Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(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 43(2), Article 114 and Article 168(4)(b) 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 impact of transmissible animal diseases and the measures necessary to control those diseases can be devastating for individual animals, animal populations, animal keepers and the economy.

(2) As recent experiences have demonstrated, transmissible animal diseases may also have a significant impact on public health and food safety.

(3) In addition, adverse interactive effects can be observed with regard to biodiversity, climate change and other environmental aspects. Climate change may influence the emergence of new diseases, the prevalence of existing diseases and the geographic distribution of disease agents and vectors, including those affecting wildlife.

(4) In order to ensure high standards of animal and public health in the Union and the rational development of the agriculture and aquaculture sectors, and to increase productivity, animal health rules should be laid down at Union level. Those rules are necessary in order, inter alia, to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Those rules should also ensure, as far as possible, that the existing animal health status in the Union is maintained and that consequent improvement of that status is supported.

(5) The current Union legislation on animal health consists of a series of linked and interrelated basic acts that lay down rules on animal health applying to intra–Union trade, entry into the Union of animals and products, disease eradication, veterinary controls, notification of diseases and financial support in relation to different animal species, but an overarching legal framework, laying down harmonised principles across the sector, is missing.

(6) Financial rules relating to the support of animal health objectives are provided for in Regulation (EU) No 652/2014 of the European Parliament and of the Council[(3)] and do not form part of this Regulation. In addition, the rules covering the official controls of animal health measures provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council[(4)] and in Council Directives 89/662/EEC[(5)], 90/425/EEC[(6)], 91/496/EEC[(7)] and 97/78/EC[(8)] should be used to regulate official controls in the area of animal health.

(7) This Regulation does not contain provisions which regulate animal welfare. However, animal health and welfare are linked: better animal health promotes better animal welfare, and vice versa. When disease prevention and control measures are carried out in accordance with this Regulation, their effect on animal welfare, understood in the light of Article 13 of the Treaty on the Functioning of the European Union (TFEU), should be considered in order to spare the animals concerned any avoidable pain, distress or suffering. Animal welfare legislation, such as Council Regulations (EC) No 1/2005[(9)] and (EC) No 1099/2009[(10)], should necessarily continue to apply and should be properly implemented. The rules laid down in this Regulation should not duplicate, or overlap with, the rules laid down in that legislation.

(8) The Commission's communication of 19 September 2007 on a new Animal Health Strategy for the European Union (2007-2013) where ‘Prevention is better than cure’ aims to promote animal health by placing greater emphasis on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. It proposes the adoption of a single and simplified regulatory framework for animal health seeking convergence with international standards while ensuring a firm commitment to high standards of animal health.

(9) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the ‘One health’ principle, and to consolidate the legal framework for a common Union animal health policy through a single, simplified and flexible regulatory framework for animal health.

(10) Animals may suffer from a broad range of infectious or non–infectious diseases. Many diseases can be treated, or have an impact only on the individual animal concerned, or do not spread to other animals or to humans. On the other hand, transmissible diseases may have a broader impact on animal or public health, with effects felt at population level. The animal health rules laid down in this Regulation should be limited to those latter diseases alone.

(11) In laying down those animal health rules, it is essential that consideration be given to the links between animal health and public health, the environment, food and feed safety, animal welfare, food security, economic, social and cultural aspects.

(12) The Sanitary and Phytosanitary Measures (SPS) Agreement, to which the Union is a party, regulates the use of measures necessary to protect human, animal or plant life or health so that they do not arbitrarily or unjustifiably discriminate between World Trade Organisation (WTO) members. If international standards exist, they are required to be used as a basis for Union measures. However, the parties to the SPS Agreement have the right to set their own relevant standards, provided that such standards are based on scientific evidence.

(13) As regards animal health, the SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE) relating to animal health conditions for international trade. In order to reduce the risk of trade disruption, Union animal health measures should aim at an appropriate level of convergence with OIE standards.

(14) In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement, which has been interpreted for the Union in the Commission communication of 2 February 2000 on the precautionary principle, allows members of that Agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the member concerned is required to obtain the additional information necessary for a more objective assessment of risk and to review the measure accordingly within a reasonable period of time.

(15) The risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Due account should also be taken of the opinions of the European Food Safety Authority (EFSA) established by Article 22(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[(11)].

(16) Regulation (EC) No 1069/2009 of the European Parliament and the Council[(12)] lays down both public and animal health rules for certain animal by–products and derived products in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain. In order to avoid any overlap of Union legislation, this Regulation should therefore only apply to animal by-products and derived products where specific rules are not laid down in Regulation (EC) No 1069/2009, and where an animal health risk is involved. For instance, Regulation (EC) No 1069/2009 does not regulate how to handle animal by–products and derived products in the context of disease control measures, and so those issues are duly covered by this Regulation.

(17) In addition, specific rules on transmissible animal diseases, including those transmissible to humans (‘zoonoses’), are already laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council[(13)], Directive 2003/99/EC of the European Parliament and of the Council[(14)] and Regulation (EC) No 2160/2003 of the European Parliament and of the Council[(15)], and specific rules on communicable

diseases in humans are laid down in Decision No 1082/2013/EU of the European Parliament and of the Council[16]. Those acts should remain in force following the adoption of this Regulation. Accordingly, in order to avoid any overlap of Union legislation, this Regulation should only apply to zoonoses to the extent that specific rules are not already laid down in those other Union acts. In addition, this Regulation applies without prejudice to the rules provided for in other Union legislative acts, such as in the fields of veterinary medicine and animal welfare.

(18) Diseases occurring in animals which are kept by humans can have severe impacts on the agriculture and aquaculture sectors, on public health, on the environment and on biodiversity. However, as such animals are kept by humans, disease prevention and control measures are often easier to apply to them than to wild animals.

(19) Nevertheless, diseases occurring in wild animal populations may have a detrimental effect on the agriculture and aquaculture sectors, on public health, on the environment and on biodiversity. It is therefore appropriate that the scope of this Regulation should, in such cases, cover wild animals, both as potential victims of those diseases and as their vectors. For the purposes of this Regulation, the term ‘wild animals’ covers all animals that are not kept by humans, including stray and feral animals, even if they are of species that are normally domesticated.

(20) Animal diseases are not only transmitted through direct contact between animals or between animals and humans. They are also carried further afield through water and air systems, vectors such as insects, or the semen, oocytes and embryos used in artificial insemination, oocyte donation or embryo transfer. Disease agents may also be contained in food and other products of animal origin such as leather, fur, feathers, horn and any other material derived from the body of an animal. Moreover, various other objects such as transport vehicles, equipment, fodder and hay and straw may diffuse disease agents. Therefore, effective animal health rules need to cover all paths of infection and material involved therein.

(21) Animal diseases may have detrimental effects on the distribution of animal species in the wild, and thus affect biodiversity. Microorganisms causing such animal diseases can therefore be considered as invasive alien species within the framework of the United Nations Convention on Biological Diversity. The measures provided for in this Regulation also take account of biodiversity and thus this Regulation should cover animal species and disease agents, including those defined as invasive animal species, which play a role in the transmission of, or are affected by, diseases covered by this Regulation.

(22) Union legislation adopted prior to this Regulation lays down separate animal health rules for terrestrial and aquatic animals. Council Directive 2006/88/EC[17] lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance and good animal husbandry are applicable to both groups of animal species. Accordingly, this Regulation should cover both terrestrial and aquatic animals and should align those animal health rules where applicable. However, for certain aspects, in particular the registration and approval of establishments and the traceability and movements of animals within the Union, this Regulation adheres to the

approach adopted in the past, which was to lay down different sets of animal health rules for terrestrial and aquatic animals due to their different environments and accordingly different requirements to safeguard health.

(23) Union legislation adopted prior to this Regulation, and in particular Council Directive 92/65/EEC[18], also lays down basic animal health rules for other animal species not regulated in other Union acts, such as reptiles, amphibians, marine mammals, and others which are not aquatic or terrestrial animals as defined in this Regulation. Usually, such species do not present a significant health risk for humans or other animals and therefore only a few animal health rules, if any, apply. In order to avoid unnecessary administrative burdens and costs, this Regulation should adhere to the approach adopted in the past, namely to provide the legal framework enabling detailed animal health rules to be laid down for movements of such animals and their products if the risks involved so require.

