III

(Preparatory acts)

COUNCIL

POSITION (EU) No 4/2016 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Regulation of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

(Text with EEA relevance)

Adopted by the Council on 14 December 2015

(2016/C 086/01)

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]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

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.

([1]) OJ C..
([2]) OJ C..
([3]) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at the first reading of 14 December 2015.

(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 ([1]) 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 ([2]) and in Council Directives 89/662/EEC ([3]), 90/425/EEC ([4]), 91/496/EEC ([5]) and 97/78/EC ([6]) 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 ([7]) and (EC) No 1099/2009 ([8]), 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.

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

([7]) 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).

([8]) 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).

(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 ([1]).

(16) Regulation (EC) No 1069/2009 of the European Parliament and the Council ([2]) 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 ([3]), Directive 2003/99/EC of the European Parliament and of the Council ([4]) and Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([5]), 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 ([6]). 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.

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

(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 ([1]) 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 ([2]), 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

([1]) 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).

([2]) 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).

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 anti–microbial 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 ([1]) 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 Directive 64/432/EEC ([2]), Council Directive 91/68/EEC ([3]), Council Directive 2009/156/EC ([4]), Council Directive 2009/158/EC ([5]) 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.

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

(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 ([1]) respectively, based on Commission Decisions 2003/24/EC ([2]) and 2004/292/EC ([3]).

(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 timeframe 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

([1]) 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).

([2]) 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).

([3]) 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).

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 ([1]) 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 ([2]), Council Directive 78/52/EEC ([3]), Council Directive 80/1095/EEC ([4]), Council Directive 82/894/EEC ([5]), Council Directive 88/407/EEC ([6]), Council Directive 89/556/EEC ([7]), Council Directive 90/429/EEC ([8]), Directive 91/68/EEC, Council Decision

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

([7]) 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).

([8]) 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).

91/666/EEC ([1]), Council Directive 92/35/EEC ([2]), Directive 92/65/EEC, Council Directive 92/66/EEC ([3]), Council Directive 92/118/EEC ([4]), Council Directive 92/119/EEC ([5]), Council Decision 95/410/EC ([6]), Council Directive 2000/75/EC ([7]), Council Decision 2000/258/EC ([8]), Council Directive 2001/89/EC ([9]), Council Directive 2002/60/EC ([10]), Council Directive 2002/99/EC ([11]), Council Directive 2003/85/EC ([12]), Council Regulation (EC) No 21/2004 ([13]), Council Directive 2004/68/EC ([14]), Council Directive 2005/94/EC ([15]), Directive 2006/88/EC, Council Directive 2008/71/EC ([16]), Directive 2009/156/EC, Directive 2009/158/EC, Regulation (EU) No 576/2013 of the European Parliament and of the Council ([17]).

(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 ([18]) 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

([1]) 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).
([2]) 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).
([3]) 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).
([4]) 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).
([5]) 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).
([6]) Council Decision 95/410/EC of 22 June 1995 laying down the rules for 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).
([7]) 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).
([8]) 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).
([9]) 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).
([10]) 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).
([11]) 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).
([12]) 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).
([13]) 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).
([14]) 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).
([15]) 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).
([16]) Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).
([17]) 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).
([18]) 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).

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 ([1]), Council Directive 79/110/EEC ([2]), Council Directive 81/6/EEC ([3]), Council Decision 89/455/EEC ([4]), Council Directive 90/423/EEC ([5]), Council Decision 90/678/EEC ([6]), Council Directive 92/36/EEC ([7]), Council Directive 98/99/EC ([8]).

(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 … (*) should continue to apply and Regulation (EC) No 2160/2003 should be amended accordingly.

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

([7]) 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).

([8]) 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).

(*) Date of the entry into force of this Regulation.

(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 ([1]).

(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:

PART I

GENERAL RULES

CHAPTER 1

Subject matter, aim, scope and definitions

Article 1

Subject matter and aim

1. This Regulation lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans.

Those rules provide for:

(a) the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health (Part I: Articles 1 to 17);

(b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status (Part II: Articles 18 to 42);

(c) disease awareness, preparedness and control (Part III: Articles 43 to 83);

([1]) 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).

(d) the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union (Part IV: Articles 84 to 228; and Part VI: Articles 244 to 248 and 252 to 256);

(e) the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union (Part V: Articles 229 to 243; and Part VI: Articles 244 to 246 and 252 to 256);

(f) non-commercial movements of pet animals into a Member State from another Member State or from a third country or territory, (Part VI: Articles 244 to 256);

(g) the emergency measures to be taken in the event of a disease emergency situation (Part VII: Articles 257 to 262).

2. The rules referred to in paragraph 1:

(a) aim to ensure:

(i) improved animal health to support sustainable agricultural and aquaculture production in the Union;

(ii) the effective functioning of the internal market;

(iii) a reduction in the adverse effects on animal health, public health and the environment of:

— certain diseases;

— the measures taken to prevent and control diseases;

(b) take into account:

(i) the relationship between animal health and:

— public health;

— the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change;

— food and feed safety;

— animal welfare, including the sparing of any avoidable pain, distress or suffering;

— antimicrobial resistance;

— food security;

(ii) the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures;

(iii) relevant international standards.

Article 2

Scope

1. This Regulation shall apply to:

(a) kept and wild animals;

(b) germinal products;

(c) products of animal origin;

(d) animal by–products and derived products, without prejudice to the rules laid down in Regulation (EC) No 1069/2009;

(e) facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.

2. This Regulation shall apply to transmissible diseases, including zoonoses, without prejudice to the rules laid down in:

(a) Decision No 1082/2013/EU;

(b) Regulation (EC) No 999/2001;

(c) Directive 2003/99/EC;

(d) Regulation (EC) No 2160/2003.

Article 3

Scope of Parts IV, V and VI

1. Title I of Part IV (Articles 84 to 171) shall apply to:

(a) terrestrial animals, and animals which are not terrestrial animals but which may transmit diseases affecting terrestrial animals;

(b) germinal products from terrestrial animals;

(c) products of animal origin from terrestrial animals.

2. Title II of Part IV (Articles 172 to 226) shall apply to:

(a) aquatic animals, and animals which are not aquatic animals but which may transmit diseases affecting aquatic animals;

(b) products of animal origin from aquatic animals.

3. Title III of Part IV (Articles 227 and 228) shall apply to:

(a) other animals;

(b) germinal products and products of animal origin from the other animals referred to in point (a).

4. Parts IV and V shall not apply to non-commercial movements of pet animals as referred to in paragraph 6 of this Article or to non-commercial movements of pet animals within a Member State.

5. Movements of pet animals, other than non-commercial movements, shall comply with the animal health requirements laid down in Parts IV and V.

The Commission shall adopt delegated acts in accordance with Article 264 concerning the adaptations which are necessary in order to ensure that Parts IV and V are correctly applied to pet animals, in particular to take account of the fact that pet animals are kept in households by pet keepers.

6. Part VI shall only apply to non-commercial movements of pet animals that comply with the requirements laid down in Articles 245 and 246 as regards the maximum number of animals that may accompany their owner and the maximum number of days elapsing between the movement of the owner and the movement of the animal.

Article 4

Definitions

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

(1) 'animals' means vertebrate and invertebrate animals;

(2) 'terrestrial animals' means birds, terrestrial mammals, bees and bumble bees;

(3) 'aquatic animals' means animals of the following species, at all life stages, including eggs, sperm and gametes:

  (a) fish belonging to the superclass *Agnatha a*nd to the classes *Chondrichthyes, Sarcopterygii* and *Actinopterygii*;

  (b) aquatic molluscs belonging to the phylum *Mollusca;*

  (c) aquatic crustaceans belonging to the subphylum *Crustacea*;

(4) 'other animals' means animals of species other than those falling within the definition of terrestrial or aquatic animals;

(5) 'kept animals' means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals;

(6) 'aquaculture' means the keeping of aquatic animals where the animals remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting, excluding the harvesting or catching for the purposes of human consumption of wild aquatic animals which are subsequently temporarily kept while awaiting slaughter without being fed;

(7) 'aquaculture animals' means any aquatic animals subject to aquaculture,

(8) 'wild animals' means animals which are not kept animals;

(9) 'poultry' means birds that are reared or kept in captivity for:

(a) the production of:

(i) meat;

(ii) eggs for consumption;

(iii) other products;

(b) restocking supplies of game birds;

(c) the purpose of breeding of birds used for the types of production referred to in points (a) and (b);

(10) 'captive birds' means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling;

(11) 'pet animal' means a kept animal of the species listed in Annex I which is kept for private non-commercial purposes;

(12) 'pet keeper' means a natural person, and may include a pet owner, keeping a pet animal;

(13) 'pet owner' means a natural person indicated as the owner in the identification document referred to in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(14) 'non-commercial movement' means any movement of a pet animal accompanying its owner and which

(a) does not have as its aim either the sale of or another form of transfer of ownership of the pet animal concerned; and

(b) is part of the movement of the pet owner:

(i) either under his direct responsibility; or

(ii) under the responsibility of an authorised person, in cases where the pet animal is physically separated from the pet owner;

(15) 'authorised person' means any natural person who has authorisation in writing from the pet owner to carry out the non-commercial movement of the pet animal on behalf of the pet owner;

(16) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents;

(17) 'disease agent' means a pathogen transmissible to animals or to humans which is capable of causing a disease in animals;

(18) 'listed diseases' means diseases listed in accordance with Article 5(1);

(19) 'disease profile' means the criteria of a disease referred to in point (a) of Article 7(1);

(20) 'listed species' means an animal species or group of animal species listed in accordance with Article 8(2), or, in the case of emerging diseases, an animal species or group of animal species which meets the criteria for listed species laid down in Article 8(2);

(21) 'hazard' means a disease agent in, or a condition of, an animal or product with the potential to have an adverse effect on the health of humans or animals;

(22) 'risk' means the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse effect on animal or public health;

(23) 'biosecurity' means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within:

(a) an animal population, or

(b) an establishment, zone, compartment, means of transport or any other facilities, premises or location;

(24) 'operator' means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians;

(25) 'transporter' means an operator transporting animals on his own account or on account of a third party;

(26) 'animal professional' means a natural or legal person having an occupational relationship with animals or products, other than operators or veterinarians;

(27) 'establishment' means any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for:

(a) households where pet animals are kept;

(b) veterinary practices or clinics;

(28) 'germinal products' means:

(a) semen, oocytes and embryos intended for artificial reproduction;

(b) hatching eggs;

(29) 'products of animal origin' means:

(a) food of animal origin, including honey and blood;

(b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, intended for human consumption; and

(c) animals other than those referred to in point (b) intended to be prepared with a view to being supplied live to the final consumer;

(30) 'animal by–products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, excluding germinal products;

(31) 'derived products' means products obtained from one or more treatments, transformations or steps in the processing of animal by–products;

(32) 'products' means:

(a) germinal products;

(b) products of animal origin;

(c) animal by–products and derived products;

(33) 'official control' means any form of control carried out by a competent authority for the purpose of verifying compliance with this Regulation;

(34) 'health status' means the disease status as regards the listed diseases relevant for a particular listed species with respect to:

(a) an animal;

(b) animals within:

(i) an epidemiological unit;

(ii) an establishment;

(iii) a zone;

(iv) a compartment;

(v) a Member State;

(vi) a third country or territory;

(35) 'zone' means:

(a) for terrestrial animals, an area of a Member State, third country or territory with a precise geographical delimitation, containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;

(b) for aquatic animals, a contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:

(i) an entire water catchment from the source of a waterway to the estuary or lake;

(ii) more than one water catchment;

(iii) part of a water catchment from the source of a waterway to a barrier that prevents the introduction of a specific disease or diseases;

(iv) part of a coastal area with a precise geographical delimitation;

(v) an estuary with a precise geographical delimitation;

(36) 'water catchment' means an area or basin of land bounded by natural features such as hills or mountains, into which all run–off water flows;

(37) 'compartment' means an animal subpopulation contained in one or more establishments and, in the case of aquatic animals, in one or more aquaculture establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;

(38) 'quarantine' means the keeping of animals in isolation with no direct or indirect contact with animals outside the epidemiological unit, for the purpose of ensuring that there is no spread of one or more specified diseases while the animals in isolation are undergoing observation for a specified length of time and, if appropriate, testing and treatment;

(39) 'epidemiological unit' means a group of animals with the same likelihood of exposure to a disease agent;

(40) 'outbreak' means the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located;

(41) 'restricted zone' means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones;

(42) 'protection zone' means a zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread of the disease from that zone;

(43) 'surveillance zone' means a zone which is established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone;

(44) 'hatching eggs' means eggs, laid by poultry or captive birds, intended for incubation;

(45) 'ungulates' means the animals listed in Annex III;

(46) 'germinal product establishment' means:

(a) in relation to semen, an establishment where semen is collected, produced, processed or stored;

(b) in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;

(c) in relation to hatching eggs, a hatchery;

(47) 'hatchery' means an establishment which collects, stores, incubates and hatches eggs for the supply of:

(a) hatching eggs;

(b) day–old chicks or hatchlings of other species;

(48) 'confined establishment' means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are:

(a) kept or bred for the purposes of exhibitions, education, the conservation of species or research;

(b) confined and separated from the surrounding environment; and

(c) subject to animal health surveillance and biosecurity measures;

(49) 'assembly operation' means the assembling of kept terrestrial animals from more than one establishment for a period shorter than the required residency period for the species of animals concerned;

(50) 'residency period' means the minimum period necessary in order to ensure that an animal which has been introduced into an establishment is not of a lower health status than that of the animals in that establishment;

(51) 'TRACES' means the integrated computerised veterinary system with a single architecture provided for in Decisions 2003/24/EC and 2004/292/EC;

(52) 'disease control aquatic food establishment' means a food business approved in accordance with Article 179;

(53) 'official veterinarian' means a veterinarian authorised by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation;

(54) 'official veterinarian in a third country or territory' means a veterinarian in a third country or territory corresponding to an official veterinarian as referred to in point (53);

(55) 'competent authority' means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation or any other authority to which that responsibility has been delegated;

(56) 'competent authority of a third country or territory' means the authority in a third country or territory corresponding to the competent authorities referred to in point (55).

CHAPTER 2

Listed diseases and emerging diseases and listed species

Article 5

Listing of diseases

1. The disease-specific rules for the prevention and control of diseases provided for in this Regulation shall apply to:

(a) the following listed diseases:

(i) foot and mouth disease;

(ii) classical swine fever;

(iii) African swine fever;

(iv) highly pathogenic avian influenza;

(v) African horse sickness; and

(b) the listed diseases set out in the list in Annex II.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning amendments to the list referred to in point (b) of paragraph 1 of this Article.

3. A disease shall be included on the list referred to in point (b) of paragraph 1 of this Article if it has been assessed in accordance with Article 7 and it meets:

(a) all of the following criteria:

(i) scientific evidence indicates that the disease is transmissible;

(ii) animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union;

(iii) the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character;

(iv) diagnostic tools are available for the disease; and

(v) risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union; and

(b) at least one of the following criteria:

(i) the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character;

(ii) the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union;

(iii) the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union;

(iv) the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism; or

(v) the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union.

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning the removal of a disease from the list referred to in point (b) of paragraph 1 of this Article when that disease no longer fulfils the criteria provided for in paragraph 3 of this Article.

5. The Commission shall review the listing of each disease in the light of newly available significant scientific data.

Article 6

Emerging diseases

1. The rules for the prevention and control of diseases shall apply to emerging diseases as provided for in this Regulation.

2. A disease other than a listed disease shall be considered to be an emerging disease ('emerging disease') provided it has the potential to meet the criteria for listing diseases provided for in Article 5(3) and:

(a) results from the evolution or change of an existing disease agent;

(b) is a known disease spreading to a new geographic area, species or population;

(c) is diagnosed for the first time in the Union; or

(d) is caused by an unrecognised or a previously unrecognised disease agent.

3. The Commission shall, by means of implementing acts, take the necessary measures regarding an emerging disease which fulfils the criteria set out in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

5. Any obligation on operators in respect of an emerging disease, as set out in this Regulation, shall only apply if the Commission has adopted an implementing act for that disease in accordance with paragraph 3 of this Article or if the disease is covered by a contingency plan in accordance with Article 43.

Article 7

Assessment parameters for the listing of diseases

The Commission shall use the following assessment parameters in order to determine whether a disease meets the conditions requiring it to be listed in accordance with Article 5(2):

(a) the disease profile, which shall comprise the following:

(i) the animal species concerned by the disease;

(ii) the morbidity and mortality rates of the disease in animal populations;

(iii) the zoonotic character of the disease;

(iv) the resistance to treatments, including antimicrobial resistance;

(v) the persistence of the disease in an animal population or in the environment;

(vi) the routes and speed of transmission of the disease between animals and, when relevant, between animals and humans;

(vii) the absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union;

(viii) the existence of diagnostic and disease control tools;

(b) the impact of the disease on:

(i) agricultural and aquaculture production and other parts of the economy, as regards:

— the level of presence of the disease in the Union;

— the loss of production due to the disease;

— other losses;

(ii) human health, as regards:

— transmissibility between animals and humans;

— transmissibility between humans;

— the severity of human forms of the disease;

— the availability of effective prevention or medical treatment in humans;

(iii) animal welfare;

(iv) biodiversity and the environment;

(c) its potential to generate a crisis situation and its potential use in bioterrorism;

(d) the feasibility, availability and effectiveness of the following disease prevention and control measures:

(i) diagnostic tools and capacities;

(ii) vaccination;

(iii) medical treatments;

(iv) biosecurity measures;

(v) restrictions on the movement of animals and products;

(vi) killing of animals;

(vii) disposal of carcasses and other relevant animal by–products;

(e) the impact of disease prevention and control measures, as regards:

(i) the direct and indirect costs for the affected sectors and the economy as a whole;

(ii) their societal acceptance;

(iii) the welfare of affected subpopulations of kept and wild animals;

(iv) the environment and biodiversity.

Article 8

Listing of species

1. The disease-specific rules for listed diseases provided for in this Regulation and the rules adopted pursuant to this Regulation shall apply to listed species.

2. The Commission shall, by means of implementing acts, establish a list of species as referred to in paragraph 1 of this Article that fulfil the criteria set out in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

That list shall comprise those animal species, or groups of animal species which pose a considerable risk for the spread of specific listed diseases, based on the following criteria:

(a) the susceptibility of the animal population at risk;

(b) the duration of the incubation period and infective period for the animals concerned;

(c) the capability of those animals to carry those specific diseases.

3. Animal species or groups of animal species shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease because:

(a) they are susceptible to a specific listed disease or scientific evidence indicates that such susceptibility is likely; or

(b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.

4. The Commission shall, by means of implementing acts, remove animal species or groups of animal species from the list when:

(a) the relevant listed disease in relation to which the animal species or group of animal species concerned has been listed has been removed from the list of diseases; or

(b) scientific evidence indicates that the species or group of species concerned no longer fulfils the criteria set out in paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 9

Disease prevention and control rules to be applied to different categories of listed diseases

1. Disease prevention and control rules shall apply to listed diseases as follows:

(a) As regards listed diseases that do not normally occur in the Union and for which immediate eradication measures must be taken as soon as they are detected, the following rules shall apply, as relevant:

(i) the rules for disease awareness and preparedness provided for in Title I of Part III (Articles 43 to 52);

(ii) the disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71); and

(iii) the rules for compartmentalisation provided for in Article 37(1).

For those listed diseases, the measures referred to in point (b), as appropriate, as well as points (d) and (e), shall also apply, as relevant.

(b) As regards listed diseases which must be controlled in all Member States with the goal of eradicating them throughout the Union, the following rules shall apply, as relevant:

(i) the rules for compulsory eradication programmes provided for in Article 31(1);

(ii) the rules for disease-free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the disease control measures provided for in Articles 72 to 75, Articles 77 to 79 and Articles 81 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(c) 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 disease-free or that have eradication programmes for the listed disease concerned, the following rules shall apply, as relevant:

(i) the rules for optional eradication provided for in Article 31(2);

(ii) the rules for disease-free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the rules for disease control measures provided for in Articles 76, 77, 78, 80, 82 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(d) 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, the following rules shall apply, as relevant:

(i) the rules for movement within the Union provided for in Chapters 3 to 6 of Title I (Articles 124 to 169), Chapters 2 and 3 of Title II of Part IV (Articles 191 to 225) and Chapters 2 and 3 of Part VI (Articles 247 to 251); and

(ii) the rules for entry into the Union and export from the Union provided for in Part V (Articles 229 to 243).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point, as well as those referred to in point (e), where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products.

(e) As regards listed diseases for which there is a need for surveillance within the Union, the following rules shall apply, as relevant:

(i) the rules for notification and reporting provided for in Chapter 1 of Part II (Articles 18 to 23); and

(ii) the rules for surveillance provided for in Chapter 2 of Part II (Articles 24 to 30).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point.

2. The Commission shall, by means of implementing acts, determine the application of the disease prevention and control rules referred to in paragraph 1 to the respective listed diseases on the basis of the criteria set out in Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. The Commission shall, by means of implementing acts, modify the application of the disease prevention and control rules referred to in paragraph 2 to the respective listed diseases when the disease in question no longer fulfils the criteria laid down in the relevant Section of Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a listed disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

CHAPTER 3

Responsibilities for animal health

Section 1

Operators, animal professionals and pet keepers

Article 10

Responsibilities for animal health and biosecurity measures

1. Operators shall:

(a) as regards kept animals and products under their responsibility, be responsible for:

(i) the health of kept animals;

(ii) prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,

(iii) minimising the risk of the spread of diseases;

(iv) good animal husbandry;

(b) where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for:

(i) the species and categories of kept animals and products;

(ii) the type of production; and

(iii) the risks involved, taking into account:

— geographical location and climatic conditions; and

— local circumstances and practices;

(c) where appropriate, take biosecurity measures regarding wild animals.

2. Animal professionals shall take action to minimise the risk of the spread of diseases in the context of their occupational relationship with animals and products.

3. Point (a) of paragraph 1 shall also apply to pet keepers.

4. The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through:

(a) physical protection measures, which may include:

(i) enclosing, fencing, roofing, netting, as appropriate;

(ii) cleaning, disinfection and control of insects and rodents;

(iii) in the case of aquatic animals, where appropriate:

— measures concerning the water supply and discharge;

— natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses;

(b) management measures, which may include:

(i) procedures for entering and exiting the establishment for animals, products, vehicles and persons;

(ii) procedures for using equipment;

(iii) conditions for movement based on the risks involved;

(iv) conditions for introducing animals or products into the establishment;

(v) quarantine, isolation or separation of newly introduced or sick animals;

(vi) a system for safe disposal of dead animals and other animal by–products.

5. Operators, animal professionals and pet keepers shall cooperate with the competent authority and veterinarians in the application of the disease prevention and control measures provided for in this Regulation.

6. The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

Such implementing acts shall reflect the matters referred to in point (b) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 11

Knowledge of animal health

1. Operators and animal professionals shall have adequate knowledge of:

(a) animal diseases, including those that are transmissible to humans;

(b) biosecurity principles;

(c) the interaction between animal health, animal welfare and human health;

(d) good practice of animal husbandry for the animal species under their care;

(e) resistance to treatments, including antimicrobial resistance, and its implications.

2. The content and the level of knowledge required in accordance with paragraph 1 shall depend on:

(a) the species and categories of kept animals or products under the responsibility of the operators and animal professionals concerned and the nature of their occupational relationship with those animals or products;

(b) the type of production;

(c) the tasks performed.

3. The knowledge provided for in paragraph 1 shall be acquired in one of the following ways:

(a) professional experience or training;

(b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;

(c) formal education;

(d) other experience or other training which results in the same level of knowledge as that covered by points (a), (b) or (c).

4. Operators selling or otherwise transferring the ownership of future pet animals shall provide basic information to the future pet keeper, regarding the matters referred to in paragraph 1, as relevant for the pet animal in question.

Section 2

Veterinarians and aquatic animal health professionals

Article 12

Responsibilities of veterinarians and aquatic animal health professionals

1. Veterinarians shall in the course of their activities which fall within the scope of this Regulation:

(a) take all appropriate measures to prevent the introduction, development and spread of diseases;

(b) take action to ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease;

(c) play an active role in:

(i) raising animal health awareness, and awareness of the interaction between animal health, animal welfare and human health;

(ii) disease prevention;

(iii) the early detection of, and rapid response to, diseases.

(iv) raising awareness of resistance to treatments, including antimicrobial resistance, and its implications;

(d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.

2. Aquatic animal health professionals may undertake activities assigned to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so by the Member State concerned under national law. In that event, paragraph 1 shall apply to those aquatic animal health professionals.

3. Veterinarians and aquatic animal health professionals shall maintain and develop their professional capacities related to their areas of activities which fall within the scope of this Regulation.

Section 3

Member States

Article 13

Member States' responsibilities

1. In order to ensure that the competent authority for animal health has the capability to take the necessary and appropriate measures, and to carry out the activities, required by this Regulation, each Member State shall, at the appropriate administrative level, ensure that competent authority has:

(a) qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;

(b) access to laboratories with the qualified personnel, facilities, equipment and financial resources needed to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;

(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 12.

2. Member States shall encourage operators and animal professionals to acquire, maintain and develop the adequate knowledge of animal health provided for in Article 11 through relevant programmes in agricultural or aquaculture sectors or formal education.

Article 14

Delegation by a competent authority of official activities

1. The competent authority may delegate one or more of the following activities to veterinarians other than official veterinarians:

(a) practical application of measures under the eradication programmes provided for in Article 32;

(b) supporting the competent authority in carrying out surveillance as provided for in Article 26 or in relation to surveillance programmes as provided for in Article 28;

(c) activities related to:

(i) disease awareness, preparedness and control as provided for in Part III, concerning:

— sampling activities and implementation of investigations and epidemiological enquiries within the framework of Articles 54, points (b) to (g) of Article 55(1), Article 57, Article 73 and Article 74 in the event of the suspected presence of a disease, and any implementing and delegated acts adopted pursuant to those Articles;

— carrying out activities relating to disease control measures in the event of an outbreak of disease, as regards activities listed in Article 61, points (a), (b), (e), (f) and (i) of Article 65(1), Article 70(1), Article 79(1) and (2), and Article 81(1) and (2), and any implementing and delegated acts adopted pursuant to those Articles;

— carrying out emergency vaccination in accordance with Article 69;

(ii) registration, approval, traceability and movements as provided for in Part IV;

(iii) issuing and completing the identification documents for pet animals as provided for in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(iv) the application and use of means of identification as referred to in point (a)(ii) of Article 252(1).

2. Member States may provide for natural or legal persons to be authorised to perform activities referred to in point (a) and points (b)(i), (ii) and (iv) of paragraph 1 for specifically identified tasks for which those persons have sufficient specific knowledge. In that event, paragraph 1 of this Article and the responsibilities laid down in Article 12 shall apply to those persons.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning other activities which may be delegated to veterinarians in addition to those provided for in paragraph 1, and, as appropriate, to prescribe the necessary circumstances and conditions for such delegation.

The Commission shall take account of the nature of those activities and of relevant international standards when adopting those delegated acts.

Article 15

Public information

Where there are reasonable grounds to suspect that animals or products originating from within the Union or entering from outside the Union may present a risk, the competent authority shall take appropriate steps to inform the public of the nature of the risk and the measures which are taken or about to be taken to prevent or control that risk, taking into account the nature, seriousness and extent of that risk and the public interest in being informed.

Section 4

Laboratories, facilities and other natural and legal persons handling disease agents, vaccines and other biological products

Article 16

Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products

1. Laboratories, facilities and other natural or legal persons handling disease agents for the purpose of research, education, diagnosis or the production of vaccines and other biological products shall, whilst taking into account any relevant international standards:

(a) take appropriate biosecurity, biosafety and bio–containment measures to prevent the escape of the disease agents and their subsequent contact with animals outside the laboratory or other facility handling disease agents for those purposes;

(b) ensure that the movement of disease agents, vaccines and other biological products between laboratories or other facilities does not give rise to a risk of the spread of listed and emerging diseases.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the safety measures for the prevention and control of listed and emerging diseases as regards laboratories, facilities and other natural or legal persons handling the disease agents, vaccines and other biological products in relation to:

(a) biosecurity, biosafety and bio–containment measures;

(b) movement requirements for disease agents, vaccines and other biological products.

Article 17

Animal health laboratories

1. Official laboratories for animal health, consisting of Union reference laboratories, national reference laboratories and official animal health laboratories, shall, in fulfilling their tasks and responsibilities, cooperate within a network of Union animal health laboratories.

2. The laboratories referred to in paragraph 1 shall cooperate under the coordination of the Union reference laboratories, to ensure that the surveillance, notification and reporting of diseases, eradication programmes, the definition of disease-free status, and the movements of animals and products within the Union, their entry into the Union and exports to third countries or territories provided for in this Regulation, are based on state–of–the–art, solid and reliable laboratory analyses, tests and diagnoses.

3. The results and reports provided by the official laboratories shall be subject to the principles of professional secrecy and confidentiality and the duty of notification to the competent authority which designated them, irrespective of the natural or legal person who requested the laboratory analyses, tests or diagnoses.

4. In the event that an official laboratory in one Member State conducts diagnostic analyses on samples from animals originating in another Member State, that official laboratory shall notify the competent authority of the Member State from which the samples originated:

(a) immediately of any results indicating the suspicion or detection of a listed disease as referred to in point (a) of Article 9 (1);

(b) without undue delay of any results indicating the suspicion or detection of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1).

PART II

DISEASE NOTIFICATION AND REPORTING, SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS

CHAPTER 1

Disease notification and reporting

Article 18

Notification within Member States

1. Member States shall ensure that operators and other relevant natural or legal persons:

(a) immediately notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

(b) as soon as practicable notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

(c) notify a veterinarian of abnormal mortalities and other signs of serious disease or significant decreased production rates with an undetermined cause, for further investigation, including sampling for laboratory examination when the situation so requires.

2. Member States may decide that the notifications provided for in point (c) of paragraph 1 may be directed to the competent authority.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) criteria to determine whether the circumstances requiring notification described in point (c) of paragraph 1 occur;

(b) detailed rules for the further investigation provided for in point (c) of paragraph 1.

Article 19

Union notification

1. Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases as referred to in point (e) of Article 9(1) for which an immediate notification is required in order to ensure the timely implementation of necessary risk management measures, taking into account the disease profile.

2. The notification provided for in paragraph 1 shall contain the following information on the outbreak:

(a) the disease agent and, where relevant, the subtype;

(b) the relevant dates, in particular those of the suspicion and the confirmation of the outbreak;

(c) the type and location of the outbreak;

(d) any related outbreaks;

(e) the animals involved in the outbreak;

(f) any disease control measures taken in relation to the outbreak;

(g) the possible or known origin of the listed disease;

(h) the diagnostic methods used.

Article 20

Union reporting

1. Member States shall report to the Commission and to the other Member States the information on listed diseases referred to in in point (e) of Article 9(1) for which:

(a) immediate notification of an outbreak is not required under Article 19(1);

(b) immediate notification of an outbreak is required under Article 19(1), but additional information is required to be reported to the Commission and the other Member States on:

(i) surveillance in accordance with the rules laid down in an implementing act adopted in accordance with Article 30;

(ii) an eradication programme in accordance with the rules laid down in an implementing act adopted in accordance with Article 35.

2. The reports provided for in paragraph 1 shall include information on:

(a) the detection of the listed diseases referred to in paragraph 1;

(b) the results of surveillance when required in accordance with rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30;

(c) the results of surveillance programmes when required in accordance with Article 28(3) and rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30;

(d) eradication programmes when required in accordance with Article 34 and rules laid down in an implementing act adopted in accordance with Article 35.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the requirements of paragraph 2 and reporting on other matters concerning surveillance and eradication programmes where necessary in order to ensure an efficient application of the disease prevention rules and control rules laid down in this Regulation.

Article 21

Notification and reporting regions

The Member States shall establish notification and reporting regions for the purpose of the notification and reporting provided for in Articles 19 and 20.

Article 22

Computerised information system for Union notification and Union reporting of diseases

The Commission shall set up and manage a computerised information system for the operation of the mechanisms and tools for the notification and reporting requirements provided for in Articles 19, 20 and 21.

Article 23

Implementing powers concerning Union notification and Union reporting and the computerised information system

The Commission shall, by means of implementing acts, lay down rules for the notification and reporting requirements and the computerised information system provided for in Articles 19 to 22 with respect to:

(a) those listed diseases referred to in point (e) of Article 9(1) which are to be subject to immediate notification by the Member States as well as the necessary measures relating to the notification, in accordance with Article 19;

(b) the information to be provided by the Member States in the reporting provided for in Article 20;

(c) procedures for the establishment and use of the computerised information system provided for in Article 22 and transitional measures for the migration of the data and the information from existing systems into the new system and its full operability;

(d) the format and structure of the data to be entered into the computerised information system provided for in Article 22;

(e) the deadlines and frequencies of the notification and reporting provided for in Articles 19 and 20, which shall be done at times and frequencies which ensure transparency and the timely application of the necessary risk management measures, based on the disease profile and the type of outbreak.

(f) the listing of notification and reporting regions provided for in Article 21.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Surveillance

Article 24

Operators' surveillance obligation

For the purpose of detecting the presence of listed diseases and emerging diseases, operators shall:

(a) observe the health and behaviour of animals under their responsibility;

(b) observe any changes in the normal production parameters in the establishments, animals or germinal products under their responsibility that may give rise to a suspicion of being caused by a listed disease or emerging disease;

(c) look for abnormal mortalities and other signs of serious disease in animals under their responsibility.

Article 25

Animal health visits

1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian when appropriate due to the risks posed by the establishment in question, taking into account:

(a) the type of establishment;

(b) the species and categories of kept animals on the establishment;

(c) the epidemiological situation in the zone or region as regards listed and emerging diseases to which the animals in the establishment are susceptible;

(d) any other relevant surveillance, or official controls to which the kept animals and type of establishment are subject.

Such animal health visits shall take place at frequencies that are proportionate to the risks posed by the establishment concerned.

They may be combined with visits for other purposes.

2. The animal health visits provided for in paragraph 1 shall be made for the purpose of disease prevention, in particular through:

(a) the provision of advice to the operator concerned on biosecurity and other animal health matters, as relevant for the type of establishment and the species and categories of kept animals on the establishment.

(b) the detection of, and information on, signs indicative of the occurrence of listed diseases or emerging diseases;

3. The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 26

The competent authority's surveillance obligation

1. The competent authority shall conduct surveillance to detect the presence of listed diseases as referred to in point (e) of Article 9(1) and relevant emerging diseases.

2. The surveillance shall be designed in such a way as to ensure the timely detection of the presence of the listed diseases referred to in point (e) of Article 9(1) and emerging diseases by means of the collection, collation and analysis of relevant information relating to the disease situation.

3. The competent authority shall, whenever possible and appropriate, make use of the results of the surveillance conducted by operators and the information obtained through animal health visits in accordance with Articles 24 and 25, respectively.

4. The competent authority shall ensure that surveillance meets the requirements provided for in Article 27 and in any rules adopted pursuant to point (a) of Article 29.

5. The competent authority shall ensure that the information obtained through the surveillance provided for in paragraph 1 is collected and used in an effective and efficient manner.

Article 27

Methodology, frequency and intensity of surveillance

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 26 shall be appropriate and proportionate to the objectives of the surveillance, taking into account:

(a) the disease profile;

(b) the risk factors involved;

(c) the health status in:

(i) the Member State, zone or compartment thereof subject to the surveillance;

(ii) the Member States and third countries or territories which either border on, or from which animals and products enter into, that Member State, zone or compartment thereof;

(d) surveillance conducted by operators in accordance with Article 24, including animal health visits as referred to in Article 25, or by other public authorities.

Article 28

Union surveillance programmes

1. The competent authority shall undertake surveillance as provided for in Article 26(1) within the framework of a surveillance programme when a disease is relevant for the Union in accordance with point (c) of Article 29.

2. Member States establishing a surveillance programme in accordance with paragraph 1 shall submit it to the Commission.

3. Member States implementing a surveillance programme in accordance with paragraph 1 shall submit regular reports on the results of the implementation of that programme to the Commission.

Article 29

Delegation of powers

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 27;

(b) the criteria for the official confirmation and case definitions of listed diseases as referred to in point (e) of Article 9(1), and, where relevant, of emerging diseases;

(c) the criteria used to establish the relevance of a disease which is to be subject to a surveillance programme relevant for the Union for the purposes of point (a) of Article 30(1), taking into account the disease profile and the risk factors involved;

(d) requirements for surveillance programmes as provided for in Article 28(1) regarding:

(i) the contents of surveillance programmes;

(ii) the information to be included in the submission of surveillance programmes in accordance with Article 28(2) and regular reports in accordance with Article 28(3);

(iii) the period of application of surveillance programmes.

Article 30

Implementing powers

1. The Commission shall, by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes as provided for in Articles 26 and 28 and in the rules adopted pursuant to Article 29, as regards:

(a) establishing which of the listed diseases referred to in point (e) of Article 9(1) are to be subject to surveillance programmes in accordance with Article 28, including the geographical scope of such programmes;

(b) the format and procedure for:

(i) the submission of those surveillance programmes for information to the Commission and other Member States;

(ii) the reporting to the Commission on the results of the surveillance.

2. The Commission may, by means of implementing acts, lay down the criteria to be used for evaluating the surveillance programmes referred to in Article 28.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Eradication programmes

Article 31

Compulsory and optional eradication programmes

1. Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (b) of Article 9(1) throughout their territory, or in zones or compartments thereof, shall:

(a) establish a programme for the eradication of, or demonstration of freedom from, that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ('compulsory eradication programme'), to apply until the conditions for the grant of disease-free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled;

(b) submit the draft compulsory eradication programme to the Commission for approval.

2. Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (c) of Article 9(1) and which decide to establish a programme for the eradication of that listed disease, to be carried out in the animal populations concerned by the disease in question and covering the relevant parts of their territory or zones or compartments thereof ('optional eradication programme'), shall submit a draft of that programme to the Commission for approval, where the Member State concerned asks for the recognition, within the Union, of animal health guarantees as regards the disease in question for movements of animals or products.

Such an optional eradication programme shall apply until:

(a) the conditions for the grant of disease-free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled; or

(b) it is established that the conditions for the grant of disease-free status cannot be achieved and that the programme no longer fulfils its purpose; or

(c) the Member State concerned withdraws the programme.

3. The Commission shall, by means of implementing acts, approve:

(a) draft compulsory eradication programmes submitted to it for approval in accordance with paragraph 1;

(b) draft optional eradication programmes submitted to it for approval in accordance with paragraph 2,

if the conditions set out in this Chapter are met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a listed disease representing a risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts provided for in point (a) of paragraph 3 of this Article in accordance with the procedure referred to in Article 266(3).

The Commission may, for duly justified reasons, by means of implementing acts, approve an amendment proposed by the Member State concerned or withdraw the approval of eradication programmes approved in accordance with points (a) and (b) of paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the disease control strategies, intermediate and final targets for specific diseases, and period of application of eradication programmes;

(b) derogations from the requirement for the submission of eradication programmes for approval, as provided for in point (b) of paragraph 1 of this Article and in paragraph 2 thereof, where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 32(2) and 35;

(c) the information to be provided by Member States to the Commission and to the other Member States concerning derogations from the requirement for approval of eradication programmes as provided for in point (b) of this paragraph.

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 amending or discontinuing rules adopted pursuant to point (b) of this paragraph.

Article 32

Measures under compulsory and optional eradication programmes

1. Eradication programmes shall consist of at least the following measures:

(a) disease control measures for the eradication of the disease agent from establishments, compartments and zones in which a disease occurs and to prevent re–infection;

(b) surveillance to be carried out in accordance with the rules laid down in Articles 26 to 30 to demonstrate:

(i) the effectiveness of the disease control measures provided for in point (a);

(ii) freedom from the listed disease;

(c) disease control measures to be taken in the event of positive surveillance results.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the following elements to ensure the effectiveness of eradication programmes:

(a) disease control measures as provided for in point (a) of paragraph 1;

(b) disease control measures to be taken to avoid re–infection of the targeted animal population with the disease in question in establishments, zones and compartments;

(c) surveillance design, means, diagnostic methods, frequency, intensity, targeted animal population and sampling patterns;

(d) disease control measures to be taken in the event of positive surveillance results for the listed disease as provided for in point (c) of paragraph 1;

(e) criteria for vaccination, where relevant and appropriate for the disease or species in question.

Article 33

Content of compulsory and optional eradication programmes submitted for approval to the Commission

Member States shall include the following information in applications for approval of compulsory and optional eradication programmes submitted to the Commission in accordance with Article 31(1) and (2):

(a) a description of the epidemiological situation of the listed disease covered by the compulsory or optional eradication programme in question;

(b) a description and demarcation of the geographical and administrative area or the compartment covered by the eradication programme;

(c) a description of the disease control measures of the eradication programme as provided for in Article 32(1) and in the rules adopted pursuant to Article 32(2);

(d) a description of the organisation, supervision and roles of the parties involved in the eradication programme;

(e) the estimated duration of the eradication programme;

(f) the intermediate targets of, and the disease control strategies for implementing, the eradication programme.

Article 34

Reporting

Member States implementing eradication programmes shall submit to the Commission:

(a) reports enabling the Commission to monitor achievement of the intermediate targets of the on-going eradication programmes as referred to in point (f) of Article 33;

(b) a final report after completion of the eradication programme in question.

Article 35

Implementing powers

The Commission shall, by means of implementing acts, lay down rules concerning the information, format and procedural requirements provided for in Articles 31 to 34 as regards:

(a) the submission of draft compulsory and draft optional eradication programmes for approval;

(b) performance indicators;

(c) reporting to the Commission and other Member States on the results of the implementation of compulsory or optional eradication programmes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 4

Disease-free status

Article 36

Disease-free Member States and zones

1. A Member State may apply to the Commission for approval of disease-free status for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, for its entire territory or for one or more zones thereof, provided that one or more of the following conditions are fulfilled:

(a) none of the listed species for the disease covered by the application for disease-free status is present anywhere in the territory of the Member State concerned or in the relevant zone or zones covered by the application;

(b) the disease agent is known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;

(c) in the case of listed diseases only transmitted by vectors, none of the vectors are present, or they are known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;

(d) freedom from the listed disease has been demonstrated by:

(i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or

(ii) historical and surveillance data.

2. Applications by Member States for disease-free status shall include evidence demonstrating that the conditions for disease-free status laid down in paragraph 1 are fulfilled.

3. A Member State may in certain specific cases apply to the Commission for approval of disease-free status for one or more of the listed diseases referred to in point (a) of Article 9(1), and in particular for approval of non–vaccination status for the entire territory, or for one or more zones thereof, provided that the following conditions are fulfilled:

(a) freedom from the listed disease has been demonstrated by:

(i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or

(ii) historical and surveillance data;

(b) it has been demonstrated that vaccination against the disease would lead to costs which would exceed those resulting from maintaining freedom from disease without vaccination.

4. The Commission shall, by means of implementing acts, approve, subject to amendments where necessary, applications by Member States for disease-free status or non-vaccination status when the conditions referred to in paragraphs 1 and 2 and, as relevant, paragraph 3 are fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 37

Compartments

1. A Member State may apply to the Commission for recognition of the disease-free status of compartments for listed diseases referred to in point (a) of Article 9(1), and for the protection of the disease-free status of such a compartment in the event of an outbreak of one or more of those listed diseases in its territory, provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease-free status of all establishments forming part of it; and

(c) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

2. A Member State may apply to the Commission for recognition of the disease-free status of compartments for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) one or more of the following conditions are complied with:

(i) the conditions laid down in Article 36(1) are fulfilled;

(ii) the establishments of the compartment covered by the application have started or resumed their activities and have established a common biosecurity management system designed to ensure the freedom from disease of that compartment;

(c) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease-free status of all establishments forming part of it; and

(d) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

3. Applications by Member States for recognition of the disease-free status of compartments in accordance with paragraphs 1 and 2 shall include evidence demonstrating that the conditions laid down in those paragraphs are fulfilled.

4. The Commission shall, by means of implementing acts:

(a) recognise, subject to amendments where necessary, the disease-free status of compartments, when the conditions laid down in paragraph 1 or paragraph 2 and in paragraph 3 are fulfilled;

(b) determine for which of the listed diseases referred to in points (a), (b) and (c) of Article 9(1) the disease-free compartments may be established.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing those contained in this Article, on:

(a) the requirements for recognition of the disease-free status of compartments as provided for in paragraphs 1 and 2 of this Article, based on the profile of the listed diseases referred to in points (a), (b) and (c) of Article 9(1), concerning at least:

(i) surveillance results and other evidence needed to substantiate freedom from disease;

(ii) biosecurity measures;

(b) the detailed rules for the approval by the competent authority of the disease-free status of compartments as provided for in paragraphs 1 and 2; and

(c) rules concerning compartments which are located in the territory of more than one Member State.

Article 38

Lists of disease-free Member States, zones or compartments

Each Member State shall establish and maintain an up-to-date list of its territory or zones with disease-free status as provided for in Article 36(1) and (3), and of its compartments with disease-free status, as provided for in Article 37(1) and (2), when applicable.

Member States shall make those lists publicly available. The Commission shall assist the Member States in making the information contained in those lists available to the public by providing on its internet page the links to the internet–based information pages of the Member States.

Article 39

Delegation of powers concerning the disease-free status of Member States and zones

The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for the disease-free status of Member States and zones thereof, based on the different disease profiles, concerning:

(i) the criteria to be used to substantiate claims by Member States that no listed species are present or able to survive in their territory and the evidence required to substantiate such claims, as provided for in point (a) of Article 36(1);

(ii) the criteria to be used, and the evidence required, to substantiate claims that a disease agent or vector is not able to survive, as provided for in points (b) and (c) of Article 36(1);

(iii) the criteria to be used, and the conditions to be applied, to determine freedom from the disease in question, as referred to in point (d) of Article 36(1);

(iv) surveillance results and other evidence needed to substantiate freedom from disease;

(v) biosecurity measures;

(vi) restrictions and conditions for vaccination in disease-free Member States and zones thereof;

(vii) the establishment of zones separating disease-free zones or zones under the eradication programme from restricted zones ('buffer zones');

(viii) zones which are located in the territory of more than one Member State;

(b) derogations from the requirement for approval by the Commission of disease-free status for one or more listed diseases referred to in points (b) and (c) of Article 9(1), as laid down in Article 36(1), where such approval is not necessary on account of detailed rules for freedom from disease having been laid down in rules adopted pursuant to point (a) of this Article;

(c) the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease-free status, without the adoption of an implementing act in accordance with Article 36(4), as provided for in point (b) of this Article.

Article 40

Implementing powers

The Commission shall, by means of implementing acts, lay down detailed requirements concerning the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease-free status of territories, zones and compartments in accordance with Articles 36 to 39, and the format and procedures for:

(a) applications for recognition of disease-free status of the entire territory of the Member State concerned, or zones and compartments thereof;

(b) exchanges of information between the Member States and the Commission on disease-free Member States, or zones and compartments thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 41

Maintenance of disease-free status

1. Member States shall only maintain disease-free status for their territories, or zones or compartments thereof, as long as:

(a) the conditions for disease-free status laid down in Article 36(1) and Article 37(1) and (2), and rules laid down pursuant to paragraph 3 of this Article and Article 39, continue to be fulfilled;

(b) surveillance, taking into account the requirements provided for in Article 27, is undertaken to verify that the territory, zone or compartment concerned continues to be free of the listed disease for which it was approved or recognised as having disease-free status;

(c) restrictions are applied on movements of animals, and where relevant products derived therefrom, of listed species for the listed disease for which the disease-free status was approved or recognised, into the territory, zone or compartment concerned, in accordance with the rules laid down in Parts IV and V;

(d) other biosecurity measures are applied to prevent the introduction of the listed disease for which it was approved or recognised as having disease-free status.

2. A Member State shall immediately inform the Commission if the conditions referred to in paragraph 1 for maintaining disease-free status are no longer met.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning the following conditions for maintaining disease-free status:

(a) surveillance as provided for in point (b) of paragraph 1;

(b) biosecurity measures as provided for in point (d) of paragraph 1.

Article 42

Suspension, withdrawal and restoration of disease-free status

1. Where a Member State becomes aware, or has reason to suspect, that any of the conditions for maintaining its status as a disease-free Member State or zone or compartment thereof, have been breached, it shall immediately:

(a) where relevant, depending on the risk, suspend or restrict movements of the listed species, for the listed disease for which it was approved or recognised as having disease-free status, to other Member States, zones or compartments with a higher health status for that listed disease;

(b) where relevant for the prevention of the spread of a listed disease for which disease-free status has been approved or recognised, apply the disease control measures provided for in Title II of Part III.

2. The measures provided for in paragraph 1 shall be lifted where further investigation confirms that:

(a) the suspected breach has not taken place; or

(b) the suspected breach has not had a significant impact and the Member State concerned can provide assurances that the conditions for maintaining its disease-free status are again fulfilled.

3. Where further investigation by the Member State concerned confirms that there has been an outbreak of the listed disease for which it obtained disease-free status, or that other significant breaches of the conditions for maintaining disease-free status as referred to in Article 41(1) have occurred, or where there is a significant likelihood of this having occurred, the Member State shall immediately inform the Commission thereof.

4. The Commission shall, by means of implementing acts, withdraw without undue delay the approval of the disease-free status of a Member State or zone granted in accordance with Article 36(4) or the recognition of the disease-free status of a compartment granted in accordance with Article 37(4) after obtaining the information from the Member State concerned that the conditions for maintaining the disease-free status are no longer met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner, carrying with it the risk of a highly significant impact on animal or public health, the economy or society, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the rules for the suspension, withdrawal and restoration of disease-free status set out in paragraphs 1 and 2 of this Article.

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

DISEASE AWARENESS AND PREPAREDNESS

CHAPTER 1

Contingency plans and simulation exercises

Article 43

Contingency plans

1. The Member States shall, after appropriate consultation of experts and relevant stakeholders, draw up, and keep up to date, contingency plans and, where necessary, detailed instruction manuals laying down the measures to be taken in the Member State concerned in the event of the occurrence of a listed disease referred to in point (a) of Article 9(1) or, as the case may be, of an emerging disease, in order to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response.

2. Those contingency plans and, where applicable, detailed instruction manuals shall cover at least the following matters:

(a) the establishment of a chain of command within the competent authority and with other public authorities, to ensure a rapid and effective decision–making process at Member State, regional and local level;

(b) the framework for cooperation between the competent authority and the other public authorities and relevant stakeholders involved, to ensure that actions are taken in a coherent and coordinated manner;

(c) access to:

(i) facilities;

(ii) laboratories;

(iii) equipment;

(iv) personnel;

(v) emergency funds;

(vi) all other appropriate materials and resources necessary for the rapid and efficient eradication of the listed diseases referred to in point (a) of Article 9(1)or of emerging diseases;

(d) the availability of the following centres and groups with the necessary expertise to assist the competent authority:

(i) a functional central disease control centre;

(ii) regional and local disease control centres, as appropriate for the administrative and geographical situation of the Member State concerned;

(iii) operational expert groups;

(e) implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in point (a) of Article 9(1) and for emerging diseases;

(f) provisions on emergency vaccination, where appropriate;

(g) principles for the geographical demarcation of the restricted zones established by the competent authority in accordance with Article 64(1);

(h) coordination with neighbouring Member States and neighbouring third countries and territories, where appropriate.

Article 44

Implementing powers for contingency plans

The Commission shall, by means of implementing acts, lay down necessary measures concerning the implementation in the Member States of the contingency plans provided for in Article 43(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 45

Simulation exercises

1. The competent authority shall ensure that simulation exercises concerning the contingency plans provided for in Article 43(1) are carried out regularly or at appropriate intervals:

(a) to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the Member State concerned;

(b) to verify the functionality of those contingency plans.

2. Where feasible and appropriate, simulation exercises shall be carried out in close collaboration with the competent authorities of neighbouring Member States and neighbouring third countries and territories.

3. Member States shall make available to the Commission and to the other Member States, on request, a report on the main results of the simulation exercises carried out.

4. When appropriate and necessary, the Commission shall, by means of implementing acts, lay down rules concerning the practical implementation of simulation exercises in the Member States, relating to:

(a) the frequencies of simulation exercises;

(b) simulation exercises covering more than one listed disease referred to in point (a) of Article 9(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1. The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary.

Those measures may cover the following:

(a) prohibitions and restrictions on the use of veterinary medicinal products;

(b) the compulsory use of veterinary medicinal products.

2. Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

(a) the disease profile;

(b) the distribution of the listed disease in:

(i) the Member State concerned;

(ii) the Union;

(iii) where relevant, neighbouring third countries and territories;

(iv) third countries and territories from which animals and products are brought into the Union;

(c) the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;

(d) the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;

(e) the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

3. Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Article 47

Delegation of powers for the use of veterinary medicinal products

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning what might constitute appropriate and necessary measures as set out in Article 46, in relation to:

(a) prohibitions and restrictions on the use of veterinary medicinal products;

(b) specific conditions for the use of veterinary medicinal products for a specific listed disease;

(c) risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;

(d) surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

2. The Commission shall take into account the criteria set out in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.

3. Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to paragraph 1 of this Article.

CHAPTER 3

Antigen, vaccine and diagnostic reagent banks

Article 48

The establishment of Union antigen, vaccine and diagnostic reagent banks

1. For listed diseases referred to in point (a) of Article 9(1) in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47, the Commission may establish and be responsible for managing Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of one or more of the following biological products:

(a) antigens;

(b) vaccines;

(c) vaccine master seed–stocks;

(d) diagnostic reagents.

2. The Commission shall ensure that the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:

(a) store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents for the specific listed disease in question, taking into account the needs of Member States estimated in the context of the contingency plans provided for in Article 43(1);

(b) receive regular supplies and timely replacements of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents;

(c) are maintained and moved in conformity with the appropriate biosecurity, biosafety and bio–containment requirements laid down in Article 16(1) and in accordance with delegated acts adopted pursuant to Article 16(2);

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks as provided for in paragraphs 1 and 2 of this Article;

(b) the biosecurity, biosafety and bio–containment requirements for the operation of those banks, respecting the requirements provided for in Article 16(1) and taking into account the delegated acts adopted pursuant to Article 16(2).

Article 49

Access to the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall, upon request, provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks, provided that stocks are available, to:

(a) in the first place, Member States; and

(b) third countries or territories, provided that such delivery is primarily intended to prevent the spread of a disease into the Union.

2. The Commission shall, in the event of the limited availability of stocks, prioritise access to the stocks to be delivered pursuant to paragraph 1 based on:

(a) the disease circumstances under which the request is made;

(b) the existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State or third country or territory;

(c) the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47.

Article 50

Implementing powers concerning the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall, by means of implementing acts, lay down rules for Union antigen, vaccine and diagnostic reagent banks, specifying for the biological products referred to in Article 48(1):

(a) which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in point (a) of Article 9(1);

(b) the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent banks and in what quantities for each specific listed disease referred to in point (a) of Article 9(1) for which the bank in question exists;

(c) the requirements concerning the supply, storage and replacement of those biological products;

(d) the delivery of those biological products from the Union antigen, vaccine and diagnostic reagent banks to the Member States and to third countries and territories;

(e) procedural and technical requirements for the inclusion of those biological products in the Union antigen, vaccine and diagnostic reagent banks and for requesting access to them.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a listed disease referred to in point (a) of Article 9(1) representing a risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 51

Confidentiality of information concerning the Union antigen, vaccine and diagnostic reagent banks

Information on the quantities and subtypes of the biological products referred to in Article 48(1) stored in the Union antigen, vaccine and diagnostic reagent banks shall be treated by the Commission as classified information and shall not be published.

Article 52

National antigen, vaccine and diagnostic reagent banks

1. Member States that have established national antigen, vaccine and diagnostic reagent banks for listed diseases referred to in point (a) of Article 9(1) for which Union antigen, vaccine and diagnostic reagent banks exist, shall ensure that their national antigen, vaccine and diagnostic reagent banks comply with the biosecurity, biosafety and bio–containment requirements laid down in point (a) of Article 16(1) and in delegated acts adopted in accordance with Article 16(2) and point (b) of Article 48(3).

2. Member States shall provide the Commission with up-to-date information on:

(a) the existence or the establishment of the national antigen, vaccine and diagnostic reagent banks referred to paragraph 1;

(b) the types of antigens, vaccines, vaccine master-seed stocks and diagnostic reagents and the quantities thereof held in such banks;

(c) any changes in the operation of such banks.

That information shall be treated as classified information by the Commission and shall not be published.

3. The Commission may, by means of implementing acts, lay down rules specifying the content, frequency and format of the submission of the information provided for in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

TITLE II

DISEASE CONTROL MEASURES

CHAPTER 1

Disease control measures for listed diseases as referred to in point (a) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of a listed disease in kept animals

Article 53

Obligations on operators and other relevant natural and legal persons concerned

1. In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Articles 54(1) and 55(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take the appropriate disease control measures provided for in points (c), (d) and (e) of Article 55(1), to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other unaffected animals or to humans.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures provided for in paragraph 1 of this Article.

Article 54

Investigation by the competent authority in the event of suspicion of a listed disease

1. In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that:

(a) official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;

(b) official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;

(c) such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations by competent authorities as provided for in paragraph 1 of this Article.

Article 55

Preliminary disease control measures by competent authorities

1. The competent authority shall, in the event that it suspects the presence of a listed disease as referred to in point (a) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 54(1) and the carrying-out of the disease control measures provided for in Article 61(1):

(a) place the establishment, food and feed business or animal by–products establishment concerned, or any other location where the disease is suspected of having occurred, including locations where the suspected disease may have originated, under official surveillance;

(b) compile an inventory of:

(i) the kept animals in the establishment, food and feed business, or animal by–products establishment concerned, or in any other location;

(ii) the products in that establishment, food and feed business, or animal by–products establishment, or in any other location, where relevant for the spread of that listed disease;

(c) ensure that appropriate biosecurity measures are applied to prevent the spreading of that listed disease agent to other animals or to humans;

(d) when appropriate to prevent the further spread of the disease agent, ensure that the kept animals of listed species for that listed disease are isolated, and that they are prevented from coming into contact with wildlife;

(e) restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, food and feed business or animal by–products establishment, or from any other location where that listed disease is suspected, as far as necessary to prevent its spread;

(f) take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4 of this Chapter, concerning:

(i) the application of the investigation by the competent authority provided for in Article 54(1) and disease control measures provided for in points (a) to (d) of this paragraph to other establishments, food and feed businesses, or animal by–products establishments, or to any other location;

(ii) the establishment of any temporary restricted zones which are appropriate, taking into account the disease profile;

(g) initiate the epidemiological enquiry provided for in Article 57(1).

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in point (a) of Article 9(1), based on the risks involved for:

(a) the species or category of animals concerned;

(b) the type of production concerned.

Article 56

Review and extension of the preliminary disease control measures

The disease control measures provided for in Article 55(1) shall be:

(a) reviewed by the competent authority, as appropriate, following the findings of:

(i) the investigation provided for in Article 54(1);

(ii) the epidemiological enquiry provided for in Article 57(1);

(b) further extended to other locations as referred to in point (a) of Article 55(1), where necessary.

Section 2

Epidemiological Enquiry

Article 57

Epidemiological enquiry

1. The competent authority shall carry out an epidemiological enquiry in the event of the confirmation of a listed disease as referred to in point (a) of Article 9(1) in animals.

2. The epidemiological enquiry provided for in paragraph 1 shall aim to:

(a) identify the likely origin of the listed disease in question and the means of its spread;

(b) calculate the likely length of time that the listed disease has been present;

(c) identify establishments and epidemiological units therein, food and feed businesses or animal by–products establishments, or other locations, where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;

(d) obtain information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease;

(e) obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

Section 3

Disease confirmation in kept animals

Article 58

Official confirmation by the competent authority of a listed disease as referred to in point (a) of Article 9(1)

1. The competent authority shall base an official confirmation of a listed disease as referred to in point (a) of Article 9(1) on the following information:

(a) the results of the clinical and laboratory examinations provided for in Article 54(2);

(b) the preliminary or final results of the epidemiological enquiry provided for in Article 57(1);

(c) other available epidemiological data.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

Article 59

Lifting of preliminary disease control measures where the presence of the listed disease has been ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 55(1) and Article 56 until the presence of the listed disease in question, as referred to in point (a) of Article 9(1), has been ruled out on the basis of the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2).

Section 4

Disease control measures in the event of confirmation of disease in kept animals

Article 60

Immediate disease control measures to be taken by the competent authority

In the event of an official confirmation in accordance with Article 58(1) of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately:

(a) declare the affected establishment, food or feed business, animal by–products establishment or other location as officially infected with that listed disease;

(b) establish a restricted zone appropriate for that listed disease;

(c) implement the contingency plan provided for in Article 43(1) to ensure full coordination of the disease control measures.

Article 61

Affected establishments and other locations

1. In the event of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately take one or more of the following disease control measures, subject to national requirements for gaining access to private residences, in an establishment, food or feed business, animal by–products establishment, or any other location referred to in point (a) of Article 60, in order to prevent the further spread of that listed disease:

(a) the imposition of restrictions on movements of persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of the listed disease;

(b) the killing and disposal or slaughtering of animals that may be contaminated or contribute to the spread of the listed disease;

(c) the destruction, processing, transformation or treatment of products, feed, or any other substances, or the treatment of equipment, means of transport, plants or plant products, or water which may be contaminated, as appropriate to ensure that any disease agent or vector of the disease agent is destroyed;

(d) the vaccination or treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and Article 69 and any delegated acts adopted pursuant to Article 47;

(e) the isolation, quarantine or treatment of animals and products that are likely to be contaminated and contribute to the spread of the listed disease;

(f) the cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures to be applied to the affected establishment, food or feed business, animal by–products establishment or other locations to minimise the risk of spread of the listed disease;

(g) the taking of a sufficient number of appropriate samples needed to complete the epidemiological enquiry provided for in Article 57(1);

(h) the laboratory examination of samples;

(i) any other appropriate measures.

2. When determining which of the disease control measures provided for in paragraph 1 are appropriate to take, the competent authority shall take the following into account:

(a) the disease profile;

(b) the type of production, and epidemiological units within the affected establishment, food or feed business, animal by–products establishment or other location;

3. The competent authority shall only authorise the repopulation of the establishment concerned, or of any other location, when:

(a) all appropriate disease control measures and laboratory examinations provided for in paragraph 1 have been successfully completed;

(b) a sufficient period of time has elapsed to prevent re–contamination of the affected establishment, food or feed business, animal by–products establishment or other location with the listed disease that caused the outbreak referred to in paragraph 1.

Article 62

Epidemiologically linked establishments and locations

1. The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, food or feed businesses, or animal by–products establishments, or any other location, or means of transport where the epidemiological enquiry provided for in Article 57(1) or the results of clinical or laboratory investigations or other epidemiological data, give reason to suspect the spread to, from or through them of the listed disease referred to in point (a) of Article 9(1) in respect of which such measures were taken.

2. If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in point (a) of Article 9(1) is another Member State, or if it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State and the Commission without delay.

3. Should any of the events referred to in paragraph 2 occur, the competent authorities of the different Member States shall cooperate in a further epidemiological enquiry and in the application of disease control measures.

Article 63

Delegation of powers in respect of disease control measures in affected and epidemiologically linked establishments and other locations

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken by the competent authority in accordance with Articles 61 and 62 in affected and epidemiologically linked establishments, food or feed businesses, or animal by–products establishments, and other locations in respect of any listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 61(1) are to be applied in relation to each listed disease.

Those detailed rules shall cover the following matters:

(a) the conditions and requirements for the disease control measures provided for in points (a) to (e) of Article 61(1);

(b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 61(1), specifying, where appropriate, the use of biocidal products for those purposes;

(c) the conditions and requirements for sampling and laboratory examination as provided for in points (g) and (h) of Article 61(1);

(d) the detailed conditions and requirements in respect of repopulation as provided for in Article 61(3);

(e) the carrying-out of the necessary disease control measures provided for in Article 62 in epidemiologically linked establishments, other locations and means of transport.

Article 64

Establishment of restricted zones by the competent authority

1. The competent authority shall establish a restricted zone as referred to in point (b) of Article 60 around the affected establishment, food or feed business, animal by–products establishment or other location where the outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals has occurred, where appropriate taking into account:

(a) the disease profile;

(b) the geographical situation of the restricted zone;

(c) the ecological and hydrological factors of the restricted zone;

(d) the meteorological conditions;

(e) the presence, distribution and type of vectors in the restricted zone;

(f) the results of the epidemiological enquiry provided for in Article 57(1) and other studies carried out and epidemiological data;

(g) the results of laboratory tests;

(h) the disease control measures applied;

(i) other relevant epidemiological factors.

The restricted zone shall include, when appropriate, a protection and surveillance zone of a defined size and configuration.

2. The competent authority shall continuously assess and review the situation and, when appropriate in order to prevent the spread of the listed disease referred to in point (a) of Article 9(1), shall:

(a) adapt the boundaries of the restricted zone;

(b) establish additional restricted zones.

3. Where restricted zones as provided for in paragraph 1 are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing them.

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the establishment and modification of restricted zones, including protection or surveillance zones.

Article 65

Disease control measures in restricted zones

1. The competent authority shall ensure that, subject to national requirements for gaining access to private residences, one or more of the following disease control measures are taken in the restricted zone concerned, in order to prevent the further spread of a listed disease as referred to in point (a) of Article 9(1):

(a) the identification of establishments, food or feed businesses, animal by–products establishments or other locations with kept animals of listed species for that listed disease;

(b) visits to establishments, food or feed businesses, animal by–products establishments or other locations with kept animals of listed species for that listed disease, and, where necessary, examinations, sampling and laboratory examination of the samples taken;

(c) the imposition of conditions for the movement of persons, animals, products, feed, vehicles and any other material or substance that may be contaminated or contribute to the spread of that listed disease within and from the restricted zone and transport through the restricted zone;

(d) biosecurity requirements for:

(i) the production, processing and distribution of products of animal origin;

(ii) the collection and disposal of animal by–products;

(iii) the collection, storage and handling of germinal products;

(e) the vaccination and treatment with other veterinary medicinal products of kept animals in accordance with Article 46 (1) and any delegated acts adopted pursuant to Article 47;

(f) cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures;

(g) the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering of animals or the treatment of products of animal origin originating from the restricted zone;

(h) the identification and traceability requirements for the movement of animals, germinal products or products of animal origin;

(i) other necessary biosecurity and risk-mitigating measures to minimise the risk of the spread of that listed disease.

2. The competent authority shall:

(a) take all necessary measures to fully inform persons in the restricted zone of the restrictions in force and the nature of the disease control measures;

(b) impose the necessary obligations on operators in order to prevent the further spread of the listed disease in question.

3. When determining which of the disease control measures provided for in paragraph 1 are to be taken, the competent authority shall take the following into account:

(a) the disease profile;

(b) the types of production;

(c) the feasibility, availability and effectiveness of those disease control measures.

Article 66

Operators' obligations regarding movements in restricted zones

1. In restricted zones as provided for in Article 64(1), operators shall only move the kept animals and products with the permission of the competent authority and in accordance with any instructions given by that authority.

2. Operators keeping animals and products in a restricted zone as provided for in Article 64(1) shall notify to the competent authority intended movements of kept animals and products within or out of the restricted zone in question. In so far as the competent authority has imposed notification obligations in accordance with point (b) of Article 65(2), the operators concerned shall notify in accordance with those obligations.

Article 67

Delegation of powers concerning disease control measures in restricted zones

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken in restricted zones as provided for in Article 65(1) for each listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 65(1) are to be applied in the case of each listed disease.

Those detailed rules shall cover the following matters:

(a) the conditions and requirements for the disease control measures provided for in points (a), (c), (d), (e), (g), (h) and (i) of Article 65(1);

(b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 65(1), specifying, where appropriate, the use of biocidal products for those purposes;

(c) the necessary surveillance which is to be conducted following the application of the disease control measures and laboratory examinations provided for in point (b) of Article 65(1);

(d) other specific disease control measures to limit the spread of specific listed diseases as referred to in point (a) of Article 9 (1).

