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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on Animal Health - Political agreement

Proposal for a Regulation of the European Parliament and of the Council on
transmissible animal diseases ("Animal Health Law")

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 Committee¹,

¹ OJ C , , p. .

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The impact of transmissible animal diseases and the measures necessary to control these 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, the rational development of the agriculture and aquaculture sectors and to increase productivity, animal health rules should be laid down at Union level. These rules are necessary, inter alia, to contribute to the completion of the internal market, and to avoid the spread of infectious diseases. **These rules should also as far as possible ensure that the existing animal health status in the Union is maintained and consequent improvement of the status is supported.**
 - (5) The current Union animal health legislation 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, providing harmonised principles across the sector is missing.
- (5a) Financial rules relating to the support of animal health objectives are provided for in Regulation (EU) No 652/2014 and do not form part of this Regulation. In addition, the rules covering the official controls of animal health measures provided for in Regulation (EU) No 882/2004 of the European Parliament and of the Council and in Council Directives 89/662/EEC, 90/425/EEC, 91/496/EEC and 97/78/EC should be used for that purpose.**

² OJ C , , p. .

- (5b) **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 TFEU, should be considered in order to spare the animals any avoidable pain, distress or suffering. Animal welfare legislation, such as Regulation (EC) No 1/2005 and Regulation (EC) No 1099/2009 should necessarily continue to apply and be properly implemented. The rules in this Regulation should not duplicate or overlap them.**
- (6) The Animal Health Strategy for the Union (2007– 2013) proposes that ‘Prevention is better than cure’ and was adopted by the Commission in its Communication of 19 September 2007 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions³. It aims to **promote animal health through** putting greater focus 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 to international standards while ensuring a firm commitment to high standards of animal health.
- (7) 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.
- (8) Animals may suffer from a broad range of infectious or non-infectious diseases. Many diseases can be treated, 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 on a population level. The animal health rules laid down in this Regulation should only be limited to those latter diseases.
- (9) In laying down those animal health rules, it is essential that considerations are given to the link between animal health and public health, the environment, food and feed safety, animal welfare, food security, economic, social and cultural aspects.

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COM (2007) 539 final.

- (10) [...] The **Sanitary and Phytosanitary Measures (SPS) Agreement, to which the European 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 WTO members. If international standards exist, they are required to be used as a basis. However, the members have the right to set their own relevant standards provided that such standards are based on scientific evidence.
- (11) As regards animal health the SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE) as regards animal health conditions for international trade. In order to reduce the risk of trade disruption, EU measures on animal health should aim for an appropriate level of convergence with OIE standards.
- (12) 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 Communication from the Commission of 2 February 2000 on the precautionary principle⁴ allows a Member of that agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the WTO Member is required to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.
- (13) 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 established by Article 22(1) of 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 safety⁵.

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COM(2000) 1 final

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OJ L 31, 1.2.2002, p. 1

- (14) 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)⁶ 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 these issues are duly covered by this Regulation.
- (15) 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 of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies⁷, 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/EEC⁸ and 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 agents⁹, and specific rules on communicable diseases in humans in Decision No [...] **1082/2013/EU** of the European Parliament and of the Council of [...] **22 October 2013 on serious cross-border threats and repealing Decision No 2119/98/EC**¹⁰. 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.**

⁶ OJ L 300, 14.11.2009, p. 1

⁷ OJ L 147, 31.5.2001, p. 1.

⁸ OJ L 325, 12.12.2003, p. 31.

⁹ OJ L 325, 12.12.2003, p. 1.

¹⁰ OJ L 293, 5.11.2013, p. 1.

- (15b) Diseases occurring in animals which are kept by humans can have severe impacts on the agriculture and aquaculture sectors, on public health, the environment and biodiversity. However, as they are kept by humans, disease prevention and control measures are often easier to apply to kept animals than to wild animals.**
- (16) **Nevertheless**, diseases occurring in wild animal populations may have a detrimental effect on the agriculture and aquaculture sectors, on public health, the environment and 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.**
- (17) 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, ova and embryos used in artificial insemination, ovum 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.
- (18) Animal diseases may have detrimental effects on the distribution of animal species in the wild, and thus affect biodiversity. Microorganisms causing animal diseases can therefore fall within the definition of invasive alien species 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.

- (19) In Union legislation adopted prior to this Regulation separate animal health rules are laid down for terrestrial and aquatic animals. 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 animals¹¹ 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, the scope of this Regulation should cover both terrestrial and aquatic animals and aligns 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.
- (20) Union legislation adopted prior to this Regulation and in particular 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/EEC¹² 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 represent 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 for detailed animal health rules for movements of such animals and their products to be laid down if the risks involved so require.

¹¹ OJ L 328, 24.11.2006, p 14.

¹² OJ L 268, 14.9.1992, p. 54.

- (21) [...] **Natural persons often keep certain animal species as pet animals 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 represents a lower health risk compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture, **aquaculture, animal shelters and the transport of animals more generally.** Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union 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.
- (22) 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 broad scope of the group. This is the case for the group of hoofed mammals classified as ungulates. This list 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the lists of [...] ungulates set out in Annex [...] II to this Regulation.
- (23) Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example, if the disease is too widespread, 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 disrupt trade. It is therefore essential that such measures are only applied when proportionate and necessary, such as when a disease presents or is suspected to present a significant risk to animal or public health.
- (24) Furthermore, the preventive and control measures for each transmissible animal disease should be "tailor-made" in order to address its unique epidemiological profile and its consequences **and its distribution within the Union.** The preventive and control rules applying to each of them should therefore be disease specific.
- (25) 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.

- (26) 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 national rules.
- (27) 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 actions to prevent or control such diseases, for instance through self-regulatory measures or the development of codes of practice.
- (28) In contrast to the transmissible animal diseases described in recitals 26 and 27, highly transmissible animal diseases may easily spread across borders and, if they are also a zoonosis, 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.
- (29) **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 of the Communication from the Commission to the European Parliament and the Council – Action plan against the rising threats from Antimicrobial Resistance¹³ emphasises the preventive role of 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 thus it may present 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.**

¹³

COM (2011) 748.

- (30) New hazards associated with certain diseases or species may develop in particular due to changes in **trade patterns**, the environment, the climate, animal husbandry, farming traditions but also through social changes. Scientific progress may also lead to new knowledge and increased awareness concerning 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"¹⁴ and a tool for such an exercise, which aims to develop a system of disease prioritisation and categorisation. [...] This tool is an example of a systematic approach to the collection and assessment of information about animal diseases.
- (31) [...] **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 this is across the whole Union or only in parts. [...]**

The five diseases already identified in this Regulation should be complemented by an Annex.

The Commission should review and amend the 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.

¹⁴ <http://www.oie.int/en/support-to-oie-members/global-studies/categorisation-of-animal-diseases/>

- (32) Emerging diseases with the potential to cause serious public or animal health risks and impacts on health, the economy or the environment may appear in the future. [...] **The implementing powers to lay down disease prevention and control measures for 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.**
- (33) 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 obtain an endemic character, a long term compulsory eradication programme will be required.** For other diseases that might 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 testing prior to dispatch. In other instances it might be appropriate only to implement surveillance of the disease's distribution, without taking further measures. [...]
- (34) 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. [...]
- (35) The prevention and control rules of this Regulation for a specific transmissible animal disease should apply to species of animals which can transmit the disease in question, by 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 should apply at Union level ('listed species') and thus implementing powers to lay down such a list should be conferred on the Commission.

- (36a) **The categorisation process should be based on [...] predefined criteria such as the profile of the listed disease, [...] the level of its impact on animal and public health, animal welfare and the economy in the Union, the risk of its spreading and the availability of disease prevention and control measures in respect of that listed disease [...]. Implementing powers to lay down which listed diseases are to be subject to which rules, should be conferred on the Commission.**
- (36) **Such rules should apply as regards listed diseases that do normally not occur in the Union and for which immediate eradication measures should imperatively be taken as soon as they are detected, as for example classical swine fever, as regards listed diseases which should be controlled in all Member States with the goal of eradicating them throughout the Union, which could include types of 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 or that have eradication programmes for that listed disease, which could include types of 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 types of 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 types of diseases such as anthrax.**

[...]

- (37a) **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 amend which category a particular listed disease falls into, and therefore which measures it is subject to.**
- (38) Operators [...] working with animals are in the best position to observe and ensure the health of the animals and products under their responsibility. They should therefore hold primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and products under their responsibility.

- (39) 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 the EU Animal Health Law and possible impacts are specifically assessed. [...] **The biosecurity measures [...] 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 in the Member States. [...]**

Nevertheless, it always remains 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 result of reduction in animal disease should be a positive incentive for operators.

- (40) 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 as well as during animal transport. They should therefore be considered a part of biosecurity.
- (41) 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 European farmer organisations and other organisations may be valuable contributors. [...]
- (42) 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.

(43) Veterinarians have the education and the professional qualifications which ensure that they have 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 who 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 Aquatic Animal Health Code of the OIE.

[...]

(45) Member States and in particular the competent authority thereof 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, raising disease awareness, and in the facilitation of animal movements and in international trade by the issuing of animal health certificates. 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.

(46) The competent authority cannot always perform all the activities required to be carried out by it under this Regulation due to the 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.**

(46a) **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 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect to the delegation of the performance of other activities which the competent authority may delegate to veterinarians other than official veterinarians.**

- (47) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, **veterinarians, animal health professionals**, other stakeholders and trading partners. 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. [...]
- (47a) 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 and when a case is of public interest. In those cases, those animals or products may originate from within the Union or enter from outside the Union. 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.**
- (48) To avoid the release of disease agents from laboratories, institutes and other facilities handling diseases 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 while handling or transporting such disease agents, vaccines and other biological products. This obligation 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 when handling highly contagious biological agents, vaccines and other biological products, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the safety measures in those laboratories, institutes and facilities and for movements of diseases agents.
- (49) 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. [...]
- (50) Veterinarians are key actors in the investigation of diseases and a key link between operators and the competent authority. Therefore, they should be notified by the operator in cases of abnormal mortalities, other serious disease problems or significantly decreased production rates with an undetermined cause.

- (51) In order to ensure the effective and efficient notification and to clarify different circumstances related to abnormal mortalities and other serious diseases signs, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of criteria to determine when relevant circumstances for the notification occur and the rules for further investigation, where this is relevant.
- (52) For certain listed diseases it is vital that the Commission and the other Member States are immediately notified about diseases. Such Union notification will enable neighbouring or other affected Member States to take precautionary measures when so warranted. [...]
- (53) 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 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 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, which are necessary 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission concerning the matters to be reported.
- (54) 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 burden for the competent authorities of the Member States by merging disease notification and reporting within the Union and at international level into one process (that is the [...] database of the OIE). Consistency with the exchange of information in accordance with Directive 2003/99/EC¹⁵ should also be ensured.

¹⁵ OJ L 325, 12.12.2003, p. 31.

- (55) 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 provided for in this Regulation and to establish the necessary procedures, formats, data and information exchanges regarding disease notification and reporting.
- (56) Surveillance is a key element of disease control policy. It should provide for the early detection of transmissible animal diseases and efficient notification, thereby enabling the sector and the competent authority to implement, where feasible, timely disease prevention and control measures, and the eradication of a disease. Furthermore, it should supply information on the animal health status of each Member State and the Union, thereby substantiating disease freedom and facilitating trade with third countries.
- (57) 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.
- (58) 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 and other relevant factors, be subject to animal health visits. In order to ensure [...] **uniform conditions for the application of animal health visits, implementing powers should be conferred on the Commission to lay down minimum requirements.**
- (59) It is essential that the competent authority has 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 that disease should be assessed and epidemiological data collected for that assessment. To ensure the best use of resources information should be collected, shared and used in the most effective and efficient manner possible.

- (60) The surveillance methodology, frequency and intensity should be adapted to each specific disease and 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 disease signs, to a specific and comprehensive surveillance programme, which would normally include additional sampling and testing regimes.**
- (61) [...] **Depending on the epidemiological profile of a disease and relevant risk factors, a [...] specific surveillance programme comprising defined and structured activities may need to be put in place. In that case it is appropriate that Member States develop [...] targeted surveillance programmes. [...] Where such programmes are relevant for the Union as a whole, rules should be provided for a harmonised application of such programmes.**
- (62) [...] **Such programmes should be consistent with Union objectives and therefore coordinated at the EU level. To support that purpose, they should be submitted to the Commission [...]. Furthermore, the Member State implementing such specific surveillance programmes should also submit regular reports on the results of those surveillance 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.**
- (62a) **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 EU-wide specific surveillance programme should be established. Therefore, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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 those diseases and requirements for surveillance programmes in relation to their contents, information to be included and their period of application.**

- (63) 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 the eradication is compulsory in the Union [...].
- (63a) 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. Member States have the possibility 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 the Union level. This programme would entail implementing certain relevant disease control measures. It may also enable the Member State, subject to approval by the Commission, to require certain guarantees when receiving animals from other Member States or from third countries.**
- (64) 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.
- (65) Furthermore, Member States should have the possibility of declaring the whole of their 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 is officially approved and thus implementing powers to approve such status should be conferred on the Commission.
- 66) 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 only recognised 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 for the recognition, rules for approval and the requirements for compartments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission.

- (67) Member States should make their disease-free territory, zones and compartments thereof publicly known for the purpose of informing trading partners and facilitating trade.
- (68) 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the criteria **and** conditions for obtaining such status, the evidence needed to substantiate 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.
- (69) 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 lay down detailed rules on formats for the submission of applications and information exchange.
- (70) 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 this effective and efficient tool for the control of disease emergencies, which is 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.
- (71) Past animal health crises have shown the benefits of having specific, detailed and rapid management procedures for disease emergencies. Those organisational procedures should ensure a rapid and effective response and improve coordination of efforts of all involved parties, and in particular the competent authorities and the stakeholders. **They should also include cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.**
- (72) To ensure the applicability of contingency plans in real emergency situations, it is essential to practise and test that the systems are working. For that purpose 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.

- (73) 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.
- (74) 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 the EU Animal Health Law highlights in particular the importance of vaccines as a tool in the prevention, control and eradication of animal diseases.
- (75) 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 expression 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.
- (76) However, those control strategies may substantially vary between different listed diseases. Thus this Regulation should provide for rules on the use of veterinary medicinal products for the prevention and control of **certain** listed diseases and for harmonised criteria for 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 the effective treatments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the restrictions, prohibitions or obligations to use certain veterinary medicinal products in the framework of the control of certain listed diseases. In the case of urgency and in order to address emerging risks with possible devastating implications for animal or public health, economy, society or environment, it should be possible for these measures to be adopted by the urgency procedure.

- (77) Following the conclusions of the Expert opinion on vaccine and/or diagnostic banks for major animal diseases¹⁶ it should also be made 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 for animal or public health. The establishment of a Union antigen, vaccine and diagnostic reagent bank would promote the Union's animal health objectives by enabling a quick and effective response when its resources are required and represents an efficient use of limited resources.
- (78) In order to ensure such a quick and effective response, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in respect of the establishment and the management of such banks, and safety standards and requirements for the operation of those. However, this Regulation should not provide for the rules on the financing of the disease preventive and control measures, including vaccination.
- (79) 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.
- (80) 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 the treatment as classified information.**
- (81) 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 vaccines, antigens and diagnostic reagents and the frequency and content of submissions of information to the Commission.
- (82) 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 that listed disease **are taken** in order to protect animal and public health [...].

¹⁶ Doc. SANCO/7070/2010.

[...]

- (84) The competent authority should be responsible for initiating the first investigations to confirm or rule out an outbreak of a highly contagious listed disease, considered to represent a high risk to animal or public health in the Union.
- (85) The competent authority should put in place preliminary disease control measures to prevent the possible spread of the listed disease and undertake an epidemiological enquiry.
- (86) 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.
- (87) 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 for disease control and eradication measures in wild animals where needed.
- (87a) 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 case of an occurrence of a listed disease. The protection of such breeds and species may require modified measures taken by the competent authority. However, such modification should not hamper the overall control of that disease.**
- (88) For listed diseases, which are not highly contagious, and which are subject to compulsory eradication, the disease control measures should be implemented to prevent the spread of those listed diseases, in particular to non-infected areas. However, those measures may be more limited or different comparing to those applicable for the most dangerous listed diseases. This Regulation should therefore provide for special rules for those 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 take into account the characteristics of the listed disease in question, its distribution and its significance for the Member State concerned by it and the Union as a whole.

- (89) In order to ensure the effective application of the disease control measures provided for in this Regulation by operators, pet keepers and the 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in respect of the detailed disease control measures in the event of suspicion or confirmation of a listed disease in establishments, other locations and restricted zones.
- (90) In order to provide for the possibility for special disease control measures to be adopted by the Commission on a temporary basis in the event that the disease control measures laid down in this Regulation are not sufficient or appropriate to address that risk, implementing powers should be conferred on the Commission concerning the laying down of special disease control measures for a limited period of time.
- (91) The registration of certain transporters and establishments keeping terrestrial animals or handling germinal products or transporting them is necessary to allow the competent authorities to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases.
- (91a) To avoid unjustified administrative burdens and costs, a limited possibility for Member States to exempt from the registration obligation certain types of establishments posing a low risk should be provided. Implementing powers should be conferred on the Commission in order to achieve a harmonized approach for such exemptions. Such a harmonized approach is particularly necessary to prevent excluding from the registration obligation certain types of establishments. As well as those establishments posing more than insignificant risk to animal health, this is particularly relevant for such establishments posing more than insignificant risk also to public health. An example of such risk is the keeping of animals that live in close contact or proximity to humans, such as breeding of dogs at a level implying a certain continuity of activities and a certain degree of organisation with the main intention of their sale for the purpose of becoming pet animals in households.**
- (92) 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.

- (93) To avoid unjustified administrative burdens and costs, particularly to [...] enterprises [...] **posing a low risk**, flexibility should be [...] **provided for where possible** to adapt the system of registration and approval to local and regional conditions and production patterns.
- (93a) In some cases, harmonization 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 to be approved in order to comply with international standards and so the Union can provide animal health guarantees to third countries when trading. Such conditions should also involve requirements for specific training or professional qualifications for some 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 of the Treaty on the Functioning of the European Union concerning those detailed requirements, in order to provide for such specific conditions.**
- (94) In the interest of reducing administrative burdens, registration and approvals should, where possible, be integrated into a registration or approval system which Member State may already have established for other purposes.
- (95) Operators have first-hand knowledge of the animals under their care. They should therefore maintain up-to-date records of information which are 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.
- (96) In order to ensure the [...] availability of up-to-date information concerning the registered establishments and [...] **operators** and approved establishments the competent authority should establish and keep a register of such establishments and [...] operators. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in respect of the **detailed** information to be **included** [...] in the register of establishments and **operators** [...].

[...]

- (97a) In order to be approved by the competent authority, an establishment has to fulfil certain requirements. Before granting the approval, the competent authority has to verify by means of an on-site visit if all requirements have been met. In some cases all conditions cannot immediately be met, but the remaining deficiencies do not present a significant risk to animal or public health. In such cases the competent authority may 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 those establishments in order that the operator understands the deficiency and can plan for its successful resolution.**
- (98) Efficient traceability is a key element of disease control policy. Identification and registration requirements specific for 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.
- (98a) 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 that the animal be physically marked, tagged, microchipped or otherwise identified with a method that can be seen or detected on or in its body and which cannot easily be removed.**
- (99) In order to ensure the smooth operation of the identification and registration system and ensure traceability, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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.
- (100) It is appropriate to reduce administrative burdens and costs and 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 of the Treaty on the Functioning of the European Union concerning the derogations from the identification and registration requirements.

- (101) 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** the deadlines [...].
- (102) 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 interfere with the operation of the internal market. Such restrictions should therefore only be applied 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.
- (103) The general requirements laid down in this Regulation should apply to all animal movements, such as the prohibition of 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.
- (104) The legal framework, currently laid down in Union legislation for the movement of terrestrial animals lays down harmonised rules primarily for the movement of terrestrial animals and products between Member States, while leaving it up to the Member States to determine the necessary movement requirements within their territory. A comparison of the current situation with an option where rules for movements within Member States would also be harmonised at Union level, was extensively elaborated in the Impact Assessment on the EU Animal Health Law. 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.

- (105) For animals that are moved between Member States a set of basic animal health requirements apply. In particular, animals may 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 of 22 September 2010 on the protection of animals used for scientific purposes¹⁷ and which are not of infectious origin related to listed diseases, should not be a reason to prevent the movements of animals intended for scientific purposes.
- (106) However, this Regulation should provide for flexibility to facilitate the movement of species and categories of terrestrial animals, which represent a low risk for 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.

¹⁷ OJ L 276, 20.10.2010, p. 33.

(107) 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 of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine¹⁸, Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals¹⁹, Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae²⁰, 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 eggs²¹ and partially 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/EEC²². The main rules for the movement 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.

(108) As assembly operations for ungulates and poultry represent a particularly high disease risk, it is appropriate to **limit the number that can be carried out in one movement between Member States, and** 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.**

¹⁸ OJ L 121, 29.7.1964, p. 1977.

¹⁹ OJ L 46, 19.2.1991, p. 19.

²⁰ OJ L 192, 23.7.2010, p. 1.

²¹ OJ L 343, 22.12.2009, p. 74.

²² OJ L 268, 14.9.1992, p. 54.

- (109) Depending on the listed diseases and listed species, 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 movement rules for animal species including bees, bumble bees, apes, dogs and cats etc. 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.
- (110) Confined establishments, usually used for the keeping of laboratory animals or zoo animals, normally involve a high level of biosecurity, a favourable and well controlled health status and are subject to fewer movements or movements solely within the closed circuits of those establishments. The status of confined establishments, for which the operators may apply for on a voluntary basis, was first introduced in Directive 92/65/EEC, where rules and requirements for approval and movement requirements for approved bodies, institutes and centres are laid down. That system enables those establishments to exchange animals amongst themselves with fewer movement requirements and at the same time providing health guarantees within the circuit of confined establishments. Therefore it has been broadly accepted by the operators, and used as a voluntary option. It is therefore appropriate to preserve the concept of confined establishments and also to lay down rules for movement between those establishments in this Regulation.
- (111) For scientific purposes, such as research or diagnostic purposes, and in particular those authorised in accordance with Directive 2010/63/EU, it may be necessary to move animals which do not comply with the general animal health requirements laid down in this Regulation and represent a higher animal health risk. Those kinds of movements should not be prohibited or unduly restricted by the provisions of this Regulation, as this could impede otherwise authorised research activities and delay scientific progress. Nonetheless, it is essential that rules are laid down in this Regulation to ensure that movements of those animals take place in a safe manner.
- (112) 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. Specific consideration should be taken in adapting Union rules on movement to such animals, taking into account specific risks and alternative risk mitigation measures.

- (113) In order to ensure that the objectives of recitals 102 to 112 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning the disease preventive measures in transport, specific rules for 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.
- (114) In order to ensure the possibility for special rules for movements, where the 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.
- (115) Kept terrestrial animals that are moved between Member States should comply with the requirements for such movements. In the case of species presenting a health risk and of greater economic importance, they should be accompanied by an animal health certificate issued by the competent authority.
- (116) To the extent technically, practically and financially feasible, technological developments should be availed of to reduce the administrative burdens on operators and the competent authority in relation to certification and notification by using information technology to replace the paper documentation and facilitate notification procedures and using them as far as possible for multiple purposes.
- (117) In cases where an animal health certificate issued by the competent authority is not required, 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.
- (118) In order to ensure the achievement of the objectives referred to in recitals 115, 116 and 117 of this Regulation the powers to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning rules on the content, information obligations, and derogations from the animal health certification requirements, specific certification rules and the obligations of official veterinarians to conduct appropriate checks before the signing the animal health certificate.

- (119) Notification of movements of animals and germinal products between Member States and in some cases within the national territories of Member States is essential to ensure traceability of animals and those germinal products, where these movements may be linked to a risk of spreading transmissible animal diseases. Therefore, such movements should be notified and registered [...] **by means of an integrated computerised veterinary system ("TRACES"). This TRACES system is integrating into a single architecture the computerised systems provided for in Article 20 of Council Directive 90/425/EEC and in Council Decision 92/438/EEC respectively, based on Decisions 2003/24/EC and 2004/292/EC.**
- (120) 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.
- (121) The specific nature of movements of pet animals represents an animal health risk which deviates significantly from that of other kept animals. Specific rules for such movements **should** therefore be laid down in this Regulation. **Such less stringent rules are however only justified if the pet animal genuinely accompanies its owner during the owner's movement, or within a limited period thereof, and if no more than five pet animals 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 should be able to be moved within a longer period of the owner moving,** the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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.

- (122) 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning the additional requirements for movements of wild terrestrial animals.
- (123) 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, their expected high health standard and to take into account some specific uses, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning the detailed requirements for movement of germinal products of certain animal species, special requirements, such as for example their movement for scientific purposes, and derogations from the animal health certification obligation.
- (124) 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 cases specific animal health measures, such as disease control and emergency measures should be laid down in this Regulation to ensure that products of animal origin do not spread animal diseases. In order to ensure safe movements of products of animal origin in these particular cases, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning detailed rules for movements of products of animal origin in relation to disease control measures taken, the obligations for animal health certification and derogations from those rules, where the risk involved with such movements and the risk mitigating measures in place permit so.

- (125) 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. Therefore, it is appropriate to set the framework for such national measures and ensure that they remain within the limits permitted under Union law.
- (126) The registration and approval of aquaculture establishments is necessary to allow the competent authorities 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 that fact that in some official EU languages, different terms are used for this system of authorisation in this Regulation as compared to Directive 2006/88/EC.
- (127) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread transmissible animal disease, for example as a result of effluents containing pathogens being discharged from processing establishments. It is therefore necessary to approve processing establishments which fulfil the risk mitigation measures to undertake such slaughter and processing. Therefore, this Regulation should provide for the approval of disease control aquatic food establishments.
- (128) In order to ensure the public availability of up-to-date information concerning registered and approved establishments the competent authority should establish and keep such a register. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning the information to be included in register of aquaculture establishments and the record keeping requirements for aquaculture establishments and transporters.
- (129) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation for 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 [...].
- (130) As it is not feasible in most cases to individually identify aquatic animals, the keeping of records at aquaculture establishments, disease control aquatic food establishments and by transporters is an essential tool in ensuring the traceability of aquatic animals. Records are also valuable for the surveillance of the health situation of establishments.

- (131) Similarly to 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.
- (132) 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 for movement rules for aquatic animals is the health status as regards the listed diseases of the Member State, zones and compartments of destination.
- (132aa) However, that directive excludes from its scope wild aquatic animals caught or harvested for direct entry into the food chain. On the other hand, this Regulation retains them within its scope, but excludes them from the definition of aquaculture animals. It should therefore provide for possible measures for such aquatic animals, where the risks involved justify them, taking into account the proportionality of those measures.**
- (132a) Consequently, the principle explained in recital 132 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 particularly applies to those 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 awaiting slaughter.**
- (132b) However, disproportionate movement restrictions and unnecessary administrative burdens for establishments and operators within the commercial fisheries should be avoided. Consequently, in the cases where those live wild aquatic animals are intended for human consumption, those rules should in principle only apply 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.**
- (133) [...] To encourage Member States to enhance the health status of their aquatic populations, some adjustments and added flexibility should be introduced in this Regulation.

- (134) In order to ensure movement control for aquatic animals, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, concerning the disease preventive measures applicable to transport, specific rules for movements of certain categories of aquatic animals for different purposes, specific requirements or derogations for certain types of movements, such as movement for scientific purposes and additional requirements for movement of wild aquatic animals.
- (135) 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 certain listed disease, implementing powers should be conferred on the Commission for laying down special movement rules or derogations for a limited period of time.
- (136) Union aquaculture production is extremely diverse as regards species and production systems and this diversification is rapidly increasing. This may warrant that national measures concerning diseases other than those that are regarded as listed diseases in accordance with this Regulation are taken at Member State level. 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 it is necessary in order to prevent the introduction of or to control the spread of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.
- (137) Currently, listed diseases concern animal species other than those defined as terrestrial and aquatic by this Regulation, 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 apply to those animals. However, if a disease which concerns species other than terrestrial and aquatic should become listed, the relevant animal health requirements of this Regulation should apply to those species to ensure that adequate and proportionate disease prevention and control measures may be taken.

- (138) In order to ensure the possibility of laying down movement rules for those animals that are not defined as terrestrial and aquatic animals by this Regulation, and germinal products and products of animal origin from them, when a risk so warrants, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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 for animals, germinal products and products of animal origin of those species.
- (139) When necessary 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 from them, implementing powers should be conferred on the Commission to lay down detailed rules concerning those requirements.
- (140) 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.
- (141) [...] To guarantee the health status of the Union, this Regulation lays down provision for movements of animals and products within the Union. It is therefore appropriate, so as not to jeopardise that status, to require condition for entry of animals and products into the Union that are not less strict than those for movements within the Union.**
- (142) To ensure that animals, germinal products and products of animal origin from third countries or territories comply with the animal health requirements that provide guarantees that are equivalent to those provided for in Union legislation, it is essential that they are subject to appropriate controls by the competent authority of the third countries or territories exporting to the Union. Where relevant, the health status of a third country or territory of origin should be verified prior to accepting the entry 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.

- (143) 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 and pending the adoption of rules pursuant to 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.
- (144) To ensure that the animal health requirements for the entry into the Union provided for in this Regulation are complied with and are in line with the principles of the OIE Animal Health 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 for commodities which pose a low animal health risk should be permitted.
- (145) Animal health certificates may stand on their own, but certification is often required in Union legislation for other purposes, for example 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**.
- (146) 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 these routes of disease transmission by those means.

- (147) 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission [...] supplementing the 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 the animal health requirements for disease agents, other materials, means of transport and equipment, which may transmit animal diseases.
- (148) In order to ensure uniform conditions for the implementation of the 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 the contents** and the model animal health certificates.
- (149) 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 limit its introduction and spread. Such an emergency may involve listed diseases, emerging diseases or other animal health hazards. In that context, it should be made clear which sets of disease prevention and control measures laid down in this Regulation may be used in the event of the occurrence of a listed or emerging disease or hazard. In all these 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.
- (150) 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.

- (151) The Commission should adopt immediately applicable implementing acts in duly justified cases relating to inter alia [...] **the 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, the special movement rules for terrestrial and aquatic animals for a limited period of time, the emergency measures, and the listing of third countries and territories for entry into the Union.
- (152) 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 of this Regulation, and if they are not in contradiction with the rules laid down therein and provided that they do not hinder movements of animals and products between Member States, unless it is necessary in order to prevent the introduction of or to control the spread of disease.
- (153) The national measures referred to in recital 152 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 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 services²³, 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 laid down in Directive 98/34/EC applies.
- (154) 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:
- Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine²⁴,

²³ OJ L 204, 21.7.1998, p. 37.

²⁴ OJ 121, 29.7.1964, p. 1977.

- Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle²⁵,
- 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 cattle²⁶,
- 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 species²⁷,
- 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 fever²⁸,
- Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community²⁹,
- 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 species³⁰,
- 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 species³¹,
- Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals³²,
- Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines³³,

²⁵ OJ L 145, 13.6.1977, p. 44.
²⁶ OJ L 15, 19.1.1978, p. 34.
²⁷ OJ L 194, 22.7.1988, p. 10.
²⁸ OJ L 325, 1.12.1980, p. 1.
²⁹ OJ L 378, 31.12.1982, p. 58.
³⁰ OJ L 302, 19.10.1989, p. 1.
³¹ OJ L 224, 18.8.1990, p. 62.
³² OJ L 46, 19.2.1991, p. 19.
³³ OJ L 368, 31.12.1991, p. 21.

Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness³⁴,

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/EEC³⁵,

Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease³⁶,

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/EEC³⁷,

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 disease³⁸,

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 Sweden³⁹,

Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue⁴⁰,

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 vaccines⁴¹,

[...]

³⁴ OJ L 157, 10.6.1992, p. 19.

³⁵ OJ L 268, 14.9.1992, p. 54.

³⁶ OJ L 260, 5.9.1992, p. 1.

³⁷ OJ L 62, 15.3.1993, p. 49.

³⁸ OJ L 62, 15.3.1993, p. 69.

³⁹ OJ L 243, 11.10.1995, p. 25.

⁴⁰ OJ L 327, 22.12.2000, p. 74.

⁴¹ OJ L 79, 30.3.2000, p. 40.

- Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever⁴²
- 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 fever⁴³,
- 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 consumption⁴⁴,
- 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/EEC⁴⁵,
- 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 998/2003⁴⁶,
- 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/EEC⁴⁷,
- 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/EEC⁴⁸,
- Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae⁴⁹,
- Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC⁵⁰,

⁴² OJ L 316, 1.12.2001, p. 5.
⁴³ OJ L 192, 20.7.2002, p. 27.
⁴⁴ OJ L 18, 23.1.2003, p. 11.
⁴⁵ OJ L 306, 22.11.2003, p. 1.
⁴⁶ OJ L **178, 28.6.2013, p. 1–26**
⁴⁷ OJ L 5, 9.1.2004, p. 8.
⁴⁸ OJ L 139, 30.4.2004, p. 321.
⁴⁹ OJ L 192, 23.7.2010, p. 1.
⁵⁰ OJ L 10, 14.1.2006, p. 16.

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 animals⁵¹,

Council Directive 2008/71/EEC of 15 July 2008 on the identification and registration of pigs (codifying Directive 92/102/EEC)⁵²,

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 eggs⁵³.

(154a) The Regulation provides for the rules on identification and registration of bovine animals while rules for beef labelling stay outside of its scope. Regulation (EC) No 1760/2000 establishing systems for the identification and registration of bovine animals provides for the rules on identification and registration of bovine animals and for the rules on beef labelling. It should thus be amended to repeal its provisions on identification and registration of bovine animals while those concerning beef labelling would have to remain in force.

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 provides that the Member States carry out adequate and efficient control measures. Such adequate and efficient official control measures should also be preserved in the future. As part of the “Smarter rules for safer food” package of proposals, this Regulation does not envisage provisions on official controls since those rules should be provided for in the framework of the proposed horizontal legislation on official controls. However, even if the proposed new horizontal rules on official controls would not 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.

⁵¹ OJ L 328, 24.11.2006, p. 14.

⁵² OJ L 213, 8.8.2008, p. 31.

⁵³ OJ L 343, 22.12.2009, p. 74.

- (155) The rules laid down in the legislative acts referred to in recital 154 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** only take effect when the relevant delegated and implementing acts are adopted pursuant to this Regulation. It is therefore necessary to provide the Commission with the empowerment to determine the dates when the repeal of those legislative acts should take effect, **while setting a final date by the legislator**.
- (156) 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 of 25 July 1978 on health protection measures in respect of the Republic of Botswana⁵⁴; 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 cattle⁵⁵; 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 cattle⁵⁶; 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 prevention⁵⁷, Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease⁵⁸; 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 free⁵⁹, **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 equidae⁶⁰ 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 swine⁶¹.**
- (157) The requirements of 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 and their start of application, permitting Member States and operators to duly adapt to the new rules. In addition, it** is appropriate to provide for at least 36 months **for the Commission to elaborate these new rules.** [...]

⁵⁴ OJ L 213, 3.8.1978, p. 15.
⁵⁵ OJ L 29, 3.2.1979, p. 24.
⁵⁶ OJ L 14, 16.1.1981, p. 22.
⁵⁷ OJ L 223, 2.8.1989, p. 19.
⁵⁸ OJ L 224, 18.8.1990, p. 13.
⁵⁹ OJ L 373, 31.12.1990, 29.
⁶⁰ OJ L 157, 10.6.1992, p. 28–29.
⁶¹ OJ L 358, 31.12.1998, p. 107–108.

- (158) In order to ensure legal certainty as regards the application of rules for 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 of the Treaty on the Functioning of the European Union 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 cease to apply, **while setting a final date in this Regulation.**
- (158a) 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 the entry into force of this Regulation should continue to apply and Regulation (EC) No 2160/2003 should be amended accordingly.**
- (158b) Considering the recent adoption of Regulation (EC) No 576/2013 on the non-commercial movements of pet animals, it is desirable to allow for a long transitional period before the corresponding rules in this Regulation start to apply.**
- (159) 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 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 powers⁶².
- (160) 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.

⁶² OJ L 55, 28.2.2011, p. 13.

- (161) 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 to protect 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.
- (162) 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 can be involved in the spread of transmissible animal diseases, cannot be achieved sufficiently by the Member States, and can be more efficiently achieved at Union level through a common and coordinated legal framework for animal health. This Regulation is therefore in line with the principle of subsidiarity as set out in Article 5(3) 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 establishing responsibilities for animal health in Part I (**Articles 1 to 15**);
- (b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status in Part II (**Articles 16 to 42**);
- (c) disease awareness, preparedness and control in Part III (**Articles 43 to 81**);
- (d) the registration and approval of establishments and transporters, movements and traceability of [...] animals, germinal products and products of animal origin within the Union in Part IV (**Articles 82 to 229**) and Part Va (**Articles 245a to 245e and 245i to 245m**);
- (e) the entry of [...] animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union in Part V (**Articles 230 to 245**) and Part Va (**Articles 245a to 245c and 245i to 245m**);
- (ea) the non-commercial movements of pet animals into a Member State from another Member State or from a territory or a third country in Part Va (Articles 245a to 245m);**
- (f) the emergency measures to be taken in the event of a disease emergency situation in Part VI (**Articles 246 to 251**).

2. The rules referred to in paragraph 1:

(a) **aim to** ensure

- (i) **improved animal health to support** a 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 impacts 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 of this Regulation

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 Va [...]

1. Title I of Part IV (**Articles 82 to 169**) shall apply to:
 - (a) terrestrial animals, and animals that 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 170 to 227**) shall apply to:
 - (a) aquatic animals, and animals that 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 228 and 229**) shall apply to:
 - (a) **other** animals [...];
 - (b) germinal products and products of animal origin from the other animals referred to in point (a).
4. [...] Part IV **and Part V** shall not apply to **non-commercial movements of pet animals referred to in paragraph 6 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 253 concerning the adaptations which are necessary in order to ensure a correct application of the provisions in Parts IV and V to pet animals, in particular to take account of the fact that pet animals are kept in households by pet keepers.

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

Article 4 *Definitions*

1. For the purpose of this Regulation, the following definitions shall 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:
 - (i) fish belonging to the superclass Agnatha and to the classes Chondrichthyes, Sarcopterygii and Actinopterygii;
 - (ii) aquatic molluscs belonging to the phylum Mollusca;

- (iii) aquatic crustaceans belonging to the subphylum Crustacea;
- (4) 'other animals' means animals of species other than those defined as terrestrial and aquatic animals;
- (5) 'kept animals' means animals which are kept by humans; 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 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 purposes 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, **which could include a pet owner**, keeping a pet animal;
- (12a) '**pet owner**' means a natural person indicated as the owner in the identification document as referred to in Articles 245d(c), 245e(2)(c), 245f(1)(c) and 245g(1)(c);

- (13) 'non-commercial movement' means any movement of a pet animal [...] **accompanying its owner during his movement and which**
- (a) **does not have as its aim either the sale of or the transfer of ownership of the pet animal; 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 the case where the pet animal is physically separated from the pet owner;**
- (13aa) **'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;**
- (13a) **'disease agent' means a pathogen transmissible to animals or to humans capable of causing a disease in animals;**
- (14) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents [...];
- (15) 'listed diseases' mean diseases listed in accordance with Article 5([...] 1);
[...]
- (17) 'disease profile' means the criteria of a disease referred to in Article 6(1)(a);
- (18) 'listed species' means animal species or group of animal species listed in accordance with Article 7(2), or, in the case of emerging diseases, animal species or groups of animal species, which meet the criteria for listed species laid down in Article 7(2);
- (19) 'hazard' means a disease agent in, or a condition of, an animal or product with the potential to have an adverse health effect in humans or animals;
- (20) '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;
- (21) '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;
- (22) '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;
- (22a) 'transporter' means an operator transporting animals on his own account, or on account of a third party;**
- (23) 'animal professional' means a natural or legal person, with an occupational relationship with animals or products, other than operators or veterinarians;
- (24) '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;**
- [...]
- (c) veterinary practices or clinics;
- (25) 'germinal products' means:
- (a) [...] semen, oocytes and embryos intended for artificial reproduction;
- (b) hatching eggs;
- (26) '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 (b) destined to be prepared with a view to being supplied live to the final consumer;
- (27) '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;
- (28) 'derived products' means products obtained from one or more treatments, transformations or steps of the processing of animal by-products;

- (29) 'products' means:
- (a) germinal products;
 - (b) products of animal origin;
 - (c) animal by-products and derived products;
- (30) 'official control' means [...] **any form of control that the competent authorities perform for the verification of compliance with this Regulation;**
- (31) 'health status' means the disease status as regards [...] the listed diseases relevant for a particular listed species with respect to:
- (a) an animal;
 - (b) the animals within:
 - (ia) **an epidemiological unit;**
 - (i) an establishment;
 - (ii) a compartment;
 - (iii) a zone;
 - (iv) a Member State;
 - (v) a third country or territory;
- (32) '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;
- (33) '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;
- (34) '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;
- (35) 'quarantine' means the maintaining of animals in isolation [...] with no direct or indirect contact with [...] animals **outside that epidemiological unit**, for the purposes 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;
- (36) 'epidemiological unit' means a group of animals with the same likelihood of exposure to a disease agent;
- (37) '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;
- [...]
- (39) '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;
- (40) 'protection zone' means a zone [...] **around and including the location of an outbreak**, and where disease control measures are applied in order to prevent the spread of the disease from that zone;
- (41) '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;
- (42) 'hatching eggs' means eggs, laid by poultry **or captive birds**, intended for incubation;
- (43) 'ungulates' means the animals listed in Annex II;
- (44) 'germinal product establishment' means:

- (a) **in relation to semen**, an establishment [...] **where semen is collected, produced, processed or stored;**
 - (aa) **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;
 - (b) **in relation to hatching eggs**, a hatchery;
- (45) 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;
- [...]
- (47) '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;
 - (c) subject to [...] animal health surveillance and biosecurity measures;
- (48) 'assembly operation' means the assembling of kept terrestrial animals from more than one establishments for a period shorter than the required residency period for that species of animals;
- (49) 'residency period' means the minimum period **necessary to ensure that** an animal [...] **which has been introduced into** an establishment [...] **is not of a lower health status than that of** that establishment;
- (50) [...] '**TRACES**' means the integrated computerised veterinary system with a single architecture provided for in Decisions 2003/24/EC and 2004/292/EC.
- (51) 'disease control aquatic food establishment' means a food business approved in accordance with [...] Article 177 of this Regulation [...];

- (52) 'official veterinarian' means a veterinarian authorised by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation.
- (53) 'official veterinarian in a third country or territory' means a veterinarian in a third country or territory corresponding to an official veterinarian referred to in (52).
- (54) '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 conferred.
- (55) '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 (54).

[...]

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 Ia.**
2. The Commission shall [...] **adopt delegated acts in accordance with Article 253, concerning amendments to the list referred to in point (b) of paragraph 1.**

[...]

- 3. A disease shall be included on the list referred to in point (b) of paragraph 1 if it has been assessed in accordance with Article 6 and it meets all of the criteria set out in letters (a) to (e).**
- (a) Scientific evidence indicates that the disease is transmissible;**
 - (b) Animal species which are either susceptible for the disease or vectors and reservoirs thereof exist in the Union;**
 - (c) The disease causes negative effects on animal health; or the disease poses a risk to public health due to its zoonotic character;**
 - (d) Diagnostic tools are available for the disease;**
 - (e) Risk mitigating measures and where relevant, surveillance of the disease, are effective and proportionate to the risks posed by the disease in the Union.**

In order to be included on that list, a disease shall also meet at least one of the criteria set out in letters (f) to (j).

- (f) The disease causes or could cause significant negative effects in the Union on animal health; or the disease poses or could pose a significant risk to public health due to its zoonotic character;**
 - (g) The disease agent has developed resistance to treatments, which poses a significant danger to public and/or animal health in the Union;**
 - (h) The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union;**
 - (i) The disease has a potential to generate crisis or the disease agent could be used for the purpose of bioterrorism;**
 - (j) 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 253 concerning the removal of a disease from the list referred to in point (b) of paragraph 1 when that disease no longer fulfils the criteria provided for in paragraph 3.**
- 5. The Commission shall review the listing of each disease in the light of newly available significant scientific data.**

Article 5a
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; or**
 - (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 fulfilling the criteria set out in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).**
4. **On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).**
5. **Any obligation on operators in respect of an emerging disease, set out in this Regulation, shall only apply if the Commission has adopted an implementing act for that disease in accordance with paragraph 3 or if the disease is covered by a contingency plan in accordance with Article 43.**

Article 6
[...] Assessment parameters for listing diseases

- [...] The Commission shall [...] **use** the following [...] **assessment parameters in order to determine** whether a disease meets the conditions 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:
 - the level of presence of the disease in the Union;
 - the loss of production due to the disease;
 - other losses;
 - (ii) human health:
 - 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 to:
- (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 7
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 **that fulfil the criteria set out in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 and infective period for the animals;
- (c) the capability of those animals to carry those specific diseases.

[...]

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

- (a) they are susceptible for 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 has been listed has been removed from the list of diseases; or
- (b) the scientific evidence indicates that the species or group of species no longer fulfils the criteria provided for in paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 8

[...] 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) **rules for disease awareness and preparedness provided for in Title I of Part III (Articles 43 to 52);**
- (ii) **disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71); and**
- (iii) **rules for compartmentalisation provided for in Article 37(1).**

For these listed diseases, the measures referred to in (b), as appropriate, as well as (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) **rules for compulsory eradication programmes provided for in Article 30(1);**

- (ii) **rules for** disease-free Member States and zones provided for in Article 36;
- (iii) **rules for** compartmentalisation provided for in Article 37(2); and
- (iv) **disease control measures provided for in Articles 72 to 75, Articles 76 to 78 and Articles 80 and 81.**

For these listed diseases, the measures referred to in (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 that listed disease, the following rules shall apply, as relevant:**

- (i) **rules for** [...] optional eradication provided for in Article 30(2);
- (ii) **rules for disease-free Member States and zones provided for in Article 36;**
- (iii) **rules for** compartmentalisation provided for in Article 37(2); and
- (iv) **rules for** disease control measures provided for in [...] **Articles 75a, 76, 77, 79, 80a and 81.**

For these listed diseases, the measures referred to in (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) **rules for** movement within the Union provided for in Chapters 3 to 7 of Title I (Articles 121 to 148) and Chapters 2, 3 and 4 of Title II of Part IV (Articles 190 to 227); and
- (ii) **rules for** entry into the Union and export from the Union provided for in Part V (Articles 230 to 245).

The listed diseases referred to in (a), (b) and (c) shall also be considered as listed diseases under this point, and (e) where the risk posed by the disease 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) rules for notification and reporting provided for in Chapter 1 of Part II (Articles 16 to 21); and
 - (ii) rules for surveillance provided for in Chapter 2 of Part II (Articles 22 to 29).

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

- 1a. 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 based on the criteria provided for in Annex III 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 255(2).

- 1aa The Commission shall, by means of implementing acts, modify the application of the disease prevention and control rules referred to in paragraph 1a to the respective listed diseases when the disease no longer fulfils the criteria provided for in the relevant Section of Annex III, 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 255(2).

- 1b. On duly justified imperative grounds of urgency relating to a listed disease representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

[...]

Chapter 3 *Responsibilities for animal health*

SECTION 1 **OPERATORS, ANIMAL PROFESSIONALS AND PET KEEPERS**

Article 9 *Responsibilities for animal health and biosecurity measures*

1. Operators [...] shall:

- (a) **regarding 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 spreading of diseases**;
 - (iv) **good animal husbandry**.
- (b) take appropriate biosecurity measures [...] **regarding kept animals and products under their responsibility**, as appropriate for:
- (i) the categories and species of kept animals and products;
 - (ii) the type of production;
 - (iii) **the risks involved, taking into account:**
 - **geographical location and climatic conditions**;
 - **local circumstances and practices**;
- (c) **where appropriate, take biosecurity measures regarding wild animals.**

1a Animal professionals shall take action to minimise the risk of spreading of diseases in the context of their occupational relationship with animals and products.

1b Paragraph 1(a) shall also apply to pet keepers.

1c The biosecurity measures referred to in paragraph 1(b) 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 on the water supply and discharge**;
 - **natural or artificial barriers from surrounding water courses that prevent aquatic animals to enter or leave the farm, 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.**

1d. 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.

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

Such implementing acts shall be adjusted to suit the conditions referred to in paragraph 1(b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 10
[...] 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 categories and species of kept animals or products under their responsibility [...] and the **nature of their occupational relationship**;
 - (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 training which results in the same level of knowledge as in (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 11 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 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 attributed to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so **by the Member State** under **its** national legislation. In that event, paragraph 1 shall apply to those aquatic animal health professionals.

[...]

3. **Veterinarians and aquatic animal 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 12 *Member States responsibilities*

1. In order to ensure the competent authority for animal health has the capability to take the necessary and appropriate measures, and carry out the activities, required by this Regulation, the Member States shall, **at the appropriate administrative level**, ensure that it 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 qualified personnel, facilities, equipment and financial resources 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 11 [...].

2. Member States shall [...] **encourage** operators and animal professionals [...] **to acquire, maintain and develop** the [...] **adequate** knowledge of animal health provided for in Article 10 through relevant programmes in agricultural or aquaculture sectors or formal education.

Article 13

Competent authority's delegation of [...] official activities

1. The competent authority may delegate one or more of the following activities to **veterinarians other than official** veterinarians:
- (a) [...]
- (i) **practical application of measures under the eradication programmes as provided for in Article 31;**
- (ii) **supporting the competent authority in carrying out surveillance as provided for in Article 25 or in relation to surveillance programmes as provided for in Article 27;**
- (b) activities related to:
- (i) disease awareness, preparedness and control as provided for in Part III, **concerning:**
- **sampling activities and implementation of the investigations and epidemiological enquiries in the framework of Articles 54, 55(1)(b) to (g), 57, 73, and 74 in the event of the suspected presence of a disease and implementing and delegated acts based thereupon;**
 - **carrying out activities concerning disease control measures in the event of an outbreak of disease, as regards activities listed in Article 61, 65(1)(a), (b), (e), (f) and (i), 70(1), 78(1) and (2), and 80(1), and (2) and implementing and delegated acts based thereupon;**
 - **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 of the Articles 245d(c), 245e(2)(c), 245f(1)(c) and Article 245g(2)(c);**
- (iv) **the application and use of means of identification referred to in Article 245i(1)(a).**

1a Member States may provide for authorization of natural or legal persons to perform activities referred to in paragraph 1(a) and 1(b)(1), (ii) and (iv) 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 11 shall apply to those persons.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253, concerning **other activities which may be delegated to veterinarians in addition to those provided for in paragraph 1, and, as appropriate, 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 14 *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 general 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 15

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 international standards where they exist:
 - (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 the purpose of research;
 - (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 253 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 15a

Animal Health Laboratories

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

- 2. The laboratories referred to in paragraph 1 shall cooperate under the coordination of the European 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 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, independently of the natural or legal person that requested the laboratory analyses, tests or diagnoses.**
- 4. In the event where 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 referred to in Article 8(1)(a);**
 - (b) without undue delay of any results indicating the suspicion or detection of a listed disease referred to in Article 8(1)(e) other than those referred to in Article 8(1)(a).**

PART II

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

Chapter 1

Disease notification and reporting

Article 16

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 referred to in Article [...] **8(1)(a), or the presence of such disease is detected in animals;**
 - (aa) **as soon as practicable notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease referred to in Article 8(1)(e) other than those referred to in Article 8(1)(a), or the presence of such a disease is detected in animals.**
 - (b) **notify** a veterinarian of abnormal mortalities and other serious disease signs or significant decreased production rates with an undetermined cause [...], for further investigation, including sampling for laboratory examination when the situation so warrants.
2. Member States may decide that notifications provided for in paragraph 1(b) [...] **may** be directed to the competent authority.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) criteria to determine whether the circumstances requiring notification described in paragraph 1(b) [...] occur;
 - (b) detailed rules for the further investigation provided for in paragraph 1(b) [...].

Article 17
Union notification

1. Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases referred to in Article 8(1)(e) for which an immediate notification is required 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 18
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 Article 8(1)(e) for which:
 - (a) an immediate notification of outbreaks is not required in accordance with Article 17(1);
 - (b) an immediate notification of outbreak is required in accordance with Article 17(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 29;
 - (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 Article **28(c)(ii) or 29(b)(ii)**;
 - (c) the results of surveillance programmes when required in accordance with Article 27(3) and rules adopted in accordance with Article **28(c)(ii) or 29(b)(ii)**;
 - (d) eradication programmes when required in accordance with Article 33 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 253 concerning [...] supplementing the requirements of paragraph 2 [...] and reporting on other matters **concerning surveillance and eradication programmes** where necessary to ensure an efficient application of the disease prevention and control rules of this Regulation.

Article 19
*[...] 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 17 [...] and 18 [...].

Article 20
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 17, 18 and 19.

Article 21

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 17 to 20 with respect to:

- (a) **those listed diseases referred to in Article 8(1)(e) which shall be subject to immediate notification by the Member States as well as the necessary measures relating to the notification [...], in accordance with Article 17 [...];**
- (aa) **the information to be provided by the Member States in the reporting provided for in Article 18;**
- (b) procedures for the establishment and use of the computerised information system provided for in Article 20 and transitional measures for the migration of the data and the information from existing systems into the new system and its full operability;
- (c) the format and structure of the data to be entered into the computerised information system provided for in Article 20;
- (d) the deadlines and frequencies of [...] notification and [...] reporting provided for in Articles 17 [...] and 18 [...] **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.**
- (e) **the listing of [...]** notification and [...] reporting regions provided for in Article 19 [...].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Surveillance

Article 22

Operators' obligation for surveillance

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 serious disease signs in animals under their responsibility.

Article 23
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, taking into account:
 - (a) the type of establishment;
 - (b) the categories and species of kept animals on the establishment;
 - (ba) the epidemiological situation in the zone or region as regards listed and emerging diseases to which the animals in the establishment are susceptible;**
 - (c) any other relevant surveillance, [...] or official controls that the kept animals and type of establishment are subject to.

Those animal health visits shall be at frequencies that are proportionate to the risks posed by the establishment.

They may be combined with visits for other purposes.

2. The animal health visits provided for in paragraph 1 shall be for the purpose of **disease prevention, in particular through⁶³**:
 - (a) providing advice to the operator on biosecurity and other animal health matters, as relevant for the type of establishment and the categories and species 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 255(2).

[...]

⁶³ The order of subpoints (a) and (b) has been reversed

Article 25
The competent authority's obligation for surveillance

1. The competent authority shall conduct surveillance for the presence of listed diseases referred to in Article 8(1)(e) and for **relevant** emerging diseases.
2. The surveillance shall be designed to ensure the timely detection of the presence of the listed diseases referred to in Article 8(1)(e) and emerging diseases by collecting, collating and analysing relevant information relating to the disease situation.
- 2a 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 22 and 23, respectively.**
- 2b The competent authority shall ensure that surveillance meets the requirements provided for in Article 26 and in any rules adopted pursuant to Article 28(a).**
3. 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 26
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 25 [...] 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 22, **including animal health visits referred to in Article 23**, or by other public authorities.

Article 27
Union surveillance programmes

1. The competent authority shall undertake surveillance provided for in Article 25(1) in the framework of a surveillance programme when [...] **there is a relevance of the disease for the Union in accordance with Article 28 (ba).**

[...]

2. Member States establishing a surveillance programme in accordance with paragraph 1 shall [...] **submit it to** the Commission [...].
3. Member State undertaking a surveillance programme in accordance with paragraph 1 shall submit regular reports on the results of that surveillance programme to the Commission.

Article 28
Delegation of powers

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) the design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance as provided for in Article 26;
- (b) the criteria for the official confirmation and case definitions of listed diseases referred to in Article 8(1)(e) and where relevant emerging diseases;
- (ba) the criteria to establish the relevance of a disease to be subject to a surveillance programme relevant for the Union for the purpose of Article 29(1)(a), taking into account the disease profile and the risk factors involved;**
- (c) requirements for surveillance programmes provided for in Article 27(1) regarding:
 - (i) the contents of surveillance programmes;
 - (ii) the information to be included in the submission of surveillance programmes in accordance with Article 27(2) and regular reports in accordance with Article 27(3);
 - (iii) the period of application of surveillance programmes.

Article 29
Implementing powers

1. The Commission shall, by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes provided for in Articles [...] **25** and **27** and rules adopted pursuant to Article 28 on:
 - (a) establishing which of the listed diseases referred to in Article 8(1)(e) are to be subject to surveillance programmes **in accordance with Article 27, 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 27.**
3. [...] **The implementing acts referred to in paragraphs 1 and 2** shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Eradication programmes

Article 30

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 Article 8(1)(b) in their whole 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"); **which shall apply until the conditions to apply for disease-free status in the territory of the Member State or zone as provided for in Articles 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 Article 8(1)(c) and which decide to establish a programme for the eradication of that listed disease to be carried out in the animal populations concerned by it and covering the relevant parts of their territory or zones or compartments thereof ("[...] optional eradication programme") shall submit it to the Commission for approval, **where the Member State asks the recognition of animal health guarantees within the Union as regards movements of animals or products for that disease.**

Such a programme shall apply until:

 - (a) **the conditions to apply for disease-free status in the territory of the Member State or zone as provided for in Articles 36(1), or compartment, as provided for in Article 37(2) are fulfilled; or**
 - (b) **the conditions to apply for disease-free status cannot be achieved and that programme no longer fulfils its purpose; or**
 - (c) **the Member State 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.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

- 3a.** On duly justified imperative grounds of urgency relating to a listed disease representing a risk of highly significant impact the Commission shall adopt immediately applicable implementing acts provided for in point (a) of [...] paragraph **(3)** in accordance with the procedure provided for in Article 255(3).

The Commission may, **for duly justified reasons**, by means of implementing acts, [...] **approve an amendment proposed by the Member State or withdraw the approval of** eradication programmes approved in accordance with points (a) and (b). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

- 4. The Commission shall [...] adopt delegated acts in accordance with Article 253 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 paragraph 1(b) and paragraph 2 [...], where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 31(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 provided for in (b).

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 amending or terminating rules adopted pursuant to point (b) of this paragraph.

Article 31

*Measures under the 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 the disease occurs and to prevent re-infection;
 - (b) surveillance carried out in accordance with the rules laid down in Article [...] **25** to 29 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 253 concerning the **following elements to ensure the effectiveness of the eradication programmes**:
- (a) disease control measures as provided for in paragraph 1(a);
 - (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 the occurrence of positive results for the listed disease as provided for in paragraph 1(c);
 - (e) **criteria for vaccination, where relevant and appropriate for the disease or species in question.**

Article 32

*Content of the submission of compulsory and [...] **optional** eradication programmes*

Member States shall include the following information in applications for compulsory and [...] **optional** eradication programmes submitted to the Commission for approval in accordance with Article 30(1) and (2):

- (a) a description of the epidemiological situation of the listed disease covered by the compulsory or [...] **optional** eradication programme;
- (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 31(1) and the rules adopted pursuant to Article 31(2);
- (ca) a description of the organisation, supervision and roles of the parties involved in the eradication programme;**
- (d) the estimated duration of the [...] eradication programme;
- (e) the intermediate targets and the disease control strategies for undertaking the [...] eradication programme.

[...]

Article 33
Reporting

The Member State undertaking the [...] eradication programme shall submit to the Commission:

- (a) [...] reports to monitor the intermediate targets referred to in Article 32(e) of the on-going [...] **eradication** programmes;
- (b) a final report after its completion.

[...]

Article 35
Implementing powers

The Commission shall by means of implementing acts, lay down the information, format and procedural requirements concerning the rules provided for in Articles 30 to 33 on:

- (a) the submission of draft compulsory and draft [...] **optional** eradication programmes for approval;
- (b) performance indicators;
- (c) the 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 255(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 the disease-free status for one or more of the listed diseases referred to in Article 8(1)(b) and (c), **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 in the entire territory of the Member State or in the relevant zone or zones covered by that 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 that application, **according to the criteria referred to in Article 39(a)(ii);**
 - (c) in the event of listed diseases only transmitted by vectors, none of the vectors are present, or 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 that application, **according to the criteria referred to in Article 39(a)(ii);**
 - (d) freedom from the listed disease has been demonstrated by:
 - (i) an eradication programme complying with the rules laid down in Article 31(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 to substantiate that the conditions for disease-free status laid down in paragraph 1 are fulfilled.
- 2a. A Member State may in certain specific cases apply to the Commission for approval of the disease-free status for one or more of the listed diseases referred to in Article 8(1)(a) in particular for approval of the 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 31(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 exceed those resulting from maintaining disease freedom without vaccination.**
3. The Commission shall, by means of an implementing act approve, subject to amendments where necessary, applications by Member States for disease-free status **or non-vaccination status** when the conditions provided for in paragraph 1 and 2 **or, as relevant, paragraph 2a** are fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 37
Compartments

1. A Member State may apply to the Commission for the recognition of the disease-free status of compartments for listed diseases referred to in Article 8(1)(a), and for the protection of such disease-free status of that compartment in the event of outbreaks 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 that 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 to ensure the disease-free status of all establishments forming part of it;
 - (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 94 and 95 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 181 and 182 for compartments keeping aquaculture animals and products thereof.