(24) Humans often keep certain animals as pets in their households to keep them company. The keeping of such pet animals for purely private purposes, including ornamental aquatic animals in households, both indoors and outdoors, generally poses a lower health risk compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture, aquaculture, animal shelters and the transport of animals more generally. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union should apply to such pet animals, as this would represent an unjustified administrative burden and cost. Registration and record keeping requirements should therefore not apply to pet keepers. In addition, specific rules should apply to non–commercial movements of pet animals within the Union.

(25) Some defined groups of animals, for which special animal health rules exist in this Regulation, need to be listed as species in an annex, due to the varied nature of the group concerned. This is the case for the group of hoofed mammals classified as ungulates. The list of such animals may need to be changed in the future due to reasons of changed taxonomy. Therefore, in order to take account of such changes, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the list of ungulates set out in Annex III to this Regulation.

(26) Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example if the disease is too widespread, if diagnostic tools are not available, or if the private sector can take measures to control the disease by itself. Regulatory measures to prevent and control transmissible animal diseases may have important economic consequences for the relevant sectors and may disrupt trade. It is therefore essential that such measures are applied only when they are proportionate and necessary, such as when a disease presents, or is suspected to present, a significant risk to animal or public health.

(27) Furthermore, the preventive and control measures for each transmissible animal disease should be ‘tailor–made’ in order to address its unique epidemiological profile, its consequences and its distribution within the Union. The preventive and control rules applying to each of them should therefore be disease-specific.

(28) For transmissible animal diseases, a disease condition is usually associated with clinical or pathological manifestation of the infection. However, for the purpose of this Regulation, which aims to control the spread of, and eradicate, certain transmissible animal diseases, the disease definition should be wider in order to include other carriers of the disease agent.

(29) Some transmissible animal diseases do not easily spread to other animals or to humans and thus do not cause economic or biodiversity damage on a wide scale. Therefore, they do not represent a serious threat to animal or public health in the Union and can thus, if desired, be addressed by means of national rules.

(30) For transmissible animal diseases that are not subject to measures laid down at Union level, but which are of some economic importance for the private sector at a local level, the latter should, with the assistance of the competent authorities of the Member States, take action to prevent or control such diseases, for instance through self–regulatory measures or the development of codes of practice.

(31) In contrast to the transmissible animal diseases described in recitals 29 and 30, highly transmissible animal diseases may easily spread across borders and, if they are also zoonoses, they may also have an impact on public health and food safety. Hence highly transmissible animal diseases and zoonoses should be covered by this Regulation.

(32) Antimicrobial resistance, understood as the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species, is increasing. Action No 5 advocated in the Communication from the Commission to the European Parliament and the Council entitled ‘Action plan against the rising threats from antimicrobial resistance’ emphasises the preventive role to be played by this Regulation and the consequent expected reduction of the use of antibiotics in animals. This resistance of microorganisms to antimicrobials to which they were previously responsive complicates the treatment of infectious diseases in humans and animals and may thus pose a threat to human or animal health. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation. This will enable action to be taken against antimicrobial-resistant organisms where appropriate and necessary.

(33) New hazards associated with certain diseases or species may develop in particular due to changes in trade patterns, the environment, the climate, animal husbandry and farming traditions, but also as a result of social changes. Scientific progress may also lead to new knowledge concerning, and increased awareness of, existing diseases. Furthermore, diseases and species that are important today may be marginalised in the future. Therefore the scope of this Regulation should be broad and the rules laid down should be focused on diseases with high public relevance. The OIE has, with the support of the European Commission, produced a study on the ‘Listing and categorisation of priority animal diseases, including those transmissible to humans’ and a tool for such an exercise, which aims to develop a system of disease prioritisation and categorisation. That tool is an example of a systematic approach to the collection and assessment of information about animal diseases.

(34) It is necessary to establish a harmonised list of transmissible animal diseases ('listed diseases') which pose a risk to animal or public health in the Union, whether across the whole Union or only in parts. The five diseases already identified in this Regulation should be supplemented by a list of diseases set out in an annex. The Commission should review and amend that annex in accordance with a set of criteria. The power to adopt acts amending the annex should therefore be delegated to the Commission in accordance with Article 290 TFEU.

(35) Diseases with the potential to pose serious risks to public or animal health and to result in impacts on health, the economy or the environment may emerge in the future. Implementing powers to lay down disease prevention and control measures for such emerging diseases should be conferred on the Commission to adopt adequate measures to address potential negative consequences of those diseases even if they have not been fully assessed in view of their potential listing. Such measures are without prejudice to emergency measures and could continue to apply to emerging diseases pending a decision on their listing.

(36) Listed diseases will require different management approaches. Some highly contagious diseases which are currently not present in the Union require stringent measures to immediately eradicate them as soon as they occur. In cases where such diseases are not promptly eradicated and become endemic, a long-term compulsory eradication programme will be required. For other diseases that may already be present in parts of the Union, compulsory or optional eradication is required. In these cases, it is appropriate to put in place restrictions on movements of animals and products, such as a prohibition of movements to and from affected areas, or simply to test the animals or products concerned prior to dispatch. In other instances it might be appropriate merely to implement a programme of surveillance of the distribution of the disease in question, without taking further measures.

(37) Criteria should be laid down to ensure that all relevant aspects are considered when determining which transmissible animal diseases should be listed for the purposes of this Regulation.

(38) The rules laid down by this Regulation for the prevention and control of a specific transmissible animal disease should apply to species of animals which can transmit the disease in question, by virtue of being susceptible to it or by acting as its vector. In order to ensure uniform conditions for the implementation of this Regulation, it is necessary to establish a harmonised list of species to which the measures for specific listed diseases are to apply at Union level ('listed species') and implementing powers to lay down such a list should thus be conferred on the Commission.

(39) The categorisation process should be based on predefined criteria such as the profile of the listed disease in question, the level of its impact on animal and public health, animal welfare and the economy of the Union, the risk of its spreading and the availability of disease prevention and control measures in respect of that listed disease. Implementing powers should be conferred on the Commission to lay down which listed diseases are to be subject to which rules.

(40) Such rules should apply as regards listed diseases that do normally not occur in the Union and for which immediate eradication measures need imperatively to be taken as soon as they are detected, such as classical swine fever, as regards listed diseases that need to be controlled in all Member States with the goal of eradicating them throughout the Union, which could include diseases such as brucellosis, as regards listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially free of, or that have eradication programmes for that, listed disease, which could include diseases such as infectious bovine rhinotracheitis, as regards listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, which could include diseases such as equine infectious anaemia, and as regards listed diseases for which there is a need for surveillance within the Union, which could include diseases such as anthrax.

(41) The disease profile of a given disease may change, as well as the risks associated with the disease and other circumstances. For such cases, the implementing powers conferred on the Commission should also include the power to modify the category into which a particular listed disease falls, and therefore the measures to which it is subject.

(42) Operators working with animals are in the best position to observe and ensure the health of the animals and to monitor products under their responsibility. They should therefore bear primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and the monitoring of products under their responsibility.

(43) Biosecurity is one of the key prevention tools at the disposal of operators and others working with animals to prevent the introduction, development and spread of transmissible animal diseases to, from and within an animal population. The role of biosecurity is also recognised in the impact assessment for the adoption of this Regulation, in which possible impacts are specifically assessed. The biosecurity measures adopted should be sufficiently flexible, suit the type of production and the species or categories of animals involved and take account of the local circumstances and technical developments. Implementing powers should be conferred on the Commission to lay down minimum requirements necessary for the uniform application of biosecurity measures in the Member States. Nevertheless, it should always remain within the power of operators, Member States or the Commission to promote prevention of transmissible diseases through higher biosecurity standards by developing their own guides to good practice. While biosecurity may require some upfront investment, the resulting reduction in animal disease should be a positive incentive for operators.

(44) Biocidal products, such as disinfectants for veterinary hygiene or food and feed areas, insecticides, repellents or rodenticides, play an important role in biosecurity strategies, both at farm level and during animal transport. They should therefore be considered part of biosecurity.

(45) Knowledge of animal health, including of disease symptoms, consequences of diseases and possible means of prevention including biosecurity, treatment and control, is a prerequisite for efficient animal health management and essential in ensuring the early

detection of animal diseases. Operators and animal professionals should therefore acquire such knowledge as appropriate. That knowledge may be acquired by different means, for example formal education, but also through the Farm Advisory System existing in the agricultural sector or by informal training to which national and Union farmer organisations and other organisations may be valuable contributors.

(46) Veterinarians and aquatic animal health professionals play a crucial role in all aspects of animal health management, and general rules concerning their roles and responsibilities should be laid down in this Regulation.

(47) Veterinarians have the education and the professional qualifications attesting to their having acquired the knowledge, skills and competencies necessary, inter alia, to diagnose diseases and treat animals. In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called 'aquatic animal health professionals'. These professionals are traditionally not veterinarians but they practice aquatic animal medicine. This Regulation should therefore respect the decision of those Member States which recognise that profession. In those cases, aquatic animal health professionals should have the same responsibilities and obligations as veterinarians concerning their specific area of work. This approach is in line with the OIE Aquatic Animal Health Code.

(48) Member States, and in particular their competent authorities responsible for animal health, are amongst the key actors in the prevention and control of transmissible animal diseases. The competent authority for animal health plays an important role in relation to surveillance, eradication, disease control measures, contingency planning and raising disease awareness, in the facilitation of animal movements, and in international trade by the issuing of animal health certificates. In order to be able to perform their duties under this Regulation, Member States depend on having access to adequate financial, infrastructural and personnel resources throughout their territories, including laboratory capacity and scientific and other relevant know–how.

(49) The competent authority cannot always perform all the activities required to be carried out by them under this Regulation due to limited resources. For that reason, it is necessary to provide a legal basis for the delegation of the performance of certain activities to veterinarians who are not official veterinarians. For the same reason, Member States should also be allowed to authorise natural or legal persons to perform certain activities under certain conditions.

(50) In order to ensure that the necessary conditions are laid down for the general application of disease prevention and control measures across the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the delegation of the performance of other activities which the competent authority may delegate to veterinarians other than official veterinarians.

(51) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, veterinarians, animal health professionals, other stakeholders and trading partners. In order to secure their support, it is necessary to organise decision-making procedures and the application of the measures provided for in this Regulation in a clear, transparent and inclusive manner.

(52) The competent authority should also take appropriate steps to keep the public informed, especially when there are reasonable grounds to suspect that animals or products may present a risk for animal or public health or when a case is of public interest. In those cases, the animals or products concerned may originate from within the Union or enter the Union from outside. The latter may also be brought into the Union by persons travelling from outside the Union with their personal luggage. Thus, the information provided to citizens should also cover the risks involved with such situations.

(53) In order to avoid the release of disease agents from laboratories, institutes and other facilities handling disease agents, it is vital that they take appropriate biosecurity, biosafety and bio–containment measures. This Regulation should therefore provide for safety measures to be observed during the handling or transportation of such disease agents, vaccines and other biological products. The obligation imposed in that regard should also apply to any legal or natural person who is involved in such an activity. In order to ensure that safety standards are respected in the handling of highly contagious biological agents, vaccines and other biological products, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the safety measures in those laboratories, institutes and facilities and for movements of disease agents.

(54) Early detection and a clear chain of disease notification and reporting are crucial for effective disease control. In order to achieve an efficient and quick response, Member States should ensure that any suspicion or confirmation of an outbreak of certain listed diseases should be immediately notified to the competent authority.

(55) Veterinarians are key actors in the investigation of diseases and a key link between operators and the competent authority. They should therefore be notified by the operator concerned in cases of abnormal mortalities, other serious disease problems, or significantly decreased production rates with an undetermined cause.

(56) In order to ensure the effective and efficient notification of, and to clarify different circumstances related to, abnormal mortalities and other signs of serious diseases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of criteria to determine when relevant circumstances for notification occur and to lay down the rules for further investigation, where this is relevant.

(57) For certain listed diseases, it is vital that a Member State should immediately notify the Commission and the other Member States about an outbreak in its territory. Such notification will enable neighbouring or other affected Member States to take precautionary measures when appropriate.

(58) On the other hand, for some diseases immediate notification and action are not necessary. In those cases, the gathering of information and reporting in relation to the occurrence of those diseases is essential in order to control the disease situation and where necessary to take disease prevention and control measures. This reporting requirement may also apply to diseases which are subject to Union-wide notification but where additional information is needed for the implementation of effective disease

prevention and control measures. In order to ensure that the correct information and data needed to prevent the spread or to control each particular disease are collected in the right timeframe, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the matters to be reported.

(59) A key purpose of disease notification and reporting is to generate reliable, transparent and accessible epidemiological data. A computerised interactive information system for the effective collection and management of surveillance data should be established at Union level for listed diseases and, when relevant, for emerging diseases or antimicrobial-resistant pathogens. That system should promote optimal data availability, facilitation of data exchange, and reduction of administrative burdens for the competent authorities of the Member States by merging disease notification and reporting within the Union and at international level into a single process operated through the database of the OIE. Steps should also be taken to ensure consistency in exchanges of information in accordance with Directive 2003/99/EC.

(60) In order to ensure uniform conditions for the implementation of the Union disease notification and reporting rules, implementing powers should be conferred on the Commission to establish a list of diseases which are subject to Union notification and Union reporting rules as provided for in this Regulation and to establish the necessary procedures, formats, data and information exchanges regarding disease notification and reporting.

(61) Surveillance is a key element of disease control policy. It should provide for the early detection of transmissible animal diseases and efficient notification thereof, thereby enabling the sector concerned and the competent authority to implement, where feasible, timely disease prevention and control measures, and allowing the disease in question to be eradicated. Furthermore, it should supply information on the animal health status of each Member State and of the Union, thereby substantiating certification of freedom from disease and facilitating trade with third countries.

(62) Operators observe their animals on a regular basis and are best positioned to detect abnormal mortalities or other serious disease symptoms. Operators are therefore the cornerstone of any surveillance and essential for the surveillance undertaken by the competent authority.

(63) To ensure close collaboration and exchange of information between operators and veterinarians or aquatic animal health professionals, and to supplement the surveillance undertaken by operators, establishments should, as appropriate for the type of production concerned and other relevant factors, be subject to animal health visits. In order to ensure uniform conditions for the carrying-out of animal health visits, implementing powers should be conferred on the Commission to lay down minimum requirements.

(64) It is essential that the competent authority have in place a system of surveillance for the listed diseases which are subject to surveillance. This should also apply to emerging diseases, where the potential health risks of the disease concerned should be assessed and epidemiological data collected for that assessment. In order to ensure the best use

of resources, information should be collected, shared and used in the most effective and efficient manner possible.

(65) The surveillance methodology, frequency and intensity should be adapted to each specific disease and should take into account the specific purpose of the surveillance, the animal health status in the zone concerned and any additional surveillance conducted by operators. The appropriate epidemiological surveillance actions could range from a simple notification and reporting of the occurrence or suspicion of a listed or an emerging disease, or other anomalies, such as abnormal mortalities and other signs of disease, to a specific and comprehensive surveillance programme, which would normally include additional sampling and testing regimes.

(66) Depending on the epidemiological profile of a disease and the relevant risk factors, a specific surveillance programme comprising defined and structured activities may need to be put in place. In such cases, it is appropriate that Member States develop targeted surveillance programmes. Where such programmes are relevant for the Union as a whole, rules should be laid down providing for harmonised application of such programmes.

(67) Such programmes should be consistent with Union objectives and therefore coordinated at Union level. To that end, they should be submitted to the Commission. Furthermore, Member States implementing such specific surveillance programmes should also submit regular reports on the results of those programmes to the Commission. In order to ensure uniform conditions for the implementation of surveillance programmes, implementing powers should be conferred on the Commission to establish a list of diseases subject to surveillance programmes and to set up harmonised procedures, formats, data, information exchange and criteria to be used for the evaluation of the surveillance programmes.

(68) It will often be necessary to provide details about the appropriate format of surveillance for different diseases, ranging from those diseases where surveillance can be limited to activities such as reporting and notification to diseases where an in–depth Union–wide specific surveillance programme needs to be established. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the surveillance design, the criteria to establish the relevance of a disease to be subject to a surveillance programme relevant for the Union and for official confirmation of outbreaks, the case definitions of the diseases concerned and requirements for surveillance programmes in relation to their content, the information to be included in such programmes and their period of application.

(69) Member States that are not free or are not known to be free from listed diseases which are subject to eradication measures as provided for in this Regulation should be required to establish compulsory eradication programmes to eradicate those diseases where eradication is compulsory in the Union.

