Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 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 (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/686

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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

(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 94(3), Article 97(2), Article 101(3), Article 106(1), Article 122(1) and (2), Article 131(1), Article 160(1) and (2), Article 161(6), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(2) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans. Those rules provide, inter alia, for the registration and approval of germinal product establishments, and for the traceability and animal health requirements for movements of consignments of germinal products within the Union. Regulation (EU) 2016/429 also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts. It is therefore appropriate to adopt such rules in order to ensure the smooth functioning of the system in the new legal framework established by Regulation (EU) 2016/429.

(2) The rules laid down in this Regulation are required to supplement those laid down in Chapters 1, 2 and 5 of Title I of Part IV of Regulation (EU) 2016/429, as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products.

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(3) These rules are substantively linked and many are intended to be applied in tandem. In the interests of simplicity and transparency, as well as to facilitate their application and to avoid a multiplication of rules, they therefore should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

(4) Indeed, Regulation (EU) 2016/429 aims at providing a simpler and more flexible regulatory framework than previously existed, while at the same time ensuring a more risk-based approach to animal health requirements, enhanced disease preparedness, prevention and control of animal diseases. It was also adopted in order to ensure that the rules concerning animal diseases were laid down mainly in a single act, as opposed to being scattered in a number of different acts. The rules laid down in this Regulation concerning germinal products also follow the same approach.

(5) Prior to the adoption of Regulation (EU) 2016/429, Union rules on germinal products were laid down in Council Directives 88/407/EEC[(2)], 89/556/EEC[(3)], 90/429/EEC[(4)] and 92/65/EEC[(5)]. Regulation (EU) 2016/429 repeals and replaces those four Directives with effect from 21 April 2021. Those Directives laid down the animal health conditions for trade within the Union and for the entry into the Union of consignments of semen, ova and embryos of bovine, ovine, caprine, porcine and equine animals and in principle of certain other animal species. The rules laid down in those Directives have proven to be effective in preventing the spread of transmissible animal diseases within the Union. Accordingly, the main substance of those rules should be maintained, but updated to take account of the experience gained in their application and current scientific knowledge.

(6) Germinal products, and in particular semen, but also to a lesser extent oocytes and embryos may represent an important risk for the spread of animal diseases. They are collected or produced from a limited number of donors, but are used widely in the general animal population so they can, if not handled properly or not classified with the correct health status, be a source of disease for a large number of animals. Such cases have occurred in the past and have caused substantial economic losses.

(7) To prevent the risk of the spread of disease, Regulation (EU) 2016/429 provides that germinal products should be collected, produced, processed and stored at specialised germinal product establishments and be subject to special animal health and hygiene regimes. At the same time, in order for animals to be admitted into those germinal product establishments and be classified as donors of germinal products which may be moved between Member States, they are required to comply with higher animal health standards than those applicable to the general animal population. Regulation (EU) 2016/429 also lays down specific procedures to ensure the traceability of those germinal products and a special set of animal health requirements apply to their movements within the Union. Within this framework, it is appropriate to lay down in this Regulation rules with regard to the movements of consignments of germinal products on the basis of several empowering provisions laid down in Regulation (EU) 2016/429 which provide for the Commission to adopt delegated acts, and in particular those laid down in Part IV thereof.

(8) Article 160(1) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down animal health requirements for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals. One of the conditions for such movements is that those germinal products must come from a germinal product establishment approved for that purpose in accordance with conditions to be laid down in a delegated act. Furthermore, Article 94(3)(c) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts concerning the special rules for the cessation of activities of germinal product establishments previously approved in accordance with the conditions laid down in a delegated act. At the same time, Article 101(3) of that Regulation provides for the Commission to adopt delegated acts on the detailed information to be included in the registers of registered and approved germinal product establishments kept by the competent authority, which will also include germinal product establishments which have ceased their activity.

(9) As the animal health requirements and derogations to be adopted pursuant to those provisions of Regulation (EU) 2016/429 all relate to movements of germinal products of kept terrestrial animals within the Union, albeit pertaining to a number of different species, in the interests of simplication of Union rules, they should be laid down in a single delegated act, rather than scattered in a number of different delegated acts.

(10) Article 162(1) of Regulation (EU) 2016/429 lays down requirements concerning the minimum information to be included in animal health certificates for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals. They must include information on the marking of the germinal products, when so required by Article 121(1) of that Regulation or by any rules laid down in delegated acts adopted pursuant to Article 122(1) thereof, and the information needed to demonstrate that the germinal products fulfil the movement requirements as provided for in Articles 157 and 159 of that Regulation or by rules set out in delegated acts adopted pursuant to Article 160 thereof. Article 162(3) of that Regulation provides for delegated acts to be adopted concerning the information to be contained in the animal health certificates. At the same time, Article 163(5) thereof provides for delegated acts to be adopted on the notification requirements for movements between Member States of germinal products of certain kept terrestrial animals, accompanied by an animal health certificate whose content is to be established in accordance with Article 162(3) and (4) of that Regulation.