2. A Member State may apply to the Commission for the recognition of disease-free status of compartments for one or more of the listed diseases referred to in Article 8(1)(b) and (c), provided that:
 - (a) the introduction of the listed disease or listed diseases covered by that 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 provided for in Article 36(1) [...];
 - (ii) the establishments of the compartment start or resume their activities and have established a common biosecurity management system to ensure the disease freedom of the compartment;

- (c) [...] **the compartment covered by the application is subject to a single** common biosecurity management system [...] to ensure [...] the disease-free status of [...] **all establishments forming part of it;**
 - (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 94 and 95 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 181 and 182 for compartments keeping aquaculture animals and products thereof.
3. Applications by Member States for the recognition of disease-free status of compartments in accordance with paragraphs 1 and 2 shall include evidence to substantiate 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 provided for in paragraphs 1 or 2 and 3 are fulfilled;
 - (b) **determine for which of the listed diseases referred to in Article 8(1)(a), (b) and (c), the disease-free compartments may be established.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255⁽²⁾.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning **provisions supplementing those in this Article on:**
- (a) the requirements for the recognition of the disease free status of compartments as provided for in paragraphs 1 and 2 [...], **based on** the profile of the listed diseases referred to in Article 8(1)(a), (b) and (c), concerning at least:
 - (i) surveillance and other evidence needed to substantiate disease-freedom;
 - (ii) biosecurity measures;
 - (b) the detailed rules for the approval by the competent authority of the disease-free status of compartments provided for in paragraphs 1 and 2 [...];

- (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 updated list of **its territory or zones with disease-free status as provided for in Article 36(1) and 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 this information 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 253 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 and the evidence required to substantiate such claims, as provided for in Article 36(1)(a);
 - (ii) the criteria to be used to substantiate that a disease agent or vector is not able to survive and the evidence required to substantiate such claims as provided for in Article 36(1)(b) and (c);
 - (iii) the criteria to be used **and conditions** to determine freedom from the disease, as referred to in Article 36(1)(d);
 - (iv) surveillance and other evidence needed to substantiate disease freedom;
 - (v) biosecurity measures;
 - (vi) restrictions and conditions for vaccination in disease free Member States and zones thereof;
 - (vii) establishment of the zones separating the disease-free zones or zones under the eradication programme from the restricted zones ("buffer zones");
 - (viii) zones which extend over the territory of more than one Member State;

- (b) derogations from the requirement for the approval by the Commission of disease-free status for one or more listed diseases referred to in Article 8(1)(b) and (c) as provided for in Article 36(1), where such approval is not necessary due to detailed rules for disease freedom having been laid down in rules adopted pursuant to point (a) [...];
- (c) the information to be provided by Member States to the Commission and the other Member States to substantiate the declarations of disease-free status, without the adoption of an implementing act in accordance with Article 36(3), as provided for in point (b) [...].

Article 40
Implementing powers

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

[...]

- (i) the applications for the disease-free status of the entire territory of the Member State, or zones and compartments thereof;
- (ii) the information exchange 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 255(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 37(1) and (2), and rules laid down pursuant to paragraph 3 of this Article and Article 39 remain fulfilled;
 - (b) surveillance, taking into account the requirements provided for in Article 26, is undertaken to verify that the territory, zone or compartment remains free of the listed disease for which it was approved or recognised for disease-free status;
 - (c) restrictions are applied on movements of animals, and where relevant their products, of listed species for the listed disease for which the disease-free status was approved or recognised, into the territory, zone or compartment, 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 for 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 253 concerning the following conditions for maintaining disease-free status:
 - (a) surveillance as provided for in paragraph 1(b);
 - (b) biosecurity measures as provided for in paragraph 1(d).

Article 42

Suspension, withdrawal and restoration of disease-free status

- 1. Where a Member State **becomes aware of 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 for 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 was 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 did not have significant impact and the Member State can provide assurances that the conditions for maintaining its disease-free status are again fulfilled.

3. Where further investigation by the Member State confirms [...] that the listed disease for which it obtained the disease-free status or other significant breaches of the conditions for maintaining disease-free status **referred to in Article 41(1)** have occurred, **or there is a significant likelihood of this having** occurred, the Member State shall immediately inform the Commission.
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(3) 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 referred to in paragraph 3 [...] 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 255(2).

- 4a.** On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 [...] spreads in a rapid manner with risk of 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 255(3).
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning **provisions supplementing** the rules for the suspension, withdrawal and restoration of disease-free status [...] **set out** in paragraphs 1 and 2 [...].

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 in the event of the occurrence [...] of a listed disease referred to in Article 8(1)(a) or, if appropriate, an emerging diseases, in order to ensure a high level of disease awareness, preparedness and rapid response.
2. These 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 Article 8(1)(a) or the 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 States;
 - (iii) operational expert groups;
- (e) the implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in Article 8(1)(a) 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 255(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, preparedness and rapid response in the Member State;

- (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 on request a report on the main results of the simulation exercises to the Commission and to the other Member States.
 - 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 on:
 - (a) the frequencies [...] of simulation exercises;
 - (b) simulation exercises covering more than one listed disease referred to in Article 8(1)(a)
- [...]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 disease prevention or control for 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 disease 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;

- (ii) the Union;
 - (iii) where relevant, in neighbouring third countries and territories;
 - (iv) third countries and territories from which animals and products are brought into the Union;
- (c) the availability, effectiveness and risks of the veterinary medicinal products;
 - (d) the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products;
 - (e) the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products 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 253 concerning **what might constitute such appropriate and necessary measures as set out in Article 46 on:**
- (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;
[...]
 - (d) risk mitigating measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;
 - (e) surveillance **for specific listed diseases** following the use of vaccines and other veterinary medicinal products [...].
2. The Commission shall take into account the criteria provided for in Article 46(2) when laying down the rules provided for in paragraph 1 [...].
3. Where in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to rules adopted pursuant to paragraph 1 [...].

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 Article 8(1)(a) for which vaccination is not prohibited by a delegated act adopted pursuant to Article 47(1), 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 **any** [...] 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, 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 under the appropriate biosecurity, biosafety and bio-containment standards as provided for in Article 15(1) and delegated acts adopted pursuant to Article 15(2);
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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;
 - (b) the biosecurity, biosafety and bio-containment requirements for their operation [...] **respecting** the requirements provided for in Article 15(1) and **taking into account** the delegated acts adopted pursuant to Article 15(2).

Article 49
Access to the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks upon request, provided that stocks are available, to:
 - (a) **in the first place**, Member States;
 - (b) third countries or territories, provided that it is primarily intended to prevent the spread of a disease into the Union.
2. The Commission shall prioritise the access provided for in paragraph 1 in the event of the limited availability of stocks [...] **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(1).

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 Article 8(1)(a);
 - (b) the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent bank and in what quantities for each specific listed disease referred to in Article 8(1)(a), for which the bank 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 255(2).

2. On duly justified imperative grounds of urgency relating to a listed disease referred to in Article 8(1)(a) representing a risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(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 Article 8(1)(a) 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 provided for in Article 15(1)(a) and delegated acts adopted in accordance with Article 15(2) and Article 48(3)(b).
2. Member States shall provide the Commission [...] with up-to-date information on:
 - (a) the existence or the establishment of 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 their quantities in such banks;
 - (c) any changes in their operation.

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 255(2).

TITLE II
Disease control measures

Chapter 1
Disease control measures for [...]listed diseases referred to in Article 8(1)(a)

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. [...] **As regards** suspicion of a listed disease referred to in Article 8(1)(a) in kept animals, [...] in addition to **the notification** [...] in accordance with Article 16(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 Article 55(1)(c), (d) and (e) to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other animals or to humans.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for supplementing the disease control measures [...] as provided for in paragraph 1 [...].

Article 54

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

1. The competent authority shall in the event of the suspicion of a listed disease referred to in Article 8(1)(a) in kept animals, 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 that particular listed disease;
 - (b) **official veterinarians** take appropriate samples from those kept animals of listed species and other samples for laboratory examination in laboratories designated for that purpose by the competent authority;
 - (c) [...] laboratory examinations to confirm or rule out the presence of the particular listed disease **are carried out in such designated laboratories.**
3. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing the rules for the investigation by the competent authority provided for in paragraph 1 [...].

Article 55
Preliminary disease control measures by the competent authority

1. The competent authority shall in the event **it suspects the presence** [...] of a listed disease referred to in Article 8(1)(a) 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 in accordance with Article 61(1):
 - (a) place the establishment, [...] food and feed business or animal by-products establishment, or any other location where the disease suspicion occurs, **including those 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, or any other location;
 - (ii) the products in the establishment, [...] food and feed business or animal by-products establishment, or 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 [...] contact with wildlife **is prevented**;
 - (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 establishments, animal by-products establishments or any other location where that listed disease is suspected, as far as necessary to prevent its spread of the listed disease;
 - (f) take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4, 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 any other location**;
 - (ii) the establishment of 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 253 concerning detailed rules supplementing those laid down in paragraph 1[...] as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in Article 8(1)(a), [...] **based on** the risks involved for:

- (a) the species or category of animals;
- (b) the type of production.

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 Article 55(1)(a), where necessary.

SECTION 2 EPIDEMIOLOGICAL ENQUIRY

Article 57

Epidemiological enquiry

- 1. The competent authority shall carry out an epidemiological enquiry in event of the [...] confirmation of a listed disease referred to in Article 8(1)(a) in animals.
- 2. The epidemiological enquiry provided for in paragraph 1 shall aim at:
 - (a) identifying the likely origin of the listed disease and the means of its spread;
 - (b) calculating the likely length of time that the listed disease has been present;
 - (c) identifying [...] establishments and epidemiological units therein, [...] food and feed business or animal by-products establishment or any other locations where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;
 - (d) obtaining 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) obtaining 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 referred to in Article 8(1)(a)

1. The competent authority shall base an official confirmation of a listed disease referred to in Article 8(1)(a) 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 253 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 diseases referred to in Article 8(1)(a) has been ruled out based on 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 DISEASE CONFIRMATION IN KEPT ANIMALS

Article 60

Immediate disease control measures to be taken by the competent authority

In the event of official confirmation in accordance with Article 58(1) of an outbreak of a listed disease referred to in Article 8(1)(a) 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 referred to in Article 8(1)(a) 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 Article 60 point (a)**, in order to prevent the further spread of that listed disease:
 - (a) movement restrictions for 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(1);
 - (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, household, 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 [...] or 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 and 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 Article 8(1)(a) for 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 Article 8(1)(a) is another Member State or 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. In the events referred to in paragraph 2, 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

Delegating power for the disease control measures in affected and epidemiologically linked establishments and locations

The Commission shall [...] adopt delegated acts in accordance with Article 253 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 locations for any listed disease referred to in Article 8(1)(a), **including rules on which disease control measures referred to in Article 61(1) shall be applied in 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 Article 61(1)(a) to (e);
- (b) the procedures for cleaning, disinfection and [...] **control of insects and rodents or other necessary biosecurity measures** provided for in [...]Article 61(1)(f), specifying, where appropriate, the use of biocidal products for those purposes;
- (c) the conditions and requirements for sampling and laboratory examination provided for in Article 61(1)(g) to (h);
- (d) the detailed conditions and requirements of repopulation provided for in Article 61(3);
- (e) the necessary disease control measures provided for in Article 62 to be carried out in epidemiologically linked establishments, locations and means of transport.

Article 64

Establishment of restricted zones by the competent authority

1. The competent authority shall establish a restricted zone **referred to in Article 60(b)** around the affected establishment, [...] food or feed business, animal by-products establishment or other location where the outbreak of a listed disease referred to in Article 8(1)(a) in kept animals has occurred, where appropriate, taking into account:
 - (a) the disease profile;
 - (b) the geographical situation of the restricted zones;
 - (c) the ecological and hydrological factors of the restricted zones;
 - (d) the meteorological conditions;
 - (e) the presence, distribution and type of vectors in the restricted zones;
 - (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 Article 8(1)(a):
 - (a) adapt the boundaries of the restricted zone;
 - (b) establish additional restricted zones.
3. Where the restricted zones are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing the restricted zones provided for in paragraph 1.
4. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning detailed rules for the establishment and amendment of restricted zones, including protection or surveillance zones.

Article 65
Disease control measures in a restricted zone

1. The competent authority shall [...] **ensure that** one or more of the following disease control measures, **subject to national requirements for gaining access to private residences, are taken** in the restricted zone in order to prevent the further spread of the listed disease referred to in Article 8(1)(a):
 - (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;
 - (c) movement 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 zones and transport through the restricted zones;
 - (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(1);
 - (f) cleaning, disinfection and [...] **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 zones;
 - (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 risks of the spread of that listed disease.
2. The competent authority shall:
- (a) take all necessary measures to fully inform the persons in the restriction zones 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 as referred to in paragraph 1.**
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 the restricted zone provided for in Article 64(1) operators shall only move the kept animals and products following the permission by the competent authority and in accordance with any instructions of that authority.**
- 2. [...] Operators keeping animals and products in the restricted zone provided for in Article 64(1) shall notify intended movements of kept animals and products, within or out of the restricted zone, to the competent authority. Insofar as the competent authority has imposed notification obligations in accordance with Article 65(2)(b), the operator shall notify in accordance with those obligations.**

Article 67

Delegation of powers concerning the disease control measures in restricted zones

The Commission shall [...] adopt delegated acts in accordance with Article 253, concerning detailed rules on the disease control measures to be taken in a restricted zone provided for in Article 65(1) for each listed disease referred to in Article 8(1)(a), **including rules on which disease control measures referred to in Article 65(1) shall be applied in 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 Article 65(1) (a), (c), (d), (e), (g), (h) and (i);
- (b) the procedures for cleaning, disinfection and [...] **control of insects and rodents or other necessary biosecurity measures** provided for in Article 65(1)(f), 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 Article 65(1)(b);
- (d) other specific disease control measures to limit the spread of specific listed diseases referred to in Article 8(1)(a).

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 Article 8(1)(a) for which the restrictions were applied have been carried out;
 - (b) the final cleaning, disinfection or [...] **control of insects and rodents or other necessary biosecurity measures** has been carried out as appropriate for:
 - (i) the listed disease referred to in Article 8(1)(a) 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 Article 8(1)(a) for which the disease control measures have been applied, and the type of establishment or location 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 253 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 or [...] **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 to regain disease-free status after the outbreak;
 - (c) the repopulation of the restricted zones 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);
- 2a. [...] **The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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 in order to regain the disease-free status.

Article 69
Emergency vaccination

1. Where relevant for the effective control of the listed disease referred to in Article 8(1)(a) for which the disease control measures due to the outbreak apply, the competent authority may:
 - (a) develop a vaccination plan;
 - (b) establish vaccination zones.
2. The competent authority shall, when deciding on the vaccination plan and the establishment of vaccination zones provided for in paragraph 1 [...], take the following into account:
 - (a) the requirements for emergency vaccination provided for in the contingency plans provided for in Article 43[...];
 - (b) the requirements for the use of vaccines provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47(1).
3. Vaccination zones provided for in paragraph 1(b) [...] shall comply with the requirements on risk mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with Article 47(1)(d) and (e).

SECTION 5
WILD ANIMALS

Article 70
Wild animals

1. In the event [...] **the competent authority of the affected Member State suspects or officially confirms the presence** of a listed disease referred to in Article 8(1)(a) 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 paragraph 1(b) **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 253 concerning:
 - (a) **criteria and procedures for the surveillance pursuant to paragraph 1(a) in the case of official confirmation of a listed disease referred to in Article 8(1)(a), in accordance with Article 26;**
 - (b) **detailed rules supplementing the disease prevention and control measures pursuant to paragraph 1(b) in the case of official confirmation of a listed disease referred to in Article 8(1)(a).**

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.

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 by the Member States, coordination of measures by the Commission and temporary special disease control rules concerning Sections 1 to 5 (Articles 53 to 70)

1. Member States may take additional disease control measures to those provided for in **Article 55**, Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in 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 they are necessary and proportionate to control the spread of the listed disease referred to in Article 8(1)(a), taking into account:
 - (a) the particular epidemiological circumstances;
 - (b) the type of establishments, other locations and production;
 - (c) the categories and species 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 the 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 delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);
 - (b) any additional disease control measures taken by it 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, 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 Article 8(1)(a) 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 255(2).
4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

Chapter 2
Disease control measures for listed diseases referred to in Article 8(1)(b) and (c)

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 referred to in Article 8(1)(b)

1. [...] **As regards** suspicion of listed diseases referred to in Article 8(1)(b) [...] in kept animals, [...] in addition to **the notification** [...] in accordance with Article 16(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 referred to in Article 74(1)(a) and any delegated acts adopted pursuant to Article 74(3), [...] to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other animals or to humans.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for supplementing the disease control measures [...] as provided for in paragraph 1 [...].

Article 73

Investigation by the competent authority in the event of suspicion of a listed disease referred to in Article 8(1)(b)

1. The competent authority shall, in the event of the suspicion of a listed disease referred to in Article 8(1)(b) [...] in kept animals, 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 that particular listed disease;
 - (b) **official veterinarians** take appropriate samples from the kept animals of listed species and other samples for laboratory examination in laboratories designated for that purpose by the competent authority;
 - (c) [...] laboratory examinations to confirm or rule out the presence of the particular listed disease **are carried out in such designated laboratories**.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing rules for the investigation provided for in paragraph 1 [...].

Article 74

Preliminary disease control measures by the competent authority for listed diseases referred to in Article 8(1)(b)

1. The competent authority shall, in the event **it suspects** [...] a listed disease referred to in Article 8(1)(b) [...] 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 disease control measures in accordance with Article 78(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** provided for in Article 57(1) [...].
- 1a 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.**
2. The preliminary disease control measures provided for in paragraphs 1 and 1a shall be appropriate and proportionate to the risk posed by the listed disease referred to in Article 8(1)(b) [...] 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 that listed disease is suspected;
 - (d) the preliminary disease control measures provided for in Article 55(1) and Article 56 and any delegated act adopted pursuant to Article 55(2).
3. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning rules **for listed diseases referred to in Article 8(1)(b)** supplementing those laid down in paragraph 1 [...], while taking into account the matters referred to in paragraph 2 [...], as regards:
 - (a) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in paragraph 1(a);
 - (b) the application of the preliminary disease control measures provided for in paragraph 1(a) 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 due to the disease profile.

Article 75

Review and extension of the preliminary disease control measures for listed diseases referred to in Article 8(1)(b)

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 Article 74(1)(b);
- (b) further extended to other locations, as referred to in Article 74(3)(b) where necessary.

Article 75a

Obligations of operators and other relevant natural and legal persons and measures by competent authority in the event of suspicion of listed diseases referred to in Article 8(1)(c)

1. **As regards suspicion of a listed disease referred to in Article 8(1)(c) 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 30(2), the Member State shall take measures to ensure that operators and other relevant natural and legal persons concerned take measures provided for in Article 72(1), pending any disease control measures being taken by the competent authority in accordance with paragraph 2.**
2. **The competent authority of a Member State that has opted for the eradication of a listed disease referred to in paragraph 1 shall in the event 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 paragraph 2 and the carrying out of disease control measures in accordance with Article 79(1), carry out the preliminary disease control measures provided for in Article 74 (1) and (1a).**
3. **The competent authority shall review and extend the preliminary disease control measures referred to in paragraph 2(b) in accordance with Article 75.**
- 3a. **Paragraphs 1, 2 and 3 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).**

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing rules for:
- (a) the disease control measures as provided for in paragraph 1;
 - (b) the investigation provided for in paragraph 2(a);
 - (c) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in paragraph 2(b).

SECTION 2

DISEASE CONFIRMATION IN KEPT ANIMALS

Article 76

Official confirmation of disease by the competent authority

1. The competent authority shall base an official confirmation of a listed disease referred to in Article 8(1)(b) or (c) 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 Article 74(1)(b), where relevant;
 - (c) other available epidemiological data.
2. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 [...].

Article 77

Lifting preliminary disease control measures when disease occurrence is ruled out

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

SECTION 3

DISEASE CONTROL MEASURES IN THE EVENT OF DISEASE CONFIRMATION IN KEPT ANIMALS

Article 78

*Disease control measures by the competent authority for **listed diseases referred to in Article 8(1)(b)***

[...] In the event of an official confirmation in accordance with Article 76(1) of an outbreak of a listed disease referred to in Article 8(1)(b) 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 30(1) for that listed disease [...]; or**
- (b) **where the Member State or zone has obtained a disease-free status in accordance with Article 36 or compartment in accordance with Article 37:**
- (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 79

[...]Disease control measures to be taken by the competent authority for listed diseases referred to in Article 8(1)(c)

1. **In the event of an official confirmation in accordance with Article 76(1) of an outbreak of a listed disease referred to in Article 8(1)(c) 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 30(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 additional disease control measures 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 referred to in Article 8(1)(c) in question and shall take into account:**
 - (a) **the disease profile;**
 - (b) **the kept animals affected;**
 - (c) **economic and social impacts.**
- 2a. In the event of an official confirmation in accordance with Article 76(1) of an outbreak of a listed disease referred to in Article 8(1)(c) 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 Article 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease referred to in Article 8(1)(c) 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 80

Disease control measures for listed diseases referred to in Article 8(1)(b) in wild animals

[...]In the event [...] the competent authority of the affected Member State suspects or officially confirms[...] a listed disease referred to in Article 8(1)(b) in wild animals, [...] it shall in the entire territory of the Member State, area or zone, 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 30(1) for that listed disease has not yet been applied due to the previous absence or freedom of that disease and if measures for wild animals are necessary [...] to control and prevent the [...] spread of that disease.

[...]

Article 80a

Disease control measures for listed diseases referred to in Article 8(1)(c) in wild animals

1. In the event the competent authority suspects or officially confirms a listed disease referred to in Article 8(1)(c) 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 30(2) for that listed disease, the competent authority shall apply the disease control measures laid down in that optional eradication programme in the entire territory of the Member State, area or zone, as relevant for that suspicion or official confirmation.
2. The competent authority may take additional disease control measures 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 referred to in Article 8(1)(c) 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.
- 2a. In the event of an official confirmation of an outbreak of a listed disease referred to in Article 8(1)(c) 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 Article 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease referred to in Article 8(1)(c) 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 on 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 81

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

1. Member States shall inform the Commission of [...]:
 - (a) **the disease control measures taken by the competent authority** [...] in accordance with Article 76(1), Articles 7, [...], 78 and [...]80[...] and delegated acts adopted pursuant to Article 76(2) [...] **in respect of a listed disease referred to in Article 8(1)(b);**
 - (b) **the disease control measures taken by the competent authority, in accordance with Article 76(1), Article 77, Article 79(1) and Article 80a and delegated acts adopted pursuant to Article 76(2) in respect of a listed disease referred to in Article 8(1)(c).**
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 referred to in Article 8(1)(b) and (c), under conditions appropriate to the epidemiological situation, where:
 - (a) those disease control measures taken by the competent authority are found not to be suited to the epidemiological situation;
 - (b) that listed disease referred to in Article 8(1)(b) or (c) 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 255(2).
3. On duly justified imperative grounds of urgency relating to a listed disease referred to in Article 8(1)(b) and (c) representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(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 82
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 88, before they commence such activities:
 - (a) inform the competent authority of any such establishment under their responsibility;
 - (b) provide the competent authority with information on:
 - (i) the name and address of the operator;
 - (ii) the location and a description of the 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) other aspects of the establishment, which are relevant in determining the risk posed by it.
2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of any:

- (a) [...] changes in the establishment concerning the matters referred to in paragraph 1(b);
 - (b) cessation of activity [...] **by the operator or of** the establishment.
3. Establishments which are subject to approval in accordance with Article 89(1) shall not be required to provide the information referred to in paragraph 1 of this Article.

Article 83

Derogations from the obligation of operators to register establishments

By way of derogation from Article 82(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 84(2). Member States shall inform the Commission on such exemptions.**

[...]

Article 84

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 the establishments as provided for in Article 82(1), **including the time limits by which such information shall 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 83 [...] **based on:**

- (a) **the categories, species and numbers of kept terrestrial animals and germinal products on the establishment and the capacity of the 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 255(2).

Article 85

Registration obligations of transporters of kept ungulates and delegated acts

1. Transporters of kept ungulates, transporting those animals between Member States **or between a Member State and a third country** shall, in order to be registered in accordance with Article 88, before they commence such activities:
 - (a) inform the competent authority of their activity;
 - (b) provide the competent authority with information on:
 - (i) the name and address of the transporter;
 - (ii) the categories, species and numbers of kept [...] **ungulates planned to be transported**;
 - (iii) the type of transport;
 - (iv) the means of transport.
2. **The transporters referred to in paragraph 1** shall inform the competent authority of any:
 - (a) [...] changes concerning the matters referred to in paragraph 1(b);
 - (b) cessation of the transport activity.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing [...] the rules provided for in paragraph 1 concerning the obligation of other types of transporters **posing specific and significant risks for certain species or categories of animals**, to provide the information for the purposes of registration of its activity [...].

Article 86

*Derogations from the **registration** obligation [...] of transporters of kept ungulates*

By way of derogation from Article 85(1), Member States may exempt [...] **from the registration requirement** certain categories of transporters **posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 87(2)**. Member States shall inform the **Commission on such exemptions**. [...]

Article 87

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 the transporter for the purposes of the registration of its activity, as provided for in Article 85(1) and (3), including the time limits by which such information shall be provided.
2. **The Commission shall, by means of implementing acts, lay down rules concerning the types of transporters that may be exempted by the Member States from the registration requirement in accordance with Article 86, based on:**
 - (a) **the distances over which they transport those ungulates; 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 255(2).

Article 87a

Registration obligation of operators conducting assembly operations independent of an establishment

1. **Operators conducting assembly operations for kept ungulates and poultry, independent of an establishment, including those who buy and sell animals shall, in order to be registered in accordance with Article 88, before they commence their activities, provide the competent authority with information on:**
 - (i) **the name and address of the operator;**
 - (ii) **the categories and species of kept ungulates and poultry covered by their activity.**
2. **Operators referred to in paragraph 1 shall inform the competent authority of any:**
 - (a) **changes concerning the matters referred to in paragraph 1;**
 - (b) **cessation of activity by the operator.**

Article 87b

Derogations from the registration obligation of operators conducting assembly operations

By way of derogation from Article 87a(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 87c(2). Member States shall inform the Commission on such exemptions.

Article 87c

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 the registration as provided for in Article 87a(1), including the time limits by which such information shall be provided.**
2. **The Commission shall, by means of implementing acts, lay down rules concerning the types of operators that may be exempted by the Member States from the registration requirement in accordance with Article 87b, provided that their activity poses an insignificant risk and based on the categories, species 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 255(2).**

Article 88

Obligation of the competent authority concerning [...] registration [...]

The competent authority shall register:

- (a) establishments in the register [...] provided for in Article 96(1), where the operator has provided the information required in accordance with Article 82(1);
- (b) transporters in [...] **the** register [...] provided for in Article 96(1), where the transporter has provided the information required in accordance with Article 85(1);
- (c) **operators conducting assembly operations independent of an establishment, in the register provided for in Article 96(1) where the operator has provided the information required in accordance with Article 87a(1).**

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

SECTION 2

APPROVAL OF CERTAIN TYPES OF ESTABLISHMENTS

Article 89

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 91(1) and they shall not commence their activities until their establishment has been approved in accordance with Article 92(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 paragraph 3(b) [...].
2. Operators shall cease activity at an establishment referred to in paragraph 1 where:
 - (a) the competent authority withdraws or suspends its approval in accordance with Article 95(2); or
 - (b) in the event of conditional approval, granted in accordance with Article 94(3), the establishment fails to comply with the outstanding requirements referred to in Article 94(3) and does not obtain a final approval in accordance with Article 92(1).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning [...]:
 - (a) derogations from the requirement for operators of the types of establishments referred to in paragraph 1(a) to (d) to apply to the competent authority for approval by the competent authority, where those establishments pose an insignificant risk;

- (b) the types of establishments which must be approved in accordance with paragraph 1(e);
 - (c) special rules for the cessation of activities for germinal product establishments referred to in paragraph 1(b).
4. [...] **When** adopting delegated acts provided for in paragraph 3, **the Commission shall base those acts on the following criteria:**
- (a) the categories and species 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 90

Approval of status of confined establishments

Operators of establishments, who want to obtain the status of confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 91(1);
- (b) [...] move kept animals [...] **to or from their establishment** in accordance with the requirements provided for in Article 134(1) and any delegated acts adopted in accordance with Article 134(2) [...] **only after** their establishment [...] **has obtained** an approval of that status by the competent authority in accordance with Articles 92 and 94.

Article 91

Information obligation of operators in view to obtaining approval and implementing acts

1. Operators shall for the purposes of their application for the approval of their establishment provided for in Article 89(1) and Article 90(a), provide the competent authority with information on:
- (a) the name and address of the operator;
 - (b) the location of the establishment and a description of the facilities;
 - (c) the categories, species and number of kept terrestrial animals or germinal products **relevant for the approval** 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 posed by it.
2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of any:
- (a) [...] changes in the establishments concerning the matters referred to in paragraph 1(a), (b) and (c);
 - (b) the cessation of activity [...] **by the operator or of** the establishment.
3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by the operators in their application for the approval of their establishment in accordance with paragraph 1 of this Article, **and the time limits by which the information referred to in paragraph 1 and in point(b) of paragraph 2 shall be provided.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 92

Granting of and conditions for approval of establishments and delegated acts

1. The competent authority shall only grant approval of establishments as provided for in Article 89(1) and Article 90(a) where such establishments:
- (a) comply with the following requirements, where appropriate, on:
 - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in Article 9(1)(b) and rules adopted pursuant to Article 9(2);
 - (ii) surveillance requirements provided for in Article 22, and where relevant for the type of establishment and the risk involved in Article 23 [...];
 - (iii) record keeping provided for in Articles 97 and 98 and the rules adopted pursuant to Articles 100 and 101;
 - (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;
 - (ii) of adequate capacity for the number of kept terrestrial animals or volume of germinal products;

- (c) do not pose an unacceptable risk regarding the spread of diseases, taking into account the risk mitigation measures in place;
 - (d) have [...] adequately trained personnel for the activity of the establishment;
 - (e) have a system in place which enables the operator to demonstrate compliance with points (a) to (d) to the competent authority.
2. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning [...]:
- (a) quarantine, isolation and other biosecurity measures referred to in paragraph 1(a)(i);
 - (b) surveillance referred to in paragraph 1(a)(ii);
 - (c) facilities and equipment referred to in paragraph 1(b);
 - (d) responsibilities, competence and **specialised** training of personnel and veterinarians provided for in paragraph 1(d) for the activity of **germinal products establishments and establishments for assembly operations of ungulates and poultry**;
 - (e) the necessary supervision [...] **of germinal products establishments and establishments for assembly operations of ungulates and poultry** by the competent authority.
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 categories and species of kept terrestrial animals, **relevant for the approval**;
 - (c) the type of production;
 - (d) typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 93
Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 92(1) following an application made in accordance with Article 89(1) [...] **or Article 90(a):**

- (a) for which of the types of establishments referred to in Article 89(1), Article 90 and the rules adopted pursuant to 89(3)(b), the approval applies;
- (b) for which categories and species of kept terrestrial animals or germinal products of those species the approval applies.

Article 94

Procedures for granting the 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 Articles 89(1), Article 90 [...] **or** Article 91(1).
2. Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 89(1) [...] **or** Article 90(a) make an on-site visit.
- 2a. **Provided that the requirements referred to in Article 92 and paragraphs (1) and (2) are fulfilled, the competent authority shall grant the approval.**
3. **In the case where an establishment does not fulfil all requirements for approval referred to in Article 92,** the competent authority may grant conditional approval of an establishment where it appears, based on the application of the operator and the subsequent on-site visit of the establishment [...] as provided for in paragraph 2 [...], that it meets all the main requirements that provide sufficient guarantees that [...] **the** establishment does not represent a significant risk [...].
4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 [...], it shall grant full approval only where it appears from another on-site visit of the establishment, carried out within three months of the date of granting conditional approval, **or from documentation provided by the operator within three months from the date of granting conditional approval,** that the establishment meets all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2).

Where [...] **the** on-site visit **or the documentation referred to in the first subparagraph** shows that clear progress has been made but the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total period of six months.

Article 95

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep the approvals of establishments granted in accordance with Articles 92 and 94 under review, **at appropriate frequencies based on the risk involved.**
2. Where the competent authority identifies serious deficiencies in the establishment as regards compliance with the requirements laid down in Article 92(1) and the rules adopted pursuant to Article 92(2) and the operator is not able to provide adequate guarantees that those deficiencies will be resolved, the competent authority shall initiate procedures to withdraw the establishment's approval.

However, the competent authority may suspend an establishment's approval where the operator can guarantee that it will resolve 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 THE COMPETENT AUTHORITY [...]

Article 96

[...] Register of the competent authority

1. The competent authority shall establish and keep up-to-date a register of:
 - (a) all establishments and **operators** [...] registered pursuant to Article 88;
 - (b) all establishments approved in accordance with Articles 92 and 94.

It shall make [...] **the register referred to in points (a) and (b) available to the Commission and to the competent authorities of other Member States [...] insofar as that information is relevant for the movements of kept terrestrial animals and germinal products thereof between Member States.**

It shall make the register referred to in point (b) available to the public insofar as that information is relevant for the movements of kept terrestrial animals and germinal products thereof between Member States.

2. Where appropriate and relevant, the competent authority may combine the registration referred to in paragraph 1(a) and approval referred to in paragraph 1(b) with registration for other purposes.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning [...] the **detailed** information to be included in the register provided for in paragraph 1(a) and paragraph 1(b), and the **public availability of the register provided for in paragraph 1(b)**. [...]

SECTION 4 RECORD KEEPING

Article 97

Record keeping obligations of operators of establishments other than germinal products establishments

1. Operators of establishments subject to registration in accordance with Article 88, or approval in accordance with Article 92(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) the 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 Articles 106(b), 107(b), 109(c), 110(b), 113(b), Article 140(1) and (2), Article 162(2) and rules adopted pursuant to Articles 114 and 117 and Article 141(1)(b) and (c);
 - (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 category and species of kept terrestrial animals on 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 23(1) [...].

The records may be kept and maintained in electronic form.

2. Establishments [...] **presenting a low risk of spreading listed or emerging diseases** may be exempted by the Member State from the requirement to keep records of **all or some of** the information listed in paragraph 1 of this Article.
3. Operators of establishments shall keep the records provided for in paragraphs 1 **and 2** on the establishment and:
 - (a) make them **immediately** available to the competent authority on request;
 - (b) retain them for a minimum period to be determined by the competent authority, but which may not be less than a period of 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:**
 - a) **has access to the computerised database referred to in Article 103 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 98

Record keeping for 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, 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 accordance with Article 159 and Article 162(2) and rules adopted pursuant to Article 160(3) and (4);

(da) where relevant, the results of clinical and laboratory tests;

- (e) laboratory techniques used.
- 2. Establishments [...] **presenting a low risk of spreading listed or emerging diseases** may be exempted by the Member State from the requirement to keep records of **all or some of** the information listed in paragraph 1 [...].
- 3. The operators of germinal product establishments shall keep the records provided for in paragraphs 1 **and 2** on the establishment and:
 - (a) make them **immediately** available to the competent authority on request;
 - (b) retain them for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 99
Record keeping for 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;
 - (d) **details of accompanying documents, including their document numbers.**

The records may 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 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 a manner that they can be made immediately available to the competent authority on request;
 - (b) for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 99a
Record keeping obligations of operators conducting assembly operations

1. **Operators conducting assembly operations subject to registration in accordance with Article 88, 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) **the 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 Articles 106(b), 107(b), 109(c), 110(b), 113(b), Article 140(1) and (2), Article 162(2) and rules adopted pursuant to Articles 114 and 117 and Article 141(1)(b) and (c);**
 - (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 category and species of kept terrestrial animals under their responsibility.**

The records may be kept and maintained in electronic form.

2. **Operators whose activities present a low risk of spreading listed or emerging diseases may be exempted by the Member State 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 the records referred to in paragraph 1 for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.**

Article 100
Delegation of powers concerning record keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing the record keeping requirements provided for in Articles 97, 98, [...] 99 **and 99a**, as regards:

[...]

- (b) information to be recorded in addition to that provided for in Articles 97(1), 98(1), 99(1) **and 99a(1)**;
- (c) additional requirements for record keeping for germinal products collected, produced or processed in a germinal products establishment, after they ceased their activities.

2. [...] **When** establishing the rules to be laid down in delegated acts 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 categories and species of kept terrestrial animals or germinal products in the establishment or transported;
- (c) the type of production on the establishment or the type of [...] **activity**;
- (d) the typical movement patterns [...] and category of animals concerned;
- (e) the number of kept terrestrial animals or volume of germinal products **under the responsibility of the operator**. [...]

Article 101
*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 the Member States from the record keeping requirements provided for in Articles 97, 98, 99 and 99a as regards**

- (a) **establishments keeping, or operators handling or transporting a small number of kept terrestrial animals or small volume or number of germinal products;**
- (b) **categories or species of kept terrestrial animals or germinal products.**

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 100(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Traceability requirements for kept terrestrial animals and germinal products

SECTION 1

KEPT TERRESTRIAL ANIMALS

Article 102

Member States' responsibility for establishing a system for the identification and registration of kept terrestrial animals

1. The 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 rules adopted pursuant to it.** [...] **Such a system shall,** when appropriate, **provide** for the recording of **the** movements [...] **of such animals.**
- 1a When establishing the system referred to in paragraph 1, the Member States shall take into account:**
 - (a) the species or category of kept terrestrial animals;
 - (b) the risk posed by that species or category.
2. 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 referred to in Article 104;
 - (c) up-to-date records in establishments as provided for Article 97(1)(a) and (b);
 - (d) a computer database of kept terrestrial animals provided for in Article 103(1).
3. The system provided for in paragraph 1 shall be designed in 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 20;
 - (ii) [...] **TRACES**;
 - (e) ensures a coherent approach for the different animal species covered by the system.
4. 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 paragraph 3(a) and (b);
 - (b) integrate the identification documents, movement documents and other documents referred to in Article 104 with the animal health certificates or self-declaration document provided for in Article 140(1) and (2) and Article 148(1) and rules adopted pursuant to Article 141(b) and (c) and Article 148(3) and (4);
 - (c) designate another authority or authorise another body or a natural person for the practical application of the identification and registration system provided for in paragraph 1, **including the issuing of identification documents and the drawing up of models as provided for in paragraph 1(a), 1(aa) and 1(b) of Article 104.**

Article 103

Member States obligation for establishing 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 Article 106(a) [...];
 - (ii) the establishments keeping them;
 - (iii) their movements into and from establishments;
 - (aa) the following information related to kept animals of the ovine and caprine species:
 - (i) **information on their identification as provided for in Article 107(1)(a) and the number of animals at the establishment;**
 - (ii) **the establishments keeping them;**
 - (iii) **their movements into and from establishments;**

- (b) information related to kept animals of the porcine species and the establishments keeping them:
 - (i) **information on their identification as provided for in Article 110 and the number of animals at the establishment;**
 - (ii) **the establishments keeping them;**
 - (iii) **their movements into and from establishments;**
 - (c) the following information related to kept animals of the equine species:
 - (i) their unique [...] **code** as provided for in Article 109 [...];
 - (ii) the [...] **method** of identification **provided for in Article 109(1)(b)**, linking that animal with the identification document referred to in (iii) where relevant;
 - (iii) the **relevant identification details from the** identification document as provided for in Article 109(1)(c), **as determined in the rules adopted pursuant to Articles 114 and 117;**
 - (iv) the establishments where those animals are habitually kept;
 - (d) information related to kept terrestrial animals of species other than those referred to in (a), (b) and (c), when this is provided for in rules adopted pursuant to paragraph 2.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the recording of information related to animal species other than those referred to in paragraph 1(a), (b) and (c) 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, to:
- (a) ensure the efficient application of the disease prevention 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 104

Obligation of the competent authority for identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals

1. The competent authority shall [...]:

- (a) **issue** identification documents for kept terrestrial animals [...] **where those documents are** required by Articles [...] 109(c) [...] and 113(b) and rules adopted pursuant to Articles 114 and 117;
 - (aa) **issue identification documents for bovine animals as required by Article 106(b), unless Member States exchange electronic data with other Member States in the framework of an electronic exchange system from the date when the Commission recognises the full operability of that system;**
 - (b) **draw up models of** movement documents and other documents for identifying and tracing kept terrestrial animals, when required by Articles 107(b), 110(b), 113(b) and rules adopted pursuant to Articles 114 and 117.
2. **The provisions in paragraph (1)(aa) shall not prevent Member States from adopting national rules on the issuing of passports for animals not intended for movement between Member States.**

Article 105

Public availability of information on means of identification

The competent authority shall inform the Commission and make publicly available information on:

- (a) contact points for the computer databases established by the Member States in accordance with Article 103(1);
- (b) the authorities or bodies responsible for issuing identification documents, movement documents and other documents in accordance with Article 104, taking into account Article 102(4)(c);
- (c) the means of identification that are to be used for each category and species of kept terrestrial animals in accordance with Articles 106(a) and 107(1)(a), Article 109(1), Article 110(a), [...] Article 113(a) and rules adopted pursuant to Articles 114 and 117;
- (d) the prescribed format for the issuing of the identification documents and other documents referred to in Article 104.

Article 106

Operators obligations for 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, [...] **unless the conditions under Article 104(1)(aa) are met;**

(ba) ensure that that identification document:

- (i) is kept, correctly completed and updated by the operator; **and,**
 - (ii) accompanies those kept terrestrial animals at the time of movement, **when required by paragraph (b);**
- (c) transmit the information on movements of those kept animals from and into the establishment, **and all births and deaths on the establishment**, to the computer database provided for in Article 103(1) [...].

Article 107

Operators obligations for 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 104 when moved from the establishment keeping those animals **within that Member State;**
 - (c) transmit the information on movements from and into the establishment of those kept animals to the computer database provided for in Article 103(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 the Member State, provided that:
 - (a) **the information contained in the movement document is included in the computer database provided for in Article 103(1);**
 - (b) **the system for the identification and registration of kept animals of the ovine and caprine species provides an equivalent level of traceability as that provided by movements documents.**

[...]

Article 109

Operators obligations for 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) an unique [...] **code**, which is recorded in the computer database provided for in Article 103(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 104;
 - (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 103(1) [...].

Article 110

Operators obligations for the identification and registration of kept l 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 Article 104(b) when moved from the establishment keeping those animals **within the Member State**;
- (c) transmit the information related to the establishment keeping those animals to the computer database provided for in Article 103(1) [...].

Article 111
Derogations concerning movements of kept animals of the porcine species

By way of derogation from Article 110(b), the 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, provided that:

- (a) the information [...] **contained in** such movement documents is included in the computer database established by the Member State in accordance with Article 103(1);
- (b) the system for the identification and registration of kept terrestrial animals of the porcine species provides an equivalent level of traceability as that provided by such movement documents.

[...]

Article 113
Operators obligation for 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 [...] comply with the following requirements, when required by the rules adopted pursuant to Articles 114 and 117:

- (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 identifying and tracing animals, as appropriate for the animal species concerned.

Article 114
Delegation of powers concerning identification and registration

1. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning: [...]

- (a) **detailed requirements for the means and methods of identification of kept terrestrial animals provided for in Articles 106(a), 107(1)(a), 109(1), 110(a) and 113(a), including their application and use;**
- (b) **rules on the information to be included in:**
 - (i) **the computer databases provided for in Article 103(1)(a) to (c);**

- (ii) the identification and movement documents provided for in Articles 106(b), 107(b), 109(1)(c), and 110(b);
 - (c) rules on the exchange of electronic data between computer databases of Member States as referred to in Article 104(1)(aa).
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
- (a) detailed requirements for alternative means and methods of identification to those referred to in paragraph (1)(a), 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 Articles 106(b), 107(b), 109(1)(c), 110(b) and 113(b) to accompany animals when moved;
 - (c) detailed requirements for 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 that species, 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 Article 103(1)(d);
 - (ii) the identification and movement documents provided for in Articles 113(b).
 - (e) rules on identification and registration of kept terrestrial animals referred to in Articles 106 to 113 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 the on the matters provided for in Article 115(2).

Article 115

Delegation of powers concerning derogations from the traceability requirements

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations for operators from the identification and registration requirements provided for in Articles 106, 107 and 109 and 110:
 - (a) in cases where one or more of these elements are not necessary to meet the requirements provided for in Article 102(3)(a) and (b); **and**
 - (b) when other traceability measures in place in the Member States guarantee that the level of traceability of the animals in questions 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 them on the following matters:**
 - (a) the categories and species of kept terrestrial animals;
 - (b) the risks involved for those kept terrestrial animals;
 - (c) the number of animals in the establishment;
 - (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;
 - (f) considerations concerning the protection and conservation of species of kept terrestrial animals;
 - (g) the performance of the other traceability elements of the system for the identification and registration of kept terrestrial animals referred to in Article 102(2).

Article 117

Implementing powers concerning traceability of kept terrestrial animals

1. The Commission shall, by means of implementing acts, [...] **provide rules:**
 - (a) **for the uniform application of the access to data in the computer databases and the technical specifications and operational rules of the computer databases referred to in Article 103(a) to (c);**

- (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 as referred to in Article 104(1)(aa).

2. The Commission may, by means of implementing acts, provide rules:

- (a) for the uniform application of the identification and registration system provided for in Article 102(1) for different species or categories of kept terrestrial animals, to ensure its efficient operation;
- (b) for the uniform application of Article 102(4)(c) concerning the authorised bodies or natural persons as referred to in Article 102(4) and the conditions for their designation;
- (c) on the technical specifications and procedures, formats and design, 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 Articles 106(b), 107(1)(b), 109(1)(c), 110(b) and 113(b);
- (e) for the uniform application of the access to data in the computer databases and the technical specifications and operational rules of the computer databases referred to in Article 103 (d);
- (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 into the computer database;
- (g) on guidelines and procedures for electronic identification of animals where relevant;
- (h) on the practical application of exemptions from the identification and registration provided for in the rules adopted pursuant to Article 115(1).

3. [...] The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 255(2).

SECTION 2 GERMINAL PRODUCTS

Article 118

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;
 - (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 and their movements within and between Member States and their entry into the Union.

Article 119

Delegation power concerning traceability requirements for germinal products

1. The Commission shall [...] adopt delegated acts in accordance with Article 253 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 118;
 - 1a. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning** traceability requirements for germinal product of kept terrestrial animals of species other than of the bovine, caprine, ovine, **porcine** and equine [...] species, where necessary for:
 - (i) the efficient application of the disease prevention and control measures provided for in this Regulation;
 - (ii) the traceability of those germinal products, their movements within and between Member States and their entry into the Union.
2. [...] 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;
- (f) **the** movement patterns for the 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 120

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 provided for in Article 118(1);
- (b) operational requirements for the traceability requirements provided for in delegated acts adopted pursuant to Article 119(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Movements within the Union of kept terrestrial animals [...]

SECTION 1

GENERAL REQUIREMENTS FOR MOVEMENTS

Article 121

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 Article 8(1)(d);
 - (b) emerging diseases.
2. Operators shall only move kept terrestrial animals from **their** establishments and receive such animals, if they comply with the following conditions:
- (a) they come from establishments that have been **either**:
 - (i) [...] **registered** by the competent authority in accordance with Article 88 [...];
 - (ii) approved by the competent authority in accordance with Articles 92(1) **and 93**, when required by Article 89(1) or Article 90; **or**
 - (iii) granted a derogation from the registration requirement in Article 82;**
 - (b) they comply with the identification and registration requirements of Articles 106, 107, 109, 110 and 113 and the rules adopted pursuant to Articles 114 and 117 [...].

Article 122

Preventive 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 referred to in Article 8(1)(d) 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.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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 adequate biosecurity measures as provided for in paragraph 1(c).

SECTION 2 MOVEMENTS BETWEEN MEMBER STATES

Article 123

General requirements for movements of kept terrestrial animals between Member States

1. Operators shall only move kept terrestrial animals to another Member State if they comply with following conditions:
 - (aa) they show no disease symptoms;
 - (a) 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 Articles 55(1)[...], 61(1)(a), Article 62, Article 65(1)(c), Article 74(1) and Article 78[...] and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), [...] 74(3), [...] **and** 81(2) or the emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248, unless derogations have been granted for movement restrictions in accordance with those rules;
 - (iii) which is not situated in a restricted zone in accordance with rules laid down in Article 55(1)(f)(ii), Articles 64 and 65, Article 74(1), Article 78 and rules adopted pursuant to Article 67, Article 71(3), Article 74(3), [...] and Article 81(2) or the emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248, unless derogations have been granted in accordance with those rules;
 - (b) they have not been in contact with kept terrestrial animals subject to movement restrictions referred to in point (a)(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;
 - (ii) the type of establishment;
 - (iii) the species and category of kept terrestrial animals moved;

- (iv) other epidemiological factors;
 - (c) they comply with the relevant requirements provided for in Sections 3 to 8 (**Articles 121 to 151**).
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 another Member State unless they need to stop at a place of resting for animal welfare reasons.

Article 124
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 Articles 106(a) and 107(1)(a), Article 109(1) and Articles 110(a) and 113(a) and the rules adopted pursuant to Articles 114 and 117 are present;
 - (ii) the identification documents provided for in Articles 106(b) and [...] Article 109(1)(c), Article 113(b) and the rules adopted pursuant to Articles 114 and 117 are present and are correctly completed;
 - (b) check that the animal health certificates provided for in Article 140 and rules adopted pursuant to Article 141(b) and (c) or the self-declaration documents provided for in Article 148 and the rules adopted pursuant to Article 148(3) **and (4)** are present;
 - (c) inform, **after checking the kept terrestrial animals received**, the competent authority 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 point (a)(ii) and (b).

2. In the event of any irregularity as referred to in paragraph 1(c), the operator shall isolate the animals concerned by that irregularity until the competent authority has taken a decision regarding them.

Article 125

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 a part of an eradication programme provided for in Articles 30(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 126

General requirements for operators for 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 121, 122, 123 and 125.

SECTION 3

SPECIFIC REQUIREMENTS FOR MOVEMENTS TO OTHER MEMBER STATES OF UNGULATES AND POULTRY

Article 127

Movement 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 they comply with following conditions as regards the listed diseases referred to in Article 8(1)(d):

- (a) they show no clinical symptoms or signs of listed diseases referred to in Article 8(1)(d) 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 required by rules adopted in accordance with Article 128 or Article 132;**

- (d) they **comply, as appropriate, with the following conditions supporting that those animals** do not pose a significant risk for the spread of those listed diseases at the place of destination **in relation to:**
 - (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 result of laboratory or other examinations necessary to provide guarantees on the health status required for the movement;**
 - (iii) **the application of vaccination or other disease preventive or risk mitigating measures aimed at limiting the spread of the relevant disease to the places of destination or passage.**

Article 128

Delegation of powers for movement of kept ungulates and poultry to other Member States

1. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning:
 - (a) residency periods provided for in Article 127(b);
 - (b) the period of time necessary for limiting the introduction of kept ungulates or poultry into establishments prior to movement provided for in Article 127(c);
 - (c) supplementary requirements to ensure that the kept ungulates and poultry do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d), as provided for in Article 127(d);
 - (d) other **necessary** risk mitigating measures [...] supplementing the requirements laid down in Article 127.

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 matters:**
 - (a) the listed diseases referred to in Article 8(1)(d) 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 Article 8(1)(d) at the establishments, compartments, zones and Member States of origin and destination;
 - (c) the type of establishment and the type of production at the places of origin and destination;
 - (d) the type of movement;
 - (e) the categories and species 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 129

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 253 concerning the time of slaughter provided for in paragraph 1 of this Article.

SECTION 4

ASSEMBLY OPERATIONS FOR KEPT UNGULATES AND POULTRY

Article 130

Derogation for assembly operations

1. By way of derogation from Article 123(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 [...] shall only take place in an establishment approved for that purpose in accordance with Article 92(1) and Article 94(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 at:**

- (a) [...] their establishment or final place of destination; or
- (b) [...] **the subsequent** assembly operation [...] **in an establishment approved for that purpose in accordance with Article 92(1) and Article 94(3) and 94(4).**

Article 131

Disease prevention requirements for assembly operations

Operators conducting assembly operations shall ensure that:

- (a) the kept ungulates and poultry assembled are of the same health status or where they are not of the same health status, the lower health status shall apply 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 Article 132(c);
- (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 of a lower health status;
 - (ii) do not pose a significant risk for the spread of the listed diseases referred to in Article 8(1)(d) to the kept ungulates or poultry at the place of the assembly operation;
- (d) the kept ungulates [...] **and** poultry are identified **where required by this Regulation** and [...] **are** accompanied with the following documents:
 - (i) the identification and [...] **movement** documents where provided for in Articles 106(b), 107(b), 109(c), 110(b) and Article 113(b) and rules adopted pursuant to Articles 114 and 117, unless derogations are provided for according to Articles [...] **107(2) and 115**;
 - (ii) the animal health certificates where provided for in Article 140 and Article 141(1)(c), unless derogations are provided for in the rules adopted pursuant to Article 141(1)(a);
 - (iii) the self-declaration document where provided for in Article 148.

Article 132

Delegation of powers concerning assembly operations

The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning:

- (a) specific rules for assembly operations, where other risk mitigating measures, in addition to those provided for in Article 131(b) and (c), 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 130 [...];
- (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 Article 131(b);
- (d) **detailed rules as regards the** biosecurity measures provided for in Article 131(c).

SECTION 5
**MOVEMENTS TO OTHER MEMBER STATES OF KEPT TERRESTRIAL ANIMALS OTHER
THAN KEPT UNGULATES AND POULTRY**

Article 133

*Movement 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 they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) at the place of destination.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules to ensure that the kept terrestrial animals other than kept ungulates or poultry do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) 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 matters:**
 - (a) the listed diseases referred to in Article 8(1)(d) 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 Article 8(1)(d) at 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 destination;
 - (e) the categories and species 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 134

Kept terrestrial animals intended for confined establishments and delegated acts

1. Operators shall only move kept terrestrial animals to a confined establishment if they comply with the following conditions:
 - (a) they originate from another confined establishment;
 - (b) they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to listed species or to categories of animals at the confined establishment of destination, except where such movement is authorised for scientific purposes.
2. The Commission shall [...] adopt delegated acts in accordance with Article 253 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 mitigating 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 135

[...] 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 into the territory of the Member State of kept terrestrial animals for scientific purposes, which do not comply with the requirements of Sections 1 to 5 (**Articles 121 to 133**), with the exception of Articles 121 and 122, Article 123(1)(a)(ii) and Article 124.
2. The competent authority shall only grant derogations provided for in paragraph 1 under the following conditions:
 - (a) the competent authorities of the place of destination and origin:
 - (i) have agreed on the conditions for such movements;

- (ii) [...] **ensure that** the necessary risk mitigating measures [...] **are in place so** that those movements do not jeopardise the health status en route and the places of destination with regard to the listed diseases referred to in Article 8(1)(d);
 - (iii) have notified, where relevant, the competent authority of Member States of passage of the derogation granted and the conditions under which it is granted;
 - (b) those movements of those animals take place under the supervision of the competent authorities of places of origin and destination, and where relevant, the competent authority of the Member State of passage.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning [...] rules for derogations by the competent authorities, **supplementing those** provided for in paragraphs 1 and 2 of this Article.

Article 136

*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 123 to 133**), with the exception of Article 123(1)(a) and (b) and Articles 124 and 125, for intra-Union movements of kept terrestrial animals between Member States where such movements are for:
 - (a) recreational use near borders;
 - (b) exhibitions, and for sporting, cultural and similar events organised near borders;
 - (c) grazing of kept terrestrial animals in grazing areas shared between Member States;
 - (d) work of 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 mitigating measures 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 provided for in paragraph 1.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning [...] rules for derogations by the competent authority of the place of destination, **supplementing those** provided for in paragraph 1 of this Article.

Article 137

*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 253 concerning:

- (a) specific requirements supplementing the rules laid down in Sections 2 to 5 (**Articles 123 to 133**) for the movements of kept terrestrial animals for the following purposes:
 - (i) circuses, zoos, pet shops, animal shelters and wholesalers;
 - (ii) exhibitions and for sporting, cultural and similar events;
- (b) derogations from Sections 2 to 5 (**Articles 123 to 133**) with the exception of Article 123(1)(a) and (b) and Articles 124 and 125 for the movements of kept terrestrial animals referred to in point (a).

Article 138

*Implementing power for temporary **rules** [...] for movements of specific species or categories of kept terrestrial animals*

1. The Commission may, by means of implementing acts lay down rules concerning temporary **additional or alternative** [...] rules 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 127, Article 129(1), Articles 130 and 131, Articles 133(1), 134(1) and 135(1) and (2) and Article 136 and the rules adopted pursuant to Articles 128(1) and 129(2), Article 132, Articles 133(2), 134(2), 135(3) and 136(4) and Article 137 are not effectively mitigating the risks posed by the movement of such animals; or
 - (b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6 (**Articles 121 to 139**).
2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to diseases representing a risk of highly significant impact and taking into account the matters referred to in Article 139 the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Article 139

Matters to be taken into account when adopting delegated and implementing acts provided for in this Section

[...] **When** establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 134(2), 135(3) and 136(4) and Articles 137 and 138, **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 Article 8(1)(d) at the places of origin, **passage** and destination;
- (c) listed animal species for the listed diseases referred to in Article 8(1)(d);
- (d) biosecurity measures in place at the places of origin, destination and en route;
- (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 140

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 they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 146(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 Article 141(1)(c).
2. **In cases where** kept terrestrial animals are allowed to leave a restricted zone provided for in Article 55(1)(f)(ii), Article 56 and Article 64(1) and are subject to disease control measures provided for in Articles 55(1), 65(1), 74(1) or Article 78(1) and (2) or rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(3), Article 79, Article 81(3) or Article 248; **and** the kept terrestrial animals 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** they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 146(1).

The competent authority may decide that such a certificate does not have to be issued for the movements of kept terrestrial animals within that Member State when that authority considers that an alternative system ensures that the consignment of such animals is traceable and those animals 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 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 144.

Article 141

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 253 concerning:
- (a) derogations from the animal health certification requirements provided for in Article 140(1), for movements of kept terrestrial animals, which do not pose a significant risk for the spread of a disease due to:
- (i) the species or categories of the kept terrestrial animals that are being moved and the listed diseases referred to in Article 8(1)(d) 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, passing through another Member State.**
 - (b) special rules for animal health certification requirements provided for in Article 140(1) where specific risk mitigating measures concerning surveillance or biosecurity are taken, taking into account the matters provided for in paragraph 2, which ensure:
 - (i) the traceability of the kept terrestrial animals being moved;
 - (ii) that the kept terrestrial animals being moved comply with required animal health requirements for movements provided for in Sections 1 to 6 (**Articles 121 to 139**);
 - (c) the requirement for animal health certification for movements of species and categories of kept terrestrial animals other than those referred to in Article 140(1)(a)(b) and (c) in cases where animal health certification is imperative to ensure that the movement in question complies with the animal health requirements for movements provided for in Sections 1 to 6 (**Articles 121 to 139**);
2. When establishing the special rules provided for in paragraph 1(b), the Commission shall take the following matters into account:
- (a) the **assessment** of the competent authority **of** the biosecurity put in place by operators as provided for in Article 9(1)(b) and rules adopted pursuant Article 9(2);
 - (b) the capability of the competent authority to take necessary and appropriate measures and activities required by this Regulation as provided for in Article 12(1);
 - (c) the level of basic knowledge of animal health as provided for in Article 10 and the **encouragement thereof** provided for in Article 12(2);
 - (d) the performance of the animal health visits as provided for in Article 23 ~~or~~ other relevant surveillance or official controls in place;
 - (e) the performance of the Union notification and reporting as provided for in Articles 17 to 20 and the rules adopted pursuant to Articles 18(3) and Article 21 applied by the competent authority;

- (f) the application of surveillance as provided for in Article 25 and surveillance programmes as provided for in Article 27 and rules adopted pursuant to Articles 28 and 29.
3. The Commission shall take the matters referred to in paragraph 1(a)(i) to (iv) into account, when establishing the requirements for animal health certification provided for in paragraph (1)(c).

Article 142
Contents of animal health certificates

1. The animal health certificate **referred to in Article 140** 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;
 - (aa) the means of transport and the transporter;**
 - (b) a description of kept terrestrial animals;
 - (c) the number of kept terrestrial animals;
 - (d) the identification and registration of kept terrestrial animals, where required by Articles 106, 107, 109, 110 and 113 and rules adopted pursuant to Articles 114 and 117, unless derogations are provided for in accordance with Article 115; and
 - (e) the necessary information needed to demonstrate that the kept terrestrial animals comply with the relevant animal health requirements for movements provided for in Sections 1 to 6 (**Articles 121 to 139**).
2. The animal health certificate may include other information required under other Union legislation.

Article 143
Delegation of powers and implementing acts concerning the contents of animal health certificates

1. The Commission shall adopt delegated acts in accordance with Article 253 concerning:

- (a) detailed rules on the content of animal health certificates provided for in Article 142(1) for different categories and species of kept terrestrial animals and for specific types of movements provided for in the rules adopted pursuant to Article 144;
 - (b) additional information to be contained in the animal health certificate provided for in Article 142(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 255(2).

