II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/139

of 16 November 2021

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks

(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 48(3) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including rules for the establishment and management of the Union antigen, vaccine and diagnostic reagent banks. In accordance with Article 48(1) of that Regulation, the Commission may establish and be responsible for managing the Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents for the listed diseases referred to in Article 9(1), point (a), thereof, in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47 thereof. The establishment of Union antigen, vaccine and diagnostic reagent banks, in accordance with that Regulation, would promote the attainment of the Union's animal health objectives by permitting a quick and effective response when the resources of those banks are required in the event of the occurrence of a category A disease, as defined and categorised by Commission Implementing Regulation (EU) 2018/1882 ([2]), and would represent an efficient use of limited resources.

(2) Furthermore, Article 47(1) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts laying down rules concerning the use of veterinary medicinal products, including vaccines, for the purpose of the prevention and control of listed diseases in terrestrial animals. Those delegeted acts will specify the category A diseases which could be prevented or controlled by use of vaccines in kept and wild terrestrial animals. Therefore, this Regulation should supplement the rules laid down in Part III of Regulation (EU) 2016/429, and provide for the establishment of Union antigen and vaccine banks for category A diseases, for which vaccination is not prohibited, and for the establishment of Union diagnostic reagent banks for category A diseases covered by those delegated acts

([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).

that are to be adopted pursuant to Article 47(1) of Regulation (EU) 2016/429. In addition, Commission Implementing Regulation (EU) 2022/140 ([3]) provides a list of category A diseases for which the Union antigen, vaccine and diagnostic reagent banks are established and maintained.

(3) The Commission should purchase the antigens, vaccines and diagnostic reagents to be supplied to the Union antigen, vaccine and diagnostic reagent banks and should cover the expenses for the storage of the antigens, vaccines and diagnostic reagents therein. In order to establish and maintain those banks, the Commission should conclude appropriate contracts with selected manufacturers for the purchase, supply, storage and replacement of antigens, vaccines or diagnostic reagents. For that purpose, a procurement procedure should be carried out in accordance with the rules laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([4]).

(4) In addition, it is necessary to provide for a 'hybrid' mechanism, corresponding to framework supply contracts between the Commission and selected manufacturers to provide vaccines or diagnosic reagents to the Member States, third countries or territories, when requested by the Commission. Those Union antigen, vaccine and diagnostic reagents banks should be virtual given that the Commission does not keep any physical stocks, but rather calls upon a framework supply contract with one or more vaccine manufacturers for the release, shipment and delivery of the necessary vaccines or diagnostic reagents. The framework supply contracts may need to cover leasing costs. The terms of the framework supply contracts should allow the Commission to immediately require the manufacturers to release, ship and deliver vaccines or diagnostic reagents to a Member State, third country or territory that has been granted access to the Union antigen and vaccine banks. The availability of rolling stocks of vaccines or diagnostic reagents coupled with a fast decision-making process within the Commission would guarantee a service that rapidly provides high quality vaccines or diagnosic reagents.

(5) In addition to framework supply contracts, the Commission should, in the framework of a grant agreement, be permitted to include the stockpiling of essential diagnostic reagents in the annual or multiannual work programmes of the European Union reference laboratories designated for the relevant diseases in accordance with Article 93(1) of Regulation (EU) 2017/625 of the European Parliament and of the Council ([5]). Such Union diagnostic reagent banks are appropriate for the tasks of the European Union reference laboratories referred to in Article 94(2) of Regulation (EU) 2017/625, and in particular point (f), point k(iii) and point (l) thereof. The European Union reference laboratories have the necessary experience in the quality testing, storage, timely renewal and disposal of diagnostic reagents, and it would be an appropriate use of the infrastructures already in place. The annual or multiannual work programmes of the European Union reference laboratories are established in conformity with the objectives and priorities of the relevant work programmes referred to in Article 3(2), point (e), of Regulation (EU) 2021/690 of the European Parliament and of the Council ([6]) and adopted by the Commission, and thus provide the opportunity for regular review of the measures.

([3]) Commission Implementing Regulation (EU) 2022/140 of 16 November 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and the Council with regard to the Union antigen, vaccine and diagnostic reagent banks (See page 11 of this Official Journal).

