EUROPEAN
COMMISSION

Brussels, XXX
SANTE/7072/2018
(POOL/G2/2018/7072/7072-EN.doc)
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the approval of germinal product establishments and the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the approval of germinal product establishments and the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals

(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 96(3) and Article 123 thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases, which are transmissible to animals and to human. Those rules cover, inter alia, germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species and of other species. It also lays down rules for the registration and approval of establishments for germinal products of bovine, porcine, ovine, caprine and equine animals. Regulation (EU) 2016/429 also lays down rules concerning the traceability and animal health requirements for movements of consignments of germinal products within the Union. It also empowers the Commission to adopt delegated and implementing acts in order to ensure the smooth functioning of the new legal framework established by that Regulation.

(2) Commission Delegated Regulation (EU) 2020/…[2] lays down rules supplementing Regulation (EU) 2016/429, as regards the approval of germinal product establishments and for the traceability and animal health requirements for movements of consignments of certain kept terrestrial animals of germinal products within the Union.

(3) Accordingly, it is necessary to establish rules for the uniform implementation of the requirements laid down in Regulation (EU) 2016/429, and the supplementing rules laid down in Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055], concerning the information to be provided by operators in applications for approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals, and the time-limits for providing that information. It is also necessary to lay down rules concerning the technical requirements and specifications for the marking of germinal products of bovine, porcine, ovine, caprine and equine

[1] OJ L 84, 31.3.2016, p. 1.

[2] [Commission Delegated Regulation (EU) 2020/… of … supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments, and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (document SANTE/7073/2018), C(2019)4055].

animals, and the operational requirements for the traceability of consignments of those germinal products.

(4) Article 96(3) of Regulation (EU) 2016/429 provides that the Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in applications for approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are to be moved to another Member State, and the time-limits for providing such information. The timeframe for the competent authority to consider such applications should be sufficiently long in order to allow it to carry out an in-depth analysis, but it should not exceed a period of 90 days before the intended date of commencement of activities by operators, so that they are able to start their activities within a reasonable time period.

(5) As Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055] provides for five different types of approved germinal product establishments, operators should indicate in their applications for approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals, the nature of the activities that they intend to carry out therein. The biosecurity plan for the operation of the germinal product establishment should also be included in such applications. In addition, given the important role of the centre and team veterinarians responsible for the activities of approved germinal product establishments, their details should be indicated in applications for approval of germinal product establishments.

(6) Rules on the marking of straws and other packages where germinal products of bovine, porcine, ovine, caprine and equine animals are placed should be laid down at Union level in order to ensure their traceability. When setting the standards for that marking, account should be taken of practices in this regard already implemented by Member States, and also of the recommendations of the International Committee for Animal Recording (ICAR)[3]. Where a bar code is printed on a straw or other package, the ICAR recommends that it is either of type 128C, or if of a different type that three more digits corresponding to the international code of each germinal product establishment recorded in the United States National Association of Animal Breeders (NAAB)[4] are added at the beginning of the national bar code.

(7) As Regulation (EU) 2016/429 applies from 21 April 2021, 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 concerning germinal products of bovine, porcine, ovine, caprine and equine animals.

Those rules cover:

(a) the information to be provided by operators in applications for approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals and

[3] https://www.icar.org/
[4] https://www.naab-css.org/

the time-limits for providing such information, as well as the time-limits for informing the competent authority of any cessation of activity of such germinal product establishments approved by it;

(b) the technical requirements and specifications for the marking of germinal products of bovine, porcine, ovine, caprine or equine animals and the operational requirements for their traceability.

Article 2
Definitions

For the purposes of this Regulation, the definitions laid down in Article 2 of Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055] shall apply.

