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### **INFORMATION NOTE**

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the zootechnical and genealogical conditions for trade in and imports into the Union of breeding animals and their germinal products
	<ul> <li>Outcome of the European Parliament's first reading</li> </ul>
	(Strasbourg, 11 to 15 April 2016)

## I. INTRODUCTION

The Committee on Agriculture and Rural Development submitted 196 amendments (amendments 1-196) to the proposal for a Regulation.

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure <sup>1</sup>, a number of informal contacts took place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

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7865/16 JDC/cc 1
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OJ C 145, 30.6.2007, p.5

In this context, the Committee submitted a further compromise amendment (amendment 197) to the proposal for a Regulation. This amendment had been agreed during the informal contacts referred to above and was intended to supersede the Committee's original 196 amendments.

In addition, the Committee submitted two amendments to the draft legislative resolution of the Parliament (amendments 198 and 199). These two amendments referred to a different but closely related Ordinary Legislative Procedure proposal for a Directive<sup>2</sup> whose content, according to the agreement reached during the above-mentioned informal contacts, was to be incorporated into the Regulation. Amendment 199 stated that the Parliament would therefore consider that the proposal for a Directive had lapsed.

In addition, the ENF political group submitted two amendments to the proposal for a Regulation (amendments 200 and 201).

#### II. VOTE

When it voted on 12 April 2016, the plenary adopted the compromise amendment 197 as well as the two amendments (198 and 199) to the legislative resolution. No other amendments were adopted.

The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto<sup>3</sup>.

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position. The act would then be adopted in the wording which corresponds to the Parliament's position.

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7865/16 JDC/cc 2 DRI **EN** 

Proposal for a Directive of the European Parliament and of the Council amending Directives 89/608/EEC, 90/425/EEC and 91/496/EEC as regards references to zootechnical legislation (COD 2014/0033).

The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol " " indicates deleted text.

# Breeding animals and their germinal products \*\*\*I

European Parliament legislative resolution of 12 April 2016 on the proposal for a regulation of the European Parliament and of the Council on the zootechnical and genealogical conditions for trade in and imports into the Union of breeding animals and their germinal products (COM(2014)0005 - C7-0032/2014 - 2014/0032(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2014)0005 -2014/0032(COD)),
- having regard to the Commission proposal to Parliament and the Council (COM(2014)0004 -2014/0033(COD)),
- having regard to Article 294(2) and Articles 42 and 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0032/2014),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 25 March 2014<sup>4</sup>,
- after consulting the Committee of the Regions,
- having regard to the undertaking given by the Council representative by letter of 18 December 2015 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rule 59 of its Rules of Procedure,
- having regard to the report of the Committee on Agriculture and Rural Development and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0288/2015),
- 1. Adopts its position at first reading hereinafter set out;
- 2. Considers that, due to the incorporation of the content of Commission proposal COM (2014)0004 into that position, legislative procedure 2014/0033(COD) has lapsed;
- 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
- 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

OJ C 226, 16.7.2014, p. 70.

# P8\_TC1-COD(2014)0032

Position of the European Parliament adopted at first reading on 12 April 2016 with a view to the adoption of Regulation (EU) 2016/... of the European Parliament and of the Council 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)

## THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 42 and Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>5</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>6</sup>,

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<sup>&</sup>lt;sup>5</sup> OJ C 226, 16.7.2014, p. 70.

Position of the European Parliament of 12 April 2016.

## Whereas:

- The breeding of animals of the bovine, porcine, ovine, caprine and equine species occupies, in economic and social terms, a strategic place in Union agriculture and contributes to the Union's cultural heritage. This agricultural activity, which contributes to food security in the Union, is a source of income for the agricultural community. The breeding of animals of those species is best promoted by encouraging the use of purebred breeding animals or hybrid breeding pigs of recorded high genetic quality.
- (2) Consequently, as part of their agricultural policy, Member States have consistently endeavoured to promote the production of livestock with particular genetic characteristics by setting standards, sometimes doing so through public investment. Disparities between those standards have the potential to create technical barriers to trade in breeding animals and their germinal products, as well as technical barriers to their entry into the Union.

The legal framework for Union law on the breeding of purebred breeding animals of the bovine, porcine, ovine, caprine and equine species and hybrid breeding pigs is provided by Council Directives 88/661/EEC<sup>7</sup>, 89/361/EEC<sup>8</sup>, 90/427/EEC<sup>9</sup>, 91/174/EEC<sup>10</sup>, 94/28/EC<sup>11</sup> and 2009/157/EC<sup>12</sup>. The aim of those Directives *was* to develop livestock breeding in the Union, while at the same time regulating the trade in breeding animals and their germinal products and their *entry* into the Union, thereby maintaining the competitiveness of the Union *animal* breeding *sector*.

Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species (OJ L 382, 31.12.1988, p. 36).

Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ L 153, 6.6.1989, p. 30).

Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae (OJ L 224, 18.8.1990, p. 55).

Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals and amending Directives 77/504/EEC and 90/425/EEC (OJ L 85, 5.4.1991, p. 37).

<sup>11</sup> Council Directive 94/28/EC of 23 June 1994 laying down the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species (OJ L 178, 12.7.1994, p. 66).

<sup>12</sup> Council Directive 2009/157/EC of 30 November 2009 on pure-bred breeding animals of the bovine species (OJ L 323, 10.12.2009, p. 1).

- (4) Council Directives 87/328/EEC<sup>13</sup>, 90/118/EEC<sup>14</sup> and 90/119/EEC<sup>15</sup> were adopted to prevent Member States from maintaining or adopting national rules relating to the acceptance for breeding purposes of breeding animals of the bovine and porcine species and the production and use of their semen, oocytes and embryos *which could* constitute a prohibition or restriction on trade or an obstacle thereto whether in the case of natural *service*, artificial insemination or collection of semen, oocytes or embryos.
- On the basis of Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 91/174/EEC, 94/28/EC and 2009/157/EC, the Commission, after consulting Member States through the Standing Committee on Zootechnics established in accordance with Council Decision 77/505/EEC<sup>16</sup>, adopted a number of Decisions laying down species-specific criteria for the approval or recognition of breeding organisations and breeders' associations, *for* the entry of breeding animals in herd-books, flock-books and stud-books, *for* the acceptance of *purebred breeding* animals of the ovine and caprine species for breeding animals of the bovine, porcine, ovine and caprine species, and *for* the establishment of pedigree *or zootechnical* certificates for trade in breeding animals and their germinal products.

7865/16 JDC/cc 7
ANNEX DRI **EN** 

Council Directive 87/328/EEC of 18 June 1987 on the acceptance for breeding purposes of pure-bred breeding animals of the bovine species (OJ L 167, 26.6.1987, p. 54).

Council Directive 90/118/EEC of 5 March 1990 on the acceptance of pure-bred breeding pigs for breeding (OJ L 71, 17.3.1990, p. 34).

Council Directive 90/119/EEC of 5 March 1990 of hybrid breeding pigs for breeding (OJ L 71, 17.3.1990, p. 36).

Council Decision 77/505/EEC of 25 July 1977 setting up a Standing Committee on Zootechnics (OJ L 206, 12.8.1977, p. 11).

- (6) The Commission also established a list of breeding bodies in third countries and the model pedigree *or zootechnical* certificates for *entry* into the Union of breeding animals and their semen, oocytes and embryos.
- (7) Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 91/174/EEC, 94/28/EC and 2009/157/EC are largely similar in structure and content. Several of those Directives have been amended over time. In the interests of the simplicity and consistency of Union law, it is appropriate to streamline the Union rules laid down in *those Directives*.
- (8) Over the last twenty years, the Commission has had to respond to a significant number of complaints, raised by breeders and *operators carrying out* breeding *programmes*, in relation to the national transposition and interpretation of Union *legal acts* on *the* breeding of animals in different Member States. To ensure the uniform application of Union rules on breeding animals and to avoid obstacles to trade in breeding animals and their germinal products resulting from divergences in the national transposition of *those* Directives, *the* zootechnical and genealogical conditions for trade in breeding animals and their germinal products and their *entry* into the Union should be laid down in a Regulation.

- (9) In addition, experience has shown that, in order to facilitate the application of the rules provided for in those Directives, more precise wording needs to be used in a number of their provisions, along with consistent terminology *that is standard across all Member States*. In the interests of clarity and consistency of Union law, it is also appropriate to provide for more definitions, *including a definition of "breed"*.
- (10) Efforts to achieve competitiveness in the animal breeding sector should not lead to the disappearance of breeds with characteristics that are adapted to specific biophysical contexts. If their population size is too small, local breeds could be at risk of losing genetic diversity. As an important part of the agricultural biodiversity, animal genetic resources provide an essential basis for the sustainable development of the livestock sector and offer opportunities to adapt animals to changing environments, production conditions and market and consumer demands. Union legal acts on the breeding of animals should thus contribute to the preservation of animal genetic resources, to the protection of a biodiversity and to the production of typical quality regional products that rely on the specific hereditary characteristics of local breeds of domestic animals. Union legal acts should also promote viable breeding programmes for the improvement of breeds, and particularly in the case of endangered breeds or autochtonous breeds which are not commonly found in the Union, for the preservation of breeds and the preservation of the genetic diversity within and between breeds.

(11) Through selection and breeding significant progress has been achieved in the development of traits related to the productivity of farmed animals, leading to reduced production costs at farm level. However, this has, in some cases, led to undesirable side effects, raising concerns in society about animal welfare and environment-related issues. The application of genomics and the use of advanced information technologies such as "Precision livestock farming" – which allows large data sets on alternative traits, directly or indirectly related to animal welfare and sustainability issues, to be recorded – hold considerable potential to address concerns in society and achieve the objectives of sustainable animal breeding in terms of improved resource efficiency and the enhanced resilience and robustness of animals. The collection of data on these alternative traits should gain in importance within the framework of breeding programmes and should be given greater prominence in the definition of selection objectives. In this context, genetic resources of endangered breeds should be considered to be a reservoir of genes that can potentially contribute to achieving these animal welfare and sustainability goals.

- (12) This Regulation should apply to breeding animals of the bovine, porcine, ovine, caprine and equine species and their germinal products where it is intended that those animals or the offspring resulting from those germinal products be entered as purebred breeding animals in a breeding book or registered as hybrid breeding pigs in a breeding register, in particular with a view to trading within the Union, including within a Member State, or the entry into the Union of those breeding animals and their germinal products.
- (13) The term "breeding animal" or "purebred breeding animal" should not be understood as only covering animals which still possess their reproductive function. Indeed, castrated animals might contribute with their genealogical and zootechnical records to the assessment of the genetic quality of the breeding population and thus to the integrity of the rankings of breeding animals based on those results. Depending on the objectives of the breeding programme, a lack of or loss of data resulting from the explicit exclusion of castrated animals from entry in a breeding book or register would be likely to bias the results of the assessment of the genetic quality of breeding animals that are genetically related to those castrated animals.

- The aim of the rules on purebred breeding animals laid down in this Regulation shouldbe to grant access to trade based on agreed principles applicable to the recognition of breed societies managing breeds and the approval of their respective breeding programmes. This Regulation should also lay down rules governing the entry of purebred breeding animals in the main section of *the* breeding books *and*, *wherethey exist*, *in* the different *merit* classes of the main section. *It should also lay down* rules for performance testing and genetic evaluation and rules for the acceptance of breeding animals for breeding as well as the content of the zootechnical certificates.
- Similarly, the aim of the rules on hybrid breeding pigs laid down in this Regulation shouldbe to grant access to trade based on agreed principles applicable to the recognition of breeding operations managing different *breeds*, *lines or* crosses of *the porcine species* and the approval of their breeding programmes. This Regulation should also lay down rules governing the *registration* of hybrid breeding pigs in *breeding* registers. *It should also* lay down rules for performance testing *and* genetic evaluation and rules for the acceptance of hybrid breeding pigs for breeding as well as the content of the zootechnical certificates.

