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19.2.2014

***I REPORT

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))

Committee on Agriculture and Rural Development

Rapporteur: Marit Paulsen

RR\1020109EN.doc PE514.757v02-00

Symbols for procedures

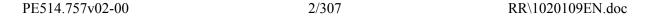
- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

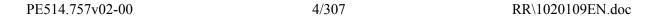
In amendments by Parliament, amendments to draft acts are highlighted in *bold italics*. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].



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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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 Article 168(4)(b) 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 2013¹,
- 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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¹ 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

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salmonella.

Amendment 4

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission

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)

(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

Text proposed by the Commission

(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 Regions¹¹. 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.

(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 Regions¹¹. 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

Amendment

¹¹ COM (2007) 539 final.

¹¹ COM (2007) 539 final.

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

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.

Amendment 9

Proposal for a regulation Recital 9

Text proposed by the Commission

(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

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

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requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals20 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.

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 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

(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 12

Proposal for a regulation

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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.

(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"23 and a tool for such an exercise. This Regulation should introduce such an approach in Union legislation.

Amendment 13

Proposal for a regulation Recital 31

Text proposed by the Commission

Amendment

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Amendment

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

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

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

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.

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.

Amendment 15

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

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

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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. 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 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.

Amendment

(38) Operators, animal professionals and pet keepers working with animals are in the best position to observe and ensure the health of the animals and products under their responsibility. They should therefore hold primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and products under their responsibility, and should work individually and collectively

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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 be carried out by it under this Regulation

Amendment

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

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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.

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.

Proposal for a regulation Recital 49

Text proposed by the Commission

(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

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operators in monitoring wild animals.

Amendment 23

Proposal for a regulation Recital 63

Text proposed by the Commission

(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

(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 24

Proposal for a regulation Recital 63 a (new)

(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 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 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.

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 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

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

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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.

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.

Amendment 28

Proposal for a regulation Recital 79

Text proposed by the Commission

(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)

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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 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.

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

(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 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 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.

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 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.

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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.

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

(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 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

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

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rules for movements of those animals. In order to ensure uniform conditions for the implementation of the animal health requirements laid down in this Regulation concerning the movements of pet animals, implementing powers should be conferred on the Commission to lay down rules concerning the disease prevention and control measures to be taken for such movements.

accordance with Article 290 *TFEU*, without prejudice to the provisions of Regulation (EU) No 576/2013.

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

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Text proposed by the Commission

Amendment

- 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 $820/97^{52}$,

deleted

⁵² OJ L 204, 11.08.2000, p. 1.

Amendment 39

Proposal for a regulation Recital 154 – indent 24

Text proposed by the Commission

Amendment

deleted

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

57 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

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

PE514.757v02-00 26/307 RR\1020109EN.doc 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.

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.

Amendment 41

Proposal for a regulation Recital 160

Text proposed by the Commission

(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;

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- (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.

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

Text proposed by the Commission

Amendment

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

Amendment 44

Proposal for a regulation 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;

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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;

Amendment 49

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

Text proposed by the Commission

Amendment

(a) kept and wild animals;

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

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

Amendment

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

(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

Text proposed by the Commission

Amendment

(8) 'wild animals' means animals which are

(8) 'wild animals' means animals which are

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not kept animals;

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 55

Proposal for a regulation Article 4 – paragraph 1 – point 14

Text proposed by the Commission

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

Amendment

(14) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents transmissible to animals or to humans; for the purposes of this Regulation, microorganisms that have developed resistance to antimicrobials shall also be considered a 'disease';

Amendment 56

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

Text proposed by the Commission

(20) 'risk' means the likelihood of the

Amendment

(20) 'risk' means the likelihood of the

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occurrence and the likely magnitude of the biological and economic consequences of an adverse effect on animal or public health: 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, 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

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Text proposed by the Commission

Amendment

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

(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 and with Title II of Part IV;

Amendment 62

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

Text proposed by the Commission

Amendment

(51) 'disease control aquatic food establishment' means a food business

deleted

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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 official activities in accordance with the provisions laid down in Regulation (EU) .../20.. on official controls.

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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

Text proposed by the Commission

Amendment

That *list* shall *comprise* diseases which meet with the conditions laid down in the following points (a) and (b) of this

That *table* shall *cover* diseases which meet with the conditions laid down in the following points (a) and (b) of this

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paragraph, taking into account the criteria for listing diseases laid down in Article 6:

paragraph, taking into account the *evaluation of the* criteria for listing diseases laid down in Article 6:

Amendment 68

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

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Proposal for a regulation Article 5 – 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 72

Proposal for a regulation 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;

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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 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

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 77

Proposal for a regulation

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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

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:

Amendment 79

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.

Proposal for a regulation Article 7 – 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 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 consultation with stakeholders and experts, modifying Annex -I and concerning the application of the disease prevention and control rules referred to in

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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:

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

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 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

2. The Commission shall take into account the following criteria when adopting *delegated* 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

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*.

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

Text proposed by the Commission

(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;

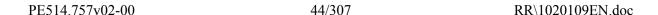
Amendment 94

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

Text proposed by the Commission

Amendment

(bb) ensure controlled use of veterinary medicines.



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:

Amendment 96

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:*

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.

- (a) professional experience or training;
- (b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;
- (c) formal education.

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

Text proposed by the Commission

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

Text proposed by the Commission

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)

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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)

Text proposed by the Commission

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)

Text proposed by the Commission

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

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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

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

Amendment

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

PE514.757v02-00 50/307 RR\1020109EN.doc

paragraph 1;

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

Amendment

(c) minimum requirements for the training 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

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 114

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

Text proposed by the Commission

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

Amendment

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

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

Amendment 116

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

Text proposed by the Commission

Amendment

(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); deleted

Amendment 117

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

PE514.757v02-00 52/307 RR\1020109EN.doc

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)

Text proposed by the Commission

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

Amendment

The Commission shall by means of

The Commission shall be empowered to

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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

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 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

deleted

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 Regulation.

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.

Amendment 123

Proposal for a regulation Article 22 – point a

PE514.757v02-00 54/307 RR\1020109EN.doc

Text proposed by the Commission

Amendment

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

(a) observe the health and *welfare* 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

(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

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

Amendment 126

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

Text proposed by the Commission

Amendment

(ca) agree to animal health visits from a veterinarian for the purpose of preventing the occurence of listed diseases and

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emerging diseases, in accordance with the criteria laid down in Article 23; such visits shall also serve as a means of providing 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)

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(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

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

Amendment

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

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

(a) the *information on* signs indicative of the occurrence of listed diseases or emerging diseases;

Amendment 132

Proposal for a regulation

RR\1020109EN.doc 57/307 PE514.757v02-00

Article 23 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(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

Amendment

Article 24

Delegation of powers concerning animal health visits

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

- (a) supplementing:
- (i) the criteria laid down in Article 23(1) to be taken into account when determining:
- which type of establishments must be subject to animal health visits;
- the frequency of such animal health visits;
- (ii) the requirements laid down in Article 23(2) as regards the content and frequency of animal health visits for the different types of establishments, to ensure that the purposes of the animal health visits are achieved;
- (b) determining the types of establishments to be subject to animal health visits.

deleted

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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

Amendment 136

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

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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.

PE514.757v02-00 60/307 RR\1020109EN.doc

Proposal for a regulation Article 30 – paragraph 2

Text proposed by the Commission

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).

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 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

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

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

Amendment

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

Amendment

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

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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

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 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 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.

Amendment

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

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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)

RR\1020109EN.doc 65/307 PE514.757v02-00

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 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.

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 Article42b (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)

Text proposed by the Commission

Amendment

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)

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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 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.

Amendment 156

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.

Amendment 158

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

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

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of veterinary medicinal products laid down in delegated acts adopted pursuant to Article 47.

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

Text proposed by the Commission

(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

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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

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

Amendment 164

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

Text proposed by the Commission

(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

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(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

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(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:

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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;

Amendment 172

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

Amendment

- (f) take any other necessary disease control measures, taking into account the disease
- (f) take any other necessary disease control measures, taking into account the disease

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control measures provided for in Section 4, concerning:

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;

Amendment 175

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;

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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

Text proposed by the Commission

(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

(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;

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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

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 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

(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*;

Amendment 181

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

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(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

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establishment or other location.

Amendment 184

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

Text proposed by the Commission

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

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

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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 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

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 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*.

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)

Text proposed by the Commission

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)

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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;

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

(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 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

(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;

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).

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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 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

1. In the event of the suspicion or official

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confirmation of a listed disease referred to in Article 8(1)(a) in wild animals, the affected Member State shall:

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

Text proposed by the Commission

(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

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Amendment

(b) the affected wild animals;

(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)

Text proposed by the Commission

Amendment

Article 71a
Scope of Chapter 2

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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

(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 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

(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;

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

Text proposed by the Commission

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

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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

Text proposed by the Commission

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:

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

Text proposed by the Commission

Amendment

(b) the affected wild animals;

(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)

Text proposed by the Commission

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

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 220

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

deleted

Amendment

(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.

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

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1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Articles 89(1), Article 90 and Article 91(1).

Amendment

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Articles 89(1), Article 90 and Article 91(1) 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 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

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approval. However, conditional approval shall not exceed a total period of six months.

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 accordance with Articles 92 and 94 under review.

Amendment

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

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EN

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 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.

Amendment

2. Establishments which are exempted from the registration requirement in accordance with Article 83 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article. Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.

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

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

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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

deleted

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

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

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

Text proposed by the Commission

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 237

Proposal for a regulation Article 108 – title

Text proposed by the Commission

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

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

Amendment 238

Proposal for a regulation Article 108 – paragraph 1 a (new)

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Amendment

By way of derogation from Article 107 (a), Member States may exempt operators from the requirements to identify kept animals of the ovine and caprine species as laid out in Article 4 (2) in Regulation (EC) No 21/2004, replacing this with a requirement to identify those kept animals in accordance with Section A.7 of the Annex to Regulation (EC) No 21/2004, until the animal leaves the holding of birth. When the animal leaves the holding of birth, it shall be identified in accordance with Article 4(2) of Regulation (EC) No 21/2004.

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;

deleted

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

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;

deleted

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

Text proposed by the Commission

Amendment

deleted

deleted

deleted

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(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

Text proposed by the Commission

Amendment

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

Amendment 246

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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

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documents for kept terrestrial pet animals provided for in Article 112(2)(b);

Amendment 247

Proposal for a regulation Article 114 – point f

Text proposed by the Commission

- (f) identification and registration decrequirements 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,
- 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.

Amendment

deleted

Amendment 248

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:

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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

Amendment

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

Amendment 252

Proposal for a regulation

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Article 122 - paragraph 1 - point b

Text proposed by the Commission

(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).

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 moved, no kept ungulates or poultry have been introduced into the establishment of origin;

Amendment

(c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be moved, no kept ungulates or poultry have been introduced into the establishment of origin, 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

(a) residency periods *and biosecurity measures* 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

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

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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 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);

Amendment

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

Amendment

(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 260

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

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 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:

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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

Amendment

(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;

deleted

Amendment 265

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

Text proposed by the Commission

Amendment

(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

deleted

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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

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 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

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 subparagraph 1 that may affect movements between Member States.

Where the conditions laid down in subparagraph 1 are not fulfilled, the Commission may object to or amend the national measures referred to in subparagraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2) and shall enter into force with immediate effect.

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

Text proposed by the Commission

Amendment

(a) aquaculture establishments where aquaculture animals are kept with the view to their being moved from that aquaculture establishment either alive or as products of aquaculture animal origin, however, such application shall not be required where they are solely moved either for:

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

Amendment 270

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

Text proposed by the Commission

Amendment

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

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

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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.

Amendment 273

Proposal for a regulation Article 177 – title

Text proposed by the Commission

Approval of disease control aquatic food establishments

Amendment

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

Amendment 274

Proposal for a regulation Article 177

Text proposed by the Commission

Amendment

Operators of disease control aquatic food

Natural and legal persons intending to

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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).

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 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

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).

Amendment 276

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

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

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authority with the information on:

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 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

Amendment

(c) all *processing establishments and* disease control aquatic food establishments

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with Article 179(1).

approved in accordance with Article 179(1).

Amendment 283

Proposal for a regulation Article 186 – title

Text proposed by the Commission

Record keeping obligation for disease control aquatic food establishments

Amendment

Record keeping obligation for *processing* 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

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Text proposed by the Commission

Amendment

- 2. Operators of disease control aquatic food establishments shall:
- 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

Commission Amendment

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

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

Text proposed by the Commission

Amendment

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

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(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

Amendment

- (i) the *aquaculture* animals received;
- (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

Text proposed by the Commission

Movement of *aquaculture* animals intended for Member States, zones or

Amendment

Movement of *kept aquatic* animals intended for Member States, zones or

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compartments which have been declared disease free or which are subject to an eradication programme and delegated acts 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

Amendment 293

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

Text proposed by the Commission

- (b) intended for: deleted
- (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.

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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

Amendment

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

Amendment

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

Amendment 297

Proposal for a regulation

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

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 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

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.

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

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 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 eradication programme and delegated acts

Amendment

Movement of *kept aquatic* animals intended for *human consumption in*Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme and delegated acts

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

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

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thereof, which has been declared diseasefree 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: thereof, which has been declared diseasefree 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

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.

Amendment 303

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

Amendment

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

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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:

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:

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Proposal for a regulation Article 200 – paragraph 3 – 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 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

(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;

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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;

Amendment 311

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

Self- declaration by operators for movements of *aquatic animals* 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,

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

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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.

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

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

Amendment 314

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

Text proposed by the Commission

(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

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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 Union;

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 health of the Union;

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

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 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

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.

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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), 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(*).

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), **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.

deleted

Amendment 322

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

Text proposed by the Commission

Amendment

3a. Delegated acts shall be based on the 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;

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*;

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(b) be in contradiction with the rules referred to in paragraph 1.

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

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

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

Text proposed by the Commission

Amendment

- Directive 2008/71/EC,

deleted

Justification

Corresponds to amendment on Article 114, paragraph (b) (i)

Amendment 328

Proposal for a regulation Article 259

Text proposed by the Commission

Amendment

Article 259

deleted

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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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

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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 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 rules as set out in	Article 8(1)(a) Immediate disease control & eradicatio n	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, reporting & surveillance	Listed species
Classical Swine Fever	X	X	0	X	X	Suidae and Tayassuidae
Bluetongue	X	X	0	X	X	All ruminants VECTORS: Culicoides, etc.
Epizootic haemorrhagi c disease of deer	X	X	0	X	X	All ruminants VECTORS: Culicoides, etc.
Swine Vesicular Disease	X	X	0	X	X	Suidae and Tayassuidae

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Highly Pathogenic Avian Influenza	X	X	0	X	X	Poultry, captive birds and wild birds
Low Pathogenic Avian Influenza (H5, H7)	X	X	0	X	X	Poultry and captive birds
African Swine Fever	X	X	0	X	X	Suidae and Tayassuidae VECTORS /RESERVOIRS SOFT TICKS – Genus Ornithodorus)
Foot and Mouth Disease	X	X	0	X	X	Any domestic or wild animal of order Artylodactyla, suborders Ruminatia, Suina and Tylopoda; (Also, some measures: Rodentia and Proboscidae)
Rinderpest	X	X	0	X	X	Ungulates
Peste des Petits Ruminants (PPR)	X	X	0	X	X	Bovidae and Suidae
Rift Valley Fever	X	X	0	X	X	All species of 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	X	0	0	X	X	Species of the genus Bos
onia African Horse Sickness	X	X	0	X	X	Equidae VECTORS: Midges: Culicoides
Equine encephalomy elitis (Incl. EEE, WEE and equine encephalomy elitis Japanese encephalomy	X	0	0	X	X	Equidae VECTORS: Mosquitoes, birds, other reservoirs
elitis) Venezuelan equine encephalomy elitis)	X	0	0	X	X	Equidae VECTORS: Mosquitoes, birds, other reservoirs
West Nile Virus	0	0	0	X	X	Equidae VECTORS: Mosquitoes
Newcastle Disease	X	X	0	X	X	Poultry, other captive birds, including pigeons
Vesicular stomatitis	X	X	0	X	X	Ungulates
Teschen Disease	X	0	0	X	X	Suidae
Glanders	0	0	0	X	X	Equidae
Dourine	0	0	0	X	X	Equidae
Equine Infectious Anaemia	0	0	0	X	X	Equidae
Rabies	0	0	0	X	X	Bovidae, Suidae, Ovidae, Capridae, Equidae, Carnivora and Chiroptera

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Anthrax	0	0	0	X	X	Bovidae, Camelidae, Cervidae, Elephantidae, Equidae and Hippopotamidae
Bovine tuberculosis (COMMENT: Mycobacteri um tuberculosis complex: bovis, caprae)	0	X	X (for apes and felids)	X	X	Mammalia, in particular Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, and Tragulidae
Brucella melitensis*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella abortus*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella ovis* (contagious epididymitis)	0	0	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella suis*	0	0	X	X	X	Cervidae, Leporidae, Ovibos moschatus, Suidae and Tayassuidae
Avian chlamydiosis	0	0	0	X	X	Psittaciformes

Enzootic bovine leukosis	0	X	0	X	X	Bovine animals (including Bison bison and Bubalus bubalus)
Small Hive Beetle (Aethina tumida)	0	0	0	X	X	Apis and Bombus
Tropilaelaps mite (Tropilealaps spp.)	0	0	0	X	X	Apis
American Foulbrood	0	0	0	X	X	Apis
Monkey Pox	0	0	0	0	X	Rodentia and non-human primates
Ebola	0	0	0	0	X	Non-human primates (Apes)
Aujesky's Disease	0	0	X	X	X	Pigs
Caseous Lymphadenit is (Corynebacte ium pseudotuberc ulosis)	0	0	X	X	0	Ovine and caprine
Pulmonary Adenomatosi s	0	0	X	X	0	Ovine and caprine
Paratubercul osis	0	0	X	X	0	Ovine and caprine
Maedi-visna	0	0	X	X	0	Ovine and caprine
Caprine Viral Arthritis/Enc ephalitis	0	0	X	X	0	Ovine and caprine
Contagious Agalactia	0	0	X	X	0	Ovine and caprine
Border Disease	0	0	0	X	0	Ovine and caprine
Infectious bovine	0	0	X	X	0	Bovine animals

rhinotracheit is/ infectious pu stular vulvov aginitis						
Bovine [genital] campylobact eriosis – C. foetus ssp. Venerealis	0	0	0	X	0	Bovine animals
Bovine Viral Diarrhoea/M ucosal Disease	0	0	0	X	0	Bovine animals
Trichomonas foetus	0	0	0	X	0	Bovine animals
Transmissibl e gastroenteriti s	0	0	X	X	0	Pigs
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 arizonae	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	0	0	X	X	X	Poultry: M. gallisepticum – fowls and turkeys

meleagridis						M. meleagridis – turkeys
Tuberculosis (other than Bovine tuberculosis)	0	0	X	X	X	Apes, felids, ruminants
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					- T	
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 Trichinellosi	s)	
Trichinellosi s	0	0	X	X	X	Pigs, horses, wild boar and other wild animals (susceptible to Tricinella infestation)
Listeriosis	0	0	0	0	X	Not specified
Campylobact	0	0	0	0	X	Not specified

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

Annex - I Part 2 Aquatic animal diseases

		дуии	uc animai ai	seuses		
Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradicatio n	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
Epizootic haematopoiet ic necrosis	X	X	0	X	X	Rainbow trout (Oncorhynchus mykiss) and redfin perch (Perca fluviatilis)
Infection with Bonamia exitiosa	X	X	0	X	X	Australian mud oyster (Ostrea angasi) and Chilean flat oyster (O. chilensis)
Infection with Perkinsus marinus	X	X	0	X	X	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) 2002/99 (95/70)
Taura syndrome	X	X	0	X	X	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 haemorrhagi c septicaemia (VHS)	0	0	X	X	X	Herring (Clupea spp.), whitefish (Coregonus sp.), pike (Esox lucius), haddock (Gadus aeglefinus), Pacific cod (G. macrocephalus), Atlantic cod (G. morhua), Pacific salmon (Oncorhynchus spp.) rainbow trout (O. mykiss), rockling (Onos mustelus), brown trout (Salmo trutta), turbot (Scophthalmus maximus), sprat (Sprattus sprattus), grayling (Thymallus thymallus) and olive flounder (Paralichthys olivaceus)
Infectious haematopoeit ic necrosis (IHN)	0	0	X	X	X	Chum salmon (Oncorhynchus keta), coho salmon (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 virus (KHV) disease	0	0	X	X	X	Common carp and koi carp (Cyprinus carpio)
Infectious salmon anaemia (ISA)	0	0	X	X	X	Rainbow trout (Oncorhynchus mykiss), Atlantic salmon (Salmo salar), and brown and sea trout (S. trutta)
Infection with Marteilia refringens	0	0	X	X	X	Australian mud oyster (Ostrea angasi), Chilean flat oyster (O. chilensis), European flat oyster (O. edulis), Argentinian oyster (O. puelchana), blue mussel (Mytilus edulis) and Mediterranean mussel (M. galloprovincialis)
Infection with Bonamia ostreae	0	0	X	X		Australian mud oyster (Ostrea angasi), Chilean 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
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, blacktailed, 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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Text proposed by the Commission

[...]

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Text proposed by the Commission

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EXPLANATORY STATEMENT

Commission proposal COM(2013) 260 on a European animal health law is intended to replace some 40 different pieces of European legislation in this field, the oldest of which dates back to 1964. Based on the priorities of Smart Regulation and taking into account scientific evidence and international norms, the aim is to establish a single, simplified, transparent and clear regulatory framework that provides for a clear and balanced distribution of roles and responsibilities between competent authorities in the Member States, EU institutions, the farming sector, animal owners and others when it comes to the monitoring, prevention and control of different animal diseases.

In recent years, Parliament has taken a position on some key issues of relevance to this proposal and has, *inter alia*, expressed its support for the principles that prevention is better than cure, that animal welfare is important for public health and that veterinary medicinal products should be used responsibly.1

Animal protection and animal health

The Commission proposal is hugely important for public health too, since approximately 70% of our infectious diseases are common to both animals and humans. The proposal is, however, not for an animal health law as such, but rather for a law on animal disease control. It deals with the prevention and control of animal diseases which are transmissible to animals or to humans. It is important to emphasise this point (which should also be reflected in the title of the regulation, so as not to be misleading), just as it is also important to clarify that this is not an animal protection law.

A European animal protection law, containing general principles on the duty of care, the division of responsibilities and educational requirements, would be of the greatest value for animals and farmers in Europe, and is something that the European Parliament has repeatedly called for. It is, however, something completely different from what the Commission has now proposed. Likewise, animal health encompasses many factors other than infectious diseases. This does not mean that animal welfare is irrelevant in this context. On the contrary. There is a clear link between animal welfare and animal and public health. This is a key approach, now called 'One Health', which, happily, is reflected in Article 10 of the proposal.

It is important that the new animal health law is shaped by this approach, and by the connection between good animal husbandry and good animal health. References to animal welfare should, in this connection, be made when they are relevant to animal health, such as when part of biosecurity measures. Moreover, an explicit reference should be made to Article 13 of the Treaty on the Functioning of the European Union, as was done in the proposal for a new Control Regulation (COM(2013) 265), in order to emphasise that animals are sentient beings. It is also appropriate that this Regulation reiterate the importance of good animal husbandry and the requirements arising from EU legislation on animal transport. With respect

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¹ cf. European Parliament resolutions of 22 May 2008 on the EU animal health strategy, of 4 July 2012 on the EU animal protection strategy and of 11 December 2012 on the EU strategy against antibiotic resistance, among others.

to the movement of live animals, this Regulation should be amended to the effect that the deciding factors should be the journey time and the number of assembly operations, not whether the journey crosses a national border.

Another important issue in this context is the problem of stray animals. These can also spread infectious diseases, so strong monitoring and control measures need to be taken by the competent authorities. For this reason, the definition of 'wild animals' in the regulation needs to be expanded to include animals that have been previously been kept but are no longer under the direct control of an owner. It is, however, important to reiterate that EU Regulation 1099/2009 of 24 September 2009 stating that animals shall be spared any avoidable pain, distress or suffering, must be taken into consideration in this context.

Predictability and flexibility

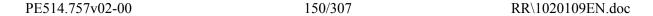
Under the proposal, the EU Commission would be given the power to supplement the content of the regulation through 106 delegated acts and 57 implementing acts. In comparison to the current legislation in this area, which involves about 600 cases of so-called comitology procedures, this is obviously a positive development. Added to that, only about half of the proposed delegated acts and implementing acts would in effect give the Commission greater power than it currently enjoys. It is obviously important that the regulation can, if necessary, be amended quickly, e.g. in the event of a disease outbreak. It also makes no sense, of course, that the Council and the European Parliament should legislate on every tiny detail of the regulations.

An appropriate balance needs to be found between predictability and flexibility. It is important that the actual text of the regulation contains the core principles and guidelines and, in that regard, the proposal should be clarified on a number of points (e.g. lists of the diseases and species covered by the regulation should be set out in annexes). While other details may well be supplemented by the Commission at a later stage, this should be subject to the condition that decisions are made on the basis of the best available science and knowledge. It is particularly important to emphasise that, as noted in recital 13 of the Commission proposal, due account should be taken of the opinions of the European Food Safety Authority. It is also important to bear in mind that the aim is for legislation that is easy to understand and apply. The Commission should therefore be required to adopt a strategic approach and to take a thematic and coherent approach to grouping any additional acts.

Overall, however, the Commission proposal is something of a 'pig in a poke', and it is difficult at the moment to grasp how all the rules and regulations will look and work in practice. For this reason, the Commission should be required to submit a report to the European Parliament and the Council no later than 31 December 2019. This report should contain a review of the experience of applying this Regulation and the supplementary legal acts adopted and, if appropriate, be accompanied by relevant proposals.

Antibiotic resistance

The Commission proposal focuses on rapid and effective measures to control and eradicate certain diseases, which is useful and welcome. Experience has indeed shown what the cost of



outbreaks of disease, such as foot and mouth disease in 2001, can be to society as a whole, both directly (for the farmers affected) and indirectly in the form of medical expenses and loss of income from tourism, etc. However, the largest costs to society are actually caused by endemic diseases that will not be listed in this regulation. They are also the types of diseases for which antibiotics are used as part of the treatment, and which thus are relevant to the growing problem of antibiotic resistance.

It is therefore of vital importance that, without making major changes to its basic structure, this regulation also include a requirement for preventive, proactive measures to monitor and control these non-listed diseases as well. Nor is there any reason to reinvent the wheel: Member States already have multiannual plans to control animal health, in accordance with EU Regulation (EC) No 882/2004, which is now under review. Similarly, Member States have control programmes to combat salmonella and other zoonoses in accordance with EU Regulation No 2160/2003. The existing system should, with reference to the above, be supplemented by strategic measures to monitor, prevent and control infectious animal diseases, including those not listed in this regulation. These measures should include a requirement for a good animal husbandry and responsible use of veterinary medicines.

A free market – but not the free spread of disease

The EU internal market is of key importance to Europe's economy, and nobody hankers after the glory days of border controls. Ultimately, it is clear that effective control of infectious animal diseases is the best basis for a functioning single market regarding trade in live animals, animal products and food. That is why this regulation is so important. At the same time, we have to accept the fact that certain Member States or regions have been more successful than others in managing to eradicate certain diseases on their territory. In this respect, the regulation must involve some balance. We want to have a free market – but not a free market in disease. For this reason, Article 169 on national measures for terrestrial animals should be amended so that additional safeguard measures are permitted – provided that they are founded on a strictly scientific basis and are not adopted for economic reasons, such as disguised restrictions on trade.

A functioning internal market also requires good control of animals living in a country bordering the Union. This requires strict buffer zones to prevent swine fever, for example, entering the EU from neighbouring countries. Member States should therefore – with any technical assistance required at EU level as regards listed diseases – be required to take effective biosecurity measures along their borders with third countries.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

Mr Paolo De Castro Chair Committee on Agriculture and Rural Development BRUSSELS

Subject: Opinion on the legal basis for 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)

Dear Mr Chair,

By letter of 9 January 2014, you asked the Committee on Legal Affairs, pursuant to Rule 37 of the Rules of Procedure, to give its opinion on the appropriateness of adding Article 13 TFEU to the legal basis of the proposal for a regulation of the European Parliament and of the Council on animal health, given that an amendment to this effect had been tabled in AGRI.

The proposal for a regulation on animal health (COM(2013)0260) was presented by the Commission on the basis of Article 43(2), Article 114(3) and Article 168(4)(b) TFEU and was accordingly submitted to Parliament under the ordinary legislative procedure.

Background

1. The proposal

The proposal has been put forward as a result of a review of the Union Animal Health Policy, and following the Animal Health Strategy developed in 2007. The proposed regulation lays down rules – concerning both terrestrial and aquatic animals – for the prevention and control of animal diseases which are transmissible to animals or to humans. It includes:

- provisions on the prioritisation and listing of diseases which are likely to have a significant impact (Part I);
- provisions on early detection, notification and reporting of diseases as well as surveillance, including animal health visits (Part II);
- provision on disease preparedness, awareness and control (Part III), in particular concerning the drawing up of contingency plans, vaccination, as well as control measures to be taken in the case of suspected or confirmed outbreaks of certain diseases;
- provisions on registration and approval of establishments and transporters, movements and traceability of consignments of animals, germinal products and products of animal origin (Part IV), with distinct rules for terrestrial, aquatic, and other animals;
- standards and requirements for third countries sending animals, germinal products, products of animal origin and other material that may transmit animal diseases into the Union, in order to prevent diseases being introduced, as well as requirements for export (Part V);
- emergency measures to be taken in the event of a disease emergency situation (Part VI).

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2. The legal bases in question

a) Legal basis of the proposal

The proposal is based on Article 43(2), Article 114(3) and Article 168(4)(b) TFEU. Those provisions read as follows:

Article 43(2) TFEU

"2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall establish the common organisation of agricultural markets provided for in Article 40(1) and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy."

Article 114(3) TFEU

"3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection taking account in particular of any development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective",

Article 168(4)(b) TFEU

- "4. [...] the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: [...]
- (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;"

b) Proposed change of the legal basis

AGRI has requested the opinion of the Legal Affairs Committee on the appropriateness of adding Article 13 TFEU to the legal basis of the proposal, given that an amendment (AM 69) to this end was tabled in AGRI. A parallel amendment has been tabled in ENVI (AM 192).

Article 13 TFEU reads as follows:

"In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, which respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."

Analysis

Certain principles emerge from the case law of the Court as regards the choice of legal basis. First, in view of the consequences of the legal basis in terms of substantive competence and

procedure, the choice of the correct legal basis is of constitutional importance¹. Secondly, under Article 13(2) TEU, each institution is to act within the limits of the powers conferred upon it by the Treaty². Thirdly, according to the case-law of the Court of Justice, "the choice of legal basis for a Community measure must rest on objective factors amenable to judicial review, including in particular the aim and the content of the measure"³. Finally, as regards multiple legal bases, if examination of a EU measure reveals that it pursues a twofold purpose or that it has a twofold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component⁴. On the other hand, where a measure has several contemporaneous objectives or components which are indissolubly linked with each other without one being secondary and indirect in respect of the others, the measure must be based on the various relevant Treaty provisions⁵.

The Commission put forward Article 43(2), Article 114(3) and Article 168(4)(b) TFEU and explains its choice of legal basis as follows⁶:

- Article 43 TFEU provides the basis for Union legislation regarding the Common
 Agricultural Policy, and also became the basis for veterinary legislation, the Common Animal
 Health Policy being considered to be part of the common Agricultural Policy;
- Article 114 TFEU provides the legal basis for the establishment and the functioning of the internal market and the approximation of provisions in this respect;
- Article 168 TFEU on health protection refers to the protection of human health, including from causes related to animal health. It has provided the legal basis for the adoption of veterinary measures directly aimed at protecting public health.

In order to establish whether this choice of legal basis is appropriate, as the principles derived from the jurisprudence of the Court indicate, the aim and content of the proposed measure are decisive and, in case of multiple legal bases, the question whether several purposes or components of equal weight can be identified within the proposed act.

Indeed, <u>Article 43(2) TFEU</u> provides the general legal basis for the common agricultural policy, under which Parliament and Council establish, apart from the organisation of the agricultural markets, other measures for the pursuit of the objectives of the common agricultural and fisheries policy. The proposal mentions "to ensure [...] the rational development of the agriculture and aquaculture sectors and to increase productivity" (recital 4) as well as "the sustainable agricultural and aquaculture production" (Article 1(2)(a)(i)) as one of its objectives. Furthermore, one of the decisive factors for a disease to be included in a list of diseases to which disease specific rules for the prevention and control of diseases apply is

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¹ Opinion 2/00 Carthagna Protocol [2001] E.C.R. I-9713, para. 5; Case C-370/07 Commission v Council [2009] E.C.R. I-8917, paras 46-49; Opinion 1/08, General Agreement on Trade in Services [2009] ECR I-11129, para. 110

² Case C-403/05 Parliament v Commission [2007] E.C.R. I-9045, para. 49, and the case-law cited therein.

³ See most recently Case C-411/06 Commission v Parliament and Council [2009] E.C.R. I-7585.

⁴ Case C-42/97 *Parliament v Council* [1999] E.C.R. I-868, paras. 39-40; Case-C 36/98 *Spain v Council* [2001] E.C.R. I-779, para. 59; Case C-211/01 Commission v Council [2003] E.C.R. I-8913, para. 39.

⁵ Case C-165/87 Commission v Council [1988] E.C.R. 5545, para. 11; Case C-178/03 Commission v. European Parliament and Council [2006] E.C.R. I-107, paras. 43-56.

⁶ COM(2013)0260, Explanatory memorandum, p. 4/5.

the impact of a specific disease "on the agricultural or aquaculture production or related sectors of the economy" (Article 5(a)(ii), Article 6(1) (b)(i)). Furthermore, a number of veterinary measures which the proposal in question is due to replace (cf. Article 258) were based on the previous Article 37 EC, which has now been replaced by Article 43 TFEU. The proposed regulation can therefore, as regards its aim and content, be qualified as a measure under the common agricultural policy legal basis.

As regards the internal market legal basis, <u>Article 114 TFEU</u>, it is to be noted that the Commission presents "to contribute to the completion of the internal market" (recital 4) and "the effective functioning of the internal market" (Article 1(2)(a)(ii)) as one of the objectives of the proposed legislation. The measures proposed indeed have a clear dimension of facilitating trade in animals and animal products within the internal market. Registration and approval of items as proposed in Part IV of the regulation are for instance classic internal market instruments. The proposed regulation therefore equally qualifies as a measure for completing the functioning of the internal market. It is thus necessary to include Article 114 TFEU in the legal basis¹.

Article 168 TFEU lays down in its paragraph 1 the general objective for the Union to ensure a "high level of human health protection". Against this background, Article 168(4) TFEU provides for specific measures to be adopted by the European Parliament and Council under the ordinary legislative procedure, i.e. harmonisation measures in order to meet common safety concerns (Article 168(4) TFEU). More specifically, Article 168(4)(b) TFEU relates to measures in the veterinary field which have as their direct objective the protection of public health.

The proposal in question addresses common safety concerns in public health matters as regards animal diseases transmissible to animals or to humans and puts forward specific veterinary measures which have as their direct objective the protection of public health. The protection of public health is repeatedly identified as one of the objectives of this regulation (recitals 2, 4, Article 5(2)(a)(i), Article 6(1)(b)(ii)). Specific health policy measures are for instance the provisions on early detection, notification and reporting of animal diseases, on disease awareness and control.

As the proposed regulation thus includes measures relating to the common agricultural policy, to the functioning of the internal market and to the protection of public health, it appears appropriate to base the proposal on the corresponding provisions under the TFEU, i.e. Article 43(2), Article 114 and Article 168(4)(b) TFEU.

As regards the possible addition of <u>Article 13 TFEU</u> to the legal basis, the justification to AM 69 tabled in AGRI reads as follows: "To include a specific reference to Article 13 of the TFEU, covering animal welfare". The identical AM 192 tabled in the ENVI committee quotes the content of Article 13 TFEU in its justification.

¹ For the sake of completeness it might appear more appropriate to mention Article 114 as a whole and not only Article 114(3) TFEU in the legal basis of the proposed regulation as Article 114 (3) TFEU does not contain a legal basis in itself but merely stipulates that the Commission, in its proposals under Article 114(1) TFEU concerning health, safety, environmental protection and consumer protection, is to take as its base a high level of protection.

Article 13 lays down the general principle and objective for the Union and the Member States to "pay full regard to the welfare requirements of animals" when formulating and implementing certain Union policies. It does not however provide for any specific measures or procedures to this end and is contained in Title II of the TFEU ("Provisions having general application). Thus, Article 13 TFEU defines a relevant objective and does not provide for the adoption of measures. It does not constitute a legal basis. The relevant legal basis providing for Union competence under the principle of conferral is to be derived from specific Treaty provisions, whereas the objectives laid down in Article 13 TFEU are to be taken into account when exercising these competences.

In the final analysis, it is considered that it is unnecessary for Article 13 TFEU to be included in a citation as forming part of the legal basis. Should it appear desirable for political reasons to highlight the relevance of Article 13 TFEU to the present piece of legislation, a possibility might be to make reference to this provision in the recitals as has for instance been proposed in AM 5 tabled in the ENVI committee or AM 1 tabled in the PECH committee.

In its note dated 15 January 2014 the Parliament's Legal Service equally comes to the conclusion that it is not appropriate to add Article 13 TFEU to the legal basis of the proposal.

Legal Affairs Committee recommendation

The Legal Affairs Committee considered the above question at its meeting of 21 January 2014. At this meeting, it accordingly decided, by unanimity¹, to recommend that the appropriate legal basis for the proposal for a regulation of the European Parliament and of the Council on animal health should be Article 43(2), Article 114 and Article 168(4)(b) TFEU without the addition of Article 13 TFEU.

Yours sincerely,		
Klaus-Heiner Lehne		

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¹ The following were present for the final vote: Raffaele Baldassarre, Sebastian Valentin Bodu, Françoise Castex, Christian Engström, Marielle Gallo, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Klaus-Heiner Lehne, Eva Lichtenberger, Antonio Masip Hidalgo, Alajos Mészáros, Angelika Niebler, Bernhard Rapkay, Evelyn Regner, Francesco Enrico Speroni, Rebecca Taylor, Alexandra Thein, Axel Voss, Cecilia Wikström, Tadeusz Zwiefka.

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on Agriculture and Rural Development

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))

Rapporteur: Kartika Tamara Liotard

SHORT JUSTIFICATION

The Regulation on Animal Health, in your rapporteur's opinion, will determine the future approach towards safeguarding animals' health. From a technical point of view this Regulation should aim to coordinate and simplify the existing legislation concerning animal health, in order to reduce the complexity and to ensure the correct implementation. From a substance point of view this Regulation should aim primarily to prevent, and in the worst case control, the diseases which affect animal health and human health.

The scope of the Regulation should be in line with the spirit of "prevention is better than cure", and the "One Health Approach", which is enshrined in the "Animal Health Strategy (2007-2013)" of the EU. Studies have demonstrated that there is a clear link between animal health and animal welfare, as well as a clear link between animal diseases and the agricultural practices of breeding, rearing and transporting of animals.

Current intensive farming systems and transport practices, which restrict natural movement of the animals, increase stress and increase the need for antibiotics, regrettably create the ideal conditions for pathogens to multiply. These conditions are factors that risk harm to animals' health and consequently to human health. Furthermore, reproduction methods such as cloning or the modification of the genome of the animal have resulted in adverse animal health effects, such as kidney and brain malformations, and impaired immune systems. This creates unknown risk factors with regards to a possible outbreak of a disease and/or a transfer of that disease to humans.

For your rapporteur the starting point should be a strategy of prevention which, when looking at the roots of the problem and taking the precautionary principle in mind, tries to eliminate the risk factors that create the problems that affect animal health. Each year more than 64 billion animals are born, raised and slaughtered for food globally. There is a significant

interconnection between livestock farming, livestock trade and wildlife trade. Therefore, EU animal health legislation should first and foremost determine how animal disease outbreaks occur and how they can be prevented, controlled and how lessons can be learned from the disease control measures taken in the past (Avian Influenza, Food and Mouth disease, Swine Flu, BSE etc.). In your rapporteur's opinion, mass-killing of animals should only be used as a last resort

Since 1980 more than 35 infectious diseases have emerged and 87 pathogens have been discovered that have originated from animals and were transferred onto humans entailing considerable economic costs, all of which could have been avoided.

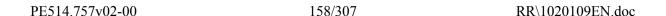
Domestic and wild animals form part of the ecosystem and interact with each other. Maltreatment of those in whichever form, from inhumane breeding methods to forced relocation for trading reasons, have an environmental impact on the balance of the ecosystem. This creates favourable conditions for disease outbreaks, which have to be remedied by measures that may harm the biodiversity and the ecosystem balance. Your rapporteur, having previously worked in the field for the Dutch Ministry of Agriculture, can only remember too well the massive impact on the environment and society of the mass culling and subsequent disposal of carcasses during the outbreaks of Avian Influenza, Foot and Mouth Disease and the Swine Flu. Contamination of groundwater and large soot clouds from the pyres have farreaching impacts, which are often not factored in by policy makers.

Improving animal welfare does not have to impose great penalties on business returns. The current boom in organic farming, and Member State initiatives as for instance the "Beter Leven" mark on beef, pork, poultry and eggs in the Netherlands, have showed that there is a demand amongst consumers for higher animal welfare standards which imply a better and safer food quality. Clearer consumer information on animal welfare would contribute positively.

Finally, some matters of a more procedural nature. Firstly, it is important that there is a coordinated framework on animal health. However, it is also important that Member States are able to take additional measures which are in line with this legislation, but go beyond the provisions of this legislation, when this is necessary for a quick response in a crisis.

Secondly, the rapporteur is concerned by the Commission proposing to repeal two legal instruments regarding non-commercial movements of pets and electronic identification of bovine animals and beef labelling, which recently have been adopted by the co-legislators or are currently going through the co-decision procedure. This behaviour by the Commission does not benefit legal certainty and should not be encouraged further.

Finally, although there is a significant interdependence of animal health and animal welfare, your rapporteur would not want to preclude the eventual outcome of a future proposal on animal welfare



AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Citation 1

Text proposed by the Commission

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114(3) and Article 168(4)(b) thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular *Article 13*, Article 43(2), Article 114(3) and Article 168(4)(b) thereof,

Justification

Article 13 says: In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.

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, *the public* and the economy *in certain regions and countries*.

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, as for example in the case of *Bovine Spongiform Encephalopathy* (BSE), avian influenza and salmonella.

Justification

The BSE crisis is worth mentioning here because apart from being a serious animal health issue that was transmitted onto humans through food, it was also a major crisis of confidence where the public lost trust in the safety of the food chain and policy makers.

Amendment 4

Proposal for a regulation Recital 3

Text proposed by the Commission

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

Amendment

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

Justification

Food security and environmental pollution are also affected by transmissible animal diseases.

Proposal for a regulation Recital 4

Text proposed by the Commission

(4) In order to ensure high standards of animal and public health in the Union, the rational development of the agriculture and aquaculture sectors and to increase productivity, animal health rules should be laid down at Union level. These rules are necessary, inter alia, to contribute to the completion of the internal market, *and* to avoid the spread of infectious diseases.

Amendment

(4) In order to ensure high standards of animal and public health in the Union, the rational development of the agriculture and aquaculture sectors and to increase *sustainable* productivity, animal health rules should be laid down at Union level. These rules are necessary, inter alia, to contribute to the completion of the internal market, to avoid the spread of infectious diseases, *and to enhance animal welfare*.

Justification

There are numerous studies, even scientific opinions from EFSA, which prove that enhancing animal welfare benefits animal health and vice versa.

Amendment 6

Proposal for a regulation Recital 5

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation Recital 6 a (new)</Article>

Text proposed by the Commission

Amendment

(6a) The Communication from the Commission on the European Union Strategy for the Protection and Welfare of Animals 2012-2015 reiterates that Article 13 of the Treaty on the Functioning of the European Union recognises animals as sentient beings and requires full regard be given to the welfare requirements of animals while formulating and enforcing EU policies. In this respect, due consideration needs to be given to the positive effect of high animal welfare standards on animal health.

Amendment 8

Proposal for a regulation Recital 7

Text proposed by the Commission

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

Amendment

(7) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the "One health" principle, as advocated in particular by the World Organisation for Animal Health (OID), and to consolidate the legal framework for a common Union animal health policy through a single, simplified, and flexible regulatory framework for animal health

Amendment 9

Proposal for a regulation Recital 7 a (new)

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Text proposed by the Commission

Amendment

(7a) Since contagious pathogens can easily be spread from one holding to another, as the Commission stresses in its communication on a new Animal Health Strategy for the EU, a collective approach to preventive and biosafety measures should be adopted, involving all stakeholders.

Amendment 10

Proposal for a regulation Recital 7 b (new)

Text proposed by the Commission

Amendment

(7b) The intensification and integration of food production and the increase of transport during production and before slaughtering is the cause of many of the infectious animal diseases that have emerged in the 20th century. This Regulation provides the base for existing methods to be carefully evaluated and reviewed in order to identify the source of problems and diseases related to animals and to take adequate measures to prevent unsustainable farming methods leading to the kind of outbreaks we have seen in the recent past.

Justification

The farming of animals has intensified over the past decades, with certain establishments housing several thousands of animals on a relatively small surface. Also, long distance transports of animals for slaughter are on the rise, where the animals are in closed confines for long periods of time. These practices create ideal circumstances for pathogens to multiply, which risks harming public and animal health.

Amendment 11

Proposal for a regulation

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Recital 9

Text proposed by the Commission

(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 and cultural aspects, and especially animal welfare, given the interdependency of animal welfare and animal health, trying to minimize animal suffering and provide pro-active solutions to disease risks.

Amendment 12

Proposal for a regulation Recital 12

Text proposed by the Commission

(12) In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement which has been interpreted for the Union in the Communication from the Commission of 2 February 2000 on the precautionary principle¹³ allows a Member of that agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the WTO Member is required to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

Amendment

(12) In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement which has been interpreted for the Union in the Communication from the Commission of 2 February 2000 on the precautionary principle, which is enshrined in European Union law in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, allows a Member of that agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the WTO Member is required to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

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Proposal for a regulation Recital 16

Text proposed by the Commission

(16) Diseases occurring in wild animal populations may have a detrimental effect on the agriculture and aquaculture sectors, on public health, the environment and biodiversity. It is therefore appropriate that the scope of this Regulation should, in such cases, cover wild animals, both as potential victims of those diseases and as their vectors.

Amendment

(16) Diseases occurring in wild animal populations, as for instance rabies and Batrachochytrium dendrobatidis (commonly referred to as the chytrid fungus), may have a detrimental effect on the agriculture and aquaculture sectors, on public health, the environment and biodiversity. It is therefore appropriate that the scope of this Regulation should, in such cases, cover wild animals, both as potential victims of those diseases and as their vectors.

Amendment 14

Proposal for a regulation Recital 17

Text proposed by the Commission

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

Amendment

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

health rules need to cover all paths of infection and material involved therein.

health rules need to cover all paths of infection and material involved therein.

Amendment 15

Proposal for a regulation Recital 18

Text proposed by the Commission

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

Amendment

(18) Animal diseases may have detrimental effects on the distribution of animal species in the wild, and thus affect biodiversity. Microorganisms causing animal diseases can therefore fall within the definition of invasive alien species of the United Nations Convention on Biological Diversity. The measures provided for in this Regulation also take account of biodiversity and thus this Regulation should cover animal species and disease agents, including those defined as invasive animal species, which play a role in the transmission of, or are affected by, diseases covered by this Regulation. This should include invasive pathogens, such as Batrachochytrium dendrobatidis, an amphibian disease listed by the World Organisation for Animal Health (OIE) and causing population declines and extinction.

Amendment 16

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

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

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products thereof, and on the prevention and control of certain diseases in aquatic animals20 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.

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 17

Proposal for a regulation Recital 20

Text proposed by the Commission

(20) Union legislation adopted prior to this Regulation and in particular Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC²¹ also lays down basic animal health rules for other animal species not regulated in other Union acts, such as reptiles, amphibians, marine mammals, and others which are not aquatic or terrestrial animals as defined in this Regulation. Usually, such species do not represent a significant health risk for

Amendment

(20) Union legislation adopted prior to this Regulation and in particular Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC²¹ also lays down basic animal health rules for other animal species not regulated in other Union acts, such as reptiles, amphibians, marine mammals, and others which are not aquatic or terrestrial animals as defined in this Regulation. These species were not considered to represent a significant health

humans or other animals and therefore only a few animal health rules, if any, apply. In order to avoid unnecessary administrative burdens and costs, this Regulation should adhere to the approach adopted in the past, namely to provide the legal framework for detailed animal health rules for movements of such animals and their products to be laid down if the risks involved so require.

risk for humans or other animals and therefore only a few animal health rules, if any, apply. Evidence of reptile and amphibian species spreading salmonella to humans and fungal pathogens (Batrachochytrium dendrobatidis) to wild amphibian populations suggest detailed rules for such species may be warranted.

Amendment 18

Proposal for a regulation Recital 21

Text proposed by the Commission

(21) The keeping of pet animals, including ornamental aquatic animals in households and non-commercial ornamental aquaria, both indoors and outdoors, generally represents a lower health risk compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union apply to such animals, as this would represent an unjustified administrative burden and cost. Registration and record keeping requirements should therefore not apply to pet keepers. In addition, specific rules should be laid down for non-commercial movements of pet animals within the Union.

Amendment

(21) The keeping of pet animals, including ornamental aquatic animals in households and non-commercial ornamental aquaria, both indoors and outdoors, a practice of a non-commercial nature, generally represents a lower health risk compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union apply to such animals, as this would represent an unjustified administrative burden and cost for citizens. Registration and record keeping requirements should therefore not apply to pet keepers. In addition, specific rules should be laid down for noncommercial movements of pet animals within the Union

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²¹ OJ L 268, 14.9.1992, p. 54.

²¹ OJ L 268, 14.9.1992, p. 54.

Proposal for a regulation Recital 25

Text proposed by the Commission

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

Amendment

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

Amendment 20

Proposal for a regulation Recital 26

Text proposed by the Commission

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

Amendment

deleted

Justification

No need to put this into the text of the Regulation, as Member States are well aware of this already.

Amendment 21

Proposal for a regulation Recital 27

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Text proposed by the Commission

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

Amendment

(27) For transmissible animal diseases that are not subject to measures laid down at Union level, but which are of some economic importance for the private sector at a local level, Member States should have the preparedness to respond and, together with the private sector, to take actions to prevent or control such diseases, for instance through developing practical measures to avert their harmful effects and establishing self-regulatory mechanisms and developing codes of practice or exchange of best practices.

Justification

There have been countless scandals, some of which quite recently, ranging from hormones to Salmonella that clearly prove that self-regulation in this sector will not work. Not only will it increase the risks towards public health and animal health, it will greatly endanger food safety and food security.

Amendment 22

Proposal for a regulation Recital 28

Text proposed by the Commission

(28) In contrast to the transmissible animal diseases described in recitals 26 and 27, highly transmissible animal diseases may easily spread *across borders* and, if they are also a zoonosis, *they* may also have an impact on public health and food safety. Hence highly transmissible animal diseases and zoonoses should be covered by this Regulation.

Amendment

(28) In contrast to the transmissible animal diseases described in recitals 26 and 27, highly transmissible animal diseases may easily spread *in cross-border areas on which joint action and decisions have to be taken by at least two countries* and, if they are also a zoonosis, *this* may also have an impact on public health and food safety. Hence highly transmissible animal diseases and zoonoses should be covered by this Regulation.

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Proposal for a regulation Recital 29

Text proposed by the Commission

(29) Action No. 5 of the Communication from the Commission to the European Parliament and the Council – Action plan against the rising threats from Antimicrobial Resistance emphasises the preventive role of this Regulation and the consequent expected reduction of the use of antibiotics in animals. Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. This resistance complicates the treatment of infectious diseases in humans and animals. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation.

Amendment

(29) Action No. 5 of the Communication from the Commission to the European Parliament and the Council – Action plan against the rising threats from Antimicrobial Resistance emphasises the preventive role of this Regulation and the consequent expected reduction of the use of antibiotics in animals. Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. This resistance complicates the treatment of infectious diseases in humans and animals. In its Resolution of 12 May 2011 on antibiotic resistance^{1a}, its Resolution of 27 October 2011 on the public health threat of antimicrobial resistance^{1b} and its Resolution of 11 December 2012 on the Microbial Challenge - Rising threats from Antimicrobial Resistance^{1c}, the European Parliament in the past repeatedly pointed to the importance of tackling antimicrobial resistance. In November 2011, the Commission adopted a Communication on an action plan against the rising threats from antimicrobial resistance^{1d}, whereas the Council dealt with the issue in its conclusions of 22 June 20121e. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation.

^{1a} P7 TA(2011)0238

^{1b} P7_TA(2011)0473

^{1c} P7_TA-PROV(2012)0483

^{1d} COM(2011)0748

1e http://ue.eu.int/press/pressreleases/employment,-social-policy,health-and-consumeraffairs?target=2012&infotarget=&max=0 &bid=79&lang=en

Amendment 24

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

(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 of the Treaty on the Functioning of the European Union.

Amendment 25

Proposal for a regulation Recital 32

Text proposed by the Commission

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

Amendment

(32) Recognising that 60% of Emerging infectious diseases are zoonotic and the majority (71.8%) originate in wildlife, it is likely that emerging diseases with the potential to cause serious public or animal health risks and impacts on health, the economy or the environment may appear in the future. Following the assessment of such diseases and after adopting temporary emergency measures, when relevant, a quick reaction and insertion of such diseases in the list of listed diseases may be necessary. Therefore, in exceptional circumstances, the power to adopt acts in accordance with the urgency procedure

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should be delegated to the Commission in these duly justified cases of risks to public or animal health

Amendment 26

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.

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 of the Treaty on the Functioning of the European Union.

Amendment 27

Proposal for a regulation Recital 35 a (new)

Text proposed by the Commission

Amendment

(35a) In the event of the outbreak of a zoonosis in a cross-border region and in order to prevent the spread of infection, the Commission should strive to harmonise certain procedures for the restriction of livestock and product movements from countries neighbouring the EU, such as prohibiting movements from and to affected areas or testing prior

to dispatch.

Amendment 28

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 29

Proposal for a regulation Recital 38

Text proposed by the Commission

(38) Operators, animal professionals and pet keepers working with animals are in the best position to observe and ensure the health of the animals and products under their responsibility. They should therefore hold primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and products under their responsibility.

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 of the Treaty on the Functioning of the European Union.

Amendment

(38) Operators, animal professionals and pet keepers working with animals are in the best position to observe and ensure the health of the animals and products under their responsibility. They should therefore hold primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and products under their responsibility, and they should contribute to the advancement of better animal health practices.

Proposal for a regulation Recital 40

Text proposed by the Commission

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

Amendment

(40) Biocidal products, such as disinfectants for veterinary hygiene or food and feed areas, insecticides, repellents or rodenticides play an important role in biosecurity strategies, both at farm level as well as during animal transport. They should therefore be considered a part of biosecurity and the impact of their use on public health, animal health and the environment should be taken into account when applying biosecurity prevention tools.

Amendment 31

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 is a prerequisite for efficient animal health management and essential in ensuring the prevention and early detection of animal diseases. Operators and other animal professionals should therefore be encouraged to acquire, maintain and develop such knowledge, including of disease symptoms, consequences of diseases, possible means of prevention including biosecurity, treatment and control, the dangers posed by antimicrobial resistance and the link between animal health and animal welfare and animal husbandry practices. 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

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European farmer organisations and other organisations may be valuable contributors. Those alternative means of acquiring such knowledge should also be recognised by this Regulation. However, with regard to the multi-facetted and international dimension in which operators and other animal professionals operate, sole reliance on professional experience is no longer compatible with an EU animal health strategy that focuses on prevention.

Amendment 32

Proposal for a regulation Recital 42

Text proposed by the Commission

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

Amendment

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

Amendment 33

Proposal for a regulation Recital 44

Text proposed by the Commission

(44) In order to ensure that the veterinarians and aquatic animal health professionals who undertake activities that fall within the scope of this Regulation are adequately qualified and receive appropriate training, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect to their

Amendment

(44) In order to ensure that the veterinarians and aquatic animal health professionals who undertake activities that fall within the scope of this Regulation are adequately qualified and receive appropriate training, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect to their qualification and training, and to develop

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procedures for the EU-wide recognition of the qualifications of those professionals.

Amendment 34

Proposal for a regulation Recital 46

Text proposed by the Commission

(46) The competent authority cannot always perform all the activities required to be carried out by it under this Regulation due to the limited resources. For that reason it is necessary to provide a legal basis for the delegation of the performance of those activities to veterinarians. In order to ensure that the necessary conditions are laid down for the general application of disease prevention and control measures across the Union, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect to the delegation of the performance of those activities to veterinarians and their appropriate training.

Amendment

(46) The competent authority cannot always perform all the activities required to be carried out by it under this Regulation due to the limited resources. For that reason it is necessary to provide a legal basis for the delegation of the performance of those activities to veterinarians. For the same reason, it is of utmost importance that these veterinarians 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 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.

Justification

Conflicts of interests are regrettably an increasing problem, especially considering the fact that many veterinarians that undertake animal health checks are paid by the establishments that they are controlling. This needs to be tackled in order to increase transparency and ensure proper safeguards for public health, animal health and food safety.

Amendment 35

Proposal for a regulation Recital 47

Text proposed by the Commission

Amendment

(47) Optimal animal health management

(47) Optimal animal health management

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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.

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 36

Proposal for a regulation Recital 49

Text proposed by the Commission

(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 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. *Member States should ensure that operators and animal professionals are adequately informed of their obligations under this Regulation*.

Amendment 37

Proposal for a regulation Recital 56

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Text proposed by the Commission

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

Amendment

(56) Surveillance is a key element of disease control policy. It should provide for the early detection of transmissible animal diseases and efficient notification, thereby enabling the sector and the competent authority to implement, where feasible, timely disease prevention and control measures, and the eradication of a disease. Furthermore, it should supply information on the animal health status of *each region* and/or each Member State and of the Union as a whole, thereby substantiating disease freedom and facilitating trade within the Union and with third countries.

Amendment 38

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 behaviour, mortalities or other serious disease symptoms. Operators are therefore the cornerstone of any surveillance and *are* essential for the surveillance undertaken by the competent authority. Despite potential economic risks for operators, it is in their own interest that abnormal mortalities or other serious disease symptoms are reported to the competent authority, as certain disease control measures may have a significant impact on operators and as Member States may decide to enforce private law accountability on operators who did not report correctly to the competent authority.

Justification

Many times a crisis has started by operators choosing to neglect disease symptoms and other animal health risks. This behaviour seriously endangers public health, animal health and food safety and needs to be tackled urgently.

Amendment 39

Proposal for a regulation Recital 58

Text proposed by the Commission

(58) To ensure close collaboration and exchange of information between operators and veterinarians or aquatic animal health professionals and to supplement the surveillance undertaken by operators, establishments should, as appropriate for the type of production and other relevant factors, be subject to animal health visits. In order to ensure a proportionate level of surveillance to the risks involved in different types of establishments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission concerning the criteria and the content of such animal health visits in different types of establishments.

Amendment 40

Proposal for a regulation Recital 58 a (new)

Text proposed by the Commission

Amendment

(58) To ensure close collaboration and exchange of information between operators and veterinarians or aquatic animal health professionals and to supplement the surveillance undertaken by operators, establishments should, as appropriate for the *type and intensity* of production and other relevant factors, be subject to animal health visits. In order to ensure a proportionate level of surveillance to the risks involved in different types of establishments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission concerning the criteria and the content of such animal health visits in different types of establishments.

Amendment

(58a) To promote sustainable, organic and biological production, and to underline the increased animal health risks of high intensive production on establishments that have a relatively high density of animals per surface level of the establishment, it is appropriate that the

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intensity of production and other relevant factors are taken into account when determine the frequency and type of animal health visits.

Justification

The farming of animals has intensified over the past decades, with certain establishments housing several thousands of animals on a relatively small surface. This practice creates ideal circumstances for pathogens to multiply, which risks harming public and animal health. Sustainable, organic and biological farming has additional safeguards built in, which benefit public health, animal health and food safety.

Amendment 41

Proposal for a regulation Recital 63

Text proposed by the Commission

(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

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, 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

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programmes.

programmes. The Commission should launch negotiated procedures with the countries neighbouring the EU aimed at establishing harmonised requirements for compulsory and voluntary and eradication programmes.

Amendment 42

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 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.

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 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 43

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

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 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. *For example, routine administering of vaccines, hyper-immune*

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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.

sera, antimicrobials and other veterinary medicines to animals by animal keepers, operators, veterinarians and animal health professionals should only be tolerated when there are no adverse effects on public health, animal health and animal welfare, both by the practice or the consumption of products of these animals. 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 44

Proposal for a regulation Recital 82

Text proposed by the Commission

(82) In the event of an outbreak of a listed disease considered to represent a high risk to animal or public health in the Union, it is necessary to take immediate disease control measures to eradicate that listed disease in order to protect animal and public health and the relevant sectors.

Amendment

(82) In the event of an outbreak of a listed disease considered to represent a high risk to animal or public health in the Union, it is necessary to take immediate disease control measures to eradicate that listed disease *in the affected region* in order to protect animal and public health and the relevant sectors. Where the disease outbreak is only limited to a certain region of a Member State and where there is no longer a danger of disease spreading to neighbouring regions, the measure of

revoking the "disease-free" status should be applied only to the affected region and not to the whole territory of the affected Member State.

Amendment 45

Proposal for a regulation Recital 86 a (new)

Text proposed by the Commission

Amendment

(86a) Some disease control measures, although they might be necessary, have in potential a greater impact than planned. Therefore, it is appropriate that the Member State or Member States concerned should, after having heard the competent authorities, draw up an initial assessment of the impact on public health, animal health and animal welfare, the environment, the economy and other socio-economic factors, of the envisaged necessary disease control measures. For example, historical evidence has shown that the killing and disposal of large groups of animals affected by a listed disease, has, aside from the direct socioeconomic impact on the operators, a vast impact on society (outrage, loss of confidence in the food chain, loss of trust in policy makers) and an often overlooked environmental impact (disposal of bodies by mass burning creating large soot plumes and permeates ground water).

Amendment 46

Proposal for a regulation Recital 86 b (new)

Text proposed by the Commission

Amendment

(86b) Disease control measures that become necessary in the event of a disease

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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 47

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

(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. Such rules should take account of the need to preserve biodiversity and should allow for the mass culling of wild animals only as a last resort.

Amendment 48

Proposal for a regulation Recital 91 a (new)

Text proposed by the Commission

Amendment

(91a) Long distance transports or movements of animals entail, apart from severe animal health implications, an increased risk of spreading disease vectors, due to the nature of the transport and the close proximity of a large number of animals in a small confined space. It is therefore appropriate to ensure that transport or movements of animals shall

not exceed a total duration of 8 hours.

Amendment 49

Proposal for a regulation Recital 98

Text proposed by the Commission

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

Amendment

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

Amendment 50

Proposal for a regulation Recital 100

Text proposed by the Commission

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

Amendment

(100) It is appropriate to reduce administrative burdens and costs and provide for flexibility of the system in circumstances where the traceability requirements can be achieved by means other than those set out in this Regulation. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union concerning the derogations from the identification and registration requirements. *However, under no circumstances can a derogation from the*

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identification and registration requirements result in an inability to determine the responsible operator, animal professional, establishment or any other natural or legal person.

Justification

Traceability is of paramount importance when dealing with matters concerning animal health.

Amendment 51

Proposal for a regulation Recital 103

Text proposed by the Commission

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

Amendment

(103) The general requirements laid down in this Regulation should apply to all animal movements, such as the prohibition of movement of animals from an establishment where there are abnormal mortalities or other disease symptoms with an undetermined cause or disease prevention requirements during transport and the maximum total duration of movement of animals of no more than 8 hours.

Amendment 52

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

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

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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.

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 shall be registered by the competent authority.*

Amendment 53

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 54

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

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.

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

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laid down in this Regulation to ensure that movements of those animals take place in a safe manner 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 55

Proposal for a regulation Recital 114

Text proposed by the Commission

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

Amendment

deleted

Amendment 56

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 requirements laid down in this Regulation concerning the movements of pet animals,

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*.

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 57

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 should *be proportionate*, *non-discriminatory and 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 58

Proposal for a regulation Recital 137

Text proposed by the Commission

(137) Currently, listed diseases concern animal species other than those defined as terrestrial and aquatic by this Regulation, such as reptiles, amphibians, insects and others only to a very limited extent. It is therefore not appropriate to require that all the provisions of this Regulation apply to those animals. However, if a disease which concerns species other than terrestrial and

Amendment

(137) Currently, listed diseases concern animal species other than those defined as terrestrial and aquatic by this Regulation, such as reptiles, amphibians, insects and others only to a very limited extent. It is therefore not appropriate to require that all the provisions of this Regulation apply to those animals. However, if a disease which concerns species other than terrestrial and

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aquatic should become listed, the relevant animal health requirements of this Regulation should apply to those species to ensure that adequate and proportionate disease prevention and control measures may be taken.

aquatic should become listed, the relevant animal health requirements of this Regulation should apply to those species to ensure that adequate and proportionate disease prevention and control measures may be taken. For example, the World Organisation for Animal Health (OIE) currently lists two amphibian diseases, Batrachochytrium dendrobatidis and ranavirus, which are currently not regulated in the EU and should be considered under this Regulation.

Amendment 59

Proposal for a regulation Recital 139 a (new)

Text proposed by the Commission

Amendment

(139a) Directive 2008/120/EC lays down minimum standards for the protection of pigs¹a, Directive 1999/74/EC lays down minimum standards for the protection of laying hens¹b, and Directive 2007/43/EC lays down minimum rules for the protection of chickens kept for meat production¹c. However, specific legislation laying down minimum standards for the protection of dairy cows and beef cattle does not yet exist. In order to take account of the clear correlations between animal health and welfare, the Commission will present proposals on this regard before the entry into force of this regulation.

^{1 a}OJ L 47, 18.2.2009, p.5

^{1b}OJ L 203, 3.8.1999, p.53

^{1c}OJ L 182, 12.7.2007, p.19

Proposal for a regulation Recital 140

Text proposed by the Commission

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

Amendment

(140) To prevent the introduction of listed diseases and emerging diseases into the Union, it is necessary to have in place efficient rules on the entry into the Union *from third countries* of animals, germinal products and products of animal origin that may transmit such diseases, *as well as measures for preventing uncontrolled cross-border livestock movement*.

Amendment 61

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]⁵⁷,

Amendment

deleted

57 O.J.L ...

Amendment 62

Proposal for a regulation Recital 155

Text proposed by the Commission

(155) The rules laid down in the legislative acts referred to in recital 154 are to be replaced by this Regulation and by subsequent Commission acts to be adopted pursuant to this Regulation. Accordingly,

Amendment

(155) The rules laid down in the legislative acts referred to in recital 154 are to be replaced by this Regulation and by subsequent Commission acts to be adopted pursuant to this Regulation. Accordingly,

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those legislative acts should be repealed. *However*, to ensure legal clarity and avoid a legal vacuum, the repeal should only take effect when the relevant delegated and implementing acts are adopted pursuant to this Regulation. It is therefore necessary to provide the Commission with the empowerment to determine the dates when the repeal of those legislative acts should take effect.

those legislative acts should be repealed, except very recent and still under negotiation ones. In order to ensure legal clarity and avoid a legal vacuum, the repeal should only take effect when the relevant delegated and implementing acts are adopted pursuant to this Regulation. It is therefore necessary to provide the Commission with the empowerment to determine the dates when the repeal of those legislative acts should take effect.

Amendment 63

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

(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 (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 64

Proposal for a regulation Recital 160

Text proposed by the Commission

(160) It is of particular importance that the Commission carry out appropriate

Amendment

(160) It is of particular importance that the Commission carry out appropriate

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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

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 65

Proposal for a regulation Article 1 – paragraph 1

Text proposed by the Commission

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

Amendment

1. This Regulation lays down: rules for the prevention and control of animal diseases, which are transmissible to animals or to humans, the instruments and arrangements for moving towards the declaration of disease-free zones, the prioritising of actions and the attribution of responsibilities in the field of animal health and puts into practice the 'One Health' approach establishing a new paradigm for the relationship between animals, humans and the environment.

Justification

This subparagraph should be amended to include three additional headings in order to define more clearly the strategy under the new proposal, in line with the animal health strategy launched by the Commission in 2006. One Health is an integrated approach to health that focuses on the interactions between animals, humans and their diverse environments, and forms part of multidisciplinary policy instruments of the European Union. It encourages collaborations, synergies and cross-fertilisation of all professional sectors and actors in general whose activities may have an impact on health.

Amendment 66

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

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Proposal for a regulation Article 1 – paragraph 2 – point a – point iii – indent 2 a (new)

Text proposed by the Commission

Amendment

- anti-microbial resistance

Amendment 68

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

Text proposed by the Commission

Amendment

- biodiversity;

Amendment 69

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

Text proposed by the Commission

Amendment

- food production;

Amendment 70

Proposal for a regulation Article 1 – paragraph 2 – point b – point i – indent 4

Text proposed by the Commission

Amendment

- animal welfare;

animal welfare and animal husbandry practices;

Proposal for a regulation Article 2 – paragraph 1 – letter a

Text proposed by the Commission

Amendment

a) kept and wild animals;

(a) **all** kept and wild animals;

Amendment 72

Proposal for a regulation Article 2 – paragraph 1 – letter e

Text proposed by the Commission

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

spread of transmissible animal diseases.

Amendment

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

Justification

It stands to reason that the scope must also include operators, veterinarians, animal professionals, as these actors interact intensively with animals and have a vast impact on animal health.

Amendment 73

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

Text proposed by the Commission

Amendment

(5b) 'descendant' means an animal produced by a traditional breeding technique, where at least one of its progenitors is a clone;

Justification

As cloned animals and their descendents are prone to a highly increased risk of contracting animal diseases which might be transmissable to humans and other serious health risks (malformations, organ failure), it is appropriate to give a definition here.

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Proposal for a regulation Article 4 – paragraph 1 – point 9 – point c

Text proposed by the Commission

(c) the purposes of breeding of birds used for the types of production referred to in *point (a)*;

Amendment

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

Justification

Breeding systems also exist for game birds.

Amendment 75

Proposal for a regulation Article 4 – paragraph 1 – point 10

Text proposed by the Commission

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

Amendment

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

Justification

This amendment is necessary in order to include in the scope of the regulation captured and specially bred wild birds used in hunting as live decoys.

Amendment 76

Proposal for a regulation Article 4 – paragraph 1 – point 17

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Text proposed by the Commission

(17) 'disease profile' means the criteria of a disease referred to in Article 6(1)(a);

Amendment

17) 'disease profile' means *assessment of* the criteria of a disease referred to in Article 6(1)(a);

Justification

Addition of the word 'assessment', which is more in line with the actual provisions of Article 6, whose straightforward aim is to assess and weigh up a set of disease factors in order to establish whether or not a disease should be included on the list.

Amendment 77

Proposal for a regulation Article 4 – paragraph 1 – point 14

Text proposed by the Commission

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

Amendment

(14) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents transmissible to animals or to humans. For the purposes of this Regulation, microorganisms that have developed resistance to antimicrobials should also be considered a 'disease';

Amendment 78

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, based on the precautionary principle, the likelihood of the occurrence and the likely magnitude of the biological, health, economic and social consequences of an adverse effect on animal or public health;

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

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, from and within:

Amendment 80

Proposal for a regulation Article 4 – paragraph 1 – point 22

Text proposed by the Commission

(22) 'operator' means a natural or legal person, having animals and products under their responsibility, including animal keepers *and transporters*, but excluding pet keepers and veterinarians;

Amendment

(22) 'operator' means a natural or legal person, having animals and products under their responsibility, including animal keepers, transporters and those engaged in the commercial breeding and sale of animals, but excluding pet keepers and veterinarians;

Amendment 81

Proposal for a regulation Article 4 – paragraph 1 – point 24 – introductory part

Text proposed by the Commission

(24) 'establishment' means any premises, structure, or any *environment*, in which animals or germinal products are kept, except for:

Amendment

(24) 'establishment' means any premises, structure, or any *place*, in which animals or germinal products are kept, except for:

Justification

By replacing "Environment" with "place" the wording would be in line with what is used further down in article 4 – paragraph 1 – point 37.

Amendment 82

Proposal for a regulation Article 4 – paragraph 1 – point 34

Text proposed by the Commission

Amendment

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

(34) 'compartment' means

Justification

Two types of compartment (terrestrial and aquatic) should be established, given that their end purposes differ and hence so will the way they are implemented.

Amendment 83

Proposal for a regulation Article 4 – paragraph 1 – point 34 – point i (new)

Text proposed by the Commission

Amendment

i) in the case of terrestrial animals, an animal subpopulation contained in one or more establishments under a common biosecurity management system and with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures; and whose initial approval should preferably take place in a country,

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territory or zone that is free of the disease concerned, before an outbreak of the specific disease(s) occurs.

Justification

Two types of compartment (terrestrial and aquatic) should be established, given that their end purposes differ and hence so will the way they are implemented.

Amendment 84

Proposal for a regulation Article 4 – paragraph 1 – point 34 – point ii (new)

Text proposed by the Commission

Amendment

ii) in the case of aquaculture animals, one or more establishments under a common biosecurity management system with a population of aquatic animals which has a distinct health status with respect to a specific disease.

Justification

Two types of compartment (terrestrial and aquatic) should be established, given that their end purposes differ and hence so will the way they are implemented.

Amendment 85

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

Text proposed by the Commission

Amendment

(51a) 'vector' means an insect or other live carrier which transmits an infecting agent from an infected animal to a susceptible one, its feed or its immediate environment. The development cycle of the organism may or may not take place in the vector.

Justification

Addition of a definition of 'vector' as this term appears throughout the proposal.

Amendment 86

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

Text proposed by the Commission

Amendment

51(b) 'notification regions' means zones or territories, or a part thereof, into which a country is divided administratively for the purposes of notification of the diseases covered by this Regulation.

Justification

This concept appears in Article 19.

Amendment 87

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

Text proposed by the Commission

Amendment

(a) listed diseases;

(a) diseases listed in Annex –I;

Amendment 88

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

Text proposed by the Commission

Amendment

(b) emerging diseases.

b) emerging diseases which fulfil similar criteria to those for the diseases under point (a) of this subparagraph.

Justification

As well as being emerging, a disease also needs to be a cause for concern before action is

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taken.

Amendment 89

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

Text proposed by the Commission

Amendment

(ba) microorganisms that have developed resistance to antimicrobials.

Amendment 90

Proposal for a regulation Article 5 – paragraph 2 – subparagraph 1

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 paragraph 1(a), is set out in Annex -I. The Commission shall be empowered to adopt delegated acts in accordance with Art. 253 concerning amendments to the listed diseases set out in this Annex to take account of technical and scientific progress, the developments of relevant international standards and changed circumstances in public and animal health.

Amendment 91

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

Text proposed by the Commission

Amendment

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

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

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

Text proposed by the Commission

Amendment

(-i) animal health;

Amendment 93

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;

Amendment 94

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 95

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.

The Commission shall no later than six weeks after adoption of these emergency measures present a report to the European Parliament and Council

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describing these measures in detail and their impact, where appropriate, on:

- the agricultural and/or aquaculture production in the Union;
- the functioning of the internal market;
- public health, animal health, animal welfare and the environment.

Amendment 96

Proposal for a regulation Article 6 – paragraph 1 – point a – point (vi)

Text proposed by the Commission

Amendment

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

Amendment 97

Proposal for a regulation Article 6 – paragraph 1 – point a – point (viii)

Text proposed by the Commission

Amendment

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

(viii) the existence of diagnostic and disease control tools, *potential vaccines* and other preventative measures;

Amendment 98

Proposal for a regulation Article 6 – paragraph 1 – point b – point (ii)

Text proposed by the Commission

Amendment

(ii) human health:

humans;

- transmissibility between animals and
- transmissibility between humans;
- (ii) human health:
- transmissibility between animals and humans;
- transmissibility between humans;

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- the severity of human forms of the disease;

- the severity of human forms of the disease;
- the risk of microorganisms developing resistance to antimicrobials due to the control measures used to combat the disease;
- the availability of effective prevention or medical treatment in humans;
- the availability of effective prevention or medical treatment in humans;

Amendment 99

Proposal for a regulation Article 6 – paragraph 1 – point b – point (iii)

Text proposed by the Commission

Amendment

(iii) animal welfare;

- (iii) animal welfare:
- the type, method and intensity of livestock farming;
- the concentration of livestock farms per area;
- the relative proximity between livestock farms and human settlements;

Amendment 100

Proposal for a regulation Article 6 – paragraph 1 – point e – point (ii)

Text proposed by the Commission

Amendment

(ii) their societal acceptance;

(ii) their societal acceptance, whereby culling and disposal of animals is always to be considered as a last resort;

Amendment 101

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

Text proposed by the Commission

Amendment

(iii) the welfare of affected subpopulations

(iii) the welfare of affected subpopulations

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EN

of kept and wild animals;

of kept, *pet* and wild animals;

Amendment 102

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

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

Amendment 103

Proposal for a regulation Article 7 – paragraph 2 – introductory part

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

2. 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.

Amendment 104

Proposal for a regulation Article 7 – paragraph 2 – subparagraph 2 – point c a (new)</Article>

Text proposed by the Commission

Amendment

(ca) the conservation status and level of protection of the animal species concerned;

Proposal for a regulation <Article 7 – paragraph 2 – subparagraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(cb) the proximity of those animals and their interaction with humans.

Amendment 106

Proposal for a regulation Article 7 – paragraph 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 107

Proposal for a regulation Article 7 – paragraph 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 108

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission shall, by means of

1. The Commission shall *be empowered to*

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implementing acts, determine the application of the disease prevention and control rules referred to in the following points to listed diseases:

adopt delegated acts in accordance with Article 253 concerning the application of the disease prevention and control rules referred to in the following points to listed diseases:

Amendment 109

Proposal for a regulation Article 8 – paragraph 1 – subparagraph 1 – point d – point ii a (new)

Text proposed by the Commission

Amendment

iia) movement in cross-border regions, including in territories outside the EU;

Amendment 110

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

Amendment 111

Proposal for a regulation Article 8 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The list of disease prevention and control rules to be applied to listed diseases is set out in a table in Annex –I.

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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

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 113

Proposal for a regulation Article 8 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

The Commission shall no later than six weeks after adoption of these emergency measures present a report to the European Parliament and Council describing these measures in detail and their impact, where appropriate, on:

- the agricultural and/or aquaculture production in the Union;
- the functioning of the internal market;
- public health, animal health, animal welfare and the environment.

Amendment 114

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

Amendment

2. The Commission shall take into account the following criteria when adopting

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paragraph 1:

delegated acts provided for in paragraph 1:

Amendment 115

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

Text proposed by the Commission

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

Amendment

a) the level of impact of the disease on animal and public health, animal welfare, the environment, food safety, the economy and economic activities in the agricultural sector;

Amendment 116

Proposal for a regulation Article 9 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Amendment 117

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

Text proposed by the Commission

(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

Amendment

(b) take appropriate biosecurity measures, taking into account the risks involved, to ensure the health *and welfare* 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 *and microorganisms that have developed resistance to antimicrobials*, except where

purposes, as appropriate for:

that is specifically authorised for scientific purposes, as appropriate for:

Amendment 118

Proposal for a regulation Article 9 – paragraph 1 – point b – point (ii)

Text proposed by the Commission

Amendment

(ii) the type of production.

(ii) the type *and intensity* of production.

Amendment 119

Proposal for a regulation Article 10 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the link between the use of antimicrobials in animals and rising antimicrobial resistance, as well as animal husbandry practices that focus on disease prevention without the prophylatic use of antimicrobials.

Amendment 120

Proposal for a regulation Article 10 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) impact of different farming practices on animal health.

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Proposal for a regulation Article 10 – paragraph 1 – subparagraph 2 (new)

Text proposed by the Commission

Amendment

Member States shall encourage operators to be specifically trained to adopt animal keeping methods that focus on the relationship between animals, humans and their diverse environments in an integrated and holistic manner.

Justification

Within this modern globalised world, where there is a high level of interaction between animals and humans, it would be foolish only to rely on professional experience without the backing up of proper education.

Amendment 122

Proposal for a regulation Article 10 – paragraph 2 – point a

Text proposed by the Commission

Amendment

- (a) the categories and species of kept animals or products under their responsibility;
- (a) the *number*, categories and species of kept animals or products under their responsibility;

Amendment 123

Proposal for a regulation Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) the type of production;

(b) the type *and intensity* of production;

Proposal for a regulation Article 10 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) professional experience *or* training;

(a) professional experience *and* training;

Amendment 125

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

Text proposed by the Commission

Amendment

(aa) advise operators on disease prevention measures;

Amendment 126

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

Text proposed by the Commission

Amendment

(i) raising animal health awareness;

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

Amendment 127

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

Text proposed by the Commission

Amendment

(iiia) encouraging the use of alternative, more environmentally friendly and sustainable animal keeping methods.

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

Text proposed by the Commission

Amendment

(iiia) raising awareness of antimicrobial resistance and its possible implications.

Amendment 129

Proposal for a regulation Article 12 – paragraph 1 – point a

Text proposed by the Commission

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

(a) qualified personnel *without any conflict of interests*, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;

Justification

Conflicts of interests are regrettably an increasing problem, especially considering the fact that many veterinarians that undertake animal health checks are paid by the establishments that they are controlling. This needs to be tackled in order to increase transparency and ensure proper safeguards for public health, animal health and food safety.

Amendment 130

Proposal for a regulation Article 12 – paragraph 1 – point b

Text proposed by the Commission

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

(b) access to laboratories with qualified personnel *without any conflict of interests*, facilities, equipment and financial resources to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;

Proposal for a regulation Article 12 – paragraph 1 – point c

Text proposed by the Commission

(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 11 which fall within the scope of this Regulation.

Amendment

(c) sufficiently trained veterinarians without any conflict of interests involved in performing the activities referred to in Article 11 which fall within the scope of this Regulation.

Amendment 132

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 and ensure that operators and animal professionals are acquiring, maintaining and developing the basic and specialist knowledge of animal health provided for in Article 10, as well as in the exchange of best practices through relevant programmes in agricultural or aquaculture sectors or formal education.

Amendment 133

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

Text proposed by the Commission

Amendment

- 2a. In order to reduce the spread of disease, the Member States shall prohibit:
- (a) the capture and keeping of wild birds for use as live decoys for hunting purposes;
- (b) imports from third countries of dead wild birds, their parts or derived products,

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for food purposes;

Justification

(a) The capture and keeping of wild birds for use as live decoys in hunting can transmit disease in a way that is impossible to monitor. The use and movement of wild birds can jeopardise measures taken to curb epidemics and the spread of disease. (b) Serious diseases, such as avian influenza, are often transmitted through the import of dead wild birds from third countries. Since these imports are very limited, it is advisable to include this type of ban as a precautionary and preventive measure.

Amendment 134

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, *animal health professionals* or other relevant stakeholders:

Justification

For certain tasks it should be possible to use other persons than veterinarians, similar to what is currently allowed.

Amendment 135

Proposal for a regulation Article 13 – paragraph 1

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, *provided there are no conflicts of interests*:

Proposal for a regulation Article 14 – paragraph 1 – introductory part

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

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.

Justification

It is always in the interest of the public to be informed, as the BSE crisis has proven. Apart from being a serious animal health issue that was transmitted onto humans through food, it was also a major crisis of confidence where the public lost trust in the safety of the food chain and policy makers. Public communication is key in ensuring a sounds basis for policy making.

Amendment 137

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

Text proposed by the Commission

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

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the listed diseases referred to in Article 8(1)(e) which shall be subject to immediate notification by the Member States in accordance with paragraph 1 of this Article.

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Proposal for a regulation Article 17 – paragraph 3 – 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

Amendment 139

Proposal for a regulation Article 20 – paragraph 1

Text proposed by the Commission

The Commission shall set up and manage a computerised information system for the operation of the mechanisms and tools for the Union notification and Union reporting requirements provided for in Articles 17, 18 and 19.

Amendment

The Commission shall set up and manage a *publicly available* computerised information system for the operation of the mechanisms and tools for the Union notification and Union reporting requirements provided for in Articles 17, 18 and 19.

Amendment 140

Proposal for a regulation Article 23 – paragraph 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. Those animal health visits shall be at frequencies that are proportionate to the risks posed by the establishment. taking into account:

Justification

Establishments with lower animal health and welfare standards should receive animal health visits at frequencies that are proportionate to the higher risks posed by the establishment.

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

Text proposed by the Commission

Amendment

(aa) the type of food production;

Amendment 142

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

Text proposed by the Commission

Amendment

(ba) the animal welfare safeguards in place at the establishment;

Amendment 143

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

Text proposed by the Commission

Amendment

(ba) the prevailing epidemiological situation in the zone or region.

Amendment 144

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 risks posed by the establishment.

deleted

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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

(a) the detection of any signs indicative of the occurrence of listed diseases or emerging diseases *and/or of risk factors leading thereto*;

Amendment 146

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

Text proposed by the Commission

Amendment

(ba) Provide information to the competent authorities in the field of animal health in order to supplement the surveillance provided for in Article 25.

Justification

Seeks to enable the competent authorities to supplement, with information provided by operators, the information under the surveillance systems established by virtue of Article 25, and the results of the animal health visits established under Article 23.

Amendment 147

Proposal for a regulation Article 24 – point a – point (i)

Text proposed by the Commission

Amendment

- (i) the criteria laid down in Article 23(1) to be taken into account when determining:
- (i) the criteria laid down in Article 23(1) to be taken into account when determining the risk posed by establishments and the frequency of such animal health visits;
- which type of establishments must be subject to animal health visits;
- the frequency of such animal health visits;

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Proposal for a regulation Article 24 – point b

Text proposed by the Commission

Amendment

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

deleted

Justification

All types of establishments should be subject to animal health visits. Exemptions shall only lead to the existence of new, potentially unknown, disease vectors.

Amendment 149

Proposal for a regulation Article 26 – introductory part

Text proposed by the Commission

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 25(1) shall be appropriate and proportionate to the objectives of the surveillance, taking into account:

Amendment

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 25(1) shall be *in accordance with the precautionary principle and* appropriate and proportionate to the objectives of the surveillance, taking into account:

Amendment 150

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

Text proposed by the Commission

Amendment

(ba) the historical experiences with diseases in the Member State, zone or compartment thereof;

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Justification

Not all Member States practice surveillance programmes in the same fashion and this diversity should be taken into account.

Amendment 151

Proposal for a regulation Article 28 – point aa (new)

Text proposed by the Commission

Amendment

(aa) listed diseases referred to in Article 8(1)(e) which are to be subject to surveillance programmes;

Amendment 152

Proposal for a regulation Article 29 – 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 153

Proposal for a regulation Article 30 – paragraph 1 – point a

Text proposed by the Commission

(a) establish a programme for the eradication of or demonstration of freedom from that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ("compulsory eradication programme");

Amendment

(a) establish a programme for the eradication, *preferably by vaccination or other treatment*, of or demonstration of freedom from that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ("compulsory eradication programme");

Proposal for a regulation <Article 30 – paragraph 2

Text proposed by the Commission

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, *preferably by vaccination or other treatment*, 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 155

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 156

Proposal for a regulation Article 31 – paragraph 1 – point a

Text proposed by the Commission

(a) disease control measures for the

Amendment

(a) disease control measures for the

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eradication of the disease agent from establishments, compartments and zones in which the disease occurs and to prevent reinfection: eradication of the disease agent from establishments, preferably by vaccination or other treatment, compartments and zones in which the disease occurs and to prevent re-infection with consideration of humane management methods. Mass culling as a disease control measure should only be an option of last resort where improved biosecurity or vaccination programmes will not be effective.

Amendment 157

Proposal for a regulation Article 32 – point c

Text proposed by the Commission

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

Amendment

(c) a description of the disease control measures of the compulsory or voluntary eradication programme as provided for in Article 31(1) and the rules adopted pursuant to Article 31(2) and in case of vaccinations or other medical treatment, a description of the exact veterinary medicinal products or procedures used;

Amendment 158

Proposal for a regulation Article 32 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) impacts of control measures on animal welfare and possible impacts on non-target animals.

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Proposal for a regulation Article 35 – title

Text proposed by the Commission

a by the Commission

Amendment

Implementing powers and delegation of powers concerning performance indicators

Implementing powers

Amendment 160

Proposal for a regulation Article 35 – point b

Text proposed by the Commission

Amendment

(b) performance indicators;

deleted

Amendment 161

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

Text proposed by the Commission

Amendment

2a. 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 162

Proposal for a regulation Article 36 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

3. The Commission shall, by means of an implementing act approve, subject to amendments where necessary, applications

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

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by Member States for disease-free status, when the conditions provided for in paragraph 1 and 2 are fulfilled.

to amendments where necessary, *of* applications by Member States for disease-free status, when the conditions provided for in paragraph 1 and 2 are fulfilled.

Justification

A disease-free status is an important health status and lies at the core of this Regulation. There should be no reasonable doubt about being granted a disease-free status and the European Parliament and Council should be given democratic oversight.

Amendment 163

Proposal for a regulation Article 36 – paragraph 3 – 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

Amendment 164

Proposal for a regulation Article 36 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Both the Commission and Members States shall promote the existence of disease-free status for territories, zones and compartments.

Amendment 165

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

Text proposed by the Commission

Amendment

4. The Commission shall, by means of implementing acts recognise, subject to amendments where necessary, the disease-free status of compartments, when

deleted

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the conditions provided for in paragraphs 1 or 2 and 3 are fulfilled.

Amendment 166

Proposal for a regulation Article 37 – paragraph 4 – 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

Amendment 167

Proposal for a regulation Article 37 – paragraph 5 – point -a (new)

Text proposed by the Commission

Amendment

(-a) recognition, subject to amendments where necessary, of the disease-free status of compartments, when the conditions provided for in paragraph 1 or 2 and 3 are fulfilled.

Amendment 168

Proposal for a regulation Article 39 – point a a (new)

Text proposed by the Commission

Amendment

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

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Proposal for a regulation Article 40 – point a

Text proposed by the Commission

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

Amendment

deleted

Amendment 170

Proposal for a regulation Article 42 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Where a Member State has reason to suspect, *or is alerted by a notification 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 171

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

Text proposed by the Commission

4. The Commission shall, by means of implementing acts, withdraw the approval of the disease-free status of a Member State or zone granted in accordance with Article 36(3) or the recognition of the disease-free status of a compartment granted in accordance with Article 37(4) after obtaining the information from the Member State referred to in paragraph 3 of this Article that the conditions for maintaining the disease-free status are no

Amendment

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the withdrawal of the approval of the disease-free status of a Member State or zone, granted in accordance with Article 36(3) or of 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

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longer met.

that the conditions for maintaining the disease-free status are no longer met.

Justification

Juridical correction of the text. The "suspension, withdrawal and restoration of disease-free status" forms a core part of this Regulation and should not be amended or supplemented by an implementing act, but should be subject to democratic oversight by both the European Parliament and Council.

Amendment 172

Proposal for a regulation Article 42 – paragraph 4 – 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

Amendment 173

Proposal for a regulation Article 42 – paragraph 4 – subparagraph 3

Text proposed by the Commission

On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner with risk of highly significant impact on animal or public health, the economy or society, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Amendment

Where in the case of the listed disease referred to in paragraph 3 of this Article spreading in a rapid manner with risk of highly significant impact on animal or public health, the economy or society imperative grounds of extreme urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.

The Commission shall no later than six weeks after adoption of these emergency measures present a report to the European Parliament and Council describing these measures in detail and their impact, where appropriate, on:

- the agricultural and/or aquaculture

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production in the Union;

- the functioning of the internal market;
- public health, animal health, animal welfare and the environment.

Amendment 174

Proposal for a regulation Article 43 – paragraph 2 – point e

Text proposed by the Commission

(e) provisions on emergency vaccination where appropriate;

Amendment

e) provisions on *preventive and* emergency vaccination where appropriate;

Amendment 175

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 176

Proposal for a regulation Article 46 – paragraph 1

Text proposed by the Commission

1. The Member States *may* take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient disease prevention or control for those diseases, provided that such measures comply with the rules on the use of veterinary medicinal products laid down in delegated acts adopted pursuant to Article 47.

Amendment

1. The Member States *shall* 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.

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Proposal for a regulation Article 46 – paragraph 1 – subparagraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) guidance and education on the responsible use of veterinary medicinal products including continuous professional development.

Amendment 178

Proposal for a regulation Article 46 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(da) the impact on human health of the use of veterinary medicinal products, in particular the threat of growing antimicrobial resistance.