Article 3
The information to be provided by operators in applications for approval of germinal product establishments for bovine, porcine, ovine, caprine or equine animals

1. Operators applying to the competent authority for approval of germinal product establishments for bovine, porcine, ovine, caprine or equine animals in accordance with Article 94(1)(b) of Regulation (EU) 2016/429 shall include the following information in their application:

   (a) the name and address of the operator of the germinal product establishment;

   (b) the following details concerning the germinal product establishment:

      (i) the address;

      (ii) the name of the centre veterinarian or team veterinarian appointed by the operator in accordance with Article 4(1)(a) of Delegated Regulation (EU) 2019/… [document SANTE/7073/2018, C(2019)4055];

      (iii) which of the following types of activity are to be carried out at the germinal product establishment:

         – the collection, processing and storage of semen;

         – the collection, processing and storage of embryos;

         – the collection, processing and storage of oocytes and of the production, processing and storage of embryos;

         – the processing and storage of fresh, chilled or frozen semen, oocytes or embryos;

         – the storage of fresh, chilled or frozen semen, oocytes or embryos;

      (iv) a description of how the processing of germinal products is to be carried out, and in the case where all or part of the processing is to be carried out at other germinal product processing establishments, the name and contact details of those germinal product processing establishments;

      (v) the biosecurity requirements for the operation of the germinal product establishment which shall include at least details of the following:

         – a structural description and blueprint of the germinal product establishment;

– the standard operating procedures for the collection, production, processing, storage and transport of germinal products, as appropriate for the type of germinal product establishment;

– the procedures and instructions from the centre veterinarian or team veterinarian for the implementation of animal health and biosecurity requirements at the germinal product establishment;

– a rodent and insect control plan;

– information on the format of records kept in accordance with Article 8 of Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055];

– the procedures for the cleaning and disinfection of the facilities and equipment;

– a contingency plan in the case of clinical signs of listed diseases or a positive test result for animal pathogens causing listed diseases;

– an undertaking to notify the competent authority prior to the implementation of any significant changes relating to the biosecurity requirements for the operation of the germinal product establishment;

(c) as regards the germinal products:

(i) the type of germinal products to be collected, produced, processed or stored, specifying if they are semen, oocytes or embryos;

(ii) the species of donor animals, specifying if they are bovine, porcine, ovine, caprine or equine animals;

(iii) the conditions of storage of the germinal products, specifying if they are fresh, chilled or frozen.

2. The application referred to in paragraph 1 shall be in writing, and either on paper or in electronic form.

Article 4

The time-limits for operators to provide information in applications for approval of germinal product establishments for bovine, porcine, ovine, caprine or equine animals and any cessation of activity

1. Each Member State shall establish time-limits for the following:

(a) for operators to provide the competent authority with:

(i) the information required in accordance with Article 3(1);

(ii) information concerning any cessation of activity of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals;

(b) for the competent authority to inform operators of:

(i) the obligation to provide the information required in accordance with Article 3(1);

(ii) any refusal of an application for approval of a germinal product establishment submitted in accordance with Article 3 of Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055].

2. The time-limits referred to in paragraph 1(a)(i) shall not exceed a period of 90 days prior to the intended date of commencement of activity by the operator at the germinal product establishment.

3. Unless the competent authority indicates otherwise, any significant change relating to the biosecurity requirements for the operation of the germinal product establishment referred to in the eighth indent of Article 3(1)(b)(v), shall be deemed to be approved within a period of 90 days from the date of notification by the operator of such change.

Article 5

Technical requirements and specifications for the marking of germinal products of bovine, porcine, ovine, caprine and equine animals and operational requirements for their traceability

1. Operators marking germinal products of bovine, porcine, ovine, caprine and equine animals as required by Article 121(1) of Regulation (EU) 2016/429 shall ensure:

(a) that each straw or other package, in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, is marked in accordance with the traceability requirements laid down in Article 10 of Delegated Regulation (EU) 2020/… [document SANTE/7073/2018, C(2019)4055] and the technical requirements and specifications for marking set out in Part 1 of the Annex to this Regulation;

(b) compliance with the operational requirements for the traceability of germinal products set out in Part 2 of the Annex.

2. Each Member State shall establish, based on the technical requirements and specifications for marking set out in Part 1 of the Annex, rules concerning the characteristics and form of the marking of straws and other packages, in which the germinal products are placed, stored and transported, used in its territory and it shall transmit that information to the Commission and to the other Member States.

Article 6

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 21 April 2021.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN