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PROPOSAL

from:	European Commission
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on Animal Health

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Animal Health

{SWD(2013) 160 final}
{SWD(2013) 161 final}

EXPLANATORY MEMORANDUM

1. JUSTIFICATION AND OBJECTIVE

Animal health is a concern for all European citizens. This concern stems from the public health, food safety and food security aspects, which are related to animal health but also from the economic costs that animal disease outbreaks can trigger and the animal welfare considerations, including the implications of disease control measures on animal welfare.

At the same time, this proposal reflects the priorities of Smart Regulation[1] by aiming to simplify the existing legal framework while reflecting stakeholders' expectations in reducing administrative burdens.

And finally, it reflects Commission priorities such as the smart growth objective of the Europe 2020 strategy[2] by helping the sector to become more resilient due to active prevention measures and more flexible risk management.

Problem analysis

The current EU animal health legislative framework involves almost 50 basic directives and regulations and some 400 pieces of secondary legislation, some of them adopted as early as 1964.

The Commission launched an external evaluation in 2004 to thoroughly review the outcomes of EU action of animal health, leading to a new Animal Health Strategy in 2007. A combination of circumstances made it imperative to re-evaluate our policy:

- The main elements of the existing policy were drawn up largely between 1988 and 1995 when we were still a Community of twelve Member States;
- New challenges have emerged. Diseases which were unknown a decade ago have appeared, while others, such as foot and mouth disease, bluetongue and avian flu, have recently presented new challenges, reminding us that they remain very serious risks;
- Trading conditions have also changed radically with the volume of trade in animals and animal products increasing greatly, both within the EU and with third countries; and
- Science, technology and our institutional framework have evolved substantially.

A number of problems have been identified in respect of the existing legislation. Some relate to the general policy approach, namely:

– The high complexity of the current Community Animal Health Policy (CAHP)

[1] COM(2010) 543 final "Smart Regulation in the European Union".
[2] COM(2010) 2020 "Europe 2020 - A strategy for smart, sustainable and inclusive growth".

– The lack of an overall strategy

– An insufficient focus on disease prevention, with a particular focus on the need for increased biosecurity.

Others were related to specific problems with the functioning of existing legislation, particularly:

– Issues related to intra-Union trade in live animals.

Both general and specific problems are either rectified in this law, or will be rectified in its delegated and implementing acts.

Objectives of the proposal

The Animal Health Law is the legal framework to support the Animal Health Strategy for the EU, published in 2007. The general objectives as outlined in the Strategy are:

- to ensure a high level of public health and food safety by minimising the incidence of biological and chemical risks to humans;

- to promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy;

- to improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements;

- to promote farming practices and animal welfare which prevent animal health related threats and minimise environmental impacts in support of the EU Sustainable Development Strategy.

The specific objectives of this Animal Health Law are:

- to establish a single, simplified, transparent and clear regulatory framework that sets out systematically the objectives, scope and principles of regulatory intervention; based on good governance and compliant with international (e.g. OIE) standards; focusing on long-term preventative measures and working together with all relevant stakeholders;

- to introduce overarching general principles allowing a simplified legal framework in order to be prepared for the new challenges, i.e. to enable quick reaction in case of emerging diseases; whilst ensuring the same quality of reaction as provided for in current legislation;

- to ensure consistency amongst the horizontal principles of the legislation in the field of animal health, animal welfare and food safety policies as well as broader EU policies on climate change, common agricultural policy and sustainability;

- to reduce the impact of animal diseases on animal and public health, animal welfare, economy and society as far as possible by enhancing disease

awareness, preparedness, surveillance and emergency response systems at national and EU level;

- to ensure the smooth functioning of the internal market of animals and animal products, with a high level of protection of animal health and public health and supporting the objectives of Europe 2020.

The operational objectives of this Animal Health Law are:

- to integrate the new prevention-driven and incentive-oriented approach into the core of animal health policy;

- to provide for a clear and balanced distribution of roles and responsibilities between competent authorities, EU institutions, the farming sector, animal owners and others;

- to introduce disease categorization as the basis for EU intervention;

- to provide for effective mechanisms for a rapid response to disease events, including new challenges, such as emerging diseases;

- to ensure effective emergency preparedness and early response to animal diseases and zoonoses, including use of vaccines as appropriate;

- to introduce simplified procedures, wherever possible for technical and other reasons, taking into account the specificity of small farmers and micro businesses and releasing unjustified administrative burdens and costs, wherever possible;

- to ensure that the new legal framework provides enough flexibility to adapt smoothly to future scientific and technological developments;

- to reduce the risk of trade disruption by seeking an appropriate level of convergence with relevant international standards, while ensuring a firm commitment to high standards of animal health.

2. LEGAL CONTEXT

Legal Basis

Articles 43, 114 and 168 of the Treaty on the Functioning of the European Union (TFEU) provide the legal basis for the EU legislative measures on animal health, as they are an essential part of EU agricultural, public health and consumer protection, trade and single market policy.

– Article 43 provides the basis for the EU legislative measures on the Common Agricultural Policy. This article also became the basis for veterinary legislation as the CAHP is considered from a legal perspective to be part of the Common Agricultural Policy, so adopting the same legislative and administrative procedures.

– Article 114 provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions in this respect.

– Article 168 on health protection refers to the protection of human health from all causes that may damage it, including those related to animal health. Veterinary measures directly aimed at protecting public health were also adopted under the co-decision procedure as a result of this article.".

Consistency with other Union policies

This set of animal health legislation interacts with the legal framework on animal welfare, food safety, public health, animal nutrition, veterinary medicinal products, environmental protection, official controls, the Common Fisheries Policy (CFP) and the Common Agricultural Policy (CAP).

Relationship to other proposals in the package

The proposal is part of a package of four reviews relating to animal health, health of plants, quality of plant reproductive material and official controls of plants, animals, food and feed.

The revision of the official controls regulation enables official controls to be more consistently applied for the purposes of protection of animal health and links more coherently with animal health regulation.

3. SUBSIDIARITY AND PROPORTIONALITY

Subsidiarity

Good animal health generates not only private benefits but is a public good with wider societal benefits. The transmissible nature of many animal diseases means that a common approach, rather than a series of individual actions, will have the greatest overall benefits.

The value of the harmonised EU approach is widely accepted and has helped to reduce the administrative burden for operators, traders, veterinarians and veterinary-related industries. It has played a key role in the establishment of the single market, facilitating intra-EU trade in animals and animal products (meat, milk, etc.) by setting up harmonised animal health conditions and promoting the success of the CAP.

The benefits of harmonised rules for the prevention, notification, control and eradication of animal diseases at EU level have been demonstrated during animal disease outbreaks in recent times. The response to these crises showed the EU's capability to react quickly, limiting the spread of diseases and minimising their impacts. This was largely due to the harmonised approach to disease control, including providing financial compensation for the losses on farms due to disease eradication measures. Also, taking into account the single market dimension, the failure to control a disease in one Member State, may severely affect the health status of the Union and jeopardise its export potential. In light of these different elements, EU action is justified, as it is clear that MS cannot achieve this satisfactorily acting

alone and that the EU would achieve a consistent approach more effectively and efficiently.

Proportionality

The Animal Health Law establishes a general framework for the prevention, control and eradication of animal diseases. This framework is built on outcome-based rules, avoiding over-prescriptiveness, and leaving room for MS to regulate or set more detailed legislation when necessary, so providing for the flexibility to adapt the rules to national, regional or local circumstances. On the other hand, rules on trade must necessarily have a certain level of detail and precision to reduce the risk of different implementation practices by operators and competent authorities and subsequent distortion of competition and possible reduction in the coherence of the approach to tackling disease. Therefore the Animal Health Law tries to achieve the balance of proportional but necessary action.

4. CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultation process

This Animal Health Law is the result of a long series of considered analyses.

In 2004, the Commission launched an independent evaluation to assess the performance of the Community Animal Health Policy (CAHP)[3] over the previous decade and its coherence with other EU policy interventions. The aim was to identify elements of the CAHP which could be further improved and to propose options to achieve these improvements.

Among other things, the CAHP evaluation recommended that a single strategy for animal health be developed to prevent piecemeal and crisis-driven development of policy. The EU Animal Health Strategy 2007-2013 (AHS) "Prevention is better than cure" was the result[4].

The AHS provides for the adoption of a "single regulatory framework for animal health with a greater focus on incentives than penalties, consistent with other EU policies and converging to international standards" and which will "define and integrate common principles and requirements of existing legislation". In their reaction to the Commission Communication on the new Strategy, the European Parliament[5], the Council[6] and the European Economic and Social Committee[7] welcomed this initiative. Subsequently, the Action Plan for the implementation of the Strategy[8] confirmed that "the main objective of the Strategy is the development of an EU Animal Health Law".

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3 http://ec.europa.eu/food/animal/diseases/strategy/cahpeval_en.htm
4 http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm
5 EP Resolution 2007/2260(INI).
6 Doc.15481/07 ADD 1.
7 NAT/376 – EU Animal Health Strategy.
8 COM (2008) 545 final, http://ec.europa.eu/food/animal/diseases/strategy/documents_en.htm

From the very start of the process, key stakeholders, Member States (MS), Competent Authorities (CA), international organisations and trading partners have been closely involved and have played a crucial role in the discussion. In addition, economic and social stakeholders such as European associations with an interest in animal health and welfare and the interested public have been consulted on a number of occasions in accordance with the Commission's standards for consultation.

5. ELEMENTS OF THE PROPOSAL

Part I: General Rules

The Animal Health Law sets out general principles for good animal health in EU legislation. It brings together animal health measures for terrestrial and aquatic animals.

Part I also provides for the prioritisation and listing of diseases which are likely to have a significant impact. For the first time, this will enable Union resources to be systematically prioritised on a scientific and evidential basis.

The responsibilities of all the different actors having a key role in the safeguarding of animal health, such as operators, veterinarians, and pet keepers, are explicitly laid down for the first time. In particular, operators and animal professionals are now required to acquire a basic knowledge of animal health and related matters.

Part II: Notification, Surveillance, Eradication Programmes, Disease Freedom

Part II clarifies the responsibilities for notification and surveillance including animal health visits. It clarifies the roles of operators, competent authorities and others as regards surveillance of the animal health situation in the Union. The new system allows for better use of the synergies between surveillance undertaken by the different actors in the field to ensure the most effective and cost efficient use of surveillance resources.

Another main change here is that compartments, permitted only for Avian Influenza related measures and in aquaculture at present, can now be used more widely. This introduces more flexibility into disease control measures, introducing the possibility of continuing movements and trade under certain circumstances, considered from a risk-based perspective.

Part III: Disease Preparedness, Awareness and Control

Part III continues to require MSs to draw up contingency plans for dealing with certain diseases, and to practise their implementation.

The regulatory framework for vaccination is now explicitly and coherently provided for.

The rules for the use of antigen, vaccine and reagent banks are laid down.

Rules on control measures to be taken in the case of suspicion of or confirmed disease outbreaks of certain diseases are laid down, with little change to the existing system, which is considered to work well.

Part IV: Requirements Concerning Registration, Approval, Traceability and Movements

Part IV is split into three titles, with distinct rules for terrestrial, aquatic, and other animals. It is necessary to consider them separately because of their different production methods and epidemiology. The titles dealing with aquatic and terrestrial animals lay down measures which help to identify and trace animals and establishments. The traceability of animals is of crucial importance during a disease outbreak so that the epidemiology of the disease is understood and can be better controlled. These titles also introduce the possibility for more animals to be registered and traced through electronic means, promoting simplicity and better regulation, and reducing administrative burden through the use of technology. A third title on other animals is introduced only for possible future provision, should new threats emerge in relation to these animals.

Part V: Entry into the Union and Export

Part V sets the standards and requirements for third countries sending animals, germinal products, products of animal origin and other material that may transmit animal diseases into the Union, in order to prevent diseases being introduced. It also sets out requirements for export. No practical changes are envisaged from existing legislation, which is considered to function well.

Part VI: Emergency Measures

Emergency measures are a crucial part of disease management. Part VI lays down the procedures to be followed in case of emergency, ensuring a rapid and consistent Union response. Only a few practical changes are envisaged from existing legislation, which is considered to function very well.

Part VII: Final and Transitional Provisions

The final and transitional provisions set out the national provisions, the conditions for adopting delegated acts, repeals, and other necessary legal provisions.

6. BUDGETARY IMPLICATIONS

This proposal does not imply expenditures which are not already included in the financial statement of the common financial framework for food chain, animal health and welfare, and relating to plant health and plant reproductive material.

2013/0136 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Animal Health

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(3) and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[9],

Having regard to the opinion of the Committee of the Regions[10],

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, as for example in the case of avian influenza and salmonella.

(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.

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9 OJ C , , p. .

10 OJ C , , p. .

(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.

(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 Regions[11]. It aims to put 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.

(10) Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994)[12] approved on behalf of the then European Community, with regard to that portion of those matters which falls within its competence the Agreement establishing the World Trade Organization (WTO), and also the Agreements set out in Annexes 1, 2 and 3 to that Agreement which include the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement 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.

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11 COM (2007) 539 final.

12 OJ L 336, 23.12.1994, p. 1.

(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 principle[13] 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 safety[14].

(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)[15] 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 encephalopathies[16], Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC[17] and Regulation (EC) No 2160/2003 of the European Parliament and of

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13 COM(2000) 1 final.
14 OJ L 31, 1.2.2002, p. 1.
15 OJ L 300, 14.11.2009, p. 1.
16 OJ L 147, 31.5.2001, p. 1.
17 *OJ L 325, 12.12.2003, p. 31.*

the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[18], and specific rules on communicable diseases in humans in Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community[19]. 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.

(16) 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.

(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 animals[20] lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance 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.

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18 OJ L 325, 12.12.2003, p. 1.
19 OJ L 268, 3.10.1998, p. 1.
20 OJ L 328, 24.11.2006, p 14.

(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/EEC[21] 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.

