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Delegations will find attached document C(2019) 4055 final.

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EUROPEAN
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Brussels, 17.12.2019
C(2019) 4055 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 17.12.2019

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

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] was published in the *Official Journal of European Union* on 31 March 2016. It came into force on 20 April 2016 and applies from 21 April 2021.

The Animal Health Law lays down rules on transmissible animal diseases, and *inter alia*, rules for the registration and approval of germinal product establishments and for traceability of consignments and the animal health requirements for germinal products moved within the Union.

The Animal Health Law, once applicable, will replace, *inter alia,* four Council Directives (namely, Council Directives 88/407/EEC[2], 89/556/EEC[3], 90/429/EEC[4] and 92/65/EEC[5]), as well as a number of Commission Decisions, adopted pursuant to those Directives, laying down animal health requirements for trade within the Union in germinal products.

The Animal Health Law aims at providing a simpler and more flexible regulatory framework, while at the same time ensuring a more risk-based approach to animal health requirements, enhanced disease preparedness, prevention and control for listed diseases[6]. These elements, however, can only become operational once more detailed requirements are laid down in delegated and implementing acts complementing the Animal Health Law.

The Animal Health Law provides for the Commission to adopt delegated acts, including delegated acts for the movement within the Union of consignments of germinal products of certain kept terrestrial animals.

This Commission Delegated Regulation lays down rules concerning the approval of germinal product establishments, and the traceability, animal health, certification and notification requirements for the movements within the Union of consignments of germinal products of certain kept terrestrial animals, that are required to be adopted pursuant to the Animal Health Law, and more particularly under Chapters 1, 2 and 5 of Title I of Part IV of that act.

The Animal Health Law was one of the first main legislative acts adopted following the adoption of the Treaty on the Functioning of the European Union. At that time, all the implications and practicalities related to the adoption of the delegated acts in accordance with Article 290 of the Treaty were not yet known nor discussed, and accordingly were not taken into consideration at the time of drafting. Hence, the various 'empowerment' articles in the

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1 OJ L 84, 31.3.2016, p. 1.

2 Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

3 Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

4 Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

5 Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

6 'Listed disease' means a disease listed in accordance with Article 5(1) of the Animal Health Law. See also Annex II to that Regulation.

Animal Health Law providing for the adoption of delegated acts are not grouped together at the end of a Chapter, Title or Part dealing with a particular subject, but instead are mostly spread across different articles of those divisions of the act, even though, content-wise, they are closely linked with each other. Therefore, this draft delegated act 'bundles' a number of the empowerment provisions provided for in the Animal Health Law and cites them all as legal bases. In addition, in the interests of coherency, transparency and to avoid duplication, it is important that these rules are laid down in the same delegated act, as they are all interrelated.

The rules laid down in this Delegated Regulation are largely 'taking over' rules currently laid down in existing Union acts establishing the animal health requirements for the movement within the Union of consignments of germinal products, as they have proven to be effective in preventing the spread of listed diseases within the Union.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The expert group meetings for the purpose of this Delegated Regulation took place on 24 April 2017, 24 November 2017, 16 April 2018, 18 May 2018 and 18 June 2018. The Member States' representatives from the national competent authorities participated in those meetings. At the first meeting of the expert group, representatives of the RepVet Group (veterinarians from European Artificial Insemination companies in the cattle and pig sectors), were also present due to the need for specific expertise.

The purpose of the expert group meetings which took place on 24 April and 24 November 2017 was to exchange views, experiences and good practices among representatives of the competent authorities of the Member States responsible for the development and implementation of animal health policy in the area of germinal products, and with the stakeholders in that sector. The aim of those meetings was to identify provisions of the existing European Union legislation on germinal products which should either be kept or improved in the upcoming acts to be adopted within the framework of the Animal Health Law, as well as to point out new obligations arising under the Animal Health Law.

The conclusions of the expert group meetings, as regards the rules to be laid down in the future delegated acts on germinal products, to be adopted within the framework of the Animal Health Law, were the following:

(a) a derogation for collection of semen of ovine and caprine animals at establishments where those animals are kept and which is then dispatched to another Member State, as currently provided for in Directive 92/65/EEC, should be maintained; however, special conditions for such dispatch (including the purpose of such movements and the consent of the Member State of destination) should be established;

(b) all three types of residency of stallions at semen collection centres, as currently provided for in Directive 92/65/EEC should be maintained; 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 - donors which may leave the semen collection centre occasionally - and the testing programme as specified in point 1.6(c) of Chapter II(I) of Annex D to Council Directive 92/65/EEC - "walk-in stallions" - should be improved and strengthened;

(c) rules for dispatch of consignments of germinal products between confined establishments should be laid down;

(d) rules for the storage and dispatch of consignments of germinal products collected by a germinal product establishment which ceases its activity should be laid down, also rules covering a situation when such a germinal product establishment should remain

in the list of approved germinal product establishments of a particular Member State, and the date when the activity was ceased should be indicated in that list;

(e) rules should be laid down concerning the dispatch of consignments of bovine oocytes and ovaries within the Union;

(f) it is necessary to lay down rules concerning mixed/pooled semen of bovine, porcine, ovine and caprine animals; however, the mixing of semen should be restricted to the semen collection centre where it was collected;

(g) the current system for the marking of straws and other packages of germinal products has been working well to date; however, further discussions on the possible standardisation of the code placed on the straws will continue;

(h) rules should be laid down covering the traceability and animal health requirements for the dispatch of consignments of germinal products of dogs and cats, of terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species kept at confined establishments and of animals of the families *Camelidae* and *Cervidae*;

(i) there was support for laying down rules for germinal product storage centres where semen, oocytes or embryos of one or more species (namely of the bovine, porcine, ovine, caprine and equine species), or any combination of those germinal products of those species, are stored under additional special conditions;

(j) there is a need for the specific rules permitting the dispatch to other Member States of consignments of germinal products for scientific purposes and those stored at gene banks, which do not necessary fulfil the requirements laid down in the existing acts. The germinal products stored at the gene banks have a particular value being a genetic material of rare, endangered or even extinct breeds, therefore derogation from standard requirements for the dispatch of such germinal products should be laid down in this Delegated Regulation;

(k) specialised units for the sex-sorting of semen should be considered to be germinal product establishments where processing and storage of germinal products takes place; they do not only process germinal products, including sex-sorting of semen, but also prepare the final product ready to be used or for storage; however, the option for processing, mainly sex-sorting, of semen outside the semen collection centre and the subsequent return of that processed semen to the semen collection centre of semen origin should also be provided for;

(l) containers transporting germinal products from approved germinal products establishments to other Member States or nationally from approved germinal product establishments to germinal product processing establishments and germinal product storage centres should be sealed. A centre or team veterinarian should ensure that such seal is applied on the transport container, whereas an official veterinarian should have a possibility of breaking that seal for the purpose of verifying the content of the transport container and later on re-sealing the transport container, before issuing of a health certificate;

(m) the transport in one container of different types of germinal products of a single species, under additional special conditions, should be allowed. Also, the transport within a single container of germinal products of ovine and caprine animals should be allowed;

(n) animal health requirements related to ovine epididymitis (*Brucella ovis*) are only relevant for ovine animals and those caprine animals which are kept together with ovine animals;

(o) the experts acknowledged the prudent use of antibiotics; however, they preferred that, in particular with the view to possible exports, the use of antibiotics in semen diluents should be in line with the recommendations of the World Organisation for Animal Health (OIE).

During the expert group meetings which took place on 16 April 2018, 18 May 2018 and 18 June 2018 a working document of a draft Commission Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards approval of germinal product establishments, traceability and animal health requirements for the movements within the Union of germinal products of certain kept terrestrial animals was presented and discussed. This working document was prepared based on current Union legislation establishing the animal health requirements for the movement within the Union of germinal products and taking into account views, opinions and comments received from the experts participating in the expert group meetings which had taken place on 24 April and 24 November 2017.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

There were no comments received from the Council.

There were no comments received from the European Parliament.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 9 January and 6 February 2019. 34 feedbacks were received in total, including opinions of the following stakeholders: ETS-Holland, European Association of Zoos and Aquaria (EAZA), European Association of Zoo and Wildlife Veterinarians, European Forum of Farm Animal Breeders (EFFAB), Association of Embryo Technologies in Europe, British and Irish Association of Zoos and Aquariums, the following public authorities: Canadian Food Inspection Agency, Animal and Plant Health Agency of the United Kingdom and U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS-IS), and some anonymous opinions.

In addition, there were several opinions submitted to the Commission by e-mail.

