kept in the vaccination zone.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF

No additional disease-specific requirements

PART 3

ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF IS CARRIED OUT

1. **Animals and products subject to prohibition of movements**

The following animals, germinal products and products of animal origin from establishments located in the vaccination zone to outside the vaccination zones:

(a) vaccinated porcine animals;

(b) offspring of seropositive sows;

(c) semen, oocytes and embryos for artificial insemination from donor porcine animals kept in approved germinal product establishments;

(d) fresh meat obtained from vaccinated porcine animals;

2. **Germinal products subject to prohibition of collection**

Semen, oocytes and embryos for artificial insemination from seropositive donor porcine animals kept in approved germinal product establishments located in the vaccination zone.

3. **Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b)**

Movements of animals and products thereof that may be authorised:

(1) movements of vaccinated porcine animals, directly from the establishment of origin to:

(a) a slaughterhouse located as close as possible to the vaccination zone, in the same Member State, under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 29(1) and (2) of Delegated Regulation (EU) 2020/687;

(b) to an animal by-product approved plant, under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 37 of Delegated Regulation (EU) 2020/687;

(2) movement of fresh meat from vaccinated animals in accordance with Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;

(3) all movements of animals and products thereof, laid down in point 1, provided that:

(a) all the vaccinated porcine animals kept in the vaccination zone have been slaughtered or killed, and the fresh meat obtained from those animals has been disposed or processed in accordance with Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;

(b) all the establishments where vaccinated porcine animals had been kept have been cleaned and disinfected in accordance with Article 57(1) of Delegated Regulation (EU) 2020/687;

(c) the repopulation of the establishments above has not taken place until at least 10 days after completion of the cleaning and disinfection operations, and after all porcine animals in the establishments where vaccination has been applied have been slaughtered or killed;

(d) after repopulation, porcine animals in all establishments of the vaccination zone have undergone clinical and laboratory examinations in accordance with Annex I to Delegated Regulation (EU) 2020/687 in order to detect the possible presence of CSF virus and those examinations have not taken place until at least 40 days have elapsed after the repopulation, during which time porcine animals are not allowed to move from that establishment.

PART 4

RECOVERY PERIODS FOR CSF FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to be implemented during the recovery period
3 months after all vaccinated porcine animals have been slaughtered or killed, excluding kept porcine animals referred to in Article 13(2) of Regulation (EU) 2020/687 when there are means, validated in accordance with the Terrestrial Manual of the WOAH, of distinguishing between vaccinated and infected kept porcine animals.	Clinical and serological
The relevant recommendations in the CSF Chapter, 30th edition 2022, of the WOAH Terrestrial Animal Health Code	

ANNEX XIII

Highly Pathogenic Avian Influenza (HPAI)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI

1. Size of the vaccination zone: No specific conditions.

2. Size of the peri-vaccination zone: No specific conditions.

3. Type of vaccine to be used: Vaccines that do not contain live avian influenza virus (vaccines containing live avian influenza virus, whether attenuated or not, shall not be used).

4. Minimum coverage: No specific conditions.

5. Targeted animals/species: poultry or captive birds kept in the establishments included in the official vaccination plan.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI

Laboratory surveillance by collection of samples for virological testing shall be implemented every two weeks in the establishments where emergency protective vaccination has been carried out to detect occurrence of infection with HPAI field virus. The surveillance has to enable detection of a prevalence of infection with the HPAI virus in the vaccinated establishment of 5 % or less with a confidence level of 95 %.

PART 3

ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI IS CARRIED OUT

1. Animals and products subject to prohibition of movements: vaccinated poultry or captive birds and their products within and outside the vaccination zone.

2. Germinal products subject to prohibition of collection: not applicable.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).

   Movements of vaccinated poultry or captive birds and their products within and outside the vaccination zone may be authorised only in the cases covered by and under the same general and specific conditions as those provided for in Articles 28, 29 and 30, Article 31(1) and Articles 33, 34 and 37 of Delegated Regulation (EU) 2020/687.

   After the end of the recovery period, the measures provided for in points 2 to 4 of Part 5 shall remain in place in the establishments keeping vaccinated animals, as long as they keep vaccinated animals.

PART 4

RECOVERY PERIODS FOR HPAI FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to be implemented during the recovery period
28 days after completion of the emergency protective vaccination or at the time of the lifting of the restricted zones established in accordance with Article 21 of Delegated Regulation (EU) 2020/687 if this comes later.	Reinforced surveillance in accordance with Article 9 (1), point (c) and Part 2.

PART 5

SPECIFIC CONDITIONS FOR PREVENTIVE VACCINATION OF HPAI

1. **Type of vaccine to be used**: Vaccines that do not contain live avian influenza virus (vaccines containing live avian influenza virus, whether attenuated or not, shall not be used).

2. Reinforced surveillance to be implemented in case of preventive vaccination:

2.1. enhanced passive surveillance shall be implemented in the vaccinated establishments by weekly virological testing of a representative sample of dead birds collected within one week;

2.2. after the start of vaccination, the following active surveillance has to be carried out by an official veterinarian in vaccinated establishments at least every 30 days to detect occurrence of infection with HPAI field virus:

(a) a clinical examination that shall include a check of the production records and health records of the establishment in each epidemiological unit, including an evaluation of its clinical history and clinical examinations of the poultry or captive birds;

(b) a collection of representative samples for laboratory surveillance by serological or virological testing to enable detection of a prevalence of HPAI virus infection in the epidemiological unit of 5 % with a confidence level of 95 %, using appropriate methods and protocols that allow early detection of the virus and taking into account the specific characteristics of the vaccine used;

2.3. Vaccinated captive birds from confined establishments are exempted from the surveillance requested in point 2.2, subpoint (b).