- (16) It is not appropriate for issues relating to cloning to be addressed in this Regulation.
- Since the objectives of this Regulation, namely to ensure a harmonised approach to trade in breeding animals and their germinal products and their *entry* into the Union, as well as to the official controls necessary to be performed on breeding programmes carried out by breed societies and breeding operations, cannot be sufficiently achieved by the Member States but can rather, by reason of its effect, complexity, *transborder* and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as referred to in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- The quality of the services provided by breed societies and breeding operations and the way that they evaluate and classify *breeding* animals has an impact on the *quality and* accuracy of zootechnical and genealogical information collected or determined in respect of those animals and their valueon the market. Accordingly, rules should be laid down for the recognition of breed societies and breeding operations and the approval of their breeding programmes based on harmonised Union criteria. Those rules should also cover their supervision by the competent authorities of Member States in order to ensure that the rules established by breed societies and breeding operations do not give rise to disparities between breeding programmes, thereby creating technical barriers to trade in the Union.

- (19) Similar procedures to those laid down in Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 91/174/EEC, 94/28/EC and 2009/157/EC for listing recognised breed societies and breeding operations, including the updating, transmission and publication of the lists, should be provided for in this Regulation.
- *(20)* Breeding programmes on purebred breeding animals are carried out with the overall aim of improving, in a sustainable manner, the production and non-production traits of animals of a breed or to preserve a breed. These breeding programmes should cover a sufficiently large number of purebred breeding animals kept by breeders which, through breeding and selection, promote and develop desirable traits in those animals or guarantee the preservation of the breed, in accordance with the objectives that are commonly accepted by the participating breeders. Likewise, breeding programmes concerning hybrid breeding pigs are carried out with the purpose of developing desirable traits by deliberate crossbreeding between different breeds, lines or crosses of pigs. Breeding animals (purebred or hybrid) participating in a breeding programme are entered in a breeding book or register, including information on their ascendants, and, depending on the breeding objectives set out in the breeding programme, undergo performance testing or any other assessment that results in the recording of data on traits in relation to the objectives of that breeding programme. Where specified in the breeding programme, genetic evaluation is carried out to estimate the breeding value of the animals which may be ranked accordingly. Those breeding values and performance test results, as well as the genealogical information, form the basis for breeding and selection.

(21) The right to be recognised as a breed society or breeding operation which meets the established criteria should be a fundamental principle of the Union law on the breeding of animals and of the internal market. The protection of the economic activity of an existing recognised breed society should *not* justifythe refusal by the competent authority of the recognition of a further breed society for the same breed or violations of the principles governing the internal market. The same applies to the approval of a further breeding programme, or to the approval of the geographical extension of an existing breeding programme, which is carried out on the same breed, or on breeding animals of the same breed that can be recruited from the breeding population of a breed society that is already carrying out a breeding programme on that breed. However, where in a Member State one or more recognised breed societies are already carrying out an approved breeding programme on a given breed, the competent authority of that Member State should, in certain specific cases, be allowed to refuse to approve a further breeding programme for the same breed, even if that breeding programme complies with all the requirements necessary for approval. One reason for refusal could be that the approval of a further breeding programme for the same breed would compromise the preservation of that breed or the genetic diversity within that breed in that Member State. The preservation of that breed might, in particular, be compromised as a result of the fragmentation of the breeding population, possibly leading to higher inbreeding, to increased incidences of observed genetic defects, to a loss in the selection potential or to reduced access of the breeders to purebred breeding animals or the germinal products thereof. Another reason for refusal could be linked to inconsistencies in the defined breed characteristics or in the main objectives of those breeding programmes. Indeed, independently of the aim of the breeding programme, namely the preservation of the breed or the improvement of the breed, the competent authority should be allowed to refuse approval for a further breeding programme in respect of the same breed where differences in the main objectives of the two breeding programmes, or in essential traits of the breed characteristics defined in those breeding programmes, would result in a loss of efficiency in terms of genetic progress in those objectives or in those traits or any correlated traits, or where an exchange of animals between both breeding populations would bear a risk of out selection or out breeding of those essential traits in the initial breeding population. Finally, in the case of an endangered breed or an autochthonous breed not commonly found in one or more of the territories of the Union, a competent

authority should also be allowed to refuse the approval of a further breeding programme for the same breed on the grounds that that further breeding programme would impede the effective implementation of the existing breeding programme, in particular due to a lack of coordination, or exchange, of genealogical and zootechnical information resulting in a failure to benefit from the common evaluation of data collected on that breed. In the event of a refusal to approve a breeding programme, the competent authority should always provide a reasoned explanation to the applicants and give them the right to appeal against that refusal.

- (22) Breeders should have the right to design and implement a breeding programme for their own use, without that breeding programme having to be approved by the competent authorities. However, each Member State or its competent authorities should retain the possibility of regulating those activities, in particular as soon as such a breeding programme leads to business transactions in respect of breeding animals or the germinal products thereof or jeopardises an already existing approved breeding programme for that same breed.
- (23) If the aim of the breeding programme is to preserve the breed, the requirements of the breeding programme could be complemented by ex situ and in situ conservation measures or any other tools for monitoring the status of the breed that would ensure a longterm, sustainable conservation of that breed. It should be possible for those measures to be laid down in the breeding programme.
- (24) Breeders' associations, breeding organisations, including breeding organisations which are private undertakings, or public bodies should only be recognised as breed societies when they have breeders participating in their breeding programmes and when they ensure that those breeders have free choice in the selection and breeding of their purebred breeding animals, the right to have the offspring descended from those animals entered in their breeding books and the possibility of owning those animals.

(25) Prior to the implementation of changes in the approved breeding programme, a breed society or breeding operation should submit those changes to the competent authority that has recognised that breed society or breeding operation. In order to avoid an unnecessary administrative burden for the competent authority and the breed society or breeding operation, only those changes which are likely to substantially affect the breeding programme should be communicated by the breed society or breeding operation to the competent authority. Those changes should, in particular, cover the extension of the geographical territory, changes in the aim or in the selection and breeding objectives of the breeding programme, changes in the description of the breed characteristics or in the delegation of tasks to third parties, as well as major changes in the system for recording pedigrees or in the methods used for performance testing and genetic evaluation and any other changes which the competent authority considers to be a substantial modification of the breeding programme. Irrespective of the mandatory submission of significant changes to the competent authority, the breed society or breeding operation should, at the request of the competent authority, provide it with an up-to-date version of the breeding programme.

- Where there is a recognised need to maintain or promote the development of a breed on a certain territory, or in the case of an endangered breed, the competent authority should itself have the possibility to carry out, on a temporary basis, a breeding programme for that breed, provided that no breeding programme is already effectively in place for that breed. A competent authority carrying out such a breeding programme should, however, no longer have that possibility if it is possible for the breeding programme to be handed over to an operator fulfilling the requirements necessary for the proper implementation of that breeding programme.
- Because the preservation of *endangered* breeds requires the setting up and recognition of breed societies with a limited number of breeding animals *participating* in their breeding *programmes*, the *size* of *the* breeding *population* should not, in general, be *considered to be* an essential requirement for the recognition of breed societies *managing endangered breeds* or for the approval of *their* breeding programmes, particularly since the recognition is carried out nationally.

- (28) Specific rules, in particular those on the upgrading from the supplementary section into the main section and on derogations for the performance testing and genetic evaluation, should be laid down in this Regulation to take account of the specific status of endangered breeds.
- Council Decision 93/626/EEC<sup>17</sup>, the objectives of which are in particular the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. That Convention stipulates that the contracting parties have sovereign rights to their biological resources and are responsible for the conservation of their biological diversity and the sustainable use of their biological resources. The Union is also a party to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, approved by Council Decision 2014/283/EU<sup>18</sup>. This Regulation should therefore take into account, where applicable, the Convention on Biological Diversity, as well as the Nagoya Protocol and should apply without prejudice to Regulation (EU) No 511/2014 of the European Parliament and of the Council<sup>19</sup>.

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Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJ L 309, 13.12.1993, p. 1).

Council Decision 2014/283/EU of 14 April 2014 on the conclusion, on behalf of the European Union, of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (OJ L 150, 20.5.2014, p. 231).

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (OJ L 150, 20.5.2014, p. 59).

- Breed societies and breeding operations recognised in one Member State should have the possibility to implement their approved breeding programme in one or more other Member States in order to ensure the best possible use, within the Union, of breeding animals of high genetic value . To this end a simplified notification procedure should ensure that the competent authority in the other Member State is aware of the intention to carrying out of crossborder activities. However, seasonal movements of breeding animals within the borders of a Member State or taking place over several Member States should not mandatorily entail the extension of the geographical territory.
- (31) Cross-border cooperation between breed societies and between breeding operations which wish to engage therein should be facilitated, while ensuring free entrepreneurship and the removal of obstacles to the free movement of breeding animals and their germinal products.

- (32) Since a competent authority might have to approve several breeding programmes carried out by one breed society or breeding operation it has recognised, and since a competent authority might have to approve the extension on its territories of breeding programmes carried out by a breed society or breeding operation recognised in another Member State, the recognition of the breed society or breeding operation should be separated from the approval of its breeding programmes. However, when evaluating an application for recognition as a breed society or breeding operation, the competent authority should also be provided with an application for the approval of at least one breeding programme.
- (33) From various complaints the Commission has had to deal with in previous years, it appears that this Regulation should provide for clear rules governing the relationship between the breed society that establishes a filial breeding book for a particular breed of purebred breeding animals of the *equine* species and the breed society that claims to have established the breeding book of the origin of that breed.

- It is necessary to clarify the relationship between breeders and breed societies, in particular to ensure their right to participate in the breeding programme within the geographical territory for which it is approved and, where membership is provided for, to ensure that those breeders have the right to be members. Breed societies should have rules in place to settle disputes with breeders participating in their breeding programmes and to ensure that those breeders are treated equally. They should also set out their own rights and obligations as well as those of breeders participating in their breeding programmes.
- (35) Breeders whose breeding animals are moved seasonally within the border of a Member State or an area straddling national borders should have the right to continue to participate in the breeding programme as long as the headquarters of their holding is located within the geographical territory of that breeding programme.
- (36) The specific situation prevailing in the hybrid breeding pig sector should be taken into account in this Regulation. Most private undertakings in the hybrid breeding pig sector have closed production systems and manage their own breeding stock. Provision should therefore be made for a number of derogations for these undertakings, in particular as regards the participation by breeders in the breeding programme and the right to register hybrid breeding pigs in the breeding registers.

- (37) The definition of "hybrid breeding pig" covers animals from all levels in the breeding and selection pyramid, that are used for optimising cross-breeding by combining specific assets of their different genotypes and exploiting heterosis effects. Depending on the level of the breeding and selection pyramid, "hybrid breeding pig" covers breeds, lines or crosses. Thus, not all animals are necessarily "hybrid" in the traditional sense.
- Experience gained, particularly in the application of Directive 90/427/EEC, and to a lesser extent Directives 89/361/EEC and 2009/157/EC, indicates that more precise rules are required to settle effectively disputes between breeders on the one hand and breed societies on the other hand, based on clearly established rules of procedure and described rights and duties of breeders. This is best achieved if the disputes are settled within the legal system of the Member State where they arise.
- (39) Breed societies which establish and maintain breeding books for purebred breeding animals of the bovine, porcine, ovine, caprine and equine species, as well as breeding operations *other than private undertakings operating in closed production systems*, which establish and maintain breed*ing* registers for hybrid breeding pigs, should enter breeding animals in their breeding books or register them in their breed*ing* registers without discrimination as regards the Member State of origin of the animals or their owners and, where this is provided for in the breeding programme, should classify those animals according to their merits.

- (40) Breed societies should also be allowed to establish supplementary sections for the recording of animals which do not meet the parentage criteria but which are judged by the breed societies to comply with the breed characteristics laid down in the breeding programme of the breed concerned, with the aim of subsequently breeding those animals with purebred breeding animals belonging to the breed covered by the breeding programme in order for the progeny to be upgraded into the main section of the breeding book. The specific rules for upgrading the progeny of those animals into the main section of a breeding book should be laid down at Union level.
- through the female line, except in the case of equine species. However, for an endangered breed of the bovine, porcine, ovine and caprine species and for "hardy" sheep breeds for which there are not enough purebred male reproductive animals, Member States should have the possibility to authorise the breed societies to apply less stringent rules for upgrading the progeny of those animals recorded in supplementary sections to the main section of the breeding book in order to avoid the further deterioration of the genetic diversity of those breeds. Likewise, special rules should be provided for to allow for the reconstruction of breeds which have disappeared or are in serious danger of disappearing. Member States making use of such derogations should carefully evaluate the risk status of those breeding populations and ensure secure management of genetic ressources.

- Where there is a need to create a new breed by associating characteristics from purebred breeding animals from different breeds or by assembling animals with a sufficient degree of physical resemblance which already reproduce with sufficient genetic stability for them to be considered as having evolved into a new breed, breed societies should be given the possibility of establishing breeding books and of carrying out breeding programmes on those new breeds.
- (43) Nothing in this Regulation should prevent animals recorded in a supplementary section of a breeding book of a certain breed from falling under the scope of the commitments of the agri-environment-climate measure referred to in Article 28 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council<sup>20</sup> and thus being eligible for support by the national or regional authorities under their rural development programmes.
- (44) For purebred breeding animals of the equine species, breed societies should be able to lay down rules in their breeding programmes that prohibit or limit the use of certain reproduction techniques and of certain purebred breeding animals, including the use of their germinal products. The breed societies should, for example, be able to request that the offspring result from natural mating only. Breed societies making use of this prohibition or limitation should lay down those rules in their breeding programme in accordance with the rules set out by the breed society which is maintaining the breeding book of origin.

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Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

- *(45)* **Purebred** breeding animals entered in breeding books **should be** identified in accordance with Regulation (EU) .../... of the European Parliament and of the Council $^{21*}$ .
- In the case of purebred breeding animals of the equine species, Regulation (EU)  $\ldots / \ldots^{**}$ (46)provides that the competent authorities in the field of animal health shall issue, for animals of the equine species, a single lifetime identification document which is to be further specified by the Commission through delegated acts. In order for the zootechnical certificate to be streamlined as far as possible with that single lifetime identification document as regards content and administrative procedure, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of the format and content of a single lifetime identification document for animals of the equine species.

7865/16 JDC/cc 27 **ANNEX** DRI EN

<sup>21</sup> Regulation (EU) .../... of the European Parliament and of the Council of ... on transmissible animal diseases and amending and repealing certain acts in the area of animal health ("Animal Health Law") (OJ L ...).

OJ: please insert the reference number and the corresponding footnote for the Regulation contained in PE-CONS 7/16.

OJ: please insert the reference number for the Regulation contained in PE-CONS 7/16.

- (47) The eligibility of purebred breeding animals of the equine species to compete internationally is regulated by international private agreements. Considering the international dimension of the equine sector, the Commission, when preparing and drawing up the relevant delegated and implementing acts, should take into account those agreements, so as to maintain the eligibility of those purebred breeding animals of the equine species to compete at international level.
- (48) The acceptance of breeding animals for breeding purposes, and in particular for natural service or assisted reproduction, should be regulated at Union level to prevent obstacles to trade, in particular where such breeding animals have undergone performance testing or genetic evaluation carried out in accordance with the rules laid down in this Regulation and in particular in Annex III.
- (49) It is understood that Member States or their competent authorities should not use this Regulation in order to prohibit, restrict or impede the use of purebred breeding animals or germinal products thereof for the production of animals not intended to be entered or registered as breeding animals in a breeding book or breeding register.

- (50) While the rules for performance testing and genetic evaluation have been established at Union level for breeding animals of the bovine, porcine, ovine and caprine species which are tested for a *certain* number of traits, the *numerous* requirements for different breeds, uses and selections of purebred breeding animals of the equine species have, to date, prevented their harmonisation. Instead, breed specific rules for performance testing and genetic evaluation are currently established by the studbook of the origin of the breed.
- In order to take account of technical developments, scientific advances or the need to preserve valuable genetic resources, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex III to this Regulation.
  In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should also be conferred on the Commission, enabling it to lay down uniform and more detailed rules for performance testing and for the genetic evaluation of purebred breeding animals of the bovine, ovine and caprine species.

(52) It should be possible for performance testing or genetic evaluation to be carried out by a third party designated by the breed society or the breeding operation or a public body including an authority excercising this mission as a sovereign task. That third party could be authorised and evaluated by the competent authority in the context of the approval of the breeding programme. A breed society or breeding operation outsourcing performance testing or genetic evaluation should, unless otherwise decided by the relevant Member State or its competent authorities, remain responsible for ensuring compliance with the requirements applicable to those activities and should specify the designated third party in its breeding programme.

*(53)* Depending inter alia on the species or on the breed, there might be a need for the harmonisation or the improvement of the methods of performance testing and genetic evaluation of purebred breeding animals used by breed societies or by the third parties designated by *them*. To ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission enabling it to designate European Union reference centres. In order, where necessary, to modify the task of those reference centres, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. Those *European Union* reference centres should qualify for Union financial support in accordance with Regulation (EU) No 652/2014 of the European Parliament and of the Council<sup>22</sup>. In the case of purebred breeding animals of the bovine species, *those tasks are* carried out by the Interbull Centre, *a permanent* subcommittee of the International Committee for Animal Recording (ICAR), which is the European Union reference *centre* designated by Council Decision 96/463/EC<sup>23</sup>.

<sup>22</sup> Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

<sup>23</sup> Council Decision 96/463/EC of 23 July 1996 designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species (OJ L 192, 2.8.1996, p. 19).

(54) In addition, in order to provide support to breed societies managing endangered breeds, where there is a recognised need, implementing powers should be conferred on the Commission, enabling it to designate European Union reference centres charged with the specific task of promoting the establishment or harmonisation of methods used by those breed societies. In order, where necessary, to modify the task of those reference centres, the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission. When designating these centres and describing their tasks, the Commission should take duly into account the activities of the European Regional Focal Point for Animal Genetic Resources (ERFP) which has been established in the framework of the Global Plan of Action for Animal Genetic Resources in Europe of the Food and Agriculture Organization (FAO). The methods established by these centres should not be binding.

- (55) Breeders who are participating in a breeding programme should have the right to receive zootechnical certificates for their breeding animals covered by that breeding programme and for the germinal products of those animals. Zootechnical certificates should accompany breeding animals or the germinal products thereof where they are traded or entered into the Union in view of an entry or registration of those animals or of the progeny produced from those germinal products in other breeding books or breeding registers. Zootechnical certificates should inform the breeder about the genetic quality and the pedigree of the acquired animal. Such certificates should, for example, be issued, where necessary, to accompany breeding animals for exhibition purposes or when they are placed in test stations or in artificial insemination centres.
- (56) It should be understood that this Regulation does not prohibit Member States or competent authorities from requiring that, when traded, the semen of purebred breeding animals of the bovine, porcine, ovine, caprine and equine species intended for artificial insemination in view of the production of animals that are not intended to become purebred breeding animals be accompanied by information on the quality and the pedigree of that animal. In general, by making the germinal products of breeding animals, and in particular their semen, and the related information on the zootechnical certificates also available for operators which reproduce animals without the intention of having their progeny entered in a breeding book, it is hoped that the competitiveness of the Union animal breeding sector could be improved.

The entry into the Union and the export to third countries of breeding animals and their germinal products is important for Union agriculture. The entry into the Union of breeding animals and their germinal products should therefore be carried out under conditions that are closely comparable to the rules applicable to trade in the Union.

However, breeding animals and their germinal products should only be entitled to entry in the main section of a breeding book or breeding register in the Union, if the level of controls carried out in the exporting third country ensures the same certainty of pedigree detailsand results of performance testing and genetic evaluation as in the Union and if the breeding bodies providing those details and results are included in a list maintained by the Commission. In addition, breeding bodies in third countries should, as a matter of reciprocity, accept breeding animals and their germinal products from the respective breed society or breeding operation recognised in the Union.

Council Regulation (EEC) No 2658/87<sup>24</sup> provides that a goods nomenclature, namely the 'Combined Nomenclature', or in abbreviated form 'CN', which meets at one and the same time the requirements of the Common Customs Tariff, the external trade statistics of the Community and other Union policies concerning the importation or exportation of goods, is to be established by the Commission. Annex I to that Regulation lists the CN codes for purebred breeding animals of the bovine, porcine, ovine, caprine and equine species and of bovine semen and indicates that they are exempt from the conventional rate of duties. In that case, those animals and their germinal products should be accompanied by the appropriate zootechnical certificate to support their classification as purebred breeding animals or germinal products thereof. In the case of purebred breeding animals, they should also be accompanied by a document indicating that they will be entered in a breeding book maintained by a breed society or registered in a breeding register maintained by a breeding operation.

7865/16 JDC/cc 35 ANNEX DRI **EN** 

Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

- (59)Upon entry *into* the Union, breeding animals and their germinal products undergo veterinary checks in accordance with Council Directives 91/496/EEC<sup>25</sup> and 97/78/EC<sup>26</sup>. In the case of *purebred breeding animals*, they should also undergo the necessary checks for the application of the exemption of the conventional rate of duty for purebred breeding animals.
- (60)It is necessary to lay down rules on official controls *performed for the verification of* compliance with the rules provided for in this Regulation and on other official activities carried out by the competent authorities in accordance with this Regulation that are adapted to the animal breeding sector. The competent authorities should have the possibility to carry out official controls on all operators that are subject to this Regulation, and in particular on breed societies, on breeding operations, on third parties carrying out performance testing or genetic evaluation and on breeders, and, if they issue zootechnical certificates, on semen collection and storage centres, embryo storage centres, and on embryo collection or production teams.

26

<sup>25</sup> Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56).

Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

- (61) Competent authorities should carry out official controls in order to verify compliance with the rules set out in this Regulation and the requirements laid down in the approved breeding programme. Those controls might include the inspection of equipment used for performance testing or the verification of the procedures put in place for recording zootechnical and genealogical data, or the examination of documents or systems used for storing and processing such data collected on breeding animals. That examination could take into account quality checks or control systems for ensuring the accuracy of the recorded data, such as parentage controls carried out in order to verify an animal's pedigree. The competent authorities might carry out official controls on the premises and offices and on the equipment of breeders, breed societies or breeding operations as well as on the breeding animals, or the germinal products collected from those breeding animals covered by the breeding programme.
- (62) Where, in this Regulation, reference is made to "other official activities", this should be interpreted as covering the recognition of breed societies and breeding operations, the approval of breeding programmes or the provision of assistance to other Member States and third countries.

- (63) For the effective application of Union rules on breeding animals and their germinal products laid down in this Regulation, it is necessary for the competent authorities of the Member States to cooperate with each other and to provide administrative assistance whenever necessary. Accordingly, general rules on administrative assistance and cooperation, similar to those currently set out in Title IV of Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>27</sup>, should be laid down, with the necessary adaptations, in this Regulation.
- (64) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt, where *there is evidence that widespread serious non-compliance with Union law on the breeding of animals is taking place in a third country*, special measures in order to limit the impact of such non-compliance.
- (65) The competent authorities of the Member States should also have the necessary powers to enforce zootechnical and genealogical rules on breeding animals laid down in this Regulation, including the suspension of *the* approval of a breeding programme or the withdrawal of the recognition of a breed society or breeding operation in the event of noncompliance with the rules laid down in this Regulation.

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Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

- (66) The Commission should carry out controls in Member States as appropriate, *inter alia* in the light of the results of the official controls carried out by Member States, to ensure the application of the rules laid down in this Regulation in all Member States.
- The Commission should carry out controls in third countries, as appropriate, with a view to establishing the *list* of third country *breeding bodies* from which *entry* into the Union of breeding animals and their semen, oocytes and embryos should be allowed, with a view to drawing up the conditions for *their entry into the Union and* with a view to obtaining *the zootechnical and genealogical* information relating to the functioning of *equivalence* agreements. The Commission should also carry out controls in third countries where any *recurring or emerging problem* in *relation to breeding animals or the germinal products thereof* so warrants.

- (68) The verification of compliance with the rules provided for in this Regulation through official controls is of fundamental importance to ensuring that, across the Union, the objectives of this Regulation are effectively achieved. Failures in a Member State's control system might in certain cases substantially hinder the achievement of those objectives and lead to situations of serious widespread non-compliance with those rules. The Commission should, therefore, be able to react to serious failures in a Member State's control system by adopting measures applicable until such time as the Member State concerned takes the necessary action to remedy the disruption. Such measures include the prohibition or the enforcement of special conditions on the trade of breeding animals or their germinal products or any other measures which the Commission deems appropriate to address that widespread infringement.
- (69) As Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 94/28/EC and 2009/157/EC are to be repealed and replaced by this Regulation, it is also necessary to repeal the Commission acts adopted pursuant to those Directives and, *where necessary*, to replace them by either delegated acts or implementing acts adopted pursuant to the respective powers conferred in this Regulation. Accordingly, those Commission acts should be repealed and, where necessary, replaced.

- (70) In order to ensure the proper application of this Regulation and to supplement it, or to amend Annexes to it, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of laying down the *requirements for* performance testing and genetic *evaluation*, the tasks of and requirements for European Union reference centres and the content and format of zootechnical certificates.
- When preparing and drawing up delegated acts, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of ... <sup>28\*</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as the Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts..

7865/16 JDC/cc 41 ANNEX DRI **EN** 

<sup>&</sup>lt;sup>28</sup> OJ C ...

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(72) In order to ensure uniform conditions for the implementation of the provisions of this Regulation concerning model forms for the information to be provided by Member States to the public on the list of recognised breed societies and breeding operations, the methods for the verification of the identity of purebred breeding animals, the performance testing and genetic evaluation, the designation of European Union reference centres, the model forms of the single lifetime identification document for equidae, the models for zootechnical certificates accompanying breeding animals and their germinal products, the recognition of equivalence of measures applied in third countries, serious disruptions in the control system of a Member State and the establishment of special measures regarding the entry into the Union of breeding animals and their germinal products, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>29</sup>. Where the Standing Committee on Zootechnics delivers no opinion, the Commission should not adopt the implementing act.

28.2.2011

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(73) The rules laid down in 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 to be replaced by the rules laid down in this Regulation and in delegated and implementing acts of the Commission adopted pursuant to the powers conferred in this Regulation. Accordingly, those legal acts should therefore be repealed.

The following Commission Decisions concerning inter alia species-specific criteria for the approval or recognition of breed societies and breeding operations, the entry of breeding animals in breeding books and the acceptance for breeding and artificial insemination, for performance testing and genetic evaluation were adopted pursuant to Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 94/28/EC and 2009/157/EC: Commission Decisions 84/247/EEC<sup>30</sup>, 84/419/EEC<sup>31</sup>, 89/501/EEC<sup>32</sup>, 89/502/EEC<sup>33</sup>, 89/504/EEC<sup>34</sup>, 89/505/EEC<sup>35</sup>, 89/507/EEC<sup>36</sup>, 90/254/EEC<sup>37</sup>, 90/255/EEC<sup>38</sup>, 90/256/EEC<sup>39</sup>, 90/257/EEC<sup>40</sup>, 92/353/EEC<sup>41</sup>, 96/78/EC<sup>42</sup> and 2006/427/EC<sup>43</sup>. This Regulation *should provide* for rules replacing those laid down in those Commission decisions.

Commission Decision 84/419/EEC of 19 July 1984 laying down the criteria for entering cattle in herd-books (OJ L 237, 5.9.1984, p. 11).

Commission Decision 89/501/EEC of 18 July 1989 laying down the criteria for approval and supervision of breeders' associations and breeding organizations which establish or maintain herd-books for pure-bred breeding pigs (OJ L 247, 23.8.1989, p. 19).

Commission Decision 89/502/EEC of 18 July 1989 laying down the criteria governing entry in herd-books for pure-bred breeding pigs (OJ L 247, 23.8.1989, p. 21).

Commission Decision 89/504/EEC of 18 July 1989laying down the criteria for approval and supervision of breeders' associations, breeding organizations and private undertakings which establish or maintain registers for hybrid breeding pigs (OJ L 247, 23.8.1989, p. 31).

Commission Decision 89/505/EEC of 18 July 1989 laying down the criteria governing entry in registers for hybrid breeding pigs (OJ L 247, 23.8.1989, p. 33).

Commission Decision 89/507/EEC of 18 July 1989 laying down methods for monitoring performance and assessing the genetic value of pure-bred and hybrid breeding pigs (OJ L 247, 23.8.1989, p. 43).

Commission Decision 90/254/EEC of 10 May 1990 laying down the criteria for approval of breeders' organizations and associations which establish or maintain flock-books for pure-bred breeding sheep and goats (OJ L 145, 8.6.1990, p. 30).

Commission Decision 90/255/EEC of 10 May 1990 laying down the criteria governing entry in flock-books for pure-bred breeding sheep and goats (OJ L 145, 8.6.1990, p. 32).

Commission Decision 90/256/EEC of 10 May 1990 laying down methods for monitoring performance and assessing the genetic value of pure-bred breeding sheep and goats (OJ L 145, 8.6.1990, p. 35).

Commission Decision 90/257/EEC of 10 May 1990 laying down the criteria for the acceptance for breeding purposes of pure-bred breeding sheep and goats and the use of their semen, ova or embryos (OJ L 145, 8.6.1990, p. 38).

Commission Decision 92/353/EEC of 11 June 1992 laying down the criteria for the approval or recognition of organizations and associations which maintain or establish studbooks for registered equidae (OJ L 192, 11.7.1992, p. 63).

Commission Decision 96/78/ECof 10 January 1996 laying down the criteria for entry and registration of equidae in stud-books for breeding purposes (OJ L 19, 25.1.1996, p. 39).

Commission Decision 84/247/EEC of 27 April 1984 laying down die criteria for the recognition of breeders' organizations and associations which maintain or establish herdbooks for pure-bred breeding animals of the bovine species (OJ L 125, 12.5.1984, p. 58).



methods and methods for assessing cattle's genetic value for pure-bred breeding animals of the bovine species (OJ L 169, 22.6.2006, p. 56).

Commission Decision 92/354/EEC of 11 June 1992 laying down certain rules to ensure coordination between organizations and associations which maintain or establish studbooks for registered equidae (OJ L 192, 11.7.1992, p. 66).

(76)The following Commission legal acts were adopted pursuant to Directives 88/661/EEC, 89/361/EEC, 90/427/EEC, 94/28/EC and 2009/157/EC: Commission Decisions 89/503/EEC<sup>45</sup>, 89/506/EEC<sup>46</sup>, 90/258/EEC<sup>47</sup>, 96/79/EC<sup>48</sup>, 96/509/EC<sup>49</sup>, **96/510/EC<sup>50</sup>** and 2005/379/EC<sup>51</sup>, and Commission Implementing Regulation (EU) 2015/262<sup>52</sup>. **This** Regulation should provide for rules replacing those laid down in those Commission legal acts.

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Commission Decision 89/503/EEC of 18 July 1989 laying down the certificate of purebred breeding pigs, their semen, ova and embryos (OJ L 247, 23.8.1989, p. 22).

<sup>46</sup> Commission Decision 89/506/EEC of 18 July 1989 laying down the certificate of hybrid breeding pigs, their semen, ova and embryos (OJ L 247, 23.8.1989, p. 34).

<sup>47</sup> Commission Decision 90/258/EEC of 10 May 1990 laying down the zootechnical certificates for pure-bred breeding sheep and goats, their semen, ova and embryos (OJ L 145, 8.6.1990, p. 39).

<sup>48</sup> Commission Decision 96/79/EC of 12 January 1996 laying down the zootechnical certificates of semen, ova and embryos from registered equidae (OJ L 19, 25.1.1996, p.

<sup>49</sup> Commission Decision 96/509/EC of 18 July 1996 laying down pedigree and zootechnical requirements for the importation of semen of certain animals (OJ L 210, 20.8.1996, p. 47).

<sup>50</sup> Commission Decision 96/510/EC of 18 July 1996 laying down the pedigree and zootechnical certificates for the importation of breeding animals, their semen, ova and embryos (OJ L 210, 20.8.1996, p. 53).

<sup>51</sup> Commission Decision 2005/379/EC of 17 May 2005 on pedigree certificates and particulars for pure-bred breeding animals of the bovine species, their semen, ova and embryos (OJ L 125, 18.5.2005, p. 15).

<sup>52</sup> Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae (Equine Passport Regulation) (OJ L 59, 3.3.2015, p. 1).

To ensure legal clarity and to avoid duplication, the Commission legal acts referred to in Recitals 74, 75 and 76 should be repealed from the date of application of this Regulation. In addition, the Commission should, at least 18 months before the date of application of this Regulation, adopt implementing acts laying down the model forms for the presentation of the information to be included in the list of recognised breed societies and breeding operations that is to be made public by the Member States, as well as the model forms for the zootechnical certificates for breeding animals and their germinal products. Those implementing acts should be applicable by the date of application of this Regulation.

*(78)* In order to ensure a smooth transition for breeders' organisations, breeding organisations, breeders' associations, private undertakings or other organisations or associations which have been approved or recognised with or without a limitation in time under the acts repealed by this Regulation and for the breeding programmes carried out by those operators, those operators and their breeding programmes should be deemed to be recognised or approved in accordance with this Regulation. Consequently, those operators should not be subject to the procedures for recognition, for approval and for notification of the extension of the geographical territory to other Member States set out in this Regulation, although the other provisions of this Regulation should apply to them. Member States should ensure that those operators comply with all the rules provided for in this Regulation in particular by carrying out risk-based official controls on them. In the event of non-compliance, the competent authorities should ensure that those operators take the necessary measures to remedy that non-compliance and, where necessary, suspend or withdraw the recognition of those operators or the approval of their breeding programmes.

The Commission recently adopted a proposal for a new Regulation on official controls and other official activities. That new Regulation is intended to repeal Regulation (EC) No 882/2004, Council Directive89/608/EEC53, Council Directive 90/425/EEC54, and Directives 91/496/EEC and 97/78/EC. It is also intended to incorporate, with the necessary adaptations, certain of the rules laid down in Regulation (EC) No 882/2004 and in those Directives. However, the breeding of animals is not intended to fall within the scope of that new Regulation. For legal clarity and certainty and pending the repeal of Directives 89/608/EEC, 90/425/EEC, 91/496/EEC and 97/78/EC by means of that new Regulation, it is necessary to delete the references to "zootechnical" from Directives 89/608/EEC and 90/425/EEC, while Directives 91/496/EEC and 97/78/EC do not require such amendment. Directives 89/608/EEC and 90/425/EEC should therefore be amended accordingly.

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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 and zootechnical matters (OJ L 351, 2.12.1989, p. 34).

Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).

- (80) Until the date of the application of Article 110 of Regulation (EU) .../...\*, breed societies carrying out approved breeding programmes on purebred breeding animals of the equine species should be able to continue to issue the identification documents for those purebred breeding animals in accordance with Article 8(1) of Directive 90/427/EEC.
- (81) **T**his Regulation **should be** applicable from the first day of the **twenty-eighth** month after the date it enters into force,

HAVE ADOPTED THIS REGULATION:

OJ: please insert the reference number for the Regulation contained in PE-CONS 7/16.

## 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 germinalproducts, 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) I 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) 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.

## **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;
- "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 ;

- "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;

- "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*;
- "class" means a horizontal *division* of the main section in which *purebred* breeding animals are entered according to their merits;
- "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;

- "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;
- "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 ;
- "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;
- "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 pigsto 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.

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).

## 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 intendedrefusal 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 timelimits*. At the same time, the competent authority shall inform the Commission of its decision to refuse recognition and of its reasons for doing so.

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 six 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.

## 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 web* site 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.

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.

## 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.

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- 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 1.

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  $\blacksquare$  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.

Breed societies and breeding operations  $\blacksquare$  shall, without prejudice to the role of the  $\blacksquare$  courts, have a responsibility to  $\blacksquare$  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  $\blacksquare$  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

## 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.

## 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 undergothe 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 *I(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 *I*(*b*) of Chapter III of Part 1 of Annex II.