The main following requests were submitted and points made:

(a) to adjust the list of antibiotics and mixtures of antibiotics used in ovine and caprine semen diluents in accordance with existing practices. Having regard that use of antibiotics in ovine and caprine semen is voluntary and in order to make the provisions of this Delegated Regulation clearer, the text of the Delegated Regulation was amended;

(b) the ovine semen sector welcomed provisions of this Delegated Regulation which supports the existing practice that most of the ovine semen is dispatched and used as fresh semen;

(c) the operators of confined establishments disagree with the requirement of no natural breeding to have taken place for at least 30 days prior to the collection of germinal products. Many non-domestic animals of the bovine, ovine, equine and caprine species, complex and highly social, are kept at confined establishments. To maximise the welfare of these animals, they are kept in social groups to replicate that of their

free-living counterparts. Therefore, it is not possible to keep donor animals in isolation for 30 days. The text of the Delegated Regulation was therefore amended;

(d) some operators disagree with a derogation provided for in this Regulation allowing collection of semen of ovine and caprine animals, which is to be moved to another Member State, at the establishment of origin of those animals instead of at a semen collection centre. They claim that it is a disadvantage for those operators which are approved as semen collection centre. This Delegated Regulation, based on the possible risk posed by the movement of such semen, allows for such derogation, which was already established by Directive 92/65/EEC;

(e) the acknowledgements for the conditions laid down in this Delegated Regulation for the movement of germinal products stored at national gene banks to other Member States, including definition of a gene bank;

(f) the request to take into account germinal products donors vaccinated against infection with bluetongue virus. This Delegated Regulation is in line with recommendations of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

3. LEGAL ELEMENTS OF THE DELEGATED ACT

3.1. Summary of the proposed rules

This Delegated Regulation will supplement the rules laid down in Chapters 1, 2 and 5 of Title I of Part IV of the Animal Health Law.

While the Animal Health Law did not substantially alter the pre-existing legal framework applicable to germinal products, it provides for the Commission to adopt rules updating those that had been previously laid down in pre-existing acts, and supplementing those laid in the basic act.

Accordingly, this Delegated Regulation will include the following additional rules supplementing those already laid down in the basic act as regards:

(a) requirements for the approval and for the cessation of activities of germinal products establishments for bovine, porcine, ovine, caprine and equine animals;

(b) the information to be included in the registers of registered and approved germinal products establishments to be kept by the competent authority;

(c) record keeping obligations for operators, including additional record-keeping requirements for germinal product establishments that have ceased their activities;

(d) traceability requirements for germinal products of bovine, porcine, ovine, caprine and equine animals;

(e) traceability requirements for germinal products of dogs, cats, and terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species kept at confined establishments and animals of the families *Camelidae* and *Cervidae;*

(f) animal health requirements for the dispatch of consignments of germinal products between Member States;

(g) animal health certification and notification requirements for the dispatch of consignments of germinal products between Member States;

(h) rules for the granting of derogations by the competent authorities for the dispatch of consignments of germinal products between Member States for scientific purposes and germinal products stored at gene banks;

(i) transitional measures to protect the acquired rights and legitimate expectations of stakeholders resulting from pre-existing Union acts.

3.2. Legal basis

The draft Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to 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.

COMMISSION DELEGATED REGULATION (EU) …/...

of 17.12.2019

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)

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')[7], 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.

(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.

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

(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[8], 89/556/EEC[9], 90/429/EEC[10] and 92/65/EEC[11]. 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)

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8 Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

9 Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

10 Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

11 Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

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 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[12]. 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[13].

(20) Article 121 of Regulation (EU) 2016/429 lays down traceability requirements for germinal products of bovine, ovine, caprine, porcine and equine animals and detailed rules in relation to the marking of those germinal products should be laid down in this Regulation. The current system for the marking of straws and other packages with germinal products is well established. Account should also be taken of the

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12 http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_coll_semen.htm.

13 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

recommendations of the International Committee for Animal Recording (ICAR)[14] in this respect.

(21) The collection and processing of semen of ovine and caprine animals also have particular characteristics. Some semen collection centres freeze semen in pellets, while others place fresh or chilled semen for a short time in receptacles, such as tubes. The individual marking of such pellets and tubes is time consuming and onerous. In order to allow the movement to other Member States of semen of ovine and caprine animals, while at the same time ensuring its traceability, group identification of pellets of frozen semen or tubes or straws with fresh or chilled semen should be available. Therefore, it is necessary to lay down in this Regulation rules for the marking of collective packages, such as goblets, where pellets of frozen semen, or tubes or straws with fresh or chilled semen of ovine and caprine animals are placed.

(22) Traceability requirements for germinal products of bovine, ovine, caprine, porcine and equine animals laid down in this Regulation are to be supplemented by the rules concerning technical requirements and specifications for marking of straws and other packages which will be laid down in Commission Implementing Regulation adopted in accordance with Article 123 of Regulation (EU) 2016/429.

(23) An increasing number of germinal products of dogs and cats, of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments and of animals of the families *Camelidae* and *Cervidae* are moved between Member States. Therefore, it is appropriate to establish harmonised rules on the marking of straws and other packages containing such germinal products. Additional rules on the traceability of germinal products of kept terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species should be laid down in this Regulation.

(24) Article 159 of Regulation (EU) 2016/429 lays down rules concerning the authorisation of movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species. In order to make those rules operational, it is necessary to lay down in this Regulation detailed rules for the collection, production, processing, storage and transport of germinal products, and animal health requirements for kept donor animals from which germinal products are collected and concerning isolation and quarantine for such animals, and requirements for the laboratory and other tests to be carried out on kept donor animals and germinal products, as well as animal health requirements for the collection, production, processing, storage or other procedures and transport of those germinal products.

(25) In addition, Directives 88/407/EEC, 90/429/EEC and 92/65/EEC provided for derogations, under certain conditions, from testing obligations for donor animals of the bovine, porcine, ovine and caprine species when those animals are moved between semen collection centres. As such derogations decrease the procedural and economic burdens for operators of semen collection centres and are justified from an animal health point of view, it is appropriate to maintain in this Regulation such derogations from certain animal health requirements for donor animals of the bovine, ovine, caprine and porcine species moved between approved semen collection centres.

(26) Based on current scientific knowledge, the transport of different types of germinal products of a single species in one container does not pose a risk for the contamination of germinal products if they are transported under certain conditions. These conditions

[14] https://www.icar.org/

include being transported in physically separated compartments of the transport container or with the use of double-bag system protecting the commodity of one type from the other. Therefore, it is appropriate to lay down rules in this Regulation permitting the transport of germinal products of different types of a single species in one container under certain conditions.

(27) The sealing of containers in which germinal products are transported from approved germinal product establishments to other Member States or nationally from approved germinal product establishments to germinal product processing establishments and germinal product storage centres ensures that the animal health conditions for the transport of germinal products are not compromised. The centre veterinarian or team veterinarian responsible for the germinal product establishment, whose name is specified in the approval of that establishment, should ensure that such seal is applied on the transport container. An official veterinarian certifying a consignment of germinal products should have the possibility of breaking that seal for the purpose of verifying the content of the transport container and later on re-sealing the transport container. Those arrangements should be taken into account in the rules laid down in this Regulation.

(28) Directive 89/556/EEC lays down conditions for intra-Union trade in and imports into the Union of embryos of animals of the bovine species. However, it is also necessary to lay down in this Regulation rules on movements within the Union of bovine oocytes as well as ovaries.

(29) Union legislation in force prior to the adoption of Regulation (EU) 2016/429 and this Regulation laid down the rules on trade in semen covering situations where each dose of the consignment consists of ejaculates of one particular donor. However, due to the fact that mixed or pooled semen from several donors may increase fertility and such semen is commonly used, this Regulation should lay down rules on movements of mixed or pooled semen of bovine, porcine, ovine and caprine animals, provided that mixing of semen is restricted only to one semen collection centre where the semen was collected and a mark on each straw or other package in which mixed semen is placed allows tracing the individual identification numbers of all donor animals. In addition, the operator should have procedures in place as regards the processing of mixed semen and should include, in its records, details of movements of such semen from semen collection centre.

(30) Article 13 of Directive 92/65/EEC lays down rules for trade in semen, ova and embryos of animals of species susceptible to the diseases listed in Annex A or B thereto which are consigned to and from bodies, institutes or centres approved in accordance with Annex C thereto. Annex E to that Directive sets out the model animal health certificate for trade which should accompany the consignments of such semen, ova or embryos. Articles 95 and 137 of Regulation (EU) 2016/429 establish the concept of 'a confined establishment' which is equivalent to 'approved body, institute or centre' defined in Article 2(1)(c) of Directive 92/65/EEC. Given that genetic material of animals is currently exchanged between approved bodies, institutes and centres, it is necessary to maintain the possibility for such intra-Union movements in this Regulation. It is therefore appropriate to lay down in this Regulation the animal health requirements for movements to other Member States of germinal products of terrestrial animals kept at confined establishments. This Regulation should thus provide for a possibility for operators of confined establishments to move to other Member States consignments of germinal products collected from animals kept at those establishments without a need for additional approval as germinal product

establishment. High animal health requirements for the approval as a confined establishment, controlled management of animals at those establishments, specific surveillance requirements and targeted movement of consignments of germinal products to another confined establishment should provide for sufficient guarantees to prevent the spread of animal diseases.

(31) Article 162 of Regulation (EU) 2016/429 lays down rules concerning the minimum information which must be included in animal health certificates for movements between Member States of germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species. Therefore, this Regulation should specify the detailed information that should be contained in such certificates.

(32) Article 163 of Regulation (EU) 2016/429 provides that operators should inform the competent authority in their Member State of origin in advance of the intended movement to another Member State of germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species and should provide all the necessary information to enable that competent authority to notify the movement of germinal products to the competent authority of the Member State of destination. Therefore, it is necessary to lay down in this Regulation detailed rules concerning the requirements for the advance notification by operators, the information necessary to notify such movements and the emergency procedures for such notifications.

(33) Article 163(2) of Regulation (EU) 2016/429 provides that Traces should be used for the notification purposes when consignments of germinal products are intended to be moved to other Member States. Traces is the integrated computerised veterinary system as provided for in Commission Decisions 2003/24/EC[15] and 2004/292/EC[16]. Article 131 of Regulation (EU) 2017/625 of the European Parliament and of the Council[17] provides for the establishment of an information management system for official controls (IMSOC) which will incorporate functionalities of Traces. IMSOC should therefore be referred to in this Regulation instead of Traces.

