

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') (Text with EEA relevance)

CHAPTER I

General Provisions

Article 1

Subject matter and scope

- 1 This Regulation lays down:
 - a zootechnical and genealogical rules for trade in breeding animals and their germinal products, and for their entry into the Union;
 - b rules for the recognition of breed societies and breeding operations and for the approval of their breeding programmes;
 - c the rights and obligations of breeders, breed societies and breeding operations;
 - d rules for the entry of breeding animals in breeding books and breeding registers and for the acceptance for breeding of breeding animals and their germinal products;
 - e rules for the performance testing and genetic evaluation of breeding animals;
 - f rules for the issuing of zootechnical certificates for breeding animals and their germinal products;
 - g rules for the performance of official controls, and in particular those on breed societies and breeding operations, and rules for the performance of other official activities;
 - h rules for administrative assistance and cooperation and rules for enforcement by Member States;
 - i rules for the performance of controls by the Commission in Member States and third countries.
- 2 This Regulation applies to breeding animals and their germinal products where those animals or the offspring resulting from those germinal products are intended to be entered as purebred breeding animals in a breeding book or registered as hybrid breeding pigs in a breeding register.
- 3 This Regulation does not apply to breeding animals and their germinal products where those animals and germinal products are intended for technical or scientific experiments carried out under the supervision of the competent authorities.
- 4 Article 9(4), Article 13, Article 14(3) and (4), Articles 23 and 24, Article 28(2) and Article 36(1) do not apply to private undertakings, recognised as breeding operations, which operate in closed production systems.
- 5 This Regulation is without prejudice to Member States' rights to take national measures to regulate the carrying out of breeding programmes that have not been approved in accordance with Article 8(3), and, where applicable, Article 12.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) ‘animal’ means a domestic animal of:
 - (a) the bovine species (*Bos taurus*, *Bos indicus* and *Bubalus bubalis*);
 - (b) the porcine species (*Sus scrofa*);
 - (c) the ovine species (*Ovis aries*);
 - (d) the caprine species (*Capra hircus*); or
 - (e) the equine species (*Equus caballus* and *Equus asinus*);
- (2) ‘breed’ means a population of animals sufficiently uniform to be considered to be distinct from other animals of the same species by one or more groups of breeders which have agreed to enter those animals in breeding books with details of their known ascendants for the purpose of reproducing their inherited characteristics by way of reproduction, exchange and selection within the framework of a breeding programme;
- (3) ‘breeding animal’ means a purebred breeding animal or a hybrid breeding pig;
- (4) ‘germinal products’ means semen, oocytes and embryos collected or produced from breeding animals for the purpose of assisted reproduction;
- (5) ‘breed society’ means any breeders' association, breeding organisation or public body, other than competent authorities, which is recognised by the competent authority of a Member State in accordance with Article 4(3) for the purpose of carrying out a breeding programme on purebred breeding animals entered in the breeding book(s) it maintains or establishes;
- (6) ‘breeding operation’ means any breeders' association, breeding organisation, private undertaking operating in a closed production system or public body, other than competent authorities, which is recognised by the competent authority of a Member State in accordance with Article 4(3) for the purpose of carrying out a breeding programme on hybrid breeding pigs registered in the breeding register(s) it maintains or establishes;
- (7) ‘breeding body’ means any breeders' association, breeding organisation, private undertaking, stock-rearing organisation or official service in a third country which, in respect of purebred breeding animals of the bovine, porcine, ovine, caprine or equine species or of hybrid breeding pigs, has been accepted by that third country in connection with the entry into the Union of breeding animals for breeding;
- (8) ‘competent authorities’ means the authorities of a Member State which are responsible, pursuant to this Regulation, for:
 - (a) the recognition of breed societies and breeding operations and the approval of the breeding programmes they carry out on breeding animals;
 - (b) official controls on operators;

- (c) the provision of assistance to other Member States and third countries in case of detected non-compliances;
 - (d) official activities other than those referred to in points (a) and (c);
- (9) ‘purebred breeding animal’ means an animal which is entered or registered and eligible for entry in the main section of a breeding book;
- (10) ‘hybrid breeding pig’ means an animal of the porcine species registered in a breeding register, which is produced by deliberate cross-breeding or used for deliberate cross-breeding between:
 - (a) purebred breeding pigs of different breeds or lines;
 - (b) breeding pigs which are themselves the outcome of a cross (hybrid) between different breeds or lines;
 - (c) breeding pigs belonging to one or the other of the categories referred to in (a) or (b);
- (11) ‘line’ means a genetically stable and uniform subpopulation of purebred breeding animals of a particular breed;
- (12) ‘breeding book’ means:
 - (a) any herd-book, flock-book, stud-book, file or data medium which is maintained by a breed society consisting of a main section and, where the breed society so decides, of one or more supplementary sections for animals of the same species that are not eligible for entry in the main section;
 - (b) where appropriate, any corresponding book maintained by a breeding body;
- (13) ‘main section’ means the section of a breeding book in which purebred breeding animals are entered or registered and eligible for entry with details of their ascendants and, where applicable, their merits;
- (14) ‘class’ means a horizontal division of the main section in which purebred breeding animals are entered according to their merits;
- (15) ‘merit’ means a quantifiable heritable characteristic or a genetic peculiarity of a breeding animal;
- (16) ‘breeding value’ means an estimate of the expected effect of the genotype of a breeding animal on a given characteristic in its progeny;
- (17) ‘breeding register’ means:
 - (a) any file or data medium which is maintained by a breeding operation in which hybrid breeding pigs are registered with details of their ascendants;
 - (b) where appropriate, any corresponding register maintained by a breeding body;
- (18) ‘official control’ means any type of control that the competent authorities perform in order to verify compliance with the rules laid down in this Regulation;

- (19) ‘other official activities’ means any activity other than an official control which is performed by competent authorities in accordance with this Regulation in order to ensure the application of the rules laid down in this Regulation;
- (20) ‘zootechnical certificate’ means breeding certificates, attestations or commercial documentation which are issued on paper or in electronic form for breeding animals and their germinal products and which provide information on pedigree, identification and, where available, results of performance testing or genetic evaluation;
- (21) ‘entering the Union’ or ‘entry into the Union’ means the action of bringing breeding animals and their germinal products into one of the territories listed in Annex VI from outside those territories excluding transit;
- (22) ‘trade’ means the action of buying, selling, exchanging or otherwise acquiring or releasing animals or their germinal products within the Union, including within a Member State;
- (23) ‘operator’ means any natural or legal person subject to the rules provided for in this Regulation, such as breed societies, breeding operations, third parties that have been designated by breed societies or breeding operations in accordance with Article 27(1) (b), semen collection and storage centres, embryo storage centres, embryo collection or production teams, and breeders;
- (24) ‘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;
- (25) ‘private undertaking operating in a closed production system’ means a private undertaking with a breeding programme in which participate either no breeders or a restricted number of breeders who are bound to that private undertaking to accept from it the supply of hybrid breeding pigs or to supply hybrid breeding pigs to it;
- (26) ‘breeding programme’ means a set of systematic actions, including recording, selection, breeding and exchange of breeding animals and their germinal products, designed and implemented to preserve or enhance desired phenotypic and/or genotypic characteristics in the target breeding population.

Article 3

General zootechnical and genealogical rules for trade in breeding animals and their germinal products, and for their entry into the Union

1 Trade in breeding animals and their germinal products and the entry into the Union of breeding animals and their germinal products shall not be prohibited, restricted or impeded on zootechnical or genealogical grounds other than those grounds resulting from the rules provided for in this Regulation.

2 Breeders of breeding animals, breed societies, breeding operations or breeding bodies shall not be discriminated against on the basis of their country of origin or of the country of origin of their breeding animals or the germinal products thereof.

CHAPTER II

Recognition of breed societies and breeding operations in Member States and approval of breeding programmes

Section 1

Recognition of breed societies and breeding operations

Article 4

Recognition of breed societies and breeding operations

1 In respect of purebred breeding animals, breeders' associations, breeding organisations or public bodies may apply to the competent authorities for recognition as a breed society.

In respect of hybrid breeding pigs, breeders' associations, breeding organisations, private undertakings operating in a closed production system or public bodies may apply to the competent authorities for recognition as a breeding operation.

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

3 The competent authorities shall evaluate the applications referred to in paragraph 1. They shall recognise as a breed society any applicant referred to in the first subparagraph of paragraph 1, and as a breeding operation any applicant referred to in the second subparagraph of paragraph 1 that complies with the following requirements:

- a it has its head office on the territory of the Member State where the competent authority is located;
- b it demonstrates in its application that it complies with the requirements set out in Part 1 of Annex I for its breeding programmes in respect of which it intends to apply for approval in accordance with Article 8(3), and, where applicable, Article 12;
- c its application contains, in respect of each of those intended breeding programmes, a draft version of the breeding programme which is to include the information set out in Part 2 of Annex I, and, additionally in the case of purebred breeding animals of the equine species, in Part 3 of Annex I;
- d when submitting its application referred to in paragraph 1 of this Article, it submits an application for approval of at least one of those intended breeding programmes, in accordance with Article 8(2).

Article 5

Refusal of recognition of breed societies and breeding operations

1 For the purposes of Article 4(1), where the competent authority intends to refuse to recognise an applicant as a breed society or breeding operation, it shall provide that applicant with a reasoned explanation for doing so. That applicant shall have the right to request that the competent authority reconsider that intended refusal within 60 days from the date of receipt of the reasoned explanation, or earlier where national rules provide for shorter time-limits.

2 Where, in the light of the reconsideration referred to in paragraph 1 the competent authority decides to confirm its refusal, it shall provide the applicant with a reasoned explanation of its decision to refuse recognition within 90 days from its receipt of the applicant's request for reconsideration, or earlier where national rules provide for shorter time-limits. At the same time, the competent authority shall inform the Commission of its decision to refuse recognition and of its reasons for doing so.

Article 6

Submission of modified breeding programmes in cases of refusal and withdrawal of the recognition of breed societies or breeding operations in the absence of approved breeding programmes

1 Where the competent authority which has recognised a breed society or breeding operation in accordance with Article 4(3) refuses to approve a breeding programme submitted by that breed society or breeding operation in accordance with Article 8, that breed society or breeding operation shall have the possibility of submitting a modified version of that breeding programme within 6 months after that refusal.

2 The competent authority shall withdraw recognition from that breed society or breeding operation if, by the end of the period referred to in paragraph 1 of this Article, no modified version of the breeding programme has been submitted and where that breed society or breeding operation has no other breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

Article 7

Lists of recognised breed societies and breeding operations

1 Member States shall draw up and keep up to date a list of breed societies and breeding operations that their competent authorities have recognised in accordance with Article 4(3) and which have at least one breeding programme that has been approved in accordance with Article 8(3). Member States shall make that list available to the public.