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.

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.

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.

## 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 $\blacksquare$ BREEDING REGISTERS $\blacksquare$ AND ACCEPTANCE FOR BREEDING $\blacksquare$

## Article 23

Registration of hybrid breeding pigs in breeding registers

- 1. Breeding operations shall, at the request of their *breeders*, register in their breed*ing* 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.

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, atan 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

- (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;

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- (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

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#### 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 2of 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 paragraphs 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 test*ing*;
  - (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  $\bullet$  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 paragraph 2(a) 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  $8 \blacksquare$ ;
  - (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 ;

- (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 accompany*ing* 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.

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.

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.

# 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.

# **R**ules on official controls

- 1. **C**ompetent 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. **C**ompetent 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 .

# 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.

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## 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.

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## 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.

# 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 noncompliance and to establish the responsibilities of the operators concerned;
  - (b) take appropriate measures to ensure that the operators concerned remedy the noncompliance 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.

# 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 performofficial 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*.

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.

Coordinated assistance and follow-up by the Commission

- 1. The Commission shall, without delay, coordinate the measures *and actions* undertaken by the competent authorit*ies* 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 authorit*ies* 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.

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.

# 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 ... [the date of application of this Regulation] 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

- 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:

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(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.

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*;
- (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).

# 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.

# Serious disruption in the control system of a Member State

- 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 shalladopt 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 shalladopt 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 in* to 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.

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 th*at* 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)*.

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.

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 *I*, 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 five years from ... [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-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 three 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 ...\*.
- 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 two 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 two months at the initiative of the European Parliament or of the Council.

<sup>\*</sup> OJ: please insert the date for ST 15506/15.

### 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 ... [18 months before the date of application of this Regulation]. In accordance with Article 69, those implementing acts shall apply from ... [the date of application of this Regulation].

### CHAPTER XIII

#### **Final Provisions**

#### Article 64

## Repeals and transitional measures

- 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 of this Regulation.

- 3. Article 8(1) of Directive 90/427/EEC shall continue to apply until ... [the date of application of Article 110 of Regulation (EU) .../...\*].
- 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.

<sup>\*</sup> OJ: please insert the reference number for the Regulation contained in PE-CONS 7/16.

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 ... [the date of entry into force of this Regulation], 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:

(a) the heading is replaced by the following:

'European Union reference laboratories and centres';

- (b) 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) .../... of the European Parliament and of the Council\* for the costs that they incur in implementing the work programmes approved by the Commission.

<sup>\*</sup> Regulation (EU) .../... of the European Parliament and of the Council of ... 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 ...).';

OJ: please insert the reference number and the corresponding footnote.

- (c) 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 titleis 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 9is 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 organization 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 penalize 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 ... [the date of application of this Regulation]. 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 ... [the first day of the **twenty-eighth** month following the date of entry into force of this Regulation].

Article 65 shall apply from ... [the date of entry into force of this Regulation].

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

Done at ...,

For the European Parliament

For the Council

The President

The President

#### ANNEX I

# RECOGNITION OF BREED SOCIETIES AND BREEDING OPERATIONS AND APPROVAL OF BREEDING PROGRAMMES REFERRED TO IN CHAPTER II

#### Part 1

- Requirements for the recognition of breed societies and breeding operations *referred to* in Article 4(3)(b)
- A. Breeders' associations, breeding organisations, private undertakings operating in closed production systems and public bodies shall:
  - 1. have legal personality in accordance with the legislation in force in the Member State where the application for recognition is made;
  - 2. have sufficient and qualified staff and adequate facilities and equipment to implement efficiently *the* breeding programmes in respect of *which it intends* to *apply for approval* in accordance with Article 8(3), and, where applicable, Article 12;
  - 3. **be capable of** carrying out the checks necessary for recording pedigrees of the breeding animals **to be covered by those** breeding programmes;

- 4. have, *in respect of each breeding programme*, a sufficiently large population of breeding animals within the geographical *territories to be covered by those* breeding programmes;
- be capable of generating, or have had generated for them, and be capable of using data collected on breeding animals necessary for carrying out those breeding programmes.
- B. In addition to the requirements referred to in point A:
- 1. breeders' associations, breeding organisations and public bodies shall:
  - (a) have a sufficient number of breeders participating in each of their breeding programmes;

- (b) have adopted rules of procedure:
  - (i) regulating the settlement of disputes with breeders participating in their breeding programmes;
  - (ii) ensuring equal treatment of breeders participating in their breeding programmes;
  - (iii) setting out the rights and obligations of breeders participating in their breeding programmes and of the breed society or breeding operation;
  - (iv) setting out the rights and obligations of member breeders where membership of breeders is provided for;
- 2. nothing in the rules of procedure referred to in point 1(b) shall prevent the breeders participating in the breeding programmes from:
  - (a) exercising free choice in the selection and breeding of their breeding animals;
  - (b) having the offspring descended from those breeding animals entered in the breeding books or registered in the breeding registers in accordance with the rules provided for in Chapter IV of this Regulation;
  - (c) having the ownership of their breeding animals.

#### Part 2

- Requirements for the approval of breeding programmes carried out by breed societies and breeding operations *referred to* in *Article* 8(3), and, *where applicable*, *Article* 12
- 1. The breeding programme referred to in Article 8(3), and, where applicable, Article 12 shall contain:
  - (a) information on its aim, which shall be the preservation of the breed, the improvement of the breed, line or cross, the creation of a new breed, line or cross, or the reconstruction of a breed, or a combination thereof;

- (b) the name of the breed, in the case of purebred breeding animals, or of the breed, line or cross, in the case of hybrid breeding pigs, covered by the breeding programme to prevent confusion with similar breeding animals of other breeds, lines or crosses entered or registered in other existing breeding books or breeding registers;
- (c) in the case of purebred breeding animals, the detailed characteristics of the breed covered by the breeding programme, including an indication of its essential traits,
- (d) in the case of hybrid breeding pigs, the detailed characteristics of the breed, line or cross covered by the breeding programme;
- (e) information on the geographical territory where it is carried out or where it is intended that it will be carried out;
- (f) *information on* the system for identifying breeding animals which *is to ensure* that *those* animals are only entered in a breeding book or registered in a breed*ing* register when they are identified *individually and* in accordance with Union animal health law on the identification and registration of animals of the species concerned;
- (g) *information* on the system for recording pedigrees of purebred breeding animals entered or registered and eligible for entry in breeding books or of hybrid breeding pigs registered in breed*ing* registers;

- (h) 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 breeding animals;
- (i) In the case of the establishment of a new breed or in the case of the reconstruction of a breed, as referred to in Article 19, the information on the detailed circumstances justifying the establishment of that new breed or the reconstruction of that breed;
- (j) 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 breeding animals;

- (k) where supplementary sections are established or the main section is subdivided into classes, 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;
- (l) where the breed society or breeding operation outsources specific technical activities related to the management of its breeding programme to third parties as referred to in Article 8(4), information on those activities and the name and contact details of the designated third parties;
- (m) where the breed society or breeding operation intends to make use of the derogation provided for in Article 31(1), information on the semen collection or storage centre, or embryo collection or production team, issuing the zootechnical certificates and information on the modalities of the issuing of those zootechnical certificates;
- (n) where the breeding operation decides to indicate information on the results of performance testing or genetic evaluation, on genetic defects and on genetic peculiarities in the zootechnical certificates issued for its hybrid breeding pigs and the germinal products thereof, as referred to in Article 30(8), information on that decision.

2. The breeding programme shall cover a sufficiently large population of breeding animals and a sufficient number of breeders within the geographical territory where it is carried out or where it is intended that it will be carried out.

#### Part 3

**Additional** requirements for breed societies establishing or maintaining breeding books for purebred breeding animals of the equine species

1. In addition to the identification requirements set out in point 1(f) of Part 2, purebred breeding animals of the equine species shall only be entered in a breeding book if they are identified by a covering certificate and, where required by the breeding programme, as "foal at foot".

By way of derogation from the first subparagraph, a Member State or, if it so decides, its competent authority may authorise a breed society to enter purebred breeding animals of the equine species in the breeding book maintained by that breed society where those animals are identified by any other appropriate method that provides at least the same degree of certainty as a covering certificate such as parentage control based on DNA analysis or analysis of their blood groups, provided that that authorisation is in accordance with the principles established by the breed society which maintains the breeding book of the origin of that breed.

- 2. In addition to the requirements set out in Part 2, breeding programmes approved in accordance with Articles 8(3), and, where applicable, Article 12, carried out on purebred breeding animals of a breed of the equine species shall contain:
  - (a) where applicable, the conditions for entering in the main section of the breeding book purebred breeding animals belonging to another breed or to a specific stallion line or mare family within that other breed;
  - (b) where that 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 that prohibition or limitation;
  - (c) rules with regard to the issuing of covering certificates, to the use of other appropriate methods as referred to in paragraph 1, and, where required by the breeding programme, to the identification as "foal at foot".

- 3. The following specific requirements shall apply to purebred breeding animals of the equine species, in addition to those set out in *Parts* 1 *and* 2:
  - (a) Where a breed society declares to the competent authority that the breeding book it has established is the breeding book of the origin of the breed covered by its breeding programme, that breed society shall:
    - (i) have in its possession a historical record of the establishment of that breeding book and have made the principles of that breeding programme publicly available;
    - (ii) *demonstrate* that there is, at the time of *the* application referred to in Article 4(1), no other known breed society or breeding body which is recognised in the same or another Member State or in a third country, which has established a breeding book for the same breed and which is *carrying out a breeding* programme on that breed based on the principles referred to in point (i);

- (iv) *have*, where necessary, established non-discriminatory rules as regards its *activities* with respect to breeding books established for the same breed by breeding bodies that are not *included in the list provided for in* Article 34 .
- (b) Where a breed society declares to the competent authority that the breeding book it has established is a filial breeding book of the breed covered by its breeding programme, that breed society shall:
  - (i) Incorporate into its own breeding programme the *principles* established by the breed society referred to in point (a) that maintains the breeding book of the origin of the same breed;
  - (ii) make the information regarding the use of the *principles* referred to in point(i) and their source publicly available;
  - (iii) have mechanisms in place to ensure the necessary adjustments of the rules set out in its breeding programme, referred to in Article 8(3), and, where applicable, Article 12, to the changes made to those principles by the breed society referred to in point (a) of this paragraph that maintains the breeding book of the origin of the breed.

- 4. The following derogations shall apply to *the requirements for the recognition of breed societies of* purebred breeding animals of the equine species:
  - (a) By way of derogation from point B(1)(b) of Part 1, where, for one breed on the territories listed in Annex VI, there are several breed societies which maintain breeding books for that breed, and where their breeding programmes, referred to in Article 8(3), cover together the whole of the territories listed in Annex VI, the rules of procedure referred to in point B(1)(b) of Part 1 established by those breed societies:
    - (i) may provide that purebred breeding animals of the equine species of that breed *must* be born in a specified territory *listed in Annex VI* to qualify for entry in the breeding book of that breed for birth declaration purposes;
    - (ii) *are to* ensure that the restriction provided for in point (i) does not apply to the entry in a breeding book of that breed for reproduction purposes.

- (b) By way of derogation from point 3(a) of this Part, where the *principles* of the breeding programme are established exclusively by an international organisation operating at a global level and where there is neither a breed society in a Member State nor a breeding body in a third country that maintains the breeding book of the origin of that breed, the competent authority in a Member State may recognise breed societies maintaining a filial breeding book for that breed, provided that they lay down the objectives and criteria referred to in point 1(h) of Part 2 in accordance with the principles established by that international organisation and that those principles are:
  - (i) made available by that breed society to the competent authority referred to in Article 4(3) for verification purposes;
  - (ii) incorporated in the breeding programme *of* that breed society.
- (c) By way of derogation from point 3(b) of this Part, a breed society maintaining a filial *breeding* book may establish additional classes according to merits, provided that the purebred breeding animals of the equine species which are entered in *the* classes in the main section of the breeding book of the origin of the breed *or of other filial breeding books of the breed* may be entered in the corresponding classes of the main section of that filial *breeding* book.