(34) Article 165 of Regulation (EU) 2016/429 provides that the competent authority of the place of destination may, subject to agreement of the competent authority of the place of origin, authorise for scientific purposes movements of germinal products into its territory where those movements do not fulfil the standard requirements for movements of germinal products. In order to allow such movements, it is appropriate to lay down in this Regulation the rules for the granting of derogations by the competent authorities for movements between Member States of germinal products for scientific purposes.

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15 Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

16 Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

17 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

(35) A national gene bank plays an important role in storing the genetic material of animal populations that are particular to that Member State. The objective of such national gene banks is *ex situ* conservation and sustainable use of animal genetic resources. Germinal products stored at the national gene banks are often of unknown animal health status or were collected, produced, processed and stored in accordance with a different animal health regime than it is currently applicable in accordance with Union and national legislation. As such germinal products have a particular value, as they are often genetic material of endangered breeds as defined in point (24) of Article 2 of Regulation (EU) 2016/1012 of the European Parliament and of the Council[18], or breeds that are extinct since collection of the germinal products, and Member States have expressed their interest in exchanging such germinal products amongst themselves, special conditions for granting derogations by the competent authorities for the movement of germinal products stored in national gene banks to other Member States should be laid down in this Regulation. As a general rule, this Regulation should lay down the conditions for movements of those germinal products between national gene banks of different Member States, while rules for national distribution of germinal products from national gene banks to operators should be left to the competent authorities of Member States. Special attention should also be paid to the animal health conditions for such movements, where testing for particular diseases may be required.

(36) This Regulation refers to Commission Implementing Regulation (EU) 2018/1882[19] and Commission Delegated Regulations 2019/2035[20], 2019/…[21] and 2019/…[22] which were also adopted under Regulation (EU) 2016/429. The references to those Regulations are necessary as they lay down requirements on surveillance, eradication programmes and disease free statuses, identification and registration, traceability and movements within the Union and entry into the Union of animals, which are also applicable to germinal product donor animals.

(37) In order to ensure a smooth transition to the new legal framework for semen collection or storage centres or embryo collection or production teams approved under acts adopted pursuant to Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, which are repealed by Regulation (EU) 2016/429 with effect from 21 April 2021, carrying out activities related to the collection, production, processing,

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18 Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).

19 Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

20 Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

21 [Commission Delegated Regulation (EU) 2019/… of … supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (document SANTE/7066/2019), C(2019)4056].

22 [Commission Delegated Regulation (EU) 2019/… of … supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (SANTE/7072/2019), C(2019)4058].

storing and transport of germinal products, they should be deemed to be approved in accordance with this Regulation. Member States should ensure that those operators comply with all the rules provided for in this Regulation, in particular by submitting them to regular and risk-based official controls. In the event of non-compliance, the competent authorities should ensure that those operators take the necessary measures to remedy that non-compliance and, where necessary, suspend or withdraw their approval.

(38) In order to ensure a smooth transition for germinal products collected and produced before the date of application of this Regulation, straws and other packages in which such semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, and which are marked before 21 April 2021 in accordance with the legislation adopted pursuant to Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, should be considered to have been marked in accordance with this Regulation and eligible for movement between Member States.

(39) This Regulation should be applicable from 21 April 2021 in accordance with the date of application of Regulation (EU) 2016/429,

HAS ADOPTED THIS REGULATION:

PART I
SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1
Subject matter and scope

1. This Regulation supplements the rules laid down in Regulation (EU) 2016/429 as regards registered and approved germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals.

2. Chapter 1 of Part II lays down the requirements for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State in relation to:

   (a) quarantine, isolation and other biosecurity measures;

   (b) surveillance requirements;

   (c) facilities and equipment;

   (d) responsibilities, competence and specialised training of personnel and veterinarians for the activity of germinal product establishments;

   (e) responsibilities of the competent authority approving germinal product establishments;

   (f) special rules for the cessation of activities of those germinal product establishments.

3. Chapter 2 of Part II lays down the requirements on:

   (a) the information to be included by the competent authority in the register of registered germinal product establishments;

(b) the information to be included by the competent authority in the register of the of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals; and the rules for the availability to the public of that register when germinal products of those animals are to be moved between Member States.

4. Chapter 3 of Part II lays down:

(a) the rules for the record-keeping obligations on operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals, and the requirements for record-keeping in respect of the germinal products collected, produced or processed in such an establishment after it has ceased its activities;

(b) the traceability requirements for germinal products of:

(i) bovine, porcine, ovine, caprine and equine animals;

(ii) dogs (*Canis lupus familiaris*) and cats (*Felis silvestris catus*);

(iii) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments;

(iv) animals of the families *Camelidae* and *Cervidae*.

5. Chapter 1 of Part III lays down the animal health requirements, including derogations, for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals, specifying:

(a) the rules for the collection, production, processing and storage of germinal products in the approved germinal product establishments;

(b) the animal health requirements for donor animals from which germinal products were collected, and concerning isolation or quarantine for those animals;

(c) the laboratory and other tests to be carried out on donor animals and germinal products;

(d) the animal health requirements for the collection, production, processing, storage and other procedures, and for the transport of germinal products.

6. Chapter 2 of Part III, for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals, lays down:

(a) the rules on animal health certification;

(b) the information to be contained in the animal health certificate;

(c) the requirements concerning self-declaration document;

(d) the notification requirements.

7. Chapter 3 of Part III lays down the animal health, certification and notification requirements for movements between Member States of germinal products of:

(a) dogs and cats;

(b) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments;

(c) animals of the families *Camelidae* and *Cervidae*.

8. Chapter 4 of Part III lays down rules for the granting of derogations by competent authorities for movements between Member States of germinal products for scientific purposes and germinal products stored at gene banks.

9. Part IV lays down certain transitional measures regarding Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC in relation to:

   (a) the approval of semen collection centres, semen storage centres, embryo collection teams and embryo production teams;

   (b) the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported.

10. This Regulation shall not apply to germinal products of wild animals.

Article 2
Definitions

For the purposes of this Regulation, in addition to the definitions laid down in Article 1 of Regulation (EU) 2018/1882, the following definitions shall apply:

(1) 'registered germinal product establishment' means a germinal product establishment, other than an approved germinal product establishment, registered with the competent authority in accordance with point (a) of the first subparagraph of Article 93 of Regulation (EU) 2016/429;

(2) ‘approved germinal product establishment’ means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment or a germinal product storage centre, approved in accordance with Article 97 of Regulation (EU) 2016/429;

(3) ‘bovine animal' or 'animal of the bovine species' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;

(4) ‘porcine animal' or 'animal of the porcine species' means an animal of the ungulate species of *Sus scrofa*;

(5) ‘ovine animal' or 'animal of the ovine species' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;

(6) ‘caprine animal' or 'animal of the caprine species' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;

(7) ‘equine animal' or 'animal of the equine species' means an animal of the species of solipeds belonging to genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species;

(8) 'animal health certificate' means a document issued by the competent authority of the Member State of origin to accompany a consignment of germinal products to their place of destination as referred to in Article 161(4) of Regulation (EU) 2016/429;

(9) 'self-declaration document' means a document issued by the operator to accompany a consignment of germinal products to their place of destination as referred to in Articles 32 and 46;

(10) ‘gene bank’ means a repository of animal genetic material for *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks;

(11) ‘semen collection centre’ means a germinal product establishment approved by the competent authority for the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;

(12) ‘embryo collection team’ means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of *in vivo* derived embryos of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;

(13) ‘embryo production team’ means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of oocytes, and the *in vitro* production, where applicable with stored semen, processing, storage and transport of embryos, of bovine, porcine, ovine, caprine or equine animals both intended for movement to another Member State, as referred to in Article 4;

(14) ‘semen’ means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;

(15) ‘oocytes’ means the haploid stages of the ootidogenesis including secondary oocytes and ova;

(16) ‘embryo’ means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;

(17) ‘consignment of germinal products’ means a quantity of semen, oocytes, *in vivo* derived embryos or *in vitro* produced embryos dispatched from a single approved germinal product establishment covered by a single animal health certificate;

(18) ‘germinal product processing establishment’ means a germinal product establishment approved by the competent authority for the processing, including semen sex-sorting where appropriate, and the storage of semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals of one or more species, or any combination of types of germinal products or species, intended for movement to another Member State, as referred to in Article 4;

(19) ‘germinal product storage centre’ means a germinal product establishment approved by the competent authority for the storage of semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals of one or more species, or any combination of types of germinal products or species, intended for movement to another Member State , as referred to in Article 4;

(20) ‘centre veterinarian’ means the veterinarian responsible for the activities carried out at the semen collection centre, at the germinal product processing establishment or at the germinal product storage centre as laid down in this Regulation;

(21) ‘team veterinarian’ means the veterinarian responsible for the activities carried out by an embryo collection team or by an embryo production team as laid down in this Regulation;

(22) 'unique approval number' means a number assigned by the competent authority;

(23) 'withdrawal date of the approval' means the date on which the competent authority has suspended or withdrawn the approval of an approved germinal product establishment in accordance with Article 100 of Regulation (EU) 2016/429;

(24) 'unique registration number' means a number assigned to a registered germinal product establishment;

(25) ‘quarantine accommodation’ means a facility authorised by the competent authority for the purpose of the isolation of bovine, porcine, ovine or caprine animals for a period of at least 28 days before they are admitted to a semen collection centre;

(26) ‘establishment free from (disease)’ means an establishment granted the status in accordance with the requirements set out in Article 20 of Regulation (EU) 2019/… [document SANTE/7066/2019, C(2019)4056];

(27) ‘official laboratory’ means a laboratory, situated in a Member State or third country or territory, designated in accordance with Article 37 of Regulation (EU) 2017/625 by the competent authority to carry out the tests provided for in Articles 24 and 25 of this Regulation;

(28) 'IMSOC' means an information management system for official controls for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged as referred to in Article 131 of Regulation (EU) 2017/625 and is the system now used instead of Traces;

(29) ‘endangered breed’ means a local breed, recognised by a Member State to be endangered, genetically adapted to one or more traditional production systems or environments in that Member State and where the endangered status is scientifically established by a body possessing the necessary skills and knowledge in the area of endangered breeds as referred to in Article 2(24) of Regulation (EU) 2016/1012;

(30) ‘approved eradication programme’ means a disease eradication programme implemented in a Member State or zone thereof as approved by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429;

(31) ‘batch of donor animals’ means a group of animals of the same health status from which germinal products are collected and processed at the same time, and transported together.