2 The list provided for in paragraph 1 shall include the following information:

- a the name, contact details and, where available, the website of the breed society or breeding operation;
- b for each breed society or breeding operation on that list:
 - (i) in the case of purebred breeding animals, the name of the breed, or, in the case of hybrid breeding pigs, the name of the breed, line or cross, covered by each of its breeding programmes approved in accordance with Article 8(3), and, where the breed society makes use of the derogations referred to in Article 19 or point 2 of Chapter III of Part 1 of Annex II, a reference to those derogations;
 - (ii) the geographical territory where each of its breeding programmes is to be carried out;
 - (iii) in the case of purebred breeding animals of the equine species, where applicable, the name and contact details of the breed society which maintains the breeding book of the origin of the breed;

- (iv) for each of its breeding programmes, where available, a reference to a website where information on those breeding programmes can be accessed.

3 Member States shall also include in the list provided for in paragraph 2 of this Article any competent authority which carries out a breeding programme in accordance with Article 38.

4 Where the recognition of a breed society or a breeding operation is withdrawn in accordance with point (e) of third subparagraph of Article 47(1) or the approval of a breeding programme is suspended or withdrawn in accordance with point (d) of third subparagraph of Article 47(1), Member States shall, without undue delay, indicate that suspension or withdrawal in the list provided for in paragraph 1 of this Article.

Where, for a period of 24 months, that recognition remains withdrawn or that approval remains suspended or withdrawn, Member States shall definitively remove that breed society, breeding operation or breeding programme from the list provided for in paragraph 1.

5 The Commission shall adopt implementing acts, laying down model forms for the presentation of the information to be included in the list of recognised breed societies and breeding operations provided for in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Section 2

Approval of breeding programmes

Article 8

Approval of breeding programmes carried out by breed societies and breeding operations

1 A breed society or a breeding operation shall submit applications for approval of its breeding programmes to the competent authority which has recognised that breed society or breeding operation in accordance with Article 4(3).

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

3 The competent authority referred to in paragraph 1 shall evaluate those breeding programmes and approve them provided that:

- a they have one or more of the following aims:
 - (i) in the case of purebred breeding animals:
 - the improvement of the breed,
 - the preservation of the breed,
 - the creation of a new breed,
 - the reconstruction of a breed;
 - (ii) in the case of hybrid breeding pigs:
 - the improvement of the breed, line or cross,
 - the creation of a new breed, line or cross;
- b they describe in detail the selection and breeding objectives;

- c they comply with the requirements set out in Part 2 of Annex I, and in addition in the case of purebred breeding animals of the equine species, in Part 3 of Annex I.
- 4 Breed societies or breeding operations may outsource to a third party specific technical activities related to the management of their breeding programmes, including performance testing and genetic evaluation, provided that:
- a the breed societies and breeding operations remain responsible to the competent authority for ensuring compliance with the requirements provided for in Parts 2 and 3 of Annex I;
 - b there is no conflict of interests between that third party and the economic activities of breeders who participate in the breeding programme;
 - c that third party fulfils all the necessary requirements to carry out those activities;
 - d those breed societies and breeding operations specify the activities which they intend to outsource and the name and contact details of those third parties in their applications referred to in paragraph 2.
- 5 Where, for at least 24 months, there are no breeders which have their holdings, on which they keep their breeding animals, located on a given part of the geographical territory that are participating in a breeding programme approved in accordance with paragraph 3, the competent authority referred to in paragraph 1 may require the breed society or breeding operation concerned to adjust the geographical territory of its breeding programme so as not to include that given part.

Article 9

Changes to an approved breeding programme

- 1 Prior to the implementation of any significant changes relating to the requirements referred to in Article 8(3) in its breeding programme approved in accordance with that provision, a breed society or breeding operation shall notify those changes to the competent authority which has recognised that breed society or breeding operation in accordance with Article 4(3).
- 2 The notification shall be in writing, either on paper or in electronic form.
- 3 Unless that competent authority indicates otherwise within a period of 90 days from the date of notification, those changes shall be considered to have been approved.
- 4 Breed societies and breeding operations shall inform in a transparent and timely manner the breeders participating in their breeding programmes of the changes in their breeding programme that have been approved in accordance with paragraph 3.

Article 10

Derogations from Article 8(3) concerning the approval of breeding programmes

- 1 By way of derogation from Article 8(3), the competent authority which has recognised a breed society in accordance with Article 4(3) may refuse to approve a breeding programme of that breed society that complies with the requirements set out in Part 2 of Annex I, and additionally in the case of purebred breeding animals of the equine species, in Part 3 of Annex I, on the grounds that that breeding programme would compromise the breeding programme carried out by another breed society for the same breed which has already been approved in that Member State as regards at least one of the following:

- a the essential traits of the breed characteristics or the main objectives of that breeding programme;
- b the preservation of that breed or of the genetic diversity within that breed; or
- c where the aim of that breeding programme is the preservation of that breed, the effective implementation of that breeding programme:
 - (i) in the case of an endangered breed; or
 - (ii) in the case of an autochthonous breed which is not commonly found in one or more of the territories of the Union.

2 For the purpose of paragraph 1, the competent authority shall take due account of the following:

- a the number of breeding programmes already approved for that breed in that Member State;
- b the size of the breeding populations covered by those breeding programmes;
- c the possible genetic input from breeding programmes carried out by other breed societies for the same breed in other Member States or by breeding bodies in third countries.

Article 11

Refusal of the approval of breeding programmes

Where the competent authority which has recognised a breed society or breeding operation in accordance with Article 4(3) refuses to approve a breeding programme submitted by such breed society or breeding operation in accordance with Article 8(1) or refuses to approve changes to a breeding programme notified in accordance with Article 9(1), it shall provide that breed society or breeding operation with a reasoned explanation for its refusal.

Article 12

Notification and approval of breeding programmes carried out in Member States other than the Member State in which the breed society or breeding operation is recognised

1 Where a breed society or a breeding operation intends to carry out a breeding programme approved in accordance with Article 8(3) also on breeding animals kept in a Member State other than the Member State where that breed society or breeding operation is recognised in accordance with Article 4(3) (for the purpose of this Article, 'that other Member State'), that breed society or breeding operation shall notify the intended extension of its geographical territory to the competent authority which has recognised that breed society or breeding operation in accordance with Article 4(3).

2 The competent authority which has recognised that breed society or breeding operation in accordance with Article 4(3) shall:

- a notify the competent authority of that other Member State at least 90 days before the intended commencement date of the breeding programme in that other Member State, and, at the request of the notified authority, provide a translation of that notification in one of the official languages of that other Member State;
- b at the request of the notified authority, provide, at least 60 days before the intended commencement date of the breeding programme in that other Member State, a copy of

the breeding programme as approved in accordance with Article 8(3) accompanied, if requested by that authority, by a translation into one of the official languages of that other Member State which shall be provided by the applying breed society or breeding operation.

3 The competent authority of that other Member State may, within 90 days from the date of receipt of the notification referred to in point (a) of paragraph 2, refuse to approve the carrying out on its territory of the breeding programme, where:

- a an approved breeding programme is already being carried out in that other Member State on purebred breeding animals of the same breed; and
- b the approval of a further breeding programme would compromise the breeding programme carried out by another breed society for the same breed which has already been approved in that other Member State as regards at least one of the following:
 - (i) the essential traits of the breed characteristics or the main objectives of that breeding programme;
 - (ii) the preservation of that breed or of the genetic diversity within that breed;
 - (iii) where the aim of that breeding programme is the preservation of that breed, the effective implementation of that breeding programme:
 - in the case of an endangered breed, or
 - in the case of an autochthonous breed which is not commonly found in one or more of the territories of the Union.

4 The competent authority of that other Member State shall inform the competent authority which has recognised the breed society or breeding operation in accordance with Article 4(3) about the result of the notification provided for in paragraph 1 of this Article and, where it refuses the approval for the carrying out on its territory of the breeding programme, shall provide a reasoned explanation for its refusal.

5 Failure by the competent authority of that other Member State to reply to the notification referred to in point (a) of paragraph 2 within 90 days from the date of receipt of that notification shall constitute approval.

6 The competent authority which has recognised the breed society or breeding operation in accordance with Article 4(3) shall inform the breed society or breeding operation of the result of the notification provided for in point (a) of paragraph 2 of this Article without undue delay and, in the case of refusal, shall provide that breed society or breeding operation with the reasoned explanation for that refusal referred to in paragraph 4 of this Article.

7 Where the competent authority of that other Member State refuses the approval in accordance with paragraph 3, it shall inform the Commission of its refusal together with a statement of reasons for that refusal.

8 Where the competent authority of that other Member State refuses the approval in accordance with paragraph 3 of this Article and the breed society or breeding operation which intends to carry out that breeding programme in that other Member State requests reconsideration of that refusal, the competent authority of that other Member State and the competent authority which has recognised the breed society or breeding operation in accordance with Article 4(3) shall cooperate with each other with regard to that request for reconsideration.

9 The competent authority which has recognised the breed society or breeding operation in accordance with Article 4(3) shall inform the competent authority of that other Member State of the changes in breeding programmes approved in accordance with Article 9(3).

10 At the request of the competent authority of that other Member State, the breed society or breeding operation operating in accordance with this Article on the territory of that other Member State shall provide up-to-date information to that competent authority in particular with regard to the number of breeders and breeding animals on which the breeding programme is carried out on that territory. Any such request shall be made in the same manner as requests to the breed societies or breeding operations recognised in that other Member State.

11 The competent authority of that other Member State may withdraw the approval of the breeding programme provided for in this Article, where, for at least 12 months, no breeder on the territory of that other Member State participates in that breeding programme.

CHAPTER III

Rights and obligations of breeders, breed societies and breeding operations

Article 13

Rights of breeders participating in breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12

1 Breeders shall have the right to participate in a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12 provided that:

- a their breeding animals are kept on holdings located within the geographical territory of that breeding programme;
- b their breeding animals belong, in the case of purebred breeding animals, to the breed, or, in the case of hybrid breeding pigs, to the breed, line or cross, covered by that breeding programme.

2 Breeders participating in a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12 shall have the right:

- a to have their purebred breeding animals entered in the main section of the breeding book established for the breed by the breed society in accordance with Articles 18 and 20;
- b to have their animals recorded in a supplementary section of the breeding book established for the breed by the breed society in accordance with Article 20;
- c to have their hybrid breeding pigs registered in a breeding register established for the breed, line or cross by a breeding operation in accordance with Article 23;
- d to participate in performance testing and genetic evaluation in accordance with Article 25;
- e to be provided with a zootechnical certificate in accordance with Article 30(1) and (4);
- f on request, to be provided, with up-to-date results of the performance testing and genetic evaluation for their breeding animals, where those results are available;
- g to have access to all the other services provided in relation to that breeding programme to the participating breeders by the breed society or breeding operation carrying out that breeding programme.