(70) On the other hand, there are some diseases which are of Union concern but for which it is not necessary to require Member States to eradicate the disease in question. It should be open to Member States to establish optional eradication programmes for such diseases if they decide that eradication is important for them. Such optional eradication

programmes would be recognised at Union level and would entail the implementation of certain relevant disease control measures. They may also enable the Member State concerned, subject to approval by the Commission, to require certain guarantees when receiving animals from other Member States or from third countries.

(71) In order to ensure uniform conditions for the implementation of disease eradication programmes, implementing powers should be conferred on the Commission to lay down the procedures for the submission of such programmes, performance indicators, and reporting.

(72) Furthermore, a Member State should have the possibility of declaring the whole of its territories, zones or compartments thereof free of one or more of listed diseases which are subject to rules on compulsory or optional eradication programmes, in order to be protected against the introduction of such listed diseases from other parts of the Union or from third countries or territories. A clear harmonised procedure, including the necessary criteria for disease–free status, should be established for that purpose. In order to ensure uniform conditions for the implementation of the recognition of disease–free status within the Union, it is necessary that such a disease–free status be officially approved, and implementing powers to approve such status should therefore be conferred on the Commission.

(73) The OIE has introduced the concept of compartmentalisation in the framework of the Terrestrial and Aquatic Animal Health Codes ('the OIE Codes'). In Union legislation adopted prior to this Regulation, that concept is recognised only for particular animal species and diseases specified in specific Union legislation, namely for avian influenza and aquatic animal diseases. This Regulation should establish the possibility of using the compartment system for other animal species and diseases. In order to lay down the detailed conditions and rules for the recognition and approval of compartments and the requirements relating to them, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission.

(74) Member States should make their disease–free territories, zones and compartments thereof publicly known for the purpose of informing trading partners and facilitating trade.

(75) In order to lay down the detailed conditions for the recognition of disease–free status, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the criteria and conditions for obtaining such status, the evidence needed to substantiate certification of freedom from disease, special disease prevention and control measures, including non–vaccination status, where relevant, restrictions, information to be provided, derogations, and conditions for the maintenance, suspension, withdrawal or restoration of disease–free status.

(76) In order to ensure uniform conditions for the implementation of procedures to obtain disease-free status, implementing powers should be conferred on the Commission to establish the listed diseases which may be subject to compartmentalisation and to lay down detailed rules on formats for the submission of applications and exchanges of information.

(77) The presence of an entirely non–immune population of animals, susceptible to certain listed diseases, requires permanent disease awareness and preparedness. Contingency plans have proved to be a crucial tool for the successful control of disease emergencies in the past. In order to ensure the availability of this effective and efficient tool for the control of disease emergencies, and that it is sufficiently flexible to adjust to emergency situations, implementing powers should be conferred on the Commission to lay down necessary rules for the implementation of contingency plans.

(78) Past animal health crises have shown the benefits of having specific, detailed and rapid procedures for the management of disease emergencies. Those organisational procedures should ensure a rapid and effective response and should improve coordination of efforts on the part of all parties involved, including in particular the competent authorities and the stakeholders. They should also include cooperation with the competent authorities of neighbouring Member States and third countries and territories, where feasible and relevant.

(79) To ensure the applicability of contingency plans in real emergency situations, it is essential to practise the systems concerned and to test that they are working. To that end, the competent authorities of the Member States should carry out simulation exercises, in cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.

(80) In order to ensure uniform conditions for the implementation of contingency plans and simulation exercises, implementing powers should be conferred on the Commission to lay down rules for the practical implementation of those plans and exercises.

(81) Veterinary medicinal products such as vaccines, hyper-immune sera and antimicrobials play an important role in the prevention and control of transmissible animal diseases. The Impact Assessment for the adoption of this Regulation highlights in particular the importance of vaccines as a tool in the prevention, control and eradication of animal diseases.

(82) However, control strategies for some transmissible animal diseases require prohibition or restriction of the use of certain veterinary medicinal products, as their use would hamper the effectiveness of those strategies. For example, certain veterinary medicinal products may mask the manifestation of a disease, make the detection of a disease agent impossible or render a swift and differential diagnosis difficult and thus endanger the correct detection of disease.

(83) However, those control strategies may vary substantially between different listed diseases. This Regulation should therefore provide for rules on the use of veterinary medicinal products for the prevention and control of certain listed diseases and for harmonised criteria to be taken into consideration when determining whether or not to use, and how to use, vaccines, hyper–immune sera and antimicrobials. In order to ensure a flexible approach and to address the specificities of different listed diseases and the availability of effective treatments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the restrictions on, prohibitions of or obligations to use certain veterinary medicinal products within

the framework of the control of certain listed diseases. In urgent cases and in order to address emerging risks with possibly devastating implications for animal or public health, the economy, society or the environment, it should be possible for the measures in this regard to be adopted by means of the urgency procedure.

(84) Following the conclusions of the expert opinion on vaccine and/or diagnostic banks for major animal diseases, steps should also be taken to make it possible for the Union and the Member States to establish reserves of antigens, vaccines and diagnostic reagents for listed diseases that represent a serious threat to animal or public health. The establishment of a Union antigen, vaccine and diagnostic reagent bank would promote attainment of the Union's animal health objectives by permitting a quick and effective response when the resources of the bank are required, and would represent an efficient use of limited resources.

(85) In order to ensure such a quick and effective response, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the establishment and management of such banks, and safety standards and requirements for their operation. However, this Regulation should not provide for the adoption of rules on the financing of the disease prevention and control measures, including vaccination.

(86) Criteria for priority access to the Union antigen, vaccine and diagnostic reagent banks' resources should be established in order to ensure their effective distribution in emergencies.

(87) For reasons of security in relation to bio–terrorism and agro–terrorism, certain detailed information concerning the Union antigen, vaccine and diagnostic reagent banks should be treated as classified information and its publication should be prohibited. As regards the same type of information in relation to national vaccine banks, the constitutional requirements of different Member States as regards freedom of information should be respected while ensuring that the information in question is treated as classified information.

(88) In order to ensure uniform conditions for the management of the Union antigen, vaccine and diagnostic reagent banks, implementing powers should be conferred on the Commission to lay down detailed rules concerning which biological products are to be included in those banks and for which diseases, and detailed rules on the supply, quantities, storage, delivery, procedural and technical requirements for antigens, vaccines and diagnostic reagents and the frequency and content of submissions of information to the Commission.

(89) In the event of an outbreak of a listed disease considered to represent a high risk to animal or public health in the Union, Member States should ensure that immediate disease control measures to eradicate the disease in question are taken in order to protect animal and public health.

(90) The competent authority should be responsible for initiating the first investigations to confirm or rule out an outbreak of a highly contagious listed disease which is considered to represent a high risk to animal or public health in the Union.

(91) The competent authority should put in place preliminary disease control measures to prevent the possible spread of the listed disease, and should undertake an epidemiological enquiry.

(92) As soon as a listed disease is confirmed, the competent authority should take the necessary disease control measures, if necessary including the establishment of restricted zones, to eradicate and prevent the further spread of that disease.

(93) The occurrence of a listed disease in wild animals may pose a risk to public health and the health of kept animals. Special rules should therefore be laid down, where necessary, for measures to control and eradicate diseases in wild animals.

(94) There may be cases where small populations of certain animals, such as rare breeds and species, may be endangered by standard disease control measures in the event of an occurrence of a listed disease. The protection of such breeds and species may require modified measures to be taken by the competent authority. However, such modification should not hamper the overall control of that disease.

(95) For listed diseases which are not highly contagious and which are subject to compulsory rules requiring their eradication, the disease control measures should be implemented in such a way as to prevent the spread of the disease in question, in particular to non–infected areas. However, those measures may possibly be more limited than, or may be different from, those applicable in relation to the most dangerous listed diseases. This Regulation should therefore provide for special rules for those less dangerous diseases. Member States that have an optional eradication programme in place should also implement such disease control measures. In some cases, depending on the disease profile and the epidemiological situation, eradication may be a long-term objective, while the short-term aim may be to control the disease. However, the level and intensity of disease control measures should be proportionate and should take into account the characteristics of the listed disease in question, its distribution and its significance for the Member State concerned by it and for the Union as a whole.