([4]) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

([5]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

([6]) Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014 (OJ L 153, 3.5.2021, p. 1).

(6) When deciding on the principles for selecting strains and variations of antigens and vaccines to be supplied to the Union antigen, vaccine and diagnostic reagent banks in order to ensure sufficient quantities, the required quality and the appropriate types of stocks in those banks, the Commission should take account of the advice of experts, including experts from institutions such as the European Union reference laboratories, or any other international standard setting bodies relevant to the disease in question, including the European Commission for the Control of Foot-and-Mouth Disease (EuFMD).

(7) The contract concluded with a selected manufacturer should guarantee appropriate conditions for the destruction and safe disposal of any unused antigen, vaccine or diagnostic reagent stored in the Union antigen, vaccine and diagnostic reagent banks after the expiry of its validity period. In cases where an antigen is supplied to a Union antigen bank and remains in that bank after the expiry of its validity period, the contract may lay down conditions for a buy-back of the antigen by the contracted manufacturer.

(8) Biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks should be established in this Regulation, taking into account the recommendations of Chapter 1.1.4 'Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities' of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021. The antigens, vaccines and diagnostic reagents should also comply with recognised quality standards, such as those laid down in Chapter 1.1.5 'Quality management in veterinary testing laboratories', in Chapter 1.1.8 'Principles of veterinary vaccine production', in Chapter 1.1.10 'Vaccine banks', and in disease-specific chapters of that Manual.

(9) It is important to verify compliance with the biosecurity, biosafety and bio-containment requirements of operations carried out by the Union antigen, vaccine and diagnostic reagent banks through controls. Therefore, in addition to regular and risk-based controls of manufactures and laboratories carried out by the competent authorities of the Member States, the Commission should perform controls at the Union antigen, vaccine and diagnostic reagent banks to ensure continuous compliance with the relevant standards agreed to in the contracts concluded between the Commission and the manufacturers. Those inspections should be carried out in accordance with Regulation (EU) 2017/625.

(10) Prior to the date of application of Regulation (EU) 2016/429 on 21 April 2021, the Commission already established and maintained the following Union banks: the foot-and-mouth disease antigen and vaccine bank in accordance with Council Decision 91/666/EEC ([7]) and with Article 80(1) of Council Directive 2003/85/EC ([8]); the classical swine fever vaccine bank in accordance with Article 18(2) of Council Directive 2001/89/EC ([9]) and with Commission Decision 2007/682/EC ([10]); and the lumpy skin disease vaccine bank, peste des petits ruminants vaccine bank and sheep pox and goat pox vaccine bank in accordance with Article 6(5) of Regulation (EU) No 652/2014 of the European Parliament and of the Council ([11]). Directives 2001/89/EC and 2003/85/EC and Decision 91/666/EEC are repealed by Regulation (EU) 2016/429 with effect from 21 April 2021. In addition, Commission Delegated Regulation (EU) 2020/687 ([12]) provides that Directives 2001/89/EC and 2003/85/EC, as well as the acts adopted on the basis thereof, including Decision 2007/682/EC, are to cease to apply with effect

([7]) Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21).

([8]) Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

([9]) Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

([10]) Commission Decision 2007/682/EC of 18 October 2007 on the renewal of the Community stocks of live attenuated vaccine against classical swine fever (OJ L 281, 25.10.2007, p. 25).

([11]) Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

([12]) 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).

from 21 April 2021. Regulation (EU) No 652/2014 is repealed by Regulation (EU) 2021/690 of the European Parliament and of the Council with effect from 1 January 2021. Article 24(1) of Regulation (EU) 2021/690 ensures that Union financial contributions for the establishment of those Union banks awarded under Article 6(5) of Regulation (EU) No 652/2014 continue to be applicable as of 1 January 2021. Therefore, the Union banks established based on those repealed acts should be maintained after the date of application of this Regulation until the date of expiry of the relevant contracts.

(11) In order to ensure the time needed for the establishment of the Union antigen, vaccine and diagnostic reagent banks based on the new rules, this Regulation should apply from 1 May 2022,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation supplements the rules laid down in Article 48 of Regulation (EU) 2016/429 as regards the Union antigen, vaccine and diagnostic reagent banks for category A diseases.

2. This Regulation lays down:

(a) the rules on the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in the Union antigen, vaccine and diagnostic reagent banks, and in particular on:

  (i) rules on the contracts and grants for the supply and storage of antigens, vaccines and diagnostic reagents;

  (ii) the conditions for the supply and storage of antigens, vaccines and diagnostic reagents;

  (iii) the principles of selecting strains and variations of antigens, vaccines and diagnostic reagents;

  (iv) the destruction and safe disposal of antigens, vaccines and diagnostic reagents which have reached the end of their validity period;

  (v) the possibilities of buy-back of the antigens for which the validity period has expired;

(b) the biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks;

(c) transitional provisions for the Union antigen and vaccine banks established and maintained prior to the date of application of this Regulation.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'category A disease' means a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in Article 9(1), point (a), of Regulation (EU) 2016/429;

2. 'Union antigen bank' means a Commission-managed reserve of antigenic components that can be rapidly formulated into the final product for emergency use or other vaccination campaigns in Member States or third countries or territories granted access by the Union;

3. 'Union vaccine bank' means a Commission-managed reserve of ready-to-use vaccines for emergency use or other vaccination campaigns in Member States or third countries or territories granted access by the Union;

4. 'Union diagnostic reagent bank' means a Commission-managed reserve of diagnostic reagents or components thereof for the rapid diagnosis of category A diseases in Member States or third countries or territories granted access by the Union;

5. 'European Union reference laboratories' means laboratories designated in accordance with Article 93(1) of Regulation (EU) 2017/625;

6. 'contracted manufacturer' means a selected manufacturer with whom the Commission has concluded a contract referred to in Articles 3(1) and 4(1);

7. '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;

8. 'ovine animal' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;

9. 'caprine animal' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;

10. 'porcine animal' means an animal of the species of ungulates of family *Suidae* listed in Annex III to Regulation (EU) 2016/429.

Article 3

Rules on the contracts with manufacturers required for the management of the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall conclude contracts with selected manufacturers in order to manage, for category A diseases as referred to in Article 3 of Commission Implementing Regulation (EU) 2022/140, the following banks:

(a) Union antigen banks;

(b) Union vaccine banks;

(c) Union diagnostic reagent banks.

2. The Commission shall implement a public procurement procedure, in accordance with the rules laid down in Regulation (EU, Euratom) 2018/1046, for the selection of the manufacturers for the contracts referred to in paragraph 1.

3. The contracts referred to in paragraph 1 shall cover at least the following matters:

(a) conditions for the supply of various quantities and types of antigens, vaccines or diagnostic reagents to the Union antigen, vaccine and diagnostic reagent banks;

(b) conditions for the secure storage and replacement of antigens, vaccines or diagnostic reagents;

(c) in the case of Union antigen banks, guarantees and conditions for:

  (i) the rapid formulation of the antigens into vaccines;

  (ii) the production, bottling and labelling of vaccines reconstituted from the antigens;

(d) conditions for the release, shipment and delivery of vaccines or diagnostic reagents;

(e) conditions for the destruction and safe disposal of the antigens, vaccines or diagnostic reagents, or for the buy-back of antigens, for which the validity period has expired.

Article 4

Framework supply contracts for the vaccines and diagnostic reagents

1. The Commission may conclude the contracts referred to in Article 3(1) in the form of framework supply contracts with selected manufacturers ('framework supply contracts').

2. By way of derogation from Article 3(3), framework supply contracts shall be required to cover at least the release, shipment and delivery of vaccines or diagnostic reagents upon the request of the Commission.

3. Framework supply contracts may cover leasing costs.

Article 5

The management of the Union diagnostic reagent banks through grants awarded to European Union reference laboratories

1. The Commission may establish and maintain Union diagnostic reagent banks for category A diseases as referred to in Article 3 of Implementing Regulation (EU) 2022/140 at the European Union reference laboratories.

2. The Commission shall include the management and maintenance of the Union diagnostic reagent banks referred to in paragraph 1 of this Article in the annual or multiannual work programmes of the European Union reference laboratories referred to in Article 94(2) of Regulation (EU) 2017/625 for which grants have been awarded in accordance with Article 180 of Regulation (EU, Euratom) 2018/1046.