3 In addition to the rights laid down in paragraphs 1 and 2, where the rules of a breed society or breeding operation provide for membership, the breeders referred to in paragraph 1 shall also have the right:

- a to become a member of that breed society or breeding operation;

- b to participate in the defining and development of the breeding programme in accordance with the rules of procedure referred to in point B(1)(b) of Part 1 of Annex I.

Article 14

Rights and obligations of breed societies and breeding operations

1 As regards their breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12, breed societies and breeding operations shall have the right to define and carry out such breeding programmes autonomously, provided that they comply with this Regulation and any conditions of their approval.

2 Breed societies or breeding operations shall have the right to exclude breeders from participating in a breeding programme where those breeders fail to comply with the rules of that breeding programme or with the obligations set out in the rules of procedure referred to in point B(1)(b) of Part 1 of Annex I.

3 In addition to the right referred to in paragraph 2, breed societies and breeding operations which provide for membership shall have the right to exclude breeders from membership where those breeders fail to comply with their obligations set out in the rules of procedure referred to in point B(1)(b) of Part 1 of Annex I.

4 Breed societies and breeding operations shall, without prejudice to the role of the courts, have a responsibility to settle disputes that may arise between breeders, and between breeders and the breed society or breeding operation, in the process of carrying out breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12, in accordance with the rules of procedure referred to in point B(1)(b) of Part 1 of Annex I.

CHAPTER IV

Entry of breeding animals in breeding books and breeding registers and acceptance for breeding

Section 1

Entry of purebred breeding animals in breeding books and acceptance for breeding

Article 15

Structure of breeding books

Breeding books shall consist of a main section and, where specified in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, one or more supplementary sections.

Article 16

Main section of breeding books

1 Where different criteria or procedures are established by breed societies for entering purebred breeding animals in different classes, those breed societies may divide the main section of breeding books into classes:

- a according to the merits of those animals and subdivide those classes according to their age or gender; or
- b according to the age or gender of those animals, provided that those classes are also subdivided according to their merits.

Those criteria and procedures may require that the purebred breeding animal undergo the performance testing or genetic evaluation provided for in Article 25 or any other assessment described in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12 prior to it being entered in a specific class of the main section.

2 Where the breeding programme establishes conditions for entry in the main section of the breeding book in addition to those set out in Chapter I of Part 1 of Annex II, the breed society carrying out that breeding programme shall establish, in that main section, at least one class for purebred breeding animals that fulfil only the conditions of Chapter I of Part 1 of Annex II and Article 21 to be entered, on application by the breeder.

Article 17

Supplementary sections of breeding books

Breed societies may establish one or more supplementary sections in the breeding book for animals of the same species that are not eligible for entry in the main section, provided that the rules set out in the breeding programme allow the progeny of those animals to be entered in the main section in accordance with the rules set out:

- (a) in the case of female animals of the bovine, porcine, ovine and caprine species, in point 1(a) of Chapter III of Part 1 of Annex II;
- (b) in the case of animals of endangered breeds of the bovine, porcine, ovine and caprine species or of 'hardy' sheep breeds, in point 2 of Chapter III of Part 1 of Annex II; or
- (c) in the case of male and female animals of the equine species, in point 1(b) of Chapter III of Part 1 of Annex II.

Article 18

Entry of purebred breeding animals in the main section of the breeding book

1 Breed societies shall, at the request of breeders, enter or register for entry in the main section of their breeding book any purebred breeding animals of the breed covered by their breeding programme, provided that those animals comply with the requirements set out in Chapter I of Part 1 of Annex II and, where applicable, that those animals are the offspring of breeding animals or result from the germinal products thereof, in accordance with the rules provided for in Article 21.

2 Breed societies shall not refuse the entry in the main section of their breeding books of a purebred breeding animal on the grounds that it has already been entered in the main section of a breeding book of the same breed or, in the case of a cross-breeding programme carried out on purebred breeding animals of the equine species, of a different breed established by another breed society recognised in accordance with Article 4(3) or by a breeding body in a third country included in the list provided for in Article 34.

3 Where the main section of the breeding book is divided into classes, purebred breeding animals meeting the criteria for entry in the main section shall be entered by the breed society in the class that corresponds to the merits of those purebred breeding animals.

Article 19

Derogations from the requirements for the entry of animals in the main section of breeding books in the case of the creation of a new breed or the reconstruction of a breed

1 By way of derogation from Article 18(1), where a breed society carries out a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, for a breed for which no breeding book exists in any Member State or third country included in the list provided for in Article 34, that breed society may enter in the main section of that newly established breeding book, purebred breeding animals or descendants from purebred breeding animals of different breeds or any animal which is judged by the breed society to conform to the characteristics of that new breed and, where applicable, fulfils the minimum performance requirements laid down in the breeding programme.

Breed societies making use of this derogation shall:

- a set in their breeding programme a period for the establishment of the new breeding book that is appropriate for the generation interval of the species or the breed concerned;
- b make reference to any existing breeding book in which the purebred breeding animals or their parents have been entered for the first time after birth, together with the original registration number in that breeding book;
- c in their system for recording pedigrees, identify the animals which are considered by them to be the breed's foundation stock.

2 Where a breed society intends to reconstruct a breed that has disappeared or that is in serious danger of disappearing, a Member State, or, if it so decides, the competent authority, may authorise the breed society to enter, in the main section of the breeding book, descendants of purebred breeding animals of the breed to be reconstructed or purebred breeding animals or descendants from purebred breeding animals of other breeds which enter in the reconstruction of that breed or any animal which is judged by the breed society to conform to the characteristics of the breed to be reconstructed and which, where applicable, fulfil the minimum performance requirements laid down in the breeding programme provided that:

- a a period for the establishment or re-establishment of that breeding book, appropriate for the breed concerned, is set in the breeding programme;
- b where applicable, reference is made to any breeding book in which those purebred breeding animals or ascendants have been entered together with the original registration number in that breeding book;
- c the animals which are considered by that breed society to be the breed's reconstruction stock are identified in the system for recording pedigrees.

3 A breed society seeking to avail itself of the derogation referred to in paragraph 1 of this Article or the derogation referred to in paragraph 2 of this Article shall lay down a detailed

plan for the creation or reconstruction of the breed in its breeding programme referred to in Article 8(1).

4 By the end of the periods referred to in point (a) of paragraph 1 of this Article and point (a) of paragraph 2 of this Article, the competent authority shall carry out an official control as provided for in Article 43.

5 Where a breed is being created or reconstructed in accordance with this Article, Member States shall make that information publicly available by including an indication to that effect in the list provided for in Article 7.

Article 20

Recording of animals in supplementary sections and upgrading of their offspring to the main section

1 Where supplementary sections are established by a breed society in accordance with Article 17, that breed society shall, on application by breeders, record in the appropriate supplementary sections provided for in Article 17 animals of the species covered by its breeding programme that are not eligible for entry in the main section, provided that those animals meet the conditions set out in Chapter II of Part 1 of Annex II.

2 Breed societies shall, on application by breeders, enter the progeny of the animals referred to in paragraph 1 of this Article in the main section provided for in Article 16 and shall regard that progeny as purebred breeding animals, provided that that progeny meets the conditions set out in Chapter III of Part 1 of Annex II.

Article 21

Acceptance of purebred breeding animals and their germinal products for breeding

1 A breed society carrying out a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12 for a breed shall accept:

- a for natural service, any purebred breeding animal of that breed;
- b for artificial insemination, semen collected from purebred breeding animals of the bovine species which have undergone genetic evaluation in accordance with Article 25;
- c for artificial insemination, semen collected from purebred breeding animals of the porcine, ovine or caprine species which have undergone performance testing or genetic evaluation in accordance with Article 25;
- d for artificial insemination, semen collected from purebred breeding animals of the equine species which have undergone, where required by the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, performance testing or genetic evaluation in accordance with Article 25;
- e for embryo transfer, oocytes collected and used for in vitro production of embryos and in vivo derived embryos conceived by use of semen referred to in point (b) or (c) of this paragraph, provided that those oocytes and embryos have been collected from purebred breeding animals of the bovine, porcine, ovine or caprine species which have undergone performance testing or genetic evaluation in accordance with Article 25;
- f for embryo transfer, oocytes collected and used for in vitro production of embryos and in vivo derived embryos conceived by use of semen referred to in point (d) of this paragraph, provided that those oocytes and embryos have been collected from purebred breeding animals of the equine species which have undergone, where required by the

breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, performance testing or genetic evaluation in accordance with Article 25;

- g for testing of male purebred breeding animals of the bovine, porcine, ovine and caprine species, semen collected from purebred breeding animals which have not undergone performance testing or genetic evaluation provided that that semen is solely used for the purpose of testing those male purebred breeding animals within the quantity limits necessary to enable that breed society to carry out such tests in accordance with Article 25.

2 In the case of purebred breeding animals of the equine species, by way of derogation from paragraph 1 of this Article, a breed society may prohibit or limit the use of one or more reproduction techniques referred to in that paragraph or the use of purebred breeding animals for one or more of those reproduction techniques, including the use of their germinal products, provided that that prohibition or limitation is specified in its breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

Any such prohibition or limitation that is specified in the breeding programme of the breed society which has established the breeding book of the origin of the breed in accordance with point 3(a) of Part 3 of Annex I shall be binding for the breeding programmes of the breed societies that establish filial breeding books for the same breed in accordance with point 3(b) of Part 3 of Annex I.

3 In the case of an endangered breed, a breed society may prohibit or restrict the use of a purebred breeding animal of that breed, including the use of its germinal products, where that use would compromise the preservation or the genetic diversity of that breed.

4 Semen referred to in point (g) of paragraph 1 collected from male purebred breeding animals which are entered in the main section of a breeding book established by a breed society carrying out a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, shall be accepted by another breed society carrying out an approved breeding programme on the same breed in the same or another Member State under the same conditions and quantity limits for performance testing and, where applicable, genetic evaluation as those applied to its own male purebred breeding animals.

5 For the purpose of paragraphs 1 and 4, the germinal products of purebred breeding animals referred to in those paragraphs shall be collected, produced, processed and stored at a semen collection or storage centre, or by an embryo collection or production team, approved for intra-Union trade in these commodities in accordance with Union animal health law.

6 By way of derogation from paragraph 5, a Member State may authorise the collection, production, processing and storage for use within the territory of that Member State of germinal products of purebred breeding animals at a semen collection or storage centre, at an embryo storage centre, by an embryo collection or production team or by specifically qualified staff, approved in accordance with the legislation of that Member State.

7 By way of derogation from points (b), (c) and (e) of paragraph 1, where the aim of a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, is the preservation of the breed or the preservation of the genetic diversity existing within the breed, performance testing or genetic evaluation shall only be carried out where that breeding programme requires such performance testing or genetic evaluation.