PART II
APPROVAL OF GERMINAL PRODUCT ESTABLISHMENTS, REGISTERS, RECORD-KEEPING AND TRACEABILITY

CHAPTER 1
Approval of germinal product establishments

Article 3

Requirements for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

Operators of the following germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall apply in accordance with Article 94(1)(b) of Regulation (EU) 2016/429 to the competent authority for approval for the purpose of moving consignments of germinal products of those animals to other Member States:

(a) the establishment where semen of bovine, porcine, ovine, caprine or equine animals is collected, processed and stored for approval as a semen collection centre;

(b) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of embryos of bovine, porcine, ovine, caprine or equine animals for approval as a embryo collection team;

(c) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of oocytes and production, processing and storage of embryos of bovine, porcine, ovine, caprine or equine animals for approval as an embryo production team;

(d) the establishment where fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals are processed and stored for approval as a germinal product processing establishment;

(e) the establishment where fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals are stored for approval as a germinal product storage centre.

Article 4

Approval by the competent authority of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. The competent authority shall only grant approval of a germinal product establishment for bovine, porcine, ovine, caprine or equine animals as referred to in Article 97 of Regulation (EU) 2016/429 after it has ensured that it complies with the following requirements:

   (a) the operator has appointed:

      (i) a centre veterinarian responsible for the activities set out in:

         – point 1 of Part 1 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (a) of Article 3 as a semen collection centre;

– point 1 of Part 4 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (d) of Article 3 as a germinal product processing establishment;

– point 1 of Part 5 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (e) of Article 3 as a germinal product storage centre; or

(ii) a team veterinarian responsible for the activities set out in:

– point 1 of Part 2 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (b) of Article 3 as a embryo collection team;

– point 1 of Part 3 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (c) of Article 3 as a embryo production team;

(b) the facilities, equipment and operational procedures for the activity in question comply with the requirements set out in:

(i) point 2 of Part 1 of Annex I, in respect of the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals;

(ii) point 2 of Part 2 of Annex I, in respect of the collection, processing, storage and transport of embryos of bovine, porcine, ovine, caprine or equine animals;

(iii) point 2 of Part 3 of Annex I, in respect of the collection of oocytes and of the production, processing, storage and transport of embryos of bovine, porcine, ovine, caprine or equine animals, including the processing and storage of semen and oocytes used for the embryo production;

(iv) point 2 of Part 4 of Annex I, in respect of the processing, storage and transport of fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals;

(v) point 2 of Part 5 of Annex I, in respect of the storage and transport of fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals.

2. When granting approval of a germinal product establishment for bovine, porcine, ovine, caprine and equine animals, as referred to in Articles 97 and 99 of Regulation (EU) 2016/429, the competent authority shall assign it with a unique approval number, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted.

Article 5

Special rules for the cessation of activities of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. Where the operator of an approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals ceases its activity, that operator shall ensure that prior to the withdrawal date of the approval all consignments of semen, oocytes or embryos collected or produced and stored in that germinal product establishment have been moved:

   (a) to a germinal product storage centre for further storage; or

   (b) for reproduction purposes to an establishment where bovine, porcine, ovine, caprine or equine animals are kept; or

   (c) for safe disposal or use as animal by-products in accordance with Article 13 of Regulation (EC) No 1069/2009.

2. Where consignments of semen, oocytes or embryos are not moved from the approved germinal product establishment prior the withdrawal date of the approval as referred to in paragraph 1, such consignments shall not be moved to another Member State.

CHAPTER 2

Registers to be kept by the competent authority of registered and approved germinal product establishments

Article 6

Register to be kept by the competent authority of registered germinal product establishments

1. The competent authority shall draw up and keep up-to-date a register of registered germinal product establishments.

2. The competent authority shall include at least the following information in the register referred to in paragraph 1, for each registered germinal product establishment:

   (a) the name, contact details and, where available, the Uniform Resource Locator (URL) of the website of the registered germinal product establishment;

   (b) the address of the registered germinal product establishment;

   (c) the type of germinal products and animal species for which it was registered;

   (d) the unique registration number assigned by the competent authority and the date of the registration;

   (e) if activities of the registered germinal product establishment have ceased, the date of cessation of those activities.

Article 7

Register to be kept by the competent authority of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. The competent authority shall draw up and keep up to date a register of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals.

2. The competent authority shall include at least the following information in the register referred to in paragraph 1 for each approved germinal product establishment:

(a) the name, contact details and, where available, the URL of the website of the germinal product establishment;

(b) the address of the germinal product establishment;

(c) the name of the centre veterinarian or the team veterinarian;

(d) the type of germinal products, the type of the germinal product establishment and animal species for which the approval has been granted;

(e) the unique approval number assigned by the competent authority and the date of the approval.

3. Where, based on requirements provided for in Article 4, a germinal product processing establishment or a germinal product storage centre is approved by the competent authority for the storage and, in respect of the germinal product processing establishment, the processing, of germinal products of more than one type or of more than one animal species, the competent authority shall include information on the type of the germinal products and on the animal species thereof stored and, if applicable, processed at the approved germinal product establishment in its register of approved germinal product establishments.

4. Where the competent authority has suspended or withdrawn the approval of an approved germinal product establishment in accordance with Article 100(2) of Regulation (EU) 2016/429, it shall, without undue delay:

(a) indicate that suspension or withdrawal in its register of approved germinal product establishments;

(b) specify in the case of the suspension of the approval, the commencement and end date, and in the case of withdrawal, the withdrawal date of the approval.

5. Where an approved germinal product establishment has ceased its activity as referred to in Article 5, the competent authority shall, without undue delay, indicate the date of cessation of those activities in its register of approved germinal product establishments.

6. The competent authority shall make the register referred to in paragraph 1 available to the public on its website, where germinal products are to be moved between Member States and notify the URL of that website to the Commission.

Where the URL of the website of a competent authority has been changed it shall notify, without undue delay, the new URL of that website to the Commission.

CHAPTER 3
Record-keeping and traceability

SECTION 1
RECORD KEEPING

Article 8

Record-keeping obligations of operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. Operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall keep and maintain records containing at least the following information:

   (a) in respect of a semen collection centre:

      (i) the species, breed, date of birth and identification of each donor animal present at the semen collection centre;

      (ii) the dates of any movement of donor animals to and from the semen collection centre and, where those animals are accompanied by any document, the reference to those documents;

      (iii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on the donor animals;

      (iv) the date of semen collection and, where relevant, the date and the place of processing of semen;

      (v) the identification of semen and details of its destination;

   (b) in respect of an embryo collection team, an embryo production team or an embryo collection and production team:

      (i) the species, breed, date of birth and identification of each donor animal from which oocytes or embryos were collected;

      (ii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on donor animals of oocytes or embryos;

      (iii) the date and place of oocytes or embryos collection, examination, and processing;

      (iv) the identification of oocytes or embryos and details of their destination;

      (v) where micromanipulation is being performed on the embryos, the details of micromanipulation techniques used which involve penetration of the *zona pellucida* or, in case of equine embryos, the embryonic capsule;

      (vi) the origin of semen used for artificial insemination of donor animals or to fertilise oocytes for *in vitro* production of embryos;

(c) in respect of a germinal product processing establishment or a germinal product storage centre:

(i) the type of germinal products either processed and stored or stored at the approved germinal product establishment with reference to the species of the donor animal;

(ii) the dates of movement of germinal products to and from the approved germinal product establishment with the reference to the documents which accompanied those germinal products;

(iii) the documents, including an animal health certificate and a self-declaration document, confirming that the health status of the donor animals whose germinal products are either processed and stored or stored at the approved germinal product establishment complies with the requirements of this Regulation;

(iv) the identification of germinal products that are either processed and stored or stored at the approved germinal product establishment.

2. Where a germinal product establishment, referred to in paragraph 1(c), is approved by the competent authority for either processing and storage or storage of germinal products of more than one type or of more than one animal species, the operator shall keep and maintain records separately for each type of germinal product and germinal products of each animal species either processed and stored or stored.