Article 68

Maintaining disease control measures in restricted zones and delegated acts

1. The competent authority shall continue to apply the disease control measures provided for in this Section until the following conditions are met:

(a) the disease control measures appropriate to the listed disease referred to in point (a) of Article 9(1) for which they were applied have been carried out;

(b) the final cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:

  (i) the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied;

  (ii) the affected species of kept animals;

  (iii) the type of production;

(c) adequate surveillance, as appropriate for the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied, and for the type of establishment or location concerned, has been carried out in the restricted zone substantiating the eradication of that listed disease.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to:

(a) the final procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures and, where appropriate, the use of biocidal products for those purposes;

(b) the design, means, methods, frequency, intensity, targeted animal population and sampling patterns of surveillance aimed at the restoration of disease-free status after the outbreak;

(c) repopulation of the restricted zone concerned after the completion of the disease control measures provided for in paragraph 1 of this Article, taking into account the conditions for repopulation provided for in Article 61(3).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to other disease control measures necessary for the restoration of disease-free status.

Article 69

Emergency vaccination

1. Where relevant for the effective control of a listed disease as referred to in point (a) of Article 9(1) for which disease control measures apply, the competent authority may:

(a) develop a vaccination plan;

(b) establish vaccination zones.

2. When deciding on the vaccination plan and the establishment of vaccination zones as provided for in paragraph 1, the competent authority shall take the following into account:

(a) the requirements for emergency vaccination set out in the contingency plans provided for in Article 43;

(b) the requirements for the use of vaccines as provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47.

3. Vaccination zones as provided for in point (b) of paragraph 1 of this Article shall meet the requirements in respect of risk-mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with points (c) and (d) of Article 47(1).

Section 5

Wild animals

Article 70

Wild animals

1. Where the competent authority of an affected Member State suspects or officially confirms the presence of a listed disease as referred to in point (a) of Article 9(1) in wild animals, it shall:

(a) conduct, where relevant for that particular listed disease, surveillance in the wild animal population;

(b) take the necessary disease prevention and control measures.

2. The disease prevention and control measures provided for in point (b) of paragraph 1 of this Article may include one or more of the measures laid down in Article 53 to 69 and shall take into account the disease profile and the affected wild animals and the risk of transmission of diseases to animals and humans.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) criteria and procedures for surveillance pursuant to point (a) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1), in accordance with Article 27;

(b) detailed rules supplementing the disease prevention and control measures to be taken pursuant to point (b) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1).

When adopting those delegated acts, the Commission shall take into account the disease profile and the listed species for the listed disease referred to paragraph 1 of this Article.

Section 6

Additional disease control measures by the Member States, coordination by the Commission and temporary special disease control rules

Article 71

Additional disease control measures, coordination of measures and temporary special disease control rules concerning Sections 1 to 5 (Articles 53 to 70)

1. Member States may take disease control measures additional to those provided for in Article 55, Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in any delegated acts adopted pursuant to Article 63, Article 67 and Article 68(2), provided that such measures respect the rules laid down in this Regulation and are necessary and proportionate to control the spread of a listed disease as referred to in point (a) of Article 9(1), taking into account:

(a) the particular epidemiological circumstances;

(b) the type of establishments, other locations and production concerned;

(c) the species and categories of animals involved;

(d) economic or social conditions.

2. Member States shall inform the Commission without delay of:

(a) the disease control measures taken by their competent authority as provided for in Articles 58, 59, 61, 62, 64 and 65, Article 68(1), Article 69 and Article 70(1) and (2) and in any delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);

(b) any additional disease control measures taken by them as provided for in paragraph 1.

3. The Commission shall review the disease situation and the disease control measures taken by the competent authority and any additional disease control measures taken by the Member State concerned, in accordance with this Chapter, and may, by means of implementing acts, lay down special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation, where:

(a) those disease control measures are found not to be suited to the epidemiological situation;

(b) the listed disease referred to in point (a) of Article 9(1) appears to be spreading despite the disease control measures taken in accordance with this Chapter.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

CHAPTER 2

Disease control measures for listed diseases as referred to in points (b) and (c) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of disease in kept animals

Article 72

Obligations on operators and other relevant natural and legal persons concerned in relation to listed diseases as referred to in point (b) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Article 74(1), Member States shall take measures to ensure that operators

and other relevant natural and legal persons concerned take disease control measures as referred to in point (a) of Article 74 (1) and in any delegated acts adopted pursuant to Article 74(4), to prevent the spread of that listed disease from the affected animals, establishments and other locations under their responsibility to other unaffected animals or to humans.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures as provided for in paragraph 1 of this Article.

Article 73

Investigation by the competent authority in the event of suspicion of a listed disease as referred to in point (b) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall ensure that:

(a) official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;

(b) official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;

(c) such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations as provided for in paragraph 1 of this Article.

Article 74

Preliminary disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

1. The competent authority shall, in the event that it suspects a listed disease as referred to in point (b) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 73(1) and the carrying-out of the disease control measures provided for in Article 79(1) and (2):

(a) apply disease control measures to limit the spread of that listed disease from the affected territory, establishment, food or feed business, animal by–products establishment or other location;

(b) initiate, where necessary, an epidemiological enquiry, taking into account the rules for such enquiry laid down in Article 57(1).

2. In addition to the measures referred to in paragraph 1, the competent authority may, in the cases referred to in that paragraph, take additional preliminary disease control measures, provided that those measures respect the provisions of this Regulation and are in accordance with Union law.

3. The preliminary disease control measures provided for in paragraphs 1 and 2 shall be appropriate and proportionate to the risk posed by the listed disease in question, taking into account the following:

(a) the disease profile;

(b) the kept animals affected;

(c) the health status of the Member State, zone, compartment or establishment in which the listed disease is suspected;

(d) the preliminary disease control measures provided for in Article 55(1) and Article 56 and in any delegated act adopted pursuant to Article 55(2).

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning rules for listed diseases as referred to in point (b) of Article 9(1) supplementing those laid down in paragraph 1 of this Article, while taking into account the matters referred to in paragraph 3, as regards:

(a) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (a) of paragraph 1;

(b) the application of the preliminary disease control measures provided for in point (a) of paragraph 1 to other establishments, epidemiological units therein, food or feed businesses and animal by–products establishments or other locations;

(c) the establishment of temporary restricted zones which are appropriate in light of the disease profile.

Article 75

Review and extension of the preliminary disease control measures for listed diseases as referred to in point (b) of Article 9(1)

The disease control measures provided for in Article 74(1) shall be:

(a) reviewed by the competent authority, as appropriate, following the findings of the investigation provided for in Article 73(1) and, where relevant, the epidemiological enquiry provided for in point (b) of Article 74(1);

(b) further extended to other locations, as referred to in point (b) of Article 74(4), where necessary.

Article 76

Obligations of operators and other relevant natural and legal persons and measures to be taken by the competent authority in the event of suspicion of listed diseases as referred to in point (c) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (c) of Article 9(1) in a Member State that has opted for the eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), that Member State shall take measures to ensure that operators and other relevant natural and legal persons concerned take appropriate measures as provided for in Article 72(1), pending any disease control measures being taken by the competent authority in accordance with paragraph 2 of this Article.

2. The competent authority of a Member State that has opted for the eradication of a listed disease as referred to in paragraph 1 shall, in the event that it suspects the disease in question in kept animals:

(a) conduct without delay an investigation to confirm or rule out the presence of that listed disease in accordance with Article 73(1) and (2);

(b) pending the results of the investigation provided for in point (a) and the carrying-out of disease control measures in accordance with Article 80(1), carry out the preliminary disease control measures provided for in Article 74(1) and (2).

3. The competent authority shall review and extend the preliminary disease control measures referred to in point (b) of paragraph 2, in accordance with Article 75.

4. Paragraphs 1, 2 and 3 of this Article shall also apply to Member States or zones which have obtained disease-free status, in order to maintain that status, in accordance with Article 36, or to compartments in accordance with Article 37(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing rules in respect of:

(a) the disease control measures provided for in paragraph 1;

(b) the investigation provided for in point (a) of paragraph 2;

(c) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (b) of paragraph 2.

Section 2

Disease confirmation in kept animals

Article 77

Official confirmation of disease by the competent authority

1. The competent authority shall base an official confirmation of a listed disease as referred to in point (b) or (c) of Article 9(1) on the following information:

(a) the results of the clinical and laboratory examinations provided for in Article 73(2);

(b) the epidemiological enquiry provided for in point (b) of Article 74(1), where relevant;

(c) other available epidemiological data.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1.

Article 78

Lifting preliminary disease control measures when the occurrence of a disease is ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 74(1), Article 75 and point (b) of Article 76(2) until the presence of the listed disease in question has been ruled out in accordance with Article 77(1) and any rules adopted pursuant to Article 77(2).

Section 3

Disease Control measures in the event of confirmation of disease in kept animals

Article 79

Disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall, in a Member State, zone or compartment, as relevant for that outbreak:

(a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 31(1) for that listed disease; or

(b) where the Member State or zone, or compartment, has obtained disease-free status in accordance with Article 36 or Article 37 respectively:

  (i) take one or more of the measures laid down in Articles 53 to 69 proportionate to the risk posed by the listed disease in question, and

  (ii) where necessary, initiate the compulsory eradication programme for that listed disease.

Article 80

Disease control measures to be taken by the competent authority for listed diseases referred to in Article 9(1)(c)

1. In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State that has opted for an eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), as relevant for that listed disease and that outbreak, the competent authority shall apply the disease control measures laid down in the optional eradication programme.

2. The competent authority may take disease control measures additional to those provided for in paragraph 1 which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the kept animals affected;

(c) economic and social impacts.

3. In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State, zone or compartment that has obtained disease-free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the kept animals affected;

(c) economic and social impacts.

Section 4

Wild animals

Article 81

Disease control measures for listed diseases as referred to in point (b) of Article 9(1) in wild animals

In the event that the competent authority of an affected Member State suspects or officially confirms the outbreak of a listed disease as referred to in point (b) of Article 9(1) in wild animals, it shall throughout its territory, or in the area or zone concerned, as relevant for that outbreak:

(a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 30(1) for that listed disease; or

(b) initiate a compulsory eradication programme, where the eradication programme provided for in Article 31(1) for that listed disease has not yet been applied due to the previous absence of that disease or freedom from it, and if measures for wild animals are necessary in order to control and prevent the spread of that disease.

Article 82

Disease control measures for listed diseases as referred to in point (c) of Article 9(1) in wild animals

1. In the event that a competent authority suspects or officially confirms a listed disease as referred to in point (c) of Article 9(1) in wild animals and the affected Member State has opted for the eradication of the disease in question, and provided that measures for wild animals are envisaged in the optional eradication programme provided for in Article 31(2) for that listed disease, the competent authority shall apply the disease control measures laid down in that optional eradication programme throughout the territory of the Member State, area or zone concerned, as relevant for that suspicion or official confirmation.

2. The competent authority may take disease control measures additional to those provided for in paragraph 1, which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the affected wild animals and the risk of transmission of diseases to animals and humans; and

(c) economic, social and environmental impacts.

3. In the event of an official confirmation of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in wild animals in a Member State, zone or compartment that has obtained disease-free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the affected wild animals and the risk of transmission of diseases to animals and humans;

(c) the relevance of the presence of the disease in wild animals in relation to the health status of kept animals; and

(d) economic, social and environmental impacts.

Section 5

Coordination by the Commission and temporary special disease control rules

Article 83

Coordination of measures by the Commission and temporary special rules concerning Sections 1 to 4

1. Member States shall inform the Commission of:

(a) disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 79 and 81 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (b) of Article 9(1);

(b) disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 80(1) and 82 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (c) of Article 9(1).

2. The Commission shall review the disease situation and the disease control measures taken by the competent authority in accordance with this Chapter and may, by means of implementing acts, lay down special rules for disease control measures for a limited period of time in respect of a listed disease as referred to in point (b) or point (c) of Article 9(1), under conditions appropriate to the epidemiological situation, where:

(a) those disease control measures taken by the competent authority in question are found not to be suited to the epidemiological situation;

(b) that listed disease appears to be spreading despite the disease control measures taken in accordance with this Chapter, where relevant.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. On duly justified imperative grounds of urgency relating to a listed disease as referred to in point (b) or point (c) of Article 9(1) representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

PART IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS

CHAPTER 1

Registration, approval, record-keeping and registers

Section 1

Registration of establishments and certain types of operators

Article 84

Obligation of operators to register establishments

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order for their establishments to be registered in accordance with Article 93, before they commence such activities:

(a) inform the competent authority of any such establishment under their responsibility;

(b) provide the competent authority with the following information:

(i) the name and address of the operator concerned;

(ii) the location of the establishment and a description of its facilities;

(iii) the categories, species and numbers or quantities of kept terrestrial animals or germinal products which they intend to keep on the establishment, and the capacity of the establishment;

(iv) the type of establishment; and

(v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of:

(a) any changes in the establishment in question concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

3. Establishments which are subject to approval in accordance with Article 94(1) shall not be required to provide the information referred to in paragraph 1 of this Article.

Article 85

Derogations from the obligation of operators to register establishments

By way of derogation from Article 84(1), Member States may exempt from the registration requirement certain categories of establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 86 (2). Member States shall inform the Commission of such exemptions.

Article 86

Implementing powers concerning the obligation of operators to register establishments

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of establishments as provided for in Article 84(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of establishments that may be exempted by the Member States from the registration requirement in accordance with Article 85, on the basis of:

(a) the species, categories and numbers of kept terrestrial animals and germinal products on the establishment in question and the capacity of that establishment;

(b) the type of establishment; and

(c) the movements of kept terrestrial animals or germinal products into and out of the establishment.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 87

Registration obligations of transporters of kept ungulates and delegated acts

1. Transporters of kept ungulates engaged in the transportation of those animals between Member States or between a Member State and a third country shall, in order to be registered in accordance with Article 93, before they commence such activities:

(a) inform the competent authority of their activity;

(b) provide that competent authority with information on:

(i) the name and address of the transporter concerned;

(ii) the categories, species and numbers of kept ungulates for which transportation is planned;

(iii) the type of transport;

(iv) the means of transport.

2. Transporters as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of the transport activity.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 supplementing the rules provided for in paragraph 1 of this Article, requiring other types of transporters whose transport activity poses specific and significant risks for certain species or categories of animals to provide adequate information for the purposes of registration of their activity.

Article 88

Derogations from the registration obligation of transporters of kept ungulates

By way of derogation from Article 87(1), Member States may exempt from the registration requirement certain categories of transporters whose transport activity poses an insignificant risk, as provided for in an implementing act adopted in accordance with Article 89(2). Member States shall inform the Commission of such exemptions.

Article 89

Implementing powers concerning the registration obligation of transporters

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by transporters for the purposes of registration of their activity, as provided for in Article 87(1) and (3), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of transporters that may be exempted by Member States from the registration requirement in accordance with Article 86, on the basis of:

(a) the distances over which they transport the ungulates in question; and

(b) the categories, species and number of ungulates which they transport.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 90

Registration obligation of operators conducting assembly operations independently of an establishment

1. Operators conducting assembly operations for kept ungulates and poultry, independently of an establishment, including those who buy and sell animals, shall, in order to be registered in accordance with Article 93, before they commence their activities, provide the competent authority with information on:

(a) the name and address of the operator concerned;

(b) the species and categories of kept ungulates and poultry covered by their activity.

2. Operators as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes concerning the matters referred to in paragraph 1;

(b) any cessation of activity by the operator concerned.

Article 91

Derogations from the registration obligation of operators conducting assembly operations

By way of derogation from Article 90(1), Member States may exempt from the registration requirement certain categories of operators conducting assembly operations posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 92(2). Member States shall inform the Commission of such exemptions.

Article 92

Implementing powers concerning the registration obligation of operators conducting assembly operations

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of registration as provided for in Article 90(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of operators that may be exempted by Member States from the registration requirement in accordance with Article 91, provided that the activity of such operators poses an insignificant risk and on the basis of species, the categories and numbers of kept terrestrial animals covered by their activity.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 93

Obligation of the competent authority concerning registration

A competent authority shall register:

(a) establishments in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 84(1);

(b) transporters in the register provided for in Article 101(1), where the transporter concerned has provided the information required in accordance with Article 87(1) and (3);

(c) operators conducting assembly operations independently of an establishment, in the register provided for in Article 101 (1), where the operator concerned has provided the information required in accordance with Article 90(1).

The competent authority shall assign each establishment, transporter and operator as referred to in points (a) to (c) of the first paragraph with a unique registration number.

Section 2

Approval of certain types of establishments

Article 94

Approval of certain establishments and delegated acts

1. Operators of the following types of establishments shall apply to the competent authority for approval in accordance with Article 96(1) and shall not commence their activities until their establishment has been approved in accordance with Article 97(1):

(a) establishments for assembly operations of ungulates and poultry from which those animals are moved to another Member State or which receive animals from another Member State;

(b) germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State;

(c) hatcheries from which hatching eggs or poultry are moved to another Member State;

(d) establishments keeping poultry from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State;

(e) any other type of establishment for kept terrestrial animals which poses a significant risk and is required to be approved in accordance with rules laid down in a delegated act adopted in accordance with point (b) of paragraph 3.

2. Operators shall cease activity at an establishment as referred to in paragraph 1 where:

(a) the competent authority withdraws or suspends its approval in accordance with Article 100(2); or

(b) in the event of conditional approval, granted in accordance with Article 99(3), the establishment in question fails to comply with the outstanding requirements referred to in Article 99(3) and does not obtain a final approval in accordance with Article 97(1).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the requirement for operators of the types of establishments referred to in points (a) to (d) of paragraph 1 to apply to the competent authority for approval, where those establishments pose an insignificant risk;

(b) the types of establishments which must be approved in accordance with point (e) of paragraph 1;

(c) special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1.

4. When adopting delegated acts as provided for in paragraph 3, the Commission shall base those acts on the following criteria:

(a) the species and categories of kept terrestrial animals or germinal products in an establishment;

(b) the number of species and number of kept terrestrial animals or germinal products kept in an establishment;

(c) the type of establishment and type of production; and

(d) the movements of kept terrestrial animals or germinal products into and out of those types of establishments.

Article 95

Approval of status of confined establishments

Operators of establishments wishing to obtain the status of a confined establishment shall:

(a) apply to the competent authority for approval in accordance with Article 96(1);

(b) move kept animals to or from their establishment in accordance with the requirements provided for in Article 137(1) and any delegated acts adopted in accordance with Article 137(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Articles 97 and 99.

Article 96

Obligation of operators to provide information with a view to obtaining approval and implementing acts

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 94 (1) and point (a) of Article 95, provide the competent authority with the following information:

(a) the name and address of the operator concerned;

(b) the location of the establishment concerned and a description of its facilities;

(c) the categories, species and number of kept terrestrial animals or germinal products relevant for the approval which are kept on the establishment;

(d) the type of establishment;

(e) other aspects of the establishment, related to its specificity, which are relevant in determining the risk, if any, posed by it.

2. Operators of establishments as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes in the establishments concerning the matters referred to in points (a), (b) or (c) of paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment in accordance with paragraph 1, and the time-limits by which the information referred to in paragraph 1 and in point (b) of paragraph 2 is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 97

Granting of, and conditions for, approval of establishments and delegated acts

1. Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(2);

(ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the number of kept terrestrial animals or the volume of germinal products concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have adequately trained personnel for the activity of the establishment concerned;

(e) have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;

(b) surveillance as referred to in point (a)(ii) of paragraph 1;

(c) facilities and equipment as referred to in point (b) of paragraph 1;

(d) responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;

(e) the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.

3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment;

(b) the species and categories of kept terrestrial animals relevant for the approval;

(c) the type of production concerned;

(d) typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 98

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 97(1), following an application made in accordance with Article 94(1) or point (a) of Article 95:

(a) for which of the types of establishments referred to in Article 94(1) and Article 95, and in the rules adopted pursuant to point (b) of Article 94(3), the approval applies;

(b) for which species and categories of kept terrestrial animals or germinal products of those species the approval applies.

Article 99

Procedures for the granting of approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 94(1), Article 95 or Article 96(1).

2. Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 94(1) or point (a) of Article 95, make an on–site visit.

3. Provided that the requirements referred to in Article 97 and paragraphs (1) and (2) of this Article are fulfilled, the competent authority shall grant the approval.

4. Where an establishment does not fulfil all requirements for approval as referred to in Article 97, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on–site visit as provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5. Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on–site visit to the establishment, carried out within three months of the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 97(1) and the rules adopted pursuant to Article 97(2).

Where the on–site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

Article 100

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep approvals of establishments granted in accordance with Articles 97 and 99 under review, at appropriate intervals based on the risk involved.

2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 97(1) and the rules adopted pursuant to Article 97(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

registers of the competent authority

Article 101

Registers to be kept by the competent authority

1. Each competent authority shall establish and keep up to date registers of:

(a) all establishments and operators registered with it pursuant to Article 93;

(b) all establishments approved by it in accordance with Articles 97 and 99.

It shall make the registers referred to in points (a) and (b) of the first subparagraph available to the Commission and to the competent authorities of other Member States in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

It shall make the register of approved establishments as referred to in point (b) of the first subparagraph available to the public in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

2. Where appropriate and relevant, a competent authority may combine the registration referred to in point (a) of the first subparagraph of paragraph 1 and the approvals referred to in point (b) of the first subparagraph of paragraph 1 with registration for other purposes.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the detailed information to be included in the registers provided for in points (a) and (b) of the first subparagraph of paragraph 1, and the availability to the public of the register provided for in point (b) of the first subparagraph of paragraph 1.

Section 4

Record-keeping

Article 102

Record-keeping obligations of operators of establishments other than germinal products establishments

1. Operators of establishments subject to the requirement of registration in accordance with Article 93, or approval in accordance with Article 97(1), shall keep and maintain records containing at least the following information:

(a) the species, categories, number and, where applicable, identification of kept terrestrial animals on their establishment;

(b) movements of kept terrestrial animals into and out of their establishment, stating as appropriate:

(i) their place of origin or destination;

(ii) the date of such movements;

(c) the documents required to accompany kept terrestrial animals arriving at or leaving their establishment in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);

(d) mortality of kept terrestrial animals on their establishment;

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:

(i) the species and categories of kept terrestrial animals in the establishment;

(ii) the type of production;

(iii) the type and size of the establishment;

(f) the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2. Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators of establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment concerned and shall:

(a) make them immediately available to the competent authority on request;

(b) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

4. By way of derogation from paragraph 3, operators may be exempted from the obligation to keep records of some or all of the matters provided for in paragraph 1 when the operator concerned:

(a) has access to the computerised database referred to in Article 109 for the relevant species and the database already contains the information to be included in the records; and

(b) has the up-to-date information entered directly into the computerised database.

Article 103

Record-keeping obligations of germinal product establishments

1. Operators of germinal product establishments shall keep and maintain records containing at least the following information:

(a) the breed, age, identification and health status of donor animals used for the production of germinal products;

(b) the time and place of collection, and the processing and storage, of germinal products collected, produced or processed;

(c) the identification of the germinal products together with details of their place of destination, if known;

(d) the documents required to accompany germinal products arriving at or leaving the establishment in question in accordance with Article 162 and Article 164(2) and any rules adopted pursuant to Article 162(3) and (4);

(e) where relevant, the results of clinical and laboratory tests;

(f) laboratory techniques used.

2. Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators of germinal product establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment and:

(a) make them immediately available to the competent authority on request;

(b) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 104

Record-keeping obligations of transporters

1. Transporters shall keep and maintain records containing at least the following information:

(a) the establishments visited by them;

(b) the categories, species and number of kept terrestrial animals transported by them;

(c) the cleaning, disinfection and disinfestation of the means of transport used;

(d) details of the documents accompanying the animals in question, including their document numbers.

The records shall be kept and maintained in paper or electronic form.

2. Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Transporters shall keep the records provided for in paragraphs 1 and 2:

(a) in such a manner that they can be made immediately available to the competent authority on request;

(b) for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 105

Record-keeping obligations of operators conducting assembly operations

1. Operators conducting assembly operations subject to the registration requirement laid down in Article 93 shall keep and maintain records containing at least the following information:

(a) the species, categories, numbers and identification of kept terrestrial animals under their responsibility;

(b) movements of kept terrestrial animals under their responsibility, stating as appropriate:

(i) their place of origin and destination;

(ii) the date of such movements;

(c) the documents required to accompany kept terrestrial animals moved under their responsibility in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);

(d) mortality of kept terrestrial animals under their responsibility; and

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for the species and categories of kept terrestrial animals under their responsibility.

The records shall be kept and maintained in paper or electronic form.

2. Operators whose activities present a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators shall:

(a) make the records referred to in paragraph 1 available to the competent authority on request;

(b) retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 106

Delegation of powers concerning record-keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

(a) information to be recorded in addition to that provided for in Articles 102(1), 103(1), 104(1) and 105(1);

(b) additional requirements for record-keeping in respect of germinal products collected, produced or processed in a germinal products establishment after that establishment ceased its activities.

2. When establishing the rules to be laid down in delegated acts as provided for in paragraph 1, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment or activity;

(b) the species and categories of kept terrestrial animals or germinal products in the establishment concerned, or transported to or from that establishment;

(c) the type of production on the establishment or the type of activity;

(d) the typical movement patterns and categories of the animals concerned;

(e) the number of kept terrestrial animals or volume of germinal products under the responsibility of the operator concerned.

Article 107

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

(a) establishments keeping, or operators handling or transporting, a small number of kept terrestrial animals or a small volume or number of germinal products;

(b) species or categories of kept terrestrial animals or germinal products.

When adopting those implementing acts, the Commission shall base those acts on the criteria laid down in Article 106(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Traceability requirements for kept terrestrial animals and germinal products

Section 1

kept terrestrial animals

Article 108

Member States' responsibility for establishing a system for the identification and registration of kept terrestrial animals

1. Member States shall have in place a system for the identification and registration of those species of kept terrestrial animals for which such a system is required by this Regulation and by any rules adopted pursuant to it. Such a system shall, when appropriate, provide for the recording of the movements of such animals.

2. When establishing the system referred to in paragraph 1, Member States shall take into account:

(a) the species or categories of kept terrestrial animals concerned;

(b) the risk posed by that species or category.

3. The system provided for in paragraph 1 shall include the following elements:

(a) the means to identify kept terrestrial animals individually or in groups;

(b) identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals as referred to in Article 110;

(c) up-to-date records in establishments as provided for in points (a) and (b) of Article 102(1);

(d) a computer database of kept terrestrial animals as provided for in Article 109(1).

4. The system provided for in paragraph 1 shall be designed in such a manner that it:

(a) ensures the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) facilitates the traceability of kept terrestrial animals and their movements within and between Member States and their entry into the Union;

(c) ensures the efficient interoperability, integration and compatibility of the elements of that system;

(d) ensures that the system, to the extent appropriate, is adapted to:

(i) the computerised information system for Union notification and reporting provided for in Article 22;

(ii) TRACES;

(e) ensures a coherent approach in respect of the different animal species covered by the system.

5. Member States may when appropriate:

(a) use the whole or part of the system provided for in paragraph 1 for purposes other than those referred to in points (a) and (b) of paragraph 4;

(b) integrate the identification documents, movement documents and other documents referred to in Article 110 with the animal health certificates or self-declaration document provided for in Article 143(1) and (2) and Article 151(1) and in any rules adopted pursuant to points (b) and (c) of Article 144(1) and Article 151(3) and (4);

(c) designate another authority or authorise another body or a natural person to ensure the practical application of the identification and registration system provided for in paragraph 1 of this Article, including the issuing of identification documents and the drawing-up of models as provided for in points (a), (b) and (c) of Article 110(1).

Article 109

Member States' obligation to establish and maintain a computer database of kept terrestrial animals

1. The Member States shall establish and maintain a computer database for the recording of at least:

(a) the following information related to kept animals of the bovine species:

(i) their individual identification as provided for in point (a) of Article 112;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(b) the following information related to kept animals of the ovine and caprine species:

(i) information on their identification as provided for in point (a) of Article 113(1) and the number of animals at the establishments keeping them;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(c) the following information related to kept animals of the porcine species:

(i) information on their identification as provided for in Article 115 and the number of animals at the establishments keeping them;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(d) the following information related to kept animals of the equine species:

(i) their unique code as provided for in Article 114;

(ii) the method of identification provided for in point (b) of Article 114(1) linking the animal concerned with the identification document referred to in point (iii) where relevant;

(iii) the relevant identification details from the identification document provided for in point (c) of Article 114(1), as determined in the rules adopted pursuant to Articles 118 and 120;

(iv) the establishments where those animals are habitually kept;

(e) information related to kept terrestrial animals of species other than those referred to in points (a), (b), (c) and (d) of this paragraph, when this is provided for in the rules adopted pursuant to paragraph 2.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the recording of information related to animal species other than those referred to in points (a), (b), (c) and (d) of paragraph 1 of this Article in the computer database provided for in that paragraph where necessary, due to the specific and significant risks posed by those species, in order to:

(a) ensure the efficient application of the disease prevention measures and control measures provided for in this Regulation;

(b) facilitate the traceability of kept terrestrial animals, their movements between Member States and their entry into the Union.

Article 110

Obligation of the competent authority in respect of identification documents, movement documents and other documents for the identification and tracing of kept terrestrial animals

1. Each competent authority shall:

(a) issue identification documents in respect of kept terrestrial animals where those documents are required by point (c) of Article 114(1) and point (b) of Article 117 and by rules adopted pursuant to Articles 118 and 120;

(b) issue identification documents in respect of bovine animals as required by point (b) of Article 112, unless Member States exchange electronic data with other Member States within the framework of an electronic exchange system from the date when the Commission recognises the full operability of that system;

(c) draw up models of movement documents and other documents for the identification and tracing of kept terrestrial animals, when required by point (b) of Article 113(1), point (b) of Article 115, point (b) of Article 117 and any rules adopted pursuant to Articles 118 and 120.

2. Point (b) of paragraph (1) is without prejudice to the right of Member States to adopt national rules on the issuing of passports for animals not intended for movement between Member States.

Article 111

Public availability of information on means of identification

Each competent authority shall inform the Commission of, and make publicly available, information on:

(a) contact points for the computer databases established by the Member States in accordance with Article 109(1);

(b) the authorities or bodies responsible for issuing identification documents, movement documents and other documents in accordance with Article 110, taking into account point (c) of Article 108(5);

(c) the means of identification that are to be used for each species and category of kept terrestrial animals in accordance with point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;

(d) the prescribed format for the issuing of the identification documents and other documents referred to in Article 110.

Article 112

Operators' obligations in respect of the identification of kept animals of the bovine species

Operators keeping animals of the bovine species shall:

(a) ensure that those kept animals are identified individually by a physical means of identification;

(b) ensure that those kept animals, when they are moved between Member States, are issued with an identification document from the competent authority or designated authority or authorised body of origin, unless the conditions laid down in point (b) of Article 110(1) are met;

(c) ensure that that identification document:

(i) is kept, correctly completed and updated by the operator concerned; and

(ii) accompanies those kept terrestrial animals at the time of movement, when such document is required by point (b);

(d) transmit the information on movements of those kept animals from and to the establishment concerned, and all births and deaths in that establishment, to the computer database provided for in Article 109(1).

Article 113

Operators' obligations in respect of the identification of kept animals of the ovine and caprine species

1. Operators keeping kept animals of the ovine and caprine species shall:

(a) ensure that those kept animals are each identified by a physical means of identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with Article 110 when they are moved from the establishment keeping those animals within the Member State concerned;

(c) transmit the information on movements of those kept animals from and to the establishment to the computer database provided for in Article 109(1).

2. Member States may exempt operators from the requirement to ensure that kept animals of the ovine and caprine species are accompanied by movement documents during movements within their territory, provided that:

(a) the information contained in the relevant movement document is included in the computer database provided for in Article 109(1);

(b) the system for the identification and registration of kept animals of the ovine and caprine species provides level of traceability equivalent to that provided by movement documents.

Article 114

Operators' obligations in respect of the identification and registration of kept animals of the equine species

1. Operators keeping kept animals of the equine species shall ensure that those animals are individually identified by:

(a) a unique code which is recorded in the computer database provided for in Article 109(1);

(b) a physical means of identification or other method which unequivocally links the kept animal with the identification document provided for in point (c) of this paragraph and issued by the competent authority in accordance with Article 110;

(c) a correctly completed single lifetime identification document.

2. Operators of kept animals of the equine species shall ensure that the information on those animals is transmitted to the computer database provided for in Article 109(1).

Article 115

Operators' obligations in respect of the identification and registration of kept animals of the porcine species

Operators keeping kept animals of the porcine species shall:

(a) ensure that those kept animals are each identified by a physical means of identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with point (b) of Article 110(1) when they are moved from the establishment keeping those animals within the Member State concerned;

(c) transmit the information relating to the establishment keeping those animals to the computer database provided for in Article 109(1).

Article 116

Derogations concerning movements of kept animals of the porcine species

By way of derogation from point (b) of Article 115, Member States may exempt operators from the requirement to ensure that kept animals of the porcine species are accompanied by correctly completed movement documents based on the model drawn up by the competent authority for movements within the Member State concerned, provided that:

(a) the information contained in such movement documents is included in the computer database established by that Member State in accordance with Article 109(1);

(b) the system for the identification and registration of kept terrestrial animals of the porcine species provides a level of traceability equivalent to that provided by such movement documents.

Article 117

Operators' obligation in respect of the identification of kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine and equine species

Operators shall ensure that kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species fulfil the following requirements, when required by the rules adopted pursuant to Articles 118 and 120:

(a) they are identified, either individually or in groups;

(b) they are accompanied by correctly completed and updated identification documents, movement documents or other documents for the identification and tracing of animals, as appropriate for the animal species concerned.