Amendment 179

Proposal for a regulation Article 48 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks for the listed diseases referred to in Article 8(1)(a);

Proposal for a regulation Article 48 – paragraph 3 – point b b (new)

Text proposed by the Commission

Amendment

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

Amendment 181

Proposal for a regulation Article 49 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(b) third countries or territories.

Amendment 182

Proposal for a regulation Article 50 – point a

Text proposed by the Commission

Amendment

(a) which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in Article 8(1)(a);

deleted

Proposal for a regulation Article 50 – point b

Text proposed by the Commission

(b) the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent bank and in what quantities for each specific listed disease referred to in Article

8(1)(a), for which the bank exists;

Amendment

deleted

Amendment 184

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;

Justification

There is no need for it to be the competent authority that applies the biosecurity measures, as this should be done by the operator concerned.

Amendment 185

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

Text proposed by the Commission

(d) when appropriate to prevent the further spread of the disease agent, keep the kept animals of listed species for that listed disease isolated, and prevent contact with wildlife;

Amendment

(d) to prevent the further spread of the disease agent, keep the kept animals of listed species for that listed disease isolated, and prevent contact with wildlife;

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Justification

Amendment 186

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

Text proposed by the Commission

(Does not affect English version);

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, 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;

Justification

Linguistic amendment.

Amendment 187

Proposal for a regulation Article 57 – paragraph 2 – point b

Text proposed by the Commission

Amendment

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

b) calculating the likely length of time *since* the listed disease *was introduced*;

Justification

Detection of an illness always comes after its introduction.

Proposal for a regulation Article 61 – point b

Text proposed by the Commission

Amendment

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

deleted

Amendment 189

Proposal for a regulation <Article 61 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Only after a thorough assessment of the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products compared to other available disease prevention and control strategies, the competent authority shall take a disease control measure which may result in the killing and disposal or slaughtering of animals that may be contaminated and contribute to the spread of the listed disease;

Amendment 190

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

Text proposed by the Commission

Amendment

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

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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*.

Justification

The Commission should also receive this information.

Amendment 192

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

(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 193

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

Text proposed by the Commission

Amendment

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

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animals should be avoided.

Justification

Animals that are vaccinated as a precautionary measure are often slaughtered at a later date as vaccinated meat has a much lower market value. However, as vaccinated meat does not pose a risk to human health, the slaughter of non-infected, vaccinated animals should be discouraged.

Amendment 194

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

Text proposed by the Commission

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

Amendment

(a) conduct, where relevant for that particular listed disease, surveillance in the wild animal population *and among wild* animals held in captivity belonging to the same species;

Justification

This amendment is needed to include also captured wild animals or those raised and held in captivity.

Amendment 195

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

Text proposed by the Commission

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

Amendment

(a) conduct, where relevant for that particular listed disease, surveillance in the wild animal population *and if relevant in kept animals;*;

Justification

In case of an outbreak in wild animals, it may be relevant to know the disease status in kept animals.

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

Text proposed by the Commission

(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 of that listed disease. Only after a thorough assessment of the economic, social, animal welfare and environmental impact the competent authority shall take a disease control measure which may result in the killing and disposal of animals that may be contaminated and contribute to the spread of the listed disease;

Amendment 197

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, especially when these belong to an endangered race or variety.

Justification

Aims to safeguard endangered species and races.

Amendment 198

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

Text proposed by the Commission

Amendment

(ca) the impact of disease control measures on the environment and non-target animals;

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Proposal for a regulation Article 80 – paragraph 3 – subparagraph 1 - point c b (new)

Text proposed by the Commission

Amendment

(cb) the impact on biodiversity of the mass culling of wild animals.

Amendment 200

Proposal for a regulation <Article>Article 80 - paragraph 3 - subparagraph 1 - point c c (new)

Text proposed by the Commission

Amendment

(cc) the availability of possible vaccines and other biosecurity measures as an alternative to mass culling of wild animals.

Amendment 201

Proposal for a regulation Article 80 – paragraph 3 – subparagraph 1a (new)

Text proposed by the Commission

Amendment

Only after a thorough assessment of the economic, social, animal welfare and environmental impact the competent authority shall take a disease control measure which may result in the killing and disposal of animals that may be contaminated and contribute to the spread of the listed disease;

Amendment 202

Proposal for a regulation Article 82 – paragraph 1 – introductory part

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Text proposed by the Commission

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order to *be* registered in accordance with Article 88, *before they commence such activities*:

Amendment

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, *before they commence such activities* in order to *get the establishment* registered in accordance with Article 88:

Justification

The article is about the obligation to register establishments. The present wording gives the impression that the registration concerns the operator and not the establishment.

Amendment 203

Proposal for a regulation Article 82 – paragraph 1 – point iv a (new)

Text proposed by the Commission

Amendment

(iva) whether the establishment has the aim to use the germinal products to produce clones or has the aim to use the germinal products in processes that result in the production of clones;

Amendment 204

Proposal for a regulation Article 83 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory. Establishments which have the aim to produce clones or take part in the production process of clones shall under no circumstances be exempted from the registration requirement.

Justification

Exemptions can lead to loopholes in the legislation and loopholes can lead to risks that harm public health and animal health. Registration of exemptions will ensure traceability.

Amendment 205

Proposal for a regulation Article 85 – paragraph 1 – point b – point (iv) a (new)

Text proposed by the Commission

Amendment

(iva) the duration and distance of transport.

Amendment 206

Proposal for a regulation Article 85 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Transporters of ungulates shall nevertheless be authorised under Council Regulation (EC) No 1/2005¹a of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97.

^{1a}OJ L 3, 5.1.2005, p.1

Justification

It is worth reiterating that any type of transport must nevertheless be authorised under Regulation (EC) No 1/2005.

Amendment 207

Proposal for a regulation Article 86

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Text proposed by the Commission

Amendment

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.

Justification

deleted

All derogations from the obligation to register transporters should be abolished, since they are all too often used to circumvent the rules and regulations that are helpful in curbing the spread of epidemics or disease.

Amendment 208

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

Text proposed by the Commission

Amendment

(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.

Justification

deleted

All derogations from the obligation to register transporters should be abolished, since they are all too often used to circumvent the rules and regulations that are helpful in curbing the spread of epidemics or disease.

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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 breeds* of kept terrestrial animals or germinal products *collected*, *produced*, *stored or processed* in an establishment;

Justification

Clarification to ensure inclusion of breeds.

Amendment 210

Proposal for a regulation Article 89 – paragraph 4 – point d a (new)

Text proposed by the Commission

Amendment

(da) the welfare conditions of the animals which may have an impact on food safety and human health.

Amendment 211

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

Text proposed by the Commission

Amendment

2a. 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

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pursuant to Article 92(2).

Justification

There must be a paragraph where the competent authority gives full approval, if the requirements are fulfilled.

Amendment 212

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 213

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 *on a dedicated website* to other Member States and to the public.

Justification

For transparency reasons it is important that there is a dedicated website where citizens, stakeholders, Member States and operators can find all the establishments and transporters.

Proposal for a regulation Article 97 – paragraph 1 – point e – point (ii)

Text proposed by the Commission

Amendment

(ii) the type of production;

(ii) the type *and intensity* of production;

Amendment 215

Proposal for a regulation Article 97 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Establishments which are exempted from the registration requirement in accordance with Article 83 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article. Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.

Justification

Exemptions can lead to loopholes in the legislation and loopholes can lead to risks that harm public health and animal health. Registration of exemptions will ensure traceability.

Amendment 216

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*

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

Justification

Exemptions can lead to loopholes in the legislation and loopholes can lead to risks that harm public health and animal health. Registration of exemptions will ensure traceability.

Amendment 217

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

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 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 218

Proposal for a regulation Article 101 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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

(a) rules adopted pursuant to Article 100;

Justification

Record book format has not yet been regulated in any European legislation, although the requisite content has. Each Member State decides on its own format and too change this arrangement would be both expensive and pointless.

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Proposal for a regulation Article 102 – paragraph 4 – point c

Text proposed by the Commission

(c) designate another authority or authorise another body or a natural person for the practical application of the identification and registration system provided for in paragraph 1.

Amendment

(c) designate another authority or authorise another body or a natural person for the practical application of the identification and registration system provided for in paragraph 1. Should another authority, another body or a natural person be appointed, the Member States shall ensure that no conflicts of interest exist.

Amendment 220

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

Text proposed by the Commission

Amendment

- (i) their individual identification as provided for in Articles 106(a) and 107(a);
- i) their individual identification, *where appropriate*, as provided for in Articles 106(a) and 107(a);

Justification

There are exceptions to the individual identification such as sheep / goats less than twelve months old intended not for trade between Member States but directly for slaughter.

Amendment 221

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

(b) information related to kept animals of the porcine species, the establishments keeping them *and their movements into* and from establishments;

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Proposal for a regulation Article 103 – paragraph 1 – point c – point iv

Text proposed by the Commission

Amendment

(iv) the establishments where those animals are *habitually* kept;

iv) the establishments where those animals are kept;

Justification

Member State databases should contain the same information regarding all kept and domestic terrestrial animals.

Amendment 223

Proposal for a regulation Article 103 – paragraph 1 – point c – point (iv) a (new)

Text proposed by the Commission

Amendment

(iva) their movements into and from establishments;

Amendment 224

Proposal for a regulation Article 108

Text proposed by the Commission

Amendment

Article 108 deleted

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

By way of derogation from Article 104 and from Articles 106(b) and 107(b), Member States may exempt operators from the requirement to ensure that kept animals of the bovine, ovine and caprine

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species are accompanied by identification documents or movement documents during movements within the Member State, provided that:

- (a) the information contained in the movement document or identification document is included in the computer database provided for in Article 103(1);
- (b) the system for the identification and registration of kept animals of the bovine, ovine and caprine species provides an equivalent level of traceability as that provided by identification documents and movements documents.

Justification

deleted

All derogations concerning identification documents and movement documents should be abolished, since they are all too often used to circumvent the rules and regulations that are helpful in curbing the spread of epidemics or disease.

Amendment 225

Proposal for a regulation Article 111

Text proposed by the Commission

Amendment

Article 111

Derogations concerning movements of kept animals of the porcine species

By way of derogation from Article 110(b), the Member States may exempt operators from the requirement to ensure that kept animals of the porcine species are accompanied by correctly completed movement documents issued by the competent authority for movements within the Member State, provided that:

(a) the information on such movement documents is included in the computer database established by the Member State in accordance with Article 103(1);

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(b) the system for the identification and registration of kept terrestrial animals of the porcine species provides an equivalent level of traceability as that provided by such movement documents.

Justification

All derogations concerning identification documents and movement documents should be abolished, since they are all too often used to circumvent the rules and regulations that are helpful in curbing the spread of epidemics or disease.

Amendment 226

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 meet the requirements laid down in Regulation (EU) No 576/2013 on the non-commercial movement of pet animals^{1a}.

^{1a} OJ L 178, 28.6.2013, p. 1.

Amendment 227

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;

deleted

Amendment 228

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

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Text proposed by the Commission

Amendment

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

deleted

Amendment 229

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 rules laid down in Regulation (EU) No 576/2013 on the non-commercial movement of pet animals^{1a}.

^{1a} OJ L 178, 28.6.2013, p. 1.

Amendment 230

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

Text proposed by the Commission

Amendment

(a) identified, either individually or in groups;

deleted

Amendment 231

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,

deleted

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movement documents or other documents for identifying and tracing animals, as appropriate for the animal species concerned.

Amendment 232

Proposal for a regulation Article 114 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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

deleted

deleted

Justification

Infringes the principle of subsidiarity.

Amendment 233

Proposal for a regulation Article 114 – paragraph 1 – 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);

Amendment 234

Proposal for a regulation Article 115 – paragraph 1

Text proposed by the Commission

Amendment

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

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

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Article 253 concerning derogations for operators from the identification and registration requirements provided for in Articles 106, 107 and 109 and 110:

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 235

Proposal for a regulation Article 116 – paragraph 1 – point d

Text proposed by the Commission

(d) the type of production in the establishments where those terrestrial animals are kept;

Amendment

(d) the type *and intensity* of production in the establishments where those terrestrial animals are kept;

Amendment 236

Proposal for a regulation Article 117 – point c

Text proposed by the Commission

Amendment

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

deleted

Amendment 237

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

Text proposed by the Commission

Amendment

(ba) the breeds;

Justification

It is important to include a reference to animal breeds in this paragraph.

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Proposal for a regulation Article 119 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the species of kept terrestrial animals from which the germinal products originate;

(a) the species *or breeds* of kept terrestrial animals from which the germinal products originate;

Amendment 239

Proposal for a regulation Article 121 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) other risk factors.

Amendment 240

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

Text proposed by the Commission

Amendment

(-a) they show no clinical signs of disease;

Justification

It should be made clear that no animal showing signs of disease should be moved, regardless of the establishment where it originates or its compliance with identification requirements.

Amendment 241

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

Text proposed by the Commission

Amendment

(ba) the total time of the movement of kept terrestrial animals does not exceed 8 hours.

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Proposal for a regulation Article 123 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) they will not have been subjected to a total time of movements which exceeds 8 hours.

Amendment 243

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

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

Amendment 244

Proposal for a regulation Article 138

Text proposed by the Commission

deleted

Article 138

Implementing power for temporary derogations for movements of specific species or categories of kept terrestrial animals

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

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the rules laid down in this Chapter for movements of specific species or categories of kept terrestrial animals where:

- (a) the movement requirements provided for in Article 127, Article 129(1), Articles 130 and 131, Articles 133(1), 134(1) and 135(1) and (2) and Article 136 and the rules adopted pursuant to Articles 128(1) and 129(2), Article 132, Articles 133(2), 134(2), 135(3) and 136(4) and Article 137 are not effectively mitigating the risks posed by the movement of such animals; or EN 129 EN
- (b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6.

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

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

Justification

Derogations, even the ones of a temporal nature, can lead to loopholes in the legislation and loopholes can lead to risks that harm public health and animal health. Traceability and registration of movements should be ensured, not avoided.

Amendment 245

Proposal for a regulation Article 139 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The Commission shall take the following matters into account, when establishing the

The Commission shall take the following matters into account, when establishing the

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rules to be laid down in the delegated and implementing acts provided for in Articles 134(2), 135(3) and 136(4) and *Articles* 137 *and* 138:

rules to be laid down in the delegated and implementing acts provided for in Articles 134(2), 135(3) and 136(4) and Article 137:

Amendment 246

Proposal for a regulation Article 141 – paragraph 1 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iv a) their origin in a Member State and transport through another Member State en route to a different part of the Member State of origin; or

Justification

This amendment provides the possibility to transit animals through another Member State back to the Member State of origin. This is already a possibility through third countries in accordance with article 241 paragraph 1 (a)(vi).

Amendment 247

Proposal for a regulation Article 142 – point e a (new)

Text proposed by the Commission

Amendment

(ea) the necessary information needed to demonstrate whether the kept terrestrial animals are clones or descendants of clones.

Justification

As cloned animals and their descendents are prone to a highly increased risk of contracting animal diseases which might be transmissable to humans and other serious health risks (malformations, organ failure), it is appropriate to register in the animal health certificate whether the animal is a clone or a descendent of a clone.

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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 compliance with the rules laid down in Regulation (EU) No 576/2013^{1a} on the non-commercial movement of pet animals.

Amendment

^{1a} OJ L 178, 28.6.2013, p. 1.

Amendment 249

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

Text proposed by the Commission

deleted

(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 250

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

Text proposed by the Commission

(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

Amendment

deleted

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emerging diseases to kept terrestrial animals at the place of destination and during transport.

Amendment 251

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

2. Without prejudice to Regulation (EU) No 576/2013 on the non-commercial movement of pet animals^{1a}, the Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease prevention and 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.

^{1a} OJ L 178, 28.6.2013, p. 1.