Article 22

Methods for identity verification

1 Where purebred breeding animals of the bovine, ovine, caprine and equine species are used for the collection of semen for artificial insemination, breed societies shall require that those purebred breeding animals are identified by analysis of their blood group or by any other appropriate method providing at least the same degree of certainty such as DNA analysis.

2 Where breeding animals of the bovine, porcine, ovine, caprine and equine species are used for the collection of oocytes and embryos, and where breeding animals of the porcine species are used for the collection of semen for artificial insemination, breed societies and breeding operations may require that those breeding animals are identified by one of the methods referred to in paragraph 1.

3 At the request of a Member State or of a European association for breeding animals of the species concerned, the Commission may adopt implementing acts, approving methods for the verification of the identity of breeding animals provided that they offer at least the same degree of certainty as the analysis of the blood group of those breeding animals, taking into account technical advances and the recommendations of the European Union reference centres referred to in Article 29, ICAR or the International Society for Animal Genetics (ISAG). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Section 2

Registration of hybrid breeding pigs in breeding registers and acceptance for breeding

Article 23

Registration of hybrid breeding pigs in breeding registers

1 Breeding operations shall, at the request of their breeders, register in their breeding register any hybrid breeding pig of the same breed, line or cross that fulfils the requirements set out in Part 2 of Annex II.

2 Breeding operations shall not refuse to register in their breeding registers any hybrid breeding pigs that have been registered in accordance with Part 2 of Annex II in a breeding register established for the same breed, line or cross by a breeding operation recognised in accordance with Article 4(3) in the same or in another Member State.

Article 24

Acceptance of hybrid breeding pigs and their germinal products for breeding

1 A breeding operation carrying out a breeding programme, approved in accordance with Article 8(3), and, where applicable, Article 12, on hybrid breeding pigs of a breed, line or cross shall accept:

- a for natural service, any hybrid breeding pig of the same breed, line or cross as defined in that breeding programme;

- b for artificial insemination, semen collected from hybrid breeding pigs which have undergone, where required by the breeding programme, approved in accordance with Article 8(3), and, where applicable, Article 12, performance testing or genetic evaluation in accordance with Article 25;
- c for embryo transfer, oocytes collected and used for in vitro production of embryos and in vivo derived embryos conceived by use of semen referred to in point (b), provided that those oocytes and embryos have been collected from hybrid breeding pigs which have undergone, where required by the breeding programme, approved in accordance with Article 8(3), and, where applicable, Article 12, performance testing or genetic evaluation in accordance with Article 25;
- d for the testing of male hybrid breeding pigs, semen collected from those hybrid breeding pigs which have not undergone performance testing or genetic evaluation, provided that that semen is solely used for the purpose of testing of those hybrid breeding pigs within the quantity limits necessary for that breeding operation to carry out such tests in accordance with Article 25.

2 Male hybrid breeding pigs which are registered in a breeding register established by a breeding operation carrying out a breeding programme, approved in accordance with Article 8(3), and, where applicable, Article 12, and the germinal products thereof, shall be accepted by another breeding operation carrying out a breeding programme on the same breed, line or cross in the same or another Member State under the same conditions and quantity limits for performance testing, and, where applicable, genetic evaluation, as applied to its own hybrid breeding pigs.

3 For the purpose of paragraphs 1 and 2, the germinal products of hybrid breeding pigs referred to in those paragraphs shall be collected, produced, processed and stored at a semen collection or storage centre, or by an embryo collection or production team, approved for intra-Union trade in these commodities in accordance with Union animal health law.

4 By way of derogation from paragraph 3, a Member State may authorise the collection, production, processing and storage for use within the territory of that Member State of germinal products of hybrid breeding pigs at a semen collection or storage centre, at an embryo storage centre, by an embryo collection or production team or by specifically qualified staff, approved in accordance with the legislation of that Member State.

CHAPTER V

Performance testing and genetic evaluation

Article 25

Methods for performance testing and genetic evaluation

Where a breed society or a breeding operation, or a third party designated in accordance with Article 27(1)(b), carries out performance testing or genetic evaluation of breeding animals, that breed society, breeding operation or third party shall ensure that such performance testing or genetic evaluation is carried out in accordance with the rules set out in:

- (a) in the case of purebred breeding animals of the bovine, porcine, ovine and caprine species and in the case of hybrid breeding pigs, Annex III;

- (b) in the case of purebred breeding animals of the equine species, the breeding programme carried out by that breed society as approved in accordance with Article 8(3), and, where applicable, Article 12.

Article 26

Delegated powers and implementing powers concerning the requirements for performance testing and genetic evaluation

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 61 concerning the amendments to Annex III as regards performance testing and genetic evaluation of purebred breeding animals of the bovine, ovine and caprine species, necessary to take account of:

- a scientific advances;
- b technical developments; or
- c the needs to preserve valuable genetic resources.

2 The Commission may adopt implementing acts, laying down uniform rules for performance testing and genetic evaluation of purebred breeding animals of the bovine, ovine and caprine species referred to in this Article, including the interpretation of the results thereof. In doing so, it shall take into account technical and scientific advances or recommendations of the relevant European Union reference centres provided for in Article 29(1) or, in the absence of such, the principles agreed by ICAR. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Article 27

Carrying out of performance testing and genetic evaluation

1 Where performance testing or genetic evaluation is to be carried out according to the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, breed societies and breeding operations shall:

- a carry out that performance testing or genetic evaluation themselves; or
- b designate the third parties to which that performance testing or genetic evaluation is to be outsourced.

2 A Member State, or, if that Member State so decides, its competent authorities, may require that, in order for the third parties to be designated in accordance with point (b) of paragraph 1, those third parties must have been authorised to carry out performance testing or genetic evaluation of breeding animals by that Member State, or its competent authorities, except where the designated third party in question is a public body subject to control by that Member State, or its competent authorities.

3 A Member State, or, if that Member State so decides, its competent authorities, making use of the provision referred to in paragraph 2 shall ensure that an authorisation is granted to the third parties referred to in that paragraph, if they have:

- a the facilities and equipment necessary to carry out that performance testing or genetic evaluation;
- b suitably qualified staff; and
- c the capability to carry out that performance testing or genetic evaluation in accordance with Article 25.

4 By way of derogation from Article 8(4)(a), a Member State or its competent authority may decide that a third party which is authorised in accordance with paragraph 2 of this Article, or the designated public body subject to control by the Member State or its competent authorities referred to in paragraph 2 of this Article, shall be responsible to that competent authority for ensuring compliance with the requirements provided for in this Regulation applicable to that outsourced performance testing or genetic evaluation.

5 Breed societies or breeding operations themselves carrying out performance testing or genetic evaluation or third parties designated by a breed society or breeding operation in accordance with point (b) of paragraph 1 of this Article or authorised by a Member State or its competent authorities as referred to in paragraph 2 of this Article may commit themselves to comply with the rules and standards established by ICAR or may participate in activities carried out by the European Union reference centres referred to in Article 29.

The results of such commitments or the participation in such activities may be taken into account by the competent authorities when recognising those breed societies or breeding operations, approving their breeding programmes, authorising those third parties or carrying out official controls on those operators.

6 Breed societies and breeding operations shall make publicly available the detailed information on those who carry out the performance testing or genetic evaluation.

Article 28

Obligations of breed societies, breeding operations and third parties carrying out performance testing or genetic evaluation

1 Where a breed society or a breeding operation carries out performance testing or genetic evaluation of breeding animals or outsources those activities to a third party in accordance with Article 27(1)(b), that breed society or breeding operation shall, at the request of the competent authority referred to in Article 8(3), or, where applicable, in Article 12(5), provide the following information:

- a records of all data resulting from performance testing and genetic evaluation in relation to breeding animals from holdings located on the territory where that competent authority operates;
- b details of the recording methods for traits;
- c details of the model of performance description used for the analysis of the results of performance testing;
- d details of the statistical methods used for the analysis of the results of performance testing for each evaluated trait;
- e details of the genetic parameters used for each evaluated trait, including, where applicable, details of the genomic evaluation.

2 The breed society or breeding operation or, on request by that breed society or breeding operation, the third party designated by that breed society or breeding operation in accordance with Article 27(1)(b), shall make the results of the genetic evaluation of breeding animals whose semen is used for artificial insemination in accordance with Article 21(1)(b), (c) and (d) and Article 24(1)(b) publicly available and shall keep them up-to-date.

CHAPTER VI

European Union reference centres

Article 29

European Union reference centres

1 Where there is a recognised need to promote the harmonisation or improvement of the methods of performance testing or genetic evaluation of purebred breeding animals used by breed societies or by third parties designated by breed societies in accordance with Article 27(1)(b), the Commission may adopt implementing acts, designating the European Union reference centres responsible for the scientific and technical contribution to the harmonisation or improvement of those methods.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

2 Where there is a recognised need to promote the establishment or harmonisation of the methods used by breed societies, third parties designated by breed societies in accordance with Article 27(1)(b), competent authorities or other authorities of the Member States for the preservation of endangered breeds or the preservation of the genetic diversity existing within those breeds, the Commission may adopt implementing acts, in order to designate the European Union reference centres responsible for the scientific and technical contribution to the establishment or harmonisation of those methods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

3 The designations provided for in paragraphs 1 and 2 shall follow a public selection process and shall be limited in time or reviewed regularly.

4 European Union reference centres designated in accordance with paragraph 1 or 2 of this Article shall:

- a comply with the requirements set out in point 1 of Annex IV; and
- b be responsible for the tasks:
 - (i) in the case of European Union reference centres designated in accordance with paragraph 1 of this Article, set out in point 2 of Annex IV;
 - (ii) in the case of European Union reference centres designated in accordance with paragraph 2 of this Article, set out in point 3 of Annex IV;

if those tasks are included in the reference centres' annual or multiannual work programmes established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014.

5 The Commission shall be empowered to adopt delegated acts in accordance with Article 61 amending:

- a the requirements for European Union reference centres set out in point 1 of Annex IV;
- b the tasks of European Union reference centres set out in points 2 and 3 of Annex IV.

The delegated acts provided for in this paragraph shall take due account of:

- a the species of purebred breeding animals for which the methods of performance testing and genetic evaluation are to be harmonised or improved and the scientific and technical advances in the area of performance testing or genetic evaluation; or
 - b the endangered breeds for which methods for the preservation of those breeds or the preservation of the genetic diversity within those breeds are to be established or harmonised and the scientific and technical advances in those areas.
- 6 European Union reference centres designated in accordance with paragraph 1 or 2 shall be subject to Commission controls to verify that:
- a they comply with the requirements set out in point 1 of Annex IV;
 - b they fulfil the tasks:
 - (i) in the case of European Union reference centres designated in accordance with paragraph 1, set out in point 2 of Annex IV;
 - (ii) in the case of European Union reference centres designated in accordance with paragraph 2, set out in point 3 of Annex IV.

If the results of such a control disclose that a European Union reference centre does not comply with the requirements set out in point 1 of Annex IV or does not fulfil the tasks set out in point 2 or 3 of Annex IV, the Commission may adopt implementing acts, reducing the Union financial contribution granted in accordance with Article 30 of Regulation (EU) No 652/2014 or withdrawing the designation as a European Union reference centre. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

CHAPTER VII

Zootechnical certificates

Article 30

Issuing, content and format of zootechnical certificates accompanying breeding animals and the germinal products thereof

- 1 Where breeders participating in a breeding programme that has been approved in accordance with Article 8, and, where applicable, Article 12, request zootechnical certificates for their breeding animals or germinal products thereof, the breed society or breeding operation carrying out that breeding programme shall issue those certificates.
- 2 Zootechnical certificates accompanying breeding animals or germinal products thereof shall only be issued by:
- a breed societies or breeding operations carrying out breeding programmes approved in accordance with Article 8, and, where applicable, Article 12, on those breeding animals;
 - b the competent authorities referred to in Article 8(3), or, where applicable, Article 12(2) (a), if those authorities so decide; or
 - c breeding bodies included in the list provided for in Article 34 carrying out breeding programmes on those breeding animals.
- 3 Breed societies or breeding operations shall ensure a timely transmission of zootechnical certificates.

4 Where breeding animals that have been entered in a breeding book maintained by a breed society or registered in a breeding register maintained by a breeding operation or their germinal products are traded and where those breeding animals, or the offspring produced from those germinal products, are intended to be entered or registered in another breeding book or breeding register, those breeding animals, or their germinal products, shall be accompanied by a zootechnical certificate.

The breed society or breeding operation of dispatch of the breeding animals, or of the germinal products thereof, maintaining the breeding book or breeding register where those breeding animals are entered or registered shall issue that zootechnical certificate.

5 Where breeding animals that have been entered in a breeding book or registered in a breeding register maintained by a breeding body included in the list provided for in Article 34, or their germinal products, enter the Union and where those breeding animals, or the offspring produced from those germinal products, are intended to be entered in a breeding book maintained by a breed society or registered in a breeding register maintained by a breeding operation, those breeding animals, or their germinal products, shall be accompanied by a zootechnical certificate.

That zootechnical certificate shall be issued by the breeding body listed in accordance with Article 34 that is maintaining the breeding book or breeding register in which those breeding animals are entered or registered, or by the official service of the third country of dispatch.

6 The zootechnical certificates referred to in paragraphs 4 and 5 shall:

- a contain the information set out in the relevant Parts and Chapters of Annex V;
- b comply with the corresponding model forms of zootechnical certificates provided for in the implementing acts adopted pursuant to paragraph 10.

7 A breed society or a breeding body that carries out performance testing or genetic evaluation, or both, in accordance with its breeding programme, or outsources those activities to third parties, in the case of a breed society in accordance with Article 27(1)(b), shall indicate, in the zootechnical certificate issued for a purebred breeding animal or its germinal products:

- a results of that performance testing;
- b up-to-date results of that genetic evaluation; and
- c genetic defects and genetic peculiarities in relation to that breeding programme affecting that breeding animal or the donors of those germinal products.

8 A breeding operation or a breeding body that carries out performance testing or genetic evaluation, or both, in accordance with its breeding programme, or outsources those activities to third parties, in the case of a breeding operation in accordance with Article 27(1)(b), shall, where required to do so by that breeding programme, indicate in the zootechnical certificate issued for a hybrid breeding pig or its germinal products:

- a results of that performance testing;
- b up-to-date results of that genetic evaluation; and
- c genetic defects and genetic peculiarities in relation to that breeding programme affecting that breeding animal or the donors of those germinal products.

9 The Commission shall be empowered to adopt delegated acts in accordance with Article 61 amending the contents of the zootechnical certificates set out in Annex V, in order to update them to take into account:

- a scientific advances;
- b technical developments;

- c the functioning of the internal market; or
- d the needs to preserve valuable genetic resources.

10 The Commission shall adopt implementing acts, laying down model forms for the zootechnical certificates for breeding animals and their germinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Article 31

Derogations from requirements concerning the issuing, content and format of zootechnical certificates for trade in breeding animals and their germinal products

1 By way of derogation from Article 30(2)(a), the competent authority may authorise that germinal products are to be accompanied by a zootechnical certificate issued, on the basis of the information received from the breed society or breeding operation, by a semen collection or storage centre, or by an embryo collection or production team, approved for intra-Union trade in those germinal products in accordance with Union animal health law.

2 By way of derogation from Article 30(6)(b), the competent authority may authorise the non-use of the model forms referred to in Article 30(6)(b) provided that:

- a in the case of breeding animals of the bovine, porcine, ovine and caprine species, the information set out in Chapter I of Part 2 of Annex V or Chapter I of Part 3 of Annex V is contained in other documents accompanying those breeding animals, issued by the breed society or breeding operation;
- b in the case of germinal products of the bovine, porcine, ovine, caprine and equine species:
 - (i) the information related to the donors of those germinal products is contained in other documents or in copies of the original zootechnical certificate accompanying those germinal products or, before or after the dispatch of those germinal products, it is, on request, made available by the breed society or breeding operation or the other operators referred to in paragraph 1;
 - (ii) the information related to the semen, oocytes or embryos is contained in other documents accompanying that semen, those oocytes or those embryos, issued by the breed society or breeding operation or the other operators referred to in paragraph 1.

3 By way of derogation from Article 30(7)(a) and (b) and Article 30(8)(a) and (b), where the results of performance testing or genetic evaluation are publicly available on a website, breed societies, breeding operations or the other operators referred to in paragraph 1 of this Article may, in the zootechnical certificate or in the documents referred to in point (a) of paragraph 2 of this Article, refer to the website where those results can be accessed.

Article 32

Derogations from requirements concerning the format of zootechnical certificates issued for purebred breeding animals of the equine species

1 By way of derogation from Article 30(6), in the case of purebred breeding animals of the equine species, the information set out in Chapter I of Part 2 of Annex V shall be contained in a single lifetime identification document for equidae. The Commission shall adopt delegated

acts in accordance with Article 61 concerning the content and format of such identification documents.

2 The Commission may adopt implementing acts, laying down model forms of the single lifetime identification document for equidae. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

3 By way of derogation from paragraph 1, where updated results of performance testing or genetic evaluation are publicly available on a website, the competent authorities may authorise the non-inclusion of the information set out in point (1)(m) of Chapter I of Part 2 of Annex V in the document referred to in paragraph 1, provided that the breed society refers to that website in that document.

4 By way of derogation from paragraph 1, the competent authorities may authorise that the information set out in points (1)(m) and (n) of Chapter I of Part 2 of Annex V is contained in other documents issued by the breed society for the purebred breeding animals entered in a breeding book maintained by that breed society.

Article 33

Derogations from requirements concerning the issuing, content and format of zootechnical certificates for the entry into the Union of breeding animals and their germinal products

1 By way of derogation from Article 30(2)(c) and (5), germinal products may be accompanied by a zootechnical certificate issued on behalf of the breeding body on the basis of the information received from that breeding body, by a semen collection or storage centre, or by an embryo collection or production team, approved for the entry into the Union of those germinal products in accordance with Union animal health law.

2 By way of derogation from Article 30(6)(b), the model forms referred to in Article 30(6)(b) do not have to be used if:

- a the information set out in the relevant Parts and Chapters of Annex V is contained in other documents accompanying the breeding animal or their germinal products;
- b the breeding body carrying out the breeding programme, or another operator referred to in paragraph 1, provides an exhaustive list of those documents, declares that the information set out in the relevant Parts and Chapters of Annex V is contained in those documents and certifies the content of those documents.

3 By way of derogation from Article 30(7)(a) and (b) and Article 30(8)(a) and (b), where the results of performance testing or genetic evaluation are publicly available on a website, breeding bodies, or the other operators referred to in paragraph 1 of this Article, may, in the zootechnical certificate or the other documents referred to in point (a) of paragraph 2 of this Article, refer to the website where those results can be accessed.

CHAPTER VIII

Entry into the Union of breeding animals and their germinal products

Article 34

Listing of breeding bodies

- 1 The Commission shall maintain, update and publish a list of breeding bodies.
- 2 The Commission shall only include in the list provided for in paragraph 1 a breeding body in respect of which it has received from an official service of the third country documentation demonstrating that the breeding body meets the following requirements:
 - a it carries out a breeding programme that is equivalent to breeding programmes approved in accordance with Article 8(3) carried out by breed societies on the same breed, or carried out by breeding operations on the same breed, line or cross, as regards:
 - (i) the entry of breeding animals in breeding books or their registration in breeding registers;
 - (ii) the acceptance of breeding animals for breeding;
 - (iii) the use of germinal products of breeding animals for testing and breeding;
 - (iv) the methods used for performance testing and genetic evaluation;
 - b it is supervised or controlled by an official service in that third country;
 - c it has adopted rules of procedure to ensure that breeding animals entered in breeding books by breed societies or registered in breeding registers by breeding operations, and the offspring produced from germinal products of such breeding animals, are entered or eligible for entry without discrimination on account of their country of origin, in the case of purebred breeding animals, in the breeding book of the same breed, or, in the case of hybrid breeding pigs, in the breeding register of the same breed, line or cross, maintained by that breeding body.
- 3 The Commission shall also include in the list provided for in paragraph 1 of this Article the reference to those third countries that have measures in place which are considered to be equivalent in accordance with Article 35, including a reference to all the breeding bodies in those third countries.
- 4 The Commission shall, without undue delay, remove from the list any breeding bodies which no longer fulfil at least one of the requirements referred to in paragraph 2.

Article 35

Equivalence of measures applied to animal breeding in third countries

- 1 The Commission may adopt implementing acts, recognising that measures applied in a third country are equivalent to those required by this Regulation in relation to the following:
 - a the recognition of breed societies and breeding operations provided for in Article 4;
 - b the approval of breeding programmes of breed societies and breeding operations provided for in Article 8;
 - c the entry of purebred breeding animals in breeding books and the registration of hybrid breeding pigs in breeding registers provided for in Articles 18, 20 and 23;

- d the acceptance of breeding animals for breeding provided for in Articles 21, 22 and 24;
- e the use of germinal products of breeding animals for testing and breeding provided for in Articles 21 and 24;
- f the performance testing and genetic evaluation provided for in Article 25;
- g the official controls on operators provided for in Article 43.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

- 2 The implementing acts referred to in paragraph 1 shall be adopted on the basis of:
- a a thorough examination of the information and data provided by the third country which is seeking to have its measures recognised as equivalent to those required by this Regulation;
 - b where appropriate, the satisfactory outcome of a control performed by the Commission in accordance with Article 57.