Article 144

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 253 concerning specific measures **derogating from or** supplementing the obligation of operators to ensure that animals are accompanied by an animal health certificate provided for in Article 140 and **in** the rules adopted pursuant to Article 141 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 130 prior to reaching their final place of destination;
- (b) movements of kept terrestrial animals, which may not continue their route to their final place of destination and 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 route was unexpectedly interrupted for animal welfare reasons;
 - (ii) unpredicted accidents or events en route;
 - (iii) the kept terrestrial animals were rejected at the place of destination in a Member State or at the external border of the Union;
 - (iv) the kept terrestrial animals were rejected at a place of assembly or resting;
 - (v) the kept terrestrial animals were rejected in a third country;
- (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 145

Operators obligations to cooperate with the competent authority for 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 140(1) and (2) and rules adopted pursuant to Article 143(1) or Article 144 **in advance of the intended movement**;
- (b) where necessary, **ensure that** the kept terrestrial animals **are subjected** to documentary, identity and physical checks as provided for in Article 146(3).

Article 146

Competent authority responsibility for animal health certification

1. The competent authority shall, upon request by the operator issue an animal health certificate for the movement of kept terrestrial animals, where required by Article 140 or by delegated acts adopted pursuant to Article 141(1) provided that the following movement requirements have been complied with:
 - (a) those provided for in Article 121, Article 122(1), Articles 123, 125, 126, 127, 130 and 131, Articles 133(1) and 134(1), Article 135 and Article 136;
 - (b) those provided for in delegated acts adopted pursuant to Articles 122(2) and 128(1), Article 132, and Articles 133(2), 134(2), 135(4) and 136(4) and Article 137;
 - (c) those provided for in implementing acts adopted pursuant to Article 138.
2. Animal health certificates shall:
 - (a) be verified, **stamped** and signed by the official veterinarian;
 - (b) remain valid for the period of time, provided for in the rules adopted pursuant to paragraph 4(c), during which the kept terrestrial animals covered by it, continue to comply with the animal health guarantees contained in it.
3. The official veterinarian shall, before signing an animal health certificate, verify that the kept terrestrial animals covered by it comply with the requirements of this Chapter by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4.

4. The Commission shall adopt delegated acts in accordance with Article 253 laying down rules for:
- (a) the types of documentary, identity and physical checks for different species and categories of kept terrestrial animals that must be carried out by the official veterinarian in accordance with paragraph 3 to verify compliance with the requirements of this Chapter;
 - (b) the timeframes for the carrying out of such documentary, identity and physical checks 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 147
Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of [...] **TRACES**, may replace accompanying animal health certificates provided for in Article 146(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 142 and rules adopted pursuant to Article 143;
- (b) the traceability of the kept terrestrial animals and the link between those animals and the electronic animal health certificate is ensured;
- (c) **the access of competent authorities of the Member State of origin, passage and destination to the electronic documents is ensured at all times during the transport.**

Article 148
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 ensure that it accompanies such animals, where they are not required to be accompanied by an animal health certificate provided for in Article 140(1) and (2).
2. The self-declaration document provided for in paragraph 1 shall contain the following information concerning the kept terrestrial animals:
 - (a) their place of origin, their place of destination and when relevant any places of assembly or rest;

- (aa) **the means of transport; and the transporter**
 - (b) a description of the kept terrestrial animals, their species, category and quantity;
 - (c) identification and registration where required in accordance with Articles 106, 107, 109 and 110, and Article 113(a) and rules adopted pursuant to Articles 114 and 117;
 - (d) information needed to demonstrate that the kept terrestrial animals comply with the animal health requirements for movements provided for in Sections 1 to 6 (**Articles 121 to 139**).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
- (a) detailed rules on the content of the self-declaration document provided for in paragraph 2 for different categories and species of animals;
 - (b) information to be contained in the self-declaration document in addition to that provided for in paragraph 2.
4. The Commission may, by means of implementing acts, lay down rules for the model forms of the self-declaration documents provided for in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

SECTION 8

NOTIFICATION OF MOVEMENTS OF KEPT TERRESTRIAL ANIMALS TO OTHER MEMBER STATES

Article 149

Obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States

Operators **except for 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 146 and 147 and rules adopted pursuant to Article 146(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 140(2);
- (ba) the animals are granted a derogation from the animal health certification provided for in Article 141(1)(a) or they are subject to special rules provided for in Article 141(1)(b);**
- (c) notification is required in accordance with delegated acts adopted pursuant to Article 151(1).

For the purposes of the first paragraph, 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 150(1).

Article 150

Competent authority responsibility for notification of 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 149.
2. The notification referred to in paragraph 1 shall be carried out **prior to the movement 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 to notify partially or completely movements of kept terrestrial animals through [...] **TRACES** to the competent authority of the Member State of destination.

Article 151

Delegation of power and implementing acts for the notification of movements by operators and the competent authority

1. The Commission shall adopt delegated acts in accordance with Article 253 concerning:

- (a) the requirement for advance notification by operators of movement of kept terrestrial animals between Member States in accordance with Article 149 of categories or species of animals 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 to ensure compliance with the animal health requirements for movements laid down in Sections 1 to 6 (**Articles 121 to 139**);
- (b) the information necessary to notify movements of kept terrestrial animals as provided for in Articles 149 and 150;
- (c) the emergency procedures for the notification of movements of kept terrestrial animals in the case of power cuts and other disturbances of [...] **TRACES**;
- (d) the requirements for the designation of regions by Member States for the management of notification of movements provided for in Article 150(3).

2. The Commission may, by means of implementing acts lay down rules concerning:

- (a) the **details on** notifications of movements of kept terrestrial animals by:
 - (i) operators to the competent authority of their Member State of origin in accordance with Article 149;
 - (ii) the competent authority of the Member State of origin to the Member State of destination in accordance with Article 150;
- (b) the deadlines for:
 - (i) the necessary information referred to in Article 149 to be provided by the operator to the competent authority of the Member State of origin;
 - (ii) the notification of movements of movements of kept terrestrial animals by the competent authority of the Member State of origin referred to in Article 150(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 5

Movement of wild terrestrial animals

Article 153 *Wild terrestrial animals*

1. Operators shall only move wild animals from a habitat in one Member State to a habitat or to an establishment in another Member State where:
 - (a) the movements of the wild animals from their habitat are carried out in such a way that they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) 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 subject to movement restrictions **concerning that animal species** due to the occurrence of a listed disease referred to in Article 8(1)(d) or **of an emerging disease, as** provided for in Article 70(2) and rules adopted pursuant to Articles 70(3)(b), 71(3) and Article 81(3) or the emergency measures provided for in Articles 246 **and 247** and rules adopted pursuant to Article 248 unless derogations have been granted in accordance to those rules;
 - (c) the wild animals are accompanied by an animal health certificate or other documents where animal health certification is necessary to ensure compliance with the animal health requirements for movements provided for in points (a) and (b) and the rules adopted pursuant to Article 154(1)(c) and (d);
 - (d) the movement is notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination, when animal health certificate is required by the rules adopted pursuant to Article 154(1)(c); **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 Article 154(1)(c) the requirements provided for in Articles 142 and 145, Article 146(1),(2) and (3), Article 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4), shall apply to movements of wild terrestrial animals.
3. When notification of movements is required in accordance with paragraph 1(d), the requirements provided for in Articles 149, 150 and the rules adopted pursuant to delegated acts laid down in Article 151 shall apply to movements of wild terrestrial animals.

Article 154
Empowerments concerning the movement of wild terrestrial animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the animal health requirements for movements of wild terrestrial animals provided for in Article 153(1)(a) and (b);
 - (b) the animal health requirements for the introduction of wild terrestrial animals when 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 153 and the delegated rules adopted pursuant to paragraph 1 concerning:
 - (a) model forms of animal health certificates and other documents which are required to accompany movements of the wild terrestrial animals, when provided for in delegated acts adopted pursuant to paragraph 1(c);
 - (b) the **details** of the notification by the competent authority of the Member State of origin and the deadlines for such notifications, when provided for in rules adopted pursuant to paragraph 1(d).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 6

Movements within the Union of germinal products

SECTION 1

GENERAL REQUIREMENTS

Article 155

General requirements for movement of germinal products

1. Operators shall take appropriate preventive measures to ensure that the movement of germinal products does not jeopardise the health status of kept terrestrial animals at the place of destination with regard to:
 - (a) the listed diseases referred to in Article 8(1)(d);
 - (b) emerging diseases.
2. Operators shall only move germinal products from their establishments, and receive such germinal products if they comply with 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 Article 88(a) and no derogation has been granted by the Member State of origin in accordance with Article 83;
 - (ii) approved by the competent authority in accordance with Article 92(1), when required by Article 89(1) or Article 90;
 - (b) they comply with the traceability requirements of Article 118(1) and rules adopted pursuant to Article 119(1).
3. Operators shall comply with the requirements of Article 122 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 a part of an eradication programme provided for in Article 30(1) or (2).

Article 156
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 118 and rules adopted pursuant to Article 119;
 - (ii) animal health certificates as provided for in Article 159;
 - (b) inform, **after checking the germinal products received**, the competent authority 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 paragraph 1(b), the operator 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 OF POULTRY

Article 157
Operators obligations for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to another Member State if those germinal products comply with the following conditions:
 - (a) they are collected, produced, processed and stored in germinal product establishments approved for that purpose in accordance with Article 92(1) and Article 94;

- (c) they have been collected from the donor animals which comply with the necessary animal health requirements to ensure that the germinal products do not spread listed diseases;
 - (d) they have been collected, produced, processed, stored and transported in a manner to ensure that they do not spread listed diseases **referred to in Article 8(1)(d)**.
2. Operators shall not move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry from a germinal product establishment which is subject to movement restrictions affecting the listed species in accordance with:
- (a) Article 55(1)(a), (c), (e) and Article 55(1)(f)(ii), Article 56 and Article 61(1)(a), Article 62(1), Article 65(1)(c) and Articles 74(1), 78(1) and (2);
 - (b) rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), 74(3) and 81(2); and
 - (c) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations have been provided for in rules adopted pursuant to Article 247.

The restrictions provided for in this paragraph shall not apply to cases where the germinal products were collected before the outbreak occurred and these products have been stored separately from other germinal products.

Article 158

Delegation of power for movements of germinal products of kept animals of the bovine, porcine, ovine, caprine and equine species and of poultry to other Member States

1. The Commission shall adopt delegated acts in accordance with Article 253 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States provided for in Article 157, specifying:
- (a) rules for the collection, production, processing and storage of germinal products of those kept animals in approved establishments as referred to in Article 157(1)(a);
 - (b) animal health requirements provided for in Article 157(1)(c):
 - (i) for kept animals from which germinal products were collected;
 - (ii) isolation or quarantine for the kept donor animals referred to in (i);
 - (c) laboratory and other tests 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 Article 157(1)(d);
2. **The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States provided for in Article 157, specifying: derogations for operators from the rules provided for in Article 157, taking into account the risks of such germinal products and any risk mitigating measures in place.**

SECTION 3

ANIMAL HEALTH CERTIFICATION AND NOTIFICATION OF MOVEMENTS

Article 159

Operators' obligations concerning animal health certification for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and 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 of poultry where they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3 when they are moved to another Member State;
- 1a. **In cases where** the germinal products of kept animals are allowed to leave a restricted zone subject to disease control measures provided for in Article 55(1)(f)(ii) and Articles 56, 64 and 65, Article 74(1) and Article 78 and rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(3), Article 81(2) or the emergency measures provided for in Articles 246 and 247 and the rules adopted pursuant to Article 248, and the germinal products of kept animals 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 146(1), unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this point.

The competent authority may decide that such a certificate does not have to be issued for the movements of germinal products within that Member State when that authority considers that an alternative system ensures that the consignment of such germinal products is traceable and those germinal products comply with the animal health requirements for such movement.

2. 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.
3. The competent authority shall upon request by the 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 6 of Part IV have been complied with.**
4. Articles 145, 146 and 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4), shall apply to the animal health certification of the germinal products referred to in paragraph 1, and Article 148(1) and the rules adopted pursuant to Article 148(3) shall apply to the for self-declaration of movements of germinal products.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the animal health certificate requirements provided for in paragraph 1 for the movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry, which do not pose a significant risk for the spread of listed diseases due to the following:
 - (a) the nature of the germinal products 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 mitigating 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, passing through another Member State.**

Article 160

Content of animal health certificates

1. The animal health certificate for the germinal products provided for in Article 159 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 118(1) and by rules adopted pursuant to Article 119(1);
 - (e) information needed to demonstrate that the germinal products of the consignment comply with the movement requirements for the relevant species provided for in Articles 155 and 157 and rules adopted pursuant to Article 158.
2. The animal health certificate for the germinal products provided for in Article 159 may include other information required under other Union legislation.
 3. The Commission shall adopt delegated acts in accordance with Article 253 concerning:
 - (a) the information to be contained in the animal health certificate pursuant to paragraph 1;
 - 3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning** animal health certification for different types of germinal products and of different animal species.
 4. 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 255(2).

Article 161

Notification of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and 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 of poultry to another Member State when:
 - (i) the germinal products are required to be accompanied by an animal health certificate in accordance with Article 159(1) **or 159(1a)**;
 - (ii) notification of movement is required in accordance with delegated acts adopted pursuant to **paragraph 5(a)** for germinal products, taking into account paragraph 3;

- (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 and, whenever possible, through TRACES** the competent authority of the Member State of destination of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry in accordance with the rules adopted pursuant to **paragraphs 5 and 6**.
- 2a. **Member States shall use for the management of notifications regions designated in accordance with Article 150(3).**
3. Article 150 (4) shall **apply** to the notification of germinal products **by operators**.
4. **The Commission shall adopt delegated acts in accordance with Article 253 concerning:**
- (a) **the requirement for advance notification by operators of movement of germinal products between Member States in accordance with paragraph 1(a) (ii), where traceability of such movements of those germinal products is necessary to ensure compliance with the animal health requirements for movements laid down in Sections 1 and 2 (Articles 155 to 158);**
 - (b) **information necessary to notify movements of germinal products as provided for in paragraph 1;**
 - (c) **the emergency procedures for the notification of movements of germinal products in the case of power cuts and other disturbances of TRACES.**
5. **The Commission may, by means of implementing acts lay down rules concerning:**
- (a) **the details on information on movements of germinal products by operators to the competent authority of their Member State of origin in accordance with paragraph 1;**
 - (b) **the details on notification on movements of germinal products 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) **the necessary information referred to in paragraph 1 to be provided by the operator to the competent authority of the Member State of origin;**

- (ii) the notification of movements of germinal products by the competent authority of the Member State of origin referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 OF POULTRY

Article 162

Germinal products of kept terrestrial animals other than those of the bovine, ovine, caprine, porcine and equine species and 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 of poultry to another Member State if they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) 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 253 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 of poultry taking into account the following matters:
 - (a) listed diseases referred to in Article 8(1)(d) for the listed species;
 - (b) the species of animals from which the germinal product have been collected and 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 the notification of movements of the germinal products are required in accordance with paragraph 2:
 - (a) the rules provided for in Articles 159, 160 and Article 161 and the rules adopted pursuant to Articles 159(5) and 160(3) shall apply for such certification;
 - (b) the rules provided for in Article 161(1) and (2) shall apply for movement notification.

SECTION 5 DEROGATIONS

Article 163

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 into the territory of the Member State of germinal products for scientific purposes, which do not comply with the requirements of Sections 1 to 4 (Articles 155 to 162), with the exception of Articles 155 and 156.**

2. **The competent authority shall only grant derogations provided for in paragraph 1 under the following conditions:**
 - (a) **the competent authorities of the place of destination and origin:**
 - (i) **have agreed on the conditions for such movements;**
 - (ii) **ensure that necessary risk mitigating measures are in place so that those movements do not jeopardise the health status en route and the places of destination with regard to the listed diseases referred to in Article 8(1)(d);**
 - (iii) **have notified, where relevant, the competent authority of Member States of passage of the derogation granted and the conditions under which it is granted;**
 - (b) **those movements of those germinal products take place under the supervision of the competent authorities of places of origin and destination, and where relevant, the competent authority of the Member State of passage.**

3. **The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the rules for derogations by the competent authorities, supplementing those provided for in paragraphs 1 and 2.**

Chapter 7

Production, processing and distribution within the Union of products of animal origin

Article 164

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that at 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 referred to in Article 8(1)(d) 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 business establishments or are obtained from animals which come from establishments subject to:
 - (a) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations from the requirement provided for in paragraph 1 are provided for in rules adopted pursuant to Article 248;
 - (b) movement restrictions applicable to kept terrestrial animals and products of animal origin, as provided for in Articles 31(1), Article 55(1)(e), Article 56, Article 61(1)(a), Article 62(1), Article 65(1)(c), Article 70(1)(b), Article 74(1)(a), **75a(2)(b) and (3)**, Article 78, **80 and 80a(2)** and **(2a)** the rules adopted pursuant to Articles 55(2), Articles 63 and **67**, Articles **70(3)**, 71(3), Articles 74(3), **75a(4)** and Article 81(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 253 concerning detailed requirements supplementing those referred to
 - (a) **in paragraph 1 on the preventive measures, including risk mitigation measures, and**
 - (b) **in paragraph 2 for the movement of products of animal origin.**
4. **When adopting the delegated acts referred to in paragraph 3, the Commission shall base them on:**

- (a) the listed disease referred to in Article 8(1)(d) and species concerned by it and
- (b) the risks involved.

Article 165

Animal health certificates obligations on operators and delegated acts

1. Operators shall only move the following products of animal origin within a Member State or to another Member State where they 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 provided for in rules adopted pursuant to Article 248;
 - (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 31(1), Article 55(1)(f)(ii), Article 56, Article 61(1)(a), Article 62(1), Article 64, Articles 65(1)(c), 70(1)(b) and 74(1)(a) and Article 78(1) and rules adopted pursuant to Articles 55(2), Articles 63 and 67 **and** Articles 71(3), 74(3) and 81(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 the movements of products of animal origin within that Member State when that authority considers that an alternative system ensures that the consignment of such products is traceable and those products comply with the animal health requirements for such movement.

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 issue an animal health certificate for the movements of products of animal origin referred to in paragraph 1, **provided that the relevant requirements referred to in this Article have been complied with.**

4. Articles 145, 146 and 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4) shall apply to the animal health certification of the movements of the products of animal origin referred to in paragraph 1.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the animal health certificate requirements provided for in paragraph 1 and the conditions for such derogations, for 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;
 - (b) the risk mitigating 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 166

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin provided for in Article 165(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;
 - (c) the quantity of the products of animal origin;
 - (d) the identification of the products of animal origin, when required by Article 65 (1)(h) or rules adopted pursuant to Article 67(a);
 - (e) information needed to demonstrate that the products of animal origin comply with the movement restriction requirements provided for in Article 164(2) and rules adopted pursuant to Article 164(3).
2. The animal health certificate for products of animal origin 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 253 concerning the information to be contained in the animal health certificate as provided for in paragraph 1.
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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 167

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 the intended movement of the products of animal origin when the consignments are required to be accompanied by an animal health certificate in accordance with Article 165(1);
 - (b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement of the products of animal origin to 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, and , whenever possible, through TRACES**, 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**.
- 2a. **Member States shall use for the management of notifications regions designated in accordance with Article 150(3).**
3. Article 150(4) shall **apply** to the notification of products of animal origin **by operators**.
4. **The Commission shall adopt delegated acts in accordance with Article 253 concerning:**
 - (a) **information necessary to notify movements of products of animal origin as provided for in paragaraph 1;**
 - (b) **the emergency procedures for the notification of movements of products of animal origin in the case of power cuts and other disturbances of TRACES.**
5. **The Commission may, by means of implementing acts, lay down rules concerning:**
 - (a) **the details on information on movements of products of animal origin by operators to the competent authority of their Member State of origin in accordance with paragaraph 1;**
 - (b) **the details on notification on movements of products of animal origin 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) **the necessary information referred to in paragraph 1 to be provided by the operator to the competent authority of the Member State of origin;**
- (ii) **the notification of movements of products of animal origin by the competent authority of the Member State of origin referred to in paragraph 2.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 8

Scope of national measures

Article 168

*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 referred to in Article 8(1)(d) and Article 8(1)(e) and** concerning the movement of terrestrial animals and germinal products thereof within their own territories.
2. Those national measures shall:
 - (a) take account of the rules on movement of animals and germinal products laid down in Chapters 3 (**Articles 121 to 151**), 5 (**Articles 153 and 154**) and 6 (**Articles 155 to 163**) and not be in contradiction 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 to prevent the introduction and spread of the listed diseases referred to in Article 8(1)(d) **and Article 8(1)(e)**.

Article 169

National measures for limiting the impact of diseases other than listed diseases

Where a disease other than listed diseases constitutes a significant risk for the animal health situation of kept terrestrial animals in a Member State, the Member State concerned may take national measures to control that disease **and 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 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 170

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 171, before they commence such activities:
 - (a) inform the competent authority of any aquaculture establishment under their responsibility;
 - (b) provide the competent authority with information on:
 - (i) the name and address of the operator;
 - (ii) the location **of the establishment** and a description of the facilities;;
 - (iii) the categories, species 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) other aspects of the establishment which are relevant in determining the risk posed by it.
2. Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority **in advance** of any:
 - (a) significant changes in the aquaculture establishments concerning the matters referred to in paragraph 1(b);

- (b) cessation of activity **by the operator or of** [...] the aquaculture establishment.
3. Aquaculture establishments which are subject to approval in accordance with Article 174(1) **and Article 175** shall not be required to provide the information referred to in paragraph 1 of this Article.
4. An operator may apply for a registration provided for in paragraph 1 to cover a group of aquaculture establishments provided that they comply with the conditions laid down in either points (a) or (b):
- (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
- (i) **are** under a common biosecurity system; and
- (ii) [...] **the aquaculture animals of the establishments belong to 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 Article 171(b) and the rules adopted pursuant to Article 173, which are applicable to a single aquaculture establishment shall be applicable to the whole group of aquaculture establishments.

Article 171

Obligations of the competent authority concerning the registration of aquaculture establishments

The competent authority shall register:

- (a) aquaculture establishments in the register of aquaculture establishments provided for in Article 183(1), where the operator has provided the information required in accordance with Article 170(1);
- (b) groups of aquaculture establishment in that register of aquaculture establishments provided that the criteria laid down in Article 170(4) are complied with.

The competent authority shall assign each establishment or group of establishments referred to in this Article with a unique registration number.

Article 172

Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 170(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 173.** [...]

Article 173

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 the aquaculture establishment as provided for in Article 170(1) **including the time limits by which such information shall 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 172, [...] **based on:**
 - (a) **the categories, species and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment and the capacity of the aquaculture 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 255(2).

SECTION 2

APPROVAL OF CERTAIN TYPES OF AQUACULTURE ESTABLISHMENTS

Article 174

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 178(1) [...]:
 - (a) aquaculture establishments where aquaculture animals are kept with the view to their being moved from that aquaculture establishment either alive or as products of aquaculture animal origin [...].

[...]

[...]
 - (b) other aquaculture establishments which pose a [...] **significant** risk due to:
 - (i) the categories, species and number of aquaculture animals on the aquaculture establishment;

- (ii) the type of aquaculture establishment;
- (iii) movements of aquaculture animals into and out of the aquaculture establishment.

- 1a. **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, provided that they do not pose a significant risk:**
- (a) **aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either to:**
 - (i) **the final consumer directly; or**
 - (ii) **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 by restocking with aquaculture animals and those animals are confined and unable to escape;**
 - (c) **aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities.**
2. [...] **Unless a derogation has been granted under paragraph 3, operators shall not commence activity at an aquaculture establishment referred to in paragraph 1 until that establishment has been approved in accordance with Article 179(1) and they shall cease such activity at an aquaculture establishment referred to in paragraph 1 where:**
- (a) the competent authority withdraws or suspends its approval in accordance with Article 182(2); or
 - (b) in the event of conditional approval, granted in accordance with Article 181(3), the aquaculture establishment fails to comply with the outstanding requirements referred to in Article 181(3) and does not obtain a final approval in accordance with Article [...]181(2a).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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 paragraph 1(a), concerning types of establishments other than those specified in the subpoints (i) and (ii) of paragraph 1a(a), where those establishments do not pose a significant risk;**

- (b) the types of aquaculture establishments that must be approved in accordance with paragraph 1(b).
4. [...] **When** adopting delegated acts provided for in paragraph 3, **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 and concerned species or category of aquaculture animals.
5. An operator may apply for an approval of group of aquaculture establishments provided that the requirements provided for in Article 175(a) and (b) are complied with.

Article 175

Approval by the competent authority of group of aquaculture establishments

The competent authority may grant approval as provided for in Article 179(1) covering a group of aquaculture establishments, provided that they comply with the conditions laid down in either point (a) or point (b):

- (a) they are located in an epidemiologically linked area and all operators 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) under a common biosecurity system; and
 - (ii) [...] **the aquaculture animals of these establishments are part of the same epidemiological unit.**

When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 176 and Articles 178 to 182 and the rules adopted pursuant to Articles 178(2) and 179(2) which are applicable to a single aquaculture establishment shall be applicable to the group of aquaculture establishments.

Article 176

Approval of status of confined aquaculture establishments

Operators of aquaculture establishments, who want to obtain the status of confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 178(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 by the competent authority in accordance with Article 179 or Article 181.

Article 177

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 has been obtained; and**
- (b) **apply to** the competent authority, **in accordance with Article 178(1), for an approval** to slaughter **or process** aquatic animals for disease control purposes in accordance with Article 61(1)(b), Article 62 and Articles 68(1), 78(1) and (2) and the rules adopted pursuant to Article 63 and Articles 70(3), 71(3) and 78(3) **of this Regulation.**

Article 178

[...]Obligation of operators to supply information in view order to obtain approval [...]

1. Operators shall, for the purposes of their application for the approval of their establishment provided for in Article 174(1), Article 175, Article 176(a) and Article 177 provide the competent authority with the information on:
 - (a) the name and address of the operator;
 - (b) the location of the establishment and a description of **the** facilities;

- (c) the categories, species and **quantities** (numbers, **volume or weight**) of aquaculture animals **relevant for the approval** on the establishment;
 - (d) the type of **aquaculture** establishment;
 - (e) [...] the details of the approval of a group of aquaculture establishments **necessary to demonstrate that the group complies with the conditions laid down** in [...] Article 175, **in cases of such group approval**;
 - (f) other aspects of the **mode of operation of the** aquaculture establishment, which are relevant in determining the risk posed by it;
 - (g) **the water supply and discharge of water from the establishment**;
 - (h) **the establishment's biosecurity measures.**
2. Operators of establishments referred to in paragraph 1 shall inform the competent authority **in advance** of any:
- (a) [...] changes in the establishments concerning the matters referred to in paragraph 1[...];
 - (b) cessation of activity [...] **by the operator or of** the establishment.
3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in the application for the approval of their establishment, in accordance with paragraph 1 [...], **including the time limits by which such information shall be provided.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 179

Granting of approval and conditions for approval and delegated acts

1. The competent authority shall only grant approvals of aquaculture establishment referred to in Article 174(1) and, Article 176(a), group of aquaculture establishments referred to in Article 175 and disease control aquatic food establishments referred to in Article 177 where such establishments:
- (a) comply with the following requirements, where appropriate on:
 - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in Article 9(1)(b) and rules adopted pursuant to Article 9(2);

- (ii) surveillance requirements provided for in Article 22 and where relevant for the type of establishment and the risk involved, in Article 23 [...];
 - (iii) record keeping provided for in Articles 185 to 187 and the rules adopted pursuant to Articles 188 and 189;
 - (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;
 - (ii) of adequate capacity for the **categories, species and quantity (numbers, volume or weight)** of aquatic animals;
 - (c) do not lead to an unacceptable risk for the spread of disease, taking into account the risk mitigating measures in place;
 - (d) have a system in place which enables the operator 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 253 concerning [...]:
- (a) quarantine, isolation and other biosecurity measures referred to in paragraph 1(a)(i);
 - (b) surveillance referred to in paragraph 1(a)(ii);
 - (c) facilities and equipment referred to in paragraph 1(b).
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;
 - (d) typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

Article 180
Scope of the approval of establishments

The competent authority shall expressly specify in approvals of aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 179(1) **following an application made in accordance with Article 174, 175 or Article 176(a), 177:**

- (a) for which of the types of aquaculture establishments referred to in Article 174(1), Article 176(a), groups of aquaculture establishments referred to in Article 175 and disease control aquatic food establishments referred to in Article 177, and rules adopted pursuant to Article 174(3)(b) the approval applies;
- (b) for which species and categories of aquaculture animals the approval applies.

Article 181
Procedures for granting the 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 174(1) and Articles 176 and 177.
2. Upon receipt of an application for approval from an operator in accordance with Article 174(1), Article 176 [...] **or** Article 177, the competent authority shall make an on-site visit.
- 2a. **Provided that the requirements referred to in Article 179 are fulfilled, the competent authority shall grant the approval.**
3. **In the case where an establishment does not fulfil all requirements for approval referred to in Article 179,** the competent authority may grant conditional approval of an establishment where it appears, based on the application of the operator and the subsequent on-site visit [...] as provided for in paragraph 2 [...], that it meets all the main requirements that provide sufficient guarantees that [...] **the** establishment does not represent a significant risk [...].
4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 [...], it shall grant full approval only where it appears from another on-site visit of the establishment, carried out within three months from the date of granting conditional approval, **or from documentation provided by the operator within three months from the date of granting conditional approval,** that the establishment meets all the requirements for approval provided for in Article 179(1) and the rules adopted pursuant to Article 179(2).

Where [...] **the** on-site visit **or the documentation referred to in the first subparagraph** shows that clear progress has been made but the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total period of six months.

Article 182

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep the approvals of establishments granted in accordance with Article 179(1) under review, **at appropriate frequencies based on the risk involved.**
2. Where the competent authority identifies serious deficiencies in the establishment as regards compliance with the requirements laid down in Article 179(1) and the rules adopted pursuant to Article 179(2) and the operator is not able to provide adequate guarantees that those deficiencies will be resolved, the competent authority shall initiate procedures to withdraw the establishment's approval.

However, the competent authority may suspend an establishment's approval where the operator can guarantee that it will resolve 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 183

Register of aquaculture establishments and disease control aquatic food establishments

1. The competent authority shall establish and keep up-to-date a register of:
 - (a) all aquaculture establishments registered in accordance with Article 171;
 - (b) all aquaculture establishments approved in accordance with Articles 179(1);
 - (c) all disease control aquatic food establishments approved in accordance with Article 179(1).
2. The register of aquaculture establishments provided for in paragraph 1 shall contain information on:
 - (a) the name and address of the operator and its registration number;

- (b) the [...] **location** of the aquaculture establishment or when applicable, the group of aquaculture establishments;
 - (c) the type of production at the establishment;
 - (d) the water supply and discharge of 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 when applicable, the group of establishments, as regards the listed diseases referred to in Article 8(1)(d).
3. For establishments approved in accordance with Article 179(1), the competent authority shall make publicly available by electronic means at least the information referred to in paragraph 2(a), (c), (e) and (f) [...], **subject to data protection requirements.**
4. Where appropriate and relevant, the 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 254 concerning:**
- (a) **the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1;**
 - (b) **the public availability of that register of establishments.**

[...]