2.4. The measures provided for in points 2.1 and 2.2 shall remain in place in the establishments keeping vaccinated animals as long as they keep vaccinated animals.

3. Animals and products subject to prohibition of movements in accordance with Article 14(1): vaccinated poultry or captive birds and their products

4. Conditions for granting a derogation in accordance with Article 14(2), point (b).

4.1. Conditions for granting a derogation for movements of vaccinated poultry or captive birds including day-old chicks and hatching eggs derived from such poultry or captive birds:

(a) They are vaccinated poultry or captive birds for which the results of the reinforced passive and active surveillance, implemented in accordance with point (2) are negative for detection of infection with HPAI field virus or day-old chicks and hatching eggs derived from such poultry or captive birds

and

(i) in case of poultry, these are moved to a slaughterhouse for immediate slaughter; or

they are moved from their establishments to other establishments:

(ii) where vaccination is carried out; or

(iii) where only vaccinated poultry or captive birds are kept; or

(iv) where complete separation between vaccinated and non-vaccinated poultry or captive birds can be ensured;

and

(v) the moved poultry or captive birds remain in the establishment of destination, referred to in subpoints (ii), (iii) or (iv), for at least 21 days, unless these are poultry moved from the establishment of destination to a slaughterhouse for immediate slaughter;

(vi) the poultry or captive birds, including day-old chicks and hatching eggs derived from such poultry or captive birds, referred to in subpoints (i), (ii), (iii) or (iv) are not moved to another Member State;

or

(b) they are vaccinated captive birds from confined establishments moved to a confined establishment in another Member State provided that:

(i) approval of such type of movements has been granted by the competent authority of the Member State of destination;

(ii) they have been subjected to a virological test with negative results within 72 hours before movement;

or

(c) they are vaccinated poultry sent for immediate slaughter to another Member State, provided that:

(i) the surveillance applied in the establishment of origin in accordance with point (2) has favourable results;

(ii) poultry of the consignment to be dispatched were clinically inspected with favourable results by an official veterinarian within 72 hours before the time of loading, and, in case of poultry of Anseriforme species, favourable results were obtained on virological tests performed on samples taken within 72 hours prior to the time of departure from 20 birds from that consignment;

or

(d) they are hatching eggs derived from vaccinated poultry or captive birds which:

(i) originate from a vaccinated breeding flock for which the reinforced passive and active surveillance in accordance with point (2) has favourable results;

(ii) have been disinfected before dispatch in accordance with a method approved by the competent authority;

(iii) are transported directly to the hatchery of destination;

(iv) are traceable within the hatchery;

(v) in case they are moved to another Member State, in addition to the requirements in subpoints (i) to (iv), the Member State of destination has informed the Commission and the other Member States that such movements are authorised;

or

(e) they are day-old chicks derived from vaccinated poultry which:

(i) originate from a vaccinated breeding flock for which the reinforced passive and active surveillance in accordance with point (2) has favourable results;

(ii) are placed in a poultry house or shed where there is no resident poultry;

(iii) remain in the establishment of destination for at least 21 days;

(iv) in case they are moved to another Member State, in addition to the requirements in subpoints (i) to (iii), the Member State of destination has informed the Commission and the other Member States that such movements are authorised.

4.2. Conditions for granting a derogation for the movement of eggs for human consumption and meat derived from vaccinated poultry:

(a) The eggs originate from a vaccinated flock for which the surveillance in point (2) has favourable results and

are directly transported to:

(i) a packing centre designated by the competent authority provided that they are packed in disposable packaging or in a packaging which can be cleaned and disinfected in such way as to inactivate the HPAI virus;

(ii) an establishment for the manufacture of egg products as set out in Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 to be handled and treated in accordance with Chapter XI of Annex II to Regulation (EC) No 852/2004.

(b) The movement of meat obtained from poultry in accordance with the conditions laid down in points 4.1(a)(i), 4.1(a)(v) and 4.1(c) may be authorised without further conditions;

ANNEX XIV

Infection with Newcastle disease virus (NCD)

PART 1

SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF NCD

1. Size of the vaccination zone: No specific conditions.

2. Size of the peri-vaccination zone: No specific conditions.

3. Type of vaccine to be used: No specific conditions.

4. Minimum coverage: all poultry of the species included in the official vaccination plan or captive birds hatched in or transferred to an establishment inside the vaccination zone must be or have been vaccinated.

5. Targeted animals/species: Poultry and captive birds.

PART 2

SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF NCD

No specific conditions in addition to the reinforced surveillance in accordance with Article 9(1), point (c).

PART 3

ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF NCD IS CARRIED OUT

1. Animals and products subject to prohibition of movements: vaccinated poultry or captive birds and their products within and outside the vaccination zone.

2. Germinal products subject to prohibition of collection: not applicable.

3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).

   Movements of vaccinated poultry or captive birds and their products within and outside the vaccination zone may be authorised only in the cases covered by and under the same general and specific conditions as those provided for in Articles 28, 29, 30, 31, 33, 34 and 37 of the Delegated Regulation (EU) 2020/687.

PART 4

RECOVERY PERIODS FOR NCD FOLLOWING EMERGENCY PROTECTIVE VACCINATION

Recovery period	Type of surveillance to be implemented during the recovery period
3 months after completion of the emergency protective vaccination or at the time of the lifting of the restricted zones established in accordance with Article 21 of Delegated Regulation (EU) 2020/687 if this comes later.	The reinforced surveillance in accordance with Article 9(1), point (c)