

# COUNCIL OF THE EUROPEAN UNION

# Brussels, 24 April 2014

8306/14

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# **INFORMATION NOTE**

from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a regulation of the European Parliament and of the Council on Animal Health
	- Outcome of the European Parliament's first reading
	(Strasbourg, 14 to 17 April 2014)

# I. INTRODUCTION

The Committee on Agriculture and Rural Development presented a report consisting of 334 amendments (amendments 1-334) to the proposed Regulation. In addition:

- the Greens/EFA political group tabled three amendments (amendments 335-337); and
- the EUL/NGL political group tabled fourteen amendments (amendments 338-351).

#### II. DEBATE

The debate, which took place on 14 April 2014, was a joint debate, which is summarised in document 8304/14.

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#### III. **VOTE**

When it voted on 15 April 2014, the Parliament voted to adopt 331 amendments to the Commission's proposal (amendments 1-54, 56-236 and 239-334).

The text of the amendments adopted and the European Parliament's legislative resolution are set out in the Annex hereto.

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# Animal health \*\*\*I

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on Animal Health (COM(2013)0260-C7-0124/2013-2013/0136(COD))

# (Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0260),
- having regard to Article 294(2) and Articles 43(2) and 114(3) and point (b) of Article 168(4) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0124/2013),
- having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Austrian Federal Council, asserting that the draft legislative act does not comply with the principle of subsidiarity,
- having regard to the opinion of the European Economic and Social Committee of 10 December 2013<sup>1</sup>,
- after consulting the Committee of the Regions,
- having regard to Rules 55 and 37 of its Rules of Procedure,
- having regard to the report of the Committee on Agriculture and Rural Development and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Fisheries (A7-0129/2014),
- 1. Adopts its position at first reading hereinafter set out;
- 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
- 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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Not yet published in the Official Journal.

# Proposal for a regulation Title

Text proposed by the Commission

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Animal Health

#### Amendment

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the prevention and control of animal diseases which are transmissible among animals or to humans

#### Amendment 2

# Proposal for a regulation Recital 1

Text proposed by the Commission

(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.

#### Amendment

(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 and can have a major influence on public health and food safety.

## **Amendment 3**

# Proposal for a regulation Recital 2

Text proposed by the Commission

(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.

## Amendment

(2) As recent experiences have demonstrated, transmissible animal diseases may also have a significant impact on public health *and food safety*, as for example in the case of avian influenza and salmonella.

## **Amendment 4**

Proposal for a regulation Recital 3 a (new)

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#### Amendment

(3a) Proper control of infectious animal diseases, including zoonotic diseases, is a prerequisite for a functioning single market for trade in live animals, animal products and food.

#### Amendment 5

Proposal for a regulation Recital 4 a (new)

Text proposed by the Commission

#### Amendment

(4a) Article 13 of the Treaty on the Functioning of the European Union (TFEU) recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect animal welfare requirements guaranteeing their humane treatment and avoiding them unnecessary pain and suffering. Such rules are based on scientific evidence and may improve animal health.

### Amendment 6

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

# Amendment

(5a) With a view to making these provisions as clear as possible, and thus ensuring that they are fully and correctly implemented, a criterion and principle for organising the delegated and implemented acts adopted pursuant to this Regulation needs to be laid down.

Amendment 7

Proposal for a regulation Recital 6

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(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<sup>11</sup>. 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.

<sup>11</sup> COM (2007) 539 final.

## **Amendment 8**

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

## Amendment 9

Proposal for a regulation Recital 9

#### Amendment

(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<sup>11</sup>. It aims to promote animal health through putting greater focus on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. It proposes the adoption of a 'single and simplified regulatory framework for animal health' seeking convergence to international standards while ensuring a firm commitment to high standards of animal health.

<sup>11</sup> COM (2007) 539 final.

## Amendment

(7a) The Commission Communication on the new Animal Health Strategy for the European Union stresses that a joint approach should be taken to prevention and biosecurity measures, given that contagious disease agents can spread easily from one farm to another.

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(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.

#### Amendment

(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, food security, economic, social, cultural aspects and especially animal welfare, given the interdependency of animal welfare and animal health.

#### Amendment 10

# Proposal for a regulation **Recital 19**

Text proposed by the Commission

(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.

### Amendment

(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 lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance and good animal husbandry are applicable to both groups of animal species. Accordingly, the scope of this Regulation should cover both terrestrial and aquatic animals and aligns those animal health rules where applicable. However, for certain aspects, in particular the registration and approval of establishments and the traceability and movements of animals within the Union, this Regulation adheres to the approach adopted in the past, which was to lay down different sets of animal health rules for terrestrial and aquatic animals due to their different environments and accordingly different requirements to safeguard health.

# **Amendment 11**

# Proposal for a regulation

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#### Recital 24

## Text proposed by the Commission

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

## **Amendment 12**

# Proposal for a regulation Recital 30

Text proposed by the Commission

(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.

#### Amendment

(24) Furthermore, the preventive and control measures for each transmissible animal disease should be "tailor-made" in order to address its unique epidemiological profile and its consequences. The preventive and control rules applying to each of them should therefore be disease specific, and strict attention should be paid to different regional conditions.

#### Amendment

(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 and changes in economic and trade relations inside and outside the Union. Unless they are totally eradicated, diseases currently confined to limited geographical areas could spread and cause economic damage over wider areas. Furthermore, scientific progress may also lead to new knowledge and increased awareness concerning existing diseases. At the same time, 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"<sup>23</sup> and a tool for such an exercise. This Regulation should introduce such an

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approach in Union legislation.

<sup>23</sup> http://www.oie.int/en/support-to-oiemembers/global-studies/categorisation-of-

animal-diseases/.

# **Amendment 13**

# Proposal for a regulation Recital 31

Text proposed by the Commission

(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.

#### **Amendment 14**

# Proposal for a regulation **Recital 35**

Text proposed by the Commission

(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.

<sup>23</sup> http://www.oie.int/en/support-to-oiemembers/global-studies/categorisation-ofanimal-diseases/.

#### Amendment

(31) It is necessary to establish a harmonised list of transmissible animal diseases ('listed diseases'), which should be set out in a table in an Annex attached to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.

# Amendment

(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. It is thus necessary to establish a harmonised list of species to which the measures for specific listed diseases should apply at Union level ('listed species') and which should be set out in a table in an Annex to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.

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# Proposal for a regulation Recital 36

Text proposed by 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.

# Amendment

(36) Based on the importance and the level of impact of a listed disease, its distribution, prevalence and incidence in the Union, *the risk of its spreading* 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.

## **Amendment 16**

# Proposal for a regulation Recital 37

Text proposed by the Commission

(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.

## Amendment

(37) It is necessary to determine, and lay down in a list, the application of the rules, provided for in this Regulation, to listed diseases at Union level. Such a list should be kept and updated in a table in an Annex to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.

# **Amendment 17**

# Proposal for a regulation Recital 38

Text proposed by the Commission

(38) Operators, animal professionals and pet keepers working with animals are in the

#### Amendment

(38) Operators, animal professionals and pet keepers working with animals are in the

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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. 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, and should work individually and collectively to improve animal health practices.

## **Amendment 18**

# Proposal for a regulation Recital 41

Text proposed by the Commission

(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.

## Amendment

(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. The same may also be said of pet keepers, while bearing in mind their different position and level of responsibility.

## **Amendment 19**

# Proposal for a regulation Recital 46

Text proposed by the Commission

(46) The competent authority cannot always perform all the activities required to

#### Amendment

(46) The competent authority cannot always perform all the activities required to

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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.

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 and other qualified professionals. For the same reason, it is of utmost importance that those veterinarians and professionals have no conflicts of interest. In order to ensure that the necessary conditions are laid down for the general application of disease prevention and control measures across the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect to the delegation of the performance of those activities to veterinarians and their appropriate training.

#### Amendment 20

# Proposal for a regulation Recital 47

Text proposed by the Commission

(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.

## Amendment

(47) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, veterinarians, animal health professionals, other stakeholders and trading partners. To secure their support it is necessary to organise decision making procedures and the application of the measures provided for in this Regulation in a clear 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, food safety or the environment and when a case is of public interest.

# **Amendment 21**

Proposal for a regulation Recital 49

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(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.

# Amendment

(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 veterinarians or aquatic animal health professionals. At the same time, a professional approach to notification and reporting must be ensured, in order avoid unnecessary health scares. Those notification obligations should therefore be applicable to all operators, animal professionals and pet keepers.

## **Amendment 22**

# Proposal for a regulation Recital 57

## Text proposed by the Commission

(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.

## Amendment

(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. In the context of this Regulation and with respect to wild animals, the role of hunters should also be recognised as instrumental in monitoring diseases due to their experience and knowledge of the diseases affecting wild animals. Similarly hunting associations and holder of hunting rights could also supplement the work of operators in monitoring wild animals.

## **Amendment 23**

Proposal for a regulation Recital 63

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(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.

# **Amendment 24**

Proposal for a regulation Recital 63 a (new)

Text proposed by the Commission

#### Amendment

(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.

#### Amendment

(63a) On the other hand, there are some diseases which are of Union concern but for which it is not necessary to require Member States to eradicate the disease. Member States have the possibility to establish voluntary eradication programmes for such diseases, if they decide that eradication is important for them. Such voluntary eradication programmes would be recognised at the Union level. This programme would entail

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implementing certain relevant disease control measures. It may also enable the Member State, subject to approval by the Commission, to require certain guarantees when receiving animals from other Member States or from third countries, such as additional testing for the disease and assurances about those test results in a movement certificate. Their programme may also be eligible for a Union financial contribution, if the disease is listed in [the new financial regulation] and they submit an application for funding.

## **Amendment 25**

Proposal for a regulation Recital 63 b (new)

Text proposed by the Commission

### Amendment

(63 b) 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 TFEU 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.

#### **Amendment 26**

# Proposal for a regulation Recital 75

Text proposed by the Commission

(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

## Amendment

(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

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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.

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, thereby significantly putting at risk public and animal health.

#### **Amendment 27**

# Proposal for a regulation Recital 76

Text proposed by the Commission

(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.

# **Amendment 28**

Proposal for a regulation Recital 79

## Amendment

(76) However, those control strategies may substantially vary between different listed diseases. Thus this Regulation should provide for rules on the use of veterinary medicinal products for the prevention and control of certain 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 **TFEU** 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 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.

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(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.

## Amendment

(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. Similarly, for those Member States which have not set up national antigen, vaccine and diagnostic reagent banks or which find that stocks are limited in the Union banks, criteria for access to the resources of other Member States should be established.

#### **Amendment 29**

Proposal for a regulation Recital 85 a (new)

Text proposed by the Commission

#### Amendment

(85a) According to Directive 2003/99/EC, Member States is to transmit a report to the Commission every year on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance. Similarly, as part of the control plans and control programme provided for in Regulation (EU) No. XX/201X on official controls and in Regulation (EC) No 2160/2003, Member States should take strategic measures to monitor, prevent and control other infectious animal diseases, including those not listed in the Annex to this Regulation. These measures should include a strategy for good animal husbandry and responsible use of veterinary medicines.

**Amendment 30** 

Proposal for a regulation Recital 86 a (new)

Text proposed by the Commission

Amendment

(86a) Disease control measures that

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become necessary in the event of a disease outbreak may adversely affect biodiversity and the conservation of farm animal genetic resources. In keeping with the Convention on Biological Diversity and the EU Biodiversity Strategy, the competent authority should take account of the impact on biodiversity and farm animal genetic resources when determining the application of disease control measures.

## **Amendment 31**

# Proposal for a regulation Recital 87

Text proposed by the Commission

(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.

#### **Amendment 32**

# Proposal for a regulation **Recital 88**

Text proposed by the Commission

(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

#### Amendment

(87) The occurrence of a listed disease in wild animals may pose a risk to public health and the health of kept animals, or vice versa. Special rules should therefore be laid down for disease control and eradication measures in wild animals, or, where needed, in kept animals.

## Amendment

(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

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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.

proportionate and take into account the characteristics of the listed disease in question, its distribution and its significance for the Member State *or region* concerned by it and the Union as a whole.

#### **Amendment 33**

# Proposal for a regulation Recital 105

Text proposed by the Commission

(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 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.

#### Amendment

(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 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. Nonetheless, these mortalities should be registered by the competent authority.

#### **Amendment 34**

# Proposal for a regulation Recital 108

Text proposed by the Commission

(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.

#### **Amendment**

(108) As *movements and* 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.

JDC/cc 19

DPG EI

# Proposal for a regulation Recital 111

# Text proposed by the Commission

(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.

## **Amendment 36**

# Proposal for a regulation Recital 121

# Text proposed by the Commission

(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

#### Amendment

(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 and are registered by the competent authority.

#### Amendment

(121) The specific nature of movements of pet animals represents an animal health risk which deviates significantly from that of other kept animals. Such movements should therefore *continue to* be *governed* by the provisions already adopted. This will ensure that pet animals do not pose a significant risk for the spread of transmissible animal diseases. The power to adopt rules concerning the disease prevention and control measures to be taken for such movements should be conferred on the Commission in accordance with Article 290 TFEU, without prejudice to the provisions of *Regulation (EU) No 576/2013.* 

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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.

#### **Amendment 37**

# Proposal for a regulation Recital 125

Text proposed by the Commission

(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.

#### Amendment

(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 may only interfere with the rules on the internal market laid down in Union legislation when this is scientifically justified on the grounds of controlling infectious disease and is proportionate in relation to the risk. Therefore, it is appropriate to set the framework for such national measures and ensure that they remain within the limits permitted under Union law.

#### **Amendment 38**

Proposal for a regulation Recital 154 – indent 19

Text proposed by the Commission

- 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  $820/97^{52}$ ,

Amendment

deleted

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EN

# <sup>52</sup> OJ L 204, 11.08.2000, p. 1.

#### Amendment 39

Proposal for a regulation Recital 154 – indent 24

Text proposed by the Commission

- 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]<sup>57</sup>,

57 0 - -

# <sup>57</sup> OJ L

#### **Amendment 40**

# Proposal for a regulation Recital 158

Text proposed by the Commission

(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.

## **Amendment 41**

Proposal for a regulation Recital 160

Amendment

deleted

#### Amendment

(158) In order to ensure legal certainty as regards the application of rules for identification and registration of animals, and disease control measures for certain zoonoses, the power to adopt acts in accordance with Article 290 *TFEU* should be delegated to the Commission in respect of the date on which Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC *and* 2005/94/EC cease to apply.

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(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.

#### Amendment

(160) It is of particular importance that the Commission carry out appropriate consultations *with stakeholders* 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.

#### **Amendment 42**

# Proposal for a regulation Article 1 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

#### Amendment

This Regulation lays down:

- (a) rules for the prevention and control of animal diseases, which are transmissible to animals or to humans;
- (b) instruments and mechanisms to facilitate progress towards the declaration of disease-free zones and territories;
- (c) priority actions; and
- (d) the division of responsibilities in the area of animal health.

# **Amendment 43**

Proposal for a regulation Article 1 – paragraph 2 – point a – point ii

Text proposed by the Commission

(ii) the effective functioning of the internal market;

#### Amendment

(ii) the effective functioning of the internal market, *and food and feed safety*;

#### Amendment 44

# Proposal for a regulation

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# Article 1 – paragraph 2 – point a – point iii – introductory part

Text proposed by the Commission

Amendment

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

### **Amendment 45**

Proposal for a regulation

Article 1 – paragraph 2 – point a – point iii – indent 1

Text proposed by the Commission

Amendment

certain diseases;

 certain diseases and risk factors leading up to diseases;

#### Amendment 46

Proposal for a regulation

Article 1 – paragraph 2 – point b – point i – indent 2 a (new)

Text proposed by the Commission

Amendment

- biodiversity;

#### **Amendment 47**

Proposal for a regulation

Article 1 – paragraph 2 – point b – point i – indent 4 a (new)

Text proposed by the Commission

Amendment

- antimicrobial resistance;

## **Amendment 48**

Proposal for a regulation

Article 1 – paragraph 2 – point b – point i – indent 5 a (new)

Text proposed by the Commission

Amendment

 the need to protect and conserve rare animal breeds, and to preserve genetic diversity;

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# Proposal for a regulation Article 2 – paragraph 1 – point a

Text proposed by the Commission

(a) kept, non-kept and wild animals;

Amendment

(a) kept and wild animals;

## Amendment 50

Proposal for a regulation Article 4 – paragraph 1 – point 5

Text proposed by the Commission

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

#### Amendment

(5) 'kept animals' means *living* animals which are kept by humans;

## **Amendment 51**

Proposal for a regulation Article 4 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

## Amendment

(5a) 'non-kept animals of domesticated species' means animals which are not, or are no longer, under human supervision;

#### Amendment 52

Proposal for a regulation Article 4 – paragraph 1 – point 7

Text proposed by the Commission

(7) 'aquaculture animals' means aquatic animals subject to aquaculture;

# Amendment

(7) 'aquaculture animals' means aquatic animals subject to techniques designed to increase production above the natural capacity of the environment in question;

## **Amendment 53**

Proposal for a regulation Article 4 – paragraph 1 – point 8

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

#### Amendment

(8) 'wild animals' means animals which are *neither* kept animals *nor non-kept animals of domesticated species*;

## **Amendment 54**

Proposal for a regulation Article 4 – paragraph 1 – point 13

Text proposed by the Commission

(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;

## Amendment

(13) 'non-commercial movement' means movement for non-commercial purposes as defined in point (a) of Article 3 of Regulation (EU) No 576/2013;

## **Amendment 56**

Proposal for a regulation Article 4 – paragraph 1 – point 20

Text proposed by the Commission

(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;

### Amendment

(20) 'risk' means the likelihood of the *scientifically demonstrated or demonstrable* occurrence and the likely magnitude of the biological and economic consequences of *scientifically proven or provable* adverse effect on animal or public health:

## **Amendment 57**

Proposal for a regulation Article 4 – paragraph 1 – point 21 – introductory part

Text proposed by the Commission

(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:

#### Amendment

(21) 'biosecurity' means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases or microorganisms that have developed resistance to antimicrobials to,

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## from and within:

#### Amendment 58

Proposal for a regulation Article 4 – paragraph 1 – point 23

Text proposed by the Commission

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

Amendment

does not concern the EN version

#### **Amendment 59**

Proposal for a regulation Article 4 – paragraph 1 – point 37

Text proposed by the Commission

(37) 'outbreak' means one or more cases in an establishment, *household* or other place where animals are kept or located;

#### Amendment

(37) 'outbreak' means one or more cases in an establishment or other place where animals are kept or located;

#### Amendment 60

Proposal for a regulation Article 4 – paragraph 1 – point 50 a (new)

Text proposed by the Commission

# Amendment

(50a) 'processing establishment' means a food business approved in accordance with Article 4 of Regulation (EC) No 853/2004 for processing aquaculture animals for food purpose;

#### **Amendment 61**

Proposal for a regulation Article 4 – paragraph 1 – point 50 b (new)

Text proposed by the Commission

Amendment

(50b) 'disease control aquatic food establishment' means a food business approved in accordance with Article 177

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# and with Title II of Part IV;

Amendment

#### Amendment 62

Proposal for a regulation Article 4 – paragraph 1 – point 51

Text proposed by the Commission

deleted

- (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.

# **Amendment 63**

Proposal for a regulation Article 4 – paragraph 1 – point 51 a (new)

Text proposed by the Commission

Amendment

(51a) "veterinarian" means a professional with a comprehensive scientific education, licensed by the legal authority, to carry out, in an independent, ethical and personally responsible capacity, all aspects of veterinary medicine, in the interest of the animals, the client and society;

#### Amendment 64

Proposal for a regulation Article 4 – paragraph 1 – point 51 b (new)

Text proposed by the Commission

Amendment

(51b) "official veterinarian" means a veterinarian appointed by the competent authorities and appropriately qualified to perform the official controls and other

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official activities in accordance with the provisions laid down in Regulation (EU) .../2014 on official controls.

#### Amendment 65

Proposal for a regulation Article 5 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) listed *diseases*;

(a) the diseases listed in Annex -I;

#### **Amendment 66**

Proposal for a regulation Article 5– paragraph 2

Text proposed by the Commission

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

#### Amendment

2. A table of listed diseases, as referred to in point (a) of paragraph 1, is set out in Annex -I. The Commission shall be empowered to adopt delegated acts, taking due account of the opinions of the European Food Safety Authority, and after due public consultation with stakeholders and experts, in accordance with Article 253, concerning amendments to the listed diseases set out in this Annex to take account of technical and scientific progress, of the developments of relevant international standards and of the changed circumstances in public and animal health.

## **Amendment 67**

Proposal for a regulation Article 5 - paragraph 2 - subparagraph 2 - introductory part

That *list* shall *comprise* diseases which meet with the conditions laid down in the

paragraph, taking into account the criteria

for listing diseases laid down in Article 6:

following points (a) and (b) of this

Text proposed by the Commission

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

Amendment

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# Proposal for a regulation Article 5 – paragraph 2 – subparagraph 2 – point a – point iii

Text proposed by the Commission

Amendment

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

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

#### **Amendment 69**

Proposal for a regulation Article 5 – paragraph 2 – subparagraph 2 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iva) animal welfare and animal health;

#### Amendment 70

Proposal for a regulation Article 5 – paragraph 2 – subparagraph 3

*Text proposed by the Commission* 

Amendment

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

deleted

#### Amendment 71

Proposal for a regulation Article 5 – paragraph 2 – subparagraph 4

*Text proposed by the Commission* 

Amendment

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).

Where in the case of a disease representing an emerging risk of highly significant impact, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.

### Amendment 72

### Proposal for a regulation

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# Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

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)*:

#### Amendment

1. When modifying the list of diseases in accordance with Article 5(2), the Commission shall take account of the following criteria in determining whether a disease meets the conditions to be listed:

#### Amendment 73

Proposal for a regulation Article 6 – paragraph 1 – point a – point iv

Text proposed by the Commission

(iv) the capacity to develop resistance to treatments:

## Amendment

(iv) the capacity of pathogens to develop resistance to treatments with a focus on antimicrobial resistance;

### **Amendment 74**

Proposal for a regulation Article 6 – paragraph 1 – point e – point iii

Text proposed by the Commission

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

#### Amendment

(iii) the welfare of affected subpopulations of kept *animals*, *non-kept animals of* domesticated species and the health of wild animals:

## Amendment 75

Proposal for a regulation Article 6 – paragraph 2

Text proposed by the Commission

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.

## **Amendment**

2. The Commission shall be empowered, after due public consultation with stakeholders and experts, 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

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international standards.

# Amendment 76 Proposal for a regulation Article 7 – paragraph 1

Text proposed by the Commission

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*.

## Amendment 77

Proposal for a regulation Article 7 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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

## Amendment

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

## Amendment

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to the list of species, as referred to in paragraph 1 and set out in a table in Annex -I, to take account of technical progress, scientific developments and changed circumstances in public and animal health, after due public consultation with stakeholders and experts and taking due account of the opinions of the European Food Safety Authority.

### **Amendment 78**

Proposal for a regulation Article 7 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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:

## Amendment

That list shall *cover* 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:

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Proposal for a regulation Article 7 – paragraph 2 – subparagraph 2 – point ca (new)

Text proposed by the Commission

Amendment

ca) the use of those animals for breeding, production or slaughter.

**Amendment 80** 

Proposal for a regulation Article 7 – paragraph 2 – subparagraph 3

Text proposed by the Commission

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

Amendment

deleted

**Amendment 81** 

Proposal for a regulation Article 7 – paragraph 2 – subparagraph 4

Text proposed by the Commission

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).

Amendment

Where in the case of a disease representing an emerging risk of highly significant impact, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.

**Amendment 82** 

Proposal for a regulation Article 8 – paragraph 1 – introductory part

Text proposed by the Commission

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:

Amendment

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253, with due regard to the opinions of the European Food Safety Authority and after due public

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consultation with stakeholders and experts, modifying Annex -I and concerning the application of the disease prevention and control rules referred to in the following points to listed diseases:

## **Amendment 83**

# Proposal for a regulation Article 8 – paragraph 1 – point a – introductory part

Text proposed by the Commission

Amendment

(a) listed diseases subject to rules on:

(a) listed diseases for which immediate eradication measures must be taken as soon as they are detected, subject to rules on:

## **Amendment 84**

# Proposal for a regulation Article 8 – paragraph 1 – point b – introductory part

Text proposed by the Commission

Amendment

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

(b) listed diseases which should be controlled in all Member States with the long-term goal of eradicating them throughout the Union, subject to the disease prevention and control rules on:

#### **Amendment 85**

# Proposal for a regulation Article 8 – paragraph 1 – point c – introductory part

Text proposed by the Commission

Amendment

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

(c) listed diseases that are of relevance for certain Member States, and for which measures are needed to prevent them spreading to parts of the Union that are officially disease-free or have eradication programmes, subject to the disease prevention and control rules on:

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# Proposal for a regulation Article 8 – paragraph 1 – point d – introductory part

Text proposed by the Commission

Amendment

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

(d) listed diseases that are subject to the provisions of points (a), (b) and (c) above, and other diseases for which measures are needed to prevent them spreading on account of their introduction into the Union or movements between Member States, subject to the disease prevention and control rules on:

#### Amendment 87

# Proposal for a regulation Article 8 – paragraph 1 – point e – introductory part

Text proposed by the Commission

Amendment

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

(e) listed diseases that are subject to the provisions of points (a) and (b) above, and other diseases for which there is a need for monitoring within the Union, subject to the disease prevention and control rules on:

# **Amendment 88**

Proposal for a regulation Article 8 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

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

deleted

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# Proposal for a regulation Article 8 – paragraph 1 – subparagraph 3

Text proposed by the Commission

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).

#### **Amendment 90**

Proposal for a regulation Article 8 – paragraph 2 – introductory part

Text proposed by the Commission

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

#### **Amendment 91**

Proposal for a regulation Article 8 – paragraph 2 – point c

Text proposed by the Commission

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.

#### Amendment

Where, in the case of a disease representing an emerging risk of highly significant impact, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.

#### Amendment

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

## Amendment

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, *paying strict attention to the prevailing regional conditions*.

#### **Amendment 92**

Proposal for a regulation Article 9 – paragraph 1 – point b – introductory part

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(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:

#### Amendment

(b) take appropriate biosecurity measures, assisted by professional guides to good practice, especially applying good microbiological practice, 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:

## **Amendment 93**

Proposal for a regulation Article 9 – paragraph 1 – point ba (new)

Text proposed by the Commission

#### Amendment

(ba) observe the principle of good animal husbandry;

## **Amendment 94**

Proposal for a regulation Article 9 – paragraph 1 – point bb (new)

Text proposed by the Commission

## Amendment

(bb) ensure controlled use of veterinary medicines.

## Amendment 95

Proposal for a regulation Article 10 – paragraph 1 – introductory part

Text proposed by the Commission

1. Operators *and* animal professionals shall acquire knowledge of:

## Amendment

1. Operators, animal professionals *and pet keepers* shall acquire knowledge of:

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## Proposal for a regulation Article 10 – paragraph 1 – point b

Text proposed by the Commission

(b) biosecurity principles;

## Amendment

(b) biosecurity principles, *good animal* husbandry and responsible use of veterinary medicines,

## **Amendment 97**

Proposal for a regulation Article 10 – paragraph 3 – introductory part

Text proposed by the Commission

- 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.

## **Amendment 98**

Proposal for a regulation Article 11 – paragraph 1 – point a a (new)

Text proposed by the Commission

## Amendment

3. The knowledge provided for in paragraph 1 shall be acquired through professional experience or training in accordance with the requirements laid down in the respective Member State. Such training can also be provided by professional organisations.

## Amendment

(aa) advise operators about measures to minimise the risk of zoonotic diseases, food borne pathogens, residues, contaminants in order to ensure safe food;

## **Amendment 99**

Proposal for a regulation Article 11 – paragraph 1 – point c – point i

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EN

Amendment

(i) raising animal health awareness;

(i) raising animal health *and animal* welfare awareness;

## **Amendment 100**

Proposal for a regulation Article 11 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) continuous education on disease prevention, and the early detection and control of diseases;

## **Amendment 101**

Proposal for a regulation Article 11 – paragraph 1 – point c – point iii b (new)

Text proposed by the Commission

Amendment

(iiib) raising awareness on antimicrobial resistance and implications that might follow;

#### **Amendment 102**

Proposal for a regulation Article 11 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) advise operators and animal professionals on the basis of the latest knowledge available on matters concerning protection against biological hazards and other animal health aspects that are of importance to the type of establishment and the categories and species of animals kept there.

## **Amendment 103**

Proposal for a regulation Article 11 – paragraph 2 a (new)

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#### Amendment

2a. Bee health professionals may undertake activities attributed to veterinarians under this Regulation in relation to bees and bumble bees provided that they are authorised to do so under national legislation. In that event, paragraph 1 shall apply to those bee health professionals.

## **Amendment 104**

## Proposal for a regulation Article 11 – paragraph 3

Text proposed by the Commission

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.

#### Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the qualifications of veterinarians, *in accordance with Directive* 2005/36/EC and aquatic animal health professionals undertaking activities which fall within the scope of this Regulation.

## **Amendment 105**

## Proposal for a regulation Article 12 – paragraph 2

Text proposed by the Commission

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.

## Amendment

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, and ensure that the necessary level of knowledge is attained.

## **Amendment 106**

Proposal for a regulation Article 12 – paragraph 2 a (new)

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Amendment

2a. Member States shall establish the conditions under which the acquisition, maintenance and development of the basic knowledge of animal health under Article 10 by operators, animal professionals and pet owners can be ensured.

**Amendment 107** 

Proposal for a regulation Article 12 a (new)

Text proposed by the Commission

Amendment

Article 12a

Strategic measures for non-listed diseases

Member States shall take strategic measures for the monitoring, prevention and control of infectious animal diseases, including those not listed in the Annex to this Regulation, also with the aim of reducing the risk of development of antimicrobial resistance. These measures shall be adopted as part of the national control plans and control programme provided for in Article X of Regulation (EC) XX/201X on the official control of animal health or Article 5 of Regulation (EC) No 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents.

**Amendment 108** 

Proposal for a regulation Article 12 b (new)

Text proposed by the Commission

Amendment

Article 12b

**Border controls** 

Member States shall, with technical assistance at Union level as regards animal diseases listed in Annex -I to this

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Regulation, ensure that appropriate preventive, risk-based biosecurity measures are applied along their external borders, in cooperation with the competent authorities of the third countries concerned.

## **Amendment 109**

## Proposal for a regulation Article 13 – paragraph 1 – introductory part

Text proposed by the Commission

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

#### Amendment

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

## **Amendment 110**

Proposal for a regulation Article 13 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1 a. The competent authority may delegate one or more of the activities laid down in paragraph 1 to bee health professionals.

## **Amendment 111**

Proposal for a regulation Article 13 – paragraph 2 – point a

Text proposed by the Commission

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

## Amendment

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

## **Amendment 112**

Proposal for a regulation Article 13 – paragraph 2 – point c

Text proposed by the Commission

(c) minimum requirements for the training

**Amendment** 

(c) minimum requirements for the training

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of veterinarians provided for in Article 12(1)(c).

of veterinarians provided for in Article 12(1)(c), in accordance with Directive 2005/36/EC.

#### Amendment 113

# Proposal for a regulation Article 14

Text proposed by the Commission

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.

#### **Amendment 114**

Proposal for a regulation Article 14 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

Where measures are required with respect to the probable outbreak of a disease, 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, the need to avoid spreading panic unnecessarily and extent of that risk and the public interest in being informed.

## Amendment

The competent authority shall adopt all the necessary measures to inform citizens on the basic principles in the field of preventing the outbreak and spread of animal diseases, with a particular focus on the risk of persons travelling outside the Union bringing disease agents into the Union.

## **Amendment 115**

Proposal for a regulation Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

1. *Natural and legal persons* shall immediately notify:

Amendment

1. *Operators, animal professionals and pet keepers* shall immediately notify:

8306/14 JDC/cc 43

## Proposal for a regulation Article 16 – paragraph 1 – point a

Text proposed by the Commission

(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);

#### Amendment

## deleted

## **Amendment 117**

Proposal for a regulation Article 16 – paragraph 1 – point b

Text proposed by the Commission

(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.

## Amendment

(b) a veterinarian *or aquatic animal health professional* of abnormal mortalities and other serious *transmissible* 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.

## **Amendment 118**

Proposal for a regulation Article 16 – paragraph 1a (new)

Text proposed by the Commission

## **Amendment**

1a. Veterinarians or aquatic animal health professionals shall immediately notify the competent authority in the event of an outbreak or suspicion of an outbreak of a listed disease referred to in point (e) of Article 8(1).

## **Amendment 119**

Proposal for a regulation Article 16 – paragraph 1b (new)

8306/14 JDC/cc 44

#### Amendment

1b. Doctors shall immediately inform the competent authority of any sign of a zoonotic disease.

## **Amendment 120**

Proposal for a regulation Article 17 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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.

#### **Amendment 121**

Proposal for a regulation Article 17 – paragraph 3 – subparagraph 2

Text proposed by the Commission

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

## **Amendment 122**

Proposal for a regulation Article 18 – paragraph 3

Text proposed by the Commission

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

## Amendment

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

Amendment

deleted

## Amendment

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

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EN

## Regulation.

#### **Amendment 123**

## Proposal for a regulation Article 22 – point a

Text proposed by the Commission

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

#### **Amendment 124**

Proposal for a regulation Article 22 – paragraph 1 – point a a (new)

Text proposed by the Commission

## Amendment

Amendment

(a) observe the health and welfare of

animals under their responsibility;

(aa) observe any changes in animal products under their responsibility, that may give rise to a suspicion of being caused by a listed disease or emerging disease;

## **Amendment 125**

Proposal for a regulation Article 22 – point c

Text proposed by the Commission

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

## **Amendment 126**

Proposal for a regulation Article 22 – point c a (new)

Text proposed by the Commission

## Amendment

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

## **Amendment**

(ca) agree to animal health visits from a veterinarian for the purpose of preventing the occurrence of listed diseases and emerging diseases, in accordance with the criteria laid down in Article 23; such visits shall also serve as a means of providing

8306/14 JDC/cc 46

advice to the operator on biosecurity matters.

#### Amendment 127

Proposal for a regulation Article 22 – paragraph 1a (new)

Text proposed by the Commission

Amendment

Operators may take part in any existing voluntary collective steps to monitor animal diseases.

#### **Amendment 128**

Proposal for a regulation Article 23 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

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:

Amendment

1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian *or other qualified professionals as* appropriate due to the risks posed by the establishment, taking into account:

## **Amendment 129**

Proposal for a regulation Article 23 – paragraph 1 – subparagraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the epidemiological situation in the zone or region;

## **Amendment 130**

Proposal for a regulation Article 23 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

Those animal health visits shall be at frequencies that are proportionate to the

Those animal health visits shall be at frequencies that *ensure a satisfactory prevention of animal diseases and* are

8306/14 JDC/cc 47

risks posed by the establishment.

proportionate to the risks posed by the establishment. The competent authority shall lay down detailed rules as regards the content and frequency of animal health visits for the different types of risk posed by the different types of establishments.

## **Amendment 131**

Proposal for a regulation Article 23 – paragraph 2 – point a

Text proposed by the Commission

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

## **Amendment 132**

Proposal for a regulation Article 23 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

Amendment

(a) the *information on* signs indicative of

the occurrence of listed diseases or

emerging diseases;

(ba) providing information to the competent authority to complement the surveillance provided for in Article 25.

## **Amendment 133**

Proposal for a regulation Article 24

Text proposed by the Commission

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:

Amendment

deleted

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- 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.

## Proposal for a regulation Article 25 – paragraph 2

Text proposed by the Commission

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.

## Amendment

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. This surveillance shall complement and be based on the surveillance carried out by operators both on an individual basis and in the framework of collective voluntary programmes.

## **Amendment 135**

Proposal for a regulation Article 27 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) The historical experience with diseases in the Member State, zone or compartment

8306/14 JDC/cc 49

Proposal for a regulation Article 28 – paragraph 1 – point ba (new)

Text proposed by the Commission

Amendment

(ba) establishing which of the listed diseases referred to in point (e) of Article 8(1) are to be subject to surveillance programmes;

**Amendment 137** 

Proposal for a regulation Article 29 – paragraph 1 – point a

Text proposed by the Commission

**Amendment** 

(a) establishing which of the listed diseases referred to in Article 8(1)(e) are to be subject to surveillance programmes;

deleted

**Amendment 138** 

Proposal for a regulation Article 29 – paragraph 1 – point b – point i

Text proposed by the Commission

Amendment

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

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

**Amendment 139** 

Proposal for a regulation Article 29 – paragraph 1 – point b – point ii a (new)

Text proposed by the Commission

Amendment

(iia) the programme evaluation tools used by the Commission and the Member States.

**Amendment 140** 

Proposal for a regulation Article 30 – paragraph 2

8306/14 JDC/cc 50

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

## Amendment

- 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 *where:*
- (a) the Member State asks the recognition of animal health guarantees within the Union as regards movements of animals or products for that disease; or
- (b) the voluntary eradication programme is a candidate for a Union financial contribution.

## **Amendment 141**

Proposal for a regulation Article 30 – paragraph 3 – subparagraph 4

Text proposed by the Commission

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).

## **Amendment**

The Commission may, by means of implementing acts, *require the Member States to* 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).

## **Amendment 142**

Proposal for a regulation Article 32 – point f a (new)

Text proposed by the Commission

#### Amendment

(fa) a precise indication of the various public authorities and/or private parties

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variously involved in the programmes, as well as clear information regarding their respective roles and responsibilities in the implementation thereof.

**Amendment 143** 

Proposal for a regulation Article 35 – title

Text proposed by the Commission

Amendment

Implementing powers

Implementing powers and delegation of powers concerning performance indicators

**Amendment 144** 

Proposal for a regulation Article 35 – point b

Text proposed by the Commission

Amendment

(b) performance indicators;

deleted

**Amendment 145** 

Proposal for a regulation Article 35 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the establishment of indicators measuring the performance of compulsory or voluntary eradication programmes provided for in Articles 30, 31 and 32.

**Amendment 146** 

Proposal for a regulation Article 42 – paragraph 1

Text proposed by the Commission

Amendment

1. Where a Member State has reason to suspect that any of the conditions for

1. Where a Member State has reason to suspect, *or is alerted by a notification* 

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maintaining its status as a disease-free Member State, or zone or compartment thereof have been breached, it shall immediately: from the Commission, 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:

#### **Amendment 147**

Proposal for a regulation Article 42 – paragraph 1 – point a

Text proposed by the Commission

(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;

#### **Amendment 148**

Proposal for a regulation Article 42 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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.

## **Amendment 149**

Proposal for a regulation Article 42 – paragraph 5

Text proposed by the Commission

5. The Commission shall be empowered to adopt delegated acts in accordance with

## Amendment

(a) take the appropriate measures based on the risk that animal movements may constitute for the disease in question;

## Amendment

The Commission shall, by means of implementing acts, *then immediately* 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).

## Amendment

5. The Commission shall be empowered to adopt delegated acts in accordance with

8306/14 JDC/cc 53

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.

Article 253 concerning the *measures to be taken and the investigations to be carried out by the Member State concerned as* provided for in paragraphs 1 and 2 of this Article.

## **Amendment 150**

Proposal for a regulation Part 2 – chapter IV a (new) – title

Text proposed by the Commission

Amendment

## CHAPTER IV A. OFFICIAL ANIMAL HEALTH LABORATORIES

**Amendment 151** 

Proposal for a regulation Article 42 a (new)

Text proposed by the Commission

Amendment

Article 42a

European network of official animal health laboratories

- 1. The European network of laboratories shall consist of Union reference laboratories, national reference laboratories and official animal health laboratories.
- 2. European network laboratories shall, in fulfilling their tasks and responsibilities, cooperate to ensure that the surveillance of animal diseases and control and eradication programmes provided for in this Regulation are based on state-of-the-art scientific standards and sound and reliable diagnosis.

**Amendment 152** 

Proposal for a regulation Article 42 b (new)

8306/14 JDC/cc 54

#### Article 42b

## Union reference laboratories

- 1. The Commission shall designate Union reference laboratories for illnesses for which, owing to their impact on health or the economy, this is necessary to achieve the objectives of this Regulation.
- 2. That designation shall take the form of a public selection process that is reviewed regularly.
- 3. Union reference laboratories shall:
- (a) operate in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and be assessed and accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008;
- (b) be impartial and free of conflict of interests as regards the exercise of its tasks as Union reference laboratories;
- (c) have suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence, and support staff as appropriate;
- (d) possess or have access to the infrastructure, equipment and products necessary to carry out the tasks assigned to them:
- (e) ensure that their staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;
- (f) be equipped to perform their tasks in emergency situations;
- (g) where relevant, be equipped to comply with the biosecurity standards relating to their work and take into account the latest

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developments in research at national, Union and international level; be equipped to perform their tasks in emergency situations; where relevant, be equipped to comply with relevant biosecurity standards.

4. The Commission shall be responsible, by means of implementing acts, for establishing the specific tasks and responsibilities of the Union reference laboratories and, where necessary, the minimum requirements in terms of the facilities, equipment and personnel needed.

#### Amendment 153

Proposal for a regulation Article 42 c (new)

Text proposed by the Commission

Amendment

## Article 42c

National reference laboratories

- 1. Member States shall designate one or more national reference laboratories for each Union reference laboratory designated in accordance with Article 42b(1).
- 2. The national reference laboratories must meet the requirements of Article 42b *(2)*.
- 3. The Commission shall be responsible, by means of implementing acts, for establishing the specific tasks and responsibilities of the national reference laboratories and, where necessary, the minimum requirements in terms of the facilities, equipment and personnel needed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in *Article* 255(2).

**Amendment 154** 

Proposal for a regulation Article 42 d (new)

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#### Article 42d

General coordination of the laboratories

- 1. The Union reference laboratories and the national reference laboratories shall, within the limits of their competencies:
- i. ensure that the official animal health laboratories provided for in Article 42e receive updated information on the available methods.
- ii. organise comparative tests between laboratories and insist on their active participation;
- iii. identify and satisfy the training needs of the laboratories' personnel.
- iv. assess the quality and the suitability of the reagents and kits used in laboratory diagnoses, and produce and distribute reference materials.
- 2. The Union reference laboratories and the national reference laboratories shall be responsible for the general coordination of the network of animal health laboratories which come under their territorial jurisdiction.

## **Amendment 155**

Proposal for a regulation Article 42 e (new)

Text proposed by the Commission

Amendment

## Article 42e

Official animal health laboratories

- 1. The competent authorities shall designate official laboratories to conduct laboratory analyses and diagnoses of animal diseases.
- 2. The competent authorities may only designate as an official laboratory a laboratory which:
- (a) has the expertise, equipment and

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- infrastructure required to carry out analyses or tests or diagnoses on samples;
- (b) has a sufficient number of suitably qualified, trained and experienced staff;
- (c) is impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;
- (d) can deliver the results of the analysis, test or diagnosis in a timely manner;
- (e) has a quality assurance system in place to ensure sound and reliable results from the methods used for laboratory analysis and diagnosis.
- 3. The official animal health laboratories shall work with the national reference laboratories of the Member States to ensure that their tasks and responsibilities are pursued in accordance with state-of-the-art scientific and quality standards.

Proposal for a regulation Article 43 – paragraph 2 – point c – point v

Text proposed by the Commission

Amendment

(v) emergency funds;

(v) budget resources and, where necessary, the establishment of special funds:

#### **Amendment 157**

Proposal for a regulation Article 43 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Member States shall consult relevant stakeholders when drawing up and updating contingency plans.

8306/14 JDC/cc 58

## Proposal for a regulation Article 44 – paragraph 1 – point c

Text proposed by the Commission

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

## Amendment

(c) new knowledge of and developments *on the listed diseases and* in disease control tools.

## **Amendment 159**

## Proposal for a regulation Article 46 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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.

## Amendment

The Member States *shall* take measures concerning the *responsible* use of veterinary medicinal products for *infectious* 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.

## **Amendment 160**

## Proposal for a regulation Article 46 – paragraph 2 – introductory part

Text proposed by the Commission

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:

#### Amendment

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 disease:

## **Amendment 161**

Proposal for a regulation Article 46 – paragraph 2 – point c

8306/14 JDC/cc 59

(c) the availability, effectiveness and risks of the veterinary medicinal products;

#### Amendment

(c) the availability, effectiveness and risks of the veterinary medicinal products, as well as the detrimental effects of antimicrobial resistance:

## **Amendment 162**

Proposal for a regulation Article 46 – paragraph 3 a (new)

Text proposed by the Commission

## Amendment

3 a. With the view to reduce antimicrobial resistance and in accordance with 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, Member States shall within two years after the entry into force of this Regulation, at the latest, report to the Commission on the usage of veterinary medicinal products containing antibiotics in their territory. The Union shall thereafter proceed to establish appropriate reduction targets, within three years after the entry into force of this Regulation, at the latest.

## **Amendment 163**

Proposal for a regulation Article 47 – paragraph 1 – point b

Text proposed by the Commission

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

## **Amendment 164**

Proposal for a regulation Article 47 – paragraph 1 – point d

## Amendment

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

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(d) risk mitigating measures to prevent the spread of *listed* diseases through animals treated with the veterinary medicinal products or products from such animals;

#### Amendment

(d) risk mitigating measures to prevent the spread of diseases through animals treated with the veterinary medicinal products or products from such animals;

## **Amendment 165**

Proposal for a regulation Article 47 – paragraph 1 – point e

Text proposed by the Commission

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

## Amendment

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

#### **Amendment 166**

Proposal for a regulation Article 47 – paragraph 1 – point e a (new)

Text proposed by the Commission

#### **Amendment**

(e a) provisions specifying the purpose to which animals which have undergone emergency vaccination may be put.

## **Amendment 167**

Proposal for a regulation Article 48 – paragraph 1 a (new)

Text proposed by the Commission

## Amendment

1 a. The Commission shall ensure a fast track development and registration process for newly emerging disease agents and/or import appropriately registered animal health products.

## **Amendment 168**

Proposal for a regulation Article 55 – paragraph 1 – point a

8306/14 JDC/cc 61

(a) place the establishment, *household*, food and feed business or animal byproducts establishment, or any other location where the disease suspicion occurs under official surveillance:

## Amendment

(a) place the establishment, food and feed business, *transport business*, *livestock trading business* or animal by-products establishment, or any other location where the disease suspicion occurs, under official surveillance;

## **Amendment 169**

## Proposal for a regulation Article 55 – paragraph 1 – point b – point i

Text proposed by the Commission

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

#### Amendment

(i) the kept animals in the establishment, food and feed business, *transport business*, *livestock trading business* or animal byproducts establishment, or any other location;

#### Amendment 170

## Proposal for a regulation Article 55 – paragraph 1 – point b – point ii

Text proposed by the Commission

(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;

## Amendment

(ii) the products in the establishment, food and feed business, *transport business*, *livestock trading business* or animal byproducts establishment, or any other location, where relevant for the spread of that listed disease;

## **Amendment 171**

## Proposal for a regulation Article 55 – paragraph 1 – point c

Text proposed by the Commission

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

## Amendment

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

8306/14 JDC/cc 62

## Proposal for a regulation Article 55 – paragraph 1 – point e

## Text proposed by the Commission

(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;

## Amendment

(e) restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, food and feed business establishments, *transport businesses*, *livestock trading businesses*, 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;

#### **Amendment 173**

## Proposal for a regulation Article 55 – paragraph 1 – point f – introductory part

## Text proposed by the Commission

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

#### Amendment

(f) take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4, and ensure that any control measures spare the affected animals avoidable pain and suffering, concerning:

#### **Amendment 174**

## Proposal for a regulation Article 55 – paragraph 1 – point f – point i

## Text proposed by the Commission

(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 byproducts establishments;

## Amendment

(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, food and feed businesses, *transport businesses*, *livestock trading businesses* or animal byproducts establishments;

8306/14 JDC/cc 63

## Proposal for a regulation Article 57 – paragraph 2 – point c

Text proposed by the Commission

(c) identifying contact establishments and epidemiological units therein, *households*, food and feed business or animal byproducts establishment or any other locations where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;

## Amendment

(c) identifying contact establishments and epidemiological units therein, food and feed business, *transport business*, *livestock trading 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;

## **Amendment 176**

## Proposal for a regulation Article 59 – title

Text proposed by the Commission

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

## Amendment

Lifting of preliminary disease control measures where the presence of the listed disease *or an emerging disease* has been ruled out

## **Amendment 177**

# Proposal for a regulation Article 59

Text proposed by the Commission

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).

## Amendment

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) *or an emerging disease* has been ruled out based on the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2).

## **Amendment 178**

Proposal for a regulation Article 60 – point a

8306/14 JDC/cc 64

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

#### **Amendment 179**

## Proposal for a regulation Article 61 – paragraph 1 – introductory part

Text proposed by the Commission

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:

## **Amendment 180**

## Proposal for a regulation Article 61 – paragraph 1 – point b

Text proposed by the Commission

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

## **Amendment 181**

Proposal for a regulation Article 61 – paragraph 1 – point d

#### Amendment

(a) declare the affected establishment, food or feed business, *transport business*, *livestock trading business*, animal byproducts establishment or other location as officially infected with that listed disease;

#### Amendment

1. In the event of an outbreak of a listed disease referred to in Article 8(1)(a) in kept animals in an establishment, food or feed business, *transport business, livestock trading 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:

## Amendment

(b) the *humane* killing and disposal or slaughtering of animals that may be contaminated and contribute to the spread of the listed disease, *provided that this is done in such a way as to spare the animals any avoidable pain, distress or suffering*;

8306/14 JDC/cc 65

(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);

#### Amendment

(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), preferably vaccination which involves animals remaining alive and has no adverse impact on trade within the Union and with third countries:

## **Amendment 182**

Proposal for a regulation Article 61 – paragraph 1 – point f

Text proposed by the Commission

(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:

#### Amendment

(f) the cleaning, disinfection, disinfestation or other necessary biosecurity measures to be applied to the affected establishment, food or feed business, *transport business*, *livestock trading business*, animal byproducts establishment or other locations to minimise the risk of spread of the listed disease;

## **Amendment 183**

Proposal for a regulation Article 61 – paragraph 2 – point b

Text proposed by the Commission

(b) the type of production, and epidemiological units within the affected establishment, *household*, food or feed business, animal by-products establishment or other location.

## Amendment

(b) the type of production, and epidemiological units within the affected establishment, food or feed business, *transport business*, *livestock trading business*, animal by-products establishment or other location.

## **Amendment 184**

Proposal for a regulation Article 61 – paragraph 2 – point b a (new)

8306/14 JDC/cc 66

## Amendment

(ba) the effect of the measures on farm animal genetic diversity and the need to conserve farm animal genetic resources.

## **Amendment 185**

## Proposal for a regulation Article 61 – paragraph 3 – introductory part

Text proposed by the Commission

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

#### Amendment

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

#### Amendment 186

## Proposal for a regulation Article 61 – paragraph 3 – point b

Text proposed by the Commission

(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.

## Amendment

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

## **Amendment 187**

## Proposal for a regulation Article 62 – paragraph 1

Text proposed by the Commission

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 byproducts establishments, or any other location, or means of transport where the

#### **Amendment**

1. The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, food or feed businesses, *transport businesses*, *livestock trading businesses* or animal by-products establishments, or any other location, or

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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.

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.

## **Amendment 188**

## Proposal for a regulation Article 62 – paragraph 2

Text proposed by the Commission

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.

## Amendment

2. If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in Article 8(1)(a) is another Member State or it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State *and the Commission*.

#### **Amendment 189**

## Proposal for a regulation Article 64 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

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:

## Amendment

The competent authority shall establish a restricted zone around the affected establishment, food or feed business, *transport business, livestock trading 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:

## **Amendment 190**

Proposal for a regulation Article 64 – paragraph 1 – subparagraph 1 – point h a (new)

8306/14 JDC/cc 68

## Amendment

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

## **Amendment 191**

Proposal for a regulation Article 64 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

**Amendment** 

The competent authority shall establish the restricted zone in a manner consistent with the principle of proportionality.

#### **Amendment 192**

Proposal for a regulation Article 65 – paragraph 1 – point a

Text proposed by the Commission

(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;

## Amendment

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

## **Amendment 193**

Proposal for a regulation Article 65 – paragraph 1 – point b

Text proposed by the Commission

(b) visits to establishments, *households*, food or feed businesses, animal byproducts 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;

## Amendment

(b) visits to establishments, food or feed businesses, *transport businesses*, *livestock trading 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;

8306/14 JDC/cc 69

## Proposal for a regulation Article 65 – paragraph 1 – point g

Text proposed by the Commission

(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;

## **Amendment 195**

Proposal for a regulation Article 67 – subparagraph 2 – point b

*Text proposed by the Commission* 

(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;

## **Amendment 196**

Proposal for a regulation Article 69 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Animals which have undergone emergency vaccination may be used for a specific purpose in accordance with the provisions of Article 47(1)(f).

## **Amendment 197**

Proposal for a regulation Article 69 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. Where the vaccine used is certified as safe for human consumption, subsequent slaughter of non-infected, vaccinated

## Amendment

(g) the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering, using *pre-stunning*, of animals or the treatment of products of animal origin originating from the restricted zones;

Amendment

(b) *principles concerning* 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;

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**DPG** 

## animals should be avoided.

#### **Amendment 198**

Proposal for a regulation Part 3 – title 2 – chapter 1 – section 5 – title

Text proposed by the Commission

Amendment

Wild animals

Wild animals and stray domestic animals

**Amendment 199** 

Proposal for a regulation Article 70 – title

Text proposed by the Commission

Amendment

Wild animals Wild animals and stray domestic animals

**Amendment 200** 

Proposal for a regulation Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

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:

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

**Amendment 201** 

Proposal for a regulation Article 70 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) monitor the population of stray domestic animals where this is relevant for this specific listed disease;

**Amendment 202** 

Proposal for a regulation Article 70 – paragraph 1 – point b

8306/14 JDC/cc 7

(b) take the necessary disease prevention and control measures to avoid the further spread of that listed disease.

#### Amendment

(b) take the necessary disease prevention and control measures to avoid the further spread *or bring about the eradication* of that listed disease *and ensure that any control measures spare the affected animals avoidable pain and suffering*.

#### Amendment 203

Proposal for a regulation Article 70 – paragraph 2 – point b

Text proposed by the Commission

(b) the affected wild animals;

#### Amendment

(b) the affected wild animals *and non-kept domestic animals*;

## **Amendment 204**

Proposal for a regulation Article 70 – paragraph 2 – point b a (new)

Text proposed by the Commission

## Amendment

(ba) contact between wild and kept animals and the associated risk of mutual infection;

## **Amendment 205**

Proposal for a regulation Article 70 – paragraph 2 – point b b (new)

Text proposed by the Commission

#### Amendment

(b b) direct contact between the affected animals and people and physical proximity to people;

**Amendment 206** 

Proposal for a regulation Article 71 a (new)

8306/14 JDC/cc 72

#### Amendment

#### Article 71a

# Scope of Chapter 2

As regards diseases listed in Article 8(1)(c), the following provisions of Chapter 2 shall apply only to Member States which have drawn up a national programme.

# **Amendment 207**

# Proposal for a regulation Article 74 – paragraph 1 – point a

# Text proposed by the Commission

(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;

## **Amendment 208**

# Proposal for a regulation Article 74 – paragraph 3 – point b

# Text proposed by the Commission

(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 byproducts establishments or other locations;

## **Amendment 209**

Proposal for a regulation Article 78 – paragraph 2 – point b

## Amendment

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

### Amendment

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

8306/14 JDC/cc 73

Amendment

(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.

deleted

## **Amendment 210**

Proposal for a regulation Article 78 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) the kept animals affected;

(b) the kept animals affected, particularly when they belong to an endangered race or variety;

#### **Amendment 211**

Proposal for a regulation
Part 3 – title 2 – chapter 2 – section 4 – title

Text proposed by the Commission

Amendment

Wild animals

Wild animals and animals of domestic species which are not kept

## **Amendment 212**

Proposal for a regulation Article 80 – title

Text proposed by the Commission

Amendment

Wild animals

Wild animals and animals of domestic species which are not kept

**Amendment 213** 

Proposal for a regulation Article 80 – paragraph 1 – introductory part

8306/14 JDC/cc 74

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:

#### Amendment

1. In the event of suspicion or official confirmation of a listed disease referred to in Article 8(1)(b) in wild animals *and animals of domestic species which are not kept*, the competent authority of the affected Member State shall:

#### **Amendment 214**

Proposal for a regulation Article 80 – paragraph 2 – introductory part

Text proposed by the Commission

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:

#### Amendment

2. In the event of an outbreak of a listed disease in wild animals and animals of domestic species which are not kept and are not covered by the provisions of Article 8(1)(b), the competent authority of the affected Member State shall:

## **Amendment 215**

Proposal for a regulation Article 80 – paragraph 3 – point b

Text proposed by the Commission

(b) the affected wild animals;

# Amendment

(b) the affected wild animals and animals of domestic species which are not kept;

# **Amendment 216**

Proposal for a regulation Article 80 – paragraph 3 – point b a (new)

Text proposed by the Commission

# Amendment

(b a) contact between animals living in the wild and kept animals, and the associated risk of mutual infection;

# **Amendment 217**

Proposal for a regulation Article 80 – paragraph 3 – point b b (new)

8306/14 JDC/cc 75

#### Amendment

(b b) direct contact between the animals concerned and human beings, and spatial proximity to people;

## **Amendment 218**

# Proposal for a regulation Article 80 – paragraph 4

Text proposed by the Commission

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.

## Amendment

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 and animals of domesticated species which are not kept as provided for in paragraph 2(b) of this Article.

### **Amendment 219**

# Proposal for a regulation Article 86

Text proposed by the Commission

# 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.

Amendment

deleted

8306/14 JDC/cc 76

# Proposal for a regulation Article 87 – paragraph 1 – point b

Text proposed by the Commission

(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.

# Amendment

deleted

## **Amendment 221**

# Proposal for a regulation Article 89 – paragraph 4 – point a

Text proposed by the Commission

(a) the categories and species of kept terrestrial animals or germinal products in an establishment;

#### Amendment

(a) the categories and species *or races* of kept terrestrial animals or germinal products in an establishment;

## **Amendment 222**

# Proposal for a regulation Article 92 – paragraph 1 – introductory part

Text proposed by the Commission

1. The competent authority shall *only* grant approval of establishments as provided for in Article 89(1) and Article 90(a) where such establishments:

# Amendment

1. The competent authority shall grant approval of establishments as provided for in Article 89(1) and Article 90(a) where such establishments:

# **Amendment 223**

# Proposal for a regulation Article 94 – paragraph 1

Text proposed by the Commission

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Articles

#### Amendment

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Articles

8306/14 JDC/cc 77

89(1), Article 90 and Article 91(1).

89(1), Article 90 and Article 91(1) and deadlines for the on-the-spot inspections referred to in the paragraph below.

#### **Amendment 224**

Proposal for a regulation Article 94 – paragraph 2 a (new)

Text proposed by the Commission

## Amendment

2 a. The competent authority grants 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 and 2 of this Article, that it meets all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2).

#### **Amendment 225**

Proposal for a regulation Article 94 – paragraph 4 – subparagraph 2

Text proposed by the Commission

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.

# Amendment

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 and shall provide the necessary effective guidance in order to contribute to the successful resolve of the deficiency. However, conditional approval shall not exceed a total period of six months.

## **Amendment 226**

Proposal for a regulation Article 95 – paragraph 1

Text proposed by the Commission

1. The competent authority shall keep the approvals of establishments granted in

## **Amendment**

1. The competent authority shall keep the approvals of establishments granted in

8306/14 JDC/cc 78

accordance with Articles 92 and 94 under review.

accordance with Articles 92 and 94 under review. The competent authority, based on the risk factor, shall define review frequency or minimum and maximum review deadlines, as well as those instances in which such deadlines cannot be met.

### **Amendment 227**

# Proposal for a regulation Article 96 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

#### Amendment

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

## **Amendment 228**

# Proposal for a regulation Article 97 – paragraph 1 – point a

Text proposed by the Commission

(a) the species, categories, numbers and identification of kept terrestrial animals on their establishment;

## Amendment

(a) the species, categories, numbers and, *where applicable*, identification, of kept terrestrial animals on their establishment;

## **Amendment 229**

# Proposal for a regulation Article 97 – paragraph 1 – point d

Text proposed by the Commission

(d) *any* animal health problems concerning kept animals on their establishment;

# Amendment

(d) *treatments of* animal health problems concerning kept animals on their establishment;

## **Amendment 230**

# Proposal for a regulation Article 97 – paragraph 2

Text proposed by the Commission

2. Establishments which are exempted

## **Amendment**

2. Establishments which are exempted

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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.

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. Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.

#### **Amendment 231**

Proposal for a regulation Article 98 – paragraph 1 – point d a (new)

Text proposed by the Commission

#### Amendment

(d a) the results of clinical and laboratory tests;

#### Amendment 232

Proposal for a regulation Article 98 – paragraph 2

Text proposed by the Commission

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.

### Amendment

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. Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.

# **Amendment 233**

Proposal for a regulation Article 99 – paragraph 2

Text proposed by the Commission

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

#### Amendment

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

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keep records of the information listed in paragraph 1 of this Article.

keep records of the information listed in paragraph 1 of this Article. Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.

## **Amendment 234**

Proposal for a regulation Article 100 – paragraph 1 – point a

Text proposed by the Commission

- (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;

### **Amendment 235**

Proposal for a regulation Article 103 – paragraph 1 – point b

Text proposed by the Commission

(b) information related to kept animals of the porcine species and the establishments keeping them; Amendment

deleted

## Amendment

- (b) the *following* information related to kept animals of the porcine species:
- (i) the establishments keeping them;
- (ii) their movements into and from establishments;

**Amendment 236** 

Proposal for a regulation Article 103 – paragraph 2 a (new)

8306/14 JDC/cc 81

#### Amendment

2 a. By 1 January 2018, Member States shall introduce a registration requirement for dogs. The Commission shall submit to the European Parliament and the Council by 31 July 2019 a report on the experience of the Member States with the registration and identification of dogs, with particular reference to stray animals. This report shall, if appropriate, be accompanied by a proposal concerning the minimum requirements applicable to databases pursuant to paragraph 1.

# **Amendment 239**

Proposal for a regulation **Article 112 – paragraph 1 – introductory part** 

Text proposed by the Commission

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:

#### Amendment

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 comply with the requirements of Regulation (EU) No 576/2013.

#### Amendment 240

Proposal for a regulation Article 112 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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

**Amendment 241** 

Proposal for a regulation **Article 112 – paragraph 1 – point b** 

Text proposed by the Commission

Amendment

(b) are accompanied by a correctly completed and updated identification deleted

deleted

8306/14 JDC/cc 82 **DPG** 

EN

# document issued by the competent authority in accordance with Article 104.

## **Amendment 242**

Proposal for a regulation Article 112 – paragraph 2 – introductory part

Text proposed by the Commission

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:

#### Amendment

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 comply with the requirements of Regulation (EU) No 576/2013.

#### **Amendment 243**

Proposal for a regulation Article 112 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) identified, either individually or in groups;

Amendment 244

Proposal for a regulation Article 112 – paragraph 2 – point b

Text proposed by the Commission

**Amendment** 

(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.

**Amendment 245** 

Proposal for a regulation Article 114 – point a deleted

deleted

8306/14 JDC/cc 83

Amendment

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

deleted

**Amendment 246** 

Proposal for a regulation Article 114 – point c – point vi

Text proposed by the Commission

Amendment

(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);

deleted

deleted

**Amendment 247** 

Proposal for a regulation Article 114 – point f

Text proposed by the Commission

Amendment

- (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.

8306/14 JDC/cc EN

**DPG** 

# Proposal for a regulation Article 115 – paragraph 1

Text proposed by the Commission

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:

Amendment

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, provided that full traceability is ensured:

## **Amendment 249**

Proposal for a regulation Article 118 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the breed;

**Amendment 250** 

Proposal for a regulation Article 121 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the movement complies with Council Regulation (EC) No 1/2005.

**Amendment 251** 

Proposal for a regulation Article 122 – paragraph 1 – introductory part

Text proposed by the Commission

1. Operators shall take the appropriate and necessary preventive measures to ensure that:

Amendment

1. Operators shall take the appropriate and necessary preventive *and health-promotion* measures to ensure that:

**Amendment 252** 

Proposal for a regulation Article 122 – paragraph 1 – point b

8306/14 JDC/cc 85

(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;

## Amendment

(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, *loading*, *unloading*, *reloading*, resting and destination;

#### Amendment 253

Proposal for a regulation Article 122 – paragraph 1 – point ca (new)

Text proposed by the Commission

#### Amendment

(ca) the relevant requirements of Council Regulation (EC) No 1/2005 are taken into account.

## **Amendment 254**

# Proposal for a regulation Article 125

Text proposed by the Commission

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).

## Amendment

Operators shall not move kept terrestrial animals to another Member State, unless the Member State of destination *and the Member States of transit give* 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).

# **Amendment 255**

Proposal for a regulation Article 127 – point c

Text proposed by the Commission

(c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be

## Amendment

(c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be

8306/14 JDC/cc 86

moved, no kept ungulates or poultry have been introduced into the establishment of origin; moved, no kept ungulates or poultry have been introduced into the establishment of origin, *except in cases where appropriate biosecurity measures have been taken*;

## **Amendment 256**

# Proposal for a regulation Article 128 – paragraph 1 – point a

Text proposed by the Commission

(a) residency periods provided for in Article 127(b);

# Amendment 257

# Proposal for a regulation Article 129 – paragraph 1

Text proposed by the Commission

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.

## **Amendment 258**

# Proposal for a regulation Article 130 – paragraph 1

Text proposed by the Commission

- 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

## Amendment

(a) residency periods *and biosecurity measures* provided for in Article 127(b);

#### Amendment

1. Operators of slaughterhouses receiving kept ungulates and poultry from another Member State shall slaughter, *using prestunning*, 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.

#### Amendment

1. By way of derogation from Article 123(2), operators may subject kept ungulates and poultry to a maximum of *three assembly operations*.

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## State of destination.

#### Amendment 259

# Proposal for a regulation Article 131 – paragraph 1 – point b

Text proposed by the Commission

(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);

(b) the kept ungulates and poultry are assembled and moved to their final place of destination 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);

Amendment

### **Amendment 260**

# Proposal for a regulation **Article 132 – paragraph 1 – introductory part**

Text proposed by the Commission

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

#### Amendment

The Commission shall be empowered to adopt delegated acts in accordance with Article 253, provided that such acts are based on scientific facts and due regard for the opinions of the European Food Safety Authority, concerning:

# **Amendment 261**

# Proposal for a regulation Article 132 – paragraph 1 – point c

Text proposed by the Commission

(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);

## Amendment

(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 as referred to in Article 131(b);

## **Amendment 262**

# Proposal for a regulation

8306/14 JDC/cc 88 **DPG** 

# **Article 140 – paragraph 2 – introductory part**

Text proposed by the Commission

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:

#### Amendment

2. Operators shall not move kept terrestrial animals unless they are accompanied by an animal health certificate issued by the competent authority of the Member State in accordance with Article 146(1), where the conditions referred to in the following points (a) and (b) are meet:

## **Amendment 263**

Proposal for a regulation Article 152 – paragraph 1 – introductory part

Text proposed by the Commission

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:* 

#### Amendment

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 *in accordance with the provisions of Regulation (EU) No 576/2013*.

# **Amendment 264**

Proposal for a regulation Article 152 – paragraph 1 – point a

Text proposed by the Commission

(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;

**Amendment 265** 

Proposal for a regulation Article 152 – paragraph 1 – point b Amendment

deleted

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(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.

### **Amendment 266**

Proposal for a regulation Article 152 – paragraph 2

Text proposed by the Commission

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.

#### **Amendment 267**

Proposal for a regulation Article 152 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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.

#### Amendment

deleted

#### Amendment

2. The Commission shall, without prejudice to the provisions laid down in Regulation (EU) No 576/2013, be empowered to adopt delegated acts in accordance with Article 253 concerning prevention and disease control measures 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.

# Amendment

Without prejudice to the Regulation on the non-commercial movement of pet animals, the Commission may, by means of implementing acts lay down rules concerning the disease prevention and control measures provided for in paragraph 2 of this Article.

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# Proposal for a regulation Article 169 – paragraph 1

Text proposed by the Commission

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.

### Amendment

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 *prevent the introduction or spread of* that disease, provided those measures:

- (a) *only* hinder the movement of animals and products between Member States *when* this is scientifically justified on the grounds of controlling infectious disease;
- (b) are proportionate in relation to the risk and do not exceed the limits of what is appropriate and necessary to control that disease.

Member States shall notify the Commission in advance of any proposed national measures referred to in the first subparagraph that may affect movements between Member States.

Where the conditions laid down in the first subparagraph are not fulfilled, the Commission may object to or amend the national measures referred to in the second subparagraph by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2) and shall enter into force with immediate effect.

## **Amendment 269**

Proposal for a regulation Article 174 – paragraph 1 – point a – introductory part

Text proposed by the Commission

(a) aquaculture establishments where aquaculture animals are kept with the view

Amendment

(a) aquaculture establishments where aquaculture animals are kept with the view

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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:

to their being moved from that aquaculture establishment either alive or as products of aquaculture animal origin.

Amendment

**Amendment 270** 

Proposal for a regulation Article 174 – paragraph 1 – point a – point i

Text proposed by the Commission

deleted

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

**Amendment 271** 

Proposal for a regulation Article 174 – paragraph 1 – point a – point ii

Text proposed by the Commission

**Amendment** 

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

deleted

**Amendment 272** 

Proposal for a regulation Article 174 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. By way of derogation from paragraph 1, the competent authority may exempt from the obligation to apply for approval operators of aquaculture establishments where aquaculture animals are solely moved either:

- (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,

provided that such movements do not pose a significant risk.

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# Proposal for a regulation Article 177 – title

Text proposed by the Commission

Approval of disease control aquatic food establishments

# Amendment 274

# Proposal for a regulation Article 177

Text proposed by the Commission

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).

## **Amendment 275**

# Proposal for a regulation Article 177 – paragraph 1

Text proposed by the Commission

1. Operators of disease control aquatic food establishments shall ensure that their establishments are approved by the aquatic animals for disease control competent authority to slaughter 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).

#### Amendment

Approval of *processing establishments*and disease control aquatic food
establishments

#### Amendment

Natural and legal persons intending to operate 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).

#### Amendment

1. Operators of *processing establishments* and 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).

8306/14 JDC/cc 93

# Proposal for a regulation Article 178 – paragraph 1 – introductory part

Text proposed by the Commission

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:

## Amendment

1. *Intending* 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:

### **Amendment 277**

# Proposal for a regulation Article 178 – paragraph 1 – point c

Text proposed by the Commission

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

## Amendment

(c) the categories, species and numbers of aquaculture animals *intended to be kept* on the establishment;

## **Amendment 278**

Proposal for a regulation Article 178 – paragraph 1 – point f a (new)

Text proposed by the Commission

### Amendment

(f a) the water supply and discharge of the establishment

#### **Amendment 279**

Proposal for a regulation Article 182 – paragraph 1

Text proposed by the Commission

1. The competent authority shall keep the approvals of establishments granted in accordance with Article 179(1) under review.

## Amendment

1. The competent authority shall keep the approvals of establishments granted in accordance with Article 179(1) under review. The competent authority, based on the risk factor, shall define review frequency or minimum and maximum

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review deadlines, as well as those instances in which such deadlines cannot be met.

#### Amendment 280

Proposal for a regulation PART IV – Title II – Chapter 1 – Section 3 – title

Text proposed by the Commission

REGISTER OF THE COMPETENT AUTHORITY OF AQUACULTURE ESTABLISHMENTS AND DISEASE CONTROL AQUATIC FOOD **ESTABLISHMENTS** 

Amendment

REGISTER OF THE COMPETENT **AUTHORITY OF AQUACULTURE** ESTABLISHMENTS, PROCESSING **ESTABLISHMENTS** AND DISEASE CONTROL AQUATIC FOOD **ESTABLISHMENTS** 

**Amendment 281** 

Proposal for a regulation Article 183 – title

Text proposed by the Commission

Register of aquaculture establishments and disease control aquatic food establishments Amendment

Register of aquaculture establishments, processing establishments and disease control aquatic food establishments

**Amendment 282** 

Proposal for a regulation Article 183 – paragraph 1 – point c

Text proposed by the Commission

(c) all disease control aquatic food establishments approved in accordance with Article 179(1).

Amendment

(c) all processing establishments and disease control aquatic food establishments approved in accordance with Article 179(1).

**Amendment 283** 

**Proposal for a regulation** Article 186 – title

Text proposed by the Commission

Amendment

Record keeping obligation for disease

Record keeping obligation for *processing* 

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EN

# control aquatic food establishments

# establishments and disease control aquatic food establishments

## **Amendment 284**

# Proposal for a regulation Article 186 – paragraph 1

Text proposed by the Commission

1. Operators of disease control aquatic food establishments subject to approval in accordance with Article 177 shall keep upto-date records of all movement of aquaculture animals and products of animal origin obtained from such animals into and out of such establishments.

#### Amendment

1. Operators of *processing establishments* and disease control aquatic food establishments subject to approval in accordance with Article 177 shall keep upto-date records of all movement of aquaculture animals and products of animal origin obtained from such animals into and out of such establishments.

## **Amendment 285**

# Proposal for a regulation Article 186 – paragraph 2

Text proposed by the Commission

2. Operators of disease control aquatic food establishments shall:

## Amendment

2. Operators of *processing establishments* and disease control aquatic food establishments shall:

## **Amendment 286**

# Proposal for a regulation **Article 187 – paragraph 1 – introductory part**

Text proposed by the Commission

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

## Amendment

Transporters of aquaculture animals and wild aquatic animals intended for aquaculture or for release in a natural environment in order to replenish wild stocks shall keep up-to date records on:

## **Amendment 287**

Proposal for a regulation Article 193 – paragraph 1 – introductory part

8306/14 JDC/cc 96 **DPG** 

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

## Amendment

1. Operators of establishments and food business establishments receiving aquatic animals shall, before the aquatic animals are unloaded:

### **Amendment 288**

Proposal for a regulation Article 193 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) inspect the consignment for any irregularity;

#### Amendment 289

Proposal for a regulation Article 193 – paragraph 1 – point b – point i

Text proposed by the Commission

(i) the *aquaculture* animals received;

Amendment

(i) the *aquatic* animals received;

# **Amendment 290**

Proposal for a regulation Article 193 – paragraph 2

Text proposed by the Commission

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.

# Amendment

2. In the event of any irregularity as referred to in paragraph 1(b), the operator shall *not permit* the aquaculture animals concerned by that irregularity to be unloaded until the competent authority has taken a decision regarding them.

## **Amendment 291**

Proposal for a regulation Article 196 – title

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**DPG** 

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

## Amendment

Movement of *kept 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

#### **Amendment 292**

# Proposal for a regulation Article 196 – paragraph 1

Text proposed by the Commission

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:

## Amendment

1. Operators shall only move *kept aquatic animals* from an establishment for the purposes referred to in *points* (a) *and* (b) of this Article, if those 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 *kept aquatic* animals are:

## **Amendment 293**

Proposal for a regulation Article 196 – paragraph 1 – point b

Text proposed by the Commission

- (b) intended for:
- (i) an aquaculture establishment subject to:
- registration in accordance with Article171: or
- approval in accordance with Articles 174, 175, 176 and Article 177; or
- (ii) release into the wild.

Amendment

deleted

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# Proposal for a regulation Article 196 – paragraph 2 – point a

Text proposed by the Commission

(a) the species, categories, and life stage of the *aquaculture* animals;

# Amendment

(a) the species, categories, and life stage of the *kept aquatic* animals;

## **Amendment 295**

Proposal for a regulation Article 196 – paragraph 2 – point c

Text proposed by the Commission

(c) the intended use of the *aquaculture* animals:

## Amendment

(c) the intended use of the *kept aquatic* animals;

## **Amendment 296**

Proposal for a regulation Article 196 – paragraph 2 – point d

Text proposed by the Commission

(d) the place of destination of the *aquaculture* animals;

## Amendment

(d) the place of destination of the *kept aquatic* animals;

## **Amendment 297**

# Proposal for a regulation Article 197

Text proposed by the Commission

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

# Amendment

By way of derogation from Article 196(1), Member States may authorise operators to move aquaculture animals into a zone or compartment *within their territory* 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 *a* zone or compartment *in another Member State* for which such a programme has also been established for the same listed diseases, provided that such

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jeopardise the health status of the Member State, zone or compartment of destination.

movement will not jeopardise the health status of the Member State, zone or compartment of destination.

#### **Amendment 298**

# Proposal for a regulation Article 198

Text proposed by the Commission

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.

#### **Amendment 299**

# Proposal for a regulation Article 199 – paragraph 1

Text proposed by the Commission

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:

# **Amendment 300**

Proposal for a regulation Article 200 – title

Text proposed by the Commission

Movement of *aquaculture* animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an

#### Amendment

Member States may require that *aquatic* animals shall only be released into the wild if they originate from a Member State, or zone or compartment declared disease-free in accordance with Article 36(1) or Article 37(1) as regards the listed diseases referred to in Article 8(1)(b) and (c) for which the species of *aquatic* animals to be moved is a listed species, regardless of the health status of the area where the *aquatic* animals are to be released.

#### Amendment

1. Articles 196 and 197 shall also apply to movements of wild aquatic animals intended for an aquaculture establishment, *processing establishment* or disease control aquatic food establishment subject to:

### Amendment

Movement of *kept aquatic* animals intended for *human consumption in* Member States, zones or compartments which have been declared disease-free or

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eradication programme and delegated acts

which are subject to an eradication programme and delegated acts

#### Amendment 301

# Proposal for a regulation Article 200 – paragraph 1

Text proposed by the Commission

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:

## **Amendment 302**

# Proposal for a regulation Article 200 – paragraph 2

Text proposed by the Commission

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.

### Amendment

1. Operators shall only move *kept aquatic* animals intended for human consumption from an establishment for the purposes referred to in point (a) or (b) of this paragraph, if those 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:

## Amendment

2. By way of derogation from paragraph 1 of this Article Member States may authorise operators to introduce *kept* aquatic 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.

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DPG

# Proposal for a regulation Article 200 – paragraph 3

Text proposed by the Commission

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:

## Amendment

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 *kept aquatic* animals which do not pose significant risk of spreading of diseases due to:

## Amendment 304

Proposal for a regulation Article 200 – paragraph 3 – point a

Text proposed by the Commission

(a) the species, categories, and live stage of the *aquaculture* animals;

## Amendment

(a) the species, categories, and live stage of the *kept aquatic* animals;

## **Amendment 305**

Proposal for a regulation Article 200 – paragraph 3 – point b

Text proposed by the Commission

(b) the methods of keeping the *aquaculture* animals and type of production in the *aquaculture* establishments of origin and of destination;

# Amendment

(b) the methods of keeping the *aquatic* animals and type of production in the establishments of origin and of destination;

# **Amendment 306**

Proposal for a regulation Article 200 – paragraph 3 – point c

Text proposed by the Commission

(c) the intended use of the *aquaculture* animals;

#### **Amendment**

(c) the intended use of the *kept aquatic* animals;

8306/14 JDC/cc 102

# Proposal for a regulation Article 200 – paragraph 3 – point d

Text proposed by the Commission

(d) the place of destination of the *aquaculture* animals;

# aquatic animals;

## **Amendment 308**

# Proposal for a regulation Article 205 – point b

Text proposed by the Commission

(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).

## Amendment

Amendment

(d) the place of destination of the kept

(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), provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.

## **Amendment 309**

# Proposal for a regulation Article 207 – paragraph 1 – point e

Text proposed by the Commission

(e) any specific conditions under which the *aquaculture* animals are kept;

# Amendment

(e) any specific conditions under which the *aquatic* animals are kept;

## **Amendment 310**

# Proposal for a regulation Article 207 – paragraph 1 – point f

Text proposed by the Commission

(f) specific movement patterns of the type of *aquaculture* establishment and concerned species or category of *aquaculture* animals;

#### Amendment

(f) specific movement patterns of the type of establishment and concerned species or category of *aquatic* animals;

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# Proposal for a regulation Article 218 – title

Text proposed by the Commission

Self- declaration by operators for movements of *aquaculture* to other Member States and delegated acts

#### **Amendment 312**

# Proposal for a regulation Article 218 – paragraph 1

Text proposed by the Commission

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.

## **Amendment 313**

# Proposal for a regulation Article 218 – paragraph 2

Text proposed by the Commission

2. The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the *aquaculture* animals:

# **Amendment 314**

Proposal for a regulation Article 218 – paragraph 2 – point b

#### Amendment

Self- declaration by operators for movements of *aquatic animals* to other Member States and delegated acts

#### Amendment

1. Operators at the place of origin, shall issue a self-declaration document for movements of *aquatic* 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 *aquatic* 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.

## Amendment

2. The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the *aquatic* animals:

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(b) a description of the *aquaculture* animals, the species, their quantity, weight or volume as relevant for the animals concerned:

# Amendment

(b) a description of the *aquatic* animals, the species, their quantity, weight or volume as relevant for the animals concerned;

## **Amendment 315**

# Proposal for a regulation Article 218 – paragraph 2 – point c

Text proposed by the Commission

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

## Amendment

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

# **Amendment 316**

# Proposal for a regulation Article 218 – paragraph 3 – point a

Text proposed by the Commission

(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;

# Amendment

(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 *aquatic* animals;

## **Amendment 317**

# Proposal for a regulation Article 233 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

(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

## **Amendment**

(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 *or public 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

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Union:

health of the Union;

#### **Amendment 318**

# Proposal for a regulation Article 252

Text proposed by the Commission

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.

#### **Amendment 319**

# Proposal for a regulation Article 253 – paragraph 1

Text proposed by the Commission

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

## Amendment

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

#### Amendment

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article and the requirement for coherent legislation that is easy to understand and apply. In order to ensure the full accessibility and the correct interpretation and application of the provisions of the delegated acts referred to in paragraph 2 of this article, the Commission is required to specify an organizational criterion to simplify the structure and the number of delegated acts it will adopt.

# **Amendment 320**

# Proposal for a regulation Article 253 – paragraph 2

Text proposed by the Commission

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),

#### Amendment

2. The power to adopt delegated acts referred to in Articles 4(2), *5*(2), 6(2), *7*(2), *8*(*1*), 9(2), 11(3), 13(2), 15(2), 16(3), *17*(3), 18(3), 24, 28, 30(4), 31(2), 34(2),

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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(\*).

**35(2a)**, 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 a period of 5 years from(\*). The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

## **Amendment 321**

Proposal for a regulation Article 253 – paragraph 3

Text proposed by the Commission

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.

# **Amendment 322**

Proposal for a regulation Article 253 – paragraph 3a (new)

Text proposed by the Commission

deleted

Amendment

3a. Delegated acts shall be based on the

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scientific evidence available and be adopted after consultation with stakeholders and experts and having taken due account of the scientific opinions of the European Food Safety Authority.

## **Amendment 323**

# Proposal for a regulation Article 257 – paragraph 2

Text proposed by the Commission

- 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.

### Amendment

- 2. The national measures referred to in paragraph 1 shall be in accordance with the rules laid down in this Regulation and shall:
- (a) *only* hinder the movement of animals and products between Member States *when* this is scientifically justified on the grounds of controlling infectious disease;
- (b) *not* be in contradiction with the rules referred to in paragraph 1.

## **Amendment 324**

Proposal for a regulation Article 258 – paragraph 2 – subparagraph 1 – indent 19

Text proposed by the Commission

Amendment

- Regulation (EC) No 1760/2000,

deleted

**Amendment 325** 

Proposal for a regulation Article 258 – paragraph 2 – subparagraph 1 – indent 24

Text proposed by the Commission

Amendment

- Regulation (EU) No[XXX/XXX [Publication office: Number to be inserted... non-commercial movements of pet animals and repealing Regulation (EC) No 998/2003], deleted

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### **Amendment 326**

Proposal for a regulation Article 258 – paragraph 2 – subparagraph 1 – indent 25

Text proposed by the Commission

Amendment

- Regulation (EC) No 21/2004,

deleted

**Amendment 327** 

Proposal for a regulation Article 258 – paragraph 2 – subparagraph 1 – indent 29

Text proposed by the Commission

Amendment

- Directive 2008/71/EC,

deleted

deleted

**Amendment 328** 

Proposal for a regulation Article 259

Text proposed by the Commission

Amendment

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.

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#### **Amendment 329**

# Proposal for a regulation Article 261

Text proposed by the Commission

Amendment

deleted

#### 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.

**Amendment 330** 

Proposal for a regulation Article 261 a (new)

Text proposed by the Commission

Amendment

Article 261a

Report to the European Parliament and the Council

No later than 31 December 2019, the Commission shall submit a report to the European Parliament and the Council. The Commission report shall contain a review of the impact of this Regulation, including the experience gained from its delegated powers according to Article 253 and, if appropriate, shall be accompanied

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# by relevant proposals.

## **Amendment 331**

Proposal for a regulation Annex -1 (new)

Text proposed by the Commission

Amendment

## Annex - I

# Part 1 Diseases of terrestrial animals

Subject to	Article	Article	Article	Article	Article	Listed species
rules as set	8(1)(a)	<i>8</i> ( <i>1</i> )( <i>b</i> )	8(1)(c)	8(1)(d)	8(1)(e)	
out in	Immediate	Compulsor	Optional	Trade	Notification,	
	disease	y	"voluntary"		reporting &	
	control &	eradicatio	eradication		surveillance	
	eradicatio	n				
	n					
Classical	X	X	0	X	X	Suidae and
Swine Fever						Tayassuidae
Bluetongue	X	X	0	X	X	All ruminants
						<b>VECTORS:</b>
						Culicoides, etc.
Epizootic	X	X	0	X	X	All ruminants
haemorrhagi						
c disease of						<b>VECTORS:</b>
deer						Culicoides, etc.
Swine	X	X	0	X	X	Suidae and
Vesicular						Tayassuidae
Disease						
Highly	X	X	0	X	X	Poultry, captive
Pathogenic						birds and wild

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Avian						birds
Influenza						
Low	X	X	0	X	X	Poultry and
Pathogenic						captive birds
Avian						
Influenza						
(H5, H7)						
African	X	X	0	X	X	Suidae and
Swine Fever						Tayassuidae
						VECTORS
						/RESERVOIRS
						SOFT TICKS –
						Genus
						Ornithodorus)
Foot and	X	X	0	X	X	Any domestic or
Mouth						wild animal of
Disease						order
						Artylodactyla,
						suborders
						Ruminatia,
						Suina and
						Tylopoda;
						(Also, some
						measures:
						Rodentia and
						Proboscidae)
Rinderpest	X	X	0	X	X	Ungulates
Peste des	X	X	0	X	X	Bovidae and
Petits						Suidae
Ruminants						
(PPR)						
Rift Valley	X	X	0	X	X	All species of
Fever						ungulates other

						than those of family Suidae VECTORS: mosquitos (Aedes, Culex) midges
						(Culicoides)
Lumpy Skin Disease	X	X	0	X	X	Bovidae and Giraffidae
Sheep and Goat Pox (Capripox)	X	X	0	X	X	Bovidae
Contagious bovine pleuropneum onia	X	0	0	X	X	Species of the genus Bos
African Horse Sickness	X	X	0	X	X	Equidae VECTORS: Midges: Culicoides
Equine encephalomy elitis (Incl. EEE, WEE and equine encephalomy elitis Japanese encephalomy elitis)	X	0	0	X	X	Equidae  VECTORS:  Mosquitoes, birds, other reservoirs
Venezuelan equine	X	0	0	X	X	Equidae VECTORS:

encephalomy	,					Mosquitoes,
elitis)						birds, other
						reservoirs
West Nile	0	0	0	X	X	Equidae
Virus						<b>VECTORS:</b>
						Mosquitoes
Newcastle	X	X	0	X	X	Poultry, other
Disease						captive birds,
						including
						pigeons
Vesicular	X	X	0	X	X	Ungulates
stomatitis						
Teschen	X	0	0	X	X	Suidae
Disease						
Glanders	0	0	0	X	X	Equidae
Dourine	0	0	0	X	X	Equidae
Equine	0	0	0	X	X	Equidae
Infectious						
Anaemia						
Rabies	0	0	0	X	X	Bovidae, Suidae,
						Ovidae,
						Capridae,
						Equidae,
						Carnivora and
						Chiroptera
Anthrax	0	0	0	X	X	Bovidae,
						Camelidae,
						Cervidae,
						Elephantidae,
						Equidae and
						Hippopotamidae
Bovine	0	X	X	X	X	Mammalia, in