#### ANNEX II

## ENTRY IN BREEDING BOOKS AND REGISTRATION IN BREEDING REGISTERS REFERRED TO IN CHAPTER IV

#### Part 1

Entry of purebred breeding animals in breeding books *and recording of animals in supplementary*sections

### Chapter I

Entry of purebred breeding animals in the main section

- 1. The requirements referred to in Article 18(1) are as follows:
  - (a) the animal shall meet the following parentage criteria :
    - (i) for the bovine , porcine , ovine and caprine species , the animal shall have descended from parents and grandparents which have been entered in the main section of a breeding book of the same breed;
    - (ii) for the equine species , the animal shall have descended from parents which have been entered in the main section of a breeding book of the same breed;

- (b) *the animal shall* have its pedigree established in accordance with the rules set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
- (c) the animal shall be identified in accordance with Union animal health law on the identification and registration of animals of the species concerned and the rules set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
- in the case of trade in or entry into the Union of an animal and where that animal is intended to be entered or registered for entry in the breeding book, that animal shall be accompanied by a zootechnical certificate issued in accordance with Article 30 ;
- (e) where an animal is produced from a germinal product which is traded or which entered into the Union and where that animal is intended to be entered or registered for entry in a breeding book, that germinal product shall be accompanied by a zootechnical certificate issued in accordance with Article 30.

- 2. By way of derogation from point 1(a)(ii) *of this Chapter*, a breed society which carries out a breeding programme on purebred breeding animals of the equine species may enter in the main section of its breeding book a purebred breeding animal of the equine species:
  - (a) which, in the case of cross-breeding, is entered in the main section of a breeding book of a different breed, provided that that other breed and the criteria for entry of that purebred breeding animal are set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12; or
  - (b) which, in the case of lineage breeding, belongs to a specific stallion line or mare family of a different breed, provided that those lines and families and the criteria for the entry of that purebred breeding animal are set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

3. In addition to the rules set out in point 1(c) of this Chapter, a breed society that enters in its breeding book a purebred breeding animal of the equine species which has already been entered in a breeding book established by another breed society carrying out a breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12 shall enter that purebred breeding animal under the identification number ascribed to it under Regulation (EU) .../... \* which shall ensure the uniqueness and continuity of the identification of that animal and, except where a derogation has been agreed by the two breed societies concerned, under the same name, with an indication, in accordance with international agreements for the breed concerned, of the code of the country of birth.

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<sup>\*</sup> OJ: please insert the reference number for the Regulation contained in PE-CONS 7/16.

## Chapter II

## **Recording of animals in supplementary sections**

- 1. The conditions referred to in Article 20(1) are as follows:
  - (a) the animal shall be identified in accordance with Union animal health law on the identification and registration of animals of the species concerned and the rules set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
  - (b) *the animal shall have been* judged by the breed society to conform to the characteristics of the breed referred to in point (1)(c) of Part 2 of Annex I;
  - (c) the animal shall, where applicable, fulfil at least the minimum performance requirements laid down in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12, for those traits for which purebred breeding animals entered in the main section are tested in accordance with Annex III.

- 2. The breed society may apply different requirements for the conformity with the breed characteristics referred to in point 1(b) of this Chapter or the performance requirements referred to in point 1(c) of this Chapter depending on whether the animal:
  - (a) belongs to the breed, although it has no known origin; or
  - (b) was obtained from a cross-breeding programme mentioned in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

### Chapter III

Upgrading of the progeny of animals recorded in supplementary sections to the main section

- 1. The conditions referred to in Article 20(2) are as follows:
  - (a) for the bovine, porcine, ovine and caprine species, the female animal shall have descended from:
    - (i) a mother and a maternal grandmother which are recorded in a supplementary section of a breeding book of the same breed as provided for in Article 20(1);
    - (ii) a father and two grandfathers which are entered in the main section of a breeding book of the same breed.

The first generation offspring descended from the female animal referred to in the introductory phrase of the first subparagraph and a male purebred breeding animal entered in the main section of the breeding book of the same breed shall likewise be regarded as a purebred breeding animal and be entered or registered and eligible for entry in the main section of that breeding book.

- (b) for the equine species, the animal shall meet the conditions for entry in the main section of male and female animals descending from animals recorded in the supplementary section as set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.
- 2. By way of derogation from point 1 of this Chapter and point 1(a)(i) of Chapter I, a
  Member State or, if it so decides, its competent authority referred to in Article 4(3), may
  authorise a breed society which carries out a breeding programme on purebred breeding
  animals of an endangered breed of the bovine, porcine, ovine or caprine species or of a
  "hardy" sheep breed to enter in the main section of its breeding book, an animal
  descending from parents and grandparents entered or recorded in the main or
  supplementary sections of a breeding book of that breed.

A Member State, or, if it so decides, its competent authority authorising a breed society to make use of that derogation, shall ensure that:

(a) that breed society has justified the need for making use of that derogation, in particular by demonstrating the lack of male purebred breeding animals of that breed available for breeding purposes;

- (b) that breed society has established one or more supplementary sections in its breeding book;
- (c) the rules under which the breed society enters or records animals in the main or supplementary sections of that breeding book are laid down in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

Member States making use of this derogation shall make publicly available the breeds which are granted such a derogation in the list referred to in Article 7.

#### Part 2

# Registration of hybrid breeding pigs in breeding registers

The requirements referred to in Article 23 are as follows:

- (a) the hybrid breeding pig shall have descended from parents and grandparents entered in breeding books or registered in breeding registers;
- (b) the hybrid breeding pig shall be identified after birth in accordance with Union animal health law on the identification and registration of animals of the porcine species and the rules set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
- (c) the hybrid breeding pig shall have a parentage established in accordance with the rules set out in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12;
- (d) *the hybrid breeding pig shall be* accompanied, where required, by a zootechnical certificate issued in accordance with Article 30 .

#### ANNEX III

# PERFORMANCE TESTING AND GENETIC EVALUATION REFERRED TO IN *ARTICLE 25*

#### Part 1

# General requirements

Where breed societies or breeding operations, or third parties designated by those breed societies or breeding operations in accordance with Article 27(1) (b), carry out performance testing or genetic evaluation, they shall establish and use methods for performance testing or genetic evaluation which shall be scientifically acceptable according to established zootechnical principles and shall take into account, where they exist:

- (a) the rules and standards established by the relevant European Union reference *centres* provided for in Article **29**(1); *or*
- (b) in the absence of those rules and standards, the principles agreed by ICAR.

#### Part 2

# Requirements for performance testing

- 1. Performance testing shall be carried out on the basis of one or more of the following performance testing schemes set up in accordance with the methods referred to in Part 1:
  - (a) individual performance testing of breeding animals themselves or of breeding animals based on their progeny, siblings ("sib") or collaterals at test stations;
  - (b) individual performance testing of breeding animals themselves or of breeding animals based on their progeny, siblings ("sib"), collaterals and other relatives on farms;
  - (c) performance testing through survey data collected by farms, points of sale, points of slaughter or other operators;
  - (d) performance testing of contemporary groups of breeding animals (contemporary group comparison);
  - (e) any other performance testing scheme carried out in accordance with the methods referred to in Part 1.

The performance testing schemes shall be set up in such a way to allow a valid comparison between the breeding animals. The progeny, siblings or collaterals to be tested at test stations or on farm shall be chosen in an unbiased manner and not be treated selectively. In the case of on-farm testing, they shall be distributed amongst farms in such a way as to allow a valid comparison between the tested breeding animals.

Breed societies and breeding operations carrying out those performance testing schemes at test stations shall in accordance with the methods referred to in Part 1 lay down, in a test protocol , the terms of admission of breeding animals, information on the identity and relevant previous test results of the participating animals, the traits to be recorded, the test methods used and any other relevant information.

2. Breed societies and breeding operations shall define in their breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12, the traits to be recorded in relation to the selection objectives set out in those breeding programmes.

- 3. Where milk production traits are to be recorded, data shall be recorded on milk production, milk composition traits and other relevant traits set out in the methods referred to in Part 1. Additional data may be recorded on other milk or milk quality traits.
- 4. Where meat production traits are to be recorded, data shall be recorded on meat production traits and other relevant traits set out in the methods referred to in Part 1.

  Additional data may be recorded on other meat or meat quality traits.
- 5. Where other traits than those referred to in points 3 and 4 of this Part are to be recorded, those traits shall be recorded in accordance with the methods referred to in Part 1. They may include species and breed specific traits such as body conformation , fertility, ease of parturition, health related traits, viability of progeny, longevity, fiber quality, feed efficiency, docility, sustainability traits and any other relevant traits in relation to the selection objectives of the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.

- 6. Data collected on the traits referred to in points 3, 4 and 5 shall only be included in the genetic evaluation where that data is generated on the basis of a recording system specified in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.
- 7. For each of the traits recorded referred to in points 3, 4 and 5 information on the applied performance testing schemes, the applied test protocol, and, where relevant, the applied method for the validation of the test results, shall be specified in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.
- 8. Where genetic evaluation is carried out on the traits referred to in points 3, 4 and 5, the recording of those traits shall ensure that, at the end of the testing, reliable breeding values can be estimated for those traits.
- 9. Survey data referred to in point 1(c) of this Part may only be recorded and included in the genetic evaluation where that data has been validated in accordance with the methods referred to in Part 1.

#### Part 3

# Requirements for genetic evaluation

- 1. The genetic evaluation of breeding animals shall include the relevant production and non-production traits referred to in Part 2 in relation to the selection objectives set out in the breeding programmes approved in accordance with Article 8(3), and, where applicable, Article 12.
- 2. The genetic evaluation shall only include traits referred to in Part 2 in respect of which the recording is carried out as specified in the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12.
- 3. Breeding values of breeding animals shall be estimated in accordance with the methods referred to in Part 1 on the basis of:
  - (a) data collected on breeding animals through performance testing, referred to in Part 2;
  - (b) genomic information collected on breeding animals;

- (c) data generated by any other method in accordance with the methods referred to in Part 1; or
- (d) a combination of the information and data, referred to in points (a), (b) and (c).
- 4. The statistical methods applied for the genetic evaluation shall comply with the methods referred to in Part 1. Those statistical methods shall guarantee a genetic evaluation that is not biased by the main environmental effects and data structure, and that takes into account all information available for the breeding animal, its progeny, siblings, collaterals and other relatives depending on the performance testing scheme.
- 5. The reliabilities of the estimated breeding values shall be calculated in accordance with methods referred to in Part 1. When publishing the estimated breeding values for breeding animals, the reliabilities of those published breeding values and the date of evaluation shall be indicated.

- 6. Male purebred breeding animals of the bovine species of which the semen is intended to be used for artificial insemination shall be subject to genetic evaluation. That genetic evaluation shall be carried out on the main production traits in relation to the breeding programme as set out in the methods referred to in Part 1 and may be carried out on other relevant production and non-production traits set out in the methods referred to in Part 1. Where for those traits a genetic evaluation is carried out on male purebred breeding animals of the bovine species of which the semen is intended to be used for artificial insemination, the breeding values relating to those traits shall be published at the exception of those relating to animals referred to in Article 21(1)(g) (unproven bulls).
- 7. For male purebred breeding animals of the bovine species of which the semen is intended to be used for artificial insemination, the minimum reliability of the breeding values shall be at least:
  - (a) in the case of bulls belonging to dairy breeds (including dual-purpose breeds), 0,5 for the main milk production traits or for the main composite indexes combining breeding values estimated for several individual traits;
  - (b) in the case of bulls belonging to beef breeds (including dual-purpose breeds), 0,3 for the main meat production traits or for the main composite indexes combining breeding values estimated for several individual traits.

- 8. The requirements on minimum reliability values referred to in point 7 shall not apply to male purebred breeding animals of the bovine species which are:
  - (a) used for the purpose of testing within the quantity limits necessary for a breed society to carry out such tests as referred to in Article 21(1)(g) (unproven bulls); or
  - (b) participating in a breeding programme which requires performance testing and genetic evaluation and which has as its aim the preservation of the breed or the preservation of the genetic diversity within the breed.
- **9.** Genomically evaluated *male purebred breeding animals of the bovine species* shall be considered suitable for artificial insemination if their genomic evaluation is:
  - (a) validated in accordance with the methods referred to in Part 1 for each genomically evaluated trait;
  - (b) revalidated for each of those traits at regular intervals and at any time when there are major changes either in the genomic evaluation or in the genetic evaluation or in the reference population.