SECTION 4

RECORD KEEPING AND TRACEABILITY

Article 185

Record keeping obligations of operators of aquaculture establishments

1. Operators of aquaculture establishments subject to registration in accordance with Article 171 or approval in accordance with Article 179(1) shall keep **and maintain** [...] records containing at least the following information:
- (a0) **the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;**

- (a) [...] **the** movements of aquaculture animals and products of animal origin obtained from those animals into and out of the aquaculture establishment, stating as appropriate:
 - (i) their place of origin or destination;
 - (ii) the date of such movements;
- (b) 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 Articles 211(b) and (c) and Article 213(2);
- (c) the mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;
- (d) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
 - (i) the category and species 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;
- (e) the results of the animal health visits [...] required in accordance with Article 23(1) [...];

The records may be kept and maintained in paper or electronic form.

- 1a. Aquaculture establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State 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.**
- 2. Operators of aquaculture establishments shall **keep the records provided for in paragraph 1 on the aquaculture establishment and:**
 - (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 determined by the competent authority, but which may not be less than a period of three years.

By way of derogation from the requirement that the records shall be kept on the establishment set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, those records shall be kept in the office from which the business is administered.

Article 186

Record keeping obligation for disease control aquatic food establishments

1. Operators of disease control aquatic food establishments subject to approval in accordance with Article 177 shall keep [...] **and maintain** records of:
 - (a) all movement of aquaculture animals and products of animal origin obtained from such animals [...];
 - (b) **discharge of water and other relevant biosecurity measures.**
2. Operators of disease control aquatic food establishments shall:
 - (a) keep the records provided for in paragraph 1 on the disease control aquatic food establishment and make them available to the competent authority on request;
 - (b) retain the records provided for in paragraph 1 for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

The records may be kept and maintained in paper or electronic form.

Article 187

Record keeping obligation for transporters

1. Transporters of [...] aquatic animals **intended for aquaculture establishments or to be released into the wild** shall keep [...] **and maintain** records on:
 - (a0) **the categories, species and quantities (numbers, volume or weight) of aquatic animals transported by them;**
 - (a) mortality rates of the aquaculture animals and wild aquatic animals during transport, as practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;

- (b) aquaculture establishments and disease control aquatic food establishments visited by the means of transport;
- (c) any exchange of water that took place during transport, specifying the sources of new water and sites of release of water.
- (d) the cleaning and disinfection of the means of transport.**

The records may be kept and maintained in paper or electronic form.

1a Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member States from the requirement to keep records of all or some of the information listed in paragraph 1, provided that traceability is ensured.

2. Transporters shall **keep the records provided for in paragraph 1:**

- (a) [...] **in a manner that they can be made immediately** available to the competent authority on request;
- (b) [...] for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 188

Delegation of powers concerning record keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing the record keeping requirements provided for in Articles 185, 186 and 187 laying down rules on [...] information to be recorded by operators in addition to that provided for in Articles 185(1), 186(1) and 187(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 categories or species of [...] **aquatic** animals on the aquaculture establishment **or being transported;**
- (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 at the establishment or being transported.

Article 189

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 the Member States from the record keeping requirements provided for in Articles 185 and 187 as regards :**

- (a) **operators of certain categories of aquaculture establishments and transporters;**
- (b) **aquaculture establishments keeping a small number of aquaculture animals or transporters transporting a small number of aquatic animals;**
- (c) **certain categories or species of aquatic animals.**

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 188(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Movements within the Union of aquatic animals [...]

SECTION 1

GENERAL REQUIREMENTS

Article 190

General requirements for movement 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 Article 8(1)(d);
 - (b) emerging diseases.
2. Operators shall [...] **only** move aquatic animals into an aquaculture establishment or for human consumption or release them into the wild [...], **if they comply with the following conditions:**
 - (a) **they come, except for wild aquatic animals, from establishments that have been either:**

- (i) registered by the competent authority in accordance with Article 171, or
- (ii) approved by the competent authority in accordance with Articles 179 and 180, when required by Articles 174(1) , 175 or 176;
- (iii) granted a derogation from the registration requirement in 171.

(b) the aquatic animals are not subject to:

- (i) movement restrictions affecting the category and species concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, Article 70(1)(b) [...], Articles 74(1), 78 [...], **and** 80 and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3), [...] 74(3) [...] and 81(2); or
- (ii) the emergency measures laid down in Articles 244 and 247 and the rules adopted pursuant to Article 248.

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 53-81**) or derogations from emergency measures in rules adopted pursuant to Article 248.

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 191

[...] Preventive measures in relation to transport [...]

1. Operators shall take the appropriate and necessary disease preventive 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 referred to in Article 8(1)(d) 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;

- (d) any exchanges of water **and discharge 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 Article 8(1)(d) 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 253 concerning:
- (a) the **conditions and requirements for cleaning and disinfection** [...] of equipment and means of transport in accordance with paragraph 1(c) and the use of biocidal products for such purposes;
 - (b) other appropriate biosecurity measures during transport as provided for in paragraph 1(c);
 - (c) water exchanges **and discharge of water** during transport as provided for in paragraph 1(d).

Article 192
Change of intended use

1. Aquatic animals which are moved for destruction or slaughter in accordance with the measures referred to in point (a) or (b) shall not be used for any other purpose:
- (a) disease control measures provided for in Articles 31(1) and 55(1), Articles 56, 61, 62, 64, 65 [...] and 70, Articles 74(1) **and 74(1a)** and Articles 78, **79**, [...] **80 and 80a** and the rules adopted pursuant to Article 55(2), Article 63 and **67**, Articles 70(3), 71(3) and 74(3) [...], and Article 81(2);
 - (b) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248.
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 present a higher risk to the health status of the aquatic animals at the place of destination than the originally intended use.**

Article 193
Obligations for 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 224(1) and the rules adopted pursuant to Articles 188, 211 and 213 [...];
 - (ii) the self-declaration documents provided for in Article 218(1) and the rules adopted pursuant to Article 218(3) and (4) [...];
 - (b) inform, **after checking the aquatic animals received**, the competent authority 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 paragraph 1(b), the operator shall isolate the [...] **aquatic** animals concerned by that irregularity until the competent authority has taken a decision regarding them.

Article 194
General requirements for 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 other Member States fulfil the requirements laid down in Articles 190, 191 and 192.

SECTION 2
**AQUATIC ANIMALS INTENDED FOR AQUACULTURE ESTABLISHMENTS OR TO BE
RELEASED INTO THE WILD**

Article 195
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 [...] **such animals:**
 - (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 authorise [...] movement or release of aquatic animals **referred to in that paragraph**, based on an evaluation of risks, provided that the aquatic animals 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 were to another Member State, the competent authority shall only authorise such movements if the competent authorities of the Member State of destination and, where relevant, the Member State of passage, have given their consent to such movement.

Article 196
Movement 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 Article 8(1)(b) or 8(1)(c) to an aquaculture establishment or for release into the wild in a Member State, zone or compartment, which has been declared disease-free of those listed diseases in accordance with Article 36(3) or 37(4), if those aquaculture animals originate from a Member State, [...] zone or compartment thereof, which has been declared [...] free of those diseases.**

[...]

- 1a. Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in Article 8(1)(b) or 8(1)(c) 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 30(1) or (2), if those aquaculture animals originate from a Member State, zone or compartment declared free of those listed diseases.**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the movement or release requirements of paragraphs 1 **and 1a** [...], which do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) due to:
- (a) the species, categories, and life stage of the aquaculture animals;
 - (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 mitigating measures applied at places of origin or destination.

Article 197

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 196(1) **and 196(1a)**, 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 30(1) and (2) as regards the listed diseases referred to in Article 8(1)(b) and (c), 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 were to another Member State, the competent authority shall only authorise them if the competent authorities of the Member State of destination and, where relevant, the Member States of passage, has given its consent to them.

Article 198

Member States' measures concerning the release of [...] aquatic animals into the wild

Member States may require that [...] **aquatic** animals shall only be released into the wild if they originate from a Member State, or zone or compartment 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 Article 8(1)(b) and (c) for which the species of [...] **aquatic** animals to be moved is a listed species, regardless of the health status of the area where the [...] **aquatic** animals are to be released.

Article 199

Movement of wild aquatic 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. Articles **195**, 196 and 197 shall also apply to movements of wild aquatic animals intended for an aquaculture establishment **or release into the wild.**

[...]
2. Operators shall take **the appropriate and necessary** disease preventive 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 referred to in Article 8(1)(d) to aquatic animals at the place of destination; **and**
 - (b) **risk mitigating or other adequate biosecurity measures are in place where necessary to ensure that the conditions provided in point (a) are met.**
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease preventive **and risk mitigating** measures to be taken by operators as provided for in paragraph 2 [...]. **Pending 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 200

*Movement of **live** aquaculture animals intended for **human consumption** in 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 **live** aquaculture animals [...] **of listed species relevant for listed diseases referred to in Article 8(1)(b) or (c) intended for human consumption to a Member State, zone or compartment which has been declared disease free in accordance with Articles 36(3) or 37(4) or for which a eradication programme has been established in accordance with Article 30(1) or (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c)) if those aquaculture animals originate from a Member State, zone or compartment which has been declared disease-free in accordance with Article 36(3) or 37(4).**

[...]

2. By way of derogation from paragraph 1 [...] 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 30(1) or (2) as regards the listed diseases referred to in Article 8(1)(b) and (c), 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 zone or compartment thereof.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the derogations from movement requirements provided for in paragraph 2 [...] for those movements of **live** aquaculture animals which do not pose significant risk of spreading of diseases due to:
 - (a) the species, categories, and live stage of the aquaculture animals;

- (b) the methods of keeping the aquaculture animals and 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 mitigating measures applied at place of origin or place of destination.

Article 201

*Movement of **live** wild aquatic 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. Article 200(1) and (2) and the rules adopted pursuant to Article 200(3) shall also 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(3) or 37(4) or are subject to an eradication programme in accordance with Article 30(1) or (2), where such measures are necessary to ensure that those **live** wild aquatic animals do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to aquatic animals at the place of destination.
- 1a. Paragraph 1 shall also apply to live aquatic animals not covered by the definition of aquaculture animals in Article 4(7).**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning movement requirements for wild aquatic animals intended for human consumption supplementing paragraphs 1 **and 1a** [...].

[...]

SECTION 5

DEROGATIONS FROM SECTIONS 1 TO 4 (ARTICLES 190 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 they comply with 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 referred to in Article 8(1)(d) to listed species of animals at the confined [...] establishment **for aquaculture** of destination except where such movement is authorised for [...] scientific purposes.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
- (a) detailed requirements for movements of aquaculture animals to confined [...] establishments **for aquaculture** in addition to those provided for in paragraph 1 [...];
 - (b) specific rules for movements of aquaculture animals to confined [...] establishments **for aquaculture** where the risk mitigating 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 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 into their territory of aquatic animals for scientific purposes, which do not comply with the requirements of Sections 1 to 4 (**Articles 190 to 202**), with the exception of Articles 190(1) and (3), and Articles 191, 192 and Article 193.
2. The competent authority[...] shall only grant derogations for movements of aquatic animals for scientific purposes, as provided for in paragraph 1 under the following conditions:
- (a) the competent authorities of the place of destination and of the place of origin:
 - (i) have agreed on the conditions for such movements;
 - (ii) [...] **ensure that** the necessary risk mitigating measures [...] **are in place so** that the movements of those aquatic animals do not jeopardise the health status en route and of the places of destination with regard to the listed diseases referred to in Article 8(1)(d);

- (iii) have notified, where relevant, the competent authority of Member States of passage of the derogation granted and the conditions under which this authorisation is granted;
 - (b) **those** [...] movements of those aquatic animals take place under the supervision of the competent authorities of the places of origin [...] **and** destination, and where relevant, the competent authority of the Member State of passage.
- 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning [...] the rules for derogations by the competent authorities, **supplementing those** provided for in paragraphs 1 and 2 [...].

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 points (i) to (iv) of paragraph 2(a) do not pose a risk for the spread of listed diseases referred to in Article 8(1)(d) to aquatic animals at the place of destination.**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) specific requirement supplementing the rules laid down in [...] Sections 1 to 3 (**Articles 190 to 201**) and for the movements of aquatic animals for the following purposes:
 - (i) zoos, pet shops, [...] wholesalers **and garden ponds**;
 - (ii) exhibitions
 - (**ia**) [...] sports **fishing, including fishing baits**;
 - (**ib**) cultural and similar events; [...]
 - (iii) [...] commercial aquaria; **or**
 - (**iv**) **health care and other similar uses.**
 - (b) derogations from Sections 1 to 4 (**Articles 190 to 202**) with the exception of Article 190(1) and (3) and Articles 191, 192 and 193 for the movements of aquatic animals referred to in point (a), **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 for temporary [...] **rules** for movements of specific species or categories of aquatic animals*

1. The Commission **may** [...], by means of implementing acts lay down rules concerning temporary **alternative or additional** [...] rules laid down in this Chapter for movements of specific species or categories of aquatic animals where:
 - (a) the movement requirements provided for in Article 195, Article 196(1), Articles 197 and 198, Article 199(1) and (2), Article 200 and Articles 201(1), 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 196(2), 199(3), 201(2), 202(2), 203(2) and 204(3) and Article 205 are not efficiently mitigating the risks posed by certain movements of those aquatic animals; or
 - (b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 5 (**Articles 190 to 207**).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

2. On duly justified imperative grounds of urgency relating to a listed disease representing a risk of 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 255(3).

Article 207

Matters to be taken into account when adopting delegated and implementing acts provided for in this Section

[...] **When** establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 203(2), 204(3) and Articles 205 and 206, **the Commission shall base those acts on:**

- (a) the risks involved with the movement;
- (b) the health status as regards the listed diseases referred to in Article 8(1)(d) at the places of origin, **passage** and destination;
- (c) listed aquatic animal species for the listed diseases referred to in Article 8(1)(d);
- (d) biosecurity measures in place;
- (e) any specific conditions under which the aquaculture animals are kept;
- (f) specific movement patterns of the type of aquaculture establishment and concerned species or category of [...] **aquatic** animals;
- (g) other epidemiological factors.

SECTION 6 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 at the place of origin in accordance with Article 216(1) when they are of listed species for the listed diseases referred to in [...] **Article 8(1)(b) and (c) and** they are intended for introduction into a Member State, or zone or compartment thereof which has been declared disease-free in accordance with Articles 36(3) and 37(4) or for which an eradication programme has been established as provided for in Article 30(1) or (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c)[...].

[...]

2. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority at the place of origin in accordance with Article 216(1) when they are of listed species for the relevant disease(s) referred to in **Article 8(1)(a) and (b) and** [...] they are allowed to leave a restricted zone subject to disease control measures provided for in Article 55(1)(f)(ii), Articles 56 and 64, Articles 65(1), 74(1), 78 [...] or the rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3), [...] 74(3) **and** 81(2) and Article 248 for one or more of listed diseases referred to in Article 8(1)(a) and (b).

[...]

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 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 Article 211(1)(aa), operators shall only move those aquatic animals if they are accompanied by an animal health certificate** issued by the competent authority at the place 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 origin concludes that the certification is not feasible due to the nature of the place of origin of those [...] aquatic animals, **it may authorise the movement without an animal health certificate subject to the consent of the competent authority of the place of destination.**
- 2a. **This Article shall not apply to wild aquatic animals harvested or caught for direct human consumption.**

[...]

Article 210

Member States' derogation for national animal health certification

By way of derogation from the animal health certification requirements of 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 an alternative system in place to ensure that [...] consignments of **such animals** are traceable and they comply with the animal health requirements for such movement provided for in Sections 1 to 5 (**Articles 190 to 207**).

Article 211

*Delegation of powers **and implementing acts** concerning animal health certification for aquatic animals*

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (aa) **the requirement for animal health 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 to ensure that the movement in question complies with the following animal health requirements for the listed species of animals:**
 - (i) **the requirements provided for in Sections 1 to 5 (Articles 190 to 207) and the rules adopted pursuant to those Sections;**
 - (ii) **disease control measures provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, Articles 65(1), 74(1) and 78(1) and (2) or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, Articles 71(3), 74(3) and 81(2);**

- (iii) **emergency measures provided for in the rules adopted pursuant to Article 248;**
- (b) special rules for animal health certification provided for in Articles 208 and 209 where [...] **specific** risk mitigating measures taken by the competent authority, ensure:
 - (i) the traceability of the aquatic animals;
 - (ii) that the aquatic animals being moved comply with required animal health conditions provided for in Sections 1 to 5 (**Articles 190 to 207**).
- (a) 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 significant risk of the spread of diseases due to:
 - (i) the categories, live stage or species of the aquatic animals;
 - (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, 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 255(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 species and category**, of the aquatic animals;

- (c) the **quantity** (number, volume or weight) of aquatic animals;
 - (d) the necessary information needed to demonstrate that the **aquatic** animals comply with the [...] **relevant animal health** requirements **for movements** provided for in Sections 1 to 5 (**Articles 190 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 253 concerning the content of animal health certificates 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 categories and species 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 255(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 253 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 may not continue their route to their final place of destination and are required to return to their place of origin or be moved to a different destination, for one or more of the following reasons:
 - (i) their intended route was unexpectedly interrupted for animal welfare reasons;
 - (ii) unpredicted accidents or events on the route;
 - (iii) the aquatic animals were rejected at the place of the destination in another Member State or at the external border of the Union;

- (iv) the aquatic animals were rejected in a third country;
- (b) movements of aquaculture animals intended for exhibitions and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 215

Operators obligation to cooperate with the competent authorities for animal health certification purposes

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 the rules adopted pursuant to Articles 211, 213 and 214 **in advance of the intended movement**;
- (b) where necessary, [...] **ensure that** the aquatic animals **are subjected** to identity, physical and documentary checks as provided for in Article 216(3) and the rules adopted pursuant to Article 216(4).

Article 216

Competent authority responsibility for animal health certification and delegated acts

1. The competent authority shall, upon request by the 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 that Articles 211 and Article 214 provided that the following animal health requirements have been complied with, as relevant:
 - (a) those provided in Article 190, Article 191(1), Articles 192, 194 and 195, Article 196(1), Articles 197 and 198, Article 199(1) and (2), Article 200, Articles [...] 203(1) and 204(1) and (2);
 - (b) those provided in delegated acts adopted pursuant to Articles 191(2), 196(2), 199(3), 200(3), 201(2), [...], 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 the official veterinarian;

- (b) remain valid for **the** period of time provided for in the rules adopted pursuant to paragraph 4(c), during which [...] the **aquatic** animals covered by it must continue to comply with the animal health guarantees contained in it.
3. The official veterinarian shall, before signing an animal health certificate verify that the aquatic animals covered by it comply with the requirements of this Chapter by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, 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 253 laying down rules concerning:
- (a) the types of documentary, identity and physical checks and examinations for different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 [...] to verify compliance with the requirements of this Chapter;
 - (b) the timeframes for the carrying out of such documentary, identity and physical checks, examination 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 health certificates

Electronic animal health certificates, produced, handled and transmitted by means of [...] **TRACES**, may replace accompanying animal health certificates provided for in Article [...] **216(1)** where such electronic animal health certificates:

- (a) contain all the information that the model 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 and the link between those animals and the electronic animal health certificate;

- (c) **the access of the competent authorities of the Member States of origin, passage and destination to the electronic documents is ensured 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 the place of destination in another Member State and ensure that it accompanies such aquaculture animals, where they are not required to be accompanied by an animal health certificate provided for in Articles 208 and 209 or rules adopted pursuant to that 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:
 - (a) their places of origin and destination, and when relevant any places en route;
 - (aa) means of transport**
 - (b) a description of the aquaculture animals, **their categories**, species, [...] quantity [...] **(numbers, volume or weight)** as relevant for the animals concerned;
 - (c) the information needed to demonstrate that the aquaculture animals comply with the movement requirements provided for in Sections 1 to 5 (**Articles 190 to 207**).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) detailed rules on the content of the self-declaration document provided for in paragraph 2 [...] 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 [...].
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 255(2).

SECTION 7

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 shall notify the competent authority in their Member State of origin in advance of the intended movement 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 or 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 208(2)(a);
- (c) the aquaculture animals and wild aquatic animals being moved are intended for:
 - (i) an establishment subject to registration in accordance with Article 171 or approval in accordance with Articles 174 to 177;
 - (ii) for release into the wild;
- (d) notification is required in accordance with the delegated acts adopted pursuant to Article 221.

2. For the purposes of the notification provided for in [...] paragraph 1 [...], the operators shall provide the competent authority of the 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

The responsibility of the competent authority for the notification of 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 Article 221(1)(c) for such notification.

2. The notification referred to in paragraph 1 [...] shall be carried out **prior to the movement and**, whenever possible, through [...] **TRACES**.
3. Member States shall designate regions for the management of notifications of movements by the competent authority 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 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 the competent authority

1. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning:
 - (a) the requirement for notification by operators in accordance with Article 219 [...] of movements between Member States of aquatic animals of categories or species other than those referred to in Article 219[...] (a), (b) and (c) where traceability of such movements is necessary to ensure compliance with the animal health requirements laid down in this Chapter;
 - (b) the information necessary to notify movements of aquatic animals by operators and the competent authority as provided for in Articles 219 [...] and 220(1);
 - (c) derogations from the notification requirements provided for in Article 219 [...] (c) for categories or species 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 case of power cuts or other disturbances of the [...] **TRACES**;
 - (e) the requirements for the designation of regions by Member States provided for in Article 220(3).
2. The Commission may, by means of implementing acts, lay down rules concerning:
 - (a) the [...] **details on** 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 necessary information to be provided to the competent authority of the Member State of origin by operators referred to in Article 219[...];
- (ii) the notification of movements by the competent authority of the Member State of origin referred to in Article 220(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

[...]

Chapter 4

Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals

Article 223

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 referred to in Article 8(1)(d) 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 obtained from animals, which come from [...] **such** establishments **or** food businesses subject to:
 - (a) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations have been provided for those rules in Part VI (Articles 246 to 251);

- (b) movement restrictions applicable to the aquatic animals and products of animal origin from aquatic animals, as provided for in Articles 31(1) and 55(1)(e), Article 56, Article 61(1)(a), Article 62(1), Articles 65(1)(c), 70(1)(b) and 74(1)(a), **75a(2)(b) and (3)**, Articles 78 [...], 80 [...] **and 80a(2) and (2a)** and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles **70(3)**, 71(3) and 74(3), **75a(4)** [...] and 81(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 253 concerning detailed requirements supplementing **those referred to in** paragraph 2 [...]for 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 disease, for which emergency measures or movement restrictions referred to in paragraph 2 apply;
 - (b) the types of products of animal origin from aquatic animals;
 - (c) the risk mitigating 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.
- 3a. This Article shall not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption.**

Article 224
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 they are accompanied by an animal health certificate issued by the competent authority at the place 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 provided for in rules adopted pursuant to Article 248; 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 [...] Articles 31(1), Article 55(1)(c), Article 56, Article 61(1)(a), Articles 62(1) and 63(1), Article 65(1)(c), 70(1)(b) and 74(1)(a), Article 78 [...] and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), 74(3) [...] and 81(2); and
 - (ii) [...] originate from aquatic animals of species subject to those disease control measures.

1a. 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 mitigating measures authorised by the competent authority are in place to ensure that those movements do not pose a risk of spread of listed diseases;**
- (b) **consignments of such products are traceable.**

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 issue an animal health certificate for the movements of products of animal origin other than live aquatic animals referred to in paragraph 1, **provided that the relevant requirements referred to in this Article have been complied with.**
4. Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the certification of movements of products of animal origin other than live aquatic animals, referred to in paragraph 1 [...].
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, referred to in paragraph 1 [...] taking into account:
 - (a) the types of products of animal origin;
 - (b) the risk mitigating measures applied to the products of animal origin which reduce 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 225

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 the place of origin and the establishment or place of destination;
 - (b) a description of the products of animal origin;
 - (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 Article 65(1)(h) or rules adopted pursuant to Article **67**;
 - (e) information needed to demonstrate that the products of animal origin of the consignment comply with the movement restriction requirements provided for in Article 223(2) and rules adopted pursuant to Article 223(3).
2. The animal health certificate for products of animal origin **from aquatic animals**, other than live aquatic animals, may include other information required under other Union legislation.
3. The Commission shall [...] adopt delegated acts in accordance with Article 253 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 provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 226

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 the intended movement of products of animal origin **from aquatic animals**, other than live aquatic animals, when the consignments are required to be accompanied with an animal health certificate in accordance with Article 224(1);
 - (b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement of products of animal origin **from aquatic animals**, other than live aquatic animals, to the Member State of destination in accordance with paragraph 2.
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 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 5

National measures

Article 227

National measures for limiting the impact of diseases other than listed disease

1. Where a disease other than a listed disease referred to in Article 8(1)(d) constitutes a significant risk for aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction of 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 to prevent the introduction of or to control the spread of the disease within the Member State.

2. Member States shall notify the Commission in advance of any proposed national measures referred to in paragraph 1 that may affect movements between Member States.
3. The Commission shall approve and if necessary amend the national measures referred to in paragraph 2 [...] by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).
4. The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary to prevent the introduction of or to control the spread of the disease referred to in paragraph 1, taking into account the overall impact of the disease and the measures taken on the Union.

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 228

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 referred to in **Article 8(1)(d)**, 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 animal health requirements shall apply:

- (a) the requirements concerning registration, approval, record keeping and registers for establishments and transporters provided for in Chapters 1 of Titles I and II (**Articles 82 to 96 and Articles 170 to 173**);
- (b) the requirements concerning traceability provided for in Articles 102 to 105 and Article [...] 113 for other animals and Article 119 for germinal products;
- (c) movement requirements:

- (i) for other animals mainly living in terrestrial environment or **that** are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in [...] Article 229(3)(d) and (e), **the requirements** provided for in Section 1 (**Articles 121 and 122**) and Section 6 of Chapter 3 of Title I of Part IV (**Articles 134 to 139**), and Chapter[...] 5 of Title I of Part IV (**Articles 153 and 154**);
- (ii) for 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 Article 229(3)(d) and (e), the requirements provided for in Sections 1 to 5 of Chapter 2 of Title II of Part IV (**Articles 190 to 207**) [...];

[...]

- (iv) for germinal products the general requirements for movements provided for in Articles 155 and 156 and the special requirements for movements to other Member States provided for in Articles 162 and 163;
 - (v) for products of animal origin, the general animal health obligations for operators for the production, processing and distribution within the Union of products of animal origin provided for in Articles 164 and 223;
- (d) the following animal health certification obligation for operators and the competent authority and self-declaration for operators:
- (i) for other animals, pursuant to the rules provided for in Articles 140 to 148 or Articles 208 to 218;
 - (ii) for germinal products, pursuant to the rules provided for in Articles 159 and 160;
 - (iii) for products of animal origin, pursuant to the rules provided for in Articles 165 and 166 or Articles 224 and 225;
- (e) notification of movements by operators and by the competent authority, taking into account the requirements provided for in Articles 149, 150, 151, 161, 167 and in Articles 219 to 221 and 226.

Article 229

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 253 concerning [...] **any specific** requirements for other animals, and their germinal products or products of animal origin, [...] which are necessary to mitigate the risk of the **listed** diseases referred to [...] in Article 8(1)(d), **as provided for in Article 228** [...].

[...]

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 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 are listed in accordance with Article 7(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, 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 such measures;
 - (d) the prevailing terrestrial or aquatic living environment of those other animals;
 - (e) the type of diseases that are affecting such other animals, which can be either diseases normally affecting terrestrial or normally affecting aquatic animals, regardless of the prevailing living environment referred to in point (b).

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 230

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 they comply with the following requirements, **unless such animals, germinal products or products of animal origin are covered by a derogation adopted pursuant to Article 241(1)**:
 - (a) **without prejudice to Article 231(2)**, they come from a third country or territory, listed in accordance with Article 231(1) for the particular species and category of animals, or germinal products or products of animal origin, or zone or compartment thereof [...];
 - (b) they come from establishments which are approved and listed where such approval and listing is required by Article 234 [...];
 - (c) they comply with the animal health requirements for entry into the Union laid down in **Article 236(1) and** delegated acts adopted pursuant to Article 236(2), where such requirements are laid down for the animal, germinal product or product of animal origin of the consignment;
 - (d) they are accompanied by an animal health certificate, declarations and other documents where required by Article 239(1) or rules adopted pursuant to Article 239(4);
2. [...] **The operators responsible for the consignment** shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control provided for in [...] **Article 3 of Directive 91/496 and Article 3 of Directive 97/78** [...].

SECTION 2

LISTING OF THIRD COUNTRIES AND TERRITORIES

Article 231

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 [...] shall be permitted, [...] **based on consideration of** the following criteria:
 - (a) the animal health legislation of the third country or territory and the rules on the entry into that 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 concerning 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;
 - (d) the animal health certification procedures in the third country or territory;
 - (e) the animal health status of the third country or territory, or 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, or zone or compartment thereof, which may pose a risk to the animal or public health or the environmental status of the Union;
 - (f) the guarantees which the competent authority of the third country or territory 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 supplies the 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 Aquatic or Terrestrial Animal Health Codes of the OIE;

- (h) the results of Commission controls carried out in the third country or territory;
- (i) any experience gathered from previous entries of animals, germinal products and products of animal origin from the third country or territory 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 255(2).

2. Pending the adoption of the lists of third countries and territories provided for in paragraph 1, and provided that such lists have not been drawn up pursuant to the Union legislation referred to in Article 258(2), Member States shall determine from which third countries and territories specific species or categories of animals, germinal products or products of animal origin may enter the Union.

For the purposes of the first subparagraph, Member States shall take into account the criteria for inclusion in the lists of third countries and territories provided for in paragraph 1(a) to (i) of this Article.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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 or 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 or category of animal, germinal product or product of animal origin.

