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 1

Contingency plans and simulation exercises

Article 43

Contingency plans

1 The Member States shall, after appropriate consultation of experts and relevant stakeholders, draw up, and keep up to date, contingency plans and, where necessary, detailed instruction manuals laying down the measures to be taken in the Member State concerned in the event of the occurrence of a listed disease referred to in point (a) of Article 9(1) or, as the case may be, of an emerging disease, in order to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response.

2 Those contingency plans and, where applicable, detailed instruction manuals shall cover at least the following matters:

a the establishment of a chain of command within the competent authority and with other public authorities, to ensure a rapid and effective decision–making process at Member State, regional and local level;

b the framework for cooperation between the competent authority and the other public authorities and relevant stakeholders involved, to ensure that actions are taken in a coherent and coordinated manner;

c access to:

(i) facilities;

(ii) laboratories;

(iii) equipment;

(iv) personnel;

(v) emergency funds;

(vi) all other appropriate materials and resources necessary for the rapid and efficient eradication of the listed diseases referred to in point (a) of Article 9(1) or of emerging diseases;

d the availability of the following centres and groups with the necessary expertise to assist the competent authority:

(i) a functional central disease control centre;

(ii) regional and local disease control centres, as appropriate for the administrative and geographical situation of the Member State concerned;

(iii) operational expert groups;

e implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in point (a) of Article 9(1) and for emerging diseases;

f provisions on emergency vaccination, where appropriate;

g principles for the geographical demarcation of the restricted zones established by the competent authority in accordance with Article 64(1);

h coordination with neighbouring Member States and neighbouring third countries and territories, where appropriate.

Article 44

Implementing powers for contingency plans

The Commission shall, by means of implementing acts, lay down necessary measures concerning the implementation in the Member States of the contingency plans provided for in Article 43(1).

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

Article 45

Simulation exercises

1 The competent authority shall ensure that simulation exercises concerning the contingency plans provided for in Article 43(1) are carried out regularly or at appropriate intervals:

a to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the Member State concerned;

b to verify the functionality of those contingency plans.

2 Where feasible and appropriate, simulation exercises shall be carried out in close collaboration with the competent authorities of neighbouring Member States and neighbouring third countries and territories.

3 Member States shall make available to the Commission and to the other Member States, on request, a report on the main results of the simulation exercises carried out.

4 When appropriate and necessary, the Commission shall, by means of implementing acts, lay down rules concerning the practical implementation of simulation exercises in the Member States, relating to:

a the frequencies of simulation exercises;

b simulation exercises covering more than one listed disease referred to in point (a) of Article 9(1).

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

CHAPTER 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1 The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary.

Those measures may cover the following:

a prohibitions and restrictions on the use of veterinary medicinal products;

b the compulsory use of veterinary medicinal products.

2 Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

a the disease profile;

b the distribution of the listed disease in:

(i) the Member State concerned;

(ii) the Union;

(iii) where relevant, neighbouring third countries and territories;

(iv) third countries and territories from which animals and products are brought into the Union;

c the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;

d the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;

e the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

3 Member States shall 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.

Article 47

Delegation of powers for the use of veterinary medicinal products

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning what might constitute appropriate and necessary measures as set out in Article 46, in relation to:

a prohibitions and restrictions on the use of veterinary medicinal products;

b specific conditions for the use of veterinary medicinal products for a specific listed disease;

c risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;

d surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

2 The Commission shall take into account the criteria set out in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.

3 Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to paragraph 1 of this Article.

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).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2016/429 of the European Parliament and of the Council, TITLE I.