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tuberculosis			(for apes			particular
			and felids)			Antilocapridae,
(COMMENT						Bovidae,
:						Camelidae,
Mycobacteri						Cervidae,
um						Giraffidae, and
tuberculosis						Tragulidae
complex:						
bovis,						
caprae)						
Brucella	0	X	0	X	X	Antilocapridae,
melitensis*						Bovidae,
						Camelidae,
						Cervidae,
						Giraffidae,
						Hippopotamidae
						and Tragulidae
Brucella	0	X	0	X	X	Antilocapridae,
abortus*						Bovidae,
						Camelidae,
						Cervidae,
						Giraffidae,
						Hippopotamidae
						and Tragulidae
Brucella	0	0	0	X	X	Antilocapridae,
ovis*						Bovidae,
(contagious						Camelidae,
epididymitis)						Cervidae,
						Giraffidae,
						Hippopotamidae
						and Tragulidae
Brucella	0	0	X	X	X	Cervidae,
suis*						Leporidae,
						Ovibos

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						moschatus,
						Suidae and
						Tayassuidae
Avian	0	0	0	X	X	Psittaciformes
chlamydiosis						
Enzootic	0	X	0	X	X	Bovine animals
bovine						(including Bison
leukosis						bison and
						Bubalus
						bubalus)
Small Hive	0	0	0	X	X	Apis and
Beetle						Bombus
(Aethina						
tumida)						
Tropilaelaps	0	0	0	X	X	Apis
mite						
(Tropilealaps						
spp.)						
American	0	0	0	X	X	Apis
Foulbrood						
14 1 D	0	0	0	0	X	Rodentia and
Monkey Pox						non-human
						primates
Ebola	0	0	0	0	X	Non-human
						primates (Apes)
Aujesky's	0	0	X	X	X	Pigs
Disease						
Caseous	0	0	X	X	0	Ovine and
Lymphadenit						caprine
is						
(Corynebacte						
ium						
iuiii						

pseudotuberc						
ulosis)						
Pulmonary	0	0	X	X	0	Ovine and
Adenomatosi						caprine
S						
Paratubercul	0	0	X	X	0	Ovine and
osis						caprine
Maedi-visna	0	0	X	X	0	Ovine and
						caprine
Caprine	0	0	X	X	0	Ovine and
Viral						caprine
Arthritis/Enc						
ephalitis						
Contagious	0	0	X	X	0	Ovine and
Agalactia						caprine
Border	0	0	0	X	0	Ovine and
Disease						caprine
Infectious	0	0	X	X	0	Bovine animals
bovine						20,,,,,
rhinotracheit						
is/						
infectious pu						
stular vulvov						
aginitis						
Bovine	0	0	0	X	0	Bovine animals
[genital]						
campylobact						
eriosis – C.						
foetus ssp.						
Venerealis						
Bovine Viral	0	0	0	X	0	Bovine animals
Diarrhoea/M						
ucosal						

Disease						
Trichomonas foetus	0	0	0	X	0	Bovine animals
Transmissibl e gastroenteriti	0	0	X	X	0	Pigs
s European Foulbrood	0	0	X	X	0	Bees
Echinococcu s multiloculari s	0	0	X	X	X	Dogs
Salmonella of animal health relevance Salmonella Pullorum, Salmonella Gallinarum and Salmonella	0	0	X	X	0	Poultry
Zoonotic Salmonellosi s (other than above)	X	0	X	X	X	Poultry (Also, some measures: pigs)
Mycoplasma gallisepticum and Mycoplasma meleagridis	0	0	X	X	X	Poultry:  M. gallisepticum  – fowls and  turkeys  M. meleagridis -

						turkeys
Tuberculosis (other than Bovine	0	0	X	X	X	Apes, felids, ruminants
tuberculosis) **						
Tularaemia	0	0	X	X	0	Lagomorphs
Myxomatosis	0	0	X	X	0	Lagomorphs
Rabbit haemorrhagi c disease	0	0	X	X	0	Lagomorphs
Viral Enteritis (Mink)	0	0	X	X	0	Mink
Aleutian Disease (Mink)	0	0	X	X	0	Mink
Varroosis	0	0	X	X	0	Bees
Acariasis	0	0	X	X	0	Bees
Crimean Congo haemorrhagi c fever	0	0	0	X	0	Ratites
TSEs (Reg 999	 9/2001 ar	nd Dir 92/65)				
Bovine Spongiform Encephalopa thy	X	X	0	X	X	Bovine animals, ovine and caprine animals
Scrapie	X	X	0	X	X	Ovine or caprine animals
Chronic Wasting Disease	X	X	0	X	X	Cervidae

TSEs not BV/OV/CP	X	X	0	0	X	All animals
Zoonoses (Dir	2003/99	/EC and Reg	2075/2005 fo	r Trichinellos	sis)	
Trichinellosi	0	0	X	X	X	Pigs, horses, wild
S						boar and other wild animals (susceptible to Tricinella infestation)
Listeriosis	0	0	0	0	X	Not specified
Campylobact eriosis	0	0	0	0	X	Not specified
Verotoxigeni c E.coli	0	0	0	0	X	Not specified
Leptospirosis	0	0	0	0	X***	Not specified
Yersiniosis	0	0	0	0	X***	Not specified
Vibriosis	0	0	0	0	X***	Not specified
Toxoplasmos is	0	0	0	0	X***	Not specified
Cryptosporid iosis	0	0	0	0	X***	Not specified
Cysticercosis	0	0	0	0	X***	Not specified
Anisakiasis	0	0	0	0	X***	Not specified
Borreliosis	0	0	0	0	X***	Not specified
Botulism	0	0	0	0	X***	Not specified
Influenza Virus	0	0	0	0	X***	Not specified
Echinococco sis [hydatidosis] - 'echinococco sis and	0	0	0	0	X	Not specified

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agents						
thereof'						
Antimicrobia	0	0	0	0	X	Poultry, pigs and
l Resistance						bovine animals
(AMR)						
hazards						
(resistant						
microorganis						
m and						
resistance						
determinants						
)						
Calicivirus	0	0	0	0	X***	Not specified
Hepatitis A	0	0	0	0	X***	Not specified
virus						
Viruses	0	0	0	0	X***	Not specified
transmitted						
by						
arthropods						
Other	0	0	0	0	X***	Not specified
zoonoses and						
zoonotic						
agents						

# Annex - I Part 2 Aquatic animal diseases

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradicatio	Article 8(1)(b) Compulsor y eradicatio n	Article 8(1)(c) Optional "voluntary" eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification & surveillanc e	Listed species	
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	n					
Epizootic haematopoiet ic necrosis	X	X	0	X	X	Rainbow trout (Oncorhynchus mykiss) and redfin perch (Perca
Infection with Bonamia exitiosa	X	X	0	X	X	fluviatilis)  Australian mud oyster (Ostrea angasi) and Chilean flat oyster
Infection with Perkinsus marinus	X	X	0	X	X	(O. chilensis)  Pacific oyster (Crassostrea gigas) and Eastern oyster (C. virginica)
Infection with Microcytos mackini	X	X	0	X	X	Pacific oyster (Crassostrea gigas), Eastern oyster (C. virginica), Olympia flat oyster (Ostrea conchaphila) and European flat oyster (O. edulis)
Taura syndrome	X	X	0	X	X	2002/99 (95/70)  Gulf white shrimp (Penaeus setiferus), Pacific blue shrimp

						(P. stylirostris), and Pacific white shrimp (P. vannamei)
Yellowhead	X	X	0	X	X	Gulf brown shrimp
disease						(Penaeus aztecus),
						Gulf pink shrimp
						(P.
						duorarum),
						Kuruma prawn (P.
						japonicus), black
						tiger shrimp (P.
						monodon), Gulf
						white shrimp (P.
						setiferus), Pacific
						blue shrimp (P.
						stylirostris), and
						Pacific white
						shrimp (P.
						vannamei)
Viral	0	0	X	X	X	Herring (Clupea
haemorrhagi						spp.), whitefish
c septicaemia						(Coregonus sp.),
(VHS)						pike (Esox lucius),
						haddock (Gadus
						aeglefinus), Pacific
						cod (G.
						macrocephalus),
						Atlantic cod (G.
						morhua), Pacific
						salmon
						(Oncorhynchus
						spp.) rainbow trout
						(O. mykiss),

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	T	1	1		1	,
						rockling (Onos
						mustelus), brown
						trout (Salmo
						trutta), turbot
						(Scophthalmus
						maximus), sprat
						(Sprattus sprattus),
						grayling
						(Thymallus
						thymallus) and
						olive flounder
						(Paralichthys
						olivaceus)
Infectious	0	0	X	X	X	Chum salmon
haematopoeit						(Oncorhynchus
ic necrosis						keta), coho salmon
(IHN)						(O. kisutch),
						Masou salmon (O.
						masou), rainbow
						or steelhead trout
						(O. mykiss),
						sockeye salmon (O.
						nerka), pink
						salmon (O.
						rhodurus) chinook
						salmon (O.
						tshawytscha), and
						Atlantic salmon
						(Salmo salar)
Koi herpes	0	0	X	X	X	Common carp and
virus (KHV)						koi carp (Cyprinus
disease						carpio)
Infectious	0	0	X	X	X	Rainbow trout
salmon						(Oncorhynchus
Ì						1

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anaemia						mykiss), Atlantic
(ISA)						salmon (Salmo
						salar), and brown
						and sea trout (S.
						trutta)
Infection	0	0	X	X	X	Australian mud
with						oyster (Ostrea
Marteilia						angasi), Chilean
refringens						flat oyster (O.
						chilensis),
						European flat
						oyster (O. edulis),
						Argentinian oyster
						(O. puelchana),
						blue mussel
						(Mytilus edulis)
						and Mediterranean
						mussel (M.
						galloprovincialis)
Infection	0	0	X	X	$\square X$	Australian mud
with						oyster (Ostrea
Bonamia						angasi), Chilean
ostreae						flat oyster (O.
						chilensis), Olympia
						flat oyster (O.
						conchaphila),
						Asiatic oyster (O.
						denselammellosa),
						European flat
						oyster (O. edulis),
						and Argentinian
						oyster (O.
						puelchana)
White spot	0	0	X	X	X	All decapod
			1	I	1	l

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disease			crustaceans (order
			Decapoda)

#### Notes:

\* OIE Code = in future B. abortus, B. melitensis or B. suis in one chapter, with recommandations for (according to current draft): bovids [cattle (Bos taurus, B. indicus, B. frontalis, B. javanicus and B. grunniens), bison (Bison bison and B.

bonasus) and water buffalo (Bubalus bubalis)], sheep (Ovis aries) and goats (Capra aegagrus), pigs (Sus scrofa), camelids [dromedary camel (Camelus dromedarius), Bactrian camel (Camelus bactrianus), llama (Lama glama), alpaca (Lama pacos), guanaco (Lama guanicoe) and vicuna (Vicugna vicugna)], cervids [roe deer (Capreolus capreolus), red deer (Cervus elaphus elaphus), wapiti/elk (C. elaphus canadensis), sika (C. nippon), samba (C. unicolor unicolor), rusa (C. timorensis), fallow deer (Dama dama,), white-tailed, black-tailed, mule deer (Odocoileus spp.) and reindeer (Rangifer tarandus), European hare (Lepus europaeus).

\*\* M. tuberculosis not OIE listed; however included in Chapter 6.11. on Zoonoses transmissible form non-human primates as M. tuberculosis complex, for specific testing / treatment recommendations during quarantine

\*\*\* Optional in Directive 2003/99/EC, depending on the epidemiological situation in MS

Regulation (EU) No 142/2011 (on ABPs) defines 'serious transmissible diseases' as follows: "The diseases listed by the OIE in Article 1.2.3 of the Terrestrial Animal Health Code, 2010 edition, and in Chapter 1.3 of the Aquatic Animal Health Code, 2010 edition, shall be regarded as serious transmissible diseases for the purposes of general animal health restrictions, as provided for in Article 6(1)(b)(ii) of Regulation (EC) No 1069/2009".

**Amendment 332** 

Proposal for a regulation Annex 3 – point 18

Text proposed by the Commission

Amendment

*[...]* 

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**Amendment 333** 

Proposal for a regulation Annex 3 – point 24

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**DPG** 

Text proposed by the Commission

[...] deleted

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Proposal for a regulation
Annex 3 – point 28

Text proposed by the Commission

Amendment

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[...]