3 The implementing acts referred to in paragraph 1 may set out the detailed arrangements governing the entry of breeding animals and the germinal products thereof into the Union from the third country concerned and may include:

- a the format and content of the zootechnical certificates accompanying those breeding animals or the germinal products thereof;
- b specific requirements applicable to the entry into the Union of those breeding animals or the germinal products thereof and the official controls to be performed on those breeding animals or on the germinal products thereof upon entry into the Union;
- c where necessary, procedures for drawing up and amending lists of breeding bodies, located in the third country concerned, from which the entry into the Union of breeding animals and the germinal products thereof is permitted.

4 The Commission shall, without undue delay, adopt implementing acts repealing the implementing acts referred to in paragraph 1 where any of the conditions for the recognition of equivalence of measures established at the time of their adoption are no longer fulfilled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Article 36

Entry in breeding books or registration in breeding registers of breeding animals and offspring produced from germinal products that have entered the Union

1 On application by a breeder, a breed society or breeding operation shall enter in the main section of its breeding book or register in its breeding register any breeding animals that have entered the Union and the offspring produced from germinal products that have entered the Union where:

- a that breeding animal or the donors of those germinal products are entered in a breeding book or registered in a breeding register maintained by a breeding body in the third country of dispatch;
- b those germinal products meet the conditions laid down in Article 21(1) or (2), where that is a requirement of the breeding programme carried out by that breed society or that breeding operation;
- c that breeding animal meets the characteristics of the breed or, in the case of a hybrid breeding pig, the characteristics of the breed, line or cross set out in the breeding programme carried out by that breed society or breeding operation;

- d the breeding body referred to in point (a) is included in the list of breeding bodies provided for in Article 34.

2 Member States or competent authorities shall not prohibit, restrict or impede, on zootechnical or genealogical grounds, the entry into the Union of breeding animals or the germinal products thereof and the subsequent use of those animals or the germinal products thereof, where those breeding animals or the donors of those germinal products are entered in a breeding book or registered in a breeding register maintained by a breeding body included in the list of breeding bodies established in accordance with Article 34.

Article 37

Checks for entitlement to the conventional rate of duty for purebred breeding animals entering the Union

1 Where the operator responsible for a consignment of purebred breeding animals requests the application of the conventional rate of duty for purebred breeding animals provided for in Regulation (EEC) No 2658/87 on the animals of that consignment:

- a those animals shall be accompanied by:
 - (i) the zootechnical certificate referred to in Article 30(5) or Article 32;
 - (ii) a document indicating that they are to be entered in a breeding book maintained by a breed society or registered in a breeding register maintained by a breeding operation;
- b checks shall be carried out on that consignment at the border inspection post in which the documentary, identity and physical checks referred to in Article 4 of Directive 91/496/EEC are carried out.

2 The purpose of the checks provided for in point (b) of paragraph 1 shall be to verify that:

- a the consignment is accompanied by the documents referred to in point (a) of paragraph 1;
- b the content and the labelling of the consignment correspond to the information provided in the documents referred to in point (a) of paragraph 1.

CHAPTER IX

Competent authorities carrying out a breeding programme on purebred breeding animals

Article 38

Competent authorities carrying out a breeding programme on purebred breeding animals

1 If, in a Member State or on a territory where a competent authority operates, there is no breeding organisation, breeders' association or public body carrying out a breeding programme on purebred breeding animals belonging to a breed of the bovine, porcine, ovine, caprine or equine species, that competent authority may decide to carry out a breeding programme for that breed, provided that:

- a there is a need to maintain that breed or to establish that breed in the Member State or territory where that competent authority operates; or
- b that breed is an endangered breed.

2 A competent authority which carries out a breeding programme in accordance with this Article shall take the necessary measures to ensure that this does not have a negative effect on the possibility:

- a for breeding organisations, breeders' associations or public bodies to be recognised as breed societies in accordance with Article 4(3);
- b for breed societies to have their breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12.

3 Where a competent authority carries out a breeding programme on purebred breeding animals, that competent authority shall:

- a have sufficient and qualified staff and adequate facilities and equipment to implement efficiently that breeding programme;
- b be capable of carrying out the checks necessary for recording pedigrees of the purebred breeding animals covered by that breeding programme;
- c have a sufficiently large population of purebred breeding animals and a sufficient number of breeders within the geographical territory covered by that breeding programme;
- d be capable of generating, or have had generated for them, and be capable of using data collected on purebred breeding animals necessary for carrying out that breeding programme;
- e have adopted rules of procedure:
 - (i) regulating the settlement of disputes with breeders participating in that breeding programme;
 - (ii) ensuring equal treatment of breeders participating in that breeding programme;
 - (iii) setting out the rights and obligations of breeders participating in that breeding programme.

4 The breeding programme referred to in paragraph 1 shall contain:

- a information on its aim which is to be the preservation of the breed, the improvement of the breed, the creation of a new breed or the reconstruction of a breed, or any combination thereof;
- b the name of the breed covered by that breeding programme to prevent confusion with similar purebred breeding animals of other breeds entered in other existing breeding books;
- c the detailed characteristics of the breed, including an indication of the essential traits, covered by that breeding programme;
- d information on the geographical territory where it is carried out;
- e information on the system for identifying purebred breeding animals which is to ensure that purebred breeding animals are only entered in the breeding book when they are identified individually and in accordance with Union animal health law on the identification and registration of animals of the species concerned;
- f information on the system for recording pedigrees of purebred breeding animals entered or registered and eligible for entry in breeding books;

- g the selection and breeding objectives of the breeding programme, including an indication of the main objectives of that breeding programme, and, where applicable, the detailed evaluation criteria related to those objectives for the selection of purebred breeding animals;
- h where the breeding programme requires performance testing or genetic evaluation:
 - (i) the information on the systems used to generate, record, communicate and use the results of performance testing;
 - (ii) the information on the systems for the genetic evaluation and, where applicable, for the genomic evaluation of purebred breeding animals;
- i where supplementary sections are established, as provided for in Article 17, or where the main section is subdivided into classes, as provided for in Article 16, the rules for the division of the breeding book and the criteria or procedures applied for recording animals in those sections or classifying them in those classes;
- j where in the case of purebred breeding animals of the equine species, the breeding programme prohibits or limits the use of one or more reproduction techniques or the use of purebred breeding animals for one or more reproduction techniques as referred to in Article 21(2), information on such prohibitions or limitations;
- k where the competent authority outsources specific technical activities related to the management of its breeding programme to third parties, information on those activities and the name and contact details of the designated third parties.

5 Where a competent authority carries out a breeding programme on purebred breeding animals of the equine species, the requirements set out in points 1, 2, 3, 4(a) and 4(c) of Part 3 of Annex I shall apply in addition to those set out in paragraphs 3 and 4.

6 Where a competent authority carries out a breeding programme on purebred breeding animals, that competent authority shall inform in a transparent and timely manner the breeders participating in that breeding programme of any changes therein.

7 Where a competent authority carries out a breeding programme on purebred breeding animals, Articles 3, 13 to 22, 25, 27, Article 28(2), Articles 30, 31, 32 and Article 36(1) shall apply *mutatis mutandis*.

CHAPTER X

Official controls and other official activities, administrative assistance, cooperation and enforcement by Member States

Article 39

Designation of competent authorities

1 Member States shall designate the competent authorities with the responsibility for performing official controls for the verification of compliance of operators with the rules provided for in this Regulation, and for performing other official activities to ensure the application of those rules.

2 Each Member State shall:

- a draw up and keep up to date a list of the competent authorities it has designated in accordance with paragraph 1, including their contact details;

- b specify in the list provided for in point (a) the address to which the following is to be sent:
 - (i) the notifications referred to in Article 12; or
 - (ii) the information, requests or notifications referred to in Articles 48 and 49;
 - c make the list referred to in point (a) available to the public on a website and notify that website to the Commission.
- 3 The Commission shall draw up and keep up to date a list of the websites referred to in point (c) of paragraph 2 and make such list available to the public.

Article 40

Compliance by competent authorities carrying out breeding programmes

By way of derogation from this Chapter, Member States shall take the necessary measures to verify that competent authorities carrying out breeding programmes in accordance with Article 38 comply with the rules laid down in that Article.

Article 41

General obligations of competent authorities

Competent authorities shall:

- (a) have procedures or arrangements, or both, in place to ensure and verify the effectiveness, appropriateness, impartiality, quality and consistency of the official controls and of the other official activities that they perform;
- (b) have procedures or arrangements, or both, in place to ensure that their staff performing official controls and other official activities are free from any conflict of interest as regards the operators in respect of which they perform those official controls and other official activities;
- (c) have, or have access to, a sufficient number of suitably qualified, trained and experienced staff so that official controls and other official activities can be performed efficiently and effectively;
- (d) have appropriate and properly maintained facilities and equipment to ensure that their staff can perform official controls and other official activities efficiently and effectively;
- (e) have the legal powers to perform official controls and other official activities and to take the action provided for in this Regulation;
- (f) have legal procedures in place in order to ensure that their staff have access to the premises of, and documents and computerised information management systems kept by, operators so as to be able to carry out their tasks properly.

Article 42

Confidentiality obligations of the competent authorities

1 Without prejudice to situations where its disclosure is required by Union law or national law, competent authorities shall require members of their staff to undertake not to disclose to third parties information acquired when undertaking their duties, in the context of official controls and other official activities, which is, by its nature, covered by professional confidentiality, unless there is an overriding public interest in its disclosure.

2 Information covered by professional confidentiality shall include information the disclosure of which would undermine:

- a the purpose of official controls or investigations;
- b the protection of commercial interests of an operator or any other natural or legal person;
- c the protection of court proceedings and legal advice.

Article 43

Rules on official controls

1 Competent authorities shall perform official controls on operators with appropriate frequency, taking account of:

- a the risk of non-compliance with the rules provided for in this Regulation;
- b the past records of operators as regards the results of official controls performed in their respect and their compliance with the rules provided for in this Regulation;
- c the reliability and results of self-checks performed by the operators, or by third parties at their request, for the purpose of verifying compliance with the rules provided for in this Regulation;
- d any information that might indicate non-compliance with the rules provided for in this Regulation.

2 Competent authorities shall perform official controls in accordance with documented procedures, which shall contain instructions for staff performing official controls.

3 Official controls shall be performed after the operator has been notified in advance unless there are reasons to carry out the official controls without prior notice.

4 Official controls shall, as far as possible, be performed in a manner that minimises the burden on the operators without this negatively affecting the quality of those official controls.

5 Competent authorities shall perform official controls in the same manner irrespective of whether the breeding animals or the germinal products thereof:

- a originate in the Member State where the official controls are performed or in another Member State; or
- b are entering the Union.

Article 44

Transparency of official controls

The competent authority shall perform official controls with a high level of transparency and shall make relevant information concerning the organisation and the performance of official controls publicly available.

Article 45

Written records of official controls

1 Competent authorities shall draw up written records of every official control that they perform.

Those written records shall contain:

- a a description of the purpose of the official control;
- b the control methods applied;
- c the results of the official control;
- d where appropriate, action that the competent authorities require the operators to take as a result of the official control.