(21) The keeping of pet animals, including ornamental aquatic animals in households and non-commercial ornamental aquaria, 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. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union apply to such 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 be laid down for 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, scientific development or technical updates justified by science. Similarly, the list of species of pet animals may need to be adjusted due to developments in society, or changed habits of keeping pet animals, in particular where these animals transmit diseases. 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 pet animals and ungulates set out in Annexes I and 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

[21] OJ L 268, 14.9.1992, p. 54.

and its consequences. 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) Action No. 5 of the Communication from the Commission to the European Parliament and the Council – Action plan against the rising threats from Antimicrobial Resistance[22] emphasises the preventive role of this Regulation and the consequent expected reduction of the use of antibiotics in animals. Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. This resistance complicates the treatment of infectious diseases in humans and animals. 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.

(30) New hazards associated with certain diseases or species may develop in particular due to changes in 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, developed a system of disease prioritisation and categorisation, by producing a study on the "Listing and categorisation of priority animal diseases, including those transmissible to humans"[23] and a tool for such an exercise. This Regulation should introduce such an approach in Union legislation.

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22 COM (2011) 748.

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

(31) In order to ensure uniform conditions for the implementation of this Regulation in relation to transmissible animal diseases at Union level, it is necessary to establish a harmonised list of transmissible animal diseases ('listed diseases'). Thus implementing powers to lay down such a list should be conferred on the Commission.

(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. Following the assessment of such diseases and after adopting temporary emergency measures, when relevant, a quick reaction and insertion of such diseases in the list of listed diseases may be necessary. Therefore the power to adopt acts in accordance with the urgency procedure should be delegated to the Commission in these duly justified cases of risks to public or animal health.

(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. For other diseases that might already be present in parts of the Union, compulsory or voluntary eradication is required. In both 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. This would be the case, in particular, in the event of an emerging disease for which there is limited information.

(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 and to determine the applicability of disease prevention and control rules of the Regulation to the different listed diseases to ensure coherence and consistency. In order to ensure that technical and scientific progress and developments of relevant international standards are taken into account, 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 with respect to the possible amendments of those criteria.

(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.

(36) Based on the importance and the level of impact of a listed disease, its distribution, prevalence and incidence in the Union and the availability of disease prevention and control measures in respect of that listed disease, a different category of specific disease prevention and control rules provided for in this Regulation should apply coherently and consistently to each listed disease.

(37) In order to ensure uniform conditions for the implementation of this Regulation in relation to the disease prevention and control measures applicable to listed diseases, it is necessary to determine the application of the rules, provided for in this Regulation,

to listed diseases at Union level. Thus implementing powers to lay down which listed diseases are to be subject to which rules, should be conferred on the Commission.

(38) Operators, animal professionals and pet keepers 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. In order to ensure that the biosecurity measures applied by operators, animal professionals and pet keepers are sufficiently flexible, that they are adjusted to suit the type of production and the species or categories of animals involved and that they take account of the local circumstances and technical developments, 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 with respect to supplementary and more detailed biosecurity requirements.

(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 other 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. Those alternative means of acquiring such knowledge should also be recognised by this Regulation.

(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.

(44) In order to ensure that the veterinarians and aquatic animal health professionals who undertake activities that fall within the scope of this Regulation are adequately qualified and receive appropriate training, 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 their qualification and training.

(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 those activities to veterinarians. 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 those activities to veterinarians and their appropriate training.

(47) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, 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 and transparent manner. Therefore the competent authority should 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.

(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 any

suspicion or confirmation of an outbreak of certain listed diseases should be immediately notified to the competent authority. Those notification obligations should be applicable to any natural and legal person in order to ensure that no disease outbreaks remain unnoticed.

(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. In order to ensure uniform conditions for the implementation of such Union notification, implementing powers shall be conferred on the Commission.

(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 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 WAHIS/WAHID database of the OIE). Consistency with the exchange of information in accordance with Directive 2003/99/EC[24] should also be ensured.

(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

[24] *OJ L 325, 12.12.2003, p. 31.*

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 a proportionate level of surveillance to the risks involved in different types of establishments, 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 criteria and the content of such animal health visits in different types of establishments.

(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 region concerned and any additional surveillance conducted by operators.

(61) In some cases, and depending on the epidemiological profile of a disease and relevant risk factors, a structured surveillance programme may need to be put in place. In that case it is appropriate that Member States develop epidemiologically based surveillance programmes. 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 for official confirmation of outbreaks and the case definitions of those diseases and requirements for surveillance programmes in relation to their contents, information to be included and the period of application.

(62) To promote coordination between the Member States and ensure that those surveillance programmes are consistent with Union objectives, they should be

submitted to the Commission and other Member States for information. Furthermore, the Member State implementing the surveillance programme should also submit regular reports on the results of that surveillance programme 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 and information exchange.

(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, or have the possibility to establish voluntary eradication programmes, to eradicate those diseases where the eradication is envisaged in the Union, but is not compulsory. To ensure uniform conditions of general application throughout the Union, it is necessary to lay down harmonised requirements for such compulsory or voluntary eradication programmes. In order to ensure effective disease eradication, 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 objectives of disease control strategies, disease control measures under the compulsory or voluntary eradication programmes and requirements of such programmes.

(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 voluntary 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 for obtaining such status, the evidence needed to substantiate freedom from disease, special disease prevention and control measures, 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 the emergency situations, 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 requirements and conditions for 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.

(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, hyper immune sera or antimicrobial agents 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 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 diseases[25] 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.

(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.

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[25] Doc SANCO/7070/2010.

(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, it is necessary to take immediate disease control measures to eradicate that listed disease in order to protect animal and public health and the relevant sectors.

(83) Operators, animal professionals and pet keepers should have the primary responsibility for controlling and preventing the spread of transmissible animal diseases. They should take immediate action in case of suspicion or confirmation of highly contagious diseases.

(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.

(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 a voluntary eradication programme in place, should also implement such disease control measures. 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.

(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 small and medium size enterprises (SMEs), flexibility should be given to the Member States to adapt the system of registration and approval to local and regional conditions and production patterns.

(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 public availability of up-to-date information concerning the registered establishments and transporters and approved establishments the competent authority should establish and keep a register of such establishments and transporters. 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 information to be contained in the register of establishments and transporters and the record keeping requirements, as regards the information to be recorded, derogations from the record keeping requirements and the specific additional requirements for germinal products.

(97) In order to ensure uniform conditions for the implementation of the requirements laid down in this regulation on the registration and approval of establishments and on the record keeping and registers, implementing powers should be conferred to the Commission to lay down rules concerning the information obligations, exemptions and other rules, the formats and operational specifications of the registers and records.

(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.

(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 the obligations concerning databases, designation of the

competent authority, detailed identification and registration requirements for different animal species 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, the deadlines, and criteria for derogations from such systems.

(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 purposes[26] 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.

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[26] OJ L 276, 20.10.2010, p. 33.

(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.

(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 swine[27], Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[28], Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae[29], Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs[30] 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/EEC[31]. 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 lay down specific rules in this Regulation to protect the health of the animals involved and prevent the spread of transmissible animal diseases.

(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

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27 OJ 121, 29.7.1964, p. 1977.
28 OJ L 46, 19.2.1991, p. 19.
29 OJ L 192, 23.7.2010, p. 1.
30 OJ L 343, 22.12.2009, p. 74.
31 OJ L 268, 14.9.1992, p. 54.

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. The IMSOC system provided for in Article 130(1) of the Regulation (EU) No xxx/xxx of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [….]/2013, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)[32] [*Publication office*] should be used for that purpose.

(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. In order to ensure that pet 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 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

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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, and the format and operational specifications of the registers and records.

(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.

(133) The same system should also be provided for in this Regulation. However, to encourage Member States to enhance the health status of their aquatic populations, some adjustments and added flexibility should be introduced.

(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) The requirements for entry of animals and products into the Union should mirror the requirements for movements of animal and products of the same category, species and intended use 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 food and feed safety legislation.

(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, to supplement and amend the criteria for the listing of third countries and territories, criteria for the suspension or withdrawal from that list, 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, contents of animal health certificates, 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 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 listing of diseases and species, the listed diseases that are to be subject to the sets of disease prevention and control rules, 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 services[33], has been an important tool for guiding and improving the quality of national technical regulations – in terms of increased transparency, readibility 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:

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[33] OJ L 204, 21.7.1998, p. 37.

– Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine[34],

– Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle[35],

– Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle[36],

– Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species[37],

– Council Directive 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever[38],

– Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community[39],

– Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species[40],

– Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra- Community trade in and imports of semen of domestic animals of the porcine species[41],

– Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[42],

– Council Decision 91/666/ EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines[43],

– Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness[44],

– 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

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34 OJ 121, 29.7.1964, p. 1977.
35 OJ L 145, 13.6.1977, p. 44.
36 OJ L 15, 19.1.1978, p. 34.
37 OJ L 194, 22.7.1988, p. 10.
38 OJ L 325, 1.12.1980, p. 1.
39 OJ L 378, 31.12.1982, p. 58.
40 OJ L 302, 19.10.1989, p. 1.
41 OJ L 224, 18.8.1990, p. 62.
42 OJ L 46, 19.2.1991, p. 19.
43 OJ L 368, 31.12.1991, p. 21.
44 OJ L 157, 10.6.1992, p. 19.

in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC[45],

– Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease[46],

– Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC[47],

– Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease[48],

– Council Decision 95/410/EC of 22 June 1995 laying down the rules for testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden[49],

– Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue[50],

– Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines[51],

– Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97[52],

– Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever[53],

– Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever[54],

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45 OJ L 268, 14.9.1992, p. 54.
46 OJ L 260, 5.9.1992, p. 1.
47 OJ L 62, 15.3.1993, p. 49.
48 OJ L 62, 15.3.1993, p. 69.
49 OJ L 243, 11.10.1995, p. 25.
50 OJ L 327, 22.12.2000, p. 74.
51 OJ L 79, 30.3.2000, p. 40.
52 OJ L 204, 11.8.2000, p. 1.
53 OJ L 316, 1.12.2001, p. 5.
54 OJ L 192, 20.7.2002, p. 27.

– Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption[55],

– Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC[56],

– Regulation (EU) No XXX/XXXX of the European Parliament and of the Council of …. on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 *[Publication office]* [57],

– 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/EEC[58],

– Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC[59],

– Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae[60],

– Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC[61],

– Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals[62],

– Council Directive 2008/71/EEC of 15 July 2008 on the identification and registration of pigs (codifying Directive 92/102/EEC)[63],

– Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs[64].

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55 OJ L 18, 23.1.2003, p. 11.
56 OJ L 306, 22.11.2003, p. 1.
57 OJ L …
58 OJ L 5, 9.1.2004, p. 8.
59 OJ L 139, 30.4.2004, p. 321.
60 OJ L 192, 23.7.2010, p. 1.
61 OJ L 10, 14.1.2006, p. 16.
62 OJ L 328, 24.11.2006, p. 14.
63 OJ L 213, 8.8.2008, p. 31.
64 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 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.

(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 Botswana[65]; Council Directive 79/110/EEC of 24 January 1979 authorizing the Italian Republic to postpone the notification and implementation of its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle[66]; Council Directive 81/6/EEC of 1 January 1981 authorizing the Hellenic Republic to communicate and to implement its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle[67]; Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention[68]; Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease[69]; Council Decision 90/678/EEC of 13 December 1990 recognizing certain parts of the territory of the Community as being either officially swine fever free or swine fever free[70].

(157) The requirements of this Regulation should not apply until all the delegated and implementing acts to be adopted by the Commission pursuant to this Regulation, have applied. It is appropriate to provide for at least 36 months to elapse between the date of entry into force of this Regulation and the date of application of the new rules, to allow the operators affected sufficient time to adapt.

(158) In order to ensure legal certainty as regards the application of rules for identification and registration of animals, disease control measures for certain zoonoses and non-commercial movements of pet 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 in respect of the date on which Regulations (EC) No 1760/2000, (EU) No XXX/XXX *[Ex-998/2003]* and (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.

(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

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65 OJ L 213, 3.8.1978, p. 15.
66 OJ L 29, 3.2.1979, p. 24.
67 OJ L 14, 16.1.1981, p. 22.
68 OJ L 223, 2.8.1989, p. 19.
69 OJ L 224, 18.8.1990, p. 13.
70 OJ L 373, 31.12.1990, 29.

mechanisms for control by the Member States of the Commission's exercise of implementing powers[71].

(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.

(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, scope and definitions

Article 1
Subject matter

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:

[71] OJ L 55, 28.2.2011, p. 13.

(a) the prioritisation and categorisation of diseases of Union concern and for establishing responsibilities for animal health in Part I;

(b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status in Part II;

(c) disease awareness, preparedness and control in Part III;

(d) the registration and approval of establishments and transporters, movements and traceability of consignments of animals, germinal products and products of animal origin within the Union in Part IV;

(e) the entry of consignments of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union in Part V;

(f) the emergency measures to be taken in the event of a disease emergency situation in Part VI.