Article 232

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 231(1):

- (a) the categories or species 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 233

Suspension and withdrawal from the list of third countries and territories and implementing acts

1. The Commission shall, by means of implementing acts, [...] withdraw from the list provided for in Article 231(1) **or suspend the entry into the Union from** a third country or territory, or zone or compartment thereof, for any of the following reasons:
 - (a) the third country or territory, or one or more zones or compartments thereof, no longer complies with the criteria laid down in Article 231(1), where relevant for the entry into the Union of a particular species or category of animal, germinal product or product of animal origin;
 - (b) the animal health situation in the third country or territory, or zone or compartment thereof is such that a suspension or withdrawal from that list is necessary to protect the animal health status of the Union;
 - (c) in spite of a request of the Commission to the third country or territory for up-to-date information on the animal health situation and other matters referred to in Article 231(1), that third country or territory has not provided such information;
 - (d) the third country or territory has refused to agree to Commission control being carried out on behalf of the Union in its territory.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

1a. On duly justified imperative grounds of urgency relating to a serious risk for the introduction into the Union of a listed disease referred to in Article 8(1)(d), the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

2. The Commission may, by means of implementing acts, reinsert a third country or territory, or zone or compartment thereof, that has been [...] withdrawn from the list provided for in Article 231(1), **or re-authorise the entry into the Union from a third country or territory, or zone or compartment thereof, from which the entry into the Union has been suspended,** for one of the following reasons:
 - (a) for the reasons referred to in paragraph 1(a) or (c) of this Article, provided that the third country or territory demonstrates that it complies with the criteria for being listed provided for in Article 231(1);

- (b) for the reasons referred to in paragraph 1(b) of this Article, provided that the third country or territory provides appropriate guarantees that the animal health situation that gave rise to that suspension or withdrawal [...] has been resolved or no longer represents a threat to the animal or public health of the Union;
- (c) for the reasons referred to in paragraph 1(d) of this Article, provided that:
 - (i) the third country or territory agreed to a Commission control being carried out on behalf of the Union in its territory; and
 - (ii) the results of that Commission control shows that the third country or territory, and zones or compartments thereof comply with the criteria for being listed provided for in Article 231(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

3. [...]

SECTION 3

APPROVAL AND LISTING OF ESTABLISHMENTS IN THIRD COUNTRIES AND TERRITORIES

Article 234 *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 a type of establishment for which approval is required in the Union in accordance with in Article 89(2) and the rules adopted pursuant to Article 89(3) and Article 90, if that establishment in the third country or territory:
 - (a) complies with animal health requirements in that third country or territory which are equivalent to the rules for that type of establishments applicable in the Union;
 - (b) is approved and listed by the competent authority of the third country or territory of dispatch, **unless alternative risk mitigating measures in place in the third country or territory provide equivalent guarantees for the animal health within the Union.**
2. The Commission shall collect the lists of approved establishments referred to in paragraph 1(b) received from the competent authorities of the third countries or territories.

3. The Commission shall provide to the Member States any new or updated lists of approved establishments received from the third countries or territories and shall make them publicly available.
4. **The Commission shall, by means of implementing acts, adopt necessary rules to ensure uniform application of paragraph 1(b).** .

[...]

SECTION 4

ENTRY INTO THE UNION OF SPECIES AND CATEGORIES OF ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN

Article 236

[...] Animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin

01. 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 the rules adopted pursuant thereto applicable to the movement 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 82 to 229**) of this Regulation.
1. The Commission shall [...] adopt delegated acts in accordance with Article 253 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 it 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 or category of animal, germinal product or product of animal origin, provided for in paragraph 1 [...], Members State may, **following an evaluation of risks**, apply national rules, provided that those rules [...] comply with the requirements laid down in paragraph 1[...] and take the matters referred to in Articles 237 and 238 into account.
- [...].

Article 237

Matters to be taken into account in delegated acts provided for in Article 236 with regard to entry into the Union of animals

The Commission shall take the following matters into account when laying down animal health requirements in delegated acts provided for in Article 236(1), for the entry into the Union of particular species and categories of animals:

- (a) the listed diseases referred to in Article 8(1)(d) and emerging diseases;
- (b) the health status of the Union concerning the listed diseases referred to in Article 8(1)(d) and emerging diseases;
- (c) the listed species with regard to those listed diseases referred to in Article 8(1)(d) and emerging diseases;
- (d) the age and sex of the animals;
- (e) the origin of the animals;
- (f) the type of establishment 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;
- (i) any risk mitigating measures in place in the third countries or territories of origin or transit, or after the arrival 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 238

Matters to be taken into account in delegated acts provided for in Article 236 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 the animal health requirements, in delegated acts provided for in Article 236(1), for the entry into the Union of germinal products and products of animal origin:

- (a) the listed diseases referred to in Article 8(1)(d) 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 Article 8(1)(d) and emerging diseases;
- (c) the type and nature of particular germinal products or products of animal origin, treatments, processing methods and other risk mitigating measures that have been applied at the place 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;
- (g) animal health requirements applicable to movements of the germinal products and products of animal origin within the Union;
- (h) other epidemiological factors;
- (i) international animal health trade standards, relevant for the particular germinal products and products of animal origin.

SECTION 5

ANIMAL HEALTH CERTIFICATES, DECLARATIONS AND OTHER DOCUMENTS

Article 239

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 **either 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 paragraph 4(a)**;
 - (b) declarations or other documents, where required by the rules adopted pursuant to paragraph 4(b).
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 paragraph 1(a) has been verified and signed by an official veterinarian in a third country or territory in compliance with the certification requirements equivalent to those laid down in Articles 146(3) or 216(3) and rules adopted pursuant to Articles 146(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 paragraph 1(a) of this Article is required to contain in accordance with Article 240(1) and rules adopted pursuant to Article 240([...]4);
 - (b) ensure the traceability of the consignments of animals, germinal products and products of animal origin and links those consignments to the electronic animal health certificate.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
- (a) derogations from the animal health **certificate** requirements provided for in paragraphs 1(a) **and 2**, for consignments of animals, germinal products and products of animal origin and specific rules for the animal health certification of those consignments, that pose an insignificant risk to the animal health or public health within the Union, due to one or more of the following factors:
 - (i) the category or species of animals, germinal products or products of animal origin;
 - (ii) the methods of keeping and types of production of the animals, germinal products and products of animal origin;
 - (iii) their intended use;
 - (iv) alternative risk mitigating measures which are in place in the third countries or territories of origin or transit, or after the arrival into the territory of the Union, providing equivalent protection of the animal health and public health of the Union provided for in this Regulation;

- (v) the provision by the third country or territory of guarantees that compliance with the requirements for entry into the Union is demonstrated by means other than an animal health certificate;
- (b) the requirements for 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 entering into the Union meet the animal health requirements for entry into the Union laid down in rules adopted pursuant to Article 236(2)

Article 240
Content of animal health certificates

1. The animal health certificate referred to in Article 239(1)(a) 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;
 - (b) a description of the animals, germinal products or products of animal origin;
 - (c) the number or volume of the animals, germinal products or products of animal origin;
 - (d) where applicable, the identification and registration of the animals, [...] germinal products **or products of animal origin**;
 - (e) the information needed to demonstrate that the animals, germinal products and products of animal origin in the consignment comply with the animal health requirements for entry into the Union provided for in Article 230 and Article 236(3) and the rules adopted pursuant to Article 236(2) and Article 241.
 2. The animal health certificate referred to in Article 239(1)(a) may include other information required under other Union legislation.
- [...]
4. 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 Article 239(1)(a) in addition to that referred to in paragraph 1 of this Article;**
 - (b) **information to be contained in declarations or other documents referred to in Article 239(1)(b);**
 - (c) model forms for the animal health certificates, declarations and other documents referred to in Article 239(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).
5. Pending the establishment of rules in [...] implementing acts adopted pursuant to paragraph [...] 4 [...], as regards a particular species or categories of animals, germinal product or product of animal origin, [...] Members State may, **following an evaluation of risks**, apply national rules, provided they comply with the conditions laid down in paragraph 1 [...].

SECTION 6

DEROGATIONS AND ADDITIONAL REQUIREMENTS FOR CERTAIN CATEGORIES OF ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN

Article 241

Derogations and additional requirements for certain categories of animals, germinal products and products of animal origin

01. **For certain specific types of entry of animals, germinal products and products of animal origin, the application of the rules set out in Article 230(1) and Articles 234 and 239 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 such circumstances.**
1. The Commission shall [...] adopt delegated acts in accordance with Article 253 concerning **the special rules referred to in paragraph 01 regarding** derogations from the requirements provided for in Article 230(1) and Articles 234 and 239 and additional requirements for the entry into the Union of the following:
- (a) animals:
 - (i) intended for circuses, events, exhibitions, display, shows and confined establishments;
- [...]

- (iii) intended to be used for scientific **or diagnostic** purposes;
 - (iv) for which the Union is not the final destination;
 - (v) which originate in the Union and which are moved to a third country or territory, and then are moved back to the Union from that third country or territory;
 - (vi) which originate in the Union and which are transported through a third country or territory en route to another part of the Union;
 - (vii) which are intended for grazing purposes on a temporary basis, in the vicinity of the Union borders;
 - (viii) 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 then are 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 237 and 238.

2. 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 1;

- (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 255(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 242

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 their entry 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 Article 8(1)(d) and emerging diseases;
 - (b) take appropriate disease control and preventive measures to ensure that entry into the Union of those disease agents 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 253 laying down requirements for the entry into the Union of disease agents concerning:
- (a) the packaging of disease agents;
 - (b) other risk mitigating measures required to prevent the release and spread of disease agents.

Article 243
Plant material and delegated and implementing acts

- 01. 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 referred to in Article 8(1)(d) or emerging diseases, where this is required in the rules adopted in accordance with paragraph 2.**
1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning **the measures referred to in paragraph 01 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 on:
 - (i) animal health certification, taking into account the rules provided for in Article 239(1)(a) and Article 239 (2) and (3); or
 - (ii) declarations or other documents, taking into account the rules provided for in Article 239(1)(b).
2. The Commission shall lay down the animal health requirements provided for in paragraph 1 [...] **based on** the following criteria:
- (a) whether a listed or emerging disease that can be transmitted by means of plant material representing 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 be in direct or indirect contact with the plant material referred to in paragraph 1;
 - (c) the availability and effectiveness of alternative risk mitigating measures in relation to that plant material, which may eliminate or minimise the risk of transmission referred to in 2(a).
3. The Commission may, by means of implementing acts lay down rules indicating, for the plant material referred to in paragraph 1 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 255(2).

Article 244

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 preventive measures during transport, as provided for in Articles 122(1) and 191(1).
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 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 on:
 - (i) animal health certification, taking into account the rules provided for in Article 239(1)(a) and Article 239 (2) and (3); or
 - (ii) declarations or other documents, taking into account the rules provided for in Article 239(1)(b).
3. The Commission shall lay down the animal health requirements provided for in paragraph 2 in the event of a unfavourable disease situation concerning one or more listed diseases referred to in Article 8(1)(d) or emerging diseases, which present a serious risk to animal and to human health in the Union, in:
 - (a) a neighbouring third country;
 - (b) the third country of origin;
 - (c) a third country of transit.
4. The Commission may, by means of implementing acts, lay down rules indicating, for the goods referred to in paragraph 2(a) 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 255(2).

Chapter 3

Export

Article 245

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 82 to 229**), while taking into account the animal health status within the third country or territory of destination, or zone or compartment thereof, with regard to the listed diseases referred to in Article 8(1)(d) and emerging diseases.
- 1a** [...] **By way of derogation from paragraph 1**, if requested by the competent authority of [...] a third country or territory **importing those animals and products**, or if established by the [...] legal and administrative procedures in force in that country or territory, export and re-export from the Union may take place in accordance with those provisions **in that third country or territory, provided that such exports do not jeopardise public or animal health.**
2. Where the provisions of a bilateral agreement concluded between the Union and a third country or territory is applicable, animals and products exported from the Union to that third country or territory shall comply with those provisions.

PART Va: NON-COMMERCIAL MOVEMENTS OF PET ANIMALS INTO A MEMBER STATE FROM ANOTHER MEMBER STATE OR FROM A TERRITORY OR A THIRD COUNTRY

Chapter I General provisions

Article 245a Scope of Part Va

- 1. This Part shall apply to the non-commercial movement of pet animals into a Member State from another Member State or from a territory or a third country.**
- 2. It shall apply without prejudice to:**
 - (a) Regulation (EC) No 338/97;**
 - (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.**

Article 245b General provisions

- 1. Non-commercial movement of pet animals that comply with 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, such non-commercial movement 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 253 concerning requirements supplementing the rules laid down in paragraph 2 for 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.

4. The Commission may, by means of implementing acts, lay down requirements for the layout, languages and validity of the declaration authorising in writing the authorised person to carry out the non-commercial movement of the pet animal on behalf of the pet owner. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 245c

Maximum number of pet animals

1. The maximum 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 maximum 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 of pet animals is for the purpose of participating in competitions, exhibitions or sporting events or in training for such events;
 - (b) the pet owner or the authorised person submits written evidence that the pet animals are registered either to attend an event 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 movement of pet animals of the species listed in Part B of Annex I from being fraudulently disguised as non-commercial movement the Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules setting the maximum number of pet animals of those species which may be moved during a single non-commercial movement

Chapter II
Conditions applicable to the non-commercial movement of pet animals into a Member State from another Member State

Article 245d

Conditions applicable to the non-commercial movement 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 they fulfil the following conditions:

- (a) they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to Article 245j(1)(a);**
- (b) they comply with the relevant prevention and risk mitigating measures for listed diseases referred to in Article 8(1)(d) adopted pursuant to Article 245j(1)(b);**
- (c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to Article 245k(1)(d).**

Article 245e

Conditions applicable to the non-commercial movement of pet animals of the species listed in Part B of Annex I

- 1. Insofar as the Commission has adopted a delegated act pursuant to Article 245j(1)(b) with regard to pet animals of one of the species listed in Part B of Annex I, the non-commercial movement 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 they fulfil the following:**
 - (a) they are identified or described, either individually or in groups identification in accordance with the rules adopted pursuant to Article 245j(1)(a);**
 - (b) they comply with the relevant prevention and risk mitigating measures for listed diseases referred to in Article 8(1)(d) adopted pursuant to Article 245j(1)(b);**
 - (c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to Article 245k(1)(d);**
- 3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to the non-commercial movement 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 the non-commercial movement of the 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 III

Conditions applicable to the non-commercial movement of pet animals into a Member State from a territory or a third country

Article 245f

Conditions applicable to the non-commercial movement 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 territory or a third country unless they fulfil the following conditions:**
 - (a) **they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to Article 245(i)(a);**
 - (b) **they comply with the relevant prevention and risk mitigating measures for listed diseases referred to in Article 8(1)(d) adopted pursuant to Article 245(i)(b);**
 - (c) **they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to Article 245k(1)(d);**
2. **Pet animals of the species listed in Part A of Annex I may be moved into a Member State from a territory or a third country other than those listed pursuant to Article 245j(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 253 concerning the conditions for granting derogations from paragraph 2.**

Article 245g
Conditions applicable to the non-commercial movement of pet animals of the species listed in Part B of Annex I

1. Insofar as the Commission has adopted a delegated act pursuant to Article 245i(1)(b) with regard to pet animals of one of the species listed in Part B of Annex I, the non-commercial movement of pet animals of that species into a Member State from a territory or a third country 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 territory or a third country only if they fulfil the following:
 - (a) they are identified or described, either individually or in groups identification in accordance with the rules adopted pursuant to Article 245i(1)(a);
 - (b) they comply with the relevant prevention and risk mitigating measures for listed diseases referred to in Article 8(1)(d) adopted pursuant to Article 245(1)(b);
 - (c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to Article 245(k)(d);
 - (d) when coming from a territory or a third country other than those listed pursuant to Article 245j(1)(d) 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 the non-commercial movement of pet animals of the species listed in Part B of Annex I into their territory from a territory or a third country, provided that such rules are:
 - (a) applied proportionately to the risk to public or animal health associated with the non-commercial movement of the 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 245h
Derogation from the conditions applicable to the non-commercial movement of pet animals between certain countries and territories

By way of derogation from Articles 245f and 245g, the non-commercial movement 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) Faeroe Islands and Denmark;
- (h) Greenland and Denmark.

Chapter IV
Identification and prevention and risk mitigating measures

Article 245i
Delegation of powers concerning the identification of pet animals and prevention and risk mitigating measures

1. **The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:**
 - (a) **detailed species-specific requirements for:**
 - (i) **the means of identification of pet animals of the species listed in Annex I provided for Articles 245d(a), 245e(2)(a), 245f(1)(a) and 245g(2)(a);**
 - (ii) **the application and use of those means of identification;**
 - (b) **detailed species-specific requirements for the prevention and risk mitigating measures to ensure that the pet animals do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) due to the movement of pet animals of the species listed in Annex I as provided for in Article 245d(b), 245e(2)(b), 245f(1)(b) and 245g(2)(b).**
2. **Where in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to rules adopted pursuant to paragraph 1(b) of this Article.**

3. **The species-specific prevention and risk mitigating measures authorised by a delegated act adopted pursuant to paragraph 1(b) shall be based on adequate, reliable and validated scientific information and applied proportionately to the risk to public or animal health associated with the non-commercial movement of pet animals likely to be affected by listed diseases referred to in Article 8(1)(d).**
4. **The delegated acts provided for in paragraph 1(b) 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 the movement of the 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 mitigating measures referred to in paragraph 1(b);**
 - (c) **the conditions for applying and documenting the prevention and risk mitigating measures referred to in paragraph 1(b);**
 - (d) **the criteria for granting and where appropriate documenting derogations in certain specified circumstances from the application of the prevention and risk mitigating measures referred to in paragraph 1(b);**
 - (e) **the criteria for granting and documenting derogations in certain specified circumstances from the conditions referred to in Articles 245d, 245e, 245f and 245g.**

Article 245j

Implementing acts concerning the prevention and risk mitigating 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 Article 245(i)(4)(c) and (d);**
 - (b) **adopt a list of Member States that comply with the conditions referred to in Article 245(i)(4)(d) and remove Member States from that list should any change in relation to those conditions occur;**
 - (c) **adopt a list of Member States that comply with the rules for categorisation of Member States or parts thereof referred to in Article 245(i)(4)(a) and remove Member States from that list should any change in relation to those rules occur;**

- (d) adopt a list of territories and third countries that comply with the conditions referred to in Article 245(i)(4)(d) and remove territories or third countries from that list should any change in relation to those conditions occur;
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 territories and third countries that comply with the conditions referred to in Article 245(i)(4)(d) and remove territories or third countries from that list should any change in those conditions occur.
 3. Those implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 255(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 paragraph 1(b) and (d) in accordance with the procedure referred to in Article 255(3).

Chapter V **Identification documents**

Article 245k

Delegation of powers concerning identification documents

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) entries for the insertion of the information to be included in the identification documents referred to in Articles 245d(c), 245e(2)(c), 245(f)(1)(c) and 245g(2)(c);
- (b) the distribution of blank identification documents referred to Article 245d(c);
- (c) the conditions for granting derogations to the format of the identification documents provided for in Articles 245d(c) and 245f(1)(c);
- (d) issuing, completing and, where applicable, endorsing the identification documents provided for in Articles 245d(c), 245e(2)(c), 245 (f)(1)(c) and 245g(2)(c).

Article 245l

Implementing acts concerning identification documents

1. The Commission shall adopt implementing acts laying down the model of identification documents referred to in Article 245d(c) and Article 245f(1)(c) which shall contain the respective entries referred to in Article 245k(a), 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 of identification documents referred to in Articles 245e(2)(c) and 245g(2)(c) which shall contain the respective entries referred to in Article 245k(a), as well as requirements concerning the languages, layout, validity or security features of those identification documents;
 - (b) the rules necessary for the transition to the model of identification document referred to Article 245d(c).
3. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter VI
Information obligations

Article 245m
Information obligations

1. Member States shall provide the public with clear and easily accessible information concerning the animal health requirements applicable to the non-commercial movement of pet animals including:
 - (a) conditions for granting certain derogations referred to in Article 245i(4)(d);
 - (b) conditions for granting derogations referred to in Article 245i(4)(e);
 - (c) requirements for the application of the means of identification as referred to in Article 245i(a)(ii);
 - (d) conditions applicable to the non-commercial movements into the Member States territories of pet animals of the species of Part B of Annex I, laid down by their national rules as provided for in Articles 245e(3) and 245g(3);
 - (e) conditions applicable to the non-commercial movement into the Member States' territory of pet animals from certain countries and territories laid down by their national rules as referred to in Article 245h;
 - (f) any relevant information concerning certain prevention and risk mitigating measures referred to in Article 245i(1)(b);
2. Member States shall establish internet-based pages providing the information referred to in paragraph 1 and 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) the links to the internet-based information pages of the Member States;**
 - (b) the information referred to in paragraph 1(a) and (d), and the information made available to the public as referred to in Article 245a(2)(b) in additional languages, as appropriate.**

PART VI

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 246

Emergency measures to be taken by the competent authority of the affected Member State in the event of an outbreak of a listed disease or an emerging disease or the occurrence of a hazard in their territory

1. In the event of an outbreak of a listed disease or an 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 Article 8(1)(a) the disease control measures laid down in Chapter 1 of Title II of Part III (**Articles 53 to 71**);
 - (ii) referred to in Article 8(1)(b) [...], the disease control measures laid down in **Articles 72 to 81** of Chapter 2 of Title II of Part III;
 - (iii) **referred to in Article 8(1)(c), the disease control measures laid down in Articles 75a to 77 and 80a of Chapter 2 of Title II of Part III;**
 - (b) for emerging diseases and hazards:
 - (i) movement restrictions on 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 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 an outbreak or the occurrence of a hazard referred to in paragraph 1;
 - (b) without delay of the emergency measures taken pursuant to paragraph 1.

Article 247

Emergency measures to be taken by a Member State other than [...] where the outbreak or hazard occurred

1. The competent authority of Member States other than the Member State where the outbreak or hazard referred to in Article 246(1) occurred, **depending on the gravity of the situation and the disease or hazard in question**, shall take one or more of the emergency measures referred to in Article 246(1), where it detects on its territory animals or products from the Member State referred to in Article 246(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 248, take the emergency measures referred to in Article 246(1) on an interim basis, depending on the gravity of the situation with regard to animals or products originating from the establishments or any other locations, or where relevant from the restricted zones of the Member State where the disease or hazard referred to in Article 246(1) occurred, or means of transport or other material that may have come into contact with such animals.
- 2a A Member State may take measures referred to in Article 246(1) in the event of an outbreak in a third country or territory bordering the Union of a disease referred to in Article 8(1)(a) or an emerging disease in such a third country or territory, as far as those measures are necessary to prevent the spread of the disease into the territory of the Union.**
3. The competent authority referred to in paragraph 1 **and the competent authority of the Member State referred to in paragraph 2a** 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 248
Commission emergency measures

1. In the event of an outbreak or the occurrence of a hazard, as referred to in Article 246(1) and of emergency measures taken by the competent authorities of the Member States in accordance with Articles 246(1) and 247(1), [...] (2) **and (2a)**, the Commission shall review the situation and the emergency measures taken, and adopt, by means of an implementing act one or more of the emergency measures provided for in Article 246(1) concerning the animals and products 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) the Commission has not been informed of any measures taken pursuant to Article 246(1) and 247(1), [...] (2) **and (2a)**;
 - (b) the Commission considers the measures taken pursuant to Article 246(1) and 247(1), [...] (2) **and (2a)** to be inadequate;
 - (c) the Commission considers it necessary to approve or replace the measures taken by the competent authorities of the Member States pursuant to Articles 246(1) and 247(1), [...] (2) **and (2a)** 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 255(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 255(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 249

Emergency measures to be taken by the competent authority of the Member State

Where the competent authority of a Member State becomes aware of [...] animals or products originating from a third country or territory, or means of transport or materials which may have come into contact with such [...] **animals and products**, that is 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**;
 - (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 a 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 250

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 and, 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 [...] of animals and products and 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 that disease or hazard into the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 255(3).

Article 251

Emergency measures taken by the Member States when the Commission does not act

1. Where a Member State requests the Commission to take emergency measures in accordance with Article 250 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 emergency measures referred to in point (a) of Article 249 on an interim basis in respect of the [...] animals and products and 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 250(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 in accordance with paragraph 1 of this Article and shall, where necessary adopt by means of an implementing act one or more emergency measures provided for in Article 250.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(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 255(3).

PART VII COMMON PROVISIONS

TITLE I Procedural provisions

Article 252 Amendment to Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to [...] **Annex II, limited exclusively to taking into account changes in taxonomy.**

Article 253 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.
- 1a. **It is of particular importance that the Commission carry out consultations with experts, including Member States' experts, before adopting those delegated acts**
2. The power to adopt delegated acts referred to in Articles **3(5), 5(2), [...]**13(2), 15(2), 16(3), 18(3), [...] 28, 30(4), 31(2), [...] 37(5), 39, 41(3), 42(5), [...] 47, 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64(4), 67, 68(2), **68(2a)**, 70(3), 72(2), 73(3), 74(3), **75a(4)**, 76(2), [...] 85(3), 89(3), 92(2), 96(3), 100(1), 103(2), 114, 115, 119(1), **119(1a)**, 122(2), 128(1), 129(2), 132, 133(2), 134(2), 135(3), 136(4), 137, 141(1), 143(1), 144, 146(4), 148(3), 151(1), 152(2), 154(1), 158(1), **158(2)**, 159(5), 160(3), **160(3a)**, **161(4)**, 162(2), 163(3), 164(3), 165(5), 166(3), **167(4)**, 174(3), 179(2), **183(5)**, 184(1), 188(1), 191(2), 196(2), 199(3), 200(3), 201(2), [...] 203(2), 204(3), 205(2), 211(1), 213(1), 214, 216(4), 218(3), 221(1), [...] 223(3), 224(5), 225(3), 229(1), 231(3), [...] 236(1), 239(4), [...] 241(1), 242(2), 243(1), 244(2), **245b(4)**, **245i((1))**, **245k**, 252, 259(2), 260(2), **261b(2)**, and [...] **261c(4)** shall be conferred on the Commission for [...] a period of [...] **five years** from^(*).^(*) **Date of entry into force of the basic legislative act or any other date set by the legislator.**

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 listed in paragraph 2 [...] may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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 provisions listed in paragraphs 2 and 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 the Council.
7. **The Commission shall allow a period of at least 6 months between the adoption of the respective initial delegated acts, referred to in Articles 3(5), 13(2), 15(2), 18(3), 119(1a), 162(2) and 229(1), and the start of their application.**

Article 254
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 253(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 255
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 6 months between the adoption of the respective initial implementing acts referred to in Articles 23(3), 229(2), and 117 when those implementing acts relate to the implementation of Article 113, and the start of their application.**

Article 255a
Data protection

1. **Member States shall apply Directive 95/46/EC⁶⁴ to the processing of personal data carried out in the Member States pursuant to this Regulation.**
2. **Regulation (EC) No 45/2001⁶⁵ shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.**

TITLE II

Penalties

Article 256
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 [*date to be inserted: one year from the date of application of this Regulation*] at the latest and shall notify it without delay of any subsequent amendments affecting them.

⁶⁴ *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).*

⁶⁵ *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. 1–22).*

TITLE III

Member States measures

Article 257

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 additional or more stringent measures within their territories than those laid down in this Regulation concerning [...]:
 - (a) responsibilities for animal health provided for in Chapter 3 of Part I (**Articles 9 to 15**);
 - (b) notification within Member States provided for in Article 16;
 - (c) surveillance provided for in Chapter 2 of Part II (**Articles 22 to 29**);
 - (d) registration, approval, record keeping and registers provided for in Chapter 1 of Title I (**Articles 82 to 101**) and Chapter 1 of Title II of Part IV (**Articles 170 to 189**);
 - (e) traceability requirements for kept terrestrial animals and germinal products provided for in Chapter 2 of Title I of Part IV (**Articles 102 to 120**).

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 in contradiction with the rules referred to in paragraph 1.

PART VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 258

Repeals

1. Decision 78/642/EEC, Directive 79/110/EEC, Directive 81/6/EEC, Decision 89/455/EEC, Directive 90/423/EEC, Decision 90/678/EEC, **Directive 92/36/EEC and Directive 98/99/EC** are repealed.
2. The following acts are repealed as from [*the date of application of this Regulation*]:
 - 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 (EU) No 576/2013, [...]**
- Regulation (EC) No 21/2004,
- Directive 2004/68/EC,
- Directive 2005/94/EC,
- Directive 2006/88/EC,
- Directive 2008/71/EC,
- Directive 2009/156/EC,
- Directive 2009/158/EC.

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 III hereto.

[...]

Article 259

*Transitional measures related to the **amendment** of Regulation (EC) No 1760/2000 and repeal of Regulation (EC) No 21/2004 and Directive 2008/71/EC*

1. Notwithstanding Article 258(2) and **261a** of this Regulation, **Articles 1 to 10** of Regulation (EC) No 1760/2000 and 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 [...] **3 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 [...] **253** concerning the date [...] referred to in paragraph 1 [...].

That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 103(2) and [...] 115 **and the implementing acts provided for in Article 114** of this Regulation.

Article 260

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 258(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 [...] **3 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 253 concerning the date [...] referred to in paragraph 1 [...].

That date shall be the date of the application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Articles [...] 47(1) 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 260a

Existing special provisions with regard to salmonella following the repealing of Council Decision 95/410/EC

Regulation EC 2160/2003 is amended as follows:

The following wording shall be added at the end of Article 9(3):

"This shall include measures based on the provisions contained in Council 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 at the time of the repeal of Council Directive 90/539/EEC."

Article 260aa

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 262, the Commission shall adopt the delegated acts referred to in Articles 30(4) first subparagraph, 31(2), 39, 41(3), 54(3), 55(2), 58(2), 64(4), 67, 68(2), 74(3), 76(2), 92(2), 119(1)(a), 128(1), 129(2), 132, 134(2), 143(1), 146(4), 151(1), 160(3), 161(4), 164(3), 167(4), 179(2), 183(5), 213(1), 216(4), 221(1), 223(3), 225(3), 236(1), 241(1) and the implementing acts referred to in Articles 7 and 8 at the latest on 24 months before the start of application provided for in Article 262. In accordance with Article 262, those delegated and implementing acts apply from the date of application set out in that Article.

Article 260ab

*Prior review and amendments of
Annex Ia*

The Commission shall, at the latest 24 months before the date of application provided for in Article 262, review the listed diseases in Annex Ia. Should this review demonstrate that an application of the rules set out in this Regulation requires amendments to be made to Annex Ia, by adding to or deleting from that list, such amendments shall be adopted by the Commission at the latest on the date referred to in this Article.

260ac
Review

The Commission shall, at the latest 24 months before the date of application provided for in Article 262, review the existing legislation on the identification and registration of kept animals of the equine species.

The Commission shall take into account the results of this review in the framework of the application of Articles 114, 115 and 117.

Article 261

Transitional measures related to the repeal of Regulation (EU) No 576/2013 on the non-commercial movement of pet animals

1. Notwithstanding Article 258(2) of this Regulation, Regulation (EU) No 576/2013 shall continue to apply until [...] **10 years after the date of entry into force of this Regulation in respect of non-commercial movements of pet animals in the place of Part Va of this Regulation.**

[...]