Article 9

Record-keeping obligations of operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals that cease their activity

1. Where an approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals ceases its activity as referred to in Article 5, the operator of that establishment shall only move consignments of stored germinal products to a germinal product storage centre if such consignments are accompanied by originals or copies of the records required in accordance with Article 8(1).

2. The operator of the germinal product storage centre receiving the consignment of germinal products from the establishment that has ceased its activity as referred to in paragraph 1 shall record the entry and details of the germinal products based on the accompanying records required in accordance with Article 8(1)(c).

SECTION 2
TRACEABILITY

Article 10
Traceability requirements for germinal products of bovine, porcine, ovine, caprine and equine animals

1. Operators collecting, producing, processing or storing germinal products of bovine, porcine, ovine, caprine or equine animals shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, in such a way that the following information can be readily established:

   (a) the date of collection or production of those germinal products;

   (b) the species and identification of the donor animal(s);

   (c) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products;

   (d) any other relevant information.

2. In case of sex-sorting of semen at a germinal product processing establishment, the operator of the semen collection centre shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the germinal product processing establishment where that semen was sex-sorted.

3. Where a single straw or another package contains semen of bovine, porcine, ovine or caprine animals collected from more than one donor animal, the operator shall ensure that the information referred to in paragraph 1 permits the identification of all donor animals that have contributed to the dose of semen used for insemination.

4. By way of derogation from paragraph 1, where the semen of ovine or caprine animals is

   (a) frozen in pellets, the operator may mark the goblet containing the semen pellets of a single donor instead of marking each individual pellet in that goblet;

   (b) fresh or chilled semen, the operator may mark the goblet containing the semen tubes or straws of a single donor instead of marking each individual tube or straw in that goblet.

5. By way of derogation from paragraph 1(c), the operator shall ensure that the marking of each straw or other package in which semen, oocytes or embryos are placed, stored and transported, is carried out in such a way that it permits the identification of:

   (a) in the case of semen of ovine and caprine animals which has been collected at the establishment where the donor animals are kept as referred to in Article 13, the unique registration number of that establishment; or

   (b) in the case of germinal products of bovine, porcine, ovine, caprine or equine animals which have been collected or produced at a confined establishment referred to in Article 14, the unique approval number of that confined establishment.

Article 11

Traceability requirements for germinal products of dogs and cats, terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, and animals of the families Camelidae *and* Cervidae

1. Operators collecting, producing, processing or storing germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported in such a way that the following information can be readily established:

   (a) the date of collection or production of those germinal products;

   (b) the species, where necessary subspecies, and identification of the donor animal(s);

   (c) one of the following:

      (i) the address of the establishment of collection or production, processing and storage of those germinal products;

      (ii) where the establishment of collection or production, processing and storage of those germinal products was assigned with a unique registration number, the unique registration number which shall include the ISO 3166-1 alpha-2 code of the country in which the establishment is registered;

      (iii) where the establishment of collection or production, processing and storage of those germinal products is a confined establishment, the unique approval number which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;

   (d) any other information.

2. In case of sex-sorting of semen at an establishment other than the establishment of its collection or production, the operator of the establishment of collection or production of that semen shall supplement the information referred to in paragraph 1 with information which permits the identification of the establishment where that semen was sex-sorted.

3. By way of derogation from paragraph 1, where the semen of the animals referred to in paragraph 1 is frozen in pellets, the operator may mark the goblet containing semen pellets of a single donor instead of marking each individual pellet in that goblet.

4. Where a single straw or another package contains semen collected from more than one donor animal, the operator shall ensure that the information, referred to in paragraph 1, includes the identification of all donor animals.

PART III
MOVEMENTS OF GERMINAL PRODUCTS BETWEEN MEMBER STATES

CHAPTER 1
Animal health requirements for movements of germinal products of bovine, porcine, ovine, caprine and equine animals

Section 1
Rules for the collection, production, processing and storage of germinal products of bovine, porcine, ovine, caprine and equine animals in approved germinal product establishments

Article 12

Rules for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals from approved germinal product establishments

Operators shall only move to another Member State semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals, which were collected, produced, processed and stored in approved germinal product establishments.

Article 13

Derogation for the movements to other Member States of semen of ovine and caprine animals from the establishments where those animals are kept

By way of derogation from Article 12, operators may move to other Member States consignments of semen of ovine and caprine animals which were collected, processed and stored at the establishment where those donor animals are kept, provided that those operators:

(a) obtain the prior consent of the competent authority of the Member State of destination to accept the consignment;

(b) ensure that the donor animals have been clinically examined by a veterinarian prior to semen collection and showed no symptoms suggesting the presence of any of the category D diseases or of the emerging diseases relevant for the ovine and caprine animals or clinical signs of such category D or emerging diseases, on the day the semen was collected;

(c) ensure that the donor animals come from establishments which fulfil the animal health requirements laid down in Article 15(1), (2), (3) and (4) of Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(d) ensure that the donor animals have undergone the following tests with negative results carried out on samples taken during the period of isolation which must commence at least 30 days prior to the date of collection of the semen:

(i) a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058] for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*;

(ii) in the case of ovine animals, a serological test for ovine epididymitis (*Brucella ovis*);

(iii) in the case of caprine animals kept together with ovine animals, a serological test for ovine epididymitis (*Brucella ovis*);

(e) ensure that the donor animals are identified in accordance with Article 45(2) or (4), or Article 46(1), (2) or (3) of Regulation (EU) 2019/2035;

(f) ensure that the semen has been marked in accordance with the requirements provided for in Article 10;

(g) keep records at the establishment which must include at least the information provided for in Article 8(1)(a);

(h) ensure that the consignment of semen is transported in accordance with Articles 28 and 29.

Article 14

Derogation for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals kept at confined establishments

By way of derogation from Article 12, operators of confined establishments may move to other Member States consignments of semen, oocytes and embryos collected at those establishments from bovine, porcine, ovine, caprine and equine animals, provided that those operators:

(a) only move consignments of those germinal products to another confined establishment;

(b) ensure that the donor animals:

(i) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for bovine, porcine, ovine, caprine or equine animals;

(ii) come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(iii) have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(iv) have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no symptoms suggesting the presence of any of the category D diseases referred to in point (ii) or of the emerging diseases or clinical signs of such diseases, on the day of collection of the semen, oocytes or embryos;

(v) as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State;

(vi) are identified in accordance with requirements laid down in Regulation (EU) 2019/2035;

– for bovine animals in Article 38;

– for porcine animals in Article 52(1) or 54(2);

– for ovine and caprine animals in Article 45(2) or (4), or Article 46(1), (2) or (3);

– for equine animals in Article 58(1) or 59(1) or 62(1);

(c) ensure that the germinal products have been marked in accordance with the requirements provided for in Article 10;

(d) ensure that the germinal products are transported in accordance with Articles 28 and 29.

Section 2
Animal health requirements for donor animals from which germinal products were collected, and isolation and quarantine requirements for those animals

Sub-Section I
General animal health requirements for donor bovine, porcine, ovine, caprine and equine animals

Article 15
Responsibilities of operators for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected

Operators shall only move to another Member State consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals which comply with the following requirements:

(a) the germinal products were collected from animals which did not show symptoms or clinical signs of transmissible animal diseases on the day of collection;

(b) the movement was authorised respectively by the centre or team veterinarian.

Article 16
Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected

Centre veterinarians, as regards donor animals of semen, or team veterinarians, as regards donor animals of oocytes and embryos, shall ensure that the donor bovine, porcine, ovine, caprine and equine animals comply with the following requirements:

(a) they were born and have remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;

(b) they come from establishments in a Member State or zone thereof, or from establishments under official control by the competent authority in a third country or territory, or a zone thereof, each of which fulfils the animal health requirements laid down in Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058]:

(i) for bovine animals in Article 10(1), Article 11(1), (2) and (3) and Article 12(1), (2) and (3);

(ii) for porcine animals in Article 19(1) and Article 20(1) and (2);

(iii) for ovine and caprine animals in Article 15(1), (2), (3) and (4);

(iv) for equine animals in Article 22(1) and (2);

(c) they have been identified in accordance with requirements laid down in Regulation (EU) 2019/2035:

(i) for bovine animals in Article 38;

(ii) for porcine animals in Article 52(1) or 54(2);

(iii) for ovine and caprine animals in Article 45(2) or (4), or Article 46(1), (2) or (3);

(iv) for equine animals in Article 58(1) or 59(1) or 62(1);

(d) for a period of at least 30 days prior to the date of the first collection of the germinal products and during the collection period:

(i) they have been kept in establishments which are not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine or equine animals of a category A disease or of an emerging disease relevant for those animals;

(ii) they have been kept in establishments where no category D diseases relevant for those animals have been reported;

(iii) they have not been in contact with animals from establishments situated in a restricted zone referred to in point (i) or from establishments which do not meet the conditions referred to in point (ii);

(iv) they have not been used for natural breeding;

(e) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in point (d)(ii) or of the emerging diseases on the day of collection of the semen, oocytes or embryos;

(f) they comply with the additional animal health requirements set out:

(i) for bovine animals in Article 20, and in Part 1 and Chapters I, II and III of Part 5 of Annex II;

(ii) for porcine animals in Article 21, and in Part 2 and Chapters I and IV of Part 5 of Annex II;

(iii) for ovine and caprine animals in Article 22, and in Part 3 and Chapters I, II and III of Part 5 of Annex II;

(iv) for equine animals in Article 23, and in Part 4 of Annex II.

