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 IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS

CHAPTER 1

Registration, approval, record-keeping and registers

Section 2

Approval of certain types of establishments

Article 97

Granting of, and conditions for, approval of establishments and delegated acts

1 Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 where such establishments:

- a comply with the following requirements, where appropriate, in relation to:
 - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(2);
 - (ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;
 - (iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;
- b have facilities and equipment that are:
 - (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;
 - (ii) of a capacity adequate for the number of kept terrestrial animals or the volume of germinal products concerned;
- c do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

- d have adequately trained personnel for the activity of the establishment concerned;
- e have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;
- b surveillance as referred to in point (a)(ii) of paragraph 1;
- c facilities and equipment as referred to in point (b) of paragraph 1;
- d responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;
- e the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.

3 When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

- a the risks posed by each type of establishment;
- b the species and categories of kept terrestrial animals relevant for the approval;
- c the type of production concerned;
- d typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2016/429 of the European Parliament and of the Council, Article 97.