10. The breed society or the breeding operation, or, at the request of 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 publicly available the information on the genetic defects and genetic peculiarities of breeding animals which are related to the breeding programme.

#### **ANNEX IV**

#### **EUROPEAN UNION REFERENCE CENTRES REFERRED TO IN ARTICLE 29**

1. Requirements referred to in Article 29(4)(a)

European Union reference centres designated in accordance with Article 29 shall:

- (a) have suitably qualified staff:
  - (i) who have adequate training:
    - where those centres are designated in accordance with Article 29(1), in performance testing and genetic evaluation of purebred breeding animals;
    - where those centres are designated in accordance with Article 29(2), in the preservation of endangered breeds;
  - (ii) who have been instructed to respect the confidential nature of certain subjects, results or communications; and
  - (iii) who have sufficient knowledge of research activities at national, Union and international level;

- (b) possess or have access to the infrastructure, equipment and products necessary to carry out the tasks:
  - (i) where those centres are designated in accordance with Article 29(1), referred to in point (2); and
  - (ii) where those centres are designated in accordance with Article 29(2), referred to in point (3);.
- 2. Tasks referred to in Article 29(4)(b)(i) for European Union reference centres designated in accordance with Article 29(1)

European Union reference centres designated in accordance with Article 29(1) shall:

- (a) work with breed societies and third parties designated by breed societies in accordance with Article 27(1)(b) to facilitate the uniform application of methods for performance testing and genetic evaluation for purebred breeding animals, referred to in Article 25;
- (b) Inform breed societies, third parties designated by those breed societies in accordance with Article 27(1)(b), or competent authorities on methods of performance testing and genetic evaluation of purebred breeding animals :

- (c) **review** regularly the results of performance testing and genetic evaluations carried out by breed societies or third parties designated by those breed societies in accordance with Article 27(1)(b) and the data on which they are based;
- (d) compare methods of performance testing and genetic evaluation of purebred breeding animals;
- (e) at the request of the Commission or a Member State:
  - (i) *provide assistance* in *the* harmonis*ation of* methods of performance testing and genetic evaluation of purebred breeding animals;
  - (ii) recommend calculation methods to be used for the performance testing and genetic evaluation of purebred breeding animals;

- (iii) establish a platform for the comparison of the results of the methods of performance testing and genetic evaluation of purebred breeding animals used in Member States, in particular by:
  - developing control protocols for performance testing and genetic
     evaluation of purebred breeding animals carried out in Member States to
     improve the comparability of *the* results and the effectiveness of
     breeding programmes;
  - carrying out an international assessment of livestock on the basis of the combined results of performance testing and genetic evaluation of purebred breeding animals carried out in Member States *and third countries*;
  - disseminating the results of those international assessments;
  - publishing the conversion formulae and the related information based on which the formulae were established;

- (f) provide data on the genetic evaluation of purebred breeding animals and training to support *breed societies or third parties* designated *by those breed societies* in accordance with Article 27(1)(b), which are participating in international comparisons of the results of genetic evaluations;
- (g) I facilitate the resolution of emerging problems in Member States linked to the genetic evaluation of purebred breeding animals;
- (h) cooperate, within the scope of their tasks, with internationally recognised organisations;
- (i) provide, at the request of the Commission, technical expertise to the Standing Committee on Zootechnics.

3. Tasks referred to in Article 29(4)(b)(ii) for European Union reference centres designated in accordance with Article 29(2).

European Union reference centres designated in accordance with Article 29(2) shall:

- (a) work with breed societies, third parties designated by breed societies in accordance with Article 27(1)(b), competent authorities and other authorities of the Member States to facilitate the preservation of endangered breeds or the preservation of the genetic diversity existing within those breeds;
- (b) inform breed societies, third parties designated by those breed societies in accordance with Article 27(1)(b), competent authorities or other authorities on methods used for the preservation of endangered breeds and the preservation of genetic diversity within those breeds;
- (c) at the request of the Commission:
  - (i) develop or harmonise methods used for the in situ and ex situ conservation of endangered breeds or the preservation of the genetic diversity within those breeds or provide assistance in such development or harmonisation;

- (ii) develop methods used for the characterisation of the status of endangered breeds with regard to their genetic diversity or their danger of being lost to farming or provide assistance in such development;
- (iii) encourage exchanges between Member States of information on the preservation of the endangered breeds or the preservation of the genetic diversity within those breeds;
- (iv) provide training to support breed societies or third parties designated by those breed societies in accordance with Article 27(1)(b), competent authorities and other authorities in the preservation of endangered breeds and the preservation of genetic diversity within those breeds;
- (v) cooperate, within the scope of their tasks, with European and internationally recognised organisations;
- (vi) provide, within the scope of their tasks, technical expertise to the Standing Committee on Zootechnics.

#### ANNEX V

# INFORMATION TO BE PROVIDED IN THE ZOOTECHNICAL CERTIFICATES REFERRED TO IN $\it CHAPTER$ VII

# Part 1 General requirements

I

The title of the zootechnical certificate shall:

- (a) indicate if the animal is a purebred breeding animal or a hybrid breeding pig or if the germinal products originate from purebred breeding animals or hybrid breeding pigs;
- (b) *include a* reference to the taxonomic species;
- (c) indicate if the consignment is intended for trade or for *entry* into the Union;
- (d) include a reference to this Regulation.

#### Part 2

Zootechnical certificates for purebred breeding animals and *their germinal products* 

#### Chapter I

Zootechnical certificates, *referred to in Article 30*, for purebred breeding animals

- 1. Zootechnical certificates, *referred to in Article 30*, for purebred breeding animals shall contain the following information:
  - (a) the name of the issuing breed society, or, in the case of *entry* into the Union *of the* purebred breeding animal, the name of the issuing breeding body, and, where available, a reference to the website of that breed society or breeding body;
  - (b) the name of the breeding book;
  - (c) where applicable, the class within the main section where the purebred breeding animal is entered;
  - (d) the name of the breed of the purebred breeding animal;
  - (e) the sex of the purebred breeding animal;

- (f) the entry number in the breeding book ("Breeding-book No") of the purebred breeding animal;
- (g) the system of identification *and* the *individual* identification number *given* to the purebred breeding animal in accordance with:
  - (i) Union animal health law on the identification and registration of animals of the species concerned;
  - (ii) in the absence of Union animal health law on the identification and registration of animals requiring an individual identification number, the rules of the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12; or
  - (iii) in the case of entry into the Union of the purebred breeding animal the legislation of the third country;
- (h) where required in accordance with Article 22(1) and (2), the method used for identity verification of purebred breeding animals used for the collection of semen, oocytes and embryos and the results of the verification of that identity;

- (i) the date *and country* of birth of the purebred breeding animal;
- (j) the name, address and, where available, the e-mail address of the breeder (place of birth of the purebred breeding animal);
- (k) the name and address and, where available, the e-mail address of the owner;
- (l) the pedigree:

Sire	Paternal Grandsire
Breeding-book No. and section	Breeding-book No. and section
I	Paternal Granddam
	Breeding-book No. and section
Dam	Maternal Grandsire
Breeding-book No. and section	Breeding-book No. and section
I	Maternal Granddam
	Breeding-book No. and section

- (m) where available results of performance testing and up-to-date results of the genetic evaluation including the date of that evaluation and genetic defects and genetic peculiarities in relation to the breeding programme affecting the purebred breeding animal itself \( \bigcirc\);
- in the case of pregnant females, the date of insemination or mating and the identification of the fertilising male, which may be indicated in a separate document;
- (o) the date and place of issue of the *zootechnical* certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breed society, or, in the case of *entry* into the Union of a *purebred breeding animal*, by the issuing breeding body; that individual shall be a representative from that breed society or breeding body, or a representative from a competent authority, referred to in Article 30(2)(b).
- 2. Where zootechnical certificates are issued for a group of purebred breeding animals of the porcine species, the information referred to in point 1 of this Chapter may be contained in a single zootechnical certificate, provided that those purebred breeding animals have the same age and the same genetic dam and sire.

# Chapter II

Zootechnical certificates, *referred to in Article 30*, for semen of purebred breeding animals

Zootechnical certificates, *referred to in Article 30*, for semen *of purebred breeding animals* shall contain the following information:

- (a) all the *information* referred to in Chapter I of this *Part* concerning the purebred breeding animal that provided the semen ;
- (b) information allowing the identification of the semen, the *number of doses to be*dispatched, the place and the date of its collection, the name, the address and the

  approval number of the semen collection or storage centre and the name and the

  address of the consignee;
- (c) for semen intended for  $\blacksquare$  testing of purebred breeding animals which have not undergone performance testing or genetic evaluation, the number of doses of that semen which shall be in accordance with the quantity limits referred to in Article 21(1)(g), the name and address of the breed society, or the third party designated by that breed society in accordance with Article 27(1)(b), responsible for carrying out that testing in accordance with Article 25  $\blacksquare$ ;

(d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breed society, or in the case of *entry* into the Union *of semen*, *by* the issuing breeding body; *that individual* shall be a representative from that breed society or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority, referred to in Article 30(2)(b).

# Chapter III

Zootechnical certificates, referred to in Article 30, for oocytes of purebred breeding animals

Zootechnical certificates, *referred to in Article 30*, for *oocytes of* purebred breeding animals shall contain the following information:

- (a) all the information referred to in Chapter I *of this Part* concerning the donor female that provided the oocytes ;
- (b) information allowing the identification of the oocytes, *the number of straws*, the *place and the* date of their collection, the *name*, *the address and the approval number* of the embryo collection *or production team* and the *name* and *the address* of the consignee;
- (c) where there is more than one oocyte in a straw, a clear indication of the number of oocytescollected from the same purebred breeding animal;
- (d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breed society, or in the case of *entry* into the Union of *oocytes*, *by* the issuing breeding body; that individual shall be a representative from that breed society or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority referred to in Article 30(2)(b).

### Chapter IV

Zootechnical certificates, *referred to in Article 30*, for embryos of purebred breeding animals

Zootechnical certificates, *referred to in Article 30*, for embryos *of purebred breeding animals* shall contain the following information:

- (a) all the information referred to in Chapter I of this Part concerning the donor female and the fertilising male **I**;
- (b) information allowing *the* identification of the embryos, *the number of straws*, the *place*and the date of their collection or production, the *name*, the address and the approval

  number of the embryo collection or production team and the name and the address of the consignee;
- (c) where there is more than one embryo in a straw, a clear indication of the number of embryos hav*ing* the same parentage;
- (d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breed society, or in the case of entry into the Union of embryos, by the issuing breeding body; that individual shall be a representative from that breed society or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority referred to in Article 30(2)(b).