2. The rules referred to in paragraph 1:

(a) ensure

(i) 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 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 as well as the impacts of climate change;

– food and feed safety;

– animal welfare;

– food security;

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

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 2119/98/EC;

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

   (c) Directive 2003/99/EC;

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

Article 3
Scope of Part IV on registration, approval, traceability and movements

1. Title I of Part IV 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 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 shall apply to:

   (a) animals other than those defined as terrestrial animals and aquatic animals in Article 4(1)(4);

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

4. Chapters 1 and 3 of Title I and Chapters 1 and 2 of Title II of Part IV shall not apply to pet animals.

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 rearing of aquatic animals using techniques designed to increase the production of those animals beyond the natural capacity of the environment and 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 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 point (a);

(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 an animal of the species listed in Annex I, which:

(a) is kept in a household, or in the case of aquatic animals, kept in non-commercial ornamental aquaria;

(b) when moved, accompanies for the purpose of a non-commercial movement the pet keeper, or a natural person acting on behalf of and in agreement with the pet keeper, and which remains during such non-commercial movement under the responsibility of the pet keeper or such person;

(12) 'pet keeper' means a natural person keeping a pet animal;

(13) 'non-commercial movement' means any movement of pet animals which does not involve or aim, directly or indirectly, at a financial gain or a transfer of ownership;

(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 transmissible to animals or to humans;

(15) 'listed diseases' mean diseases listed in accordance with Article 5(2);

(16) 'emerging disease' means a disease other than a listed disease which has the potential to meet the criteria for listed diseases provided for in Article 6(1)(a) due to:

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

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

(c) a previously unrecognised disease agent or a disease diagnosed for the first time;

(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 a natural or legal person, having animals and products under their responsibility, including animal keepers and transporters, but excluding pet keepers and veterinarians;

(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 any environment, in which animals or germinal products are kept, except for:

(a) households keeping pet animals;

(b) non-commercial aquaria keeping aquatic animals;

(c) veterinary practices or clinics;

(25) 'germinal products' means:

(a) sperm, 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 an official control as defined in point (1) of Article 2 of Regulation (EU) XXX/XXX *[Publication office – Number to be added: on official controls and other official activities.]*;

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

(a) an animal;

(b) the animals within:

(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 a clearly defined part of a Member State, third country or territory 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 under the control of the competent authority with no direct or indirect contact with other animals, for the purposes of ensuring that there is no spread of diseases while the animals 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 one or more cases in an establishment, household or other place where animals are kept or located;

(38) 'case' means the official confirmation of the presence of a listed disease or an emerging disease in a live or dead animal;

(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 with one or more disease cases which is established after the official confirmation 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, established after the official confirmation of an outbreak and which is situated around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from that zone and the protection zone;

(42) 'hatching eggs' means eggs, laid by poultry, intended for incubation;

(43) 'ungulates' means the animals listed in Annex II;

(44) 'germinal product establishment' means:

(a) an establishment for the collection, production, processing and storage of germinal products;

(b) a hatchery;

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

(a) eggs for incubation;

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

(46) 'transporter' means an operator transporting animals on its own account, or for a third party;

(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 strict 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 an animal is required to stay at an establishment prior to being moved from that establishment;

(50) 'IMSOC' means the computerised information management system provided for by Article 130(1) of Regulation (EU) No. XXX/XXX *[Publication office: Number to be added -on official controls and other official activities]*;

(51) 'disease control aquatic food establishment' means a food business approved in accordance with the following provisions:

(a) Article 4 of Regulation (EC) No 853/2004, for processing aquaculture animals for food purposes;

(b) Article 177 of this Regulation for the slaughter of aquatic animals for disease control purposes in accordance with Title II of Part III.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to the list of:

(a) pet animals set out in Annex I;

(b) ungulates set out in Annex II.

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) listed diseases;

   (b) emerging diseases.

2. The Commission shall, by means of implementing acts, establish a list of listed diseases, as referred to in paragraph 1(a).

   That list shall comprise diseases which meet with the conditions laid down in the following points (a) and (b) of this paragraph, taking into account the criteria for listing diseases laid down in Article 6:

   (a) diseases which are likely to have a significant impact on at least one of the following:

      (i) public health;

      (ii) agricultural or aquaculture production or related sectors of the economy;

      (iii) the society in Member States and where appropriate in third countries or territories;

      (iv) the environment;

   (b) diseases for which risk mitigating measures are available, or can be developed and are proportionate to the risks posed by such diseases.

   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 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).

Article 6
Criteria for listing diseases

1. The Commission shall take account of the following criteria in determining 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 capacity to develop resistance to treatments;

(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 environmental pollution;

(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) culling and disposal of animals;

(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.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to the criteria provided for in paragraph 1 of this Article to take account of technical and scientific progress and the developments of relevant international standards.

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 list shall comprise those animal species or groups of animal species, which pose a considerable risk for the spread of specific listed diseases, taking into account 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.

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 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).

Article 8
Application of disease prevention and control rules to listed diseases

1. The Commission shall, by means of implementing acts, determine the application of the disease prevention and control rules referred to in the following points to listed diseases:

(a) listed diseases subject to rules on:

(i) disease awareness and preparedness provided for in Title I of Part III and disease control measures provided for in Chapter 1 of Title II of Part III;

(ii) compartmentalisation provided for in Article 37(1);

(b) listed diseases subject to the disease prevention and control rules on:

(i) compulsory eradication programmes provided for in Article 30(1);

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

(iii) compartmentalisation provided for in Article 37(2);

(iv) disease control measures provided for in Chapter 2 of Title II of Part III;

(c) listed diseases subject to the disease prevention and control rules on:

(i) voluntary eradication provided for in Article 30(2);

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

(iii) compartmentalisation provided for in Article 37(2);

(iv) disease control measures provided for in Chapter 2 of Title II of Part III;

(d) listed diseases subject to the disease prevention and control rules on:

(i) movement within the Union provided for in Chapters 3 to 7 of Title I and Chapters 2, 3 and 4 of Title II of Part IV;

(ii) entry into the Union and export from the Union provided for in Part V;

(e) listed diseases subject to the disease prevention and control rules on:

(i) notification and reporting provided for in Chapter 1 of Part II;

(ii) surveillance provided for in Chapter 2 of Part II.

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 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).

2. The Commission shall take into account the following criteria when adopting implementing acts provided for in paragraph 1:

(a) the level of impact of the disease on animal and public health, animal welfare and the economy;

(b) the prevalence, incidence and distribution of the disease in the Union;

(c) the availability, feasibility and effectiveness of the different sets of disease prevention and control measures provided for in this Regulation with respect to the disease.

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, animal professionals and pet keepers shall:

(a) be responsible for the health of kept animals and products under their responsibility;

(b) take appropriate biosecurity measures, taking into account the risks involved, to ensure the health of those kept animals and products and to prevent the introduction into, development and multiplication within and spread between and from such kept animals and products under their responsibility of diseases, except where that is specifically authorised for scientific purposes, as appropriate for:

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

(ii) the type of production.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning biosecurity measures supplementing the rules laid down in paragraph 1(b) of this Article.

Article 10
Basic knowledge of animal health

1. Operators and animal professionals shall acquire 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.

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;

   (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.

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) ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease before symptomatic treatment is commenced;

   (c) play an active role in:

      (i) raising animal health awareness;

(ii) disease prevention;

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

(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 under national legislation. In that event, paragraph 1 shall apply to those aquatic animal health professionals.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the qualifications of veterinarians and aquatic animal health professionals undertaking 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 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 which fall within the scope of this Regulation.

2. Member States shall support operators and animal professionals in acquiring, maintaining and developing the basic 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 other official activities

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

   (a) activities concerning notification and reporting as provided for in Chapter 1 of Part II and surveillance as provided for in Chapter 2 of that Part;

   (b) activities related to:

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

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

      (iii) emergency measures as provided for in Part VI.

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

   (a) the circumstances and conditions for delegating the activities provided for in paragraph 1;

   (b) which other activities may be delegated to veterinarians in addition to those provided for in paragraph 1 of this Article, and under which circumstances and under which conditions;

   (c) minimum requirements for the training of veterinarians provided for in Article 12(1)(c).

   The Commission shall take account of the nature of those tasks and the international obligations of the Union and the Member States, when adopting those delegated acts.

Article 14
Public information

Where there are reasonable grounds to suspect that animals or products 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 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.

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. Natural and legal persons shall immediately notify:

   (a) the competent authority in the event of an outbreak or suspicion of an outbreak of a listed disease referred to in Article 8(1)(e);

   (b) a veterinarian of abnormal mortalities and other serious disease signs or significant decreased production rates with an undetermined cause in animals 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) shall 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) of this Article occur;

   (b) detailed rules for the further investigation provided for in paragraph 1(b) of this Article.

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 dates of the suspicion and confirmation of the outbreak;

(c) the location of the outbreak;

(d) any related outbreaks;

(e) the animals affected by 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.

3. The Commission shall by means of implementing acts establish which of the listed diseases referred to in in Article 8(1)(e) shall be subject to immediate notification by the Member States in accordance with paragraph 1 of this Article.

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

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 29(b)(ii);

(c) the results of surveillance programmes when required in accordance with Article 27(3) and rules adopted in accordance with Article 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 amending and supplementing the requirements of paragraph 2 of this Article and reporting on other matters where necessary to ensure an efficient application of the disease prevention and control rules of this Regulation.

Article 19
Common rules for Union notification and Union reporting

1. The Union notification and Union reporting provided for in Articles 17(1) and 18(1) shall be done at times and frequencies which ensure transparency and the timely application of the necessary risk management measures, taking into account:

   (a) the disease profile;

   (b) the type of outbreak.

2. The Member States shall establish notification and reporting regions for the purpose of the Union notification and Union reporting provided for in Articles 17(1) and 18(1).

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 Union notification and Union 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 Union notification and Union reporting requirements and the computerised information system provided for in Articles 17 to 20 with respect to:

(a) the information to be provided by the Member States in the Union notification and Union reporting provided for in Articles 17(1) and 18(1);

(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 Union notification and Union reporting provided for in Articles 17(1) and 18(1);

(e) Union notification and Union reporting regions provided for in Article 19(2).

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;

   (c) any other relevant surveillance, quality assurance schemes 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 purposes of:

   (a) the detection of any signs indicative of the occurrence of listed diseases or emerging diseases;

   (b) 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.

Article 24
Delegation of powers concerning animal health visits

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

(a) supplementing:

(i) the criteria laid down in Article 23(1) to be taken into account when determining:

– which type of establishments must be subject to animal health visits;

– the frequency of such animal health visits;

(ii) the requirements laid down in Article 23(2) as regards the content and frequency of animal health visits for the different types of establishments, to ensure that the purposes of the animal health visits are achieved;

(b) determining the types of establishments to be subject to animal health visits.

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 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.

3. The competent authority shall ensure that the surveillance information 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(1) 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, or by other public authorities.

Article 27
Surveillance programmes

1. The competent authority shall undertake surveillance provided for in Article 25(1) in the framework of a surveillance programme, when structured surveillance is necessary due to:

(a) the disease profile;

(b) the risk factors involved.

2. Member State establishing a surveillance programme in accordance with paragraph 1 shall inform the Commission and the other Member States thereof.

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;

(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

The Commission shall by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes provided for in Articles 26 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;

(b) the format and procedure for:

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

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

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

Chapter 3
Eradication programmes

Article 30
Compulsory and voluntary 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");

(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 ("voluntary eradication programme") shall submit it to the Commission for approval

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 voluntary 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).

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 this paragraph in accordance with the procedure provided for in Article 255(3).

The Commission may, by means of implementing acts, amend or terminate where necessary 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 be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) the objectives, disease control strategies and intermediate targets of compulsory and voluntary eradication programmes;

(b) derogations from the requirement for the submission of compulsory eradication programmes and voluntary eradication programmes for approval, as provided for in paragraph 1(b) and paragraph 2 of this Article, where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 31(2) and 34(2) and Article 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 compulsory eradication programmes and voluntary 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 voluntary eradication programmes

1. Compulsory eradication programmes and voluntary 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 26 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 be empowered to adopt delegated acts in accordance with Article 253 concerning:

(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) the surveillance design, means, diagnostic methods, frequency, intensity, targeted animal population and sampling patterns as provided for in Article 26;

(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) vaccination.

Article 32
Content of the submission of compulsory and voluntary eradication programmes

Member States shall include the following information in applications for compulsory and voluntary 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 voluntary eradication programme;

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

(c) a description of the disease control measures of the compulsory or voluntary eradication programme as provided for in Article 31(1) and the rules adopted pursuant to Article 31(2);

(d) the estimated duration of the compulsory or voluntary eradication programme;

(e) the intermediate targets and the disease control strategies for undertaking the compulsory or voluntary eradication programme;

(f) an analysis of the estimated costs and benefits of the compulsory or voluntary eradication programme.

Article 33
Reporting

The Member State undertaking the compulsory or voluntary eradication programme shall submit to the Commission:

(a) regular intermediate reports to monitor the intermediate targets referred to in Article 32(e) of the on-going compulsory or voluntary programmes;

(b) a final report after its completion.

Article 34
Period of application of eradication programmes

1. Compulsory and voluntary eradication programmes 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(1) are fulfilled; or

   (b) in the case of voluntary eradication programmes, the conditions to apply for disease-free status cannot be achieved and that programme no longer fulfils its purpose; in that event it shall be withdrawn by the competent authority or by the Commission in accordance with the procedure under which it was established.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the requirements provided for in paragraph 1 of this Article as regards the period of application of compulsory and voluntary eradication programmes.

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 voluntary 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 voluntary 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 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;

   (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;

   (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.

3. The Commission shall, by means of an implementing act approve, subject to amendments where necessary, applications by Member States for disease-free status, when the conditions provided for in paragraph 1 and 2 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)(a) to (d);

(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 operators in control of the establishments of the compartment have a common biosecurity management system in place to ensure that the disease-free status of the compartment is guaranteed;

(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 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.

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:

(a) the requirements for the recognition of the disease free status of compartments as provided for in paragraphs 1 and 2 of this Article, taking into account 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 of this Article;

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

Article 38
Lists of disease-free zones or compartments

Each Member State shall establish and maintain an updated list of:

(a) disease-free territory or zones as provided for in Article 36(1);

(b) disease-free status of compartments as provided for in Article 37(1) and (2).

Member States shall make those lists publicly available.

Article 39
Delegation of powers concerning the disease-free status of Member States and zones

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

(a) detailed rules for the disease-free status of Member States and zones thereof taking into account 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 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) of this Article;

(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) of this Article.

Article 40
Implementing powers

The Commission shall by means of implementing acts, lay down requirements for the disease-free status of territories, zones and compartments concerning the rules provided for in Articles 36, 37 and 38, and rules laid down in delegated acts adopted pursuant to Article 39 concerning:

(a) establishing for which of the listed diseases referred to in Article 8(1)(a), (b) and (c), the disease-free compartments may be established in accordance with Article 37;

(b) requirements concerning the information to be submitted, 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 no longer apply.

3. The Commission shall be empowered to 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(c).

Article 42
Suspension, withdrawal and restoration of disease-free status

1. Where a Member State 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) suspend 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 diseas 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 a significant likelihood that the listed disease for which it obtained the disease-free status or other significant breaches of the conditions for maintaining disease-free status have occurred, the Member State shall immediately inform the Commission.

4. The Commission shall, by means of implementing acts, withdraw 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 of this Article 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).

On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner 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 the rules for the suspension, withdrawal and restoration of disease-free status provided for in paragraphs 1 and 2 of this Article.

PART III
DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I
Disease awareness and preparedness

Chapter 1
Contingency plans and simulation exercises

Article 43
Contingency plans

1. The Member States shall 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 case or an outbreak of a listed disease referred to in Article 8(1)(a) or an emerging diseases in order to ensure a high level of disease awareness, preparedness and rapid response.