Article 17

Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected from establishments subject to movement restrictions on animal health grounds

Centre veterinarians, as regards donor animals of semen, or team veterinarians, as regards donor animals of oocytes and embryos, shall ensure that semen, oocytes and embryos, collected at either a semen collection centre or an establishment which is subjected to movement restrictions on animal health grounds concerning the diseases referred to in Article 16(b), 20, 21, 22 or 23, comply with the following requirements:

(a) they must be kept in separate storage;

(b) they must not be moved between Member States until the movement restrictions applied to either the semen collection centre or the establishment where the semen was collected has been removed by the competent authorities; and

(c) the semen, oocytes and embryos stored must have undergone the appropriate official investigations to rule out the presence in the semen, oocytes and embryos of animal pathogens causing the diseases for which the movement restrictions were established.

Article 18

Additional responsibilities of centre veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which semen was collected

Centre veterinarians shall ensure that donor bovine, porcine, ovine, caprine and equine animals comply with the following requirements:

(a) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in Article 16(d)(ii) on the day of their admission to a semen collection centre;

(b) in the case of donor bovine, porcine, ovine and caprine animals, prior to the day of their admission to a semen collection centre, they were kept in a quarantine accommodation which on that day complied with the following conditions:

  (i) none of the category D diseases relevant for the bovine, porcine, ovine or caprine animals has been reported for a period of at least the preceeding 30 days;

  (ii) it was not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine or caprine animals of a category A disease or of an emerging disease relevant for those animals;

(c) they are kept at the semen collection centre which:

  (i) during a period which comprises at least 30 days prior to date of collection and at least 30 days following the date of collection of the semen or, in the case of fresh semen, until the date of dispatch of the consignment of semen, none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported;

  (ii) it is not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine or equine animals of a category A disease or of an emerging disease relevant for those animals.

Article 19

Derogation from the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals moved between semen collection centres

1. By way of derogation from point (b) of Article 18, operators may move donor bovine, porcine, ovine and caprine animals, and donor equine animals subjected to the testing programme for certain diseases as referred to in point 1(b)(i) of Chapter I of Part 4 of Annex II, directly from one semen collection centre to another semen collection centre:

   (a) without quarantine or testing, before and after the movement, as referred to in Annex II for the following animals:

      (i) for bovine animals, in Part 1 and Chapters I, II and III of Part 5 thereof;

      (ii) for porcine animals, in Part 2 and Chapters I and IV of Part 5 thereof;

      (iii) for ovine and caprine animals, in Part 3 and Chapters I, II and III of Part 5 thereof ;

      (iv) for equine animals, in point 1(a) of Chapter I of Part 4 thereof ; and

   (b) provided that the donor animals:

      (i) show no disease symptoms or signs of any of the category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals on the day of that movement;

      (ii) before that movement, they were permanently present since the date of their admission at the semen collection centre and were subjected to the following tests relevant for the bovine, porcine, ovine, caprine or equine animals referred to in paragraph 1(a), with negative results:

         – all compulsory routine tests referred to in Annex II in the period of the preceding 12 months prior to date of that movement; or

         – where the compulsory routine tests have not yet been carried out at the semen collection centre, all tests required before admission to a semen collection centre carried out during the period immediately preceding quarantine and during the quarantine period.

2. Operators shall only move donor animals, as referred to in the introductory phrase of paragraph 1, where the movement is authorised by the competent authority of the semen collection centre of origin and with the prior consent of the centre veterinarian of the semen collection centre of destination.

3. Operators shall ensure that donor animals referred to in the introductory phrase of paragraph 1 do not come into direct or indirect contact with animals of a lower health status during the movement and the means of transport used have been cleansed and disinfected before use.

4. Operators of semen collection centres of destination shall subject donor animals referred to in the introductory phrase of paragraph 1 to all compulsory routine tests referred to in paragraph 1(a) not later than 12 months following the date the last compulsory routine tests were carried out on those animals.

Sub-Section II
Additional animal health requirements for certain species of ungulates

Article 20
Additional animal health requirements for donor bovine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor bovine animals comply with the following requirements:

   (a) they came from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, that was free from the following diseases and have never been kept previously in any establishment of a lower health status:

      (i) infection with *Mycobacterium tuberculosis complex* (*M. bovis, M. caprae* and *M. tuberculosis*);

      (ii) infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*;

      (iii) enzootic bovine leukosis;

      (iv) infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;

   (b) they fulfil the additional animal health requirements laid down in Part 1 and Chapters I, II and III of Part 5 of Annex II.

2. By way of derogation from paragraph 1(a)(iii), the centre veterinarian may accept that a donor animal of semen came from an establishment which was not free from enzootic bovine leukosis provided that the animal either:

   (a) is less than 2 years of age and has been produced by a dam which was subjected, with negative results, to a serological test for enzootic bovine leukosis after removal of that animal from its dam; or

   (b) has reached the age of 2 years and was subjected, with negative results, to a serological test for enzootic bovine leukosis.

3. By way of derogation from paragraph 1(a)(iii), the team veterinarian may accept a donor animal of oocytes and embryos that was less than 2 years of age which came from an establishment which was not free from enzootic bovine leukosis provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.

4. By way of derogation from paragraph 1(a)(iv),

   (a) the centre veterinarian, as regards donor animals of semen, may accept a donor animal which came from an establishment which was not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis provided that the animal has undergone the test required in accordance with point 1(b)(iv) of Chapter I of Part 1 of Annex II, or

   (b) the team veterinarian, as regards donor animals of oocytes and embryos, may accept a donor animal which came from an establishment which was not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis provided that the official veterinarian responsible for the establishment of

origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during a period of at least the preceding 12 months.

Article 21

Additional animal health requirements for donor porcine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor porcine animals comply with the following requirements:

   (a) they came from an establishment, in the case of donor animals of semen prior their admission to a quarantine accommodation, where no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus had been detected during a period of at least the preceding 12 months;

   (b) they fulfil additional animal health requirements laid down in Part 2 and Chapters I and IV of Part 5 of Annex II.

2. The centre veterinarian shall ensure that donor porcine animals of semen comply with the following requirements:

   (a) prior to their admission to a quarantine accommodation, they came from an establishment which was free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* in accordance with the requirements laid down in Chapter IV of Part 5 of Annex II;

   (b) they were kept at the quarantine accommodation which on the day of admission was free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* for the period of at least the preceding 3 months;

   (c) they are kept in a semen collection centre where no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus has been reported for a period comprising at least 30 days prior to the date of admission and at least 30 days immediately prior to the date of collection;

   (d) they have not been vaccinated against infection with porcine reproductive and respiratory syndrome virus and were kept, since birth or for a period comprising at least 3 months prior to the date of entry into the quarantine accommodation, in an establishment where no animals have been vaccinated against infection with porcine reproductive and respiratory syndrome virus and no infection with porcine reproductive and respiratory syndrome virus was detected during that period.

Article 22

Additional animal health requirements for donor ovine and caprine animals from which semen, oocytes and embryos were collected

The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor ovine and caprine animals comply with the following requirements:

(a) they did not come from an establishment, nor have been in contact with animals from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, which has been the subject to movement restrictions as

regards infection with *Brucella abortus, Brucella melitensis* and *Brucella suis.* The movement restrictions concerning the establishment are lifted after the period comprising of at least 42 days from the date of slaughter or killing and the disposal of the last animal infected or susceptible to that disease;

(b) they came from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, which was free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* and have never been kept previously in any establishment of a lower health status;

(c) they fulfil additional animal health requirements laid down in Part 3 and Chapters I, II and III of Part 5 of Annex II.

Article 23

Additional animal health requirements for donor equine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian shall ensure that equine animals admitted to a semen collection centre and the team veterinarian shall ensure that equine animals used for the collection of oocytes and embryos or the production of embryos comply with the following requirements prior to the collection of the germinal products:

(a) they come from an establishment:

(i) where surra (*Trypanosoma evansi*) has not been reported during the period of the preceding 30 days, or where surra (*Trypanosoma evansi*) has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:

– the infected animals have been removed from the establishment; and

– the remaining animals in the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058], with negative results carried out on samples taken at least 6 months after the last infected animal has been removed from the establishment;

(ii) where dourine has not been reported during the period of the preceding 6 months, or where dourine has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:

– the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated; and

– the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in the first indent kept apart from female equine animals, have been subjected to a test for dourine with one of the diagnostic methods provided for in Part 8 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058], with negative results, carried out on samples taken at least 6 months after the measures described in the first indent have been completed;

(iii) where equine infectious anaemia has not been reported during the period of the preceding 90 days, or where equine infectious anaemia has been reported during the period of the preceding 12 months and following the last outbreak the affected establishment remained under movement restrictions until:

– the infected animals have been killed and destroyed or slaughtered; and

– the remaining equine animals in the establishment have been subjected to a test for equine infectious anaemia with one of the diagnostic methods provided for in Part 9 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058], with negative results, carried out on samples taken on two occasions at least 3 months apart after the measures described in the first indent have been completed and the establishment was cleaned and disinfected;

(b) in the case of semen donors, they were kept for a period of 30 days prior to the date of semen collection in establishments where no equine animal has shown any clinical sign of infection with equine arteritis virus or of contagious equine metritis during that period;

(c) they fulfil the additional animal health requirements laid down in Part 4 of Annex II.