#### Part 3

Zootechnical certificates, *referred to in Article 30*, for hybrid breeding pigs and their *germinal products* 

### Chapter I

Zootechnical certificates for hybrid breeding pigs

- 1. Zootechnical certificates, *referred to in Article 30*, for hybrid breeding pigs shall contain the following information:
  - (a) the name of the issuing breeding operation or, in the case of *entry* into the Union of the hybrid breeding pig, the name of the breeding body and, where available, a reference to the website of that breeding operation or breeding body;
  - (b) the name of the breed*ing* register;
  - (c) the name of the breed, line or cross of the hybrid breeding pig and the parents and grandparents of that pig;
  - (d) the sex of the hybrid breeding pig;
  - (e) the entry number in the breeding register ("Breeding-register No") of the hybrid breeding pig;

- (f) the system of identification *and* the *individual* identification number *given* to the hybrid breeding pig in accordance with:
  - (i) Union animal health law on the identification and registration of animals of the porcine species;
  - (ii) in the absence of Union animal health law on the identification and registration of animals requiring an individual identification number, the rules of the breeding programme approved in accordance with Article 8(3), and, where applicable, Article 12; or
  - (iii) in the case of entry into the Union of the hybrid breeding pig, in accordance with the legislation of the third country;
- (g) where required in accordance with Article 22(2), the method used for identity verification of the hybrid breeding pig and the results of the verification of that identity;
- (h) the date *and country* of birth *of the hybrid breeding pig*;

- (i) the name and address and, where available, the e-mail address of the breeder (place of birth of the hybrid breeding pig);
- (j) the name and address and, where available, the e-mail address of the owner;

# (k) the pedigree:

	Paternal Grandsire
Sire	Breeding-register No.
Breeding-register No.	Breed, line or cross
Breed, line or cross	Paternal Granddam
	Breeding-register No.
	Breed, line or cross
	Maternal Grandsire
Dam	Breeding-register No.
Breeding-register No.	Breed, line or cross
Breed, line or cross	Maternal Granddam
	Breeding-register No.
	Breed, line or cross

- (l) where required to do so by the breeding programme, results of performance testing or up-to-date results of the genetic evaluation or both, including the date of that evaluation and genetic defects and genetic pecularities in relation to the breeding programme affecting the hybrid breeding pig itself or, to the extent known, its progeny;
- (m) in the case of pregnant females, the information on the date of insemination or mating, as well as the identification of the fertilising male, which may be indicated in a separate document;
- (n) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breeding operation, or in the case of *entry* into the Union of *a hybrid breeding pig*, *by* the issuing breeding body; *that individual shall be a representative from that breeding operation or breeding body, or a representative from a competent authority referred to in Article 30(2)(b).*
- 2. Where zootechnical certificates are issued for a group of hybrid breeding pigs, the information referred to in point 1 of this Chapter may be contained in a single zootechnical certificate provided that those hybrid breeding pigs have the same age and the same genetic dam and sire.

### Chapter II

Zootechnical certificates, referred to in Article 30, for semen of hybrid breeding pigs

Zootechnical certificates, *referred to in Article 30*, for semen of hybrid breeding pigs shall contain the following information:

- (a) all the information referred to in Chapter I *of this Part* concerning the hybrid breeding pig that provided the semen;
- (b) information allowing the identification of the semen, *the number of doses*, the date of its collection, the *name*, *the address* and *the approval number* of the semen collection *or storage* centre and *the name and the address* of the consignee;
- (c) for semen intended for performance testing or genetic evaluation of hybrid breeding pigs, which have not undergone such testing or evaluation, the number of doses of that semen, which shall be in accordance with the quantity limits referred to in Article 24(1)(d), the name and address of the breeding operation, or the third party designated by that breeding operation in accordance with Article 27(1)(b), responsible for carrying out that testing in accordance with Article 25;

(d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breeding operation or, in the case of *entry* into the Union *of semen*, *by* the issuing breeding body; that individual *shall be a representative from that breeding operation or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority referred to in Article 30(2)(b).* 

# Chapter III

Zootechnical certificates, referred to in Article 30, for oocytes of hybrid breeding pigs

Zootechnical certificates, *referred to in Article 30*, for oocytes of hybrid breeding pigs shall contain the following information:

- (a) all the information referred to in Chapter I *of this Part* concerning the *donor female* that provided the oocytes;
- (b) information allowing *the* identification of the oocytes, the *number of straws, the* date of their collection, *the name, the address and the approval number* of the embryo collection or production team and *the name and the address* of the consignee;
- (c) where there is more than one oocyte in a straw, a clear indication of the number of oocytes collected from the same hybrid breeding pig;
- (d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breeding operation or, in the case of *entry* into the Union *of the oocytes*, *by* the issuing breeding body; that individual shall be a representative from that breeding operation or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority referred to in Article 30(2)(b).

# Chapter IV

Zootechnical certificates, referred to in Article 30, for embryos of hybrid breeding pigs

Zootechnical certificates, *referred to in Article 30*, for embryos *of* hybrid breeding pigs shall contain the following information:

- (a) all the information referred to in Chapter I *of this Part* concerning the donor female and the fertilising male;
- (b) information allowing the identification of the embryos, the number of straws, the place and the date of their collection or production, the name, the addresss and the approval number of the embryo collection or production team and the name and the address of the consignee;
- (c) where there is more than one embryo in a straw, a clear indication of the number of embryos that have the same parentage;
- (d) the date and place of issue of the zootechnical certificate and the name, capacity and signature of the individual authorised to sign that certificate by the issuing breeding operation or, in the case of *entry* into the Union *of embryos*, authorised *by* the issuing breeding body; *that individual shall be a representative from that breeding operation or breeding body or an operator referred to in Article 31(1) or Article 33(1), or a representative from a competent authority referred to in Article 30(2)(b).*

#### ANNEX VI

### TERRITORIES REFERRED TO IN POINT 21 OF ARTICLE 2

- 1. The territory of the Kingdom of Belgium
- 2. The territory of the Republic of Bulgaria
- 3. The territory of the Czech Republic
- 4. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland
- 5. The territory of the Federal Republic of Germany
- 6. The territory of the Republic of Estonia
- 7. The territory of Ireland
- 8. The territory of the Hellenic Republic
- 9. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
- 10. The territory of the French Republic
- 11. The territory of the Republic of Croatia
- 12. The territory of the Italian Republic

13.	The territory	of the	Republic	of Cyprus
13.	THE LETTION	or uic	Kepublic	or Cyprus

- 14. The territory of the Republic of Latvia
- 15. The territory of the Republic of Lithuania
- 16. The territory of the Grand Duchy of Luxembourg
- 17. The territory of Hungary
- 18. The territory of the Republic of Malta
- 19. The territory of the Kingdom of the Netherlands in Europe
- 20. The territory of the Republic of Austria
- 21. The territory of the Republic of Poland
- 22. The territory of the Portuguese Republic
- 23. The territory of Romania
- 24. The territory of the Republic of Slovenia
- 25. The territory of the Slovak Republic
- 26. The territory of the Republic of Finland
- 27. The territory of the Kingdom of Sweden
- 28. The territory of the United Kingdom of Great Britain and Northern Ireland

# ANNEX VII

# **CORRELATION TABLE**

Council Directive 2009/157/EC	This Regulation
Article 1	Article 2, points 9 and 12
Article 2(a),(b), (e)	Article 3(1)
Article 2(c)	Article 8(3)
Article 2(d)	Article 4(3)
Article 3	Article 18(1)
Article 4(1)	Article 7(1)
Article 4(2)	Article 7(5)
Article 5	Article 30(1), Article 30(4), first subparagraph,
	Article 30(6) and point 1(d) of Chapter I of Part
	1 of Annex II
Article 6(a)	Articles 26(1) and Annex III
Article 6(b)	Part 1 of Annex I
Article 6(c)	Part 2 of Annex I
Article 6(d)	Part 1 of Annex II
Article 6(e)	Article 30(9) and (10) and Annex V
Article 7(1)	Article 62(1)
Article 7(2)	Article 62(2)
Article 8	_
Article 9	_
Article 10	_
Article 11	_

Council Directive 87/328/EEC	This Regulation
Article 1	Article 21(1)
Article 2(1)	Article 21(4)
Article 2(2)	Articles 12 and 13-
Article 2(3)	_
Article 3	Article 22(1) and (3)
Article 4	Article 21(5)
Article 5	Article 29(1)
Article 6	-
Article 7	-
Council Decision 96/463/EC	This Regulation
Article 1(1)	Article 29(1)
Article 1(2)	Article 29(4)(a) and (b)(i)
Article 2	_
Annex II	Points 1 and 2 of Annex IV

Council Directive 88/661/EEC	This Regulation
Article 1	Article 2, points 9, 10, 12 and 17
Article 2(1)	Article 3(1), Article 4(3) and Article 8(3)
Article 2(2)	
Article 3	Article 21(2)-
Article 4(1)	Article 18(1)
Article 4(2)	Article 64(7)
Article 4a, first paragraph	Article 7(1)
Article 4a, second paragraph	Article 7(5)
Article 5	Article 30(1), Article 30(4), first subparagraph,
	Article 30(6) and point 1(d) of Chapter I of Part
	1 of Annex II
Article 6(1)	Article 30(9) and (10), Parts 1 and 2 of Annex I,
	Part 1 of Annex II, Annex III and Annex V
Article 6(2)	_
Article 7(1)	Article 3(1), Article 8(3) and Article 4(3)
Article 7(2)	Article 1(3)-
Article 7a	Article 7(1) and (5)
Article 8	Article 25(2)-
Article 9	Article 30(1), Article 30(4), first subparagraph,
	Article 30(6) and point 1(d) of Part 2 of Annex
	II
Article 10 (1)	Article 30(9) and (10), Parts 1 and 2 of Annex I,
	Part 2 of Annex II, Annex III and Annex V

Article 10 (2)	_
Article 11(1)	Article 62(1)
Article 11(2)	Article 62(2)
Article 11(3)	Article 62(2)
Article 12	Article 1(3)-
Article 13	_
Article 14	_

Council Directive 90/118/EEC	This Regulation
Article 1	Article 21(1)
Article 2(1)	Article 21(4)
Article 2(2)	Articles 12 and 13 and Article 28(2)
Article 2(3)	Article 14 and Article 28(2)-
Article 3	Article 21(5)
Article 4	Article 62(1)
Article 5	<b>-</b> .
Article 6	

Council Directive 90/119/EEC	This Regulation
Article 1	Article 24(1) and Article 25
Article 2	Article 24(3)
Article 3	_
Article 4	_

Council Directive 89/361/EEC	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(3)-
Article 2	Article 2, points 9 and 12
Article 3(1)	Article 3(1), Article 4(3) and Article 8(3)
Article 3(2)	Article 1(3)
Article 4	Parts 1 and 2 of Annex I, Part 1 of Annex II,
	Annex III
Article 5	Article 7(1) and (5)
Article 6	Article 30(1), Article 30(4), first subparagraph,
	Article 30(6) and point 1(d) of Chapter I of Part
	1 of Annex II
Article 7	Article 1(3)-
Article 8	Article 62(1)
Article 9	_
Article 10	_

Council Directive 90/427/EEC	This Regulation
Article 1	Article 1(1)
Article 2	Article 2, points 9 and 12
Article 3, first paragraph	Article 3(1)
Article 3, second paragraph	Article 1(3)-
Article 4(1)(a)	Parts 1 and 3 of Annex I
Article 4(1)(b)	Point 1(c) of Chapter I of Part 1 of Annex II
Article 4(2)	Article 4(3), Article 19(4), Article 33, Article
	34(1)(c), Article 30(9) and (10), Article 32,
	Annex I, Part 1 of Annex II and Annex V
Article 5	Article 7(1) and (5)
Article 6	Point 3 of Chapter I of Part 1 of Annex II
Article 7	Part 1 of Annex II and Part 1 of Annex III
Article 8(1)	Point 1(c) of Chapter I of Part 1 of Annex II
Article 8(2)	Article 30(1), Article 30(4), first subparagraph,
	Article 30(6), Article 32 and point 1(d) of
	Chapter I of Part 1 of Annex II
Article 9	Article 1(3)
Article 10	Article 62(1)
Article 11	_
Article 12	_
Annex	_

Council Directive 91/174/EEC	This Regulation
Article 1	Article 2-
Article 2	Article 3, Article 35(1) and Article 45(1)-
Article 3	
Article 4	
Article 5	_
Article 6	_
Article 7	_
Article 8	_

Council Directive 94/28/EC	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	_
Article 1(3)	_
Article 1(4)	Article 3(1) and Article 36(2)
Article 2	Article 2
Article 3	Articles 34
Article 4	Article 36(1)(a), (c) and (d) and Article 37(1)(a)
Article 5	Article 36(1)(b) and (d)
Article 6	Article 36(1)(b) and (d)
Article 7	Article 36(1)(b) and (d)

Article 8	Article 39(2)-
Article 9(1) and (2)	Article 37(1)(b) and (2)
Article 9(3)	_
Article 10	Articles 57 and 60
Article 11	_
Article 12	Article 62(1)
Article 13	_
Article 14	_
Article 15	_