Article 118

Delegation of powers concerning identification and registration

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed requirements for the means and methods of identification of kept terrestrial animals provided for in point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115 and point (a) of Article 117, including their application and use;

(b) rules on the information to be included in:

(i) the computer databases provided for in points (a) to (d) of Article 109(1);

(ii) the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), and point (b) of Article 115;

(c) rules on the exchange of electronic data between computer databases of Member States as referred to in point (b) of Article 110(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed requirements for alternative means and methods of identification to those referred to in point (a) of paragraph 1 of this Article, as well as exemptions and special provisions for certain categories of animals or circumstances and conditions for such exemptions;

(b) specific provisions for the identification or movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117 that have to accompany animals when they are moved;

(c) detailed requirements for the identification and registration of kept terrestrial animals of species other than the bovine, ovine, caprine, porcine and equine species where necessary, taking into account the risks posed by the species concerned, in order to:

(i) ensure the efficient application of the disease prevention and control measures provided for in this Regulation;

(ii) facilitate the traceability of kept terrestrial animals, and their movements within and between Member States and their entry into the Union;

(d) rules on the information to be included in:

(i) the computer databases provided for in point (e) of Article 109(1);

(ii) the identification and movement documents provided for in point (b) of Article 117;

(e) rules on the identification and registration of kept terrestrial animals as referred to in Articles 112 to 117 after their entry into the Union.

3. When establishing the rules to be laid down in the delegated acts provided for in this Article, the Commission shall base those rules on the considerations provided for in Article 119(2).

Article 119

Delegation of powers concerning derogations from the traceability requirements

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations for operators from the identification and registration requirements provided for in Articles 112, 113, 114 and 115:

(a) in cases where one or more of the elements listed in Article 108(3) are not necessary in order to meet the requirements provided for in points (a) and (b) of Article 108(4); and

(b) when other traceability measures in place in the Member States guarantee that the level of traceability of the animals in question is not compromised,

as well as transitional measures required for the practical application of such derogations.

2. When establishing the rules to be laid down in the delegated acts provided for in paragraph 1, the Commission shall base those rules on the following considerations:

(a) the species and categories of kept terrestrial animals concerned;

(b) the risks involved for those kept terrestrial animals;

(c) the number of animals in the establishments concerned;

(d) the type of production in the establishments where those terrestrial animals are kept;

(e) movement patterns for the species and categories of kept terrestrial animals concerned;

(f) considerations concerning the protection and conservation of the species of kept terrestrial animals concerned;

(g) the performance of the other traceability elements of the system for the identification and registration of kept terrestrial animals referred to in Article 108(3).

Article 120

Implementing powers concerning the traceability of kept terrestrial animals

1. The Commission shall, by means of implementing acts, adopt rules:

(a) for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in points (a) to (d) of Article 109(1);

(b) on the technical conditions and modalities for the exchange of electronic data between computer databases of Member States and the recognition of full operability of the data exchange systems referred to in point (b) of Article 110(1).

2. The Commission may, by means of implementing acts, adopt rules:

(a) for the uniform application of the identification and registration system provided for in Article 108(1) for different species or categories of kept terrestrial animals, in order to ensure its efficient operation;

(b) for the uniform application of point (c) of Article 108(5) concerning the authorised bodies or natural persons referred to in Article 108(5) and the conditions for their designation;

(c) on the technical specifications and procedures, formats, design and operational rules for the means and methods of identification, including:

(i) the time periods for the application of the means and methods of identification;

(ii) the removal, modification or replacement of the means and methods of identification and the deadlines for such operations; and

(iii) the configuration of the identification code;

(d) on the technical specifications, formats and operational rules for the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117;

(e) for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in point (e) of Article 109(1);

(f) on the deadlines, obligations and procedures for the transmission of information by operators or other natural or legal persons and for the registration of kept terrestrial animals in the computer databases;

(g) on guidelines and procedures for electronic identification of animals, where relevant;

(h) on the practical application of exemptions from the identification and registration requirements provided for in the rules adopted pursuant to Article 119(1).

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 2

Germinal products

Article 121

Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species

1. Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, porcine and equine species in such a way that they can be clearly traced to:

(a) the donor animals;

(b) the date of collection; and

(c) the germinal product establishments where they were collected, produced, processed and stored.

2. The marking provided for in paragraph 1 shall be designed in such a way as to ensure:

(a) the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) the traceability of the germinal products, their movements within and between Member States and their entry into the Union.

Article 122

Delegation of powers concerning traceability requirements for germinal products

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species supplementing the rules laid down in Article 121;

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of species other than of the bovine, caprine, ovine, porcine and equine species, where necessary for:

(a) the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) the traceability of those germinal products, their movements within and between Member States and their entry into the Union.

3. When adopting the delegated acts provided for in paragraph 1, the Commission shall base those acts on the following matters:

(a) the species of kept terrestrial animals from which the germinal products originate;

(b) the health status of donor animals;

(c) the risk involved with such germinal products;

(d) the type of germinal products;

(e) the type of collection, production, processing or storage of germinal products;

(f) the movement patterns for the relevant species and categories of kept terrestrial animals and their germinal products;

(g) considerations concerning the protection and conservation of species of kept terrestrial animals;

(h) other elements that may contribute to the traceability of germinal products.

Article 123

Implementing powers concerning traceability requirements for germinal products

The Commission shall, by means of implementing acts, lay down rules concerning:

(a) technical requirements and specifications for marking as provided for in Article 121(1);

(b) operational requirements for the traceability provided for in delegated acts adopted pursuant to Article 122(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Movements within the Union of kept terrestrial animals

Section 1

General requirements for movements

Article 124

General requirements for movements of kept terrestrial animals

1. Operators shall take appropriate preventive measures to ensure that the movement of kept terrestrial animals does not jeopardise the health status at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move kept terrestrial animals from their establishments and receive such animals if the animals in question fulfil the following conditions:

(a) they come from establishments that have been:

(i) registered by the competent authority in accordance with Article 93; or

(ii) approved by the competent authority in accordance with Articles 97(1) and 98, when required by Article 94(1) or Article 95; or

(iii) granted a derogation from the registration requirement laid down in Article 84;

(b) they fulfil the identification and registration requirements laid down in Articles 112, 113, 114, 115 and 117 and the rules adopted pursuant to Articles 118 and 120.

Article 125

Disease prevention measures in relation to transport

1. Operators shall take the appropriate and necessary preventive measures to ensure that:

(a) the health status of kept terrestrial animals is not jeopardised during transport;

(b) transport operations of kept terrestrial animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans and animals;

(c) cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the conditions and requirements for cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and the use of biocidal products for those purposes;

(b) other appropriate biosecurity measures as provided for in point (c) of paragraph 1 of this Article.

Section 2

Movements between Member States

Article 126

General requirements for movements of kept terrestrial animals between Member States

1. Operators shall only move kept terrestrial animals to another Member State if the animals in question fulfil the following conditions:

(a) they show no disease symptoms;

(b) they come from a registered or approved establishment:

(i) where there are no abnormal mortalities with an undetermined cause;

(ii) which is not subject to movement restrictions affecting the species to be moved in accordance with the rules laid down in Article 55(1), point (a) of Article 61(1), Article 62, point (c) of Article 65(1), Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), 74(4), and 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations from movement restrictions have been granted in accordance with those rules;

(iii) which is not situated in a restricted zone in accordance with rules laid down in point (f)(ii) of Article 55(1), Articles 64 and 65, Article 74(1), Article 79 and any rules adopted pursuant to Article 67, Article 71(3), Article 74 (4) and Article 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;

(c) they have not been in contact with kept terrestrial animals which are subject to movement restrictions as referred to in point (b)(ii) and (iii) or kept terrestrial animals of a listed species of a lower health status, for an adequate period of time prior to the date of the intended movement to another Member State, thereby minimising the possibility of spreading disease, taking into account the following matters:

(i) the incubation period and routes of transmission of the listed diseases and emerging diseases in question;

(ii) the type of establishment concerned;

(iii) the species and category of kept terrestrial animals moved;

(iv) other epidemiological factors;

(d) they fulfil the relevant requirements provided for in Sections 3 to 8 (Articles 130 to 154).

2. Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in that other Member State unless they need to stop at a place of resting for animal welfare reasons.

Article 127

Obligations of operators at the place of destination

1. Operators of establishments and slaughterhouses receiving kept terrestrial animals from another Member State shall:

(a) check that:

(i) the means or methods of identification provided for in point (a) of Article 112, point (a) of Article 113(1), points (a) and (b) Article 114(1), point (a) of Article 115 and point (a) of Article 117 and the rules adopted pursuant to Articles 118 and 120 are in place;

(ii) the identification documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 117 and the rules adopted pursuant to Articles 118 and 120 are in place and are correctly completed;

(b) check that the animal health certificates provided for in Article 143 and in any rules adopted pursuant to points (b) and (c) of Article 144(1) or the self-declaration documents provided for in Article 151 and the rules adopted pursuant to Article 151(3) and (4) are in place;

(c) inform the competent authority of the place of destination, after checking the kept terrestrial animals received, of any irregularity with regard to:

(i) the kept terrestrial animals received;

(ii) the means or methods of identification referred to in point (a)(i);

(iii) the documents referred to in points (a)(ii) and (b).

2. In the event of any irregularity as referred to in point (c) of paragraph 1, the operator shall isolate the animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 128

Prohibition on movements of kept terrestrial animals for disease eradication purposes outside the territory of a Member State

Operators shall not move kept terrestrial animals intended to be slaughtered for disease eradication purposes as part of an eradication programme, as provided for in Article 31(1) or (2), to another Member State unless the Member State of destination and, where relevant, the Member State of passage authorise the movement in advance.

Article 129

General requirement applicable to operators in respect of movements of kept terrestrial animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that kept terrestrial animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 124, 125, 126 and 128.

Section 3

Specific requirements in respect of movements to other Member States of ungulates and poultry

Article 130

Movements of kept ungulates and poultry to other Member States

Operators shall only move kept ungulates and poultry from an establishment in one Member State to another Member State if the animals in question fulfil the following conditions as regards the listed diseases referred to in point (d) of Article 9(1):

(a) they show no clinical symptoms or signs of listed diseases as referred to in point (d) of Article 9(1) at the time of movement;

(b) they have been subject to a residency period appropriate to those listed diseases, taking into account the species and category of kept ungulates and poultry to be moved;

(c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be moved, no kept ungulates or poultry have been introduced into the establishment of origin when a requirement to that effect is laid down in the rules adopted in accordance with Article 131 or Article 135;

(d) they are presumed not to pose a significant risk of spreading of those listed diseases at the place of destination, based on:

(i) the health status concerning relevant diseases for species or categories of kept ungulates and poultry moved, taking into account the health status at the place of destination;

(ii) the results of laboratory or other examinations necessary in order to provide guarantees regarding the health status required for the movement in question;

(iii) the application of vaccination or other disease prevention or risk-mitigation measures aimed at limiting the spread of the relevant disease to the places of destination or passage.

Article 131

Delegation of powers in respect of movements of kept ungulates and poultry to other Member States

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) residency periods as referred to in point (b) of Article 130;

(b) the period of time necessary in order to limit the introduction of kept ungulates or poultry into establishments prior to movement as provided for in point (c) of Article 130;

(c) supplementary requirements to ensure that kept ungulates and poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in point (d) of Article 130);

(d) other necessary risk-mitigation measures supplementing the requirements laid down in Article 130.

2. When establishing the rules to be laid down in the delegated acts provided for in paragraph 1, the Commission shall base those rules on the following considerations:

(a) the listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept ungulates or poultry to be moved;

(b) the health status as regards listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and destination;

(c) the type of establishment concerned and the type of production at the places of origin and destination;

(d) the type of movement concerned;

(e) the species and categories of kept ungulates or poultry to be moved;

(f) the age of the kept ungulates or poultry to be moved;

(g) other epidemiological factors.

Article 132

Kept ungulates and poultry moved to another Member State and intended for slaughter

1. Operators of slaughterhouses receiving kept ungulates and poultry from another Member State shall slaughter those animals as soon as possible following their arrival and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to paragraph 2.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the time of slaughter provided for in paragraph 1 of this Article.

Section 4

Assembly operations in respect of kept ungulates and poultry

Article 133

Derogation in respect of assembly operations

1. By way of derogation from Article 126(2), operators may subject kept ungulates and poultry to a maximum of three assembly operations during a movement from a Member State of origin to another Member State.

2. The assembly operations provided for in paragraph 1 of this Article shall only take place in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(3) and (4).

However, the Member State of origin may allow an assembly operation on its territory to take place on a means of transport, collecting kept ungulates or poultry directly from their establishments of origin, provided that those animals are not unloaded again during that operation and before arriving:

(a) at the establishment or final place of destination; or

(b) for the subsequent assembly operation in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(4) and (5).

Article 134

Disease prevention requirements in respect of assembly operations

Operators conducting assembly operations shall ensure that:

(a) the kept ungulates and poultry assembled have the same health status; where they do not, the lower health status applies to all such animals assembled;

(b) the kept ungulates and poultry are assembled and moved to their final place of destination in another Member State as soon as possible after leaving their establishment of origin, and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to point (c) of Article 135;

(c) the necessary biosecurity measures are taken to ensure that the kept ungulates and poultry assembled:

(i) do not come into contact with kept ungulates or poultry having a lower health status;

(ii) do not pose a significant risk for the spread of the listed diseases referred to in point (d) of Article 9(1) to the kept ungulates or poultry at the place where the assembly operation takes place;

(d) the kept ungulates and poultry are identified where so required by this Regulation and are accompanied by the following documents:

(i) the identification and movement documents as provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117 and any rules adopted pursuant to Articles 118 and 120, unless derogations are provided for in accordance with Articles 113(2) and 119;

(ii) the animal health certificates as provided for in Article 143 and point (c) of Article 144(1), unless derogations are provided for in the rules adopted pursuant to point (a) of Article 144(1);

(iii) the self-declaration document as provided for in Article 151.

Article 135

Delegation of powers concerning assembly operations

The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) specific rules for assembly operations, where other risk-mitigation measures, in addition to those provided for in points (b) and (c) of Article 134, are in place;

(b) criteria under which Member States of origin may allow assembly operations to take place on means of transport, as provided for in the second subparagraph of Article 133(2);

(c) the timeframe between the time of departure of the kept ungulates or poultry from their establishment of origin and their departure from the assembly operation to their final destination in another Member State, as referred to in point (b) of Article 134;

(d) detailed rules as regards the biosecurity measures provided for in point (c) of Article 134.

Section 5

Movements to other Member States of kept terrestrial animals other than kept ungulates and poultry

Article 136

Movements of kept terrestrial animals other than kept ungulates and poultry to other Member States and delegated acts

1. Operators shall only move kept terrestrial animals other than kept ungulates or poultry from an establishment in one Member State to another Member State if the animals in question do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules to ensure that kept terrestrial animals other than kept ungulates or poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in paragraph 1 of this Article.

3. When establishing the detailed rules to be laid down in the delegated acts provided for in paragraph 2, the Commission shall base those rules on the following considerations:

(a) the listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept terrestrial animals to be moved;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and the place of destination;

(c) the types of establishment and the types of production at the place of origin and the place of destination;

(d) the types of movement in respect of the final use of animals at the place of destination;

(e) the species and categories of kept terrestrial animals to be moved;

(f) the age of the kept terrestrial animals to be moved;

(g) other epidemiological factors.

Section 6

Derogating from, and supplementing, risk-mitigation measures for movements of kept terrestrial animals

Article 137

Kept terrestrial animals intended for confined establishments and delegated acts

1. Operators shall only move kept terrestrial animals to a confined establishment if the animals in question fulfil the following conditions:

(a) they originate from another confined establishment;

(b) they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species or to categories of animals at the confined establishment of destination, except where the movement in question is authorised for scientific purposes.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article;

(b) specific rules for movements of kept terrestrial animals into confined establishments where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment and the surrounding establishments.

Article 138

Movements of kept terrestrial animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of kept terrestrial animals into the territory of the Member State of destination, for scientific purposes, where those movements do not comply with the requirements of Sections 1 to 5 (Articles 124 to 136), with the exception of Articles 124 and 125, point (b)(ii) of Article 126(1) and Article 127.

2. The competent authority of the place of destination shall only grant derogations as provided for in paragraph 1 under the following conditions:

(a) the competent authorities of the places of destination and origin:

(i) have agreed on the conditions for such movements;

(ii) ensure that the necessary risk-mitigation measures are in place so that those movements do not jeopardise the health status in places en route and in the place of destination with regard to the listed diseases referred to in point (d) of Article 9(1); and

(iii) have notified, where relevant, the competent authorities of the Member States of passage of the derogation granted and of the conditions under which it is granted; and

(b) those movements of those animals take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, the competent authorities of the Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

Article 139

Derogations concerning recreational use, sporting and cultural events, work near borders and grazing

1. The competent authority of the place of destination may grant derogations from the requirements of Sections 2 to 5 (Articles 126 to 136), with the exception of points (a),(b) and (c) of Article 126(1) and Articles 127 and 128, for intra-Union movements of kept terrestrial animals between Member States where such movements are for:

(a) recreational use near borders;

(b) exhibitions, and sporting, cultural and similar events, organised near borders;

(c) grazing of kept terrestrial animals in grazing areas shared between Member States; or

(d) work done by kept terrestrial animals near borders of Member States.

2. Derogations by the competent authority of the place of destination for movements of kept terrestrial animals for the purposes provided for in paragraph 1 shall be agreed on between the Member States of origin and destination and appropriate risk-mitigation measures shall be taken to ensure that such movements do not pose a significant risk.

3. The Member States referred to in paragraph 2 shall inform the Commission of the granting of derogations as provided for in paragraph 1.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by the competent authority of the place of destination, supplementing those provided for in paragraph 1 of this Article.

Article 140

Delegation of power concerning circuses, exhibitions, sporting events and recreational use, zoos, pet shops, animal shelters and wholesalers

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific requirements supplementing the rules laid down in Sections 2 to 5 (Articles 126 to 136) for movements of kept terrestrial animals for the following purposes:

(i) circuses, zoos, pet shops, animal shelters and wholesalers;

(ii) exhibitions and sporting, cultural and similar events;

(b) derogations from Sections 2 to 5 (Articles 126 to 136), with the exception of points (a), (b) and (c) of Article 126(1) and Articles 127 and 128, for movements of kept terrestrial animals as referred to in point (a) of this Article.

Article 141

Implementing power to adopt temporary rules for movements of specific species or categories of kept terrestrial animals

1. The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of kept terrestrial animals where:

(a) the movement requirements provided for in Article 130, Article 132(1), Articles 133 and 134, Articles 136(1), 137(1) and 138(1) and (2) and Article 139 and the rules adopted pursuant to Articles 131(1) and 132(2), Article 135, Articles 136(2), 137(2), 138(3) and 139(4) and Article 140 are not effectively mitigating the risks posed by the movement of such animals; or

(b) a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6 (Articles 124 to 142).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to diseases representing a risk of a highly significant impact and taking into account the matters referred to in Article 142, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 142

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 137(2), 138(3) and 139(4) and Articles 140 and 141, the Commission shall base those rules on the following matters:

(a) the risks involved with the movements referred to in those provisions;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;

(c) listed animal species for the listed diseases referred to in point (d) of Article 9(1);

(d) biosecurity measures in place at the places of origin, passage and destination

(e) any specific conditions in establishments under which the kept terrestrial animals are kept;

(f) specific movement patterns of the type of establishment and the species and category of kept terrestrial animals concerned;

(g) other epidemiological factors.

Section 7

animal health certification

Article 143

Obligation of operators to ensure that animals are accompanied by an animal health certificate

1. Operators shall only move the following species and categories of kept terrestrial animals to another Member State if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1):

(a) ungulates;

(b) poultry;

(c) kept terrestrial animals other than ungulates and poultry, intended for a confined establishment;

(d) kept terrestrial animals other than those referred to in points (a), (b) and (c) of this paragraph, when required in accordance with delegated acts adopted pursuant to point (c) of Article 144(1).

2. In cases where kept terrestrial animals are allowed to leave a restricted zone as provided for in point (f)(ii) of Article 55 (1), Article 56 and Article 64(1) and are subject to disease control measures as provided for in Articles 55(1), 65(1), 74(1) or Article 79(1) and (2) or rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 80, Article 83(3) or Article 259, and the animals in question are of species subject to those disease control measures, operators shall only move such kept terrestrial animals within a Member State or from one Member State to another Member State when the animals to be moved are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1).

The competent authority may decide that such a certificate does not have to be issued for movements of kept terrestrial animals within the Member State in question when that authority considers that an alternative system is in place ensuring that the consignment of such animals is traceable and that those animals fulfil the animal health requirements for such movement.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 of this Article accompanies the kept terrestrial animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 147.

Article 144

Delegation of powers concerning the obligation of operators to ensure that animals are accompanied by an animal health certificate

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the animal health certification requirements provided for in Article 143(1), for movements of kept terrestrial animals which do not pose a significant risk for the spread of a disease on account of:

(i) the species or categories of the kept terrestrial animals that are being moved and the listed diseases referred to in point (d) of Article 9(1) for which they are listed species;

(ii) the methods of keeping and the type of production of those species and categories of kept terrestrial animals;

(iii) the intended use of the kept terrestrial animals; or

(iv) the place of destination of the kept terrestrial animals; including those cases where their place of destination is in the same Member State as their place of origin but they pass through another Member State in order to reach their place of destination;

(b) special rules for animal health certification as provided for in Article 143(1) where specific risk-mitigation measures concerning surveillance or biosecurity are taken, taking into account the matters provided for in paragraph 2 of this Article, which ensure:

(i) the traceability of the kept terrestrial animals being moved;

(ii) that the kept terrestrial animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142);

(c) the requirement for animal health certification for movements of species and categories of kept terrestrial animals other than those referred to in points (a), (b) and (c) of Article 143(1) in cases where animal health certification is imperative in order to ensure that the movement in question complies with the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

2. When establishing the special rules provided for in point (b) of paragraph 1, the Commission shall take the following matters into account:

(a) the assessment by the competent authority of the biosecurity put in place by operators as provided for in point (b) of Article 10(1) and any rules adopted pursuant Article 10(6);

(b) the ability of the competent authority, in so far as may be necessary and appropriate, to take measures and to engage in activities required by this Regulation as provided for in Article 13(1);

(c) the level of knowledge of animal health as provided for in Article 11 and the encouragement thereof provided for in Article 13(2);

(d) the carrying-out of the animal health visits provided for in Article 25 or other relevant surveillance or official controls in place;

(e) the performance by the competent authority of its obligations under the Union notification and reporting system provided for in Articles 19 to 22 and in the rules adopted pursuant to Articles 20(3) and Article 23;

(f) the application of surveillance as provided for in Article 26 and surveillance programmes as provided for in Article 28 and in any rules adopted pursuant to Articles 29 and 30.

3. The Commission shall take the matters referred to in point (a)(i) to (iv) of paragraph 1 into account when establishing the requirements for animal health certification provided for in point (c) of paragraph (1).

Article 145

Contents of animal health certificates

1. The animal health certificate referred to in Article 143 shall contain the following information:

(a) the establishment or place of origin, the establishment or place of destination and, where relevant, establishments for assembly operations or for rests, of the kept terrestrial animals concerned;

(b) the means of transport and the transporter;

(c) a description of the kept terrestrial animals;

(d) the number of kept terrestrial animals;

(e) the identification and registration of kept terrestrial animals, where required by Articles 112, 113, 114, 115 and 117 and by any rules adopted pursuant to Articles 118 and 120, unless derogations are provided for in accordance with Article 119; and

(f) the information needed to demonstrate that the kept terrestrial animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 6 (Articles 124 to 142).

2. The animal health certificate may include other information required under other Union legislation.

Article 146

Delegation of powers and implementing acts concerning the content of animal health certificates

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of animal health certificates as provided for in Article 145(1) for different species and categories of kept terrestrial animals and for specific types of movements as provided for in the rules adopted pursuant to Article 147;

(b) additional information to be contained in the animal health certificate provided for in Article 145(1).

2. The Commission may, by means of implementing acts, lay down rules for model forms of animal health certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 147

Delegation of powers concerning specific types of movements of kept terrestrial animals

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures derogating from, or supplementing, the obligation of operators to ensure that animals are accompanied by an animal health certificate as provided for in Article 143 and in the rules adopted pursuant to Article 144, for the following types of movements of kept terrestrial animals:

(a) movements of kept ungulates and poultry passing through the assembly operations provided for in Article 133 prior to reaching their final place of destination;

(b) movements of kept terrestrial animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:

(i) their intended journey was unexpectedly interrupted for animal welfare reasons;

(ii) unforeseen accidents or events during the journey;

(iii) they were rejected at the place of destination in a Member State or at the external border of the Union;

(iv) they were rejected at a place of assembly or resting;

(v) they were rejected in a third country or territory;

(c) movements of kept terrestrial animals intended for exhibitions, and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 148

Operators' obligations to cooperate with the competent authority for the purposes of animal health certification

Operators shall:

(a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Article 143(1) and (2) and in any rules adopted pursuant to Article 146(1) or Article 147, in advance of the intended movement;

(b) where necessary, ensure that the kept terrestrial animals in question are subjected to documentary, identity and physical checks as provided for in Article 149(3).

Article 149

Responsibility of the competent authority for animal health certification

1. The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of kept terrestrial animals, where required by Article 143 or by delegated acts adopted pursuant to Article 144(1), provided that the following movement requirements have been complied with:

(a) those provided for in Article 124, Article 125(1), Articles 126, 128, 129, 130, 133 and 134, Articles 136(1) and 137 (1), Article 138 and Article 139;

(b) those provided for in delegated acts adopted pursuant to Articles 125(2) and 131(1), Article 135, Articles 136(2), 137 (2), 138(4) and 139(4) and Article 140;

(c) those provided for in implementing acts adopted pursuant to Article 141.

2. Animal health certificates shall:

(a) be verified, stamped and signed by an official veterinarian;

(b) remain valid for the period of time provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the kept terrestrial animals covered by it continue to fulfil the animal health guarantees contained in it.

3. Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4, that the kept terrestrial animals covered by it fulfil the requirements of this Chapter.

4. The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:

(a) the types of documentary, identity and physical checks and examinations in relation to different species and categories of kept terrestrial animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;

(b) the timeframes for the carrying-out of such documentary, identity and physical checks and examinations and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of kept terrestrial animals;

(c) the duration of the validity of animal health certificates.

Article 150

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of TRACES, may replace accompanying animal health certificates as provided for in Article 149(1) where:

(a) such electronic animal health certificates contain all the information that the model form of animal health certificate is required to contain in accordance with Article 145 and any rules adopted pursuant to Article 146;

(b) the traceability of the kept terrestrial animals in question and the link between those animals and the electronic animal health certificate is ensured;

(c) the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 151

Self-declaration by operators for movements to other Member States

1. Operators at the place of origin shall issue a self-declaration document for movements of kept terrestrial animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such animals, where they are not required to be accompanied by an animal health certificate as provided for in Article 143(1) and (2).

2. The self-declaration document provided for in paragraph 1 shall contain the following information concerning the kept terrestrial animals in question:

(a) their place of origin, their place of destination and, when relevant, any places of assembly or rest;

(b) the means of transport and the transporter;

(c) a description of the kept terrestrial animals, their species, category and quantity;

(d) identification and registration where required in accordance with Articles 112, 113, 114 and 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;

(e) the information needed to demonstrate that the kept terrestrial animals fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of animals;

(b) information to be contained in the self-declaration document in addition to that provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for the model forms of the self-declaration document provided for in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 8

Notification of movements of kept terrestrial animals to other Member States

Article 152

Obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States

Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of kept terrestrial animals from that Member State to another Member State where:

(a) the animals must be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 149 and 150 and any rules adopted pursuant to Article 149(4);

(b) the animals must be accompanied by an animal health certificate for kept terrestrial animals where they are being moved from a restricted zone and are subject to disease control measures as referred to in Article 143(2);

(c) the animals are granted a derogation from the animal health certification requirement provided for in point (a) of Article 144(1) or are subject to special rules as provided for in point (b) of Article 144(1);

(d) notification is required in accordance with delegated acts adopted pursuant to Article 154(1).

For the purposes of the first paragraph of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movements of the kept terrestrial animals to the competent authority of the Member State of destination in accordance with Article 153(1).

Article 153

Responsibility of the competent authority to notify movements to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of kept terrestrial animals as referred to in Article 152.

2. The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through TRACES.

3. Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4. By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the operator concerned to notify, partially or completely, movements of kept terrestrial animals through TRACES to the competent authority of the Member State of destination.

Article 154

Delegation of power and implementing acts for the notification of movements by operators and by the competent authority

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators, in accordance with Article 152, of movements between Member States of kept terrestrial animals of species or categories other than those referred to in points (a) and (b) of that Article, where traceability of such movements of those species or categories is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 to 6 (Articles 124 to 142);

(b) the information needed in order to notify movements of kept terrestrial animals as provided for in Articles 152 and 153;

(c) the emergency procedures for the notification of movements of kept terrestrial animals in the event of power cuts and other disturbances of TRACES;

(d) the requirements for the designation of regions by Member States for the management of notifications of movements, as provided for in Article 153(3).

2. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the details concerning notifications of movements of kept terrestrial animals by:

(i) operators to the competent authority of their Member State of origin in accordance with Article 152;

(ii) the competent authority of the Member State of origin to the Member State of destination in accordance with Article 153;

(b) the deadlines for:

(i) the provision by the operator of the necessary information referred to in Article 152 to the competent authority of the Member State of origin;

(ii) the notification of movements of kept terrestrial animals by the competent authority of the Member State of origin as referred to in Article 153(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 4

Movements of wild terrestrial animals

Article 155

Wild terrestrial animals

1. Operators shall only move wild animals from a habitat in one Member State to a habitat or an establishment in another Member State where:

(a) the movements of the wild animals in question from their habitat are carried out in such a way that they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) or emerging diseases en route or at the place of destination;

(b) the wild animals do not come from a habitat in a restricted zone which is subject to movement restrictions concerning the animal species to which they belong due to the occurrence of a listed disease as referred to in point (d) of Article 9(1) or of an emerging disease, as provided for in Article 70(2) and in any rules adopted pursuant to point (b) of Article 70 (3), Article 71(3) and Article 83(3) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;

(c) the wild animals are accompanied by an animal health certificate or other documents where animal health certification is necessary in order to ensure compliance with the animal health requirements for movements provided for in points (a) and (b) of this paragraph and the rules adopted pursuant to points (c) and (d) of Article 156(1);

(d) the movements are notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination, where animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1); and

(e) the competent authority of the Member State of origin and the competent authority of the Member State of destination have agreed to such movement.

2. When animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1), the requirements provided for in Articles 145 and 148, Article 149(1), (2) and (3) and Article 150, and in the rules adopted pursuant to Articles 146 and 147 and Article 149(4) shall apply to movements of wild terrestrial animals.

3. When notification of movements is required in accordance with point (d) of paragraph 1 of this Article, the requirements provided for in Articles 152 and 153 and in the delegated acts adopted pursuant to Article 154(1) shall apply to movements of wild terrestrial animals.

Article 156

Empowerments concerning the movement of wild terrestrial animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the animal health requirements for movements of wild terrestrial animals provided for in points (a) and (b) of Article 155(1);

(b) the animal health requirements for the introduction of wild terrestrial animals when they are moved from the wild into establishments;

(c) the types of movements of wild terrestrial animals for which, or the situations in which, an animal health certificate or other document is required to accompany such movements, and the requirements concerning the contents of such certificates or other documents;

(d) the notification by the competent authority of the Member State of origin to the competent authority of the Member State of destination in the case of movements of wild terrestrial animals between Member States, and the information to be included in such notification.

2. The Commission may, by means of implementing acts, lay down rules specifying the requirements provided for in Article 155 and in the delegated acts adopted pursuant to paragraph 1 of this Article, concerning:

(a) model forms of animal health certificates and other documents which are required to accompany movements of wild terrestrial animals, when provided for in delegated acts adopted pursuant to point (c) of paragraph 1 of this Article;

(b) the details of the notification to be given by the competent authority of the Member State of origin and the deadlines for such notifications, when provided for in rules adopted pursuant to point (d) of paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 5

Movements within the Union of germinal products

Section 1

General requirements

Article 157

General requirements for movements of germinal products

1. Operators shall take appropriate preventive measures to ensure that movements of germinal products do not jeopardise the health status of kept terrestrial animals at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move germinal products from their establishments, and receive such germinal products, if the products in question fulfil the following conditions:

(a) they come from establishments that have been:

(i) entered in the register of establishments by the competent authority in accordance with point (a) of Article 93 and no derogation has been granted by the Member State of origin in accordance with Article 85;

(ii) approved by the competent authority in accordance with Article 97(1), when such approval is required by Article 94(1) or Article 95;

(b) they fulfil the traceability requirements of Article 121(1) and any rules adopted pursuant to Article 122(1).

3. Operators shall comply with the requirements of Article 125 for the transport of germinal products of kept terrestrial animals.

4. Operators shall not move germinal products from an establishment in one Member State to an establishment in another Member State unless the competent authority of the Member State of destination gives its express authorisation for such movement, where those germinal products are required to be destroyed for disease eradication purposes as part of an eradication programme as provided for in Article 31(1) or (2).

Article 158

Obligations for operators at the place of destination

1. Operators of establishments at the place of destination receiving germinal products from an establishment in another Member State shall:

(a) check for the presence of:

(i) marks in accordance with Article 121 and with rules adopted pursuant to Article 122;

(ii) animal health certificates as provided for in Article 161;

(b) after checking the germinal products received, inform the competent authority of the place of destination of any irregularity with regard to;

(i) the germinal products received;

(ii) the marks referred to in point (a)(i);

(iii) the animal health certificates referred to in point (a)(ii).

2. In the event of an irregularity as referred to in point (b) of paragraph 1, the operator concerned shall keep the germinal products stored separately until the competent authority has taken a decision regarding them.

Section 2

Movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 159

Operators' obligations in respect of movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those germinal products fulfil the following conditions:

(a) they are collected, produced, processed and stored in germinal product establishments approved for that purpose in accordance with Article 97(1) and Article 99;

(b) they have been collected from donor animals which fulfil the necessary animal health requirements, in order to ensure that the germinal products do not spread listed diseases;

(c) they have been collected, produced, processed, stored and transported in such a way as to ensure that they do not spread listed diseases as referred to in point (d) of Article 9(1).

2. Operators shall not move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry from a germinal product establishment which is subject to movement restrictions affecting the listed species in question in accordance with:

(a) points (a), (c) and (e) of Article 55(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1) and Articles 74(1) and 79(1) and (2);

(b) rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 71(3), 74(4) and 83(2); and

(c) emergency measures as provided for in Articles 257 and 258 and rules adopted pursuant to Article 259, unless derogations have been provided for in rules adopted pursuant to Article 258.