Article 261a

Amendments to Regulation (EC) No 1760/2000

Regulation (EC) No 1760/2000 is amended as follows:

- (a) **Articles 1 to 10 are deleted;**
- b) **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.**

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 the first indent 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 made 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. This report shall, where appropriate, contain recommendations for Member States on the improvement of compliance with this Regulation.";**

- (c) 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.
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.";

(d) 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) by the Standing Committee on the Food Chain and Animal Health established by Article 58 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**.

⁺ *OJ: please insert the date of entry into force of this Regulation (the amending Regulation).*

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 261b

Existing operators and establishments

1. Establishments and operators registered or approved in accordance with Council Directive 64/432/EEC, Council Directive 88/407/EC, Council Directive 89/556/EC, Council Directive 90/429/EC, Council Directive 91/68/EEC, Council Directive 92/65/EEC, Regulation (EC) No. 1760/2000, Regulation (EC) No 21/2004, Council Directive 2006/88/EC, Council Directive 2008/71/EC, Council Directive 2009/156/EC, Council 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 253 concerning rules necessary to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraph 1, in particular to protect acquired rights and legitimate expectations of natural and legal persons concerned.

Article 261c

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 Article 8(1)(b) and (c), for one or more of the relevant animal species, in accordance with Council Directive 64/432/EEC, Council Directive 91/68/EEC, Council Directive 92/65/EEC, Council Directive 2006/88/EC, Council Directive 2009/156/EC or Council 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 Article 8(1)(b) and (c), for one or more of the relevant animal species, in accordance with Council Directive 64/432/EEC, Council Directive 91/68/EEC, Council Directive 92/65/EEC, Council Directive 2006/88/EC, Council Directive 2009/156/EC or Council 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 Article 8(1)(a), (b) or (c) in accordance with Council Directive 2005/94/EC and Council Directive 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 253 concerning rules necessary to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraph 1, 2 and 3.**

Article 261d

Relation with acts on official controls

In case of conflict between the provisions in this Regulation and the provisions in Regulation (EC) No 882/2004, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, the provisions in this Regulation shall prevail.

Article 261e
Evaluation

The Commission shall evaluate this Regulation together with the delegated acts referred to in Article 253 and submit the results of the evaluation in a report to the European Parliament and to the Council no later than five years after the date of application of this Regulation.

Article 262
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 **24 + 36 months** from the date of entry into force of the Regulation, **except Articles 258(1) and 260aa, which shall apply from the date of entry into force of the Regulation.**

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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

Amphibia

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 I a - List of diseases

- **Rinderpest (cattle plague)**
- **Sheep and goat plague (Peste des petits ruminants)**
- **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 septicaemia (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 II

Species of Ungulates

Taxon		
Order	Family	Genera/Species
Perissodactyla	Equidae	<i>Equus</i> spp.
	Tapiridae	<i>Tapirus</i> spp.
	Rhinocerotidae	<i>Ceratotherium</i> spp., <i>Dicerorhinus</i> spp., <i>Diceros</i> spp., <i>Rhinoceros</i> spp.

Artiodactyla	Antilocapridae	<i>Antilocapra</i> ssp.
	Bovidae	<i>Addax</i> ssp., <i>Aepyceros</i> ssp., <i>Alcelaphus</i> ssp., <i>Ammelaphus</i> ssp. , <i>Ammodorcas</i> ssp., <i>Ammotragus</i> ssp., <i>Antidorcas</i> ssp., <i>Antilope</i> ssp., <i>Arbitragus</i> ssp. , <i>Beatragus</i> ssp. , <i>Bison</i> ssp., <i>Bos</i> ssp. (including <i>Bibos</i> , <i>Novibos</i> , <i>Poephagus</i>), <i>Boselaphus</i> ssp., <i>Bubalus</i> ssp. (including <i>Anoa</i>), <i>Budorcas</i> ssp., <i>Capra</i> ssp., <i>Cephalophus</i> ssp., <i>Connochaetes</i> ssp., <i>Damaliscus</i> ssp. (including <i>Beatragus</i>), <i>Dorcatragus</i> ssp., <i>Eudorcas</i> ssp. , <i>Gazella</i> ssp., <i>Hemitragus</i> ssp., <i>Hippotragus</i> ssp., <i>Kobus</i> ssp., <i>Litocranius</i> ssp. [...] <i>Madoqua</i> ssp. , <i>Naemorhedus</i> ssp. (including <i>Nemorhaedus</i> and <i>Capricornis</i>), <i>Nanger</i> ssp. , <i>Neotragus</i> ssp., <i>Nilgiritragus</i> ssp. , [...] <i>Oreamnos</i> ssp. , <i>Oreotragus</i> ssp., <i>Oryx</i> ssp., <i>Ourebia</i> ssp., <i>Ovibos</i> ssp., <i>Ovis</i> ssp., <i>Pantholops</i> ssp., <i>Philantomba</i> ssp. , <i>Pelea</i> ssp., <i>Procapra</i> ssp., <i>Pseudois</i> ssp., <i>Pseudoryx</i> ssp., <i>Raphicerus</i> ssp., <i>Redunca</i> ssp., <i>Rupicapra</i> ssp., <i>Saiga</i> ssp., <i>Sigmoceros-Alecelaphus</i> ssp., <i>Strepticerus</i> ssp. , <i>Sylvicapra</i> ssp., <i>Syncerus</i> ssp., <i>Taurotragus</i> ssp., <i>Tetracerus</i> ssp., <i>Tragelaphus</i> ssp. (including <i>Boocerus</i>).
	Camelidae	<i>Camelus</i> ssp., <i>Lama</i> ssp., <i>Vicugna</i> ssp.
	Cervidae	<i>Alces</i> ssp., <i>Axis-Hyelaphus</i> ssp., <i>Blastoceros</i> ssp., <i>Capreolus</i> ssp., <i>Cervus</i> [...] ssp., <i>Dama</i> ssp., <i>Elaphodus</i> ssp. , <i>Elaphurus</i> ssp., <i>Hippocamelus</i> ssp., <i>Hydropotes</i> ssp., <i>Mazama</i> ssp., <i>Megamuntiacus</i> ssp., <i>Muntiacus</i> ssp., <i>Odocoileus</i> ssp., <i>Ozotoceros</i> ssp., <i>Przewalskium</i> ssp. , <i>Pudu</i> ssp., <i>Rangifer</i> ssp., <i>Rucervus</i> ssp. , <i>Rusa</i> ssp.
	Giraffidae	<i>Giraffa</i> ssp., <i>Okapia</i> ssp.
	Hippopotamidae	<i>Hexaprotodon-Choeropsis</i> ssp., <i>Hippopotamus</i> ssp.
	Moschidae	<i>Moschus</i> ssp.
	Suidae	<i>Babyrousa</i> ssp., <i>Hylochoerus</i> ssp., <i>Phacochoerus</i> ssp., <i>Porcula</i> ssp. , <i>Potamochoerus</i> ssp., <i>Sus</i> ssp.,
	Tayassuidae	<i>Catagonus</i> ssp., <i>Pecari-Tayassu</i> ssp.
Tragulidae	<i>Hyemoschus</i> ssp., <i>Tragulus-Moschiola</i> ssp.	
Proboscidea	Elephantidae	<i>Elephas</i> ssp., <i>Loxodonta</i> ssp.

Criteria for the application of the disease prevention and control rules referred to in Article 8(1) to diseases listed in accordance with Article 5.

The scope of this Annex is to detail the criteria that the Commission shall consider 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 categorization shall take into account the profile of the disease, the level of impact of the 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 Article 8(1)(a)

The diseases to which the disease prevention and control rules referred to in Article 8(1)(a) apply shall be considered to have the most severe animal health, public health, economic, social or environmental impacts in the Union. Those diseases need to fulfill the following criteria:

1. the disease is:
 - (a) not present in the territory of the Union; or
 - (b) present only in exceptional cases (irregular introductions); or
 - (c) present in only in a very limited part of the territory of the Union; and
2. the disease 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 it may result in high morbidity and significant mortality rates.

In addition to the criteria set out in points 1 to 2, those diseases need to fulfill one or more of the following criteria:

3. the disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential or possible significant threats to food safety;
4. the disease 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;
5. the disease has a significant impact on one or more of the following:
 - (a) society, with in particular an impacts on labour markets;
 - (b) animal welfare, by causing suffering of large numbers of animals;
 - (c) the environment, due to the direct impact of the disease or due to its control measures;
 - (d) a long-term effect on biodiversity or protection of endangered species or breeds, including the possible disappearance 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 Article 8(1)(b)

The diseases for which the disease prevention and control rules referred to in Article 8(1)(b) 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:

1. the disease is present in the whole or part of the Union territory with an endemic character. However, several Member States or zones of the Union are free of the disease; and
2. 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 1 and 2, those diseases need to fulfill one or more of the following criteria.

3. The disease has a zoonotic potential with significant consequences on public health, including epidemic potential or possible significant threats to food safety.
4. The disease 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.
5. The disease has a significant impact on one or more of the following:
 - (a) society, with in particular an impact on labour markets;
 - (b) animal welfare, by causing suffering of large numbers of animals;
 - (c) the environment, due to the direct impact of the disease or due to its control measures;
 - (d) a long-term effect on biodiversity or protection of endangered species or breeds, including the possible disappearance or long term damage to those species or breeds.

A disease to which the measures referred to in Article 8(1)(a) 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 Article 8(1)(b), in that part of the Union.

Section 3

Criteria for the application of the disease prevention and control rules referred to in Article 8(1)(c)

The diseases for which the disease prevention and control rules referred to in Article 8(1)(c) 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 that listed diseases.

Those diseases need to fulfill the following criteria:

1. in terrestrial animals the disease is present in the whole or part of the Union territory with an endemic character or in aquatic animals, several Member States or zones of the Union are free of the disease; and
2. (a) in terrestrial animals, the disease is moderately to highly transmissible, mainly through direct and indirect transmission. The disease mainly affects multiple or single animal species and usually does not result in high morbidity and has negligible or no mortality. Often the most observed effect is production loss;
(b) 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 1 and 2, those diseases need to fulfill one or more of the following criteria:

3. The disease has a zoonotic potential with significant consequences on public health, or possible threats to food safety;
4. The disease 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.
5. The disease has a significant impact on one or more of the following:
 - (a) society, with in particular an impact on labour markets;
 - (b) animal welfare, by causing suffering of large numbers of animals;
 - (c) the environment, due to the direct impact of the disease or of (to) its control measures;
 - (d) A long-term effect on biodiversity or protection of endangered species or breeds, including the possible disappearance 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 Article 8(1)(d)

The disease prevention and control rules referred to in Article 8(1)(d) shall apply to diseases that fulfil the criteria of Section 1, 2 or 3 and to other diseases fulfilling criteria of Section 5 where the risk posed by the disease 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 Article 8(1)(e)

The disease prevention and control rules referred to in Article 8(1)(e) shall apply to diseases that fulfill the criteria of 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 III

Correlation table referred to in Article 257 (2)

1. Directive 64/432/EEC

Directive 64/432/EEC	This Regulation
Article 1	-
Article 2	Articles 4 (partially), 150(3) and 220(3)
Article 3(1)	Articles 121 and 123
Article 3(2)	Articles 121 (2), 123(1) and 146(3) and (4)
Article 4(1)	Article 121(1)
Article 4(2) and (3)	Article 122(1) and (2)
Article 5(1)	Article 140(1), 142 and 143,
Article 5(2)	Article 146(3) and (4),
Article 5(2)(a)	Article 144(a)
Article 5(2)(b)	Article 141(1)(b),
Article 5(3)	Article 146(3) and (4),
Article 5(4)	Article 150,
Article 5(5)	Articles 130, 132 and 150
Article 6	Articles 127, 128, 129
Article 6a	-
Article 7	Articles 129, 130, 131(a) and 132
Article 8	Articles 16, 17, 18 and Articles 16(3), 17(3), 18(3) and 19
Article 9	Articles 30(1), 31, 32 and Article 30 (3) and (4), 31(2)
Article 10	Articles 30(2), 31, 32, 36, 41, 42 and Articles 39, 40, 41(3) and 42(5) and (6)

Article 11(1)	Article 89(1)(a), 92, 93 and Article 92(2),
Article 11(2)	Articles 97, 100 and 101
Article 11(3)	Article 93, 94
Article 11(4)	Article 95
Article 11(5)-(6)	Article 92(1)(d) and (2)(d)
Article 12(1)	Article 122,
Article 12(2)	Article 99 and Article 100
Article 12(3)	Article 122(1)(a) and (b)
Article 12(4)	Article 140(3)
Article 12(5) and (6)	-
Article 13(1) and (2)	Articles 89, 92, 93, 94, 97, 100 and 101
Article 13(3)	Article 95
Article 13(4)	-
Article 13(5) and (6)	Article 96
Article 14(1) and (2)	-
Article 14(3)A and B	-
Article 14(3) C	Article 103
Article 14(4) to (6)	-
Article 15(1)	Article 256
Article 15(2) to (4)	-
Article 16	-
Article 17	-
Article 17a	-
Article 18	Article 103
Article 19	-

Article 20	-
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2. Directive 77/391/EEC

Directive 77/391/EEC	This Regulation
Article 1	-
Article 2(1)	Article 30(1)
Article 2(2)	Articles 31, 32
Article 2(3)	Article 33
Article 2(4)	Articles 36 and 41
Article 3(1)	Article 30(1)
Article 3(2)	Articles 31, 32
Article 3(3)	Article 33
Article 3(4)	Articles 36 and 41
Article 4	Articles 30(1), 31, 32, 33, 36 and 41
Article 5	-
Article 6	-
Article 7	-
Article 8	-
Article 9	-
Article 10	-
Article 11	-
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 30(1), 31, 34 and 35
Article 3(2)	-
Article 3(3)	-
Article 3(4)	Articles 30(1) and 31
Article 4	Articles 30(1), 31 and 35
Article 5	Articles 16, 17, 18, 46 and 47
Article 6(1)	Articles 73 to 75
Article 6(2)	Articles 76 and 77
Article 6(3)	Articles 78 and 79
Article 7	Articles 78 and 79
Article 8	Articles 78 and 79
Article 9	Articles 78 and 79
Article 10	Articles 78 and 79
Article 11	Articles 78 and 79
Article 12	Articles 78 and 79
Article 13	Articles 16, 17, 18, 46 and 47
Article 14(1)	Articles 73 to 75
Article 14(2)	Articles 76 and 77
Article 14(3)	Articles 78 and 79
Article 15	Articles 78 and 79
Article 16	Articles 78 and 79
Article 17	Articles 78 and 79

Article 18	Articles 78 and 79
Article 19	Articles 78 and 79
Article 20	Articles 78 and 79
Article 21	-
Article 22	Articles 16, 17, 18, 46 and 47
Article 23	Articles 73 to 79
Article 24	Articles 78 and 79
Article 25	Articles 78 and 79
Article 26	Articles 78 and 79
Article 27	Article 121(1), 123(1)(b)
Article 28	-
Article 29	-
Article 30	-

4. Directive 80/1095/EEC

Directive 80/1095/EEC	This Regulation
Article 1	Articles 30(1) and 36
Article 2	Article 4 (partially)
Article 3	Articles 30(1), 34 and 35
Article 3a	Articles 30(1), 34 and 35
Article 4	Articles 31, 32 and 35
Article 4a	Articles 31, 32 and 35
Article 5	-
Article 6	Article 30(1)(b), 30(3) and Article 31
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 17, 19, 20 and 21
Article 4	Articles 17,18, 19, 20 and 21
Article 5	Article 21(b) and (c)
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 157 and 158
Article 4	Article 158(b) and (c)
Article 5	Article 89, 92, 95 and 96

Article 6(1)	Articles 159 and 160
Article 6(2)	-
Article 6(3) and (4)	-
Article 8	Articles 230(1)(a) and 231
Article 9	Articles 230(1)(b), 234 and 235
Article 10	Articles 230(1)(c), 231, 236 and 238
Article 11	Article 230(1)(d) and Articles 239, 240
Article 12	Article 230(2)
Article 15	Articles 246 to 251
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 157, 158, 159
Article 5(1)	Articles 89 and 92
Article 5(2)	Article 96
Article 5(2a) and (3)	Article 92
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Article 7	Articles 230(1)(a) and 231

Article 8	Articles 230(1)(b), 234 and 235
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Article 11	Articles 230(2) and 249 to 251
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Article 16	-
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Article 18	-
Article 19	-
Article 20	-
Article 21	-

8. Directive 90/429/EEC

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Article 2	Article 4 (partially)
Article 3	Articles 157 and 158
Article 4	-
Article 5(1)	Articles 89 and 92
Article 5(2)	Article 96
Article 6(1)	Articles 159 and 160
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Article 7	Articles 230(1)(a) and 231
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Article 9	Articles 230(1)(c), 236 and 238

Article 10	Article 230(1)(d), 239, 240
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Article 11(2) and (3)	-
Article 12	Article 239
Article 13	-
Article 14	-
Article 15	Articles 246 to 251
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-
Article 22	-

9. Directive 91/68/EEC

Directive 91/68/EEC	This Regulation
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Article 2	Articles 4 (partially), 150(3) and 220(3)
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Article 5	Article 128
Article 6	Article 128
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Article 11	-
Article 12	Article 141(b)
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Article 15	-
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Article 18	-

10. Decision 91/666/EEC

Decision 91/666/EEC	This Regulation
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Article 2	Article 4 (partially)
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Article 4	Articles 48, 49 and 50
Article 5	Articles 48 and 50
Article 6	Articles 15 and 48(3)(b)

Article 7	Article 50
Article 8	-
Article 9	-
Article 10	-
Article 11	-
Article 12	-

11. Directive 92/35/EEC

Directive 92/35/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
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Article 4	Articles 53 to 57 and 59
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Article 6	Articles 60 to 69
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Article 8	Article 64
Article 9	Articles 65, 66 and 67
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Article 11	Article 68
Article 12	Article 71(1)
Article 13	Article 65(2)

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Article 15	-
Article 16	-
Article 17	Articles 43, 44 and 45
Article 18	-
Article 19	-
Article 20	-
Article 21	-
Article 22	-

12. Directive 92/65/EEC

Directive 92/65/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	-
Article 4	Articles 121, 123, 16, 17, 18, 30(2), 140 to 143, 146 and 148
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Article 18	Article 230(1)(d), 239
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Article 21	Article 141, 142, 143, 160, 209 and 211
Article 22	-
Article 23	-
Article 24	Articles 230(1)(d), 239 and 241(1)(a)(v) and (1)(c)(iv)
Article 25	-
Article 26	-
Article 27	-
Article 28	-
Article 29	-
Article 30	-

13. Directive 92/66/EEC

Directive 92/66/EEC	This Regulation
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Article 2	Article 4 (partially)
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Article 9(1)	Article 64
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Article 10	Articles 65 and 67
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Article 12	Article 54
Article 13	Article 65(2)
Article 14	-
Article 15	-
Article 16	Articles 46 and 47
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Article 19(5)	Article 71(2)
Article 20	-
Article 21	Articles 43 and 44
Article 22	-
Article 23	-
Article 24	-
Article 25	-
Article 26	-
Article 27	-

14. Directive 92/118/EEC

Directive 92/118/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Article 164, 223 and 228(c)(v)
Article 4(1)	Articles 164, 223 and 228(c)(v)
Article 4(2)	-
Article 5	Articles 164 and 223

Article 6	Article 15(1)(b) and (2)(b)
Article 7(1)	-
Article 7(2)	Articles 246 to 248
Article 7(3)	-
Article 7(4)	Article 256
Article 8	-
Article 9	Articles 230 and 236
Article 10	Articles 230, 236, 239 and 241
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Article 12	-
Article 13	Article 241(1)(c)(i)
Article 14	-
Article 15	-
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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)
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Article 5	Articles 60 to 63
Article 6	Article 70 and 71(2)
Article 7	Article 63
Article 8	Article 57
Article 9	Articles 62 and 63
Article 10	Article 64
Article 11	Articles 65 to 68 and 71(2)
Article 12	Articles 65 to 68
Article 13	Article 67(a)
Article 14	Article 65(2)
Article 15	-
Article 16	Articles 63(b), 67(b), 68(1)(b) and (2)(a)
Article 17	-
Article 18	-

Article 19	Articles 46, 47 and 69
Article 20	Articles 43, 44 and 45
Article 21	-
Article 22	-
Article 23	-
Article 24	-
Article 25	-
Article 26	-
Article 27	-
Article 28	-

16. Decision 95/410/EEC

Decision 95/410/EEC	This Regulation
Article 1	Articles 127 to 129
Article 2	Article 128(1)(c)
Article 3	Articles 140, 142 and 143
Article 4	-
Article 5	-
Article 6	-

17. Directive 2000/75/EC

Directive 2000/75/EC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4(1) and (2)	Articles 54 and 55
Article 4(3)	Article 53
Article 4(4)	Article 56
Article 4(5)	Article 70
Article 4(6)	Article 59
Article 5	Articles 46 and 47
Article 6	Articles 60 to 64
Article 7	Article 57
Article 8	Articles 64,68 and 71(3)
Article 9	Articles 65 and 67
Article 10(1)	Articles 64 and 67
Article 10(2)	Articles 46 and 47
Article 11	-
Article 12	Articles 65 and 67
Article 13	Article 71(1)

Article 14	Article 65(2)
Article 15	-
Article 16	-
Article 17	-
Article 18	Articles 43, 44 and 45
Article 19	-
Article 20	-
Article 21	-
Article 22	-
Article 23	-

18. Regulation (EC) No 1760/2000

Regulation (EC) No 1760/2000	This Regulation
Article 1	Article 102
Article 2	Article 4 (partially)
Article 3	Article 102(2) and 105
Article 4	Articles 106(a), 108, 114, 115 and 117
Article 5	Article 103(1)(a)
Article 6	Article 104, 106(b), 108, 114, 115 and 117
Article 7	Article 97, 100, 101 and 106(b)(i) and (c)
Article 8	Article 105
Article 9	-

Article 10(a) to (c)	Articles 114, 115, 117
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Article 12	-
Article 13	-
Article 14	-
Article 15	-
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-
Article 22	-
Article 23	-
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 16, 17, 18 and 21
Article 4	Articles 53 to 57(1) and 59
Article 5	Articles 60 to 63 and 71(2)
Article 6	Articles 63 and 71
Article 7	Articles 62, 63 and 65(1)(b)
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65 to 68
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Article 18	Articles 15, 46 and 47
Article 19	Articles 65(1)(e), 67 and 69

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Article 21	-
Article 22	Articles 43, 44 and 45
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Article 24	-
Article 25	-
Article 26	-
Article 27	-
Article 28	-
Article 29	-
Article 30	-
Article 31	-

20. Directive 2002/60/EC

Directive 2002/60/EC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Articles 16, 17, 18 and 21
Article 4	Articles 53 to 56, 57(1) and 59
Article 5	Articles 60 to 63 and 71(2)

Article 6	Articles 63 and 71
Article 7	Articles 62 and 63
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65, 67 and 68
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Article 12	Article 65(1)(f), 67(b) and 68(1)(b)
Article 13	Articles 61(3), 63(d) and 68
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Article 17	Articles 61(f) and 63
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Article 19	Articles 15, 46 and 47
Article 20	-
Article 21	Articles 43, 44 and 45
Article 22	Articles 43(2)(d) and 44
Article 23	-

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 164, 223 and 228(c)(v)
Article 4	Articles 65(1)(c),(d)(i),(g),(h),(i), 67, 164, 223 and 229(1)(d)
Article 5	Articles 165, 166, 224 and 225
Article 6	-
Article 7	Articles 236 and 238
Article 8	Article 231, 232 and 233
Article 9	Articles 239 and 240

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 16, 17, 18 and 21
Article 4	Articles 53 to 56 and 57(1)
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, 63
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Article 12	Article 65(1)(h),(i) and Article 67

Article 13	Article 57
Article 14	Articles 61 and 63
Article 15	Articles 61 and 63
Article 16	Articles 61, 62 and 63
Article 17	Article 71(2) and (3)
Article 18	Articles 61 and 63
Article 19	Articles 62 and 63
Article 20	Article 71(2) and (3)
Article 21	Articles 64
Article 22	Articles 65 to 67
Article 23	Articles 65 to 67
Article 24	Articles 67 and 71(1)
Article 25	Article 65(1)(c),(d)(i),(g), (h), (i) and Article 67
Article 26	Articles 65(1)(c),(d)(i),(g),(h),(i), 67 and 164
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Article 29	Article 65(1)(c),(d)(ii) and 67
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Article 35	Article 71
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Article 38	Articles 65 and 67
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Article 40	Articles 65(1)(c),(d)(i),(g), (h), (i), 67, 164
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Article 51	Articles 46, 47 and 69
Article 52	Articles 46 and 47

Article 53	Articles 46 and 47
Article 54	Articles 46, 47, 65, 67 and 69(3)
Article 55	Articles 46, 47, 65, 67, and 69(3)
Article 56	Articles 47, 68(1)(c) and 69(3)
Article 57	Articles 47, 68(1)(c) and 69(3)
Article 58	Article 65(1)(c) and 67
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 140(2), 159 and 165
Article 64	Articles 69(3) and 128
Article 65	Article 15
Article 66	-
Article 67	-
Article 68	-
Article 69	-
Article 70	Article 15
Article 71	Articles 54(2) and (3), 58, 61(1)(g), 63(c) and 65(1)(b), 67(c), 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	Article 43(2)(d) and 44
Article 77	Article 44
Article 78	Article 43(2)(d)
Article 79	Article 52
Article 80	Article 48
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Article 83	Article 49
Article 84	Articles 48(3) and 50
Article 85	Articles 70 and 71
Article 86	Article 256
Article 87	-
Article 88	Article 71(3)
Article 89	-
Article 90	-

Article 91	-
Article 92	-
Article 93	-
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Article 95	-

23. Regulation (EC) No. 998/2003

Regulation (EC) No. 998/2003	This Regulation
Article 1	-
Article 2	-
Article 3	Article 4 (partially)
Article 4	Articles 112, 114(e) and 117
Article 5	Articles 152, 222 and 228
Article 6	-
Article 7	Articles 152(2) and (3) and 222(2) and (3)
Article 8	Article 241(1)(a)(ii)
Article 9	Article 241(1)(a)(ii)
Article 10	Article 231
Article 11	-
Article 12	-
Article 13	-

Article 14 (1 st and 2 nd paragraph)	Article 239
Article 14 (3 rd paragraph)	-
Article 14 (4 th paragraph)	Articles 236(1)(b) and 241(1)(a)(ii)
Article 15	-
Article 16	-
Article 17	Articles 152(2) and (3), 222(2) and (3), 228, and 241(1)(a)(ii)
Article 18	Articles 246 to 251
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Article 20	-
Article 21	-
Article 22	-
Article 23	-
Article 24	-
Article 25	-

24. Regulation (EC) No 21/2004

Regulation (EC) No 21/2004	This Regulation
Article 1	Article 102
Article 2	Article 4 (partially)
Article 3(1)	Article 102(2)
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Article 4(1) and (2)	Articles 107(a), 114, 115 and 117
Article 4(3)	Articles 114(b) and 115(a)
Article 4(4) to (7)	Article 114
Article 4(8)	Article 105
Article 4(9)	Article 114(b)
Article 5	Articles 97, 100, 101, 105 and 106(b) and (c)
Article 6	Articles 105(b), 107(b), 108, 114(c)(ii), 115 and 117
Article 7	Article 96
Article 8(1)	Article 103,
Article 8(2)	Article 107(c),
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Article 9	Articles 114(b) and 117

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Article 10(1)(b)	Article 256
Article 10(1)(c)	Article 258
Article 10(2)	Article 117
Article 11	Article 105
Article 12(1)	-
Article 12(2)	Article 256
Article 12(4) to (7)	-
Article 13	-
Article 14	-
Article 15	-
Article 16	-
Article 17	-

25. Directive 2004/68/EC

Directive 2004/68/EC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3(1)	Article 230(1)(a)
Article 3(2)	Article 233(1)
Article 4	Article 231(1)
Article 5	Articles 231(1),(3) and 232

Article 6	Articles 236 and 237
Article 7	Article 236(1)(a) and 2 and Article 237
Article 8	Articles 236, 239(4) and 241(1)(a)
Article 9	Articles 236(1) and 239 (4)
Article 10	Article 236(1) and 239(4)
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Article 12	-
Article 13	-
Article 14	-
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-

26. Directive 2005/94/EC

Directive 2005/94/EC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
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Article 4	Articles 27 and 28

Article 5	Article 16, 17, 18 and 21
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Article 7	Articles 53 to 56 and 57(1)
Article 8	Article 55(2)
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Article 10	Articles 55(1)(e),(f) and 56
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Article 14	Article 63(a)
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Article 17	Articles 65 and 67
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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
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Article 30	Articles 65 and 67
Article 31	Article 68
Article 32	Articles 64, 65, 67 and 71(3)
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Article 35	Articles 54 and 61
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Article 38	Articles 61, 63, 65 and 67
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Article 55	Articles 46, 47, 65, 67 and 69
Article 56	Articles 46 and 47
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Article 60	-
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Article 63	-
Article 64	-

Article 65	-
Article 66	-
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27. Directive 2006/88/EC

Directive 2006/88/EC	This Regulation
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Article 2	Articles 2 and 3(2)
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Article 4(3)	Article 183(2)
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Article 4(5)	-
Article 5	Article 179
Article 6	Articles 183, 184
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Article 8	Articles 185, 186, 187 and 188
Article 9	Article 179(1)(a)(i), (2) and (3)
Article 10	Articles 179 (1)(a)(ii), (2) and (3)
Article 11	Articles 190 and 204
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Article 14(1) and (2)	Article 208
Article 14(3) and (4)	Articles 219 and 220
Article 15(1) and (2)	Articles 195, 196
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Article 21	Articles 202, 203 and 205
Article 22	Article 230(1)(a)
Article 23	Articles 231 and 232
Article 24	Articles 230(1)(d) and 239
Article 25	Articles 236, 239 and 240
Article 26	Article 16

Article 27	Articles 17 and 18
Article 28	Articles 53 to 55 and 72 to 74
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Article 32	Articles 60, 61, 62 and 64
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Article 34	Article 61(1)(b)and (c) and Article 63
Article 35	Article 61(3) and 63
Article 36	-
Article 37	Article 68
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Article 40	Article 80
Article 41	Article 246(1)(b) and (c)
Article 42	Article 71(3)
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Article 48	Article 46 and 47
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Article 53	Article 42
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Article 55	-
Article 56	-
Article 57(a)	-
Article 57(b)	Articles 54(2)(c) and (3), 58, 61(1)(h), 63(c), 67(1)(b) and 67(c)
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Article 58	-
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28. Directive 2008/71/EC

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29. Directive 2009/156/EC

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30. Directive 2009/158/EC

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