(11) Article 94(1) of Regulation (EU) 2016/429 provides that germinal products of bovine, porcine, ovine, caprine and equine animals may be moved to another Member State if those germinal products were collected at germinal product establishments which have been approved by the competent authorities in accordance with Article 97(1) thereof. Such approval may only be granted if those germinal product establishments comply with particular requirements relating to quarantine, isolation and other biosecurity measures, surveillance, facilities and equipment, as well as responsibilities, competence and specialised training of personnel and veterinarians. Therefore, based on those requirements, it is necessary to set out in this Regulation the detailed rules and

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conditions for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals may be moved to another Member State.

(12) Directive 92/65/EEC provides that semen of ovine and caprine animals, which is to be moved to another Member State, may be collected at the establishment of origin of those animals instead of at a semen collection centre. This Regulation should provide for a similar derogation. However, special conditions for movements of consignments of such semen, including the purpose of such movements and the consent of the Member State of destination, should be established. Therefore, based on the possible risk posed by the movement of such semen, the rules and conditions authorising such derogations should be laid down in this Regulation.

(13) The collection of equine semen has its own particular characteristics due to the special breeding system of equine animals which takes account of the participation of such animals in dedicated equine competitions, shows and other equestrian events. Currently, Directive 92/65/EEC provides for three types of residency of stallions at semen collection centres. The main rules laid down in the current system provided for in that Directive should be maintained in this Regulation. However, the conditions for the testing programme as specified in point 1.6(b) of Chapter II(I) of Annex D to Directive 92/65/EEC for donors which may leave the semen collection centre occasionally and for the testing programme as specified in point 1.6(c) of Chapter II(I) of Annex D to Directive 92/65/EEC for ‘walk-in stallions’, should be improved and strengthened in this Regulation.

(14) This Regulation should also provide for germinal product storage centres storing germinal products of any type and originating from more than one species, under one unique approval number and subject to rules that ensure traceability, as there are no animal health reasons requiring separate storage centres per type of germinal product or per species. Information on the types and species of stored germinal products should be specified in the approval of such establishments and in the publicly available register of approved germinal product establishments kept by the competent authorities. This Regulation should also lay down specific provisions on the storage of fresh, chilled and frozen semen.

(15) The continual progress in germinal products processing techniques has lead to the establishment of specialised units for that purpose. Those units not only process germinal products, including sex-sorting of semen, but they also prepare the final product ready for use or for storage. Therefore, such units should be considered to be germinal product establishments where the processing and storage of germinal products takes place. However, as equipment for sex-sorting of semen is costly, semen collection centres may use services of other operators for processing, including sex-sorting, of semen. In that case, semen is sent out for processing and is then returned to the semen collection centre of origin. Therefore, it is appropriate to lay down in this Regulation rules for the processing of germinal products, including the possibility for their processing at germinal product processing establishments, as well as detailed rules for the transport and the marking of semen and other germinal products to and from such

germinal product processing establishments. Where semen is processed at a germinal product processing establishment, a marking on the straw or another package should include the approval or registration number of both the semen collection centre and the germinal product processing establishment in order to ensure traceability of the semen.

(16) While antibiotics should be used prudently, at the same time, in particular with a view to possible international trade, the inclusion of antibiotics in semen diluents should be in line with the provisions of Article 4.6.7 of the Terrestrial Animal Health Code ('the Code') of the World Organisation for Animal Health (OIE), Edition 2017[6]. In accordance with Directive 88/407/EEC, there is an obligation to add to bovine semen antibiotics that are effective against campylobacters, leptospires and mycoplasmas, and in accordance with Directive 90/429/EEC there is an obligation to add to porcine semen antibotics which are effective against leptospires, while Directive 92/65/EEC provides for the voluntary use of antibiotics. This Regulation should maintain the rules for the usage of antibiotics laid down in Directives 88/407/EEC, 90/429/EEC and 92/65/EEC, as well as those recommended by the OIE. Where antibiotics are are added to semen, information about the active substance(s) and their concentration should be indicated in the accompanying health certificate.

(17) Article 101(1) of Regulation (EU) 2016/429 provides that each competent authority should establish and keep up-to-date registers of registered germinal product establishments and of approved germinal product establishments which should be made available to the Commission and the competent authorities of the Member States. In addition, the register of approved germinal product establishments should be made available to the public. Therefore, it is appropriate to lay down in this Regulation the detailed information which should be included in those registers and the public availability of the register of the approved germinal product establishments.

(18) Due to the lengthy stocking capabilities for semen, oocytes and embryos, it is necessary to lay down in this Regulation special rules for the storage and movement of germinal products collected by approved germinal product establishments which cease their activity. Information concerning such germinal product establishments should be retained in the register of approved germinal product establishments of the Member State concerned and dates when the activity was stopped should be included. In addition, the date of withdrawal of the approval should be indicated in that register. The period for retaining information concerning such germinal product establishments in that register should also be established.

(19) In addition, this Regulation should also lay down rules to ensure that operators of approved germinal product establishments who cease their activity, prior to the date of withdrawal of the approval of their germinal product establishment, move the semen, oocytes or embryos collected or produced and stored in those germinal product establishments for further storage to a germinal product storage centre, or for reproduction purposes to an establishment where bovine, porcine, ovine, caprine or equine animals are kept, or for safe disposal or use as animal by-products in accordance with Article 13 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council[7].