The restrictions provided for in this paragraph shall not apply to cases where the germinal products were collected before the outbreak in question occurred and those products have been stored separately from other germinal products.

Article 160

Delegation of power in respect of movements to other Member States of germinal products of kept animals of the bovine, porcine, ovine, caprine and equine species and germinal products of poultry

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying:

(a) rules for the collection, production, processing and storage of germinal products of those kept animals in approved establishments as referred to in point (a) of Article 159(1);

(b) animal health requirements as provided for in point (b) of Article 159(1) for kept donor animals from which germinal products were collected, and concerning isolation or quarantine for those animals;

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

(d) animal health requirements for the collection, production, processing, storage or other procedures and transport provided for in point (c) of Article 159(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying derogations for operators from the rules provided for in Article 159, taking into account the risks attached to such germinal products and any risk-mitigation measures in place.

Section 3

Animal health certification and notification of movements

Article 161

Operators' obligations concerning animal health certification for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry and delegated acts

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State where such products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3;

2. In cases where germinal products of kept animals are allowed to leave a restricted zone subject to:

(a) disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56, 64 and 65, Article 74(1) and Article 79, and the rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 83(2), or

(b) emergency measures as provided for in Articles 257 and 258 and the rules adopted pursuant to Article 259,

and those germinal products are of species subject to those disease control or emergency measures, operators shall only move such germinal products within a Member State or from one Member State to another Member State when they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1), unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this subparagraph.

The competent authority may decide that such a certificate does not have to be issued for movements of germinal products within the Member State concerned when that authority considers that an alternative system is in place ensuring that the consignment of such germinal products is traceable and that those germinal products comply with the animal health requirements for such movement.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the germinal products from their place of origin to their place of destination.

4. The competent authority shall, upon request by an operator, issue an animal health certificate for the movements of germinal products referred to in paragraph 1, provided that the relevant requirements referred to in Chapter 5 of Title I of Part IV have been complied with.

5. Articles 148, 149 and 150, and the rules adopted pursuant to Articles 146 and 147 and Article 149(4), shall apply to the animal health certification of the germinal products referred to in paragraph 1 of this Article. Article 151(1) and the rules adopted pursuant to Article 151(3) shall apply to the self-declaration of movements of germinal products.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article as regards movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry which do not pose a significant risk for the spread of listed diseases due to:

(a) the nature of the germinal products concerned or the species of animal that those products come from;

(b) the methods of production and processing at the germinal product establishment;

(c) the intended use of the germinal products;

(d) alternative risk-mitigation measures in place for the type and category of germinal products and the germinal product establishment;

(e) the place of destination of the germinal products, when the place of destination is in the same Member State as the place of origin but the germinal products pass through another Member State in order to reach the place of destination.

Article 162

Content of animal health certificates

1. The animal health certificate for the germinal products provided for in Article 161 shall contain at least the following information:

(a) the germinal product establishment of origin and the establishment or place of destination;

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

(c) the volume or number of the germinal products;

(d) the marking of the germinal products, when required by Articles 121(1) and by any rules adopted pursuant to Article 122(1);

(e) the information needed to demonstrate that the germinal products of the consignment fulfil the movement requirements for the relevant species as provided for in Articles 157 and 159 and in any rules adopted pursuant to Article 160.

2. The animal health certificate for germinal products as provided for in Article 161 may include other information required under other Union legislation.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate pursuant to paragraph 1 of this Article;

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health certification for different types of germinal products and of different animal species.

5. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for germinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 163

Notification of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States

1. Operators shall:

(a) inform the competent authority in their Member State of origin in advance of the intended movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State when:

  (i) the germinal products in question are required to be accompanied by an animal health certificate in accordance with Article 161(1) or (2);

  (ii) notification of movement is required in accordance with delegated acts adopted pursuant to point (a) of paragraph 5 of this Article for germinal products, taking into account paragraph 3 of this Article;

(b) provide all the necessary information to enable the competent authority of the Member State of origin to notify the movement of the germinal products to the competent authority of the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall notify, prior to the movement in question and whenever possible through TRACES, the competent authority of the Member State of destination of any movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry in accordance with the rules adopted pursuant to paragraphs 5 and 6.

3. Member States shall use, for the management of notifications, regions designated in accordance with Article 153(3).

4. Article 153(4) shall apply to the notification of germinal products by operators.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators of movements of germinal products between Member States in accordance with point (a)(ii) of paragraph 1 of this Article, where traceability of such movements is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 and 2 (Articles 157 to 160);

(b) information necessary to notify movements of germinal products as provided for in paragraph 1 of this Article;

(c) the emergency procedures for the notification of movements of germinal products in the event of power cuts and other disturbances of TRACES.

6. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the provision of information on movements of germinal products by operators to the competent authority of their Member State of origin in accordance with paragraph 1;

(b) notification by the competent authority of the Member State of origin to the Member State of destination of movements of germinal products in accordance with paragraph 2;

(c) the deadlines for:

(i) the provision of the information referred to in paragraph 1 by the operator to the competent authority of the Member State of origin;

(ii) notification by the competent authority of the Member State of origin of movements of germinal products as referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 4

Movements to other Member States of germinal products of kept terrestrial animals of species other than bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 164

Germinal products of kept terrestrial animals other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

1. Operators shall only move germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those products do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species at the place of destination, taking into account the health status at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health requirements, animal health certification and notification requirements for movements of germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry, taking into account the following matters:

(a) listed diseases as referred to in point (d) of Article 9(1) for the listed species concerned;

(b) the species of animals from which the germinal products have been collected and the type of germinal product;

(c) the health status at the places of origin and of destination;

(d) the type of collection, production, processing and storage;

(e) other epidemiological factors.

3. Where animal health certification and notification of movements of germinal products are required in accordance with paragraph 2:

(a) the rules provided for in Articles 161(1) to (5), 162 (1) and (2) and the rules adopted pursuant to Articles 161(6) and 162(3) to (5) shall apply for such certification;

(b) the rules provided for in Article 163(1), (2) and (4) and the rules adopted pursuant to Article 163(5) shall apply for notification of movements.

Section 5

Derogations

Article 165

Germinal products intended for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of germinal products into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Articles 159 to 164.

2. The competent authority shall only grant derogations provided for in paragraph 1 under the following conditions:

(a) the competent authorities of the places of destination and origin:

(i) have agreed on the conditions for the movements proposed;

(ii) ensure that necessary risk-mitigation measures are in place so that those movements do not jeopardise the health status en route and in the place of destination with regard to the listed diseases referred to in point (d) of Article 9 (1);

(iii) have notified, where relevant, the competent authorities of Member States of passage of the derogation granted and of the conditions under which it is granted;

(b) those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, of the competent authorities of any Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

CHAPTER 6

Production, processing and distribution within the Union of products of animal origin

Article 166

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin in the Union, such products do not cause the spread of:

(a) listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing or destination;

(b) emerging diseases.

2. Operators shall ensure that products of animal origin do not come from establishments or food businesses, or are not obtained from animals which come from establishments, that are subject to:

(a) emergency measures as provided for in Articles 257 and 258 or any rules adopted pursuant to Article 259, unless derogations from the requirement provided for in paragraph 1 of this Article are provided for in rules adopted pursuant to Article 259;

(b) movement restrictions applicable to kept terrestrial animals and products of animal origin, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Article 70(3), Article 71(3), Article 74(4), Article 76(5) and Article 83(2), unless derogations from those movement restrictions have been provided for in those rules.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to:

(a) in paragraph 1 of this Article on preventive measures, including risk-mitigation measures, and

(b) in paragraph 2 of this Article in relation to restrictions on movements of products of animal origin.

4. When adopting the delegated acts referred to in paragraph 3, the Commission shall base those acts on:

(a) the listed disease in question, as referred to in point (d) of Article 9(1), and species concerned by it and

(b) the risks involved.

Article 167

Operators' obligations with regard to animal health certificates and delegated acts

1. Operators shall only move the following products of animal origin within a Member State or to another Member State where the products in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

(a) products of animal origin that:

(i) are allowed to be moved from a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259;

(ii) originate from animals of species subject to those emergency measures;

(b) products of animal origin that:

(i) are allowed to be moved from a restricted zone subject to disease control measures in accordance with Article 32(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), Article 64, point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1) and Article 79(1) and any rules adopted pursuant to Article 55 (2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2),

(ii) originate from animals of species subject to those disease control measures.

The competent authority may decide that such a certificate does not have to be issued for movements of products of animal origin within the Member State concerned when that authority considers that an alternative system is in place ensuring that consignments of such products are traceable and that those products fulfil the animal health requirements for such movements.

2. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

3. The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

4. Articles 148, 149 and 150 and the rules adopted pursuant to Articles 146 and 147 and Article 149(4) shall apply to the animal health certification of movements of products of animal origin as referred to in paragraph 1 of this Article.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article and the conditions for such derogations, in respect of movements of products of animal origin which do not pose a significant risk for the spread of diseases due to:

(a) the types of products of animal origin concerned;

(b) the risk-mitigation measures applied to the products of animal origin, thereby reducing the risks of the spread of diseases;

(c) the intended use of the products of animal origin;

(d) the place of destination of the products of animal origin.

Article 168

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin provided for in Article 167(1) shall contain at least the following information:

(a) the establishment or place of origin and the establishment or place of destination;

(b) a description of the products of animal origin concerned;

(c) the quantity of the products of animal origin;

(d) the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to point (a) of Article 67;

(e) the information needed to demonstrate that the products of animal origin fulfil the movement restriction requirements provided for in Article 166(2) and in any rules adopted pursuant to Article 166(3).

2. The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate provided for in paragraph 1 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for products of animal origin referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 169

Notification of movements of products of animal origin to other Member States

1. Operators shall:

(a) inform the competent authority in their Member State of origin in advance of intended movements of products of animal origin when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 167(1);

(b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the competent authority of the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall, prior to the movement and whenever possible through TRACES, notify the competent authority of the Member State of destination of movements of products of animal origin in accordance with the rules adopted pursuant to paragraphs 5 and 6.

3. Member States shall use, for the management of notifications, regions designated in accordance with Article 153(3).

4. Article 153(4) shall apply to the notification of movements of products of animal origin by operators.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the information needed for the notification of movements of products of animal origin as provided for in paragraph 1 of this Article;

(b) the emergency procedures for the notification of movements of products of animal origin in the event of power cuts and other disturbances of TRACES.

6. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the information to be provided by operators to the competent authority of their Member State of origin concerning movements of products of animal origin in accordance with paragraph 1;

(b) notification of movements of products of animal origin to be given by the competent authority of the Member State of origin to the Member State of destination in accordance with paragraph 2;

(c) the deadlines for:

(i) provision of the information referred to in paragraph 1 by the operator concerned to the competent authority of the Member State of origin;

(ii) notification of movements of products of animal origin to be given by the competent authority of the Member State of origin as referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 7

Scope of national measures

Article 170

National measures concerning disease control and movements of animals and germinal products

1. Member States shall remain free to take national measures to control listed diseases as referred to in points (d) and (e) of Article 9(1) with regard to movements of terrestrial animals and germinal products thereof within their own territories.

2. Those national measures shall:

(a) take account of the rules on movements of animals and germinal products laid down in Chapters 3 (Articles 124 to 154), 4 (Articles 155 and 156) and 5 (Articles 157 to 165), and shall not be inconsistent with those rules;

(b) not hinder the movement of animals and products between Member States;

(c) not exceed the limits of what is appropriate and necessary in order to prevent the introduction and spread of the listed diseases referred to in points (d) and (e) of Article 9(1).

Article 171

National measures designed to limit the impact of diseases other than listed diseases

Where a disease other than a listed disease constitutes a significant risk for the health of kept terrestrial animals in a Member State, the Member State concerned may take national measures to control that disease and may restrict movements of kept terrestrial animals and germinal products, provided those measures do not:

(a) hinder the movement of animals and products between Member States;

(b) exceed the limits of what is appropriate and necessary in order to control that disease.

TITLE II

AQUATIC ANIMALS AND PRODUCTS OF ANIMAL ORIGIN FROM AQUATIC ANIMALS

CHAPTER 1

Registration, approval, record-keeping and registers

Section 1

Registration of aquaculture establishments

Article 172

Obligation of operators to register aquaculture establishments

1. Operators of aquaculture establishments shall, in order for their establishments to be registered in accordance with Article 173, before they commence such activities:

(a) inform the competent authority of any aquaculture establishment under their responsibility;

(b) provide the competent authority with the following information:

(i) the name and address of the operator concerned;

(ii) the location of the establishment and a description of its facilities;

(iii) the species, categories and quantities (numbers, volume or weight) of aquaculture animals which they intend to keep on the aquaculture establishment and the capacity of the aquaculture establishment;

(iv) the type of aquaculture establishment; and

(v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2. Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority in advance of:

(a) any significant changes in the aquaculture establishment in question concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of activity by the operator or aquaculture establishment concerned.

3. Aquaculture establishments which are subject to approval in accordance with Article 176(1) and Article 177 shall not be required to provide the information referred to in paragraph 1 of this Article.

4. An operator may apply for registration as provided for in paragraph 1 to cover a group of aquaculture establishments, provided that they fulfil either of the following conditions:

(a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;

(b) they are under the responsibility of the same operator and operate under a common biosecurity system, and the aquaculture animals of the establishments concerned form part of a single epidemiological unit.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and in point (b) of Article 173, and the rules adopted pursuant to Article 175 which are applicable to a single aquaculture establishment, shall be applicable to the group of aquaculture establishments as a whole.

Article 173

Obligations of the competent authority concerning the registration of aquaculture establishments

A competent authority shall register:

(a) aquaculture establishments in the register of aquaculture establishments provided for in Article 185(1), where the operator concerned has provided the information required in accordance with Article 172(1);

(b) groups of aquaculture establishment in that register, provided that the criteria laid down in Article 172(4) are complied with.

The competent authority shall assign each establishment or group of establishments as referred to in this Article with a unique registration number.

Article 174

Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 172(1), Member States may exempt from the registration requirement certain aquaculture establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 175.

Article 175

Implementing powers concerning derogations from the obligation to register aquaculture establishments

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of aquaculture establishments as provided for in Article 172(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of aquaculture establishments that may be exempted by Member States from the registration requirement in accordance with Article 174, based on:

(a) the species, categories and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment in question and the capacity of that establishment;

(b) the movements of aquaculture animals into and out of the aquaculture establishment.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 2

Approval of certain types of aquaculture establishments

Article 176

Approval of certain aquaculture establishments and delegated acts

1. Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

(a) aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;

(b) other aquaculture establishments which pose a significant risk due to:

(i) the species, categories and number of aquaculture animals kept there;

(ii) the type of aquaculture establishment concerned;

(iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2. By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

(a) aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:

(i) to the final consumer directly; or

(ii) to local retail establishments directly supplying the final consumer;

(b) ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;

(c) aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3. Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

(a) the competent authority withdraws or suspends its approval in accordance with Article 184(2); or

(b) in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;

(b) the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5. When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

(a) the species and categories of aquaculture animals kept in an aquaculture establishment;

(b) the type of aquaculture establishment and the type of production; and

(c) typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6. An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of Article 177 are complied with.

Article 177

Approval by the competent authority of groups of aquaculture establishments

The competent authority may grant approval as provided for in Article 181(1) covering a group of aquaculture establishments, provided that the aquaculture establishments in question comply with either of the following conditions:

(a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system; however, any on–shore or off–shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption (so-called 'dispatch centres'), establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption (so-called 'purification centres') and similar establishments located inside such an epidemiologically linked area must be approved individually;

(b) they are under the responsibility of the same operator; and

(i) operate under a common biosecurity system; and

(ii) the aquaculture animals of the establishments concerned form part of the same epidemiological unit.

When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 178 and Articles 180 to 184 and the rules adopted pursuant to Articles 180(2) and 181(2), which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

Article 178

Approval of status of confined aquaculture establishments

Operators of aquaculture establishments wishing to obtain the status of a confined establishment shall:

(a) apply to the competent authority for approval in accordance with Article 180(1);

(b) move aquaculture animals to or from their establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Article 181 or 183.

Article 179

Approval of disease control aquatic food establishments

Operators of disease control aquatic food establishments shall:

(a) ensure that the necessary approval in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council ([1]) has been obtained; and

(b) apply to the competent authority, in accordance with Article 180(1), for approval to slaughter or process aquatic animals for disease control purposes in accordance with point (b) of Article 61(1), Article 62 and Articles 68(1), 79(1) and (2) and the rules adopted pursuant to Article 63 and Articles 70(3), 71(3) and 79(3).

Article 180

Obligation of operators to provide information with a view to obtaining approval

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, provide the competent authority with the following information:

(a) the name and address of the operator concerned;

([1]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(b) the location of the establishment concerned and a description of its facilities;

(c) the species, categories and quantities (numbers, volume or weight) of aquaculture animals relevant for the approval which are kept on the establishment;

(d) the type of aquaculture establishment;

(e) in cases of approval of a group of aquaculture establishments, details showing that the group in question complies with the conditions laid down in Article 177;

(f) other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it;

(g) the water supply to, and discharge of water from, the establishment;

(h) the establishment's biosecurity measures.

2. Operators of establishments as referred to in paragraph 1 shall inform the competent authority in advance of:

(a) any changes in the establishments concerning the matters referred to in paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment, in accordance with paragraph 1, including the time-limits by which such information is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 181

Granting of, and conditions for, approval and delegated acts

1. The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1)) and any rules adopted pursuant to Article 10(6);

(ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;

(b) surveillance as referred to in point (a)(ii) of paragraph 1;

(c) facilities and equipment as referred to in point (b) of paragraph 1.

3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment;

(b) the species and categories of aquaculture or aquatic animals relevant for the approval;

(c) the type of production concerned;

(d) typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

Article 182

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 181(1) following an application made in accordance with Article 176, Article 177, point (a) of Article 178 or Article 179:

(a) for which of the types of aquaculture establishments referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments referred to in Article 177 and disease control aquatic food establishments referred to in Article 179, and in any rules adopted pursuant to point (b) of Article 176(4), the approval applies;

(b) for which species and categories of aquaculture animals the approval applies.

Article 183

Procedures for the granting of approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 176(1) and Articles 178 and 179.

2. Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on–site visit.

3. Provided that the requirements referred to in Article 181 are fulfilled, the competent authority shall grant the approval.

4. Where an establishment does not fulfil all requirements for approval as referred to in Article 181, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5. Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on–site visit to the establishment, carried out within three months from the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 181(1) and the rules adopted pursuant to Article 181(2).

Where the on–site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

Article 184

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) under review, at appropriate intervals based on the risk involved.

2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

Register of aquaculture establishments and disease control aquatic food establishments

Article 185

Register of aquaculture establishments and disease control aquatic food establishments

1. Each competent authority shall establish and keep up to date a register of:

(a) all aquaculture establishments registered in accordance with Article 173;

(b) all aquaculture establishments approved in accordance with Article 181(1);

(c) all disease control aquatic food establishments approved in accordance with Article 181(1).

2. The register of aquaculture establishments provided for in paragraph 1 shall contain the following information:

(a) the name and address of the operator and the registration number of the establishment in question;

(b) the location of the aquaculture establishment or, as the case may be, of the group of aquaculture establishments concerned;

(c) the type of production at the establishment;

(d) the water supply to, and discharge from, the establishment, when relevant;

(e) the species of aquaculture animals kept at the establishment;

(f) up-to-date information on the health status of the registered aquaculture establishment, or, as the case may be, of the group of establishments, as regards the listed diseases referred to in point (d) of Article 9(1).

3. For establishments approved in accordance with Article 181(1), the competent authority shall make publicly available by electronic means at least the information referred to in points (a), (c), (e) and (f) of paragraph 2 of this Article, subject to data protection requirements.

4. Where appropriate and relevant, a competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1 of this Article;

(b) the public availability of that register.

Section 4

Record-keeping and traceability

Article 186

Record-keeping obligations of operators of aquaculture establishments

1. Operators of aquaculture establishments subject to the requirement of registration in accordance with Article 173, or approval in accordance with Article 181(1), shall keep and maintain records containing at least the following information:

(a) the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;

(b) movements of aquaculture animals and products of animal origin obtained from those animals into and out of their establishment, stating as appropriate:

(i) their place of origin or destination;

(ii) the date of such movements;

(c) the animal health certificates, in paper or electronic form, required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to points (a) and (c) of Article 211(1) and Article 213(2);

(d) mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:

(i) the species and categories of the aquaculture animals on the establishment;

(ii) the type of production at the aquaculture establishment;

(iii) the type and size of the aquaculture establishment;

(f) the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2. Aquaculture establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in points (c), (d) and (e) of paragraph 1, provided that traceability is ensured.

3. Operators of aquaculture establishments shall keep the records provided for in paragraph 1 on their aquaculture establishment concerned and shall:

(a) keep them in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;

(b) make them available to the competent authority on request;

(c) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

By way of derogation from the requirement that the records are to be kept on their establishment concerned, as set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, they shall be kept in the office from which the business is administered.

Article 187

Record-keeping obligations of disease control aquatic food establishments

1. Operators of disease control aquatic food establishments subject to approval in accordance with Article 179 shall keep and maintain records of:

(a) all movements into and from their establishment of aquaculture animals and products of animal origin obtained from such animals;

(b) discharge of water and relevant biosecurity measures.

2. Operators of disease control aquatic food establishments shall:

(a) keep the records provided for in paragraph 1 on their establishment and shall make them available to the competent authority on request;

(b) retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

The records shall be kept and maintained in paper or electronic form.

Article 188

Record-keeping obligations of transporters

1. Transporters of aquatic animals intended for aquaculture establishments or to be released into the wild shall keep and maintain records in relation to:

(a) the species, categories and quantities (numbers, volume or weight) of aquatic animals transported by them;

(b) mortality rates of the aquaculture animals and wild aquatic animals in question during transport, in so far as is practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;

(c) aquaculture establishments and disease control aquatic food establishments visited by the means of transport;

(d) any exchange of water that took place during transport, specifying the sources of new water and sites of release of water;

(e) the cleaning and disinfection of the means of transport.

The records shall be kept and maintained in paper or electronic form.

2. Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1, provided that traceability is ensured.

3. Transporters shall keep the records provided for in paragraph 1:

(a) in such a manner that they can be made immediately available to the competent authority on request;

(b) for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 189

Delegation of powers concerning record-keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 186, 187 and 188, as regards information to be recorded by operators in addition to that provided for in Articles 186(1), 187(1) and 188(1).

2. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

(a) the risks posed by each type of aquaculture establishment or transport;

(b) the species and categories of aquatic animals kept on the aquaculture establishment concerned, or transported to or from that establishment;

(c) the type of production of the establishment;

(d) typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;

(e) the numbers, volume or weight of aquatic animals kept on the establishment or transported to or from it.

Article 190

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of aquaculture establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 186 and 188, as regards:

(a) operators of certain categories of aquaculture establishments and transporters;

(b) aquaculture establishments keeping, or transporters transporting, respectively, a small number of aquaculture animals or a small number of aquatic animals;

(c) certain species and categories of aquatic animals.

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 189 (2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Movements within the Union of aquatic animals

Section 1

General Requirements for movements

Article 191

General requirements for movements of aquatic animals

1. Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move aquatic animals into an aquaculture establishment or for human consumption purposes, or release them into the wild, if the animals in question fulfil the following conditions:

(a) they come, except in the case of wild aquatic animals, from establishments that have been:

(i) registered by the competent authority in accordance with Article 173,

(ii) approved by that competent authority in accordance with Articles 181 and 182, when required by Article 176(1), Article 177 or Article 178, or

(iii) granted a derogation from the registration requirement laid down in Article 173.

(b) they are not subject to:

(i) movement restrictions affecting the species and categories concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or

(ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259.

3. Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned directly to the final place of destination.

Article 192

Disease prevention measures in relation to transport

1. Operators shall take the appropriate and necessary disease prevention measures to ensure that:

(a) the health status of aquatic animals is not jeopardised during transport;

(b) transport operations of aquatic animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans or animals en route, and at places of destination;

(c) cleaning and disinfection of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned;

(d) any exchanges of water and discharges of water during the transport of aquatic animals intended for aquaculture or release into the wild are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in point (d) of Article 9(1) of:

(i) the aquatic animals being transported;

(ii) any aquatic animals en route to the place of destination;

(iii) aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the conditions and requirements for cleaning and disinfection of equipment and means of transport in accordance with point (c) of paragraph 1 of this Article and the use of biocidal products for such purposes;

(b) other appropriate biosecurity measures during transport as provided for in point (c) of paragraph 1 of this Article;

(c) water exchanges and discharges of water during transport as provided for in point (d) of paragraph 1 of this Article.

Article 193

Change of intended use

1. Aquatic animals which are moved for destruction or slaughter in accordance with the following measures shall not be used for any other purpose:

(a) any of the disease control measures provided for in point (c) of Article 32(1) and Article 55(1), Articles 56, 61, 62, 64, 65 and 70, Articles 74(1) and (2) and Articles 79, 80, 81 and 82 and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3) and 74(4), and Article 83(2);

(b) emergency measures as provided for in Articles 257 and 258 and in rules adopted pursuant to Article 259.

2. Aquatic animals moved for human consumption, aquaculture, release into the wild or any other purpose, shall not be used for any purpose other than the intended one.

3. By way of derogation from paragraph 2, the competent authority of the place of destination may authorise a change of use of aquatic animals for a purpose other than that originally intended, provided that the new use does not pose a higher risk to the health status of the aquatic animals at the place of destination than the originally intended use.

Article 194

Obligations of operators at the place of destination

1. Operators of aquaculture establishments and disease control aquatic food establishments receiving aquatic animals and operators receiving aquatic animals for release into the wild shall, before the aquatic animals are unloaded:

(a) check that, where required, one of the following documents is present:

(i) the animal health certificates provided for in Article 208(1), Article 209 and Article 223(1) and in the rules adopted pursuant to Articles 189, 211 and 213;

(ii) the self-declaration documents provided for in Article 218(1) and in the rules adopted pursuant to Article 218(3) and (4);

(b) inform the competent authority of the place of destination, after checking the aquatic animals received, of any irregularity with regard to:

(i) the aquatic animals received;

(ii) the documents referred to in point (a)(i) and (ii).

2. In the event of any irregularity as referred to in point (b) of paragraph 1, the operator shall isolate the aquatic animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 195

General requirements in respect of movements of aquaculture animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that aquaculture animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 191, 192 and 193.

Section 2

Aquatic animals intended for aquaculture establishments or release into the wild

Article 196

Abnormal mortalities or other serious disease symptoms

1. Operators shall only move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment, or release them into the wild, if the animals in question:

(a) show no disease symptoms; and

(b) originate from an aquaculture establishment or environment where there are no abnormal mortalities with an undetermined cause.

2. By way of derogation from paragraph 1, the competent authority may, on the basis of an evaluation of the risks involved, authorise the movement or release of aquatic animals as referred to in that paragraph, provided that the animals in question originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

If the movement or release referred to in this paragraph is to be made to another Member State, it shall only be authorised by the competent authority if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage have given their consent to such movement or release.

Article 197

Movements of aquaculture animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1. Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment which has been declared free of those listed diseases in accordance with Article 36(4) or 37(4), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those diseases.

2. Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment subject to an eradication programme for one or more of those listed diseases as provided for in Article 31(1) or (2), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those listed diseases.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the movement or release requirements laid down in paragraphs 1 and 2 of this Article which do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) on account of:

(a) the species, categories, and life stage of the aquaculture animals concerned;

(b) the type of establishment of origin and of destination;

(c) the intended use of the aquaculture animals;

(d) the place of destination of the aquaculture animals;

(e) treatments, processing methods and other special risk-mitigation measures applied at the place of origin or destination.

Article 198

Derogations by Member States concerning the obligation of operators for movement of aquaculture animals between Member States, zones or compartments which are subject to an eradication programme

By way of derogation from Article 197(1) and (2), Member States may authorise operators to move aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) and (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established for the same listed diseases, provided that such movement will not jeopardise the health status of the Member State, zone or compartment of destination.

If such movements are to be made to another Member State, the competent authority shall only authorise them if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage, have given their consent to them.

Article 199

Member States' measures concerning the release of aquatic animals into the wild

Member States may require that aquatic animals may be released into the wild only if they originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(1) or Article 37(1) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1) for which the species of aquatic animals to be moved is a listed species, regardless of the health status of the area where those aquatic animals are to be released.

Article 200

Movements of wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1. Articles 196, 197 and 198 shall apply to movements of wild aquatic animals intended for an aquaculture establishment or for release into the wild.

2. Operators shall take the appropriate and necessary disease prevention measures when moving wild aquatic animals between habitats to ensure that:

(a) such movements do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination; and

(b) risk-mitigation or other adequate biosecurity measures are in place where necessary to ensure compliance with point (a).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the disease prevention and risk-mitigation measures to be taken by operators as provided for in paragraph 2 of this Article. Pending the adoption of such delegated acts, the competent authority of the place of destination may decide on such measures.

Section 3

Aquatic animals intended for human consumption

Article 201

Movements of live aquaculture animals intended for human consumption in Member States, or in zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1. Operators shall only move live aquaculture animals of listed species relevant for listed diseases as referred to in points (b) or (c) of Article 9(1) intended for human consumption to a Member State, or to a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4) or for which a eradication programme has been established in accordance with Article 31(1) or (2), as regards one or more of the listed diseases referred to in points

(b) and (c) of Article 9(1), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4).

2. By way of derogation from paragraph 1 of this Article, Member States may authorise operators to introduce live aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) or (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established as regards the same diseases within that Member State, provided that such movement will not jeopardise the health status of the Member State or of the zone or compartment thereof.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the derogations provided for in paragraph 2 of this Article in respect of movements of live aquaculture animals which do not pose a significant risk of spreading of diseases on account of:

(a) the species, categories, and live stage of the aquaculture animals concerned;

(b) the methods of keeping the aquaculture animals and the type of production in the aquaculture establishments of origin and of destination;

(c) the intended use of the aquaculture animals;

(d) the place of destination of the aquaculture animals;

(e) treatments, processing methods and other special risk-mitigation measures applied at the place of origin or the place of destination.

Article 202

Movements of live wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1. Article 201(1) and (2) and the rules adopted pursuant to Article 201(3) shall apply to movements of live wild aquatic animals intended for human consumption and which are intended for Member States, or zones or compartments thereof, which have been declared disease-free in accordance with Articles 36(4) or 37(4) or which are subject to an eradication programme in accordance with Article 31(1) or (2), where the measures adopted pursuant thereto are necessary in order to ensure that the animals in question do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2. Paragraph 1 of this Article shall also apply to live aquatic animals not covered by the definition of aquaculture animals contained in Article 4(7).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning movement requirements for wild aquatic animals intended for human consumption, supplementing paragraphs 1 and 2 of this Article.

Section 4

Derogations from sections 1 to 3 (Articles 191 to 202) and Additional risk-mitigation measures

Article 203

Aquatic animals intended for confined establishments for aquaculture and delegated acts

1. Operators shall only move aquatic animals to a confined establishment for aquaculture if the animals in question fulfil the following conditions:

(a) they originate from another confined establishment for aquaculture;

(b) they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species of animals at the confined establishment for aquaculture of destination, except where the movement in question is authorised for scientific purposes.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for movements of aquaculture animals to confined establishments for aquaculture in addition to those provided for in paragraph 1 of this Article;

(b) specific rules for movements of aquaculture animals to confined establishments for aquaculture where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of aquaculture animals within that confined establishment for aquaculture and the surrounding establishments.

Article 204

Movements of aquatic animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of aquatic animals into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Sections 1 to 3 (Articles 191 to 202), with the exception of Article 191(1) and (3) and Articles 192, 193 and Article 194.

2. The competent authority referred to in paragraph 1 shall only grant derogations as provided for in that paragraph under the following conditions:

(a) the competent authorities of the places of destination and origin:

(i) have agreed on the conditions for such movements;

(ii) ensure that the necessary risk-mitigation measures are in place so that movements of the aquatic animals in question do not jeopardise the health status in places en route and in the places of destination with regard to the listed diseases referred to in point (d) of Article 9(1);

(iii) have notified, where relevant, the competent authorities of the Member States of passage of the derogation granted and of the conditions under which it is granted;

(b) those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, the competent authorities of the Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

Article 205

Other specific uses of aquatic animals, specific requirements and derogations and delegation of powers

1. Operators shall take the necessary preventive measures to ensure that movements of aquatic animals intended for the specific purposes or uses listed in point (a)(i) to (vi) of paragraph 2 of this Article do not pose a risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific requirement supplementing the rules laid down in Sections 1 to 3 (Articles 191 to 202) and for movements of aquatic animals for the following purposes:

(i) zoos, pet shops, wholesalers and garden ponds;

(ii) exhibitions;

(iii) sports fishing, including fishing baits;

(iv) cultural and similar events;

(v) commercial aquaria; or

(vi) health care and other similar uses.

(b) derogations from Sections 1 to 3 (Articles 191 to 202) with the exception of Article 191(1) and (3) and Articles 192, 193 and 194 for the movements of aquatic animals referred to in point (a) of this paragraph, provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.

Article 206

Implementing power to adopt temporary rules for movements of specific species or categories of aquatic animals

1. The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of aquatic animals where:

(a) the movement requirements provided for in Article 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201 and Articles 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 197(3), 200(3), 202 (3), 203(2) and 204(3) and Article 205 do not efficiently mitigate the risks posed by the movement of those aquatic animals; or

(b) a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 4 (Articles 191 to 207).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a listed disease representing a risk of a highly significant impact and taking into account the matters referred to in Article 205, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 207

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Article 203(2), Article 204(3) and Articles 205 and 206, the Commission shall base those rules on:

(a) the risks involved with the movements referred to in those provisions;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;

(c) listed aquatic animal species for the listed diseases referred to in point (d) of Article 9(1);

(d) biosecurity measures in place at the places of origin, passage and destination;

(e) any specific conditions under which the aquaculture animals are kept;

(f) specific movement patterns of the type of aquaculture establishment and the species or category of aquatic animals concerned;

(g) other epidemiological factors.