2. By way of derogation from paragraph 1(a), the movement restrictions referred to in paragraph 1(a)(i) to (iii) must remain in place for a period of at least 30 days, beginning on the day on which all the animals on the establishment of species listed for the respective disease referred to in paragraph 1(a)(i) to (iii) were either killed and destroyed or slaughtered, where allowed in accordance with paragraph 1(b), and the establishment was cleaned and disinfected.

Section 3

Laboratory and other tests to be carried out on kept donor animals of the bovine, porcine, ovine, caprine and equine species and germinal products thereof

Article 24

Laboratory and other tests to be carried out on donor bovine, porcine, ovine, caprine and equine animals and germinal products thereof

Operators shall ensure that:

(a) donor animals whose germinal products are to be moved to other Member States have undergone the following tests:

(i) for bovine animals, in Part 1 and as applicable in Chapters I, II and III of Part 5 of Annex II;

(ii) for porcine animals, in Part 2 and as applicable Chapters I and IV of Part 5 of Annex II;

(iii) for ovine and caprine animals, in Part 3 and as applicable in Chapters I, II and III of Part 5 of Annex II;

(iv) for equine animals, in Part 4 of Annex II;

(b) all the tests referred to in point (a) are carried out in official laboratories.

Article 25

Authorisation for laboratory tests to be carried out on donor animals of the bovine, porcine, ovine and caprine species in quarantine accommodation

1. The competent authority may authorise the following tests referred to in Annex II to be carried out on samples taken in the quarantine accommodation:

   (a) for bovine animals, the tests referred to in point 1(b) of Chapter I of Part 1 thereof;

   (b) for porcine animals, the tests referred to in point 1(b) of Chapter I of Part 2 thereof;

   (c) for ovine and caprine animals, the tests referred to in point 1(c) of Chapter I of Part 3 thereof.

2. Where the competent authority has granted the authorisations referred to in paragraph 1, the following conditions shall be met:

   (a) the period of quarantine in the quarantine accommodation must not commence before the date of sampling for the purpose of testing referred to in paragraph 1(a), (b) and (c);

   (b) where results of any of the tests referred to in paragraph 1 are positive, the animal concerned must be immediately removed from the quarantine accommodation;

   (c) in the case of quarantine of a group of animals, if any of the animals prove positive for a test referred to in paragraph 1, the quarantine in the quarantine accommodation must not commence for the remaining animals until the animal which proved positive has been removed from the quarantine accommodation.

Section 4

Animal health requirements for the collection, production, processing, storage and other procedures of germinal products of bovine, porcine, ovine, caprine and equine animals

Article 26

Obligations on operators as regards the animal health requirements for the collection, production, processing and storage of germinal products of bovine, porcine, ovine, caprine and equine animals

Operators shall ensure that consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals are only moved to other Member States if those consignments fulfil the animal health requirements for the collection, production, processing and storage of germinal products set out in Annex III.

Section 5
Animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals

Article 27

Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals

1. Where germinal products of bovine, porcine, ovine, caprine and equine animals are moved to another Member State or to a germinal product processing establishment or a germinal product storage centre within the same Member State, the centre veterinarian or the team veterinarian shall ensure that:

   (a) the transport containers are sealed and numbered prior to their dispatch from the approved germinal product establishment;

   (b) the mark on the straws or other packages, applied in accordance with Article 10, corresponds with the number provided either in the animal health certificate or in the self-declaration document and on the container in which they are transported.

2. The seal referred to in paragraph 1(a) applied under the responsibility of the centre veterinarian or the team veterinarian may be replaced by the official veterinarian.

Article 28

Responsibilities of operators for compliance with the animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals

1. Operators shall only move semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals to other Member States subject to compliance with the following conditions:

   (a) only one type of germinal product of one species has been placed in the transport container;

   (b) the transport container, referred to in point (a):

      (i) has been cleaned and either disinfected or sterilised before use, or is a new single-use container;

      (ii) has been filled in with the cryogenic agent which has not been previously used for other products.

2. By way of derogation from paragraph 1, operators may place in one transport container semen, oocytes and embryos of the same species provided that:

   (a) straws or other packages in which germinal products are placed are securely and hermetically sealed;

   (b) the germinal products of different types are separated from each other by physical compartments or by being placed in secondary protective bags.

3. By way of derogation from paragraphs 1 and 2, operators may place in one transport container semen, oocytes and embryos of ovine and caprine animals.

Article 29
Additional responsibilities on operators for the transport of semen of bovine, porcine, ovine and caprine animals

Where operators move to another Member State consignments of semen of bovine, porcine, ovine or caprine animals which has been collected from more than one donor animal and placed in a single straw or another package, the operators shall:

(a) ensure that the semen is collected and dispatched from a single semen collection centre or, in the case of the derogations provided for in Articles 13 and 14, a single establishment where it was collected;

(b) have procedures in place as regards the processing of that semen in order to ensure its traceability in accordance with Articles 10 and 19.

CHAPTER 2
Animal health certification, self-declaration and movement notification for germinal products of bovine, porcine, ovine, caprine and equine animals

Article 30
Rules on animal health certification

1. Before issuing an animal health certificate for movements between Member States of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals, the official veterinarian shall carry out:

   (a) a visual examination of the transport container in order to verify if the requirements referred to in Article 28 have been fulfiled and to check:

      (i) the seal and number applied by the centre or team veterinarian on the transport container as referred to in Article 27(1)(a); or

      (ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;

   (b) a documentary check of the data submitted by the centre or team veterinarian to ensure that:

      (i) the information to be certified is supported by the records kept in accordance with Article 8;

      (ii) the mark on the straws or other packages, applied in accordance with Article 10, corresponds with the number provided in the animal health certificate and on the container in which they are transported;

      (iii) the requirements referred to in Chapter 1 of Part III have been fullfiled.

2. The official veterinarian shall carry out the checks and examinations as provided for in paragraph 1 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.

3. The animal health certificate shall be valid for a period of 10 days from the date of issuing.

Article 31

Information to be contained in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine moved between Member States

The animal health certificates for movements between Member States of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals, shall contain at least the information set out in point 1 of Annex IV.

Article 32

Requirements concerning the self-declaration document for movements to and from germinal product processing establishments of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals

1. Where an operator of an approved germinal product establishment of bovine, porcine, ovine, caprine and equine animals arranges for germinal products to be processed by a germinal product processing establishment, that operator shall ensure that a self-declaration document accompanies the consignment of the germinal products during the transport to and from that germinal product processing establishment.

2. An operator of an approved germinal product establishment shall ensure that the self-declaration document referred to in paragraph 1 includes at least the following information:

   (a) the name and address of the approved germinal product establishment of the collection or production of the germinal products;

   (b) the name and address of the germinal product processing establishment to which the germinal products are moved for processing;

   (c) the dates of movement of the consignment of the germinal products to and from a germinal product processing establishment;

   (d) the type and the quantity of the germinal products;

   (e) the marking of the germinal products, as required by Article 10.

Article 33

Requirement for advance notification by operators of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States

Where consignments of germinal products of bovine, porcine, ovine, caprine and equine animals are moved to another Member State, operators of approved germinal product establishments, establishments where ovine and caprine animals are kept as referred to in Article 13 or confined establishments as referred to in Article 14 shall notify the competent authority in their Member State of origin in advance of the intended movement of those consignments of germinal products.

Article 34

Information necessary to notify movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States

Operators notifying the competent authority in their Member State of origin in accordance with Article 33, shall provide that competent authority with the information concerning each consignment of germinal products to be moved to another Member State provided for in:

(a) points 1(a) to (f) of Annex IV, where the germinal products are accompanied by an animal health certificate; or

(b) Article 32(2), where the germinal products are accompanied by a self-declaration document.

Article 35

Emergency procedures for the notification of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of IMSOC

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products of bovine, porcine, ovine, caprine and equine animals to be moved to another Member State shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or e-mail.

2. The notification, referred to in paragraph 1, shall be done by the competent authority of the place of origin of the consignment of germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities IMSOC.

CHAPTER 3

Animal health requirements, animal health certification and notification for germinal products of animals other than bovine, porcine, ovine, caprine and equine animals

Article 36

Animal health requirements for movements to other Member States of germinal products of dogs and cats

Operators shall only move to other Member States semen, oocytes and embryos collected from dogs (*Canis lupus familiaris*) and cats (*Felis silvestris catus*) which:

(a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;

(b) come from an establishment where infection with rabies virus has not been confirmed for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(c) showed no disease symptoms on the day of collection of the semen, oocytes or embryos;

(d) are marked by the implantation of a transponder or by a clearly readable tattoo in accordance with Article 17(1) of Regulation (EU) No 576/2013 of the European Parliament and of the Council[23] or identified in accordance with Article 70 of Regulation (EU) 2019/2035;

[23] Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

(e) have received an anti-rabies vaccination that complies with the validity requirements set out in Part 1 of Annex VII to Regulation (EU) 2019/…[document SANTE/7072/2018, C(2019)4058];

(f) comply with any preventive health measure for diseases or infections other than rabies set out in Part 2 of Annex VII to Regulation (EU) 2019/…[document SANTE/7072/2018, C(2019)4058];

(g) were not used for natural breeding during a period of at least 30 days prior to the date of collection of semen, oocytes or embryos and during the collection period.

Article 37

Animal health requirements for movements to other Member States between confined establishments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals

Operators of confined establishments shall only move germinal products of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at those establishments to confined establishments in other Member States when the donor animals:

(a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;

(b) have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(c) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species in those kept terrestrial animals;

(d) come from an establishment where no category D disease relevant for that species has been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(e) are identified and registered in accordance with the rules of that confined establishment;

(f) as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State;

(g) have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and show no disease symptoms on the day the semen, oocytes or embryos are collected.

