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') (Text with EEA relevance)

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

DISEASE AWARENESS AND PREPAREDNESS

CHAPTER 3

Antigen, vaccine and diagnostic reagent banks

Article 48

The establishment of Union antigen, vaccine and diagnostic reagent banks

1 For listed diseases referred to in point (a) of Article 9(1) in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47, the Commission may establish and be responsible for managing Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of one or more of the following biological products:

a antigens;

b vaccines;

c vaccine master seed–stocks;

d diagnostic reagents.

2 The Commission shall ensure that the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:

a store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents for the specific listed disease in question, taking into account the needs of Member States estimated in the context of the contingency plans provided for in Article 43(1);

b receive regular supplies and timely replacements of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents;

c are maintained and moved in conformity with the appropriate biosecurity, biosafety and bio–containment requirements laid down in Article 16(1) and in accordance with delegated acts adopted pursuant to Article 16(2);

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

a the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks as provided for in paragraphs 1 and 2 of this Article;

b the biosecurity, biosafety and bio–containment requirements for the operation of those banks, respecting the requirements provided for in Article 16(1) and taking into account the delegated acts adopted pursuant to Article 16(2).

Article 49

Access to the Union antigen, vaccine and diagnostic reagent banks

1 The Commission shall, upon request, provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks, provided that stocks are available, to:

a in the first place, Member States; and

b third countries or territories, provided that such delivery is primarily intended to prevent the spread of a disease into the Union.

2 The Commission shall, in the event of the limited availability of stocks, prioritise access to the stocks to be delivered pursuant to paragraph 1 based on:

a the disease circumstances under which the request is made;

b the existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State or third country or territory;

c the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47.

Article 50

Implementing powers concerning the Union antigen, vaccine and diagnostic reagent banks

1 The Commission shall, by means of implementing acts, lay down rules for Union antigen, vaccine and diagnostic reagent banks, specifying for the biological products referred to in Article 48(1):

a which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in point (a) of Article 9(1);

b the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent banks and in what quantities for each specific listed disease referred to in point (a) of Article 9(1) for which the bank in question exists;

c the requirements concerning the supply, storage and replacement of those biological products;

d the delivery of those biological products from the Union antigen, vaccine and diagnostic reagent banks to the Member States and to third countries and territories;

e procedural and technical requirements for the inclusion of those biological products in the Union antigen, vaccine and diagnostic reagent banks and for requesting access to them.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2 On duly justified imperative grounds of urgency relating to a listed disease referred to in point (a) of Article 9(1) representing a risk of a highly significant impact, the Commission

shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 51

Confidentiality of information concerning the Union antigen, vaccine and diagnostic reagent banks

Information on the quantities and subtypes of the biological products referred to in Article 48(1) stored in the Union antigen, vaccine and diagnostic reagent banks shall be treated by the Commission as classified information and shall not be published.

Article 52

National antigen, vaccine and diagnostic reagent banks

1 Member States that have established national antigen, vaccine and diagnostic reagent banks for listed diseases referred to in point (a) of Article 9(1) for which Union antigen, vaccine and diagnostic reagent banks exist, shall ensure that their national antigen, vaccine and diagnostic reagent banks comply with the biosecurity, biosafety and bio–containment requirements laid down in point (a) of Article 16(1) and in delegated acts adopted in accordance with Article 16(2) and point (b) of Article 48(3).

2 Member States shall provide the Commission with up–to–date information on:

- a the existence or the establishment of the national antigen, vaccine and diagnostic reagent banks referred to paragraph 1;
- b the types of antigens, vaccines, vaccine master-seed stocks and diagnostic reagents and the quantities thereof held in such banks;
- c any changes in the operation of such banks.

That information shall be treated as classified information by the Commission and shall not be published.

3 The Commission may, by means of implementing acts, lay down rules specifying the content, frequency and format of the submission of the information provided for in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) 2016/429 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Art. 17(1A) words substituted by S.I. 2021/1273 reg. 8Sch. 2 para. (t)