Section 5

Animal health certification

Article 208

Obligation of operators to ensure that aquaculture animals are accompanied by an animal health certificate

1. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the listed diseases referred to in points (b) and (c) of Article 9(1) and are intended for introduction into a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Articles 36(4) and 37(4) or for which an eradication programme has been established as provided for in Article 31(1) or (2) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1).

2. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the relevant disease(s) referred to in points (a) and (b) of Article 9(1) and are allowed to leave a restricted zone subject to disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56 and 64 or Articles 65(1), 74(1), 79 and rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3), 74(4) and 83(2) and Article 259 for one or more of the listed diseases referred to in points (a) and (b) of Article 9(1).

3. Operators shall take all necessary measures to ensure that the animal health certificate accompanies the aquaculture animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 214.

Article 209

Obligation of operators to ensure that other aquatic animals are accompanied by an animal health certificate and implementing power

1. In cases where, due to the risk involved with the movement of aquatic animals other than aquaculture animals, animal health certification is required in accordance with the rules provided for in point (a) of Article 211(1), operators shall only move those aquatic animals if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1).

2. Article 208 shall also apply to aquatic animals other than aquaculture animals intended for an aquaculture establishment or release into the wild. Where the competent authority of the Member State of origin concludes that certification is not feasible due to the nature of the place of origin of the aquatic animals in question, it may authorise their movement without an animal health certificate subject to the consent of the competent authority of the place of destination.

3. This Article shall not apply to wild aquatic animals harvested or caught for direct human consumption.

Article 210

Grant of derogations by Member States in respect of national animal health certification

By way of derogation from the animal health certification requirements laid down in Articles 208 and 209, Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have in place an alternative system to ensure that consignments of such animals are traceable and those consignments comply with the animal health requirements for such movements provided for in Sections 1 to 4 (Articles 191 to 207).

Article 211

Delegation of powers and implementing acts concerning animal health certification in respect of aquatic animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for animal heath certification for movements of aquatic animals other than aquaculture animals as referred to in Article 209(1), in cases where animal health certification is imperative in order to ensure that the movement in question complies with the following animal health requirements for the listed species of animals concerned:

(i) the requirements provided for in Sections 1 to 4 (Articles 191 to 207) and the rules adopted pursuant to those Sections;

(ii) disease control measures as provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, and Articles 65(1), 74(1) and 79(1) and (2) or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, and Articles 71(3), 74(4) and 83(2);

(iii) emergency measures as provided for in the rules adopted pursuant to Article 259;

(b) special rules for animal health certification as provided for in Articles 208 and 209 where specific risk-mitigation measures are taken by the competent authority to ensure:

(i) the traceability of the aquatic animals being moved;

(ii) that the aquatic animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 4 (Articles 191 to 207);

(c) derogations from the animal health certificate requirements provided for in Articles 208 and 209 and the conditions for such derogations for movements of aquatic animals which do not pose a significant risk of the spread of diseases, on account of:

(i) species, the categories or live stage of the aquatic animals concerned;

(ii) the methods of keeping and the type of production of those species and categories of aquaculture animals;

(iii) the intended use of the aquatic animals; or

(iv) the place of destination of the aquatic animals.

2. The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, as provided for in Article 209(2), to ensure that wild aquatic animals intended for an aquaculture establishment are accompanied by an animal health certificate.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 212

Contents of animal health certificates

1. The animal health certificate referred to in Articles 208, 209 and 210 shall contain at least the following information:

(a) the establishment or place of origin, the establishment or place of destination and, where relevant for the spread of diseases, any establishment or place visited en route;

(b) a description, including the species and category, of the aquatic animals concerned;

(c) the quantity (number, volume or weight) of aquatic animals;

(d) the information needed to demonstrate that the aquatic animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 4 (Articles 191 to 207).

2. The animal health certificate may include other information required under other Union legislation.

Article 213

Delegation of powers and implementing acts concerning the content of animal health certificates

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning the content of animal health certificates as provided for in Article 212(1):

(a) detailed rules on the content of those animal health certificates provided for in Article 212(1) for different species and categories of aquatic animals;

(b) additional information to be contained in the animal health certificate provided for in Article 212(1).

2. The Commission may, by means of implementing acts, lay down rules concerning the model forms for the animal health certificates.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 214

Delegation of powers concerning specific types of movements of aquatic animals to the place of destination

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures supplementing the requirements for animal health certification provided for in Article 208 and 209 for the following types of movements of aquatic animals:

(a) movements of aquatic animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:

(i) their intended journey was unexpectedly interrupted for animal welfare reasons;

(ii) unforeseen accidents or events during the journey;

(iii) they were rejected at the place of the destination in another Member State or at the external border of the Union;

(iv) they were rejected in a third country or territory;

(b) movements of aquaculture animals intended for exhibitions and for sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 215

Operators' obligations to cooperate with the competent authorities for the purposes of animal health certification

Operators shall:

(a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Articles 208 and 209 and in the rules adopted pursuant to Articles 211, 213 and 214, in advance of the intended movement;

(b) where necessary, ensure that the aquatic animals in question are subjected to documentary, identity and physical checks as provided for in Article 216(3) and in the rules adopted pursuant to Article 216(4).

Article 216

Responsibility of the competent authority for animal health certification and delegated acts

1. The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of aquatic animals, where required by Articles 208 and 209, or by rules adopted pursuant to Articles 211 and Article 214, provided that the following animal health requirements have been complied with, as relevant:

(a) those provided for in Article 191, Article 192(1), Articles 193, 195 and 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201, Article 203(1) and Article 204(1) and (2);

(b) those provided for in delegated acts adopted pursuant to Articles 192(2), 197(3), 200(3), 201(3), 202(3), 203(2) and 204(3) and Article 205;

(c) those provided for in implementing acts adopted pursuant to Article 206.

2. Animal health certificates shall:

(a) be verified, stamped and signed by an official veterinarian;

(b) remain valid for the period of time, provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the aquatic animals covered by it must continue to fulfil the animal health guarantees contained in it.

3. Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, that the aquatic animals covered by it fulfil the requirements of this Chapter, taking into account the species and categories of aquatic animals concerned and the animal health requirements.

4. The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:

(a) the types of documentary, identity and physical checks and examinations in relation to different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;

(b) the timeframes for the carrying-out of such documentary, identity and physical checks and examinations, and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of aquatic animals;

(c) the duration of the validity of animal health certificates.

Article 217

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of TRACES, may replace accompanying animal health certificates as provided for in Article 216(1) where such electronic animal health certificates:

(a) contain all the information that the model form of animal health certificate is required to contain in accordance with Article 212(1) and the rules adopted pursuant to Article 213;

(b) ensure the traceability of the aquatic animals in question and the link between those animals and the electronic animal health certificate;

(c) ensure that the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 218

Self–declaration by operators for movements of aquaculture animals to other Member States and delegated acts

1. Operators at the place of origin shall issue a self-declaration document for movements of aquaculture animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such aquaculture animals, where they are not required to be accompanied by an animal health certificate as provided for in Articles 208 and 209 or in any rules adopted pursuant to Articles 211 and Article 214.

2. The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the aquaculture animals in question:

(a) their places of origin and destination, and, when relevant, any places en route;

(b) the means of transport

(c) a description of the aquaculture animals, and their categories, species and quantity (numbers, volume or weight), as relevant for the animals concerned;

(d) the information needed to demonstrate that the aquaculture animals fulfil the movement requirements provided for in Sections 1 to 4 (Articles 191 to 207).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of aquaculture animals;

(b) additional information to be contained in the self-declaration document to the one provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for a model form of the self-declaration document provided for in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 6

Notification of movements of aquatic animals to other Member States

Article 219

Obligation of operators concerning the notification of movements of aquatic animals to other Member States

1. Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of aquatic animals from one Member State to another Member State where:

(a) the aquatic animals are required to be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 208 and 209 and any rules adopted pursuant to Article 211 and Article 214(2);

(b) the aquatic animals are required to be accompanied by an animal health certificate for aquatic animals when they are being moved from a restricted zone as referred to in Article point (a) of 208(2);

(c) the aquaculture animals and wild aquatic animals being moved are intended for:

(i) an establishment subject to registration in accordance with Article 173 or approval in accordance with Articles 176 to 179;

(ii) release into the wild;

(d) notification is required in accordance with delegated acts adopted pursuant to Article 221.

2. For the purposes of the notification provided for in paragraph 1 of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movement to the competent authority of the Member State of destination in accordance with Article 220(1).

Article 220

Responsibility of the competent authority to notify movements of aquatic animals to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of aquatic animals as referred to in Article 219, unless a derogation has been granted in accordance with point (c) of Article 221(1) as regards such notification.

2. The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through TRACES.

3. Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4. By way of derogation from paragraph 1, the competent authority of Member State of origin may authorise the operator concerned to notify, partially or completely, movements of aquatic animals through TRACES to the competent authority of the Member State of destination.

Article 221

Delegation of powers and implementing acts for the notification of movements of aquatic animals by operators and by the competent authority

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators, in accordance with Article 219, of movements between Member States of aquatic animals of species or categories other than those referred to in points (a), (b) and (c) of Article 219(1), where traceability of such movements is necessary in order to ensure compliance with the animal health requirements laid down in this Chapter;

(b) the information needed in order to notify movements of aquatic animals as provided for in Articles 219 and 220(1);

(c) derogations from the notification requirements provided for in point (c) of Article 219(1) for species and categories of aquatic animals or types of movements which pose an insignificant risk;

(d) the emergency procedures for notification of movements of aquatic animals in the event of power cuts or other disturbances of TRACES;

(e) the requirements for the designation of regions by Member States as provided for in Article 220(3).

2. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the details of notifications by:

(i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219;

(ii) the competent authority of the Member State of origin to the Member State of destination of movements of aquatic animals in accordance with Article 220(1);

(b) the deadlines for:

(i) the provision by operators of the necessary information referred to in Article 219(2) to the competent authority of the Member State of origin;

(ii) the notification of movements by the competent authority of the Member State of origin as referred to in Article 220(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266 (2).

CHAPTER 3

Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals

Article 222

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin from aquatic animals, other than live aquatic animals, those products do not cause the spread of:

(a) listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing and destination;

(b) emerging diseases.

2. Operators shall ensure that products of animal origin from aquatic animals, other than live aquatic animals, do not come from establishments or food businesses, or are not obtained from animals which come from such establishments or food businesses, that are subject to:

(a) emergency measures as provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been provided for in respect of those rules in Part VII (Articles 257 to 262);

(b) movement restrictions applicable to aquatic animals and products of animal origin from aquatic animals, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 70 (3), 71(3), 74(4), 76(5) and 83(2), unless derogation from those movement restrictions have been provided for in those rules.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to in paragraph 2 of this Article in relation to movements of products of animal origin from aquatic animals other than live aquatic animals, as regards:

(a) the diseases, and species of aquatic animals concerned by the diseases, for which emergency measures or movement restrictions as referred to in paragraph 2 of this Article apply;

(b) the types of products of animal origin from aquatic animals;

(c) the risk-mitigation measures applied to the products of animal origin from aquatic animals at the places of origin and destination;

(d) the intended use of the products of animal origin from aquatic animals;

(e) the place of destination of the products of animal origin from aquatic animals.

4. This Article shall not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption.

Article 223

Animal health certificates and delegated acts

1. Operators shall only move the following products of animal origin from aquatic animals other than live aquatic animals where those products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

(a) products of animal origin from aquatic animals that:

(i) are allowed to leave a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259; and

(ii) originate from aquatic animals of species subject to those emergency measures;

(b) products of animal origin from aquatic animals that:

(i) are allowed to leave a restricted zone subject to disease control measures in accordance with point (c) of Article 32 (1), point (c) of Article 55(1), Article 56, point (a) of Article 61(1), Articles 62(1) and 63(1), point (c) of Article 65 (1), point (b) of Article 70(1), point (a) of Article 74(1) and Article 79 and the rules adopted pursuant to Article 55 (2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2); and

(ii) originate from aquatic animals of species subject to those disease control measures.

2. By way of derogation from paragraph 1, such a certificate shall not be required for movements of products of animal origin from wild aquatic animals, provided that:

(a) alternative risk-mitigation measures authorised by the competent authority are in place to ensure that those movements do not pose a risk of the spread of listed diseases;

(b) consignments of such products are traceable.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

4. The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin other than live aquatic animals as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

5. Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the animal health certification of movements of products of animal origin other than live aquatic animals as referred to in paragraph 1 of this Article.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, as referred to in paragraph 1 of this Article, taking into account:

(a) the types of products of animal origin concerned;

(b) the risk-mitigation measures applied to the products concerned which reduce the risks of the spread of diseases;

(c) the intended use of those products;

(d) the place of destination of those products.

Article 224

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin from aquatic animals, other than live aquatic animals, shall contain at least the following information:

(a) the establishment or place of origin and the establishment or place of destination;

(b) a description of the products of animal origin concerned;

(c) the quantity (numbers, volume or weight) of the products of animal origin;

(d) the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to Article 67;

(e) the information needed to demonstrate that the products concerned fulfil the movement restriction requirements provided for in Article 222(2) and in any rules adopted pursuant to Article 222(3).

2. The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning amending and supplementing the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates as provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 225

Notification of movements of products of animal origin to other Member States

1. Operators shall:

(a) inform the competent authority in the Member State of origin in advance of intended movements of products of animal origin from aquatic animals, other than live aquatic animals, when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 223(1);

(b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the Member State of destination in accordance with paragraph 2 of this Article.

2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin from aquatic animals, other than live aquatic animals, in accordance with Article 220(1).

3. Articles 219 and 220 and any rules adopted pursuant to Article 221 shall be applicable to the notification of products of animal origin from aquatic animals, other than live aquatic animals.

CHAPTER 4

National measures

Article 226

National measures designed to limit the impact of diseases other than listed disease

1. Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction, or to control the spread, of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or to control the spread, of the disease in question within the Member State concerned.

2. Member States shall notify the Commission in advance of any proposed national measures as referred to in paragraph 1 that may affect movements of aquatic animals and products of animal origin from aquatic animals between Member States.

3. The Commission shall approve and, if necessary, amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary in order to prevent the introduction, or to control the spread, of the disease referred to in paragraph 1, taking into account the overall impact on the Union of the disease in question and of the measures taken.

TITLE III

ANIMALS OF SPECIES OTHER THAN THOSE DEFINED AS TERRESTRIAL AND AQUATIC ANIMALS, AND GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM SUCH OTHER ANIMALS

Article 227

Animal health requirements concerning other animals, and germinal products and products of animal origin of such other animals

Where other animals are of a listed species for a listed disease as referred to in point (d) of Article 9(1), and those other animals or their germinal products or products of animal origin represent a risk to public or animal health in the Union, one or more of the following requirements shall apply:

(a) the requirements concerning registration, approval, record-keeping and registers for establishments and transporters provided for in Chapter 1 of Title I and Chapter 1 of Title II (Articles 84 to 101 and Articles 172 to 175);

(b) the requirements concerning traceability provided for in Articles 108 to 111 and Article 117 for other animals and Article 122 for germinal products;

(c) movement requirements:

(i) as regards other animals mainly living in a terrestrial environment or that are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Section 1 (Articles 124 and 125) and Section 6 of Chapter 3 of Title I of Part IV (Articles 137 to 142) and Chapter 4 of Title I of Part IV (Articles 155 and 156);

(ii) as regards other animals mainly living in aquatic environment or that are normally affected by diseases of aquatic animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Sections 1 to 4 of Chapter 2 of Title II of Part IV (Articles 191 to 207);

(iii) as regards germinal products, the general requirements for movements provided for in Articles 157 and 158 and the special requirements for movements to other Member States provided for in Articles 164 and 165;

(iv) as regards products of animal origin, the general animal health obligations incumbent on operators in respect of the production, processing and distribution within the Union of products of animal origin provided for in Articles 166 and 222;

(d) the animal health certification obligation incumbent on operators and competent authorities and the self-declaration incumbent on operators:

(i) as regards other animals, pursuant to the rules provided for in Articles 143 to 151 or Articles 208 to 218;

(ii) as regards germinal products, pursuant to the rules provided for in Articles 161 and 162;

(iii) as regards products of animal origin, pursuant to the rules provided for in Articles 165 and 168 or Articles 223 and 224;

(e) the obligation to notify movements incumbent on operators and competent authorities, taking into account the requirements provided for in Articles 152, 153, 154, 163 and 169 and in Articles 219 to 221 and 225.

Article 228

Delegation of powers and implementing acts concerning animal health requirements for other animals, and germinal products and products of animal origin of other animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning any specific requirements for other animals, and their germinal products or products of animal origin, which are necessary in order to mitigate the risk of the listed diseases referred to in point (d) of Article 9(1), as provided for in Article 227.

2. The Commission may adopt implementing acts concerning detailed rules for the implementation of the disease control and prevention measures provided for in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. When adopting the delegated acts and implementing acts provided for in paragraphs 1 and 2, the Commission shall base those acts on the following criteria:

(a) the species or categories of other animals listed in accordance with Article 8(2) as listed species for one or more listed diseases, for which certain disease prevention and control measures provided for in this Regulation apply;

(b) the profile of the listed disease in question, which concerns species and categories of other animals referred to in point (a);

(c) the feasibility, availability and effectiveness of disease prevention and control measures for the listed species concerned by those measures;

(d) the prevailing terrestrial or aquatic living environment of those other animals;

(e) the types of diseases that are affecting such other animals, which can be either diseases normally affecting terrestrial or aquatic animals, regardless of the prevailing living environment referred to in point (d).

PART V

ENTRY INTO THE UNION AND EXPORT

CHAPTER 1

Entry into the Union of animals, germinal products and products of animal origin from third countries and territories

Section 1

Requirements for the entry into the Union

Article 229

Requirements for entry into the Union of animals, germinal products and products of animal origin

1. Member States shall permit the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries or territories only if those consignments fulfil the following requirements, unless such animals, germinal products or products of animal origin are covered by a derogation granted pursuant to Article 239(2):

(a) without prejudice to Article 230(2), they come from a third country or territory listed in accordance with Article 230(1) for the particular species and category of animals, or germinal products or products of animal origin concerned, or from a zone or compartment thereof;

(b) they come from establishments which are approved and listed, where such approval and listing is required by Article 233;

(c) they fulfil the animal health requirements for entry into the Union laid down in Article 234(1) and in any delegated acts adopted pursuant to Article 234(2), where such requirements are laid down for the animal, germinal product or product of animal origin concerned;

(d) they are accompanied by an animal health certificate and by declarations and other documents where required by Article 237(1) or by rules adopted pursuant to Article 237(4);

2. The operators responsible for the consignment in question shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control as provided for in Article 3 of Directive 91/496/EEC and Article 3 of Directive 97/78/EC.

Section 2

Listing of third countries and territories

Article 230

Lists of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is permitted, and implementing and delegated acts

1. The Commission may, by means of implementing acts, draw up lists of third countries and territories from which the entry into the Union of specific species and categories of animals, germinal products and products of animal origin is to be permitted, based on the following criteria:

(a) the animal health legislation of the third country or territory concerned and the rules on the entry into that third country or territory of animals, germinal products and products of animal origin from other third countries and territories;

(b) the assurances provided by the competent authority of the third country or territory concerned as regards the efficient implementation and control of the animal health legislation referred to in point (a);

(c) the organisation, structure, resources and legal powers of the competent authority in the third country or territory concerned;

(d) the animal health certification procedures in the third country or territory concerned;

(e) the animal health status of the third country or territory concerned, or of zones and compartments thereof, with regard to:

(i) listed diseases and emerging diseases;

(ii) any aspects of animal and public health or the environmental situation in the third country or territory concerned, or in a zone or compartment thereof, which may pose a risk to animal or public health or the environmental status of the Union;

(f) the guarantees which the competent authority of the third country or territory concerned can provide regarding compliance or equivalence with the relevant animal health requirements applicable in the Union;

(g) the regularity and speed with which the third country or territory concerned supplies information concerning infectious or contagious animal diseases in its territory to the World Organisation for Animal Health (OIE), in particular information concerning the diseases listed in the OIE Codes;

(h) the results of controls carried out by the Commission in the third country or territory concerned;

(i) any experience gathered from previous entries of animals, germinal products and products of animal origin from the third country or territory concerned and the results of official controls carried out at the point of entry into the Union on such animals, germinal products and products of animal origin.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. Pending the adoption of the lists provided for in paragraph 1, and provided that such lists have not been drawn up pursuant to the Union legislation referred to in Article 270(2), Member States shall determine from which third countries and territories specific species and categories of animals, germinal products or products of animal origin may enter the Union.

For the purposes of the first subparagraph of this paragraph, Member States shall take into account the criteria for inclusion in the lists of third countries and territories provided for in points (a) to (i) of paragraph 1 of this Article.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from paragraph 2 of this Article, limiting the possibility for Member States to decide from which third countries and territories a specific species and category of animal, germinal product or product of animal origin may enter the Union, where necessary due to the risk posed by that specific species and category of animal, germinal product or product of animal origin.

Article 231

Information to be included in the lists of third countries and territories

The Commission shall specify the following information for each third country or territory in the lists provided for in Article 230(1):

(a) the species and categories of animals, germinal products or products of animal origin that may enter the Union from that third country or territory;

(b) whether the animals, germinal products or products of animal origin specified in accordance with point (a) may enter the Union from the whole territory of that third country or territory or only from one or more zones or compartments thereof;

(c) specific conditions and animal health guarantees concerning listed diseases.

Article 232

Suspension and withdrawal from the lists of third countries and territories and implementing acts

1. The Commission shall, by means of implementing acts, withdraw a country or territory from the lists provided for in Article 230(1), or suspend the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, for any of the following reasons:

(a) the third country or territory concerned, or one or more zones or compartments thereof, no longer complies with the criteria laid down in Article 230(1), where relevant for the entry into the Union of a particular species and category of animal, germinal product or product of animal origin;

(b) the animal health situation in the third country or territory concerned, or in a zone or compartment thereof, is such that a suspension or withdrawal from the lists is necessary in order to protect the animal health status of the Union;

(c) the Commission has requested the third country or territory concerned to supply up-to–date information on the animal health situation and other matters referred to in Article 230(1), and that third country or territory has not provided such information;

(d) the third country or territory concerned has refused to agree to controls being carried out by the Commission on behalf of the Union in its territory.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a serious risk of the introduction into the Union of a listed disease as referred to in point (d) of Article 9(1), the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

3. The Commission may, by means of implementing acts, reinstate in the lists provided for in Article 230(1) a third country or territory, or a zone or compartment thereof, that has been withdrawn from those lists, or may re–authorise the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, from which entry into the Union has been suspended, for one of the following reasons:

(a) for the reasons referred to in point (a) or (c) of paragraph 1 of this Article, provided that the third country or territory concerned demonstrates that it complies with the listing criteria provided for in Article 230(1);

(b) for the reason referred to in point (b) of paragraph 1 of this Article, provided that the third country or territory concerned provides appropriate guarantees that the animal health situation that gave rise to the suspension or withdrawal has been resolved or no longer represents a threat to animal or public health within the Union;

(c) for the reason referred to in point (d) of paragraph 1 of this Article, provided that:

(i) the third country or territory concerned has agreed to controls being carried out by the Commission on behalf of the Union in its territory; and

(ii) the results of those controls by the Commission show that the third country or territory concerned, and the zones or compartments thereof, comply with the listing criteria provided for in Article 230(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 3

Approval and listing of establishments in third countries and territories

Article 233

Approval and listing of establishments

1. Member States shall only permit the entry into the Union of terrestrial animals and germinal products thereof originating from an establishment of a type for which approval is required in the Union in accordance with Article 94(2) and the rules adopted pursuant to Article 94(3) and Article 95, if the establishment in question in the third country or territory concerned:

(a) complies with animal health requirements in that third country or territory which are equivalent to the rules for establishments of that type applicable in the Union;

(b) is approved and listed by the competent authority of the third country or territory of dispatch, unless alternative risk-mitigation measures in place in that third country or territory provide equivalent guarantees for animal health within the Union.

2. The Commission shall collect the lists of approved establishments referred to in point (b) of paragraph 1 received from the competent authorities of the third countries or territories concerned.

3. The Commission shall provide to the Member States any new or updated lists of approved establishments received from the third countries or territories concerned, and shall make them publicly available.

4. The Commission shall, by means of implementing acts, adopt any rules necessary in order to ensure uniform application of point (b) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 4

Entry into the Union of species and categories of animals, germinal products and products of animal origin

Article 234

Animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin

1. The animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories shall:

(a) be as stringent as the animal health requirements laid down in this Regulation and in the rules adopted pursuant thereto applicable to movements of the species and categories of animals, germinal products or products of animal origin in question within the Union; or

(b) offer equivalent guarantees to the animal health requirements applicable to the species and categories of animals, germinal products or products of animal origin provided for in Part IV (Articles 84 to 228) of this Regulation.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for:

(a) the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories;

(b) the movement within the Union and handling of those animals, germinal products and products of animal origin after their entry into the Union, where this is necessary in order to mitigate the risk involved.

3. Pending the adoption of delegated acts laying down animal health requirements as regards a particular species and category of animal, germinal product or product of animal origin provided for in paragraph 1 of this Article, Members State may, following an evaluation of the risks involved, apply national rules, provided that those rules comply with the requirements laid down in that paragraph and provided that they take into account the matters referred to in Articles 235 and 236.

Article 235

Matters to be taken into account in delegated acts provided for in Article 234 with regard to the entry into the Union of animals

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), animal health requirements for the entry into the Union of particular species and categories of animals:

(a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) the health status of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(c) the listed species with regard to those listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(d) the age and sex of the animals concerned;

(e) the origin of the animals concerned;

(f) the type of establishment concerned and the type of production at the places of origin and of destination;

(g) the intended place of destination;

(h) the intended use of the animals concerned;

(i) any risk-mitigation measures in place in the third countries or territories of origin or transit, or after the arrival of the animals concerned into the territory of the Union;

(j) animal health requirements applicable to movements of those animals within the Union;

(k) other epidemiological factors;

(l) international animal health trade standards, relevant to the species and categories of those animals.

Article 236

Matters to be taken into account in delegated acts as provided for in Article 234 with regard to the entry into the Union of germinal products and products of animal origin

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), the animal health requirements for the entry into the Union of germinal products and products of animal origin:

(a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) the health status of the animals from which the germinal products or products of animal origin originate and of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(c) the type and nature of particular germinal products or products of animal origin, treatments, processing methods and other risk-mitigation measures that have been applied at the places of origin, dispatch of consignment or destination;

(d) the type of establishment and the type of production at the places of origin and of destination;

(e) the intended place of destination;

(f) the intended use of the germinal products or products of animal origin concerned;

(g) animal health requirements applicable to movements of the germinal products and products of animal origin concerned within the Union;

(h) other epidemiological factors;

(i) international animal health trade standards, relevant for the germinal products and products of animal origin in question.

Section 5

animal health certificates, declarations and other documents

Article 237

Animal health certificates, declarations and other documents for entry into the Union

1. Member States shall only permit the entry into the Union of consignments of animals, germinal products and products of animal origin if such consignments are accompanied by one or both of the following:

(a) an animal health certificate issued by the competent authority of the third country or territory of origin, unless a derogation is provided for in point (a) of paragraph 4;

(b) declarations or other documents, where required by the rules adopted pursuant to point (b) of paragraph 4.

2. Member States shall not permit the entry into the Union of consignments of animals, germinal products and products of animal origin unless the animal health certificate referred to in point (a) of paragraph 1 has been verified and signed by an official veterinarian in a third country or territory in compliance with certification requirements equivalent to those laid down in Article 149(3) or 216(3) and any rules adopted pursuant to Article 149(4) or 216(4).

3. Member States shall permit electronic animal health certificates that are produced, handled and transmitted by means of TRACES to replace the accompanying animal health certificates referred to in paragraph 1, where such electronic animal health certificates:

(a) contain all the information that the animal health certificate referred to in point (a) of paragraph 1 of this Article is required to contain in accordance with Article 238(1) and any rules adopted pursuant to Article 238(3);

(b) ensure the traceability of the consignments of animals, germinal products and products of animal origin concerned and link those consignments to the electronic animal health certificate.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the animal health certificate requirements provided for in point (a) of paragraph 1 and paragraph 2 of this Article, for consignments of animals, germinal products and products of animal origin, and in specific rules for the animal health certification of those consignments, where the consignments in question pose an insignificant risk to animal health or public health within the Union, due to one or more of the following factors:

(i) the species and categories of animals, germinal products or products of animal origin concerned;

(ii) the methods of keeping and types of production of the animals, germinal products and products of animal origin concerned;

(iii) their intended use;

(iv) alternative risk-mitigation measures which are in place in the third countries or territories of origin or transit, or after their arrival into the territory of the Union, affording equivalent protection of animal health and public health within the Union as provided for in this Regulation;

(v) the provision by the third country or territory concerned of guarantees of compliance with the requirements for entry into the Union, demonstrated by means other than an animal health certificate;

(b) rules requiring consignments of animals, germinal products and products of animal origin entering into the Union to be accompanied by declarations or other documents needed to demonstrate that the animals, germinal products and products of animal origin in question meet the animal health requirements for entry into the Union laid down in rules adopted pursuant to Article 234(2).

Article 238

Content of animal health certificates

1. The animal health certificate referred to in point (a) of Article 237(1) shall contain at least the following information:

(a) the name and address of:

(i) the establishment or place of origin;

(ii) the establishment or place of destination;

(iii) where applicable, establishments for assembly operations or rest of the kept animals concerned;

(b) a description of the animals, germinal products or products of animal origin concerned;

(c) the number or volume of the animals, germinal products or products of animal origin concerned;

(d) where applicable, the identification and registration of the animals, germinal products or products of animal origin concerned;

(e) the information needed to demonstrate that the animals, germinal products and products of animal origin concerned fulfil the animal health requirements for entry into the Union provided for in Article 229 and Article 234(2) and in the rules adopted pursuant to Article 234(1) and Article 239.

2. The animal health certificate referred to in point (a) of Article 237(1) may include other information required under other Union legislation.

3. The Commission may, by means of implementing acts, lay down rules concerning:

(a) information to be contained in the animal health certificate referred to in point (a) of Article 237(1) in addition to that referred to in paragraph 1 of this Article;

(b) information to be contained in declarations or other documents as referred to in point (b) of Article 237(1);

(c) model forms for the animal health certificates, declarations and other documents referred to in Article 237(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. Pending the establishment of rules in implementing acts adopted pursuant to paragraph 3, as regards a particular species and category of animal, germinal product or product of animal origin, Member States may, following an evaluation of the risks involved, apply national rules, provided those national rules comply with the conditions laid down in paragraph 1.

Section 6

Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin

Article 239

Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin

1. For certain specific types of entry of animals, germinal products and products of animal origin, the application of the rules set out in Article 229(1) and Articles 233 and 237 may not be adequate, and special rules may need to be adopted by the Commission through delegated acts which take into account the particular risks, the final destination, the type of final use and other circumstances.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the special rules referred to in paragraph 1 of this Article regarding derogations from the requirements provided for in Article 229(1) and Articles 233 and 237 and imposing additional requirements for the entry into the Union of the following:

(a) animals:

(i) intended for circuses, events, exhibitions, display, shows and confined establishments;

(ii) intended to be used for scientific or diagnostic purposes;

(iii) for which the Union is not the final destination;

(iv) which originate in the Union and which are moved to a third country or territory, and are then moved back to the Union from that third country or territory;

(v) which originate in the Union and which are transported through a third country or territory en route to another part of the Union;

(vi) which are intended for grazing purposes on a temporary basis, in the vicinity of the Union's borders;

(vii) which pose an insignificant risk to the animal health status within the Union;

(b) products of animal origin:

(i) intended for personal use;

(ii) for consumption by the crew and passengers on means of transport arriving from third countries or territories;

(c) germinal products and products of animal origin:

(i) intended to be used as trade samples;

(ii) intended to be used as research and diagnostic samples;

(iii) for which the Union is not the final destination;

(iv) which originate in the Union and are moved to a third country or territory, and are then moved back to the Union from that third country or territory;

(v) which originate in the Union and are transported through a third country or territory en route to another part of the Union;

(vi) which pose an insignificant risk to the animal health status within the Union.

Those delegated acts shall take into account the matters referred to in Article 235 and 236.

3. The Commission may, by means of implementing acts, lay down rules:

(a) concerning model forms for the animal health certificates, declarations and other documents for the categories of animals, germinal products and products of animal origin referred to in paragraph 2 of this Article;

(b) indicating, for the products referred to in paragraph 1 of this Article, the codes from the Combined Nomenclature, where such codes are not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Entry into the Union of certain goods other than animals, germinal products and products of animal origin from third countries and territories

Article 240

Disease agents and delegated acts

1. Operators, veterinarians, aquatic animal health professionals and animal professionals bringing disease agents into the Union shall:

(a) take appropriate measures to ensure that the entry of those disease agents into the Union does not pose a risk to animal health or public health within the Union with regard to listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) take appropriate disease control and preventive measures to ensure that the entry of those disease agents into the Union does not present a risk of bioterrorism.

This paragraph shall also apply to any other natural or legal person bringing such agents into the Union intentionally.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 laying down requirements for the entry into the Union of disease agents concerning:

(a) the packaging of disease agents;

(b) other risk-mitigation measures required in order to prevent the release and spread of disease agents.

Article 241

Plant material and delegated and implementing acts

1. The Member States shall take measures to restrict the entry into the Union of consignments of plant material in the event of an unfavourable disease situation in third countries or territories concerning listed diseases as referred to in point (d) of Article 9(1) or emerging diseases, where this is required by the rules adopted in accordance with paragraph 3 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the measures referred to in paragraph 1 of this Article, setting out:

(a) specific animal health requirements for the entry into the Union of plant material which acts as a path of transmission of listed or emerging diseases;

(b) requirements in relation to:

(i) animal health certification, taking into account the rules provided for in point (a) of Article 237(1) and Article 237 (2) and (3); or

(ii) declarations or other documents, taking into account the rules provided for in point (b) of Article 237(1).

3. The Commission shall lay down the animal health requirements provided for in paragraph 2 on the basis of the following criteria:

(a) whether a listed or emerging disease that can be transmitted by means of plant material represents a serious risk to animal or to human health in the Union;

(b) the likelihood that animals of listed species for a particular listed disease or emerging disease will come into direct or indirect contact with the plant material referred to in paragraph 2;

(c) the availability and effectiveness of alternative risk-mitigation measures in relation to that plant material, which may eliminate or minimise the risk of transmission referred to in point (a).