(96) In order to ensure the effective application of the disease control measures provided for in this Regulation by operators, pet keepers and competent authorities, and taking into account the specificities of the disease-control measures for particular listed diseases and the risk factors involved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed disease-control measures to be implemented in the event of suspicion or confirmation of a listed disease in establishments, other locations and restricted zones.

(97) In order to provide for the possibility for the Commission to adopt special disease control measures on a temporary basis in the event that the disease control measures laid down in this Regulation are not sufficient or appropriate to address the risk involved, implementing powers should be conferred on the Commission concerning the laying down of special disease control measures for a limited period of time.

(98) The registration of certain transporters and establishments keeping terrestrial animals or handling germinal products or transporting them is necessary in order to allow

the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases.

(99) To avoid unjustified administrative burdens and costs, Member States should be able, on a limited basis, to exempt from the registration obligation certain types of establishments posing a low risk. Implementing powers should be conferred on the Commission in order to achieve a harmonised approach to the granting of such exemptions. Such a harmonised approach is particularly necessary in order to prevent certain types of establishments from being excluded from the registration obligation. This is particularly relevant not only as regards those establishments which pose a more than insignificant risk to animal health but also as regards establishments which pose a more than insignificant risk to public health. An example of such risk is the keeping of animals that live in close contact with, or proximity to, humans, such as the breeding of dogs at a level involving a certain continuity of activities and a certain degree of organisation with the primary aim of their being sold for the purpose of becoming pet animals in households.

(100) Where a certain type of establishment keeping terrestrial animals or handling or storing germinal products poses a particular animal health risk, it should be subject to approval by the competent authority.

(101) To avoid unjustified administrative burdens and costs, particularly to enterprises posing a low risk, flexibility should where possible be built into the relevant measures, making it possible to adapt the system of registration and approval to local and regional conditions and production patterns.

(102) In some cases, harmonisation of certain conditions for registration or approval across the Union is desirable or necessary. For example, germinal products establishments and assembly operations should meet certain conditions and should be approved in order to comply with international standards, thereby enabling the Union to provide animal health guarantees to third countries when trading. Such conditions should also involve requirements for specific training or professional qualifications for certain very specific establishments or operations (e.g. for embryo collection teams), or even the obligation for specific supervision by the competent authority. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning those detailed requirements, in order to provide for such specific conditions.

(103) In the interest of reducing administrative burdens, registrations and approvals should, where possible, be integrated into a registration or approval system which the Member State concerned may already have established for other purposes.

(104) Operators have first–hand knowledge of the animals under their care. They should therefore maintain up–to–date records of information which is relevant for assessing the animal health status, for traceability and for an epidemiological enquiry in the event of the occurrence of a listed disease. Those records should be easily accessible to the competent authority.

(105) In order to ensure the availability of up–to–date information concerning registered establishments and operators and approved establishments, competent authorities

should establish and keep a register of such establishments and operators. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed information to be included in the register of establishments and operators.

(106) In order to be approved by the competent authority, an establishment should have to fulfil certain requirements. Before granting the approval, the competent authority should have to verify by means of an on–site visit whether all requirements have been met. In some cases, not all conditions can be met immediately, but the remaining deficiencies do not present a significant risk to animal or public health. In such cases, it should be possible for the competent authority to grant a conditional approval, followed by another on–site visit to verify that progress has been made. In those cases, the competent authority should provide the necessary effective guidance to the operators of the establishments concerned, in order that the operator in question understands the deficiency and can plan for its successful resolution.

(107) Efficient traceability is a key element of disease control policy. Identification and registration requirements specific to the different species of kept terrestrial animals and germinal products should be in place in order to facilitate the effective application of the disease prevention and control rules provided for in this Regulation. In addition, it is important to provide for the possibility of establishing an identification and registration system for species for which such arrangements do not exist at present, or when changing circumstances and risks so warrant.

(108) For certain animal species for which it is important to be able to trace individual animals or groups, a physical means of identification should be required. This entails the animal in question being physically marked, tagged, microchipped or otherwise identified by means of a method which can be seen or detected on or in its body and which cannot easily be removed.

(109) In order to ensure the smooth operation of the identification and registration system and to ensure traceability, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of obligations concerning databases, detailed identification and registration requirements concerning different animal species, including exemptions and conditions for such exemptions, and documents.

(110) It is appropriate to reduce administrative burdens and costs and to provide for flexibility of the system in circumstances where the traceability requirements can be achieved by means other than those set out in this Regulation. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning derogations from the identification and registration requirements.

(111) In order to ensure uniform conditions for the implementation of the identification and registration system and traceability, implementing powers should be conferred on the Commission to lay down rules concerning the technical specifications for databases, means of identification, documents and formats, and deadlines.

(112) An important tool for preventing the introduction and spread of a transmissible animal disease is the use of restrictions on movements of animals and products that may transmit that disease. However, restricting the movement of animals and products may have a severe economic impact and may interfere with the operation of the internal market. Such restrictions should therefore be applied only where necessary and proportionate to the risks involved. This approach is in line with the principles laid down in the SPS Agreement and the OIE international standards.

(113) The general requirements laid down in this Regulation should apply to all animal movements, such as the prohibition of the movement of animals from an establishment where there are abnormal mortalities or other disease symptoms with an undetermined cause or disease prevention requirements during transport.

(114) The legal framework currently laid down in Union animal health legislation, for the movement of terrestrial animals and products lays down harmonised rules primarily for such movements between Member States, while leaving it up to the Member States to determine the necessary movement requirements within their territory. A comparison between the current situation and an option whereby rules for movements within Member States would also be harmonised at Union level was set out at length in the impact assessment for the adoption of this Regulation. It has been concluded that the current approach should be maintained, as complete harmonisation of all movements would be very complex and the benefits in terms of the facilitation of movements between Member States do not outweigh the negative impact this could have on the ability to control diseases.

(115) For animals that are moved between Member States, a set of basic animal health requirements should apply. In particular, animals should not be moved from establishments with abnormal mortalities or signs of disease of unknown cause. However, mortalities, even if abnormal, which are linked to scientific procedures authorised under Directive 2010/63/EU of the European Parliament and of the Council[(19)] and which are not of infectious origin related to listed diseases, should not be a reason to prevent movements of animals intended for scientific purposes.

(116) However, this Regulation should provide for flexibility in order to facilitate the movement of species and categories of terrestrial animals that pose a low risk in terms of spreading listed diseases between Member States. In addition, further possibilities for derogations should be provided for in cases where Member States or operators successfully put in place alternative risk-mitigating measures such as high levels of biosecurity and effective surveillance systems.

(117) Ungulates and poultry are groups of animal species of high economic significance and are subject to specific movement requirements under Union legislation adopted prior to this Regulation, namely Council Directives 64/432/EEC[(20)], 91/68/EEC[(21)], 2009/156/EC[(22)], 2009/158/EC[(23)] and, in part, Directive 92/65/EEC. The main rules governing the movement of animals of those species should be laid down in this Regulation. The detailed requirements which largely depend on the diseases that may be transmitted by different species or categories of animals should be regulated in

subsequent Commission acts, taking into account the specificities of the diseases, species and categories of animals in question.

(118) As assembly operations for ungulates and poultry pose a particularly high risk of disease, it is appropriate to limit the number that can be carried out in one movement between Member States, and to lay down specific rules in this Regulation to protect the health of the animals involved and prevent the spread of transmissible animal diseases. Those assembly operations would normally take place in an establishment approved for that purpose, or, when permitted by a Member State of origin, the first assembly operation, on one means of transport such as a lorry, through the collection of animals from different locations in that Member State.

(119) Depending on the listed diseases and listed species concerned, it is necessary to lay down specific animal health requirements for certain animal species other than kept ungulates and poultry. Rules for these species were also laid down in the legal framework applicable prior to this Regulation and in particular in Directive 92/65/EEC. That Directive lays down specific rules for the movement of animal species including bees, bumble bees, apes, dogs and cats and this Regulation should therefore provide a legal basis for the adoption of delegated and implementing acts laying down specific movement rules for those animal species.