3. The annual or multiannual work programmes, referred to in paragraph 2, for the purpose of the Union diagnostic reagent banks shall cover at least the following:

(a) the supply of various quantities and types of diagnostic reagents to the Union diagnostic reagent banks;

(b) the secure storage and replacement of diagnostic reagents;

(c) the release, shipment and delivery of diagnostic reagents;

(d) the destruction and safe disposal of the diagnostic reagents for which the validity period has expired.

Article 6

Conditions for the supply and storage of antigens, vaccines and diagnostic reagents

1. The Commission shall ensure that the contracts, referred to in Articles 3(1) and 4(1), and the annual or multiannual work programmes of the European Union reference laboratories for the Union diagnostic reagent banks, referred to in Article 5(2), guarantee conditions for the supply and storage of the antigens, vaccines or diagnostic reagents that are at least equivalent to those laid down in Annex I.

2. In addition to the requirements laid down in paragraph 1 of this Article, the contracts referred to in Articles 3(1) and 4(1) for the purchase, supply, storage and replacement of the concentrated inactivated antigens of the foot and mouth disease virus for the production of foot and mouth disease vaccines shall guarantee conditions for the supply and storage of concentrated inactivated antigens of the foot and mouth disease virus that are at least equivalent to those laid down in Annex II.

Article 7

Principles of selecting strains and variations of antigens, vaccines and diagnostic reagents

The Commission, in consultation with experts from scientific and reference institutions, including the European Union reference laboratories, and international standard setting bodies, shall select the vaccine strains and decide the characteristics of the antigens, vaccines and diagnostic reagents held in the Union antigen, vaccine and diagnostic reagent banks.

Article 8

Destruction and safe disposal of antigens, vaccines and diagnostic reagents

The Commission shall ensure that the contracts, referred to in Article 3(1), or the annual or multiannual work programmes of the European Union reference laboratories, referred to in Article 5(2), guarantee appropriate conditions for the destruction and safe disposal of any unused antigen, vaccine or diagnostic reagent after the expiry of its validity period.

Article 9

Buy-back of the antigens for which the validity period has expired

By way of derogation from Article 8, the Commission may agree with contracted manufacturers on the buy-back of the antigen supplied to a Union antigen bank and remaining in that bank after the expiry of its validity period.

Article 10

Biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks

The Union antigen, vaccine and diagnostic reagent banks shall operate at least in accordance with the following biosecurity, biosafety and biocontainment requirements:

(a) the facilities where the antigens, vaccines and diagnostic reagents are stored shall:

  (i) comply with the recognised quality standards provided for in international standards referred to in point 3 of Annex I and in point 4 of Annex II;

  (ii) be subjected to controls by the Commission to ensure continuous compliance with the recognised quality standards referred to in point (i), in addition to regular and risk-based controls by the competent authorities;

  (iii) be secure and protected from accidental or intentional damage, including microbial contamination;

(b) where a Union antigen, vaccine or diagnostic reagent bank is co-located with a laboratory or other facility where pathogens are handled, the storage facilities referred to in point (a) shall be effectively protected from contamination by physical separation and biosafety procedures for the personnel;

(c) the personnel shall, where they have had possible exposure to relevant pathogens of the category A diseases referred to in Article 3(1) or 5(1), comply with a quarantine procedure before entering the Union antigen, vaccine and diagnostic reagent banks.

Article 11

Transitional measures

The Union banks established before the date of application of this Regulation shall be maintained until the date of expiry of the relevant contracts under which those Union banks were established for the following commodities:

(a) antigens of foot-and-mouth disease virus, established in accordance with Decision 91/666/EEC and with Article 80(1) of Directive 2003/85/EC;

(b) vaccines against classical swine fever, established in accordance with Article 18(2) of Directive 2001/89/EC and with Decision 2007/682/EC;

(c) vaccines against lumpy skin disease, established in accordance with Article 6(5) of Regulation (EU) No 652/2014;

(d) vaccines against peste des petits ruminants, established in accordance with Article 6(5) of Regulation (EU) No 652/2014;

(e) vaccines against sheep pox and goat pox, established in accordance with Article 6(5) of Regulation (EU) No 652/2014.

