Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding (‘Animal Breeding Regulation’) (Text with EEA relevance)

REGULATION (EU) 2016/1012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2016

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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[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) 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.

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(3) 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[(3)], 89/361/EEC[(4)], 90/427/EEC[(5)], 91/174/EEC[(6)], 94/28/EC[(7)] and 2009/157/EC[(8)]. 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.

(4) Council Directives 87/328/EEC[(9)], 90/118/EEC[(10)] and 90/119/EEC[(11)] 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.

(5) 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[(12)], 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 and artificial insemination, for performance testing and genetic evaluation of 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.

(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 20 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

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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 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

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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.

(14) The aim of the rules on purebred breeding animals laid down in this Regulation should be 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, where they 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.

(15) Similarly, the aim of the rules on hybrid breeding pigs laid down in this Regulation should be 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.

(17) 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.

(18) 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 value on 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

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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. Those 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 justify the 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