(120) Confined establishments, usually used for the keeping of laboratory animals or zoo animals, normally involve a high level of biosecurity and a favourable and well-controlled health status, and are subject to fewer movements or to movements solely within the closed circuits of those establishments. The status of confined establishments, for which operators may apply on a voluntary basis, was first introduced in Directive 92/65/EEC, which lays down rules and requirements for approval and movement requirements for approved bodies, institutes and centres. The system thereby established enables those establishments to exchange animals amongst themselves with fewer movement requirements, at the same time providing health guarantees within the circuit of confined establishments. Consequently, it has been broadly accepted by the operators and used as a voluntary option. It is therefore appropriate in this Regulation to preserve the concept of confined establishments and also to lay down rules for movement between those establishments.

(121) For scientific purposes, such as research or diagnostic purposes, and in particular for those authorised in accordance with Directive 2010/63/EU, it may be necessary to move animals which do not fulfil the general animal health requirements laid down in this Regulation and which represent a higher animal health risk. Those kinds of movements should not be prohibited or unduly restricted by this Regulation, as this could impede otherwise authorised research activities and delay scientific progress. None the less, it is essential that rules be laid down in this Regulation to ensure that movements of those animals take place in a safe manner.

(122) Movement patterns of circus animals, animals kept in zoos, animals intended for exhibition and certain other animals often deviate from the movement patterns of other kept species. In adapting Union rules on animal movements specific consideration

should be given to such animals, taking into account specific risks and alternative risk-mitigation measures.

(123) In order to ensure that the objectives referred to in recitals 112 to 122 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning disease prevention measures in transport operations, specific rules for the movement of certain animal species and special circumstances, such as assembly operations or rejected consignments, and special requirements or derogations for other types of movements, such as movement for scientific purposes.

(124) In order to ensure the possibility of applying special rules for movements where the usual movement rules are not sufficient or appropriate to limit the spread of a certain disease, implementing powers should be conferred on the Commission to lay down special movement rules for a limited period of time.

(125) Movements of kept terrestrial animals between Member States should comply with the requirements applicable to such movements. In the case of animals of species which present a health risk or which are of greater economic importance, they should be accompanied by an animal health certificate issued by the competent authority.

(126) To the extent technically, practically and financially feasible, there should be recourse to technological developments in order to reduce the administrative burdens on operators and competent authorities in relation to certification and notification by using information technology to replace paper documentation and to facilitate notification procedures, and by using such technology as far as possible for multiple purposes.

(127) In cases where there is no requirement for an animal health certificate to be issued by a competent authority, an operator who moves animals to another Member State should issue a self–declaration document which confirms that the animals meet the movement requirements laid down in this Regulation.

(128) In order to ensure that the objectives referred to in recitals 125, 126 and 127 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning rules on the content of animal health certificates, information obligations, derogations from the animal health certification requirements, specific certification rules, and the obligations of official veterinarians to conduct appropriate checks before the signing an animal health certificate.

(129) Notification of movements of animals and germinal products between Member States, and in some cases within the national territories of Member States, is essential in order to ensure the traceability of the animals and germinal products concerned, where these movements may be linked to a risk of spreading transmissible animal diseases. Such movements should therefore be notified and registered by means of an integrated computerised veterinary system (‘Traces’). The Traces system integrates into a single architecture the computerised systems provided for in Article 20 of Directive 90/425/EEC and in Council Decision 92/438/EEC[(24)] respectively, based on Commission Decisions 2003/24/EC[(25)] and 2004/292/EC[(26)].

(130) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation on animal health certification and movement notification, implementing powers should be conferred on the Commission to lay down rules concerning the model animal health certificates, self–declaration documents, formats and deadlines for movement notification for both terrestrial and aquatic animals, germinal products and, where also relevant, products of animal origin.

(131) The specific nature of movements of pet animals represents an animal health risk which deviates significantly from that of other kept animals. Specific, less stringent rules for such movements should therefore be laid down in this Regulation. Such less stringent rules are only justified, however, if the pet animal genuinely accompanies its owner during the owner's movement, or within a limited period thereafter, and if no more than five pet animals as referred to in Part A of Annex I are moved together with their owner at one time. In order to ensure that pet animals do not pose a significant risk for the spread of transmissible animal diseases, and in order to clarify the exceptional situations in which more than five pet animals may accompany the owner, or when the pet animal is to be moved within a longer time-frame before or after the owner moves, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed rules for movements of those animals. In order to ensure uniform conditions for the implementation of the animal health requirements laid down in this Regulation concerning the movements of pet animals, implementing powers should be conferred on the Commission to lay down rules concerning the disease prevention and control measures to be taken for such movements.

(132) Wild animals may for various reasons represent an animal and public health risk, for example if they are moved into an establishment or from one environment to another environment. Appropriate preventive measures for movement of those animals may need to be taken to avoid the spread of transmissible animal diseases. In order to ensure that wild animals do not pose a significant risk for the spread of transmissible animal diseases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the additional requirements for movements of wild terrestrial animals.

(133) Germinal products can represent a similar risk of spreading transmissible animal diseases to live animals. In addition, there are specificities in their production which are related to high health demands for breeding animals and which call for stricter or particular animal health requirements concerning the donor animals. In order to ensure safe movements of germinal products, to maintain their expected high health standard and to take into account certain specific uses of such products, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the detailed requirements for movement of germinal products of certain animal species, special requirements applicable to, for example, their movement for scientific purposes, and derogations from the animal health certification obligation.

(134) Products of animal origin can represent a risk for the spreading of transmissible animal diseases. Food safety requirements for products of animal origin laid down in Union legislation ensure good hygiene practices and reduce the animal health risks of such

products. However, for certain types of products, specific animal health measures, such as disease control and emergency measures, should be laid down in this Regulation in order to ensure that products of animal origin do not spread animal diseases. In order to ensure safe movements of products of animal origin in these particular cases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the establishment of detailed rules for movements of products of animal origin in relation to disease control measures taken, the obligations in respect of animal health certification and derogations from those rules where the risk involved with such movements and the risk-mitigation measures in place so permit.

(135) When Member States take national measures concerning movements of animals and germinal products, or decide to take national measures to limit the impact of transmissible animal diseases other than listed diseases within their territory, those national measures should not interfere with the rules on the internal market laid down in Union legislation. It is therefore appropriate to set the framework for such national measures and to ensure that they remain within the limits permitted under Union law.

(136) The registration and approval of aquaculture establishments is necessary in order to allow the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases. Directive 2006/88/EC requires all establishments which move aquatic animals to be authorised. That system of authorisation should be maintained under this Regulation, notwithstanding the fact that, in some official languages of the Union, this Regulation uses different terms to refer to the authorisation system from those used in Directive 2006/88/EC.

(137) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread transmissible animal diseases, for example as a result of the discharge from processing establishments of effluents containing pathogens. It is therefore necessary to approve processing establishments which fulfil the risk-mitigation measures for such slaughter and processing operations. This Regulation should therefore provide for the approval of disease control aquatic food establishments.

(138) In order to ensure the availability to the public of up–to–date information concerning registered and approved establishments, the competent authority should establish and keep a register of such establishments. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the information to be included in registers of aquaculture establishments and the record-keeping requirements for aquaculture establishments and transporters.

(139) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation concerning the registration and approval of aquaculture establishments and disease control aquatic food establishments, record-keeping and registers of establishments, implementing powers should be conferred on the Commission to lay down rules concerning the information obligations, derogations and other implementing rules in that regard.

(140) As it is not feasible in most cases to individually identify aquatic animals, the keeping of records by aquaculture establishments, disease control aquatic food establishments and

transporters is an essential tool in ensuring the traceability of aquatic animals. Records also serve as a valuable tool for the surveillance of the health situation of establishments.

(141) As in the case of terrestrial animals, it is necessary to lay down harmonised rules on the movement of aquatic animals, including rules on animal health certification and movement notification.

(142) Directive 2006/88/EC lays down rules for movements of aquatic animals which apply equally to movements within and between Member States. The key determining factor in relation to rules on the movement of aquatic animals is the health status, as regards listed diseases, of the Member State, zones and compartments of destination.

(143) However, Directive 2006/88/EC excludes from its scope wild aquatic animals caught or harvested for direct entry into the food chain. By contrast, this Regulation retains them within its scope, but excludes them from the definition of aquaculture animals. It should therefore provide for possible measures in relation to such aquatic animals where, taking into account their proportionality, such measures are justified by the risks involved.