2 Unless the purposes of judicial investigations or the protection of court proceedings require otherwise, competent authorities shall provide the operators which have been subject to an official control with a copy of the written records referred to in paragraph 1.

Article 46

Obligations of operators subject to official controls or other official activities

1 To the extent that this is necessary for the performance of official controls or other official activities, operators shall, when required to do so by the competent authorities, give to the staff of those competent authorities the necessary access to:

- a their equipment, premises and other places under their control;
- b their computerised information management systems;
- c their breeding animals and the germinal products thereof under their control;
- d their documents and any other relevant information.

2 During official controls and other official activities, operators shall assist and cooperate with the staff of the competent authorities in the accomplishment of their tasks.

Article 47

Actions in case of established non-compliance

1 Where non-compliance is established, the competent authorities shall:

- a take any action necessary to determine the origin and extent of that non-compliance and to establish the responsibilities of the operators concerned;

- b take appropriate measures to ensure that the operators concerned remedy the non-compliance and prevent further occurrences of it.

When deciding which measures to take, the competent authorities shall take account of the nature of the non-compliance and the past record of the operators concerned with regard to compliance.

In particular competent authorities shall, as appropriate:

- a order that the breed society postpones the entry in breeding books of purebred breeding animals or that the breeding operation postpones the registration in breeding registers of hybrid breeding pigs;
- b order that the breeding animals or their germinal products shall not be used for breeding in accordance with this Regulation;
- c suspend the issuing of zootechnical certificates by the breed society or the breeding operation;
- d suspend or withdraw the approval of a breeding programme carried out by a breed society or breeding operation, where the activities of that breed society or breeding operation repeatedly, continuously or generally fail to comply with the requirements of the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
- e withdraw the recognition of the breed society or breeding operation granted in accordance with Article 4(3), where that breed society or breeding operation repeatedly, continuously or generally fails to comply with the requirements referred to in Article 4(3);
- f take any other measures that they deem to be appropriate to ensure compliance with the rules provided for in this Regulation.

2 The competent authorities shall provide the operators concerned, or their representatives, with:

- a a written notification of their decision concerning the action or measure to be taken in accordance with paragraph 1, together with the reasons for that decision;
- b information on any right of appeal against such decisions, and on the applicable procedure and time limits.

3 The competent authorities shall monitor the situation and shall modify, suspend or withdraw the measures that they have taken in accordance with this Article, depending on the severity of the non-compliance and the existence of clear evidence of a return to compliance.

4 Member States may provide that the operators concerned are to bear all or part of expenditure incurred pursuant to this Article by competent authorities concerned.

Article 48

Cooperation and administrative assistance

1 Where non-compliance originates in, spreads to or affects more than one Member State, the competent authorities in those Member States shall cooperate with one another as well as provide one another with administrative assistance in order to ensure the correct application of the rules provided for in this Regulation.

2 The cooperation and administrative assistance provided for in paragraph 1 may include:

- a the reasoned request by a competent authority of a Member State ('requesting competent authority') for information from a competent authority of another Member State ('requested competent authority') that is needed in order to perform official controls or to follow them up;
- b in the case of a non-compliance which might have implications in other Member States, the notification of the competent authorities of those other Member States by the competent authority aware of the non-compliance;
- c the provision, by the requested competent authority, of necessary information and documents to the requesting competent authority, without undue delay when the relevant information and documents become available;
- d the performance of investigations or official controls by the requested competent authority that are necessary to:
 - (i) provide the requesting competent authority with all necessary information and documents, including information concerning the results of such investigations or official controls and, where appropriate, the measures taken;
 - (ii) verify, where necessary 'on-the-spot', compliance within their jurisdiction with the rules provided for in this Regulation;
- e by agreement between the competent authorities concerned, participation by a competent authority of a Member State in on-the-spot official controls that the competent authorities of another Member State perform.

3 Where official controls performed on breeding animals or their germinal products originating in another Member State show repeated instances of non-compliance with the rules provided for in this Regulation, the competent authority of the Member State that has performed those official controls shall inform the Commission and the competent authorities of the other Member States thereof without undue delay.

- 4 This Article shall apply without prejudice to national rules that are:
- a applicable to the release of documents that are the object of, or related to, judicial proceedings;
 - b aimed at the protection of commercial interests vested in natural or legal persons.

5 All communications between competent authorities in accordance with this Article shall be in writing, either on paper or in electronic form.

Article 49

Notification of the Commission and Member States on the basis of information provided by third countries

- 1 Where competent authorities receive information from a third country indicating non-compliance with the rules provided for in this Regulation, they shall, without undue delay:
- a notify such information to the competent authorities of the other Member States known to be concerned by that non-compliance;
 - b where such information is or might be relevant at Union level, communicate such information to the Commission.

2 Information obtained through official controls or investigations performed in accordance with this Regulation may be communicated to the third country referred to in paragraph 1, provided that:

- a the competent authorities which have provided the information consent to such communication;
- b relevant Union and national rules applicable to the communication of personal data to third countries are complied with.

Article 50

Coordinated assistance and follow-up by the Commission

1 The Commission shall, without delay, coordinate the measures and actions undertaken by the competent authorities in accordance with this Chapter where:

- a information available to the Commission indicates the existence of activities that are, or appear to be, non-compliant with the rules provided for in this Regulation and that concern more than one Member State;
- b the competent authorities in the Member States concerned are unable to agree on appropriate actions to address the non-compliance with the rules provided for in this Regulation.

2 In the cases referred to in paragraph 1, the Commission may:

- a request that the competent authorities of the Member States concerned by the activities that are, or appear to be, non-compliant with the rules provided for in this Regulation, provide it with a report on the measures that they have taken;
- b in collaboration with the Member States concerned by the activities that are, or appear to be, non-compliant with the rules provided for in this Regulation, send an inspection team to perform an on-the-spot Commission control;
- c request that the competent authorities of the Member State of dispatch and, where appropriate, in other Member States concerned, appropriately intensify their official controls and provide it with a report on the measures that they have taken;
- d submit information concerning such cases to the Committee referred to in Article 62(1), together with a proposal for measures to remedy the cases of non-compliance referred to in point (a) of paragraph 1 of this Article;
- e take any other appropriate measures.

Article 51

General principle for the financing of official controls

Member States shall ensure that adequate financial resources are available so that the competent authorities have the staff and other resources necessary to perform official controls and other official activities.

Article 52

Penalties

Member States shall lay down the penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are applied. Those penalties must be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by 1 November 2018 and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER XI

Controls by the Commission

Section 1

Commission controls in Member States

Article 53

Commission controls in Member States

1 Commission experts may, within the scope of this Regulation, perform controls in Member States in order, as appropriate, to:

- a verify the application of the rules provided for in this Regulation;
- b verify enforcement practices and the functioning of official control systems and of the competent authorities which operate them;
- c investigate and collect information:
 - (i) on important or recurring problems concerning the application or enforcement of the rules provided for in this Regulation;
 - (ii) on emerging problems or new developments in relation to particular practices of operators.

2 The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States.

3 The controls provided for in paragraph 1 may include on-the-spot verifications performed in cooperation with the competent authorities performing official controls.

4 Member States' experts may assist the Commission experts. Member States' experts accompanying Commission experts shall be given the same rights of access as those Commission experts.

Article 54

Reports by the Commission on controls performed by its experts in Member States

1 The Commission shall:

- a prepare a draft report on the findings and on the recommendations addressing the shortcomings identified by its experts during the controls provided for in Article 53(1);
- b send to the Member State where those controls were performed a copy of the draft report referred to in point (a) for its comments;
- c take the comments of the Member State referred to in point (b) of this paragraph into account in preparing the final report on the findings resulting from the controls provided for in Article 53(1) performed by its experts in that Member State;
- d make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).

2 Where appropriate, the Commission may, in its final report referred to in point (c) of paragraph 1 of this Article, recommend corrective or preventive action to be taken by

the Member States to address the specific or systemic shortcomings identified during the Commission controls performed in accordance with Article 53(1).

Article 55

Obligations of Member States as regards Commission controls

- 1 Member States shall:
 - a at the request of the Commission experts, provide the necessary technical assistance and the available documentation and other technical support to enable those experts to perform the controls referred to in Article 53(1) efficiently and effectively;
 - b provide necessary assistance to ensure that Commission experts have access to all premises, including parts thereof, and to other places, to equipment and to information, including computerised information management systems, as well as, where appropriate, to breeding animals and the germinal products thereof, necessary to perform the controls referred to in Article 53(1).
- 2 Member States shall take appropriate follow-up action in the light of the recommendations set out in the final report referred to in Article 54(1)(c) in order to ensure compliance with the rules provided for in this Regulation.

Article 56

Serious disruption in the control system of a Member State

- 1 Where the Commission has evidence of a serious disruption in the control system of a Member State and where such disruption may result in a widespread infringement of the rules provided for in this Regulation, it shall adopt implementing acts, laying down one or more of the following:
 - a special conditions for, or a prohibition on, trade in the breeding animals or the germinal products thereof concerned by the disruption in the official control system;
 - b any other appropriate temporary measures.

Those implementing acts shall cease to apply once that disruption has been eliminated.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

- 2 The measures provided for in paragraph 1 shall be adopted only where the Commission has requested that the Member State concerned correct the situation with an appropriate time limit and the Member State has failed to do so.

- 3 The Commission shall monitor the situation referred to in paragraph 1 and shall adopt implementing acts, amending or repealing the measures adopted, depending on the way in which the situation develops. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

Section 2

Commission controls in third countries

Article 57

Commission controls in third countries

- 1 Commission experts may perform controls in a third country in order, as appropriate, to:
 - a verify the compliance or equivalence of the third country's legislation and systems with the requirements laid down in this Regulation;
 - b verify the capacity of the third country's control system to ensure that consignments of breeding animals and the germinal products thereof entering into the Union comply with relevant requirements in Chapter VIII of this Regulation;
 - c collect information and data to elucidate the causes of recurring or emerging problems in relation to breeding animals and their germinal products from the third country entering into the Union.
- 2 The Commission controls referred to in paragraph 1 shall have particular regard to:
 - a the zootechnical and genealogical legislation of the third country concerning breeding animals and their germinal products;
 - b the organisation of the competent authorities of the third country, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;
 - c the training of the staff in the third country responsible for the performance of the controls on, or the supervision of, breeding bodies;
 - d the resources that are available to the competent authorities of the third country;
 - e the existence and operation of documented control procedures and control systems based on priorities;
 - f the extent and operation of controls performed by the competent authorities of the third country on breeding animals and their germinal products arriving from other third countries;
 - g the assurances which the third country is able to give regarding compliance with, or equivalence to, the requirements laid down in this Regulation.