Article 38

Animal health requirements for movements to other Member States of germinal products of animals of the families Camelidae *and* Cervidae

Operators shall only move to another Member State germinal products collected from animals of the family *Camelidae* or *Cervidae* which:

(a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;

(b) have remained in a single establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;

(c) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species in those kept terrestrial animals;

(d) come from an establishment where during a period of at least the preceding 12 months prior to the date of collection of the semen, oocytes or embryos:

(i) a surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) has been carried out in accordance with Part 2 or 3 of Annex II to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(ii) no animals of the family *Camelidae* or *Cervidae* which do not fulfil the requirements referred to in point (i) has been introduced;

(iii) in case of suspicion of infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), investigations were carried out and the disease was ruled out;

(e) come from an establishment:

(i) where infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* has not been reported during the period of at least the preceding 42 days prior to the date of collection of the semen, oocytes or embryos;

(ii) in case of animals of the family *Camelidae,* where all animals present have been subjected to a test for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* as referred to in Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058] with negative results carried out on samples taken during the period of the preceding 30 days prior to the date of collection of the semen, oocytes or embryos;

(f) come from an establishment where infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis has not been reported during the period of at least the preceding 30 days prior to the date of collection of the semen, oocytes or embryos;

(g) come from an establishment where infection with epizootic haemorrhagic disease virus has not been reported during a period of at least the preceding 2 years prior to the date of collection of the semen, oocytes or embryos within a radius of 150 km around the establishment;

(h) come from an establishment where infection with rabies virus has not been confirmed during the period of at least the preceding 30 days prior to the date of collection of the germinal products;

(i) come from an establishment where anthrax has not been reported during the period of at least the preceding 15 days prior to the date of collection of the semen, oocytes or embryos collection;

(j) come from an establishment where surra (*Trypanosoma evansi*)

(i) has not been reported during a period of at least the preceding 30 days prior to the date of collection of the semen, oocytes or embryos; or

(ii) has been confirmed during the preceeding 2 years, but following the last outbreak of that disease the establishment has remained under movement restrictions until:

– the infected animals were removed from the establishment; and

– the remaining animals on the establishment were subjected to a test for surra (*Trypanosoma evansi*) referred to in Part 3 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058], with negative result, carried out on samples taken at least 6 months after the infected animals were removed from the establishment;

(k) fulfil animal health requirements as regards infection with bluetongue virus (serotypes 1-24) laid down in Chapter II of Part 5 of Annex II;

(l) have not been in contact with animals which did not comply with the requirements set out in point (a) and in points (c) to (k) during the residency period of at least 30 days set out in point (b);

(m) have been clinically examined by a veterinarian and showed no disease symptoms on the day of collection of the semen, oocytes or embryos;

(n) are identified in accordance with Article 73(1) or (2) or Article 74 of Regulation (EU) 2019/2035;

(o) were not used for natural breeding during a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos and during the collection period.

Article 39
Rules concerning animal health certification

1. Before signing an animal health certificate for movements between Member States of consignments of germinal products of dogs or cats, the official veterinarian shall carry out:

(a) a visual examination of the transport container in order to check:

(i) the seal and number applied by the operator on the transport container; or

(ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;

(b) a documentary check of the data submitted by the operator to ensure that:

(i) the information to be certified is supported by the records kept at the establishment;

(ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;

(iii) the requirements referred to in Article 36 have been fullfiled.

2. Before signing an animal health certificate for movements between Member States of consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments, the official veterinarian shall carry out:

(a) a visual examination of the transport container in order to check:

(i) the seal and number applied by the establishment veterinarian responsible for the activities carried out at confined establishment on the transport container; or

(ii) if necessary, germinal products placed in the transport container and to seal and number the transport container after that check;

(b) a documentary check of the data submitted by the establishment veterinarian responsible for the activities carried out at confined establishment to ensure that:

(i) the information to be certified is supported by the records kept at the confined establishment;

(ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;

(iii) the requirements referred to in Article 37 have been fullfiled.

3. Before signing an animal health certificate for movements between Member States of consignments of germinal products of animals of the family *Camelidae* or *Cervidae*, the official veterinarian shall carry out:

(a) a visual examination of the transport container in order to check:

(i) the seal and number applied by the operator on the transport container; or

(ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;

(b) a documentary check of the data submitted by the operator to ensure that:

(i) the information to be certified is supported by the records kept at the establishment ;

(ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;

(iii) the requirements referred to in Article 38 have been fullfiled.

4. The official veterinarian shall carry out the checks and examinations as provided for in paragraphs 1, 2 and 3 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.

5. The animal health certificate provided for in paragraphs 1, 2 and 3 shall be valid for 10 days from the date of issuing.

Article 40

Animal health certification requirements for movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

The animal health certificates for movements between Member States of consignments of germinal products of dogs and cats, and of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae*, shall contain at least the information set out in point 2 of Annex IV.

Article 41

Requirement for advance notification by operators of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

Where consignments of germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* are moved to another Member State, the operator shall notify the competent authority in the Member State of origin of the consignments in advance of the intended movement of those consignments of germinal products.

Article 42

Information necessary to notify movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

Operators required to notify the competent authority in the Member State of origin of the consignments in accordance with Article 41, shall provide that competent authority with the information concerning each consignment of germinal products to be moved to another Member State provided for in point 2(a) to (f) of Annex IV.

Article 43

Emergency procedures for the notification of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of IMSOC

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae*, to be moved to another Member State, shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or e-mail.

2. The notification, referred to in paragraph 1, shall be carried out by the competent authority of the place of origin of the consignment of the germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities of IMSOC.

CHAPTER 4
Additional rules for the granting of derogations by competent authorities for germinal products

Article 44
Additional rules for the granting of derogations by competent authorities for germinal products intended for scientific purposes

1. The competent authorities of the Member States of origin may grant derogation for the movement to another Member State of germinal products intended for scientific purposes which do not fulfil the animal health requirements provided for in Chapter 1 or 3, provided the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products.

2. The competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, where the operator of the establishment of destination intended to receive those germinal products ensures that the germinal products are only used for scientific purposes under conditions that prevent the spread of category D diseases.

Article 45
Additional rules for the granting of derogations by competent authorities for germinal products moved to gene banks in another Member State

1. The competent authorities of the Member States of origin may grant derogations for movements to gene banks in another Member State of germinal products, provided that the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products, of:

   (a) endangered breeds which do not fulfil the animal health requirements provided for in Chapter 1; or

   (b) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments which do not fulfil the animal health requirements provided for in Article 37.

2. The competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, provided that:

   (a) the operator of the gene bank intended to receive those germinal products ensures that the germinal products are only used for the *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals for which the receiving gene bank was established;

   (b) it has sufficient information, including information provided by the competent authority of the Member State of origin or results of testing, or carries out treatment of the germinal products enabling it to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.

Article 46

Rules on and information to be contained in the self-declaration document for germinal products intended for scientific purposes or to be moved to gene banks in another Member State

1. Where germinal products intended for scientific purposes or for storage at gene banks are to be moved to another Member State, the operator of the establishment of dispatch shall ensure that a self-declaration document accompanies the germinal products during the transport to the place of destination.

2. The operator of the establishment of dispatch shall ensure that the self-declaration document provided for in paragraph 1 includes at least the following information:

   (a) the name and address of the consignor and the consignee;

   (b) the name and address of the place of dispatch and the place of destination;

   (c) where the germinal products were moved to and from a germinal product processing establishment, the dates of those movements;

   (d) the type of the germinal products and the species of donor animals;

   (e) the number of straws or other packages in the consignment to be dispatched;

   (f) the following information allowing the identification of germinal products:

      (i) the marking applied on the straws or other packages;

      (ii) the place and date of their collection or production;

   (g) available results of the tests referred to in Article 45(2)(b).

Article 47

Advance notification by operators of movements of germinal products intended for scientific purposes or to gene banks between Member States

Where germinal products intended for scientific purposes or for storage at gene banks are moved to another Member State, the operator of the establishment of dispatch shall notify the competent authority in the Member State of origin of the consignment in advance of the intended movement of those germinal products and provide the information listed in Article 46(2)(a) to (g).

Article 48

Emergency procedures for the notification of movements between Member States of germinal products intended for scientific purposes or to gene banks in the event of power cuts and other disturbances of IMSOC

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products intended for scientific purposes or for storage at gene banks, to be moved to another Member State, shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or e-mail.

2. The notification, referred to in paragraph 1, shall be done by the competent authority of the place of origin of the consignment of the germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities of IMSOC.

PART IV
FINAL PROVISIONS

Article 49
Transitional measures

1. Semen collection centres, semen storage centres, embryo collection teams and embryo production teams which have been approved before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC referred to in the 6th, 7th, 8th and 12th indents of Article 270(2) of Regulation (EU) 2016/429 shall be considered to have been approved in accordance with this Regulation.

   In all other respects, they shall be subject to the rules provided for in this Regulation, and in Regulation (EU) 2016/429.

2. Straws and other packages in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, marked before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been marked in accordance with this Regulation.

3. Animal health certificates issued before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been issued in accordance with this Regulation.

Article 50
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, 17.12.2019

For the Commission
The President
Ursula von der LEYEN