4. The Commission may, by means of implementing acts, lay down rules indicating, for the plant material referred to in paragraph 2 of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 242

Means of transport, equipment, packaging materials, transport water and feed and fodder and delegated and implementing acts

1. Operators bringing animals and products into the Union shall take the appropriate and necessary disease prevention measures during transport, as provided for in Articles 125(1) and 192(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific animal health requirements for the entry into the Union of:

(i) means of transport for animals and products;

(ii) equipment, packaging material or transport water for animals and products, or feed and fodder which may transmit animal diseases;

(b) requirements in relation to:

(i) animal health certification, taking into account the rules provided for in point (a) of Article 237(1) and Article 237 (2) and (3); or

(ii) declarations or other documents, taking into account the rules provided for in point (b) of Article 237(1).

3. The Commission shall lay down the animal health requirements provided for in paragraph 2 of this Article in the event of a unfavourable disease situation concerning one or more listed diseases as referred to in point (d) of Article 9(1), or emerging diseases, which present a serious risk to animal and human health in the Union, in:

(a) a neighbouring third country or territory;

(b) the third country or territory of origin;

(c) a third country or territory of transit.

4. The Commission may, by means of implementing acts, lay down rules indicating, for the goods referred to in point (a) of paragraph 2 of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Export

Article 243

Export from the Union

1. Member States shall take the appropriate measures to ensure that the export and re–export from the Union to a third country or territory of animals and products takes place in accordance with the rules for the movement of animals and products between Member States provided for in Part IV (Articles 84 to 228), while taking into account the animal health status within the third country or territory of destination, or the relevant zone or compartment thereof, with regard to the listed diseases referred to in point (d) of Article 9(1) and emerging diseases.

2. By way of derogation from paragraph 1, if so requested by the competent authority of a third country or territory importing the animals and products in question, or if established by the legal and administrative procedures in force in that third country or territory, export and re–export from the Union may take place in accordance with the provisions in force in that third country or territory, provided that such exports or re-exports do not jeopardise public or animal health.

3. Where the provisions of a bilateral agreement concluded between the Union and a third country or territory are applicable, animals and products exported from the Union to that third country or territory shall comply with those provisions.

PART VI

NON-COMMERCIAL MOVEMENTS OF PET ANIMALS INTO A MEMBER STATE FROM ANOTHER MEMBER STATE OR FROM A THIRD COUNTRY OR TERRITORY

CHAPTER 1

General provisions

Article 244

Scope of Part VI

1. This Part shall apply to the non-commercial movement of pet animals into a Member State from another Member State or from a third country or territory.

2. It shall apply without prejudice to:

(a) Council Regulation (EC) No 338/97 ([1]);

(b) any national measures adopted, published and made available to the public by Member States to restrict the movement of certain species or breeds of pet animals on the basis of considerations other than those relating to animal health.

([1]) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.1997, p. 1).

Article 245

General provisions

1. Non-commercial movements of pet animals that fulfil the animal health requirements laid down in this Part shall not be prohibited, restricted or impeded on animal health grounds other than those resulting from the application of this Part.

2. Where the non-commercial movement of a pet animal is carried out by an authorised person, it may only take place within five days from the movement of the pet owner.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements supplementing the rules laid down in paragraph 2 of this Article in relation to the following:

(a) documentation of the non-commercial movement of a pet animal carried out by an authorised person;

(b) granting of derogations from the period referred to in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down requirements for the layout, languages and validity of the declaration authorising an authorised person in writing to carry out the non-commercial movement of a pet animal on behalf of the pet owner. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 246

Maximum number of pet animals

1. The number of pet animals of the species listed in Part A of Annex I which may be moved during a single non-commercial movement shall not exceed five.

2. By way of derogation from paragraph 1, the number of pet animals of the species listed in part A of Annex I may exceed five if the following conditions are fulfilled:

(a) the non-commercial movement in question is for the purpose of participating in a competition, exhibition or sporting event or training for such an event;

(b) the pet owner or the authorised person concerned submits written evidence that the pet animals are registered either to attend an event as referred to in point (a), or with an association organising such events;

(c) the pet animals are more than six months old.

3. In order to prevent commercial movements of pet animals of the species listed in Part B of Annex I from being fraudulently disguised as non-commercial movements, the Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules setting the maximum number of pet animals of those species which may be moved during a single non-commercial movement.

CHAPTER 2

Conditions applicable to non-commercial movements of pet animals into a Member State from another Member State

Article 247

Conditions applicable to non-commercial movements of pet animals of the species listed in Part A of Annex I

Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from another Member State unless:

(a) they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they fulfil the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254.

Article 248

Conditions applicable to non-commercial movements of pet animals of the species listed in Part B of Annex I

1. In so far as the Commission has adopted a delegated act pursuant to point (b) of Article 252(1) with regard to pet animals of one of the species listed in Part B of Annex I, non-commercial movements of pet animals of that species into a Member State from another Member State shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals of the species referred to in paragraph 1 may be moved into a Member State from another Member State only if:

(a) they are identified or described, either individually or in groups, in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254;

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to non-commercial movements of pet animals of the species listed in Part B of Annex I into their territory from another Member State, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with non-commercial movements of pet animals of those species; and

(b) not stricter than those applied to movements of animals of those species in accordance with Part IV.

CHAPTER 3

Conditions applicable to non-commercial movements of pet animals into a Member State from a third country or territory

Article 249

Conditions applicable to non-commercial movements of pet animals of the species listed in Part A of Annex I

1. Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from a third country or territory unless:

(a) they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in respect of listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254.

2. Pet animals of the species listed in Part A of Annex I may be moved into a Member State from a third country or territory other than those listed pursuant to Article 253(1)(d) only through a point of entry listed for that purpose. Each Member State shall draw up a list of those points of entry within its territory and shall make that list available to the public.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the conditions for granting derogations from paragraph 2 of this Article.

Article 250

Conditions applicable to non-commercial movements of pet animals of the species listed in Part B of Annex I

1. In so far as the Commission has adopted a delegated act pursuant to point (b) of Article 252(1) with regard to pet animals of one of the species listed in Part B of Annex I, non-commercial movements of pet animals of that species into a Member State from a third country or territory shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals of the species referred to in paragraph 1 may be moved into a Member State from a third country or territory only if:

(a) they are identified or described, either individually or in groups, in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254;

(d) when coming from a third country or territory other than those listed pursuant to point (d) of Article 253(1), they enter through a point of entry listed for that purpose. Each Member State shall draw up a list of those points of entry within its territory and shall make that list available to the public.

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to non-commercial movements of pet animals of the species listed in Part B of Annex I into their territory from a third country or territory, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with non-commercial movements of pet animals of those species; and

(b) not stricter than those applied to the entry into the Union of animals of those species in accordance with Part V.

Article 251

Derogation from the conditions applicable to non-commercial movements of pet animals between certain countries and territories

By way of derogation from Articles 249 and 250, non-commercial movements of pet animals between the following countries and territories may continue under the conditions laid down by the national rules of those countries and territories:

(a) San Marino and Italy;

(b) the Vatican and Italy;

(c) Monaco and France;

(d) Andorra and France;

(e) Andorra and Spain;

(f) Norway and Sweden;

(g) the Faeroe Islands and Denmark;

(h) Greenland and Denmark.

CHAPTER 4

Identification and prevention and risk-mitigation measures

Article 252

Delegation of powers concerning the identification of pet animals and prevention and risk-mitigation measures

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed species-specific requirements for:

(i) the means of identification of pet animals of the species listed in Annex I provided for in point (a) of Article 247, point (a) of Article 248(2), point (a) of Article 249(1) and point (a) of Article 250(2);

(ii) the application and use of those means of identification;

(b) detailed species-specific requirements for the prevention and risk-mitigation measures to ensure that pet animals do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) due to movements of pet animals of the species listed in Annex I as provided for in point (b) of Article 247, point (b) of Article 248(2), point (b) of Article 249(1) and point (b) of Article 250(2).

2. Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to point (b) of paragraph 1 of this Article.

3. The species-specific prevention and risk-mitigation measures authorised by a delegated act adopted pursuant to point (b) of paragraph 1 of this Article shall be based on adequate, reliable and validated scientific information and applied proportionately to the risk to public or animal health associated with non-commercial movements of pet animals likely to be affected by listed diseases as referred to in point (d) of Article 9(1).

4. The delegated acts provided for in point (b) of paragraph 1 may also comprise the following:

(a) rules for the categorisation of Member States or parts thereof according to their animal health status and their surveillance and reporting systems with regard to certain diseases that are likely to be spread by movements of pet animals of the species listed in Annex I;

(b) the conditions that Member States are to fulfil in order to remain eligible for the application of the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(c) the conditions for applying and documenting the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(d) the criteria for granting and, where appropriate, documenting derogations in certain specified circumstances from the application of the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(e) the criteria for granting and documenting derogations in certain specified circumstances from the conditions referred to in Articles 247 to 250.

Article 253

Implementing acts concerning prevention and risk-mitigation measures

1. The Commission shall, by means of implementing acts, as regards pet animals of the species listed in Part A of Annex I:

(a) lay down rules on the format, layout and languages of any documents required under points (c) and (d) of Article 252 (4);

(b) adopt a list of Member States that comply with the conditions referred to in point (d) of Article 252(4) and remove Member States from that list should any change occur in relation to those conditions;

(c) adopt a list of Member States that comply with the rules for categorisation of Member States or parts thereof referred to in point (a) of Article 252(4) and remove Member States from that list should any change occur in relation to those rules;

(d) adopt a list of third countries and territories that comply with the conditions referred to in point (d) of Article 252(4) and remove third countries or territories from that list should any change occur in relation to those conditions.

2. The Commission may, by means of implementing acts, as regards pet animals of the species listed in Part B of Annex I, adopt a list of third countries and territories that comply with the conditions referred to in point (d) of Article 252 (4) and remove third countries or territories from that list should any change occur in relation to those conditions.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall adopt immediately applicable implementing acts updating the lists referred to in points (b) and (d) of paragraph 1 of this Article in accordance with the procedure referred to in Article 266(3).

CHAPTER 5

Identification documents

Article 254

Delegation of powers concerning identification documents

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) entries for the insertion of the information to be included in the identification documents referred to in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(b) the distribution of blank identification documents as referred to in point (c) of Article 247;

(c) the conditions for granting derogations in relation to the format of the identification documents provided for in point (c) of Article 247 and point (c) of Article 249(1);

(d) the issue, completion and, where applicable, endorsement of the identification documents provided for in point (c) of Articles 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2).

Article 255

Implementing acts concerning identification documents

1. The Commission shall adopt implementing acts laying down the model for identification documents as referred to in point (c) of Article 247 and point (c) of Article 249(1). That model shall contain the respective entries referred to in point (a) of Article 254, as well as requirements concerning the languages, layout, validity or security features of those identification documents.

2. The Commission may, by means of implementing acts, adopt:

(a) the model for identification documents as referred to in point (c) of Article 248(2) and point (c) of Article 250(2), which are to contain the respective entries referred to in point (a) of Article 254, as well as requirements concerning the languages, layout, validity or security features of those identification documents;

(b) the rules necessary for transition to the model identification document referred to in point (c) of Article 247.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 6

Information obligations

Article 256

Information obligations

1. Member States shall provide the public with clear and easily accessible information concerning the animal health requirements applicable to non-commercial movements of pet animals, including:

(a) conditions for the grant of certain derogations referred to in point (d) of Article 252(4);

(b) conditions for the grant of derogations referred to in point (e) of Article 252(4);

(c) requirements for the application of the means of identification referred to in point (a)(ii) of Article 252(1);

(d) conditions applicable to non-commercial movements into Member States' territories of pet animals of the species referred to in Part B of Annex I, which are laid down by their national rules as provided for in Articles 248(3) and 250 (3);

(e) conditions applicable to non-commercial movements into Member States' territories of pet animals from certain countries and territories laid down by their national rules as referred to in Article 251;

(f) any relevant information concerning certain prevention and risk-mitigation measures as referred to in point (b) of Article 252(1).

2. Member States shall establish internet–based information pages providing the information referred to in paragraph 1, and shall communicate the internet address of those pages to the Commission.

3. The Commission shall assist the Member States in making that information available to the public by providing on its internet page:

(a) links to the internet–based information pages of the Member States;

(b) the information referred to in points (a) and (d) of paragraph 1, and the information made available to the public as referred to in point (b) of Article 244(2) in additional languages, as appropriate.

PART VII

EMERGENCY MEASURES

Section 1

Emergency measures concerning movements of animals and products within the Union and means of transport and other material that may have come into contact with such animals and products

Article 257

Emergency measures to be taken by the competent authority of the Member State in the territory of which an outbreak of a listed disease or emerging disease, or a hazard occurred

1. In the event of an outbreak of a listed disease or emerging disease, or the occurrence of a hazard which is likely to constitute a serious risk to animal or public health, the competent authority of the Member State where it occurred shall, depending on the gravity of the situation and the disease or hazard in question, immediately take one or more of the following emergency measures to prevent the spread of the disease or hazard:

(a) for listed diseases:

(i) referred to in point (a) of Article 9(1), the disease control measures laid down in Chapter 1 of Title II of Part III (Articles 53 to 71);

(ii) referred to in point (b) of Article 9(1), the disease control measures laid down in Articles 72 to 75 and 77 to 81 of Chapter 2 of Title II of Part III;

(iii) referred to in point (c) of Article 9(1), the disease control measures laid down in Articles 76 to 78 and Articles 80 and 82 of Chapter 2 of Title II of Part III;

(b) for emerging diseases and hazards:

(i) restrictions on the movement of animals and products originating from the establishments, or, where relevant, the restricted zones or compartments, where the outbreak or the hazard occurred, and on means of transport and other material that may have come into contact with those animals or products;

(ii) quarantine of animals and isolation of products;

(iii) surveillance and traceability measures;

(iv) any emergency disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71) that are appropriate;

(c) any other emergency measure which it deems appropriate in order to effectively and efficiently control and prevent the spread of the disease or hazard.

2. The competent authority referred to in paragraph 1 shall inform the Commission and the other Member States:

(a) immediately of any outbreak or the occurrence of a hazard as referred to in paragraph 1;

(b) without delay of the emergency measures taken pursuant to paragraph 1.

Article 258

Emergency measures to be taken by a Member State other than the Member State where the outbreak or hazard occurred

1. The competent authority of a Member State other than the Member State where the outbreak or hazard referred to in Article 257(1) occurred shall, depending on the gravity of the situation and the disease or hazard in question, take one or more of the emergency measures referred to in Article 257(1) where it detects on its territory animals or products from the Member State referred to in Article 257(1) or means of transport or any other material that may have come into contact with such animals and products.

2. The competent authority referred to in paragraph 1 of this Article may, where a serious risk exists pending the adoption of emergency measures by the Commission in accordance with Article 259, take the emergency measures referred to in Article 257(1) on an interim basis, depending on the gravity of the situation with regard to animals or products originating from the establishments or other locations, or where relevant from the restricted zones of the Member State, where the disease or hazard referred to in Article 257(1) occurred, or means of transport or other material that may have come into contact with such animals.

3. A Member State may take measures as referred to in Article 257(1) in the event of an outbreak in a third country or territory bordering the Union of a disease referred to in point (a) of Article 9(1) or an emerging disease in such a third country or territory, in so far as those measures are necessary in order to prevent the spread of the disease into the territory of the Union.

4. The competent authority referred to in paragraph 1 and the competent authority of the Member State referred to in paragraph 3 shall inform the Commission and other Member States:

(a) immediately of the outbreak or occurrence of a hazard referred to in paragraph 1;

(b) without delay of the emergency measures taken pursuant to paragraphs 1 and 2.

Article 259

Commission emergency measures

1. In the event of an outbreak or the occurrence of a hazard as referred to in Article 257(1), and of emergency measures taken by the competent authorities of the Member States in accordance with Article 257(1) and Article 258(1), (2) and (3), the Commission shall review the situation and the emergency measures taken, and shall adopt, by means of an implementing act, one or more of the emergency measures provided for in Article 257(1) concerning the animals and products in question and means of transport and other material that may have come into contact with those animals or products, in any of the following cases:

(a) where the Commission has not been informed of any measures taken pursuant to Article 257(1) and Article 258(1), (2) and (3);

(b) where the Commission considers the measures taken pursuant to Article 257(1) and Article 258(1), (2) and (3) to be inadequate;

(c) where the Commission considers it necessary to approve or replace the measures taken by the competent authorities of the Member States pursuant to Article 257(1) and Article 258(1), (2) and (3) in order to avoid unjustified disruptions in the movement of animals and products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to serious risks of the spread of a disease or a hazard, the Commission may adopt immediately applicable implementing acts in accordance with Article 266(3).

Section 2

Emergency measures concerning consignments of animals and products originating from third countries and territories, and means of transport and other material, that may have come into contact with such consignments

Article 260

Emergency measures to be taken by the competent authority

Where the competent authority of a Member State becomes aware of animals or products originating from a third country or territory, or of means of transport or materials, which may have come into contact with such animals and products, that are likely to constitute a serious risk in the Union due to possible infection or contamination by listed diseases or emerging diseases or hazards, it shall:

(a) immediately take one or more of the following emergency measures necessary to mitigate that risk, depending on the gravity of the situation:

(i) destruction of the animals and products concerned;

(ii) quarantine of animals and isolation of products;

(iii) surveillance and traceability measures;

(iv) any disease control measures referred to in Chapter 1 of Title II of Part III (Articles 53 to 69), where appropriate;

(v) any other emergency measure which it deems appropriate to prevent the spread of the disease or hazard into the Union;

(b) immediately inform the Commission and the other Member States of the risks associated with the animals and products in question and of the origin of those animals and products by means of TRACES, and without delay of the emergency measures taken pursuant to point (a).

Article 261

Commission emergency measures

1. Where a listed disease, an emerging disease or a hazard that is likely to constitute a serious risk occurs or spreads in a third country or territory, or if any other serious animal or public health reason so warrants, the Commission may, by means of an implementing act and acting on its own initiative or at the request of a Member State, adopt one or more of the following emergency measures, depending on the gravity of the situation:

(a) suspend the entry into the Union of consignments of animals and products, and means of transport or other material, that may have come into contact with such consignments, which may spread that disease or hazard into the Union;

(b) establish special requirements for the entry into the Union of animals and products, and of means of transport and other material that may have come into contact with such animals and products, which may spread that disease or hazard into the Union;

(c) take any other appropriate emergency disease control measures to prevent the spread of such disease or hazard into the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall, after consulting the Member State concerned, adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

Article 262

Emergency measures to be taken by Member States when the Commission does not act

1. Where a Member State has requested the Commission to take emergency measures in accordance with Article 261 and the Commission has not done so, that Member State:

(a) may, pending the adoption of emergency measures by the Commission in accordance with paragraph 2 of this Article, take one or more of the emergency measures referred to in point (a) of Article 260 on an interim basis in respect of animals and products, and any means of transport and other material that may have come into contact with such animals and products, originating from the third country or territory referred to in Article 261(1), depending on the gravity of the situation within its territory;

(b) shall inform the Commission and the competent authorities of the other Member States of such emergency measures without delay, giving the reason for their adoption.

2. The Commission shall review the situation and the emergency measures taken by the Member State concerned in accordance with paragraph 1 of this Article and shall, where necessary, adopt by means of an implementing act one or more of the emergency measures provided for in Article 261.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

PART VIII

COMMON PROVISIONS

TITLE I

PROCEDURAL PROVISIONS

Article 263

Amendments to Annex III

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning amendments to Annex III, limited exclusively to taking into account changes in taxonomy.

Article 264

Exercise of the delegation

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

2. It is of particular importance that the Commission carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The power to adopt delegated acts referred to in Articles 3(5), 5(2) 5(4), 14(3), 16(2), 18(3), 20(3), 29, 31(5), 32(2), 37(5), 39, 41(3), 42(6), 47, 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64(4), 67, 68(2), 68(3), 70(3), 72(2), 73(3), 74(4), 76(5), 77(2), 87(3), 94(3), 97(2), 101(3), 106(1), 109(2), 118, 119, 122(1), 122(2), 125(2), 131(1), 132(2), 135, 136(2), 137(2), 138(3), 139(4), 140, 144(1), 146(1), 147, 149(4), 151(3), 154(1), 156(1), 160(1), 160(2), 161(6), 162(4), 163(5), 164(2), 165(3), 166(3), 167(5), 168(3), 169(5), 176(4), 181(2), 185(5), 189(1), 192(2), 197(3), 200(3), 201(3), 202(3), 203(2), 204

(3), 205(2), 211(1), 213(1), 214, 216(4), 218(3), 221(1), 222(3), 223(6), 224(3), 228(1), 230(3), 234(2), 237(4), 239(2), 240(2), 241(2), 242(2), 245(3), 246(3), 249(3), 252(1), 254, 263, 271(2), 272(2), 279(2), and 280(4) shall be conferred on the Commission for a period of five years from … (*).

The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

4. The delegation of power referred to in paragraph 3 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

6. A delegated act adopted pursuant to the provisions listed in paragraph 3 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

7. The Commission shall allow a period of at least six months to elapse between the adoption of the respective initial delegated acts referred to in Articles 3(5), 14(3), 16(2), 20(3), 122(2), 164(2) and 228(1) and the date on which they start to apply.

Article 265

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 264(6). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 266

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

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

4. The Commission shall allow a period of at least six months to elapse between the adoption of the respective initial implementing acts referred to in Articles 25(3), 120, and 228(2), when those implementing acts relate to the implementation of Article 117, and the date on which they start to apply.

(*) Date of entry into force of the basic legislative act or any other date set by the legislator.

Article 267

Data protection

1. Member States shall apply Directive 95/46/EC of the European Parliament and of the Council [1] to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 of the European Parliament and of the Council [2] shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

TITLE II

PENALTIES

Article 268

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that those rules are implemented. The penalties provided for must be effective, proportionate and dissuasive.

The Member States shall notify those provisions to the Commission by … (*) at the latest and shall notify it without delay of any subsequent amendments affecting them.

TITLE III

MEMBER STATES' MEASURES

Article 269

Additional or more stringent measures by Member States

1. In addition to what follows from other provisions in this Regulation, allowing the Member States to adopt national measures, Member States may apply within their territories measures that are additional to, or more stringent than, those laid down in this Regulation, concerning:

(a) responsibilities for animal health as provided for in Chapter 3 of Part I (Articles 10 to 16);

(b) notification within Member States as provided for in Article 18;

(c) surveillance as provided for in Chapter 2 of Part II (Articles 24 to 30);

(d) registration, approval, record-keeping and registers as provided for in Chapter 1 of Title I (Articles 84 to 107), and Chapter 1 of Title II, of Part IV (Articles 172 to 190);

(e) traceability requirements for kept terrestrial animals and germinal products as provided for in Chapter 2 of Title I of Part IV (Articles 108 to 123).

2. The national measures referred to in paragraph 1 shall respect the rules laid down in this Regulation and shall not:

(a) hinder the movement of animals and products between Member States;

(b) be inconsistent with the rules referred to in paragraph 1.

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(1) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(2) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(*) One year from the date of application of this Regulation.

PART IX

TRANSITIONAL AND FINAL PROVISIONS

Article 270

Repeals

1. Decisions 78/642/EEC, 89/455/EEC and 90/678/EEC, and Directives 79/110/EEC, 81/6/EEC, 90/423/EEC, 92/36/EEC and 98/99/EC are repealed.

2. The following acts are repealed as from … (*):

— Directive 64/432/EEC,

— Directive 77/391/EEC,

— Directive 78/52/EEC,

— Directive 80/1095/EEC,

— Directive 82/894/EEC,

— Directive 88/407/EEC,

— Directive 89/556/EEC,

— Directive 90/429/EEC,

— Directive 91/68/EEC,

— Decision 91/666/EEC,

— Directive 92/35/EEC,

— Directive 92/65/EEC,

— Directive 92/66/EEC,

— Directive 92/118/EEC,

— Directive 92/119/EEC,

— Decision 95/410/EC,

— Directive 2000/75/EC,

— Decision 2000/258/EC,

— Directive 2001/89/EC,

— Directive 2002/60/EC,

— Directive 2002/99/EC,

— Directive 2003/85/EC,

— Regulation (EC) No 21/2004,

— Directive 2004/68/EC,

— Directive 2005/94/EC,

(*) Date of application of this Regulation.

— Directive 2006/88/EC,

— Directive 2008/71/EC,

— Directive 2009/156/EC,

— Directive 2009/158/EC,

— Regulation (EU) No 576/2013.

References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex V hereto.

Article 271

Transitional measures related to the amendment of Regulation (EC) No 1760/2000 and the repeal of Regulation (EC) No 21/2004 and Directive 2008/71/EC

1. Notwithstanding Article 270(2) and Article 278 of this Regulation, Articles 1 to 10 of Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004, and Directive 2008/71/EC, as well as the acts adopted on the basis thereof, shall continue to apply, instead of the corresponding Articles in this Regulation, until three years after the date of application of this Regulation or an earlier date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the earlier date referred to in paragraph 1 of this Article.

That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 109(2) and Article 119 and the implementing acts provided for in Article 118 of this Regulation.

Article 272

Transitional measures related to the repeals of Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC

1. Notwithstanding Article 270(2) of this Regulation, Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC, as well as the acts adopted on the basis thereof, shall continue to apply, instead of the corresponding Articles in this Regulation, until three years after the date of application of this Regulation or an earlier date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the earlier date referred to in paragraph 1 of this Article.

That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 47, Articles 48(3), 53(2), 54(3), 55(2) and 58(2), Article 63, Article 64(4), Article 67, and Articles 68(2) and 70(3) of this Regulation.

Article 273

Amendment of Regulation (EC) No 2160/2003

Regulation (EC) No 2160/2003 is amended as follows:

The following wording is added to the end of Article 9(3):

'Those special measures shall include measures based on the provisions contained in Decision 95/410/EC in its last version prior to its repeal and Commission Decisions 2003/644/EC (*) and 2004/235/EC (**) in the versions thereof at the time of the repeal of Directive 90/539/EEC.

(*) Commission Decision 2003/644/EC of 8 September 2003 establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of breeding poultry and day-old chicks for introduction into flocks of breeding poultry or flocks of productive poultry (OJ L 228, 12.9.2003, p. 29).

(**) Commission Decision 2004/235/EC of 1 March 2004 establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of laying hens (OJ L 72, 11.3.2004, p. 86).'.

Article 274

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

Without prejudice to the date of application provided for in Article 283, the Commission shall adopt the delegated acts referred to in the first subparagraph of Article 31(5), Articles 32(2), 39, 41(3), 54(3), 55(2), 58(2), 64(4), 67, 68(2), 74(4), 77(2) and 97(2), Article 122(2), and Articles 131(1), 132(2), 135, 137(2), 146(1), 149(4), 154(1), 162(3), 163(4), 166(3), 169(4), 181(2), 185(5), 213(1), 216(4), 221(1), 222(3), 224(3), 234(1), 239(1), and the implementing acts referred to in Articles 8 and 9, at the latest on … (*). In accordance with Article 283, those delegated and implementing acts shall apply from the date of application set out in that Article.

Article 275

Prior review and amendments of Annex II

The Commission shall, at the latest by … (*), review the list of diseases contained in Annex II. Should it be apparent from that review that an application of the rules set out in this Regulation requires amendments to be made to Annex II, by adding to or deleting from the list contained therein, such amendments shall be adopted by the Commission at the latest by the deadline referred to in the first sentence of this Article.

Article 276

Review

The Commission shall, by… (*) at the latest, review the existing legislation on the identification and registration of kept animals of the equine species.

The Commission shall take the results of that review into account in the framework of the application of Articles 118, 119 and 120.

Article 277

Transitional measures related to the repeal of Regulation (EU) No 576/2013 on the non-commercial movement of pet animals

Notwithstanding Article 270(2) of this Regulation, Regulation (EU) No 576/2013 shall continue to apply until … (**) in respect of non-commercial movements of pet animals, in place of Part VI of this Regulation.

Article 278

Amendments to Regulation (EC) No 1760/2000

Regulation (EC) No 1760/2000 is amended as follows:

(1) Articles 1 to 10 are deleted;

(2) Article 22 is replaced by the following:

'Article 22

1. Member States shall take all the necessary measures to ensure compliance with the provisions of this Regulation.

(*) 24 months before the date of application provided for in Article 283.

(**) 10 years after the date of entry into force of this Regulation.

The controls provided for shall be without prejudice to any controls which the Commission may carry out pursuant to Article 9 of Regulation (EC, Euratom) No 2988/95.

Any penalties imposed by the Member State on an operator or organisation marketing beef shall be effective, dissuasive and proportionate.

2. Notwithstanding paragraph 1, where operators and organisations marketing beef have labelled beef without complying with their obligations laid down in Title II, Member States shall, as appropriate, and in accordance with the principle of proportionality, require the removal of the beef from the market. In addition to the penalties referred to in paragraph 1, Member States may:

(a) if the meat concerned conforms with relevant veterinary and hygiene rules, authorise that such beef:

(i) be placed on the market after being properly labelled in accordance with Union requirements; or

(ii) be sent directly for processing into products other than those indicated in point 1 of Article 12;

(b) order the suspension or withdrawal of the approval of the operators and organisations concerned.

3. Experts from the Commission, in conjunction with the competent authorities, shall:

(a) verify that Member States comply with the requirements of this Regulation;

(b) make on-the-spot checks to ensure that the checks are carried out in accordance with this Regulation.

4. A Member State in whose territory an on-the-spot check is carried out shall provide the experts from the Commission with any assistance they may require in the performance of their tasks. The outcome of the checks made shall be discussed with the competent authority of the Member State concerned before a final report is drawn up and circulated. That report shall, where appropriate, contain recommendations for Member States on the improvement of compliance with this Regulation.';

(3) Article 22b is replaced by the following:

'*Article 22b*

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 13(6), 14(4) and 15a shall be conferred on the Commission for a period of five years from… (*). The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 13(6), 14(4) and 15a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

(*) Date of entry into force of this Regulation (the amending Regulation).

5. A delegated act adopted pursuant to Articles 13(6), 14(4) and 15a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.';

(4) Article 23 is replaced by the following:

'*Article 23*

Committee procedure

1. The Commission shall be assisted for the implementing acts adopted pursuant to Article 13(6) of this Regulation by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*).

That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

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

Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time–limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of committee members so requests.

(*) 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).

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

Article 279

Existing operators and establishments

1. Establishments and operators registered or approved in accordance with Directive 64/432/EEC, Directive 88/407/EEC, Directive 89/556/EEC, Directive 90/429/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004, Directive 2006/88/EC, Directive 2008/71/EC, Directive 2009/156/EC or Directive 2009/158/EC before the date of application of this Regulation shall be deemed to be registered or approved, as required, in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules necessary to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraph 1 of this Article, in order in particular to protect acquired rights and legitimate expectations of natural and legal persons concerned.

Article 280

Existing disease-free Member States, zones and compartments and existing Member State eradication and surveillance programmes

1. Member States and zones with an approved disease-free status for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, in accordance with Directive 64/432/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Directive 2006/88/EC, Directive 2009/156/EC or Directive 2009/158/EC, shall be deemed to have an approved disease-free status in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. Member States and zones with an approved eradication programme or surveillance programme for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, in accordance with Directive 64/432/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Directive 2006/88/EC, Directive 2009/156/EC or Directive 2009/158/EC, shall be deemed to have an approved eradication programme in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

3. Approved compartments with an approved disease-free status for one or more of the listed diseases referred to in points (a), (b) or (c) of Article 9(1), in accordance with Directives 2005/94/EC and 2006/88/EC, shall be deemed to have a recognised disease-free status under Article 37 of this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules necessary in order to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraphs 1, 2 and 3.

Article 281

Relation with acts concerning official controls

In the event of any conflict between the provisions of this Regulation and the provisions of Regulation (EC) No 882/2004, Council Directives 89/608/EEC ([1]), 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/93/EC ([2]) and 97/78/EC and Decision 92/438/EEC, the provisions of this Regulation shall prevail.

Article 282

Evaluation

The Commission shall evaluate this Regulation together with the delegated acts referred to in Article 264 and submit the results of the evaluation in a report to the European Parliament and to the Council no later than … (*).

Article 283

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from … (**), except for Articles 270(1) and 274, which shall apply from the date of its entry into force.

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

Done at …,

For the European Parliament	*For the Council*
The President	*The President*
…	…

([1]) Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351, 2.12.1989, p. 34).

([2]) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.1997, p. 28).

(*) Five years after the date of application of this Regulation.

(**) Five years from the date of entry into force of this Regulation.

ANNEX I

Species of pet animals

PART A

Dogs (*Canis lupus familiaris*)

Cats (*Felis silvestris catus*)

Ferrets (*Mustela putorius furo*)

PART B

Invertebrates (except bees, molluscs belonging to the phylum *Mollusca* and crustaceans belonging to the subphylum *Crustacea*)

Ornamental aquatic animals

Amphibians

Reptiles

Birds: specimens of avian species other than fowl, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges and ratites (*Ratitae)*.

Mammals: rodents and rabbits other than those intended for food production.