2. The 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 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
Delegation of powers and implementing powers for contingency plans

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements and conditions for the contingency plans provided for in Article 43(1) and to supplement the requirements laid down in Article 43(2), taking into account:

(a) the objectives of the contingency plans to ensure a high level of disease awareness, preparedness and rapid response;

(b) the disease profile of the listed diseases referred to in Article 8(1)(a);

(c) new knowledge of and developments in disease control tools.

2. The Commission shall, by means of implementing acts, lay down requirements concerning the practical implementation in the Member States of the contingency plans provided for in Article 43(1) with regard to:

(a) the matters provided for in Article 43(2)(a) and (c) to (h);

(b) other operational aspects of the contingency plans in the Member States;

(c) detailed requirements and conditions for the practical implementation of the delegated acts adopted pursuant to paragraph 1 of this Article.

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:

   (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, contents and format of simulation exercises;

   (b) simulation exercises covering more than one listed disease referred to in Article 8(1)(a);

   (c) collaboration between neighbouring Member States and with neighbouring third countries and territories.

   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 comply with the rules on the use of veterinary medicinal products laid down in delegated acts adopted pursuant to Article 47.

   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:

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

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

(c) the compulsory use of veterinary medicinal products;

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

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 of this Article.

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 of this Article.

Chapter 3
Antigen, vaccine and diagnostic reagent banks

Article 48
The establishment of Union antigen, vaccine and diagnostic reagent banks

1. For listed diseases referred to in 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 the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:

   (a) store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents for the specific listed disease, 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 taking into account the requirements provided for in Article 15(1) and 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) 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 taking into account:

   (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

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).

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 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 and the other Members States 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.

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 of this Article.

   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
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 of operators, animal professionals and pet keepers

1. In the event of suspicion of a listed disease referred to in Article 8(1)(a) in kept animals, animal professionals, operators and pet keepers shall, in addition to notifying the signs or suspicion to the competent authority and veterinarians 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), 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 to be taken by the operators, animal professionals and pet keepers as provided for in paragraph 1 of this Article.

Article 54
Investigation by the competent authority in the event of suspicion of a listed disease

1. 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 official veterinarians:

   (a) carry out a clinical examination of a representative sample of the kept animals of listed species for that particular listed disease;

   (b) 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) carry out laboratory examination to confirm or rule out the presence of the particular listed disease.

3. The Commission shall be empowered to 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 of this Article.

Article 55
Preliminary disease control measures by the competent authority

1. The competent authority shall in the event of a suspicion of a listed disease referred to in Article 8(1)(a) in kept animals carry out the following preliminary disease control measures 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, household, food and feed business or animal by-products establishment, or any other location where the disease suspicion occurs under official surveillance;

   (b) compile an inventory of:

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

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

   (c) apply appropriate biosecurity measures 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, keep the kept animals of listed species for that listed disease isolated, and prevent contact with wildlife;

   (e) restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, households, 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, epidemiological units therein, households, food and feed businesses or animal by-products establishments;

      (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 be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in Article 8(1)(a), taking into account 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)(e), where necessary.

SECTION 2
EPIDEMIOLOGICAL ENQUIRY

Article 57
Epidemiological enquiry

1. The competent authority shall carry out an epidemiological enquiry in event of the suspicion or 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 contact establishments and epidemiological units therein, households, 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 epidemiological enquiry provided for in Article 57(1);

   (c) other available epidemiological data.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1of 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, household, food or feed business, animal by-products establishment or other location as officially infected with that listed disease;

(b) establish a restricted zone, as 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 in an establishment, household, food or feed business, animal by-products establishment or any other location, the competent authority shall immediately take one or more of the following disease control measures 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 and 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 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, disinfestation 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.

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, household, food or feed business, animal by-products establishment or other location.

3. The competent authority shall only authorise the repopulation of the establishment, household 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, household, 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, households, 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.

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 be empowered to 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).

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 disinfestation provided for in of 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 around the affected establishment, household, 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.

   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 be empowered to 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 take one or more of the following disease control measures 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, households, 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, households, 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) artificial insemination.

   (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 disinfestation;

   (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 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.

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 in restricted zones

1. Operators keeping animals and products in the restricted zone provided for in Article 64(1) shall notify any intended movement of kept animals and products, within or out of the restricted zone, to the competent authority.

2. They shall only move the kept animals and products in accordance with the instructions of the competent authority.

Article 67
Delegation of powers concerning the disease control measures in restricted zones

The Commission shall be empowered to 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).

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 disinfestation 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:

(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 disinfestation 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 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 of this Article in relation to:

(a) the final cleaning, disinfection or disinfestation procedures, 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);

(d) 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 of this Article, take the following into account:

(a) the requirements for emergency vaccination provided for in the contingency plans provided for in Article 43(1);

(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) of this Article 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 of the suspicion or official confirmation of a listed disease referred to in Article 8(1)(a) in wild animals, the affected Member State 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 to avoid the further spread of that listed disease.

2. The disease prevention and control measures provided for in paragraph 1(b) shall take the following matters into account:

   (a) the disease profile;

   (b) the affected wild animals;

   (c) the disease control measures to be taken in the event of suspicion or official confirmation of a listed disease referred to in Article 8(1)(a) in restricted zones in kept animals pursuant to rules laid down in Sections 1 to 4.

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

   (a) surveillance pursuant to paragraph 1(a);

   (b) disease prevention and control measures pursuant to paragraph 1(b).

   When adopting those delegated acts, the Commission shall take into consideration 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

1. Member States may take additional disease control measures to those provided for in Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in delegated acts adopted pursuant to Article 67 and Article 68(2), provided that such measures are in line with 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
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 of operators, animal professionals and pet keepers

1. In the event of suspicion of listed diseases referred to in Article 8(1)(b) and (c) in kept animals, operators, animal professionals and pet keepers shall, in addition to notifying the signs and suspicion to the competent authority and veterinarians in accordance with Article 16(1) and pending any disease control measures being taken by the competent authority in accordance with Article 74(1), take appropriate 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 to be taken by the operators, animal professionals and pet keepers as provided for in paragraph 1 of this Article.

Article 73
Investigation by the competent authority in the event of suspicion of a listed disease

1. The competent authority shall, in the event of the suspicion of a listed disease referred to in Article 8(1)(b) and (c) 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 official veterinarians:

   (a) carry out a clinical examination of a representative sample of the kept animals of listed species for that particular listed disease;

   (b) 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) carry out a laboratory examination to confirm or rule out the presence of the particular listed disease.

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 of this Article.

Article 74
Preliminary disease control measures by the competent authority

1. The competent authority shall, in the event of a suspicion of a listed disease referred to in Article 8(1)(b) or (c) in kept animals carry out the following preliminary disease control measures, 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, household, 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 investigation provided for in Article 57(1) and any rules adopted pursuant to Article 57(2).

2. The preliminary disease control measures provided for in paragraph 1 shall be appropriate and proportionate to the risk posed by the listed disease referred to in Article 8(1)(b) or (c) 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 be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing those laid down in paragraph 1 of this Article, while taking into account the matters referred to in paragraph 2 of this Article, 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, households, 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

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.

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 be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1of this Article.

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) and Article 75 until the presence of the listed diseases referred to in Article 8(1)(b) or (c) has been ruled out in accordance with Article 76(1) or 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

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)(b) in kept animals the competent authority shall:

   (a) in a Member State, zone or compartment subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, apply the disease control measures laid down in that compulsory eradication programme;

   (b) in a Member State, area, zone or compartment that is not yet subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, initiate that compulsory eradication programme and apply the disease control measures laid down therein.

2. 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 the competent authority shall:

   (a) in a Member State, zone or compartment subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply the disease control measures laid down in that voluntary eradication programme;

   (b) in a Member State, area, zone or compartment that is not subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply, when appropriate, measures to control and prevent its spread.

3. The measures provided for in paragraph 2(b) of this Article shall be proportionate to the risk posed by the listed disease referred to in Article 8(1)(c) in question taking into account:

   (a) the disease profile;

   (b) the kept animals affected;

   (c) the health status of the Member State, area, zone, compartment or establishment in which the listed disease has been officially confirmed;

   (d) the disease control measures to be taken in the establishments, other locations and restricted zones provided for in Section 4 of Chapter 1 of this Title.

Article 79
Delegation of powers for the disease control measures to be taken by the competent authority

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 laying down detailed rules concerning the disease control measures to be taken in the event of outbreaks of a listed disease referred to in Article 8(1)(b) or (c) in kept animals as provided for in Article 78(2)(b) taking into account the criteria provided for in Article 78(3).

SECTION 4
WILD ANIMALS

Article 80
Wild animals

1. In the event of suspicion or official confirmation of a listed disease referred to in Article 8(1)(b) in wild animals, the competent authority of the affected Member State shall:

   (a) in the entire territory of the Member State, area or, zone subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, apply the disease control measures laid down in that compulsory eradication programme;

   (b) in the entire territory of the Member State, area or zone that is not subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, initiate that compulsory eradication programme and apply the disease control measures laid down therein where appropriate, to control and prevent its spread.

2. In the event of an outbreak of a listed disease referred to in Article 8(1)(c) in wild animals the competent authority of the affected Member State shall:

   (a) in the entire territory of the Member State, area, zone or compartment subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply the disease control measures laid down in that voluntary eradication programme;

   (b) in the entire territory of the a Member State, area, zone or compartment that is not subject to an voluntary eradication programme provided for in Article 30(2) for that listed disease, apply, when appropriate, measures to control and prevent its spread.

3. The disease control measures referred to in paragraph 2(b) shall take the following matters into account:

   (a) the disease profile;

   (b) the affected wild animals;

(c) the disease control measures to be taken in the event of suspicion or official confirmation of a listed disease in restricted zones in kept animals pursuant to rules laid down in Sections 1 to 4 of Chapter 1 of this Title.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing the disease control measures to be taken in the event of outbreaks of a listed disease referred to in Article 8(1)(b) or (c) in wild animals as provided for in paragraph 2(b) of this Article.

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 the disease control measures taken by the competent authority in respect of a listed disease referred to in Article 8(1)(b) or (c), in accordance with Article 76(1), Articles 77 and 78 and Article 80(1) and (2) and delegated acts adopted pursuant to Article 76(2), Article 79 and Article 80(4).

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 TRANSPORTERS

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 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 of kept terrestrial animal or germinal products on the establishment and the capacity of the establishment;

      (iv) the type of establishment;

      (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) significant changes in the establishment concerning the matters referred to in paragraph 1(b);

(b) cessation of activity in 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 certain categories of establishments from the registration requirement, taking into account the following criteria:

(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;

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

Article 84
Implementing powers concerning the obligation of operators to register establishments

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

(a) the information to be provided by operators for the purpose of the registration of the establishments as provided for in Article 82(1);

(b) the types of establishments that may be exempted by the Member States from the registration requirement in accordance with Article 83 provided that those establishments pose an insignificant risk and taking into account the criteria provided for in that Article.

Those implementing acts 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 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 terrestrial animals transported;

(iii) the type of transport;

(iv) the means of transport.

2. Transporters shall inform the competent authority of any:

(a) significant 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 and amending the rules provided for in paragraph 1 concerning the obligation of other types of transporters to provide the information for the purposes of registration of its activity, taking into account the risks involved with such transports.

Article 86
Derogations from the obligation to register transporters of kept ungulates

By way of derogation from Article 85(1), Member States may exempt certain categories of transporters from the registration requirement, taking into account the following criteria:

(a) the distances over which they transport those kept terrestrial animals;

(b) the categories, species and number of kept terrestrial animals, which they transport.

Article 87
Implementing acts concerning the obligation to register transporters

The Commission shall be empowered to adopt implementing acts concerning:

(a) the information to be provided by the transporter for the purposes of registration of its activity, as provided for in Article 85(1);

(b) the types of transporters that may be exempted by the Member States from the registration requirement in accordance with Article 86 provided that the type of transport poses an insignificant risk and taking into account the criteria provided for in that Article.

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

Article 88
Obligation of the competent authority concerning the registration of establishments and transporters

The competent authority shall register:

(a) establishments in the register of establishments and transporters provided for in Article 96(1), where the operator has provided the information required in accordance with Article 82(1);

(b) transporters in that register of establishments and transporters provided for in Article 96(1), where the transporter has provided the information required in accordance with Article 85(1).

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;

   (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) of this Article.

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 supplementing and amending the rules for the approval of establishments provided for in paragraph 1 of this Article 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. The Commission shall take the following criteria into account, when adopting delegated acts provided for in paragraph 3:

(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;

(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) not move kept animals to a confined establishment in accordance with the requirements provided for in Article 134(1) and any delegated acts adopted in accordance with Article 134(2) until their establishment obtains 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 numbers of kept terrestrial animals or germinal products 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) significant changes in the establishments concerning the matters referred to in paragraph 1(a), (b) and (c);

(b) the cessation of activity in 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.

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 and the rules adopted pursuant to Article 24;

(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 a sufficient number of 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 be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements provided for in paragraph 1 of this Article as regards:

(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 training of personnel and veterinarians provided for in paragraph 1(d);

(e) the necessary supervision and control by the competent authority.

3. The Commission shall take into account the following matters when establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2:

(a) the risks posed by each type of establishment;

(b) the categories and species of kept terrestrial animals;

(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) and 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 and Article 91(1).

2. Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 89(1)(a) and Article 90(a) make an on-site visit.

3. 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 by the competent authority as provided for in paragraph 2 of this Article, that it meets all the main requirements that provide sufficient guarantees that such an establishment does not represent a significant risk, with a view to ensuring compliance with all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2).

4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 of this Article, 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, 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 that on-site visit 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.

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 restored after withdrawal or 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 OF ESTABLISHMENTS AND TRANSPORTERS

Article 96
Establishment and transporter register

1. The competent authority shall establish and keep up-to-date a register of:

   (a) all establishments and transporters registered pursuant to Article 88;

   (b) all establishments approved in accordance with Articles 92 and 94.

   It shall make that register available to other Member States and to the public.

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:

   (a) the information to be included in the register provided for in paragraph 1;

   (b) additional requirements for registers of germinal products establishments, after they cease activities;

   (c) public availability of the register provided for in paragraph 1.

4. The Commission may, by means of implementing acts, lay down rules on the format of and procedures for the register of establishments and transporters and approved establishments 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).

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, numbers and 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 in paper or electronic form 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) any animal health problems concerning kept 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) and rules adopted pursuant to Article 24.

2. Establishments which are exempted from the registration requirement in accordance with Article 83 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article.

3. Operators of establishments shall keep the records provided for in paragraph 1 on the establishment and:

(a) make them 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 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 and identification 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 in paper or electronic form 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);

(e) laboratory techniques used.

2. Establishments which are exempted from the registration requirement in accordance with Article 84 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article.

3. The operators of germinal product establishments shall keep the records provided for in paragraph 1 on the establishment and:

(a) make them 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 of germinal products shall keep and maintain records containing at least the following information:

(a) the establishments visited by them;

(b) the categories, species and number of germinal products transported by them;

(c) the cleaning, disinfection and disinfestation of the means of transport.

2. Transporters which are exempted from the registration requirement in accordance with Article 86 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article.

3. 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 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 and Article 99, as regards:

   (a) derogations from the record keeping requirements for:

      (i) operators of certain types of establishments and certain types of transporters;

      (ii) establishments keeping, or transporters handling a small number of kept terrestrial animals or small volume of germinal products;

      (iii) certain categories or species of kept terrestrial animals or germinal products;

   (b) information to be recorded in addition to that provided for in Articles 97(1), 98(1) and 99(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. The Commission shall take into account the following matters when establishing the rules to be laid down in delegated acts provided for in paragraph 1:

   (a) the risks posed by each type of establishment or transporter;

   (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 transport;

   (d) the typical movement patterns of the type of establishment and category of animals concerned;

   (e) the number of kept terrestrial animals or volume of germinal products kept in the establishment or transported by the transporter.

Article 101
Implementing powers concerning record keeping

The Commission shall by means of implementing acts, lay down rules concerning:

(a) the format of records provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100;

(b) electronic keeping of records provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100;

(c) procedures for record keeping provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100.

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 kept terrestrial animals and, when appropriate, for the recording of their movements, taking 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) IMSOC;

(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.

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:

(a) the following information related to kept animals of the bovine, ovine and caprine species:

(i) their individual identification as provided for in Articles 106(a) and 107(a);

(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;

(c) the following information related to kept animals of the equine species:

(i) their unique life number as provided for in Article 109(1)(a);

(ii) the means of identification linking that animal with the identification document referred to in (iii), where relevant;

(iii) the identification document provided for in Article 109(1)(c);

(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, taking into account the 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 within and 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

The competent authority shall issue:

(a) identification documents for kept terrestrial animals when required by Articles 106(b) and 109(c), Article 112(1)(b) and (2)(b), and Article 113(b) and rules adopted pursuant to Articles 114 and 117;

(b) 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.

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(a), Article 109(1), Article 110(a), Article 112(1)(a) and (2)(a) and 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 are issued with an identification document from the competent authority or designated authority or authorised body, which is a single lifetime document and that that document:

(i) is kept, correctly completed and updated by the operator;

(ii) accompanies those kept terrestrial animals at the time of movement;

(c) transmit the information on movements of those kept animals from and into the establishment to the computer database provided for in Article 103(1) and the rules adopted pursuant to Articles 114 and 117.

Article 107

Operators obligations for the identification of kept animals of the ovine and caprine species

Operators keeping kept animals of the ovine and caprine species shall:

(a) ensure that those kept animals are identified individually by a physical means of identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document issued by the competent authority in accordance with Article 104 when moved from the establishment keeping those animals;

(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) and the rules adopted pursuant to Articles 114 and 117.

Article 108

Derogations concerning identification documents and movement documents for kept animals of the bovine, ovine and caprine species

By way of derogation from Article 104 and from Articles 106(b) and 107(b), Member States may exempt operators from the requirement to ensure that kept animals of the bovine, ovine and caprine species are accompanied by identification documents or movement documents during movements within the Member State, provided that:

(a) the information contained in the movement document or identification 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 bovine, ovine and caprine species provides an equivalent level of traceability as that provided by identification documents and 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 life number, which is recorded in the computer database provided for in Article 103(1);

   (b) a method which unequivocally links the kept animal and 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 transmit the information on those animals to the computer database provided for in Article 103(1) and by the rules adopted pursuant to Articles 114 and 117.

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 identified by a means of physical identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document issued by the competent authority in accordance with Article 104(b) when moved from the establishment keeping those animals;

(c) transmit the information related to the establishment keeping those animals to the computer database provided for in Article 103(1) and in the rules adopted pursuant to Articles 114 and 117.

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 issued by the competent authority for movements within the Member State, provided that:

(a) the information on 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 112

Pet keepers' obligation for the identification and registration of terrestrial pet animals

1. Pet keepers shall ensure that terrestrial pet animals of the species listed in Part A of Annex I which are moved from one Member State to another Member State:

   (a) are individually identified by a physical means of identification;

   (b) are accompanied by a correctly completed and updated identification document issued by the competent authority in accordance with Article 104.

2. Pet keepers shall ensure that terrestrial pet animals of the species listed in Part B of Annex I when moved from one Member State to another Member State, and when required by rules adopted pursuant to Articles 114 and 117, are:

   (a) identified, either individually or in groups;

   (b) 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 113

Operators obligation for the identification of kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine and equine species and pet animals

Operators shall ensure that kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and other than pet animals, 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

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

(a) the designation of other authorities, the authorisation of bodies or natural persons, as provided for in Article 102(4)(c);

(b) detailed requirements for:

   (i) the means of identification of kept terrestrial animals provided for in Articles 106(a) and 107(a), Article 109(1), Article 110(a), Article 112(1)(a) and (2)(a), and Article 113(a);

   (ii) the application and use of that means of identification;

(c) the information to be included in:

(i) the computer databases provided for in Article 103(1);

(ii) the identification document for kept animals of the bovine species provided for in Article 105(b);

(iii) the movement document for kept animals of the caprine and ovine species provided for in Article 107(b);

(iv) the identification document for kept animals of the equine species provided for in 109(1)(c);

(v) the movement document for kept animals of the porcine species provided for in Article 110(b);

(vi) identification documents for terrestrial pet animals provided for in Article 112(1)(b) or identification documents, movement documents or other documents for kept terrestrial pet animals provided for in Article 112(2)(b);

(vii) identification documents or movement documents for kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine, equine species and pet animals provided for in Article 113(b);

(d) detailed requirements for different species and categories of kept terrestrial animals to ensure the efficient operation of the identification and registration system provided for in Article 102(1);

(e) detailed requirements for kept terrestrial animals entering the Union from third countries and territories;

(f) identification and registration requirements for kept terrestrial pet animals of the species listed in Part B of Annex I and 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.

Article 115

Delegation of powers concerning derogations from the traceability requirements

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);

(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.

Article 116
Matters to be taken into account when adopting delegated acts provided for in Articles 114 and 115

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated acts provided for in Articles 114 and 115:

(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

The Commission shall by means of implementing acts, lay down rules for the implementation the requirements provided for in Articles 106, 107, 109, 110, 112 and 113 and those laid down in delegated acts adopted pursuant to Article 103(2) and Articles 114 and 115 concerning:

(a) technical specifications, formats and operational rules of:

  (i) means, methods and the use of identification;

  (ii) the identification document or movement document for kept animals of the bovine, ovine, caprine species;

  (iii) identification document for kept animals of the equine species;

  (iv) identification, movement and other documents for kept terrestrial animals of species; other than of the bovine, ovine, caprine and equine species

  (v) computer databases.

(b) the deadlines for:

  (i) the transmission of information by operators into the computer database;

(ii) the registration of kept terrestrial animals;

(iii) the identification of kept terrestrial animals and the replacement of identification marks;

(c) practical application of exemptions from the identification and registration provided for in the rules adopted pursuant to Article 115.

Those implementing acts 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, equine and porcine species and poultry

1. Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, equine and porcine 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 be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species amending and supplementing the rules laid down in Article 118;

(b) traceability requirements for germinal product of kept terrestrial animals of species other than of the bovine, caprine, ovine, equine and porcine 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. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

(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, processing or storage;

(f) 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 other than terrestrial pet 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 establishments and receive such animals, 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 identification and registration requirements of Articles 106, 107, 109, 110 and 113 and the rules adopted pursuant to Article 114(a) to (d) and Article 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 at places of assembly, resting and destination;

(c) cleaning, disinfection, disinfestations of 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 cleaning, disinfection and disinfestations of 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:

(a) they come from an establishment:

(i) where there are no abnormal mortalities or other disease symptoms 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)(d), 61(1)(a), Article 62, Article 65(1)(c), Article 74(1) and Article 78(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Article 71(3), Article 74(3), Article 79 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 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), Article 79 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.

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 of identification provided for in Articles 106(a) and 107(a), Article 109(1) and Articles110(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 107(b), 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(2) are present;

(c) inform the competent authority of any irregularity with regard to:

(i) the kept terrestrial animals received;

(ii) the presence of the means 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 between Member States

Operators shall not move kept terrestrial animals to another Member State, unless the Member State of destination gives express authorisation prior to the movement in the event of animals which are intended to be slaughtered for disease eradication purposes as a part of an eradication programme provided for in Article 30(1), (2) and (3).

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 poutry 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;

(d) they do not pose a significant risk for the spread of those listed diseases at the place of destination.

Article 128

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

1. The Commission shall be empowered to 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 risk mitigating measures amending and supplementing the requirements laid down in Article 127.

2. The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated acts provided for in paragraph 1:

(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 be empowered to 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:

   (a) one assembly operation in the Member State of origin;

   (b) one assembly operation in the Member State of passage;

   (c) one assembly operation in the Member State of destination.

2. The assembly operations provided for in paragraph 1 of this Article shall only take place in an establishment approved for that purpose in accordance with Article 92(1) and Article 94(3) and (4).

   However, the Member State of origin may allow assembly operations in their territory to take place on means of transport, collecting kept ungulates and poultry directly from their establishments of origin, provided that they are not unloaded again following those operations before:

   (a) arriving at their establishment or final place of destination; or

   (b) an assembly operation provided for in paragraph 1(b) and (c).

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 or poultry are identified and, where required, accompanied with the following documents:

(i) the identification and registration documents where provided for in Articles 106(b), 107(b), 109(c), 110(b) and Article113(b) and rules adopted pursuant to Articles 114 and 117, unless derogations are provided for according to Article 115;

(ii) the animal health certificates where provided for in Article 140 and Article 141(c), unless derogations are provided for in the rules adopted pursuant to Article 141(a);

(iii) the self-declaration document where provided for in Article 148.

Article 132
Delegation of powers concerning assembly operations

The Commission shall be empowered to 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(2);

(c) the timeframe between the time of departure of the kept ungulates or poultry from their establishment of origin and their departure from the assembly operation to their final destination in another Member State as referred to in Article 131(b);

(d) 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. The Commission shall take the following matters into account, when establishing the detailed rules to be laid down in the delegated acts provided for in paragraph 2:

(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

Article 134
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 be empowered to 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

Derogations for 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, with the exception of Articles 121 and 122, Article 123(1)(a)(ii) and Article 124.

2. The competent authorities 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) have taken the necessary risk mitigating measures to ensure 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 amending and supplementing the rules for derogations by the competent authorities provided for in paragraphs 1 and 2 of this Article.

Article 136

Derogations concerning recreational use, sporting and cultural events, grazing and work near borders

1. The competent authority of the place of destination may grant derogations from the requirements of Sections 2 to 5, with the exception of Article 123(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 amending and supplementing the rules for derogations by the competent authority of the place of destination provided for in paragraph 1 of this Article.

Article 137

Delegation of power concerning derogations for circuses, exhibitions, sporting events and recreational use, zoos, pet shops, 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 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 with the exception of Article 123(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 derogations for movements of specific species or categories of kept terrestrial animals

The Commission may, by means of implementing acts lay down rules concerning temporary derogations from the 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 and131, 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.

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

The Commission shall take the following matters into account, 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:

(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 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. Operators shall not move kept terrestrial animals within a Member State or from one Member State to another Member State unless 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), where the conditions referred to in the following points (a) and (b) are meet:

(a) the 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;

(b) the kept terrestrial animals are of species subject to those disease control measures.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 of this Article accompanies the kept terrestrial animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 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;

(iv) the place of destination of the kept terrestrial animals; or

(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 by the competent authority, taking into account the matters provided for in paragraph 2 of this Article, which ensure:

(i) the traceability of the kept terrestrial animals being moved;

(ii) that the kept terrestrial animals being moved comply with required animal health requirements for movements provided for in Sections 1 to 6;

(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.

2. When establishing the special rules provided for in paragraph 1(b), the Commission shall take the following matters into account:

(a) the confidence of the competent authority about 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 obtained basic knowledge of animal health as provided for in Article 10 and the support provided for in Article 12(2);

(d) the performance of the animal health visits as provided for in Article 23 and rules adopted pursuant to Article 24, where other relevant surveillance, quality assurance schemes or official controls as referred to in Article 23(1)(c) are not 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 17(3) and18(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) of this Article.

Article 142
Contents of animal health certificates

1. The animal health certificate 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;

   (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.

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 be empowered to 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 supplementing the obligation of operators to ensure that animals are accompanied by an animal health certificate provided for in Article 140 and 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;

(b) where necessary, subject the kept terrestrial animals 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 to another Member State, where required by Article 140 or by delegated acts adopted pursuant to Articles 141(1) and 143(2) 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, 129, 130 and131, 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 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 be empowered to 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 of this Article 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 IMSOC, 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.

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;

(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.

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 of this Article 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 of this Article.

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 of this Article. 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 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);

(c) notification is required in accordance with delegated acts adopted pursuant to Article 151(1).

For the purposes of the first paragraph of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movements of the kept terrestrial animals to the competent authority of the Member State of destination in accordance with Article 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, whenever possible, through IMSOC.

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 IMSOC 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 be empowered to 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;

   (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 IMSOC;

(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 format of 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 4
Movements within the Union of terrestrial pet animals

Article 152
Non-commercial movements of terrestrial pet animals and delegated and implementing acts

1. Pet keepers shall only carry out non-commercial movements of terrestrial pet animals of the species listed in Annex I from one Member State to another Member State where:

(a) those terrestrial pet animals are identified and accompanied with an identification document when required in accordance with Article 112 or rules adopted pursuant to Article 114(e) and Article 117;

(b) appropriate prevention and disease control measures have been taken during that movement, to ensure that the terrestrial pet animals do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) and emerging diseases to kept terrestrial animals at the place of destination and during transport.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the prevention and disease control measures referred to in paragraph 1(b) of this Article to ensure that the terrestrial pet animals do not pose a significant risk for the spread of diseases referred to in Article 8(1)(d) and emerging

diseases to animals during transport and at the place of destination and when relevant taking into account the health status of the place of destination.

3. The Commission may, by means of implementing acts lay down rules concerning the prevention and disease control measures provided for in paragraph 1 of this Article and the rules adopted pursuant to paragraph 2 thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 254(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 due to the occurrence of a listed disease referred to in Article 8(1)(d) or an emerging disease for the listed species provided for in Article 70(2)(c), Article 80(1) and (2) and rules adopted pursuant to Articles 70(3)(b) and Articles71(3), 80(4) and Article 81(3) or the emergency measures provided for in Articles 245 and 246 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) of this paragraph and the rules adopted pursuant to Article 154(1)(c) and (d) are complied with;

(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) .

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) of this Article, 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:

      (i) into establishments;

      (ii) for keeping as pet animals;

   (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 format 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) identification 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 the competent authority of any irregularity with regard to:

      (i) the germinal products received;

      (ii) the presence of the means of identification referred to in point (a)(i);

      (iii) the presence of 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 under its supervision 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;

   (b) they fulfil the traceability requirements for the type of germinal product in accordance with Article 118 and rules adopted pursuant to Article 119;

   (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.

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) and74(3), Article 79 and Article 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.

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

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:

(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);

(e) 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:

   (a) to another Member State;

   (b) within a Member State or to another Member State, where:

      (i) 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 Artilce78 and rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and74(3), Article 79 and Article 81(2) or the emergency measures provided for in Articles 246 and 247 and the rules adopted pursuant to Article 248 unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this point; and

      (ii) the germinal products of kept animals are of species subject to those disease control or emergency measures referred in point (i).

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.

4. Articles 142, 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 of this Article, and Article 148(1) and the rules adopted pursuant to Article 148(2) 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 of this Article 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.

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

(a) the information to be contained in the animal health certificate pursuant to paragraph 1 of this Article;

(b) 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);

      (ii) notification of movement is required in accordance with delegated acts adopted pursuant to Article 151(1) for germinal products, taking into account paragraph 3 of this Article;

   (b) provide all the necessary information to enable the competent authority of the Member State of origin to notify the movement of the germinal products to the competent authority of the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall notify 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 Article 151.

3. Articles 149 and 150 and rules adopted pursuant to Article 151 shall be applicable to the notification of germinal products.

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 of this Article:

(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. By way of derogation from Sections 1 to 4, the competent authority of the place of destination may authorise movements of germinal products for scientific purposes, which do not comply with the requirements of those Sections, with the exception of Article 155(1), Article 155(2)(c), Article 155(3) and Article156, subject to compliance with the following conditions:

(a) prior to granting such authorisation the competent authority of the place of destination must take the necessary risk mitigating measures to ensure that the movements of those germinal products 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);

(b) the movements of those germinal products take place under the supervision of the competent authority of the place of destination.

2. When granting a derogation in accordance with paragraph 1, the competent authority of the place of destination shall notify the Member States of origin and the Member States of passage of the derogation granted and the conditions under which it has been granted.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning conditions for derogations by the competent authority of the place of destination, as provided for in paragraph 1 of this Article.

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), Article 78(1) and (2) and the rules adopted pursuant to Articles 55(2), Articles 63 and 66, Article 71(3), Article 74(3) and Articles 79 and Article 81(2) unless derogations from those movement restrictions are provided for in those rules.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements amending and supplementing the requirements of paragraph 2 of this Article for the movement of products of animal origin, taking into account:

   (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 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 Article78(1) and (2) and rules adopted pursuant to Articles 55(2), Articles 63 and 67, Article 71(3) and74(3), Article 79 and Article 81(2),

      (ii) originate from animals of species subject to those disease control measures.

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.

4. Articles 145, 146 and 147 and the rules adopted pursuant to Articles 143 and144 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 of this Article.

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 of this Article 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 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for products of animal origin referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 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 the competent authority of the Member State of destination of movements of products of animal origin in accordance with Article 150 and the rules adopted pursuant to Article 151.

3. Articles 149 and 150 and rules adopted pursuant to Article 151 shall be applicable to the notification of products of animal origin.

Chapter 8
Scope of national measures

Article 168

National measures concerning movements of animals and germinal products

1. Member States shall remain free to take national measures concerning the movement of kept 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, 4, 5 and 6 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).

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, 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 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 and a description of the facilities;

      (iii) the categories, species and numbers of aquaculture animals on the aquaculture establishment and the capacity of the aquaculture establishment;

      (iv) the type of aquaculture establishment;

      (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 of any:

   (a) significant changes in the aquaculture establishments concerning the matters referred to in paragraph 1(b);

   (b) cessation of activity in the aquaculture establishment.

3. Aquaculture establishments which are subject to approval in accordance with Article 174(1) 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) under a common biosecurity system; and

(ii) located in geographical proximity.

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(2) 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.

Article 172
Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 170(1), Member States may exempt certain categories of aquaculture establishments from the registration requirement taking into account the following criteria:

(a) the categories, species and number or volume of aquaculture animals on the aquaculture establishment and the capacity of the aquaculture establishment;

(b) the type of aquaculture establishment;

(c) the movements of aquaculture animals into and out of the aquaculture establishment.

Article 173
Implementing powers concerning derogations from the obligation to register aquaculture establishments

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

(a) the information to be provided by operators for the purpose of the registration of the aquaculture establishment as provided for in Article 170(1);

(b) the types of aquaculture establishments for which the derogations from the registration requirement may be granted by Member States as provided for in Article 172, provided that they pose an insignificant risk and taking into account the criteria provided for Article 172.

Those implementing acts 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) and they shall not commence their activities until their aquaculture establishment has been approved in accordance with Article 179(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, however, such application shall not be required where they are solely moved either for:

      (i) for a direct supply for human consumption of small quantities to the final consumer; or

      (ii) to local retail establishments directly supplying the final consumer.

   (b) other aquaculture establishments which pose a high 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.

2. Operators shall cease 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 182(4).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the rules for the approval of aquaculture establishments provided for in paragraph 1 of this Article 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);

(b) the types of aquaculture establishments that must be approved in accordance with paragraph 1(b).

4. The Commission shall take the following criteria into account, when adopting delegated acts provided for in paragraph 3:

(a) the species and categories of aquaculture animals kept in an aquaculture establishment;

(b) the type of aquaculture establishment and the type of production;

(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, dispatch centres, 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) located in geographical proximity.

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) not move aquaculture animals to a confined aquaculture establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) until their establishment obtains 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 ensure that their establishments are approved by the competent authority to slaughter 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).

Article 178
Information obligation of operators in view to obtain approval and implementing acts

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 facilities;

   (c) the categories, species and numbers of aquaculture animals on the establishment;

   (d) the type of establishment;

   (e) where relevant, the details of the approval of a group of aquaculture establishments in accordance with Article 175;

   (f) other aspects of the aquaculture 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) significant changes in the establishments concerning the matters referred to in paragraph 1(c);

   (b) cessation of activity in 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 of this Article. 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, and the rules adopted pursuant to Article 24;

      (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 quantity 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 be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements provided for in paragraph 1 of this Article as regards:

   (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. The Commission shall take into account the following matters when establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2:

(a) the risks posed by each type of establishment;

(b) the species and categories of aquaculture or aquatic animals;

(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):

(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 and Article 177, the competent authority shall make an on-site visit.

3. 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 by the competent authority as provided for in paragraph 1 of this Article, that it meets all the main requirements that provide sufficient guarantees that such an establishment does not represent a significant risk, with a view to ensuring the compliance with the outstanding requirements for approval provided for in Article 179(1) and the rules adopted pursuant to Article 179(2).

4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 of this Article, 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, 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 that on-site visit 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.

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 restored after withdrawal or 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 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 geographical position 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) of this Article.

4. Where appropriate and relevant, the competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

Article 184
Delegation of powers and implementing acts concerning the register of aquaculture establishments

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 254 concerning:

(a) the information to be included in the register of aquaculture establishments provided for in Article 183(1);

(b) the public availability of that register of establishments.

2. The Commission may, by means of implementing acts, lay down rules on the format of and procedures for the register of establishments provided for in Article 183(1) and (3).

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

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 up-to-date records containing at least the following information:

(a) all 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 of aquaculture establishment;

(e) the results of the animal health visits, when required in accordance with Article 23(1) and the rules adopted pursuant to Article 24;

2. Operators of aquaculture establishments shall:

(a) record the information provided for in paragraph 1(a) in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;

(b) keep the information provided for in paragraph 1 on the aquaculture establishment and, made it available to the competent authority on request;

(c) retain the information 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.

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 up-to-date records of all movement of aquaculture animals and products of animal origin obtained from such animals into and out of such establishments.

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.

Article 187
Record keeping obligation for transporters

1. Transporters of aquaculture animals and wild aquatic animals intended for aquaculture shall keep up-to date records on:

(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.

2. Transporters shall:

(a) keep the records provided for in paragraph 1 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.

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:

(a) derogations from the record keeping requirements for:

(i) operators of certain categories of aquaculture establishments and transporters;

(ii) aquaculture establishments keeping a small number of animals or transporters transporting a small number of animals;

(iii) certain categories or species of animals;

(b) information to be recorded by operators in addition to that provided for in Articles 185(1), 186(1) and 187(1);

(c) the minimum period of time during which records provided for in Articles 185, 186 and 187 are required must be kept.

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;

(b) the categories or species of aquaculture animals on the aquaculture establishment;

(c) the type of production of the establishment;

(d) typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;

(e) the number or volume of aquaculture animals at the establishment or being transported.

Article 189
Implementing powers concerning record keeping

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

(a) the format of records to be kept in accordance with Articles 185, 186 and 187;

(b) electronic keeping of those records;

(c) operational specifications for record-keeping.

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 other than aquatic pet 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 not move aquatic animals into an aquaculture establishment or for human consumption or release them into the wild, where such aquatic animals are subject to:

(a) 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) and (2), Articles 74(1), 78(1) and (2), 80(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3 and 74(3), Article 79, and Articles 80(4) and 81(2); or

(b) 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 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 without delay to the final place of destination.

Article 191
Disease preventive measures in relation to transport and delegated acts

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, disinfection and disinfestations 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 during the transport of aquatic animals intended for aquaculture 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 cleaning, disinfection and disinfestations 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 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, 67 and 70, Article 74(1) and Articles78 and 80 and the rules adopted pursuant to Article 55(2), Articles 63 and 66, Articles 70(3), 71(3) and 74(3), Article 79, and Articles 80(3) and 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 specific purpose, shall not be used for any purpose other than the intended one.

Article 193
Obligations for operators at the place of destination

1. Operators of establishments and food business establishments receiving aquaculture animals shall:

(a) check that one of the following documents are present:

(i) the animal health certificates provided for in Article 208(1), Article 209 and Article224(1) and the rules adopted pursuant to Articles 188, 211 and 213 are present;

(ii) the self-declaration documents provided for in Article 218(1) and the rules adopted pursuant to Article 218(3) and (4) are present;

(b) inform the competent authority of any irregularity with regard to:

(i) the aquaculture animals received;

(ii) the presence of 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 aquaculture 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 not move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment or release them into the wild if they originate from an aquaculture establishment or environment where there are:

   (a) abnormal mortalities; or

   (b) other serious disease symptoms with an undetermined cause.

2. By way of derogation from paragraph 1, the competent authority may authorise such movement or release of aquatic animals, 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.

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 from an aquaculture establishment for the purposes referred to in point (a) or (b) of this Article, if those aquaculture animals originate from a Member State, or zone or compartment thereof, which has been declared disease-free in accordance with Article 36(3) or 37(4) for listed diseases referred to in Article 8(1)(b) or (c) when they are of listed species for those listed diseases and the aquaculture animals are:

   (a) to be introduced into a Member State, or zone or compartment thereof which is:

      (i) has been declared disease free in accordance with Article 36(3) or Article 37(4); or

(ii) subject to a eradication programme as provided for in Article 30(1) and (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c);

(b) intended for:

(i) an aquaculture establishment subject to:

– registration in accordance with Article 171: or

– approval in accordance with Articles 174, 175, 176 and Article 177; or

(ii) release into the wild.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the movement or release requirements of paragraph 1 of this Article, 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), Member States may authorise operators to move aquaculture animals into a zone or compartment in another Member State 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.

Article 198

Member States' measures concerning the release of aquaculture animals into the wild

Member States may require that aquaculture 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 the listed diseases referred to in Article 8(1)(b) and (c) for which the species of aquaculture animals to be moved is a listed

species, regardless of the health status of the area where the aquaculture 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 196 and 197 shall also apply to movements of wild aquatic animals intended for an aquaculture establishment or disease control aquatic food establishment subject to:

   (a) registration in accordance with Article 171; or

   (b) approval in accordance with Articles 174 to 177.

2. Operators shall take disease preventive measures when moving wild aquatic animals between habitats so that 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.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease preventive measures to be taken by operators as provided for in paragraph 2 of this Article.

SECTION 3

AQUATIC ANIMALS INTENDED FOR HUMAN CONSUMPTION

Article 200

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 from an aquaculture establishment for the purposes referred to in point (a) or (b) of this paragraph, if those aquaculture animals originate from a Member State, or zone or compartment thereof, which has been declared disease-free in accordance with Article 36(3) or 37(4) for listed diseases referred to in Article 8(1)(b) or (c) when they are of listed species for those listed diseases and they are:

   (a) to be introduced into a Member State, or zone or compartment thereof 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);

   (b) intended for human consumption.

2. By way of derogation from paragraph 1 of this Article Member States may authorise operators to introduce 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 of this Article for those movements of 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 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 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 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.

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 paragraph 1 of this Article.

SECTION 4
AQUATIC ANIMALS NOT INTENDED FOR ESTABLISHMENTS, RELEASE INTO THE WILD OR FOR HUMAN CONSUMPTION

Article 202
Movement of aquatic animals not intended for establishments, release into the wild or for human consumption and delegated acts

1. Operators shall take the necessary preventive measures to ensure that movements of aquatic animals not intended for establishments, release into the wild or for human consumption 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.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the preventive measures provided for in paragraph 1 of this Article to ensure that the aquatic animals do not spread the listed diseases referred to in Article 8(1)(d), whilst taking into account the matters referred to in paragraph 3 of this Article.

3. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 2:

   (a) the listed diseases referred to in Article 8(1)(d) relevant for the listed species or category of aquatic animals;

   (b) the health status as regards listed diseases referred to in Article 8(1)(d) at the compartments, zones or Member States of origin and destination;

   (c) the places of origin and of destination;

   (d) the type of movements of the aquatic animals;

   (e) the species and categories of the aquatic animals;

   (f) the age of the aquatic animals;

   (g) other epidemiological factors.

SECTION 5
DEROGATIONS FROM SECTIONS 1 TO 4 AND ADDITIONAL RISK MITIGATION MEASURES

Article 203
Aquatic animals intended for confined aquaculture establishments and delegated acts

1. Operators shall only move aquatic animals to a confined aquaculture establishment if they comply with the following conditions:

(a) they originate from another confined aquaculture 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 of animals at the confined aquaculture establishment of destination except where such movement is authorised for the 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 aquaculture establishments in addition to those provided for in paragraph 1 of this Article;

(b) specific rules for movements of aquaculture animals to confined aquaculture establishments 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 aquaculture establishment and surrounding establishments.

Article 204

Derogation for 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, with the exception of Articles 190(1) and (3), and Articles 191, 192 and Article 193.

2. The competent authorities 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) have taken the necessary risk mitigating measures to ensure 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) the movements of those aquatic animals take place under the supervision of the competent authorities of the place of origin, the place of 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 amending and supplementing the rules for derogations by the competent authorities provided for in paragraphs 1 and 2 of this Article.

Article 205
Delegation of power concerning specific requirements and derogations for exhibition, zoos, pet shops, garden ponds, commercial aquaria and wholesalers

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

(a) specific requirement supplementing the rules laid down in from Sections 1 to 4 and for the movements of aquatic animals for the following purposes:

  (i) zoos, pet shops and wholesalers;

  (ii) exhibitions and for sporting, cultural and similar events; or

  (iii) intended for commercial aquaria;

(b) derogations from Sections 1 to 4 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).

Article 206
Implementing power for temporary derogations for movements of specific species or categories of aquatic animals

The Commission shall, by means of implementing acts lay down rules concerning temporary derogations from the 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, Article196(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) and204(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.

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 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

The Commission shall take the following matters into account, 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:

(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 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 aquaculture 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 point (a) and they are being moved or one of following purposes:

   (a) 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 a 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); and

   (b) they are intended for one of the following purposes:

      (i) an aquaculture establishment;

      (ii) release into the wild;

      (iii) human consumption.

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 point (a) and they are being moved or one of following reasons:

(a) 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(1) and (2) or the rules adopted pursuant to Article 55(2), Articles 67 and68, Articles 71(3) and 74(3), Article 79, Article 81(2) and Article 248 for one or more of listed diseases referred to in Article 8(1)(a) and (b);

(b) they are intended for one of the following uses:

(i) an aquaculture establishment;

(ii) released into the wild;

(iii) human consumption.

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. Operators shall only move aquatic animals other than aquaculture animals referred to in Article 208(1) and (2) 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) where, due to the risk involved with the movement of those aquatic animals, animal health certification is necessary to ensure compliance with the following movement requirements for the listed species of animals:

(a) the requirements provided for in Sections 1 to 5 and the rules adopted pursuant to those Sections;

(b) 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) and 74(3), Article 79 and Article 81(2);

(c) emergency measures provided for in the rules adopted pursuant to Article 248.

2. Article 208 shall also apply to wild aquatic animals intended for an aquaculture establishment, unless the competent authority of origin concludes that the certification is not feasible due to the nature of the place of origin of those wild aquatic animals.

3. The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, provided for in paragraph 2 of this Article, 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 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 such consignments are traceable and they comply with the animal health requirements for such movement provided for in Sections 1 to 5.

Article 211
Delegation of powers concerning animal health certification for aquatic animals

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 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;

(iv) the place of destination of the aquatic animals;

(b) special rules for animal health certification provided for in Articles 208 and 209 where alternative 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.

(c) detailed rules on the animal health certificates required to accompany movements of aquatic animals for scientific purposes referred to in Article 204(1).

Article 212
Contents of animal health certificates

1. The animal health certificate 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 of the aquatic animals;

   (c) the number, volume or weight of aquatic animals;

   (d) the necessary information needed to demonstrate that the animals comply with the movement requirements provided for in Sections 1 to 5.

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 be empowered to 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
Operators obligation to ensure that animal health certificates accompany the aquatic animals to the place of destination and delegated acts

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 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;

(b) where necessary, subject the aquatic animals 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, Article196(1), Articles 197 and 198, Article 199(1) and (2), Article 200, Articles 202(1), 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), 202(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 and signed by the official veterinarian;

(b) remain valid for a period of time, provided for in the rules adopted pursuant to paragraph 4(b), during which time the aquaculture 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 be empowered to 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 of this Article 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.

Article 217
Electronic health certificates

Electronic animal health certificates, produced, handled and transmitted by means of IMSOC, may replace accompanying animal health certificates provided for in Article 208 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.

Article 218
Self- declaration by operators for movements of aquaculture 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;

(b) a description of the aquaculture animals, the species, their quantity, weight or volume 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.

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 of this Article for different species and categories of aquaculture animals;

(b) additional information to be contained in the self-declaration document to the one provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for a model form of the self-declaration document provided for in paragraph 1 of this Article.

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 between Member States

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.

For the purposes of the notification provided for in the first paragraph of this Article, 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(1), unless a derogation has been granted in accordance with Article 221(1)(c) for such notification.

2. The notification referred to in paragraph 1 of this Article shall be carried out whenever possible, through IMSOC.

3. Member States shall designate regions for the management of notifications of movements by the competent authority as provided for in paragraph 1 of this Article.

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 IMSOC 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 be empowered to adopt delegated acts in accordance with Article 253 concerning:

   (a) the requirement for notification by operators in accordance with Article 219(1) of movements between Member States of aquatic animals of categories or species other than those referred to in Article 219(1)(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(1) and 220(1);

   (c) derogations from the notification requirements provided for in Article 219(1)(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 IMSOC system;

(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 format of notifications by:

(i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219(1);

(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(1);

(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 3
Movements within the Union of aquatic pet animals

Article 222
Non-commercial movements of aquatic pet animals and delegated and implementing acts

1. Pet keepers shall only carry out non-commercial movements of aquatic pet animals of the species listed in Annex I if appropriate disease prevention and control measures have been taken to ensure that they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) and emerging diseases to animals at the place of destination and during transport.

2. Article 112 and the rules laid down in delegated acts pursuant to Article 114(f) and in implementing acts adopted pursuant to Article 117 shall apply for the identification, registration and traceability of aquatic pet animals.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease prevention and control measures referred to in paragraph 1 of this Article to ensure that the aquatic pet animals do not pose a significant risk for the spread of diseases referred to in Article 8(1)(d) and emerging diseases to animals during transport and at the place of destination, when relevant taking into account the health status of the place of destination.

4. The Commission may, by means of implementing acts lay down rules concerning the disease prevention and control measures provided for in paragraph 1 of this Article and the rules adopted pursuant to paragraph 2 thereof.

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 in the Union, 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 either establishments or food business establishments or are obtained from animals, which come from either establishments food business establishments 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;

(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), Article 56, Article 61(1)(a), Article 62(1), Articles 65(1)(c), 70(1)(b) and 74(1)(a), Articles 78(1) and (2), and 80(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3) and 74(3) and Article 79 and Article 80(3) and 81(2) unless derogation have been provided for in those rules.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements supplementing paragraph 2 of this Article for movements of products of animal origin from aquatic animals other than live aquatic animals, taking into account:

(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.

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 are allowed to leave a restricted zone subject to emergency measures provided for in rules adopted pursuant to Article 248 and such products of animal origin originate from aquatic animals of species subject to those emergency measures;

(b) products of animal origin from aquatic animals that are allowed to leave a restricted zone subject to disease control measures in accordance with the 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), Articles 78(1) and (2), 80(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3) and 74(3), Article 79 and Articles 80(3) and 81(2) and such products of animal origin originate from aquatic animals of species subject to those disease control measures.

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.

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 of this Article.

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 of this Article 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 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 or the volume 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 66;

(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 other than live aquatic animals 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 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, 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, 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, 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 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 of this Article 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 listed species for a listed disease referred to in Art 8(1)(d), and those other animals, or their germinal products or products of animal origin represent a risk to public or animal health: 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;

(b) the requirements concerning traceability provided for in Articles 102 to 105 and Articles 112 and 113 for other animals and Article 119 for germinal products;

(c) movement requirements:

  (i) for other animals mainly living in terrestrial environment or are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in paragrapah 3(d) and (e) of Article 229, provided for in Section 1 and Section 6 of Chapter 3 of Title I of Part IV, Chapers 4 and 5 of Title I of Part IV;

  (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 and Chapter 2 of Title II;

  (iii) for other pet animals, the requirements provided for in Articles 112 and 152;

  (iv) for germinal products the general requirements for movements provided for in Articles 155 and 156 and the special requiremments 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 supplementing and amending the requirements for other animals, and their germinal products or products of animal origin, as provided for in Article 228, which are necessary to mitigate the risk of the diseases referred to therein, concerning:

(a) the requirements on registration, approval, record keeping and registers for establishments keeping or transporters transporting other animals, and their germinal products or products of animal origin, as provided for in Article 228(a);

(b) traceability requirements for other animals and their germinal products, as provided for in Article 228(b);

(c) movement requirements for other animals and their germinal products and products of animal origin, as provided for in Article 228(c);

(d) requirements on animal health certification obligations by operators and the competent authority and self-declaration obligations by operators for other animals and their germinal products and products of animal origin, as provided for in Article 228(d);

(e) requirements on notification of movement by operators and the competent authority for other animals and their germinal products and products of animal origin, as provided for in Article 228(e).

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. The Commission shall take one or more of the following criteria into account when adopting the delegated acts and implementing acts provided for in paragraphs 1 and 2:

(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 evnvironment 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, regardles 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 only permit the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries or territories if they comply with the following requirements:

   (a) they come from a third country or territory, listed in accordance with Article 231 for the particular species and category of animals, or germinal products or products of animal origin, or zone or compartment thereof, unless they are covered by a derogation or additional rules adopted pursuant to Article 241(1);

   (b) they come from establishments which are approved and listed where such approval and listing is required by Article 234 and rules adopted pursuant to Article 235;

   (c) they comply with the animal health requirements for entry into the Union laid down in delegated acts adopted pursuant to Article 236(1), 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. Operators 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 45 of Regulation (EU) No XXX/XXX *[Publication office: enter number]*, unless derogation is provided for pursuant to that Regulation at the point of entry into the Union.

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 shall, 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, taking into account 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.

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, suspend or withdraw from the list provided for in Article 231(1) 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).

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 suspended or withdrawn from the list provided for in Article 231(1) 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 from that list 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. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules amending and supplementing the criteria for suspension and withdrawal of a third country or territory, or zones or compartments thereof, from the list provided for in Article 231(1), as provided for in paragraph 1 of this Article.

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.

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.

Article 235
Delegation of powers for approval and listing of establishments

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules derogating from the requirements of Article 234(1)(b) where alternative risk mitigating measures in place in the third country or territory provide equivalent guarantees for the animal health within the Union.

SECTION 4
ENTRY INTO THE UNION OF SPECIES AND CATEGORIES OF ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN

Article 236
Delegation of powers for animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin

1. The Commission shall be empowered to 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.

2. The animal health requirements provided for in paragraph 1(a) 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) be equivalent 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 of this Regulation.

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 of this Article and provided that such requirements have not already been laid down pursuant to the Union legislation referred to in Article 258(2), Members State may apply national rules, provided that those rules:

(a) comply with the requirements laid down in paragraph 2 of this Article and take the matters referred to in Articles 237 and 238 into account;

(b) are not less stringent than those which are laid down in Titles I and II of Part IV.

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 provided they are accompanied by:

   (a) an animal health certificate issued by the competent authority of the third country or territory of origin;

   (b) declarations or other documents, where required by the rules adopted pursuant to paragraph 4(a).

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 IMSOC, 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(3);

   (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 requirements provided for in paragraph 1(a), 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(1).

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 or germinal products;

(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(1) and Article 241.

2. The animal health certificate referred to in Article 239(1)(a) 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:

(a) the information to be contained in the animal health certificate referred to in Article 239(1)(a) in addition to that referred to in paragraph 1of this Article;

(b) the information to be contained in declarations or other documents referred to in Article 239(1)(b).

4. The Commission may, by means of implementing acts, lay down rules concerning 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 delegated and implementing acts adopted pursuant to paragraph 3 and 4 of this Article, as regards a particular species or categories of animals, germinal product or product of animal origin, and provided that such rules have not been laid down pursuant to the Union legislation referred to in Article 258(2), Members State may apply national rules, provided they comply with the conditions laid down in paragraph 1 of this Article.

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

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the requirements provided for in Article230(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;

(ii) which are pet animals;

(iii) intended to be used for scientific 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 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 the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No. XXX/XXX *[No to be added…on official controls*].

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. Any natural or legal person bringing disease agents into the Union shall:

   (a) 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.

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

1. 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 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 of this Article in the event of a unfavourable disease situation in third countries or territories concerning listed diseases referred to in Article 8(1)(d) or emerging diseases, and by taking into account 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 the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No. *XXX/XXX [Number to be added - on official controls]*.

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:

(a) means of transport for animals, germinal products, products of animal origin, animal by-products and derived products;

(b) equipment, packaging material or transport water for animals, germinal products, products of animal origin, animal by-products and derived 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 the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No. *XXX/XXX [Publication office: No of Regulation]* on official controls.

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, 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.

However, if requested by the competent authority of the importing third country or territory, or if established by the laws, regulations, standards, codes of practice and other 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.

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 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, 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 in of Chapter 1 of Title II of Part III;

      (ii) referred to in Article 8(1)(b) and (c), the disease control measures laid down in 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 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 Member States other than the Member State 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, 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.

3. The competent authority referred to in paragraph 1 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) and (2), 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 Article 247(1) and (2);

(b) the Commission considers the measures taken pursuant to Article 246(1) and Article 247(1) and (2) 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) and (2) 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 a consignment 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 a consignment, 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 immediately:

(a) 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 consignment;

(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, 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 consignment in question and of the origin of the consignment by means of IMSOC.

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 consignments of animals and products and means of transport and other material that may have come into contact with such consignments, 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 consignments of animals and products and means of transport and other material that may have come into contact with such consignments, 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 Annexes I and II

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to Annexes I and II in order to take account of technical progress, scientific developments and changed circumstances in public and animal health.

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.

2. The power to adopt delegated acts referred to in Articles 4(2), 6(2), 9(2), 11(3), 13(2), 15(2), 16(3), 18(3), 24, 28, 30(4), 31(2), 34(2), 37(5), 39, 41(3), 42(5), 44(1), 47, 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64(4), 67, 68(2), 70(3), 72(2), 73(3), 74(3), 76(2), 79, 80(4), 85(3), 89(3), 92(2), 96(3), 100(1), 103(2), 114, 115, 119(1), 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, 159(5), 160(3), 162(2), 163(3), 164(3), 165(5), 166(3), 174(3), 179(2), 184(1), 188(1), 191(2), 196(2), 199(3), 200(3), 201(2), 202(2), 203(2), 204(3), 205, 211, 213(1), 214, 216(4), 218(3), 221(1), 222(3), 223(3), 224(5), 225(3), 229(1), 231(3), 233(3), 235, 236(1), 239(4), 240(3), 241(1), 242(2), 243(1), 244(2), 252, 259(2), 260(2) and 261(2) shall be conferred on the Commission for an indeterminate period of time from[(*)].

3. The power to adopt delegated acts referred to in Article 229(1) 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.*

4. The delegation of power listed in paragraph 1 of this Article and referred to in Article 229(1) 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 paragraph 2 of this Article and pursuant to Article 229(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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.

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.

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.

TITLE III
Member States measures

Article 257
Member States measures

1. Member States may apply additional or more stringent measures within their territories than those laid down in this Regulation concerning only:

   (a) responsibilities for animal health provided for in Chapter 3 of Part I;

   (b) notification within Member States provided for in Article 16;

   (c) surveillance provided for in Chapter 2 of Part II;

   (d) registration, approval, record keeping and registers provided for in Chapter 1 of Titles I and Chapter 1 of Title II of Part IV;

   (e) traceability requirements for kept terrestrial animals and germinal products provided for in Chapter 2 of Title I of Part IV.

2. The national measures referred to in paragraph 1 shall be in accordance with 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 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,

– Regulation (EC) No 1760/2000,

– Directive 2001/89/EC,

– Directive 2002/60/EC,

– Directive 2002/99/EC,

– Directive 2003/85/EC,

– Regulation (EU) No[XXX/XXX [*Publication office: Number to be inserted… non-commercial movements of pet animals and repealing Regulation (EC) No 998/2003*],

– 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.

3. The acts adopted by the Commission pursuant to the acts of the Council and the European Parliament referred to in paragraph 2 shall remain in force in so far as they are not in contradiction with the rules laid down in this Regulation.

Article 259
Transitional measures related to the repeal of Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004 and Directive 2008/71/EC

1. Notwithstanding Article 258(2) of this Regulation, Regulations (EC) No 1760/2000, and (EC) No 21/2004 and Directive 2008/71/EC shall continue to apply until the 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 252 concerning the date on which the acts referred to in paragraph 1 of this Article shall no longer apply.

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 Articles 114 and 115 of this Regulation.

Article 260

Transitional measures related to the repeals of Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2000/75/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, 2000/75/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC shall continue to apply until the 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 on which the Directives referred to in paragraph 1 of this Article shall no longer apply.

   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 44(1), 47(1) 48(3), 53(1) 54(3) and 58(2), Article 63, Article 64(4), Article 67, and Articles 68(2) and 70(3) of this Regulation.

Article 261

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

1. Notwithstanding Article 258(2) of this Regulation, Regulation (EU) No [XXX/XXX] shall continue to apply until the 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 to Article 253 concerning the date on which Regulation XXX/XXX shall no longer apply.

   That date shall be the date of the application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 114(f), and Articles 152(2) and 222(3) 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 36 months 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	*For the Council*
The President	*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, and bumble bees and molluscs and crustaceans)

Ornamental aquatic animals

Amphibia

Reptiles

Birds: all species of birds except poultry

Mammals: rodents and rabbits other than those intended for food production.

ANNEX II

Species of Ungulates

Taxon		
Order	**Family**	**Genera/Species**
Perissodactyla	Equidae	*Equus* spp.
	Tapiridae	*Tapirus* spp.
	Rhinoceritidae	*Ceratotherium* spp., *Dicerorhinus* spp., *Diceros* spp., *Rhinoceros* spp.
Artiodactyla	Antilocapridae	*Antilocapra* ssp.
	Bovidae	*Addax* ssp., *Aepyceros* ssp., *Alcelaphus* ssp., *Ammodorcas* ssp., *Ammotragus* ssp., *Antidorcas* ssp., *Antilope* ssp., *Bison* ssp., *Bos* ssp.(including *Bibos, Novibos, Poephagus*), *Boselaphus* ssp., *Bubalus* ssp. (including *Anoa*), *Budorcas* ssp., *Capra* ssp., *Cephalophus* ssp., *Connochaetes* ssp., *Damaliscus* ssp.(including *Beatragus*), *Dorcatragus* ssp., *Gazella* ssp., *Hemitragus* ssp., *Hippotragus* ssp., *Kobus* ssp., *Litocranius* ssp., *Madogua* ssp., *Naemorhedus* ssp. (including *Nemorhaedus* and *Capricornis*), *Neotragus* ssp., *Oreamuos* ssp., *Oreotragus* ssp., *Oryx* ssp., *Ourebia* ssp., *Ovibos* ssp., *Ovis* ssp., *Patholops* ssp., *Pelea* ssp., *Procapra* ssp., *Pseudois* ssp., *Pseudoryx* ssp., *Raphicerus* ssp., *Redunca* ssp., *Rupicapra* ssp., *Saiga* ssp., *Sigmoceros-Alecelaphus* ssp., *Sylvicapra* ssp., *Syncerus* ssp., *Taurotragus* ssp., *Tetracerus* ssp., *Tragelaphus* ssp. (including *Boocerus*).
	Camelidae	*Camelus* ssp., *Lama* ssp., *Vicugna* ssp.
	Cervidae	*Alces* ssp., *Axis-Hyelaphus* ssp., *Blastocerus* ssp., *Capreolus* ssp., *Cervus-Rucervus* ssp., *Dama* ssp., *Elaphurus* ssp., *Hippocamelus* ssp., *Hydropotes* ssp., *Mazama* ssp., *Megamuntiacus* ssp., *Muntiacus* ssp., *Odocoileus* ssp., *Ozotoceros* ssp., *Pudu* ssp., *Rangifer* ssp.
	Giraffidae	*Giraffa* ssp., *Okapia* ssp.
	Hippopotamindae	*Hexaprotodon-Choeropsis* ssp., *Hippopotamus* ssp.
	Moschidae	*Moschus* ssp.
	Suidae	*Babyrousa* ssp., *Hylochoerus* ssp., *Phacochoerus* ssp., *Potamochoerus* ssp., *Sus* ssp.,
	Tayassuidae	*Catagonus* ssp., *Pecari-Tayassu* ssp.
	Tragulidae	*Hyemoschus* ssp., *Tragulus-Moschiola* ssp.
Proboscidae	Elephantidae	*Elephas* ssp., *Loxodonta* ssp.

ANNEX III

Correlation table referred to in Article 257 (2)

1. Directive 64/432/EC

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	-

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 41and 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
Article 6	Article 159 and 160
Article 7	Articles 230(1)(a) and 231
Article 8	Articles 230(1)(b), 234 and 235
Article 9	Articles 230(1)(c), 236 and 238
Article 10	Articles 230(1)(d), 239, 240

Article 11	Articles 230(2) and 249 to 251
Article 14	Articles 246 to 248
Article 15	-
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-

8. Directive 90/429/EEC

Directive 90/429/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Articles 157 and 158
Article 4	-
Article 5(1) Article 5(2)	Articles 89 and 92 Article 96
Article 6(1) Article 6(2)	Articles 159 and 160 -
Article 7	Articles 230(1)(a) and 231
Article 8	Articles 230(1)(b), 234 and 235
Article 9	Articles 230(1)(c), 236 and 238
Article 10	Article 230(1)(d), 239, 240
Article 11(1) Article 11(2) and (3)	Article 230(2) -

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
Article 1	-
Article 2	Articles 4 (partially), 150(3) and 220(3)
Article 3(1)(2)(3) and (5)	Articles 127 and 128
Article 3(4)	Article 136
Article 4(1)	Articles 121(2)(b), 127 and 128
Article 4(2)	Article 125
Article 4(3)	Article 128
Article 4a	Article 128
Article 4b(1) to (3)	Article 128
Article 4b(4)	Article 130
Article 4b(5)	Article 129
Article 4b(6)	Articles 121(1) and 122

Article 4c(1) and (2)	Article 128
Article 4c(3)	Articles 130 and 132
Article 5	Article 128
Article 6	Article 128
Article 7(1) to (3)	Articles 30, 31 and 32
Article 7(4)	-
Article 8(1) to (3)	Articles 36, 39 and 40
Article 8(4)	-
Article 8a(1)	Articles 89(1)(a), 92, 93 and 131
Article 8a(2)	Article 97, 100
Article 8a(3)	Articles 93, 94 and 96
Article 8a(4)	Article 95
Article 8a(5)	Article 92(1)(d) and (2)(d)
Article 8b(1)	Articles 82, 89(1)(a), 92, 93, 97, 100 and 131
Article 8b(2)	Articles 89, 92, 93
Article 8b(3)	Article 95
Article 8b(4)	-
Article 8c(1)	Articles 85 and 122
Article 8c(2)	Article 99
Article 8c(3)	Article 122(1)(a)
Article 8c(4) and (5)	-
Article 9	Articles, 140, 141, 142, 143, 144, 145, 146 and 150
Article 10	-
Article 11	-
Article 12	Article 141(b)
Article 14	-

Article 15	-
Article 17	-
Article 18	-

10. Decision 91/666/EEC

Decision 91/666/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Article 48
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)
Article 3	Article 16
Article 4	Articles 53 to 57 and 59
Article 5	Articles 46 and 47

Article 6	Articles 60 to 69
Article 7	Article 57
Article 8	Article 64
Article 9	Articles 65, 66 and 67
Article 10	Articles 65, 66 and 67
Article 11	Article 68
Article 12	Article 71(1)
Article 13	Article 65(2)
Article 14	-
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
Article 5	Articles 133, 134, 140, 141

Article 6(A)	Articles 121, 123, 127, 128, 134, 137, 140 to 143
Article 6(B)	-
Article 7(A)	Articles 121, 123, 127, 128, 134, 137 and 140 to 143
Article 7(B)	-
Article 8	Articles 121, 123, 133 and 140 to 143
Article 9	Articles 121, 123, 133 and 140 to 143
Article 10(1) to (4)	Articles 121, 123, 133, 140 to 143
Article 10(5) to (7)	-
Article 10a	-
Article 11(1)	Article 155
Article 11(2) and (3)	Articles 155, 157 and 158, 140 to 143
Article 11(4)	Articles 92 and 96
Article 11(5)	Article 162
Article 12(1)	-
Article 12(2)	Article 246 to 248
Article 12(3)	Articles 82, 97, 100
Article 12(4)	Articles 140 to 146 and 149 to 151
Article 12(5)	-
Article 12(6)	Article 256
Article 13(1)	Articles 133, 140 to 146 and 148
Article 13(2)	Articles 90, 92, 93 to 96
Article 14	Articles 30, 31 and 32
Article 15	Articles 36, 39, 40 and 41
Article 16	Articles 230(1) and 236
Article 17(1)	Article 230(1)(a)(b) and (c)

Article 17(2)	Article 231,
Article 17(3)	Article 231, 234, 235
Article 17(4) and (5)	-
Article 18	Article 230(1)(d), 239
Article 19	Article 236
Article 20	Articles 230(2), 246 to 248
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
Article 1	-
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4	Articles 53 to 56, 57(1) and 59
Article 5	Articles 60 to 63
Article 6	Article 63
Article 7	Articles 57, 43(2)(d)

Article 8	Articles 55 and 56
Article 9(1) Article 9(2) to (7)	Article 64 Articles 65 to 68
Article 10	Articles 65 and 67
Article 11	Articles 67(b), 68(1)(b) and (2)(a)
Article 12	Article 54
Article 13	Article 65(2)
Article 14	-
Article 15	-
Article 16	Articles 46 and 47
Article 17	Article 47
Article 18	Articles 65(e), 67 and 69
Article 19(1) to (3) Article 19(4) Article 19(5)	Articles 53 to 56 Articles 57(1), 60 to 63 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 and228(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
Article 11	Article 241(1)(c)(ii)
Article 12	-
Article 13	Article 241(1)(c)(i)
Article 14	-
Article 15	-
Article 16	Article 241(1)(c)(v)
Article 17	-
Article 18	-
Article 19	-
Article 20	-

15. Directive 92/119/EEC

Directive 92/119/EEC	This Regulation
Article 1	-
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4	Articles 53 to 57 and 59
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) Article 10(2)	Articles 64 and 67 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) Article 10(d) and (e) Article 10(f)	Articles 114, 115, 117 - Article 258
Article 11	-
Article 12	-
Article 13	-
Article 14	-
Article 15	-
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-
Article 22	-
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19. Directive 2001/89/EC

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20. Directive 2002/60/EC

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21. Directive 2002/99/EC

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22. Directive 2003/85/EC

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23. Regulation (EC) No. 998/2003

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24. Regulation (EC) No 21/2004

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25. Directive 2004/68/EC

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26. Directive 2005/94/EC

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27. Directive 2006/88/EC

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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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