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 of the Council with regard to the Union antigen, vaccine and diagnostic reagent 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 50(1) 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 would promote 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 in Commission Implementing Regulation (EU) 2018/1882 ([2]), and would represent an efficient use of limited resources.

(2) In addition, 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. When Member States allow the use of vaccines in kept and wild terrestrial animals against category A diseases, taking into consideration the criteria set out in Article 46(2) of Regulation (EU) 2016/429, they are also required to take into account the rules laid down in those delegated acts.

(3) In accordance with Article 48(3) of Regulation (EU) 2016/429, the Commission has adopted Delegated Regulation (EU) 2022/139 ([3]) that supplements Regulation (EU) 2016/429, as regards rules for the management, storage and replacement of stocks of antigens, vaccines and, where relevant, other biological products in the Union antigen, vaccine and diagnostic reagent banks. It also lays down biosecurity, biosafety and bio–containment requirements for the operation of those banks.

([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).

([3]) Commission Delegated Regulation (EU) 2022/139 of 16 November 2021 supplementing Regulation (EU) 2016/429 of the European Parliament and 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 (See page 1 of this Official Journal).

(4) This Regulation should lay down the necessary implementing rules to be applied in tandem with the rules laid down in Part III of Regulation (EU) 2016/429 and Delegated Regulation (EU) 2022/139 for the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in Union antigen, vaccine and diagnostic reagent banks, and also biosecurity, biosafety and bio–containment requirements for the operation of those banks.

(5) This Regulation should lay down the necessary requirements concerning the types, strains and quantities of the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks. It should also lay down the necessary requirements concerning the supply, storage and replacement of biological products in the Union antigen, vaccine and diagnostic reagent banks, as well as in relation to the formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines.

(6) Member States should have access to the Union antigen, vaccine and diagnostic reagent banks. In addition, the Commission should be able to supply or lend antigens, vaccines or diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks to third countries or territories. Therefore, it is necessary to lay down in this Regulation the procedural and technical requirements for requesting access to the Union antigen, vaccine and diagnostic reagent banks.

(7) As Delegated Regulation (EU) 2022/139 applies from 1 May 2022, this Regulation should also apply from that date.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down rules for the Union antigen, vaccine and diagnostic reagent banks, specifying:

(a) the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks, and the category A diseases for which they may be intended;

(b) the requirements concerning types, strains and quantities of the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks;

(c) the additional requirements concerning the supply and storage of antigens and vaccines to be included in the Union antigen, vaccine and diagnostic reagent banks;

(d) the requirements concerning the formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines, and the labelling of ready-to-use vaccines;

(e) the procedures for the release and delivery of vaccines from the Union antigen, vaccine and diagnostic reagent banks;

(f) the requirements concerning the replacement of antigens, vaccines and diagnostic reagents in the Union antigen, vaccine and diagnostic reagent banks;

(g) the procedural and technical requirements for requesting access to the Union antigen, vaccine and diagnostic reagent banks.

Article 2

Definitions

For the purpose of this Regulation, the definitions in Article 2 of Delegated Regulation (EU) 2022/139 shall apply.

Article 3

Biological products to be included in the Union antigen, vaccine and diagnostic reagent banks for certain category A diseases

1. The Commission shall include in the Union antigen, vaccine and diagnostic reagent banks the biological products listed in column 2 of the table in Annex I ('the table') for the category A diseases listed in column 1 of the table.

2. The Commission shall maintain in the Union antigen, vaccine and diagnostic reagent banks the types and strains of the biological products listed in column 3 of the table and the quantities of biological products listed in column 4 of the table, and take account of the validity period of the biological products indicated in column 5 thereof.

Article 4

Additional requirements concerning the supply and storage of antigens and vaccines

1. The Commission shall arrange independent testing of the potency and innocuity of the vaccines supplied and stored in the Union vaccine banks and of the vaccines reconstituted from antigens stored in the Union antigen banks.

2. The contracted manufacturer shall comply with the additional requirements concerning the storage of antigens of the foot and mouth disease virus and vaccines against category A diseases set out in Annex II.

Article 5

Requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready-to-use vaccine

1. In the case of an emergency and with due regard to the epidemiological situation in the Union or in third countries or territories where it is in the interest of the Union, the Commission shall request the contracted manufacturer, in writing, for a formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines and the bottling, labelling and temporary storage of the necessary quantities of those vaccines.

2. The contracted manufacturer shall comply with the request referred to in paragraph 1 of this Article and the requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready to use vaccines set out in Annex III.

Article 6

Procedures for the release and delivery of vaccines

1. When required, the Commission shall request the contracted manufacturer, in writing, for a delivery of the vaccines stored in the Union vaccine banks or of the formulated vaccines referred to in Article 5(1).

2. The contracted manufacturer shall comply with the request referred to in paragraph 1 of this Article and the procedures for the release and delivery of the formulated vaccines referred to in Article 5(1) set out in Annex IV.

3. The contracted manufacturer shall comply with the procedures for the delivery of vaccines stored in the Union vaccine banks set out in Annex V.

Article 7

Requirements concerning the replacement of antigens, vaccines and diagnostic reagents

Following the use of any antigen, vaccine or diagnostic reagent from the Union antigen, vaccine and diagnostic reagent banks, the Commission shall ensure that the used antigen, vaccine or diagnostic reagent is replaced, if necessary, by its equivalent, as soon as possible and with due regard to the epidemiological situation.

Article 8

Procedural and technical requirements for requesting access to the antigens, vaccines and diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall grant Member States access to the Union antigen, vaccine and diagnostic reagent banks upon their written request.

2. The Commission shall, within the limits of availability of stocks of the Union antigen, vaccine and diagnostic reagent banks, immediately arrange for the shipment of the required quantities and types of vaccines or diagnostic reagents, taking into account the criteria laid down in Article 49(2) of Regulation (EU) 2016/429 and the additional criteria for the distribution of the required quantities and types of vaccines set out in Annex VI to this Regulation.

3. Member States that maintain national antigen, vaccine and diagnostic reagent banks or Member States that are associated to an international antigen and vaccine bank shall have the same rights and obligations with regard to the Union antigen, vaccine and diagnostic reagent banks as other Member States that do not have a national antigen, vaccine and diagnostic reagent bank or access to an international antigen and vaccine bank.

4. Where it is in the interest of the Union, the Commission may supply or lend, following their request, to third countries or territories, antigens, vaccines or diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks.

5. Access of third countries and territories to the Union antigen, vaccine and diagnostic reagent banks shall be granted under detailed conditions agreed between the Commission and the third country or territory concerned.

Article 9

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

Biological products to be included in the Union antigen, vaccine and diagnostic reagent banks as referred to in Article 3

Name of category A disease	Biological product	Type and/or strain of biological product	Number of doses	Validity period of biological product
1	2	3	4	5
Foot and mouth disease	antigen	inactivated various strains representing all seven serotypes: O, A, Asia 1, C, SAT1, SAT2, SAT3	at least 1 000 000 and up to 5 000 000 for each selected antigen, depending on the priority	at least 60 months
Classical swine fever	vaccine	live attenuated	at least 1 000 000	at least 24 months
Infection with lumpy skin disease virus	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months
Infection with peste des petits ruminants virus	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months
Sheep pox and goat pox	vaccine	live attenuated or inactivated	at least 250 000	at least 20 months

ANNEX II

Additional requirements concerning the storage of antigens and vaccines as referred to in Article 4(2)

A. **Antigens of the foot and mouth disease virus**

1. Antigens of the foot and mouth disease virus shall be stored in an establishment which is specifically designed for the storage of deep-frozen antigens, meeting the principles and guidelines of good manufacturing practice for veterinary medicinal products, in accordance with Commission Directive 91/412/EEC ([1]), and as of the date of their application, implementing acts adopted pursuant to Article 93(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council ([2]), including regular checks and where necessary adjustments of the temperature regime. The antigens shall be stored at or below −70 °C.

2. The contracted manufacturer shall respect the technical requirements referred to in the specific monograph 'Foot-and-mouth disease (ruminants) vaccine (inactivated)' (number 63) of the European Pharmacopoeia in use, and in particular the technical requirements concerning safety, innocuity and sterility of the vaccines.

3. The contracted manufacturer shall report to the Commission, without delay and in any event within a period of seven days from the date of any exceptional event relating to the storage of the antigens and liable to deteriorate the antigens.

4. The contracted manufacturer shall produce a detailed annual report on the quantities and subtypes of antigens stored in the Union antigen, vaccine and diagnostic reagent banks and on the results of stability tests carried out on those antigens.

5. Small aliquots of 20 x 4,5 ml antigen samples for each of the antigen batches manufactured and supplied to the Union bank for antigens of the foot and mouth disease virus shall be stored for in-house monitoring purposes by the contracted manufacturer. The antigen samples shall be made available to the Commission if requested and be supplied either as the purified antigen or as formulated trial blends of vaccines ($> 6PD_{50}$) throughout the validity period for the relevant antigen.

6. After the end of the validity period for the antigens, and until their destruction and safe disposal or buy-back is completed, the antigens shall remain the property of the Commission and may be stored at the Commission's expense for a period not exceeding 12 months for possible formulation of antigens into vaccines.

B. **Vaccines**

1. The vaccines shall be stored under conditions ensuring that their efficacy, safety, innocuity and sterility throughout their storage period is maintained.

2. In the case of any changing condition ('an incident') in storage that may alter the efficacy, safety, innocuity and sterility of the vaccines, the contracted manufacturer shall perform all necessary testing of the vaccines to verify their conformity with the conditions specified in the contract. The contracted manufacturer shall inform the Commission immediately about the time and conditions of such an incident as well as about the tests that will be performed upon the stored vaccines and the time required for their completion. The results of such tests shall be reported, in the form of a written report, to the Commission within a period of 2 weeks following the date of their completion.

3. The contracted manufacturer shall produce a detailed annual report on the quantities and types of vaccines stored in the Union vaccine bank and the results of stability tests carried out.

([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).

4. The contracted manufacturer shall guarantee that the vaccines from each vaccine batch in the Union vaccine bank are regularly tested for their potency and sterility throughout their storage period and report the results of these tests to the Commission.

ANNEX III

Requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready-to-use vaccine as referred to in Article 5

1. The formulation of the antigen(s) into vaccines shall be performed as follows:

   (a) as regards those for immediate supply: the contracted manufacturer shall formulate, bottle and label a minimum of 300 000 doses and a maximum of 2 000 000 doses of finished vaccine ($Al(OH)_3$/Saponin and/or DOE) per formulation site during the period of 6 working days following the date of notice of the request for delivery by the Commission; or

   (b) as regards those for urgent but not immediate supply: the contracted manufacturer shall formulate, bottle and label a minimum of 300 000 doses up to a maximum of 2 000 000 doses of finished vaccine ($Al(OH)_3$/Saponin and/or DOE) per formulation site during a period of between 7 to 15 working days following the date of notice of the request for delivery by the Commission.

2. The biggest requisition may be up to 5 million doses of each of the 4 different antigens from the stock of antigens in the Union antigen, vaccine and diagnostic reagent banks formulated into 5 million doses of a tetravalent vaccine.

3. The minimum potency of vaccines formulated from the stocks of antigens in the Union antigen, vaccine and diagnostic reagent banks shall be at least 6 PD_{50}.

4. The bottling, labelling and distribution of the vaccine shall be carried out taking into account the specific needs of the area where vaccination is to be carried out.

5. The labelling of the ready-to-use vaccine shall be in accordance with the marketing authorisation for Al(OH)3/Saponin and/or DOE vaccine adjuvants adapted in accordance with the contract referred to in Article 3(1) or 4(1) of Delegated Regulation (EU) 2022/139.

6. The boxes containing the vaccines shall have the following label in A4 format:



VACCINES DONATED

BY THE

EUROPEAN UNION

ANNEX IV

Procedures for the release and delivery of vaccines formulated from the antigens of the foot and mouth disease virus as referred to in Article 6(2)

1. Following notice of the request for delivery by the Commission, the contracted manufacturer shall comply with the following deadlines for delivery:

   (a) for urgent but not immediate supply: a period of 7 to 15 working days for formulation, bottling and labelling, plus 3 working days for delivery;

   (b) for immediate supply: a period of 6 working days for formulation, bottling and labelling, plus 3 working days for delivery;

   (c) in cases of extreme urgency: the contracted manufacturer shall deliver quicker than at the deadlines referred to in points (a) and (b), subject to the necessary documentation, such as an Early Release Certificate or an introduction permit granted by the Member State, third country or territory of destination, being provided and subject to any enforced delays caused by or restrictions imposed by the shipping company.

   The contracted manufacturer shall take the necessary steps to facilitate the sourcing of any permit or licence required for performance of the contract under the laws and regulations in force at the place where the contract referred to in Article 3(1) or 4(1) of Delegated Regulation (EU) 2022/139 is to be executed.

   However, the contracted manufacturer shall not be held responsible for obtaining documents that are dependent on other legal entities and authorities which do not exercise direct control over or influence him/her.

2. For the shipment to the destination the vaccines shall be packaged in insulated cardboard boxes containing 6 cool-packs per standard sized box (45x42x45 cm) or equivalent. This combination must ensure cold-chain conditions for up to 72 hours.

   Where specifically requested by the Commission, the contracted manufacturer shall furnish the shipment of vaccines with WHO approved vaccine cold-chain monitors ([1]) in each standard box of vaccines. The vaccine cold-chain monitor card must have a time-temperature indicator with the threshold response temperatures of +10 °C and +34 °C. The vaccine cold-chain monitor card must show a blue colouration of the indicator if the temperature has been exceeded during transport or storage.

([1]) WHO, World Health Organisation, 'Temperature monitors for vaccines and the cold chain', document WHO/V&B/99.15 (1999).

ANNEX V

Procedures for the delivery of vaccines stored in the Union vaccine banks as referred to in Article 6(3)

1. Delivery of the vaccines from the site of their storage shall be within a period of 3 to 15 working days following notice of the request for delivery by the Commission, depending on the urgency.

2. The bottling, labelling and distribution of the vaccine shall be carried out taking into account the specific needs of the area where vaccination is to be carried out.

3. The boxes containing the vaccines shall have the following label in A4 format:



VACCINES DONATED

BY THE

EUROPEAN UNION

ANNEX VI

Additional criteria for the distribution of the required quantities and types of vaccines as referred to in Article 8(2)

1. A requesting Member State, third country or territory may receive not more than half of the stocks of an antigen, vaccine or diagnostic reagent available in the Union antigen, vaccine and diagnostic reagent bank.

2. In addition to the condition laid down in point 1, the following shall be taken into account:

   (a) the time needed for the contracted manufacturer to produce and to replenish the Union antigen, vaccine and diagnostic reagent bank with the equivalent type and quantity of antigen, vaccine or diagnostic reagent; and

   (b) the availability of the antigen, vaccine or diagnostic reagent on the market.