(144) Consequently, the principle explained in recital 142 should also apply to movements of aquatic animals that are not defined as aquaculture animals but are covered by the scope of this Regulation. This applies, in particular, to aquatic animals with an unknown or confirmed disease positive health status, regardless of their final use. As movements of live wild aquatic animals with an unknown or confirmed disease positive health status and intended for human consumption may also pose a risk of spreading listed or emerging diseases, the same system of rules should also apply to them. This includes those wild aquatic animals, harvested or caught for human consumption, which are moved and temporarily kept while awaiting slaughter.

(145) However, disproportionate movement restrictions and unnecessary administrative burdens for establishments and operators within the commercial fisheries sector should be avoided. Consequently, in cases where such live wild aquatic animals are intended for human consumption, the rules in question should in principle apply only to movements of live wild aquatic animals which pose a significant risk of spreading listed or emerging diseases into Member States, zones or compartments which have been declared free of certain listed diseases or which are subject to eradication programmes with regard to those diseases.

(146) To encourage Member States to enhance the health status of their aquatic populations, certain adjustments and added flexibility should be introduced in this Regulation.

(147) In order to ensure control of the movement of aquatic animals, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the disease prevention measures applicable to transport, specific rules applicable to movements of certain categories of aquatic animals for different purposes, specific requirements or derogations in respect of certain types of movements, such as movements for scientific purposes, and additional requirements for movements of wild aquatic animals.

(148) In order to ensure the possibility of temporary derogations and specific requirements for movements of aquatic animals, where the movement rules laid down in this Regulation are not sufficient or appropriate to limit the spread of a particular listed disease, implementing powers should be conferred on the Commission to lay down special movement rules or derogations for a limited period of time.

(149) Union aquaculture production is extremely diverse as regards species and production systems, and this diversification is rapidly increasing. This may require the adoption at Member State level of national measures concerning diseases other than those regarded as listed diseases in accordance with this Regulation. However, such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect movements between Member States unless they are necessary in order to prevent the introduction, or to control the spread, of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.

(150) Currently, listed diseases concern animal species other than those defined by this Regulation as terrestrial and aquatic species, such as reptiles, amphibians, insects and others, only to a very limited extent. It is therefore not appropriate to require that all the provisions of this Regulation should apply to those animal species. However, if a disease which concerns species other than terrestrial and aquatic species should become listed, the relevant animal health requirements of this Regulation should apply to those species, in order to ensure that adequate and proportionate disease prevention and control measures may be taken.

(151) In order to ensure the possibility of laying down movement rules for animals that are not defined as terrestrial or aquatic animals by this Regulation, and germinal products and products of animal origin deriving from such animals, when a risk so warrants, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the registration and approval of establishments, record-keeping and registers, identification and registration and traceability movement requirements, animal health certification and self–declaration and movement notification obligations in respect of animals, germinal products and products of animal origin deriving from those species.

(152) Whenever necessary in order to ensure uniform conditions for the implementation of the animal health requirements for those other animal species and germinal products and products of animal origin deriving from them, implementing powers should be conferred on the Commission to lay down detailed rules concerning those requirements.

(153) In order to prevent the introduction of listed diseases and emerging diseases into the Union, it is necessary to have in place efficient rules on the entry into the Union of animals, germinal products and products of animal origin that may transmit such diseases.

(154) In order to guarantee the health status of the Union, this Regulation lays down provisions concerning movements of animals and products within the Union. It is therefore appropriate, so as not to jeopardise that status, to impose conditions for the

entry of animals and products into the Union that are no less strict than those applicable to movements within the Union.

(155) In order to ensure that animals, germinal products and products of animal origin from third countries or territories fulfil animal health requirements that provide guarantees equivalent to those provided for in Union legislation, it is essential that they be subject to appropriate controls by the competent authority of the third country or territory from which they are exported to the Union. Where relevant, the health status of a third country or territory of origin should be verified prior to accepting entry into the Union of such animals, germinal products and products of animal origin. Consequently, only third countries and territories which can demonstrate that they meet the animal health standards for entry of the animals and products into the Union should be eligible to export them to the Union and be listed for that purpose.

(156) For some species and categories of animals, germinal products and products of animal origin, the Union lists of third countries and territories from which entry into the Union is permitted have not been established in Union acts adopted prior to the date of adoption of this Regulation. In those cases, pending the adoption of rules pursuant to this Regulation, Member States should be permitted to determine from which countries and territories those animals, germinal products and products of animal origin may be permitted to enter their territory. In so determining, Member States should take into account the criteria laid down in this Regulation for the Union lists of third countries and territories.

(157) In order to ensure that the animal health requirements for entry into the Union provided for in this Regulation are complied with, and that they are in line with the principles of the OIE Codes, all animals, germinal products and products of animal origin entering the Union should be accompanied by an animal health certificate issued by the competent authority of the third country or territory of origin confirming that all the animal health requirements for entry into the Union are complied with. However, deviation from this rule should be permitted in respect of commodities which pose a low animal health risk.

(158) Animal health certificates may stand on their own, but certification is often required in Union legislation for other purposes, for example in order to certify that public health or animal welfare requirements of animals or products have been complied with. This has to be taken into account. In order to minimise administrative burdens and costs, those animal health certificates should also be permitted to include information required under other Union legislation concerning food and feed safety and animal welfare.

(159) Diseases may be spread by means other than animals, germinal products, products of animal origin and animal by–products and derived products. For instance, vehicles, transport containers, hay, straw, plant products, materials that may have been in contact with infected animals and equipment may also spread disease. Where necessary, measures should be taken to prevent disease transmission by those means.

(160) In order to ensure the appropriate level of detail for the requirements for entry into the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the adoption of supplementary rules for the approval of establishments in third countries and territories and derogations, animal

health requirements for the entry into the Union of consignments from third countries and territories and animal health requirements for disease agents, other materials, means of transport and equipment which may transmit animal diseases.

(161) In order to ensure uniform conditions for the implementation of animal health requirements for the entry into the Union of consignments of animals, germinal products and products of animal origin, implementing powers should be conferred on the Commission to lay down rules on, inter alia, the list of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is allowed and on the contents and format of model animal health certificates.

(162) Past experience has shown that when an outbreak of a serious disease occurs in Member States or in third countries or territories from which animals or products enter the Union, disease prevention and control measures have to be taken immediately to prevent its introduction and limit its spread. Such an emergency may involve listed diseases, emerging diseases or other animal health hazards. In that context, it should be made clear which disease prevention and control measures provided for by this Regulation may be used in the event of the occurrence of a listed or emerging disease or hazard. In all such cases, it is essential that measures can be taken at very short notice and without any delay. As such measures would restrict movement within or into the Union, they should be implemented at Union level whenever possible.

(163) In order to ensure an effective and quick reaction to emerging risks, implementing powers should be conferred on the Commission to lay down emergency measures.

(164) The Commission should adopt immediately applicable implementing acts in duly justified cases relating to, inter alia, measures regarding emerging diseases, the stocking, supply, storage, delivery and other procedures of Union antigen, vaccine and diagnostic reagent banks, the laying down of special disease control measures and derogations for a limited period of time, special rules on movements for terrestrial and aquatic animals applying for a limited period of time, emergency measures, and the listing of third countries and territories for the purposes of entry into the Union.

(165) This Regulation lays down general and specific rules for the prevention and control of transmissible animal diseases and ensures a harmonised approach to animal health across the Union. In some areas, such as general responsibilities for animal health, notification, surveillance, registration and approval or traceability, the Member States should be allowed or encouraged to apply additional or more stringent national measures. However, such national measures should be permitted only if they do not compromise the animal health objectives set out in this Regulation and are not inconsistent with the rules laid down herein, and provided that they do not hinder movements of animals and products between Member States, unless this is necessary in order to prevent the introduction, or to control the spread, of disease.

(166) The national measures referred to in recital 165 should be subject to a simplified notification procedure in order to reduce the administrative burden. Experience has shown that the general notification procedure laid down in Directive 98/34/EC of the European Parliament and of the Council[27] has been an important tool for guiding

and improving the quality of national technical regulations — in terms of increased transparency, readability and effectiveness — in non–harmonised or partly harmonised areas. It is therefore appropriate that this general notification procedure applies.