Article 12

Entry into force and application

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

It shall apply from 1 May 2022.

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

Done at Brussels, 16 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

CONDITIONS FOR THE SUPPLY AND STORAGE OF ANTIGENS, VACCINES AND DIAGNOSTIC REAGENTS AS REFERRED TO IN ARTICLE 6(1)

1. Antigens, vaccines or diagnostic reagents shall be stored at the site and under the responsibility of the selected manufacturers referred to in Article 3(1) or Article 4(1) or the European Union reference laboratories referred to in Article 5.

2. In the case of vaccines produced and stored in the Union, the principles and guidelines of good manufacturing practice shall be maintained throughout the production process, as referred to in:

   (a) Commission Directive 91/412/EEC ([1]), or

   (b) as of the date of their application, the implementing acts adopted pursuant to Article 93(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council ([2]).

   The principles and guidelines of good manufacting practice shall also be maintained during the storage and finishing, namely filling of vials with vaccine and finishing the process of packaging for distribution, of the vaccine reconstituted from the antigens in store.

3. The antigen or vaccine shall be produced and stored at least in accordance with the principles of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021.

4. The vaccine must have a marketing authorisation granted by the Commission or by a competent authority in at least one Member State, as applicable, in accordance with:

   (a) either Chapters 3 and 4 of Title III of Directive 2001/82/EC, or Chapter 1 of Title III of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([3]), respectively, or,

   (b) as of 28 January 2022, Chapter III of Regulation (EU) 2019/6.

   However, in the event of a serious epidemic, particularly caused by an emerging disease, where a marketing authorisation has not been granted for a vaccine in the Union, a marketing authorisation or other equivalent document granted in the country of production of that vaccine shall be made available by the manufacturer to the Commission.

([1]) Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

([2]) 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).

([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

ANNEX II

ADDITIONAL CONDITIONS FOR THE SUPPLY AND STORAGE OF CONCENTRATED INACTIVATED ANTIGENS OF THE FOOT AND MOUTH DISEASE VIRUS AS REFFERED TO IN ARTICLE 6(2)

1. Each antigen shall consist of a single homogeneous batch.

2. Each batch shall be split in order to permit its storage in separate storage capacities to prevent, in the case of technical problems, the deterioration or loss of the entire batch.

3. The vaccine produced from the antigens to be supplied shall comply with the position paper on requirements for vaccines against foot-and-mouth disease of the Committee for Medicinal Products for Veterinary use of the European Medicines Agency) ([1]).

4. The antigens shall meet at least the requirements of the European Pharmacopoeia ([2]) and the relevant provisions of Chapter 3.1.8 'Foot and mouth disease (infection with foot and mouth disease virus)' of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021.

5. If not otherwise specified in the documents referred to in point 4, the antigen shall be purified to remove non-structural proteins of the foot and mouth disease virus. The purification shall at least ensure that the residual content of non-structural proteins in vaccines reconstituted from such antigen does not induce detectable levels of antibodies against non-structural proteins in animals which had received one initial and one subsequent booster vaccination.

6. The vaccine reconstituted from the antigens stored in the Union antigen bank must have a marketing authorisation granted by the Commission or by a competent authority in at least one Member State, as applicable, in accordance with:

   (a) either Chapters 3 and 4 of Title III of Directive 2001/82/EC, or Chapter 1 of Title III of Regulation (EC) No 726/2004, respectively, or,

   (b) as of 28 January 2022, Chapter III of Regulation (EU) 2019/6.

   In the absence of suitable vaccines against emerging strains of foot and mouth disease virus, a marketing authorisation may not be required for vaccines reconstituted from high and medium priority or new antigens produced under the same conditions and to the same quality standards as antigens that have a marketing authorisation.

7. Each dose of vaccine produced from antigens stored in the Union antigen bank shall have a potency of at least 6 PD_{50} in cattle, and shall be suitable for the emergency vaccination of bovine, ovine, caprine and porcine animals, depending on the request by the Commission.

([1]) European Medicines Agency (2004). Position paper on requirements for vaccines against foot-and-mouth disease, EMEA/CVMP/775/02-FINAL 01/12/2004.

([2]) https://www.edqm.eu/en