Article 58

Frequency and organisation of Commission controls in third countries

- 1 The frequency of the controls in a third country referred to in Article 57(1) shall be determined on the basis of:
 - a the principles and objectives of the rules provided for in this Regulation;
 - b the volume and nature of breeding animals and the germinal products thereof entering the Union from that third country;
 - c the results of controls referred to in Article 57(1) that have already been performed;
 - d the results of official controls on breeding animals and the germinal products thereof entering the Union from the third country and of any other official controls performed by the competent authorities of Member States;
 - e any other information that the Commission deems to be appropriate.

2 In order to facilitate the efficiency and effectiveness of the controls provided for in Article 57(1), the Commission may, prior to performing such controls, request that the third country concerned provides:

- a the information referred to in Article 34(2) or in Article 35(2)(a);
- b where appropriate and necessary, the written records on the controls performed by the competent authorities of that third country.

3 The Commission may appoint experts from the Member States to assist its own experts during the controls referred to in Article 57(1).

Article 59

Reports by the Commission on controls performed by its experts in third countries

The Commission shall report on the findings of each control performed in accordance with Articles 57 and 58.

Those reports shall, where appropriate, contain recommendations. The Commission shall make those reports publicly available.

Article 60

Establishment of special measures regarding the entry into the Union of breeding animals and their germinal products

1 Where there is evidence that widespread serious non-compliance with the rules provided for in this Regulation is taking place in a third country, the Commission shall adopt implementing acts concerning one or more of the following:

- a prohibiting the entry into the Union, as breeding animals, or the germinal products thereof, of animals, or their semen, oocytes or embryos originating from that third country;
- b prohibiting the entry in breeding books maintained by breed societies or the registration in breeding registers maintained by breeding operations of breeding animals, and the offspring produced from the germinal products thereof, originating from that third country.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2).

In addition to, or instead of those implementing acts, the Commission may do one or more of the following:

- a delete that third country or the breeding bodies of that third country from the list provided for in Article 34(1);
- b take any other appropriate measures.

2 The implementing acts and other measures referred to in paragraph 1 shall identify breeding animals and their germinal products by their codes in the Combined Nomenclature.

3 When adopting the implementing acts and other measures referred to in paragraph 1, the Commission shall take account of:

- a the information collected in accordance with Article 58(2);

- b any other information that the third country concerned by the non-compliance referred to in paragraph 1 has provided;
- c where necessary, the results of controls referred to in Article 57(1).

4 The Commission shall monitor the non-compliance referred to in paragraph 1 and shall, in accordance with the same procedure as for their adoption, amend or repeal the measures adopted, depending on how the situation develops.

CHAPTER XII

Delegation and implementation

Article 61

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Articles 26(1), 29(5), 30(9) and 32(1) shall be conferred on the Commission for a period of 5 years from 19 July 2016. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than 3 months before the end of each period.

3 The delegation of power referred to in Articles 26(1), 29(5), 30(9) and 32(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Articles 26(1), 29(5), 30(9) and 32(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 2 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 62

Committee Procedure

1 The Commission shall be assisted by the Standing Committee on Zootechnics established by Decision 77/505/EEC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 63

Transitional measures related to the date of adoption of certain implementing acts

The Commission shall adopt the implementing acts referred to in Articles 7(5) and 30(10) by 1 May 2017. In accordance with Article 69, those implementing acts shall apply from 1 November 2018.

CHAPTER XIII

Final Provisions

Article 64

Repeals and transitional measures

1 Directives 87/328/EEC, 88/661/EEC, 89/361/EEC, 90/118/EEC, 90/119/EEC, 90/427/EEC, 91/174/EEC, 94/28/EC and 2009/157/EC and Decision 96/463/EC are repealed.

2 References to the repealed Directives and to the repealed Decision shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII to this Regulation.

3 Article 8(1) of Directive 90/427/EEC shall continue to apply until 21 April 2021.

4 Breeders' organisations, breeding organisations, breeders' associations, private undertakings, other organisations or associations which have been approved or recognised in accordance with the repealed acts referred to in paragraph 1 shall be considered to have been recognised in accordance with this Regulation; in all other respects, they shall be subject to the rules provided for in this Regulation.

5 Breeding programmes carried out by the operators referred to in paragraph 4 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.

6 Where operators referred to in paragraph 4 already carry out breeding programmes in a Member State other than the Member State where their approval or recognition was granted under the repealed acts referred to in paragraph 1, those operators shall inform the competent authority which has granted the approval or recognition about those activities.

The competent authority referred to in the first subparagraph shall inform the relevant competent authority of that other Member State about the carrying out of those activities.

7 Where, before 19 July 2016, an operator referred to in paragraph 4 maintains, in accordance with the repealed acts referred to in paragraph 1, a breeding book with a specific section where purebred breeding animals of a breed of the porcine species from another Member State or a third country having specific characteristics distinguishing them from the population of that breed covered by the breeding programme carried out by that operator are entered, that operator may continue to maintain that specific section.

Article 65

Amendments to Regulation (EU) No 652/2014

Article 30 of Regulation (EU) No 652/2014 is amended as follows:

- (1) the heading is replaced by the following:

European Union reference laboratories and centres;
- (2) paragraph 1 is replaced by the following:
 1. Grants may be awarded to the European Union reference laboratories referred to in Article 32 of Regulation (EC) No 882/2004 and to the European Union reference centres referred to in Article 29 of Regulation (EU) 2016/1012 of the European Parliament and of the Council⁽¹⁾ for the costs that they incur in implementing the work programmes approved by the Commission.;
- (3) in paragraph 2, point (a) is replaced by the following:
 - (a) costs of personnel, regardless of their status, directly involved in activities of the laboratories or centres which are carried out in their capacity as European Union reference laboratory or centre.;

Article 66

Amendments to Directive 89/608/EEC

Directive 89/608/EEC is amended as follows:

- (1) the title is replaced by the following:

Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary matters;
- (2) Article 1 is replaced by the following:

Article 1

The Directive lays down the ways in which the competent authorities responsible in the Member States for monitoring legislation on veterinary matters shall cooperate with those in the other Member States and with the relevant Commission departments in order to ensure compliance with such legislation.;
- (3) in Article 2(1), the second indent is deleted;
- (4) in Article 4(1), the first indent is replaced by the following:

- communicate to the applicant authority all information, attestations, documents or certified copies thereof in its possession or which it can obtain as prescribed in paragraph 2 and which are such as to enable it to check that the provisions laid down in legislation on veterinary matters have been complied with,;

(5) Article 5(1) is replaced by the following:

1. At the request of the applicant authority, the requested authority shall, while observing the rules in force in the Member State in which it is situated, notify the applicant authority or have it notified of all instruments or decisions which emanate from the competent authorities and concern the application of legislation on veterinary matters.;

(6) Article 7 is replaced by the following:

Article 7

At the request of the applicant authority, the requested authority shall supply to it any relevant information in its possession or which it obtains in accordance with Article 4(2), in particular in the form of reports and other documents or certified copies of or extracts from such reports or documents, concerning operations actually detected which appear to the applicant authority to be contrary to legislation on veterinary matters.;

(7) Article 8(2) is replaced by the following:

2. Where they consider it useful in connection with compliance with the legislation on veterinary matters, the competent authorities of each Member State shall:
 - a as far as possible keep the watch referred to in Article 6 or arrange for such watch to be kept;
 - b communicate to the competent authorities of the other Member States concerned as soon as possible all available information, in particular in the form of reports and other documents or copies of or extracts from such reports or documents, concerning operations which are or appear to them to be contrary to legislation on veterinary matters, and particularly the means or methods used to carry out such operations.;

(8) Article 9 is replaced by the following:

Article 9

- 1 The competent authorities of each Member State shall communicate to the Commission as soon as it is available to them:
 - a any information they consider useful concerning:
 - goods which have been or are suspected of having been the subject of transactions contrary to legislation on veterinary matters,
 - the methods or processes used or suspected of having been used to contravene such legislation;
 - b any information on deficiencies of, or lacunae in, the said legislation which application thereof has revealed or suggested.
- 2 The Commission shall communicate to the competent authorities of each Member State, as soon as it is available to it, any information which is such as to enable compliance with legislation on veterinary matters to be enforced.;

- (9) Article 10 is amended as follows:
- (a) in paragraph 1, the introductory phrase is replaced by the following:
 - 1. Where the competent authorities of a Member State become aware of operations which are, or appear to be, contrary to the rules on veterinary matters and which are of particular interest at Union level, and in particular;
 - (b) paragraph 3 is replaced by the following:
 - 3. Information relating to natural or legal persons shall be communicated as provided for in paragraph 1 only to the extent strictly necessary to enable operations which are contrary to legislation on veterinary matters to be noted.;
- (10) in Article 11, the introductory phrase is replaced by the following:
- The Commission and the Member States meeting within the Standing Veterinary Committee shall;
- (11) in Article 15(2), the first subparagraph is replaced by the following:
- 2. Paragraph 1 shall not impede the use of information obtained pursuant to this Directive in any legal actions or proceedings subsequently instituted for failure to comply with legislation on veterinary matters on or in the prevention and discovery of irregularities detrimental to Union funds..

Article 67

Amendments to Directive 90/425/EEC

Directive 90/425/EEC is amended as follows:

- (1) the title is replaced by the following:

Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market;
- (2) in Article 1, the second paragraph is deleted;
- (3) Article 2 is amended follows:
 - (a) point 2 is deleted;
 - (b) point 6 is replaced by the following:
 - 6. “competent authority” shall mean the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;;
- (4) in Article 3(1), the second subparagraph of point (d) is replaced by the following:

Those certificates or documents, issued by the official veterinarian responsible for the holding, centre or organisation of origin must accompany the animals and products to their destination.;
- (5) Article 4 is amended as follows:

- (a) in paragraph 1, point (a) is replaced by the following:
 - (a) the holders of livestock and products referred to in Article 1 comply with the national or Union health requirements referred to in this Directive at all stages of production and marketing;;
 - (b) paragraph 3 is replaced by the following:
 - 3. Member States of dispatch shall take the appropriate measures to penalise any infringement of veterinary legislation by natural or legal persons where it is found that Union rules have been infringed, and in particular where it is found that certificates, documents or identification marks do not correspond to the status of the animals or to their holdings of origin or to the actual characteristics of the products.;
- (6) Article 19 is deleted;
- (7) in Annex A, Chapter II is deleted.

Article 68

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 66 and 67 by 1 November 2018. They shall immediately communicate the text of those measures to the Commission.

When Member States adopt those measures, they shall contain a reference to this Regulation or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Regulation shall be construed as references to this Regulation. Member States shall determine how such reference is to be made and how that statement is to be formulated.

Article 69

Entry into force and applicability

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 1 November 2018.

Article 65 shall apply from 19 July 2016.

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

Done at Strasbourg, 8 June 2016.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

A.G. KOENDERS

Status: This is the original version (as it was originally adopted).

- (1) 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](#)).’;