(167) Currently, Union rules on animal health are laid down in the following acts of the European Parliament and of the Council and in subsequent Commission acts adopted pursuant to them:

> Directive 64/432/EEC, Council Directive 77/391/EEC[(28)], Council Directive 78/52/EEC[(29)], Council Directive 80/1095/EEC[(30)], Council Directive 82/894/EEC[(31)], Council Directive 88/407/EEC[(32)], Council Directive 89/556/EEC[(33)], Council Directive 90/429/EEC[(34)],
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> Directive 91/68/EEC, Council Decision 91/666/EEC[(35)], Council Directive 92/35/EEC[(36)], Directive 92/65/EEC, Council Directive 92/66/EEC[(37)], Council Directive 92/118/EEC[(38)], Council Directive 92/119/EEC[(39)], Council Decision 95/410/EC[(40)], Council Directive 2000/75/EC[(41)], Council Decision 2000/258/EC[(42)], Council Directive 2001/89/EC[(43)],
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> Council Directive 2002/60/EC[(44)], Council Directive 2002/99/EC[(45)], Council Directive 2003/85/EC[(46)], Council Regulation (EC) No 21/2004[(47)], Council Directive 2004/68/EC[(48)], Council Directive 2005/94/EC[(49)], Directive 2006/88/EC, Council Directive 2008/71/EC[(50)], Directive 2009/156/EC, Directive 2009/158/EC, Regulation (EU) No 576/2013 of the European Parliament and of the Council[(51)].

(168) This Regulation provides for the rules on the identification and registration of bovine animals while rules for beef labelling remain outside of its scope. Regulation (EC) No 1760/2000 of the European Parliament and of the Council[(52)] provides for the rules on the identification and registration of bovine animals and for the rules on beef labelling. It should thus be amended to repeal its provisions on the identification and registration of bovine animals while those concerning beef labelling would have to remain in force.

(169) With a view to guaranteeing the reliability of the arrangements provided for in existing Regulations establishing systems for the identification and registration of bovine, ovine and caprine animals, that legislation requires the Member States to carry out adequate and efficient control measures. Such adequate and efficient official control measures should also be preserved in the future. As part of the ‘Smarter rules for safer food’ package of proposals, this Regulation does not envisage provisions on official controls since those rules should be provided for in the framework of the proposed horizontal legislation on official controls. However, even if the proposed new horizontal rules on official controls were not to enter into force at the same time as this Regulation, the existing horizontal rules on official controls would allow the Commission to ensure an equivalent level of control.

(170) The rules laid down in the legislative acts referred to in recital 167 are to be replaced by this Regulation and by subsequent Commission acts to be adopted pursuant to this Regulation. Accordingly, those legislative acts should be repealed. However, to ensure legal clarity and avoid a legal vacuum, the repeal should in the first place take effect only when the relevant delegated and implementing acts are adopted pursuant to this

Regulation. It is therefore necessary to empower the Commission to determine the dates when the repeal of those legislative acts is to take effect, while the legislator should set a deadline.

(171) The following Council acts in the area of animal health are obsolete and should be expressly repealed in the interests of clarity of Union legislation: Council Decision 78/642/EEC[(53)], Council Directive 79/110/EEC[(54)], Council Directive 81/6/EEC[(55)], Council Decision 89/455/EEC[(56)], Council Directive 90/423/EEC[(57)], Council Decision 90/678/EEC[(58)], Council Directive 92/36/EEC[(59)], Council Directive 98/99/EC[(60)].

(172) The requirements set out in this Regulation should not apply until the key delegated and implementing acts have been adopted by the Commission pursuant to this Regulation, allowing a period of 24 months from the adoption of the key acts until the date when they start to apply, thus permitting Member States and operators to duly adapt to the new rules. In addition, it is appropriate to provide for a period of at least 36 months for the Commission to elaborate the new rules.

(173) In order to ensure legal certainty as regards the application of rules for the identification and registration of animals and disease control measures for certain animal diseases and zoonoses, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the date on which Regulation (EC) No 21/2004 and Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC, 2005/94/EC and 2008/71/EC are to cease to apply, whilst a deadline in that regard should be set in this Regulation.

(174) In line with the preventive approach to animal health that is promoted by this Regulation, the special measures concerning salmonella that applied to live animals dispatched to Finland and Sweden prior to 20 April 2016 should continue to apply and Regulation (EC) No 2160/2003 should be amended accordingly.

(175) Considering the recent adoption of Regulation (EU) No 576/2013, it is desirable to allow for a long transitional period before the corresponding rules set out in this Regulation start to apply.

(176) The implementing powers provided for in this Regulation should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[(61)].

(177) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(178) This Regulation should not create a disproportionate administrative burden or economic impact for small and medium-sized enterprises. Under this Regulation, based on consultation with stakeholders, the special situation of small and medium-sized enterprises has been taken into account. A potential universal derogation from the requirements of this Regulation for such enterprises has not been considered, in view of the public policy objectives of protecting animal health and public health. However,

a number of derogations for such enterprises should be provided for in relation to the different requirements of this Regulation, taking into account the risks involved.

(179) Since the objectives of this Regulation, namely to lay down animal health rules for animals, germinal products, products of animal origin, animal by–products and derived products to the extent that they are not covered by specific rules in other Union legislation, and other material that may be involved in the spread of transmissible animal diseases, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level through a common and coordinated legal framework for animal health, the Union may adopt measures, in accordance with the principle of subsidiarity as set out 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,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 170, 5.6.2014, p. 104.

(**2**) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 14 December 2015.

(**3**) 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).

(**4**) 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).

(**5**) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13).

(**6**) 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).

(**7**) 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).

(**8**) 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).

(**9**) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

(**10**) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

(**11**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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

(**13**) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

(**14**) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

(**15**) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food–borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

(**16**) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

(**17**) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

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

(**19**) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

(**20**) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64).

(**21**) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra–Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).

(**22**) Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

(**23**) Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ L 343, 22.12.2009, p. 74).

(**24**) Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p. 27).

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

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

(**27**) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

(**28**) Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle (OJ L 145, 13.6.1977, p. 44).

(**29**) Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle (OJ L 15, 19.1.1978, p. 34).

(**30**) Council Directive 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever (OJ L 325, 1.12.1980, p. 1).

(**31**) Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).

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

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

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

(**35**) Council Decision 91/666/ EEC of 11 December 1991 establishing Community reserves of foot–and–mouth disease vaccines (OJ L 368, 31.12.1991, p. 21).

(**36**) Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness (OJ L 157, 10.6.1992, p. 19).

(**37**) Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).

(**38**) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the

said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49).

(**39**) Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (OJ L 62, 15.3.1993, p. 69).

(**40**) Council Decision 95/410/EC of 22 June 1995 laying down the rules for the microbiological testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden (OJ L 243, 11.10.1995, p. 25).

(**41**) Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74).

(**42**) Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79, 30.3.2000, p. 40).

(**43**) Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

(**44**) Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

(**45**) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

(**46**) Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot–and–mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

(**47**) Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).

(**48**) Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (OJ L 139, 30.4.2004, p. 321).

(**49**) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

(**50**) Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).

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

(**52**) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

(**53**) Council Decision 78/642/EEC of 25 July 1978 on health protection measures in respect of the Republic of Botswana (OJ L 213, 3.8.1978, p. 15).

(**54**) Council Directive 79/110/EEC of 24 January 1979 authorizing the Italian Republic to postpone the notification and implementation of its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 29, 3.2.1979, p. 24).

(**55**) Council Directive 81/6/EEC of 1 January 1981 authorizing the Hellenic Republic to communicate and to implement its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 14, 16.1.1981, p. 22).

(**56**) Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention (OJ L 223, 2.8.1989, p. 19).

(**57**) Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot–and–mouth disease, Directive 64/432/EEC on animal health problems affecting intra- Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (OJ L 224, 18.8.1990, p. 13).

(**58**) Council Decision 90/678/EEC of 13 December 1990 recognizing certain parts of the territory of the Community as being either officially swine fever free or swine fever free (OJ L 373, 31.12.1990, p. 29).

(**59**) Council Directive 92/36/EEC of 29 April 1992 amending, with regard to African horse sickness, Directive 90/426/EEC on animal health conditions governing the movement and import from third countries of equidae (OJ L 157, 10.6.1992, p. 28).

(**60**) Council Directive 98/99/EC of 14 December 1998 amending Directive 97/12/EC amending and updating Directive 64/432/EEC on health problems affecting intra–Community trade in bovine animals and swine (OJ L 358, 31.12.1998, p. 107).

(**61**) 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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) 2016/429 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Art. 17(1A) words substituted by S.I. 2021/1273 reg. 8Sch. 2 para. (t)