ANNEX II

List of diseases

— Rinderpest (cattle plague)

— Sheep and goat plague

— Swine vesicular disease

— Bluetongue

— Teschen disease

— Sheep pox or goat pox

— Rift Valley fever

— Lumpy skin disease

— Vesicular stomatitis

— Venezuelan equine viral encephalomyelitis

— Haemorrhagic disease of deer

— Contagious bovine pleuropneumonia

— Newcastle disease

— Bovine tuberculosis

— Bovine brucellosis (*B. abortus*)

— Ovine and caprine brucellosis (*B. melitensis*)

— Anthrax

— Rabies

— Echinococcosis

— Transmissible spongiform encephalopathies (TSE)

— Campylobacteriosis

— Listeriosis

— Salmonellosis (zoonotic salmonella)

— Trichinellosis

— Verotoxigenic *E. coli*

— Viral haemorrhagic septicæmia (VHS)

— Infectious haematopoietic necrosis (IHN)

— Epizootic haematopoietic necrosis in fish (EHN)

— Epizootic ulcerative syndrome in fish (EUS)

— Infection with *Bonamia exitiosa*

— Infection with *Perkinsus marinus*

— Infection with *Microcytos mackini*

— Taura syndrome in crustaceans

— Yellowhead disease in crustaceans

— Koi herpes virus disease (KHV)

— Infectious salmon anaemia (ISA)

— Infection with *Marteilia refringens*

— Infection with *Bonamia ostreae*

— White spot disease in crustaceans

ANNEX III

Species of Ungulates

Taxon		
Order	Family	Genera/Species
Perissodactyla	*Equidae*	*Equus* spp.
	Tapiridae	*Tapirus* spp.
	Rhinoceritidae	*Ceratotherium* spp., *Dicerorhinus* spp., *Diceros* spp., *Rhinoceros* spp.
Artiodactyla	*Antilocapridae*	*Antilocapra* ssp.
	Bovidae	*Addax* ssp., *Aepyceros* ssp., *Alcelaphus* ssp., *Ammelaphus* ssp., *Ammodorcas* ssp., *Ammotragus* ssp., *Antidorcas* ssp., *Antilope* ssp., *Arbitragus* ssp., *Beatragus* ssp., *Bison* ssp., *Bos* ssp. (including *Bibos, Novibos, Poephagus), Boselaphus* ssp., *Bubalus* ssp. (including *Anoa), Budorcas* ssp., *Capra* ssp., *Cephalophus* ssp., *Connochaetes* ssp., *Damaliscus* ssp.(including *Beatragus), Dorcatragus* ssp., *Eudorcas* ssp., *Gazella* ssp., *Hemitragus* ssp., *Hippotragus* ssp., *Kobus* ssp., *Litocranius* ssp., *Madoqua* ssp., *Naemorhedus* ssp. (including *Nemorhaedus* and *Capricornis), Nanger* ssp., *Neotragus* ssp., *Nilgiritragus* ssp., *Oreamnos* ssp., *Oreotragus* ssp., *Oryx* ssp., *Ourebia* ssp., *Ovibos* ssp., *Ovis* ssp., *Pantholops* ssp., *Philantomba* ssp., *Pelea* ssp., *Procapra* ssp., *Pseudois* ssp., *Pseudoryx* ssp., *Raphicerus* ssp., *Redunca* ssp., *Rupicapra* ssp., *Saiga* ssp., *Sigmoceros-Alecelaphus* ssp., *Strepticeros* ssp., *Sylvicapra* ssp., *Syncerus* ssp., *Taurotragus* ssp., *Tetracerus* ssp., *Tragelaphus* ssp. (including *Boocerus).*
	Camelidae	*Camelus* ssp., *Lama* ssp., *Vicugna* ssp.
	Cervidae	*Alces* ssp., *Axis–Hyelaphus* ssp., *Blastocerus* ssp., *Capreolus* ssp., *Cervus* ssp., *Dama* ssp., *Elaphodus* ssp., *Elaphurus* ssp., *Hippocamelus* ssp., *Hydropotes* ssp., *Mazama* ssp., *Megamuntiacus* ssp., *Muntiacus* ssp., *Odocoileus* ssp., *Ozotoceros* ssp., *Przewalskium* ssp., *Pudu ssp., Rangifer* ssp., *Rucervus* ssp., *Rusa* ssp.
	Giraffidae	*Giraffa* ssp., *Okapia* ssp.
	Hippopotamidae	*Hexaprotodon–Choeropsis* ssp., *Hippopotamus* ssp.
	Moschidae	*Moschus* ssp.
	Suidae	*Babyrousa ssp., Hylochoerus ssp., Phacochoerus ssp., Porcula ssp., Potamochoerus ssp., Sus ssp.*
	Tayassuidae	*Catagonus* ssp., *Pecari–Tayassu* ssp.
	Tragulidae	*Hyemoschus* ssp., *Tragulus–Moschiola* ssp.
Proboscidea	*Elephantidae*	*Elephas* ssp., *Loxodonta* ssp.

ANNEX IV

Criteria for the application of the disease prevention and control rules referred to in Article 9(1) to diseases listed in accordance with Article 5

The scope of this Annex is to detail the criteria to be considered by the Commission when determining the disease prevention and control rules to be applied to the different categories of diseases listed in accordance with Article 5.

The process of categorisation shall take into account the profile of the disease in question, the level of the impact of that disease on animal and public health, animal welfare and the economy, and the availability, feasibility and effectiveness of the diagnostic tools and different sets of disease prevention and control measures provided for in this Regulation with respect to the disease.

SECTION 1

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (A) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (a) of Article 9(1) apply shall be considered to have the most severe animal health, public health, economic, social or environmental impacts on the Union. Those diseases need to fulfil the following criteria:

(a) the disease in question is:

(i) not present in the territory of the Union;

(ii) present only in exceptional cases (irregular introductions); or

(iii) present in only in a very limited part of the territory of the Union;

and

(b) the disease in question is highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. The disease may affect multiple species of kept and wild animals, or a single species of kept animals of economic importance, and may result in high morbidity and significant mortality rates.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with in particular an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

SECTION 2

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (B) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (b) of Article 9(1) apply shall be controlled in all Member States with the goal of eradicating them throughout the Union.

Those diseases need to fulfil the following criteria:

(a) the disease in question is endemic in nature and is present in the whole or part of the Union territory. However, several Member States or zones of the Union are free of the disease; and

(b) the disease is moderately to highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. It may affect single or multiple animal species and may result in high morbidity, with in general low mortality.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease has a significant impact on one or more of the following:

(i) society, with in particular an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

A disease to which the measures referred to in point (a) of Article 9(1) apply, which has not been successfully and promptly eradicated in a part of the Union, and has, in that part of the Union, obtained an endemic character, may be subject to disease prevention and control measures under point (b) of Article 9(1), in that part of the Union.

SECTION 3

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (C) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (c) of Article 9(1) apply are of relevance to some Member States and measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease in question.

Those diseases need to fulfil the following criteria:

(a) in terrestrial animals, the disease in question is endemic in nature and is present in the whole or part of the Union territory; or in aquatic animals, several Member States or zones of the Union are free of the disease; and

(b) (i) in terrestrial animals, the disease in question is moderately to highly transmissible, mainly through direct and indirect transmission. The disease mainly affects multiple or single animal species, usually does not result in high morbidity, and has a negligible or no mortality rate. Often the most observed effect is production loss;

(ii) in aquatic animals, the disease is moderately to highly transmissible, mainly through direct and indirect transmission. The disease affects multiple or single animal species and may result in high morbidity and usually low mortality. Often the most observed effect is production loss.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, or possible threats to food safety;

(d) the disease in question has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems.

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with, in particular, an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or of the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

SECTION 4

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (D) OF ARTICLE 9(1)

The disease prevention and control rules referred to in point (d) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Section 1, 2 or 3 and to other diseases fulfilling the criteria set out in Section 5 where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread.

SECTION 5

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (E) OF ARTICLE 9(1)

The disease prevention and control rules referred to in point (e) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Sections 1, 2 or 3 and to other diseases where surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment.

ANNEX V

Correlation table referred to in Article 270(2)

1. **Directive 64/432/EEC**

Directive 64/432/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 21, 153(3) and 220(3)
Article 3(1)	Articles 124 and 126
Article 3(2)	Articles 124(2), 126(1) and 149(3) and (4)
Article 4(1)	Article 126(1)(c)
Article 4(2) and (3)	Article 125(1) and (2)
Article 5(1)	Articles 143(1), 145 and 146
Article 5(2)	Article 149(3) and (4)
Article 5(2)(a)	Article 147(a)
Article 5(2)(b)	Article 144(1)(b)
Article 5(3)	—
Article 5(4)	Article 153(1) and (2)
Article 5(5)	Article 147(a)
Article 6	Articles 130, 131 and 132
Article 6a	—
Article 7	Articles 126(1)(c),132, 134(a) and 135
Article 8	Articles 18, 19, 20 and 23(a)
Article 9	Articles 31(1), (3)(a) and (5), 32, 33 and 36
Article 10	Articles 31(2) and (3)(b), 32, 33 and 36
Article 11(1)	Articles 94(1)(a), 97 and 98
Article 11(2)	Articles 102, 106 and 107
Article 11(3)	Articles 98 and 99
Article 11(4)	Article 100
Article 11(5) and (6)	Article 97(1)(d) and (2)(d)
Article 12(1)	Article 125
Article 12(2)	Articles 104 and 106
Article 12(3)	Article 125(1)(a) and (b)
Article 12(4)	Article 143
Article 12(5) and (6)	—
Article 13(1) and (2)	Articles 90, 92, 93(c), 94, 97, 98, 99, 102, 106 and 107

Directive 64/432/EEC	This Regulation
Article 13(3)	Article 100
Article 13(4)	—
Article 13(5) and (6)	Article 101
Article 14(1) and (2)	—
Article 14(3)A and B	—
Article 14(3)C	Article 109(1)(a) and (c)
Article 14(4) to (6)	—
Article 15(1)	Article 268
Article 15(2) to (4)	—
Article 16	—
Article 17	—
Article 17a	—
Article 18	Article 109(1)(a) and (c)
Article 19	—
Article 20	—

2. **Directive 77/391/EEC**

Directive 77/391/EEC	This Regulation
Article 1	—
Article 2(1)	Article 31(1)
Article 2(2)	Articles 32, 33 and 36(1)
Article 2(3)	Article 34
Article 2(4)	Articles 36 and 41
Article 3(1)	Article 31(1)
Article 3(2)	Articles 32, 33 and 36(1)
Article 3(3)	Article 34
Article 3(4)	Articles 36 and 41
Article 4	Articles 31(1), 32, 33, 34, 36 and 41
Article 5	—
Article 6	—
Article 7	—
Article 8	—
Article 9	—
Article 10	—
Article 11	—

Directive 77/391/EEC	This Regulation
Article 12	—
Article 13	—
Article 14	—
Article 15	—

3. **Directive 78/52/EEC**

Directive 78/52/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3(1)	Articles 31(1) and 32
Article 3(2)	—
Article 3(3)	—
Article 3(4)	Articles 31(1) and 32
Article 4	Articles 32.35, 102(2) and (4) and 112
Article 5	Articles 18, 46 and 47
Article 6(1)	Articles 72 to 76
Article 6(2)	Articles 77 and 78
Article 6(3)	Articles 79 and 80
Article 7	Articles 79 and 80
Article 8	Articles 79 and 80
Article 9	Articles 79 and 80
Article 10	Articles 79 and 80
Article 11	Articles 79 and 80
Article 12	Articles 79 and 80
Article 13	Articles 18, 46 and 47
Article 14(1)	Articles 72 to 76
Article 14(2)	Articles 77 and 78
Article 14(3)	Articles 79 and 80
Article 15	Articles 79 and 80
Article 16	Articles 79 and 80
Article 17	Articles 79 and 80
Article 18	Articles 79 and 80
Article 19	Articles 79 and 80
Article 20	Articles 79 and 80
Article 21	—
Article 22	Articles 18, 19, 20, 46 and 47
Article 23	Articles 79 and 80

Directive 78/52/EEC	This Regulation
Article 24	Articles 79 and 80
Article 25	Articles 79 and 80
Article 26	Articles 79 and 80
Article 27	Articles 124(1) and 126(1)(c)
Article 28	—
Article 29	—
Article 30	—

4. **Directive 80/1095/EEC**

Directive 80/1095/EEC	This Regulation
Article 1	Articles 31(1) and 36
Article 2	Article 4 (partially)
Article 3	Articles 31(1) and 35
Article 3a	Articles 31(1) and 35
Article 4	Articles 32, 33 and 35
Article 4a	Articles 32, 33 and 35
Article 5	—
Article 6	Articles 31(1)(b), 31(3) and 32
Article 7	Articles 36, 39 and 40
Article 8	Articles 41 and 42
Article 9	—
Article 11	—
Article 12	—
Article 12a	—
Article 13	—

5. **Directive 82/894/EEC**

Directive 82/894/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 19, 21, 22 and 23
Article 4	Articles 19, 20, 21, 22 and 23
Article 5	Article 23

Directive 82/894/EEC	This Regulation
Article 6	—
Article 7	—
Article 8	—

6. **Directive 88/407/EEC**

Directive 88/407/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 159 and 160
Article 4	Article 160
Article 5	Articles 94, 97, 100 and 101
Article 6(1)	Articles 161 and 162
Article 6(2), (3) and (4)	Article 258
Article 8	Articles 229(1)(a) and 230
Article 9	Articles 229(1)(b) and 233
Article 10	Articles 229(1)(c), 234 and 236
Article 11	Articles 229(1)(d), 237 and 238
Article 12	Articles 260 to 262
Article 15	Articles 257 to 259
Article 16	—
Article 17	—
Article 18	—
Article 20	—
Article 21	—
Article 22	—

7. **Directive 89/556/EEC**

Directive 89/556/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 159, 160, 161
Article 5(1)	Articles 94 and 97
Article 5(2)	Article 101
Article 5(2a) and (3)	Articles 97, 98 and 100
Article 6	Articles 161 and 162
Article 7	Articles 229(1)(a) and 230

Directive 89/556/EEC	This Regulation
Article 8	Articles 229(1)(b) and 233
Article 9	Articles 229(1)(c), 234 and 236
Article 10	Articles 229(1)(d), 237 and 238
Article 11	Articles 260 to 262
Article 14	Articles 257 to 259
Article 15	—
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
Article 21	—

8. **Directive 90/429/EEC**

Directive 90/429/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 159 and 160
Article 4	—
Article 5(1)	Articles 94, 97, 98 and 100
Article 5(2)	Article 101
Article 6(1)	Articles 161 and 162
Article 6(2)	Article 258
Article 7	Articles 229(1)(a) and 230
Article 8	Articles 229(1)(b) and 233
Article 9	Articles 229(1)(c), 234 and 236
Article 10	Article 229(1)(d), 237 and 238
Article 11(1)	Article 229
Article 11(2) and (3)	Article 260
Article 12	Article 237
Article 13	—
Article 14	—
Article 15	Articles 257 to 262
Article 16	—
Article 17	—
Article 18	—

Directive 90/429/EEC	This Regulation
Article 19	—
Article 20	—
Article 21	—
Article 22	—

9. **Directive 91/68/EEC**

Directive 91/68/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 21, 153(3) and 220(3)
Article 3(1), (2), (3) and (5)	Articles 126(1)(b), 130 and 131
Article 3(4)	Article 139
Article 4(1)	Articles 124(2)(b), 126(1), 130, 131 and 149(3) and (4)(a) and (b)
Article 4(2)	Article 128
Article 4(3)	Article 131
Article 4a	Articles 130 and 131
Article 4b(1) and (2)	Articles 130 and 131
Article 4b(3)	Article 126(2)
Article 4b(4)	Article 133
Article 4b(5)	Article 132
Article 4b(6)	Articles 124(1), 125 and 126(1)(b)
Article 4c(1) and (2)	Articles 130 and 131
Article 4c(3)	Articles 133 and 135
Article 5	Article 131
Article 6	Articles 131 and 145(1)(e)
Article 7(1) to (3)	Articles 31, 32, 33 and 35
Article 7(4)	—
Article 8(1) to (3)	Articles 36, 39 and 40
Article 8(4)	—
Article 8a(1)	Articles 94(1)(a), 97, 98 and 134
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10. **Decision 91/666/EEC**

Decision 91/666/EEC	This Regulation
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11. **Directive 92/35/EEC**

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Article 12	Article 71(1)
Article 13	Article 65(2)
Article 14	—
Article 15	—
Article 16	—
Article 17	Articles 43 and 44
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Article 19	—
Article 20	—
Article 21	—
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12. **Directive 92/65/EEC**

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Article 12(6)	Article 268
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Article 13(2)	Articles 95, 97 and 98 to 101
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Article 17(1)	Article 229(1)
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Article 19	Articles 234 and 239

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Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—

13. **Directive 92/66/EEC**

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Article 5	Articles 60 to 63
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Article 12	Articles 54, 61(1)(h) and 63(c)
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Directive 92/66/EEC	This Regulation
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Article 23	—
Article 24	—
Article 25	—
Article 26	—
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14. **Directive 92/118/EEC**

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Article 5	Articles 166 and 222
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Article 7(2)	Articles 257 to 259
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Article 7(5)	Article 268
Article 8	—
Article 9	Articles 229 and 234
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Article 13	Article 239(2)(c)(i)
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Directive 92/118/EEC	This Regulation
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Article 17	—
Article 18	—
Article 19	—
Article 20	—

15. **Directive 92/119/EEC**

Directive 92/119/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 18
Article 4	Articles 53 to 57 and 59
Article 5	Articles 60 to 63
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Article 7	Article 63
Article 8	Articles 57 and 43(2)(d)
Article 9	Articles 55 and 57
Article 10	Articles 64 and 71(3)
Article 11	Articles 65 to 68 and 71(2)
Article 12	Articles 65 to 68 and 71(2)
Article 13	Article 67(a)
Article 14	Articles 65(2) and 71(1) and (3)
Article 15	—
Article 16	Articles 63(b), 67(b) and 68(1)(b) and (2)(a)
Article 17	—
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Article 21	—
Article 22	—
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Article 24	—
Article 25	—

Directive 92/119/EEC	This Regulation
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Article 27	—
Article 28	—

16. **Decision 95/410/EC**

Decision 95/410/EC	This Regulation
Article 1	Articles 130 to 132 and 273
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Article 3	Articles 143, 145 and 146
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17. **Directive 2000/75/EC**

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Article 9	Articles 65, 67, 69 and 71(3)
Article 10(1)	Articles 65 and 67
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Article 11	—
Article 12	Article 71(3)
Article 13	Article 71(1)
Article 14	Article 65(2)
Article 15	—
Article 16	—

Directive 2000/75/EC	This Regulation
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Article 20	—
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18. **Regulation (EC) No 1760/2000**

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Article 1	Article 108
Article 2	Article 4 (partially)
Article 3	Articles 108(3) and 111
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Article 4b	Article 118(2)(e)
Article 4c	Article 118(1)(a) and (2)(a)
Article 4d	Article 118(1)(a)
Article 5	Articles 109(1)(a) and 118(1)(b)
Article 6	Articles 110(1)(b), 112(b) and 118(1)(c)
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Article 7(1)	Articles 102, 106, 107 and 112(d)
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Article 7(3) and (4)	Article 102(3)
Article 7(5)	Article 102(4)
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Regulation (EC) No 1760/2000	This Regulation
Article 14	—
Article 15	—
Article 15a	—
Article 22	—
Article 22a	—
Article 22b	—
Article 23	—
Article 23a	—
Article 23b	—
Article 24	—
Article 25	—

19. **Directive 2001/89/EC**

Directive 2001/89/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 18, 19, 20 and 23
Article 4	Articles 54 to 56 and 59
Article 5	Articles 60 to 63 and 71(2) and (3)
Article 6	Articles 63 and 71
Article 7	Articles 62, 63, 65(1)(b) and 67
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65 to 68
Article 11	Articles 65 to 68
Article 12	Articles 61(1)(f), 63(b), 65(1)(f), 67(b) and 68(1)(b) and (2)(a)
Article 13	Articles 61(3), 63(d) and 68(2)(a) and (c)
Article 14	Articles 62 and 63
Article 15	Article 70
Article 16	Article 70 and Articles 31 to 35

Directive 2001/89/EC	This Regulation
Article 17	Articles 16, 17(2), 54(2) and (3), 58(2), 61(1)(g) and (h), 63 (c), 65(1)(b) and 67(c)
Article 18	Articles 16, 46 47, 48 and 52
Article 19	Articles 65(1)(e), 67 and 69
Article 20	Article 70
Article 21	—
Article 22	Articles 43 and 44
Article 23	Articles 43(2)(d) and 44
Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—
Article 31	—
Article 32	—

20. **Directive 2002/60/EC**

Directive 2002/60/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 18, 19, 20 and 23
Article 4	Articles 54 to 56 and 59
Article 5	Articles 60 to 63 and 71(2) and (3)
Article 6	Articles 63 and 71
Article 7	Articles 62 and 63
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65 to 68
Article 11	Articles 65 to 68
Article 12	Article 61(1)(f), 63(b), 65(1)(f), 67(b) and 68(1)(b)

Directive 2002/60/EC	This Regulation
Article 13	Articles 61(3), 63(d) and 68(2)(a) and (c)
Article 14	Articles 62 and 63
Article 15	Article 70
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Article 17(1)	Articles 61(1)(f), 63, 65(1)(f) and (i), and 67(a) and (d)
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Article 18	Articles 16, 17(2), 54(2) and (3), 58(2), 61(1)(g) and (h), 63 (c), 65(1)(b) and 67(c)
Article 19	Articles 16, 46 and 47
Article 20	—
Article 21	Articles 43 and 44
Article 22	Articles 43(2)(d) and 44
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Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—

21. **Directive 2002/99/EC**

Directive 2002/99/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 166, 222 and 227(c)(iv)
Article 4	Articles 65(1)(c),(d), (g),(h) and (i), 67, 166, 222, 227(c)(iv) and 228(1)(d)
Article 5	Articles 167, 168, 223, 224 and 227(d)(iii)
Article 6	—
Article 7	Article 234(1) and (2)

Directive 2002/99/EC	This Regulation
Article 8	Articles 230, 231 and 232
Article 9	Articles 237 and 238
Article 10	—
Article 11	—
Article 12	—
Article 13	—
Article 14	—
Article 15	—
Article 16	—

22. **Directive 2003/85/EC**

Directive 2003/85/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 18, 19, 20 and 23
Article 4	Articles 54 to 56
Article 5	Article 55(1)(d), (e) and (2)
Article 6	Articles 55(1)(f)(i) and (2), and 56(b)
Article 7	Article 55(1)(f)(ii)
Article 8	Article 55(1)(f) and (2)
Article 9	Article 59
Article 10	Articles 60, 61 and 63
Article 11	Articles 61(1)(f), 63(b), 65(1)(f), 67(b) and 68(1)(b)
Article 12	Article 65(1)(d), (h) and (i) and Article 67
Article 13	Article 57
Article 14	Articles 61 to 63
Article 15	Articles 61 to 63, 70 and 71(2)
Article 16	Articles 61, 62 and 63
Article 17	Article 71
Article 18	Articles 61 and 63
Article 19	Articles 62 and 63
Article 20	Article 71

Directive 2003/85/EC	This Regulation
Article 21	Articles 43(2)(d), 64, 65(1)(d), (h) and (i) and (2) and 67
Article 22	Articles 65 to 67
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Article 24	Articles 67 and 71(1)
Article 25	Articles 65(1)(c), (d)(i), (g), (h) and (i) and 67
Article 26	Articles 65(1)(c), (d)(i), (g), (h) and (i), 67 and 166
Article 27	Articles 65(1)(c), (d)(i), (g), (h) and (i), 67 and 166
Article 28	Articles 65(1)(c) and (d)(iii) and Article 67
Article 29	Articles 65(1)(c) and (d)(ii) and 67
Article 30	Articles 65(1)(c) and (d)(ii) and (iii) and 67
Article 31	Articles 65(1)(c) and (d)(ii) and 67
Article 32	Articles 65(1)(c) and (d) and 67
Article 33	Article 65(1)(c)(d)(ii) and 67
Article 34	Articles 67, 143(2), 161(2) and 167(1)(b)
Article 35	Article 71(1) and (2)
Article 36	Article 68
Article 37	Articles 65 to 67
Article 38	Articles 65 to 67
Article 39	Articles 65(1)(c), (d)(i), (g), (h) and (i), 67 and 166
Article 40	Articles 65(1)(c), (d)(i), (g), (h) and (i), 67 and 166
Article 41	Articles 65(1)(c) and (d)(ii) and 67
Article 42	Articles 65(1)(c) and (d) and 67
Article 43	Article 71(1)
Article 44	Article 68
Article 45	Articles 64, 67 and 71
Article 46	Articles 65 and 67

Directive 2003/85/EC	This Regulation
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Article 48	Article 66
Article 49	Articles 16, 46 and 47
Article 50	Articles 46.47 and 69
Article 51	Articles 47 and 69
Article 52	Articles 46 and 47
Article 53	Articles 46 and 47
Article 54	Articles 47, 65, 67 and 69(2) and(3)
Article 55	Articles 47, 65, 67, and 69(2) and (3)
Article 56	Articles 47, 67(c), 68(1)(c) and 69(2) and (3)
Article 57	Articles 47, 67(c), 68(1)(c) and 69(2) and (3)
Article 58	Article 68
Article 59	Articles 36, 38, 39, 40 and 68
Article 60	Articles 36, 38, 39, 40 and 68
Article 61	Articles 36, 38, 39, 40 and 68
Article 62	Article 68
Article 63	Articles 143(2), 161(2) and 167(1)(b)
Article 64	Articles 65(1)(c), 67, 69(3) and 131
Article 65	Article 16
Article 66	—
Article 67	—
Article 68	—
Article 69	—
Article 70	Article 16
Article 71	Articles 54(2) and (3), 58(2), 61(1)(g) and (h), 63(c), 65(1)(b), 67(c) and 68(1)(c) and 2(b)
Article 72	Article 43
Article 73	Article 45
Article 74	Article 43(2)(d)
Article 75	Article 44
Article 76	Articles 43(2)(d) and 44
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Directive 2003/85/EC	This Regulation
Article 78	Article 43(2)(d)
Article 79	Article 52
Article 80	Articles 48 and 51
Article 81	Articles 48(3) and 50
Article 82	Articles 48(3) and 50
Article 83	Article 49
Article 84	Articles 48(3) and 50
Article 85	Articles 70 and 71
Article 86	Article 268
Article 87	—
Article 88	Article 71(3)
Article 89	—
Article 90	—
Article 91	—
Article 92	—
Article 93	—
Article 94	—
Article 95	—

23. **Regulation (EC) No 21/2004**

Regulation (EC) No 21/2004	This Regulation
Article 1	Article 108
Article 2	Article 4 (partially)
Article 3(1)	Article 108(3)
Article 3(2)	Article 111
Article 4(1) and (2)	Articles 113(a), 118, 119 and 120
Article 4(3)	Article 118(2)(a)
Article 4(4)	Article 118(2)(e)
Article 4(5) to (7)	Article 118(1)(a) and 2(a)
Article 4(8)	Article 111
Article 4(9)	Article 118(1)(a) and (2)(a)
Article 5	Articles 102, 106, 107 and 111

Regulation (EC) No 21/2004	This Regulation
Article 6	Articles 111(b), 113(1)(b) and (2), 118(1)(b)(ii), 119 and 120 (2)(d)
Article 7	Article 101
Article 8(1)	Articles 109(1)(b) and 118(1)(b)
Article 8(2)	Article 113(1)(c)
Article 8(3) to (5)	Articles 109 and 118(1)(b)
Article 9	Article 118(1)(a) and 2(a)
Article 10(1)	—
Article 10(2)	Article 120(2)(c)
Article 11	Articles 11 and 13(2)
Article 12(1)	—
Article 12(2)	Article 268
Article 12(4) to (7)	—
Article 13	—
Article 14	—
Article 15	—
Article 16	—
Article 17	—

24. **Directive 2004/68/EC**

Directive 2004/68/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3(1)	Articles 229(1)(a) and 231
Article 3(2)	Article 232(1)
Article 4	Article 230(1)
Article 5	Articles 230(1) and (3) and 231
Article 6	Articles 234 and 235
Article 7	Articles 229(2), 234(2)(a), 235 and 238(1)(e)
Article 8	Articles 234, 237(4)(a) and 239(2)(a)
Article 9	Articles 234(2), 235 and 237 (4)(a)

Directive 2004/68/EC	This Regulation
Article 10	Articles 234(2), 235 and 237(4)(a)
Article 11	Articles 229(1)(d), 237 and 238
Article 12	—
Article 13	—
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Article 16	—
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Article 19	—
Article 20	—
Article 21	—

25. **Directive 2005/94/EC**

Directive 2005/94/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 10
Article 4	Articles 26, 28 and 29
Article 5	Articles 18, 19, 20 and 23
Article 6	Article 57
Article 7	Articles 54 to 56
Article 8	Article 55(2)
Article 9	Article 59
Article 10	Articles 55(1)(e) and (f) and 56
Article 11	Articles 61 and 63
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Article 14	Article 63(a)
Article 15	Articles 62 and 63(e)
Article 16	Article 64
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Article 18	Articles 65(1)(a) and (b) and 67
Article 19	Articles 65 to 67
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Article 22	Articles 65(1)(c) and (i) and 67
Article 23	Articles 65(1)(c) and 67
Article 24	Articles 65(1)(c) and 67
Article 25	Articles 65(1)(c) and 67
Article 26	Articles 65(1)(c) and 67
Article 27	Articles 65(1)(d)(ii) and 67
Article 28	Articles 65(1)(f) and 67(b)
Article 29	Article 68
Article 30	Articles 65 to 67
Article 31	Article 68
Article 32	Articles 65, 67 and 71(2) and (3)
Article 33	Articles 67 and 71(3)
Article 34	Article 71
Article 35	Articles 54 and 61
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Article 37	Articles 61 to 63
Article 38	Articles 61, 63, 65 and 67
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Article 41	Articles 61.63 and 71(2) and (3)
Article 42	Articles 62 and 63(e)
Article 43	Article 64
Article 44	Articles 65 and 67
Article 45	Article 68
Article 46	Articles 64(4), 67 and 71(2) and (3)
Article 47	Articles 54, 55, 61, 63 and 71
Article 48	Article 68(1)(b) and (2)(a)
Article 49	Articles 61(3) and 68
Article 50	Articles 16, 54(2)(b) and (c) and (3), 58(2), 61(1)(g) and (h), 63(c), 65(1)(b), 67(c), 68(1)(c) and 2(b)
Article 51	—
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Directive 2005/94/EC	This Regulation
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Article 54	Articles 47, 65(1)(e), 67, 69 and 71(3)
Article 55	Articles 47, 65(1)(e), 67, 69 and 71(3)
Article 56	Articles 46 and 47
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Article 58	Articles 48 to 50
Article 59	Article 52
Article 60	—
Article 61	Article 268
Article 62	Articles 43 and 44
Article 63	—
Article 64	—
Article 65	—
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Article 67	—
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26. **Directive 2006/88/EC**

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Article 1	—
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Article 3	Article 4 (partially)
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Article 4(2)	Article 179
Article 4(3)	Article 185(2)
Article 4(4)	Articles 172, 173, 174 and 175
Article 4(5)	—
Article 5	Article 181
Article 6	Article 185
Article 7	—
Article 8	Articles 186, 187, 188 and 189
Article 9	Article 181(1)(a)(i), (2) and (3)
Article 10	Article 181(1)(a)(ii), (2) and (3)
Article 11	Articles 191 and 204

Directive 2006/88/EC	This Regulation
Article 12	Article 191
Article 13	Article 192
Article 14(1) and (2)	Articles 208 and 211
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Article 15(3)	Article 193
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Article 16	Article 197
Article 17	Article 197
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Article 20	Article 200
Article 21	Articles 200, 203, 205 and 226
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Article 28	Articles 53 to 55 and 72 to 74
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Article 32	Articles 60, 61, 62 and 64
Article 33	Articles 65 to 67
Article 34	Articles 61(1)(b)and (c) and Article 63
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Article 37	Article 68
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Article 39	Articles 79 and 80
Article 40	Article 81
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Article 42	Article 71(3)
Article 43	Article 226

Directive 2006/88/EC	This Regulation
Article 44	Articles 27, 28, 31 and 32
Article 45	Article 33
Article 46	Article 31(2)
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Article 48	Article 46 and 47
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Article 57(a)	—
Article 57(b)	Articles 54(2)(c) and (3), 58, 61(1)(g) and (h), 63(c), 65(1)(b) and 67(c)
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27. **Directive 2008/71/EC**

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Article 3(2)	Articles 118(2) and 119
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Article 5(1)	Articles 115(a), 118(1)(a) and (2)(a) and 120
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28. **Directive 2009/156/EC**

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Article 2	Article 4 (partially)
Article 3	Articles 126 and 139
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Article 8	Articles 114(1)(c), 118, 120 and 143 to 146
Article 9	Articles 257 to 259 (partially)
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Article 12(1),(2) and (3)	Articles 229(1)(a), 230 and 231
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29. **Directive 2009/158/EC**

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Article 2	Article 4 (partially)
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Article 4	—
Article 5	Articles 126, 130, 131, 159 and 160
Article 6	Articles 124, 126 and 159
Article 7	Article 101
Article 8	Articles 159 and 160
Article 9	Articles 130 and 131
Article 10	Articles 130, 131 and 149(3) and (4)
Article 11	Articles 130, 131 and 149(3) and (4)
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Article 13	Articles 131 and 273
Article 14	Article 131
Article 15(1)(a)	Articles 159 and 160
Article 15(1)(b) to (d)	Articles 130 and 131
Article 15(2)	Articles 31 to 35 and 36(3)
Article 15(3)	Article 42
Article 16	Articles 31 to 35
Article 17	Articles 36, 39 and 40
Article 18	Articles 117, 118(2)(e), 122(2), 124, 125, 126(1)(a) and (2), 132 and 157(3)
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Article 23	Articles 229(1)(a), 230 and 231
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30. **Regulation (EU) No 576/2013**

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Regulation (EU) No 576/2013	This Regulation
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Article 4	Article 245(1)
Article 5(1) and (2)	Article 246(1) and (2)
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Article 5(4)	Articles 3(4) to (6)
Article 5(5)	Article 246(3)
Article 5(6)	—
Article 6	Articles 247 and 252(1)(a) and (b)
Article 7	Article 252(1)(b) and (4)(d)
Article 8(1) and (3)	Article 252(1)(b) and (d)
Article 8(2)	Article 253(1)(b)
Article 9	Articles 248 and 252(1)(a) and (b)
Article 10	Articles 249 and 252(1)(a) and (b)
Article 11	Article 252(1)(b) and (4)(d)
Article 12	Article 252(1)(b) and (4)(d)
Article 13	Articles 252(4)(d) and 253(1)(d)
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Article 23	Article 254(b)
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Article 25	Articles 254(a) and 255(1)
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Article 28	Articles 254(a) and 255(2)(a)
Article 29	Article 254(d)
Article 30	Articles 254(a) and 255(2)(a)
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Article 36	Articles 257 to 262
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