Amendment 252

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

Without prejudice to Regulation (EU) No 576/2013 on the non-commercial movement of pet animals^{1a}, the Commission may, by means of implementing acts, lay down rules concerning the disease prevention and control measures in accordance with the provisions of paragraph 2 of this Article.

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Proposal for a regulation Article 153 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) movements of wild animals must nevertheless take place in compliance with the provisions of Regulation (EC) No 338/97^{1a}, Directive 2009/147/EC and Directive 92/43/EEC and with the wildlife protection legislation of the Member States.

^{1a}OJ L 61, 3.3.1997, p.1

Amendment 254

Proposal for a regulation Article 154 – paragraph 1 – point b – point ii

Text proposed by the Commission

Amendment

(ii) for keeping as pet animals;

deleted

Justification

At present, the provision concerning the keeping of wild animals as pet animals could be in breach of wildlife protection legislation such as Regulation (EC) No 338/97 (CITES), Directive 2009/147/EC (Birds) and Directive 92/43/EEC (Habitats). Moreover, it is unadvisable, also in terms of animal welfare, to allow wildlife to be captured in order to be held in captivity as a pet animal.

Amendment 255

Proposal for a regulation Article 159 – paragraph 5 – point a

Text proposed by the Commission

(a) the nature of the germinal products or the species of animal that those products come from:

Amendment

a) the nature of the germinal products or the species *or breed* of animal that those products come from;

Amendment 256

Proposal for a regulation Article 163 – title

Text proposed by the Commission

Germinal products intended for scientific purposes and delegated acts

Amendment

Germinal products intended for scientific purposes or for the establishment of gene banks of endangered breeds and delegated acts;

Justification

It is necessary to waive certain requirements for the creation of gene banks of endangered breeds.

Amendment 257

Proposal for a regulation Article 163 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

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Proposal for a regulation Article 172 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) treatment of effluent prior to release into the environment or to intended destination.

Justification

This is a very important biosafety measure..

Amendment 259

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

Text proposed by the Commission

Amendment

(fa) the water supply and discharge of the establishment

Justification

This is not only very important information but is also included in the information in the register of aquaculture establishments as provided for in article 183, paragraph 2 (d).

Amendment 260

Proposal for a regulation Article 192 – paragraph 2

Text proposed by the Commission

2. Aquatic animals moved for human consumption, aquaculture, release into the wild or any other specific purpose, shall not be used for any purpose other than the

intended one.

Amendment

2Aquatic animals moved for human consumption, aquaculture, release into the wild or any other specific purpose, shall not be used for any purpose other than the intended one, except in the situations referred to in Article 214(a), in which case they should provide additional confirmation that this change of use does

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not endanger health status at destination.

Justification

Provision should be made for ensuring animal health where any such change occurs.

Amendment 261

Proposal for a regulation Article 195 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

b) other serious disease symptoms with an undetermined cause; *or*

Amendment 262

Proposal for a regulation Article 195 – paragraph 2

Text proposed by the Commission

2. By way of derogation from paragraph 1, the competent authority may authorise such movement or release of aquatic animals, based on an evaluation of risks, provided that the aquatic animals originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

Amendment

2. By way of derogation from paragraph 1 (a) and (b), the competent authority may authorise such movement or release of aquatic animals, based on an evaluation of risks, provided that the aquatic animals originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

Amendment 263

Proposal for a regulation Article 206

Text proposed by the Commission

Amendment

deleted

Article 206

Implementing power for temporary derogations for movements of specific

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species or categories of aquatic animals

The Commission shall, by means of implementing acts lay down rules concerning temporary derogations from the rules laid down in this Chapter for movements of specific species or categories of aquatic animals where:

- (a) the movement requirements provided for in Article 195, Article196(1), Articles 197 and 198, Article 199(1) and (2), Article 200 and Articles 201(1), 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 196(2), 199(3), 201(2), 202(2), 203(2) and 204(3) and Article 205 are not efficiently mitigating the risks posed by certain movements of those aquatic animals; or
- (b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 5.

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

On duly justified imperative grounds of urgency relating to a listed disease representing a risk of highly significant impact and taking into account the matters referred to in Article 205 the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Justification

Derogations, even the ones of a temporal nature, can lead to loopholes in the legislation and loopholes can lead to risks that harm public health and animal health. Traceability and registration of movements should be ensured, not avoided.

Proposal for a regulation Article 207 – paragraph 1

Text proposed by the Commission

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 203(2), 204(3) and *Articles* 205 *and* 206:

Amendment

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 203(2), 204(3) and *Article* 205:

Amendment 265

Proposal for a regulation Article 210

Text proposed by the Commission

Amendment

Article 210

Member States' derogation for national animal health certification

By way of derogation from the animal health certification requirements of Articles 208 and 209 Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have an alternative system in place to ensure that such consignments are traceable and they comply with the animal health requirements for such movement provided for in Sections 1 to 5.

deleted

Justification

In line with the amendment to Article 208. This article does not apply.

Amendment 266

Proposal for a regulation

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Article 217 – paragraph 1 – introductory part

Text proposed by the Commission

Electronic animal health certificates, *produced*, handled and transmitted by means of IMSOC, may replace accompanying animal health certificates provided for in Article 208 where such electronic animal health certificates:

Amendment

Electronic animal health certificates, handled and transmitted by means of IMSOC and, *if appropriate, produced using the same system,* may replace accompanying animal health certificates provided for in Article 208 where such electronic animal health certificates:

Justification

The IMSOC system is only used to handle and transmit such documents, but not necessarily to produce them, this being done by national systems.

Amendment 267

Proposal for a regulation Article 222 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

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

deleted

Amendment 268

Proposal for a regulation Article 222 – paragraph 4 – 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

Proposal for a regulation Article 240 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) A statement whether the animals, germinal products or products of animal origin are of the origin of cloned animals or their descendents;

Justification

As cloned animals and their descendents are prone to a highly increased risk of contracting animal diseases which might be transmissable to humans and other serious health risks (malformations, organ failure), it is appropriate to register in the animal health certificate whether the animal is a clone or a descendent of a clone.

Amendment 270

Proposal for a regulation Article 245 – paragraph 1 – subparagraph 2

Text proposed by the Commission

However, if requested by the competent authority of the importing third country or territory, or if established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in that country or territory, export *and re-export* from the Union may take place in accordance with those provisions.

Amendment

However, if requested by the competent authority of the importing third country or territory, or if established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in that country or territory, export from the Union may take place in accordance with those provisions.

Justification

Allowing for re-export is a potential loophole for circumventing the EU animal health protection rules and regulations. This should be avoided.

Amendment 271

Proposal for a regulation Article 252 – title

Text proposed by the Commission

Amendment

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Proposal for a regulationArticle 252 – paragraph 1

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 273

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), 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(*).

Amendment

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

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), 35(2a), 36(3), 37(5), 39, 41(3), 42(4) and (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 274

Proposal for a regulation Article 253 – paragraph 3

Text proposed by the Commission

Amendment

- 3. The power to adopt delegated acts referred to in Article 229(1) shall be conferred on the Commission for a period of five years from (*).
- (*) Date of entry into force of the basic legislative act or any other date set by the legislator.

Amendment 275

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

Text proposed by the Commission

Amendment

- *Directive 64/432/EEC*,

deleted

deleted

Amendment 276

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

Text proposed by the Commission

Amendment

- Regulation (EC) No 1760/2000,

deleted

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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

Amendment 278

Proposal for a regulation Article 259 – title

Text proposed by the Commission

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

Amendment

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

Amendment 279

Proposal for a regulation Article 259 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. Notwithstanding Article 258(2) of this Regulation, *Regulation* (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.

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 281

Proposal for a regulation Article 261 a (new)

Text proposed by the Commission

Amendment

Article 261a

Review

After 5 years from (*), the Commission shall review the impacts of this Regulation, including the use of delegated powers referred to in Article 253(2), and present a report to the European Parliament and Council. This report may,

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where appropriate, be accompanied by a legislative proposal.

(*) Date of entry into force of the basic legislative act or any other date set by the legislator.

Justification

Standard review clause.

Amendment 282

Proposal for a regulation Annex - I

Text proposed by the Commission

Amendment

	Immediate disease control	Article 8(1)(b) Compulsory eradication	Article 8(1)(c)Option al "voluntary"		Article 8(1)(e) Notification,	Listed species
Diseases:	& eradication		eradication		reporting & surveillance	
Classical Swine Fever	X	X	0	X	X	Suidae and Tayassuidae
Bluetongue	X	X	0	X	X	All ruminants
						VECTORS: Culicoides, etc.
Epizootic haemorrhagic	X	X	0	X	X	All ruminants
disease of deer						VECTORS: Culicoides,
Swine Vesicular Disease	X	X	0	X	X	Suidae and Tayassuidae
Highly Pathogenic Avian Influenza	X	X	0	X	X	Poultry, captive birds and wild birds

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Low Pathogenic Avian Influenza (H5, H7)	X	X	0	X	X	Poultry and captive birds
African Swine Fever	X	X	0	X	X	Suidae and Tayassuidae VECTORS/RESERVOIRS
						SOFT TICKS – Genus Ornithodorus)
Foot and Mouth Disease	X	X	0	X	X	Any domestic or wild animal of order Artylodactyla, suborders Ruminatia, Suina and Tylopoda;
						(Also, some measures: Rodentia and Proboscidae)
Rinderpest	X	X	0	X	X	Ungulates
Peste des Petits Ruminants (PPR)	X	X	0	X	X	Bovidae and Suidae
Rift Valley Fever	X	X	0	X	X	All species of 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 pleuropneumonia	eX	X	0	X	X	Species of the genus Bos
African Horse Sickness	X	X	0	X	X	Equidae
						VECTORS: Midges: Culicoides
Equine encephalomyelitis (Incl. EEE, WEE and equine encephalomyelitis		0	0	X	X	Equidae
Japanese encephalomyelitis)						VECTORS: Mosquitoes, birds, other reservoirs

Venezuelan	X	0	0	X	X	Equidae
equine (encephalomyelitis)						VECTORS: Mosquitoes, birds, other reservoirs
West Nile Virus	0	0	0	X	X	Equidae
, estimate vitus						VECTORS: Mosquitoes
Newcastle Disease	X	X	0	X	X	Poultry, other captive
						birds, including pigeons
Vesicular	X	X	0	X	X	Ungulates
stomatitis Teschen Disease	X	0	0	X	X	Suidae
Glanders	0	0	0	X	X	Equidae
Dourine	0	0	0	X	X	Equidae
Equine Infectious Anaemia	0	0	0	X	X	Equidae
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
Bovine tuberculosis	0	X	X	X	X	Hippopotamidae Mammalia, in particular Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, and Tragulidae
(COMMENT: Mycobacterium tuberculosis complex: bovis,			(for apes and felids)			,
Brucella melitensis*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella abortus*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella ovis* (contagious epididymitis)	0	0	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella suis*	0	0	X	X	X	Cervidae, Leporidae, Ovibos moschatus, Suidae and Tayassuidae

Avian chlamydiosis	0	0	0	X	X	Psittaciformes
Enzootic bovine leukosis	0	X	0	X	X	Bovine animals (including Bison bison and Bubalus
Small Hive Beetle (Aethina tumida)	0	0	0	X	X	Apis and Bombus
Tropilaelaps mite (Tropilealaps spp.)		0	0	X	X	Apis
American Foulbrood	0	0	0	X	X	Apis
Monkey Pox	0	0	0	0	X	Rodentia and non-human primates
Ebola	0	0	0	0	X	Non-human primates (Apes)
Aujesky's Disease	0	0	X	X	X	Pigs
Caseous Lymphadenitis (Corynebacteium pseudotuberculosi s)	0	0	X	X	0	Ovine and caprine
Pulmonary Adenomatosis	0	0	X	X	0	Ovine and caprine
Paratuberculosis	0	0	X	X	0	Ovine and caprine
Maedi-visna	0	0	X	X	0	Ovine and caprine
Caprine Viral Arthritis/ Encephalitis	0	0	X	X	0	Ovine and caprine
Contagious Agalactia	0	0	X	X	0	Ovine and caprine
Border Disease	0	0	0	X	0	Ovine and caprine
Infectious bovine rhinotracheitis/ infectious pustular vulvovagi nitis		0	X	X	0	Bovine animals
Bovine [genital] campylobacteriosi s – C. foetus ssp. Venerealis	0	0	0	X	0	Bovine animals

Bovine Viral Diarrhoea/Mucos al Disease	0	0	0	X	0	Bovine animals
Trichomonas foetus	0	0	0	X	0	Bovine animals
Transmissible gastroenteritis	0	0	X	X	0	Pigs
European Foulbrood	0	0	X	X	0	Bees
Echinococcus multilocularis	0	0	X	X	X	Dogs
Salmonella of animal health relevance Salmonella Pullorum, Salmonella Gallinarum and Salmonella	0	0	X	X	0	Poultry
Zoonotic Salmonellosis (other than above)	0	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 haemorrhagic 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
, arroosis			A	A		Dees
Acariasis	0	0	X	X	0	Bees
Crimean Congo haemorrhagic fever	0	0	0	X	0	Ratites
TSEs (Reg 999/200	01 and Dis	92/65)	l	<u> </u>		L
Bovine Spongiform Encephalopathy	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 200.	3/99/EC a	nd Reg 2075/200	05 for Trichinell	osis)	<u> </u>	l
Trichinellosis	0	0	X	X	X	Pigs, horses, wild boar and other wild animals (susceptible to Tricinella infestation)
Listeriosis	0	0	0	0	X	Not specified
Campylobacteriosi s	0	0	0	0	X	Not specified
Verotoxigenic 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
Toxoplasmosis	0	0	0	0	X***	Not specified
Cryptosporidiosis	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
L	L					1

Influenza Virus	0	0	0	0	X***	Not specified
Echinococcosis [hydatidosis] - 'echinococcosis and agents thereof'	0	0	0	0	X	Not specified
Antimicrobial Resistance (AMR) hazards (resistant microorganism and resistance determinants)	0	0	0	0	X	Poultry, pigs and bovine animals
Calicivirus	0	0	0	0	X***	Not specified
Hepatitis A virus	0	0	0	0	X***	Not specified
Viruses transmitted by	0	0	0	0	X***	Not specified
Other zoonoses and zoonotic	0	0	0	0	X***	Not specified
Annex A(2): Aquat	tic animal dised	ises				
Epizootic haematopoietic necrosis	X	X	9	X	X	Rainbow trout (Oncorhynchus mykiss) and redfin perch (Perca fluviatilis)
Infection with Bonamia exitiosa	X	X	9	X	X	Australian mud oyster (Ostrea angasi) and Chilean flat oyster (O. chilensis)
Infection with Perkinsus marinus	X	X	9	X	X	Pacific oyster (Crassostrea gigas) and Eastern oyster (C. virginica)
Infection with Microcytos mackini	X	X	9	X		Pacific oyster (Crassostrea gigas), Eastern oyster (C. virginica), Olympia flat oyster (Ostrea conchaphila) and European flat oyster (O. edulis) 2002/99 (95/70)
Taura syndrome	X	X	9	X	X	Gulf white shrimp (Penaeus setiferus), Pacific blue shrimp (P. stylirostris), and Pacific

Yellowhead disease	X	X	0	X		Gulf brown shrimp (Penaeus aztecus), Gulf pink shrimp (P. duorarum), Kuruma prawn (P. japonicus), black tiger shrimp (P.monodon), Gulf white shrimp (P. setiferus),
Viral haemorrhagic septicaemia (VHS)	0	0	X	X	X	Pacific blue shrimp (P.stylirostris), and Pacific Herring (Clupea spp.), whitefish (Coregonus sp.), pike (Esox lucius), haddock (Gadus aeglefinus), Pacific cod (G. macrocephalus), Atlantic cod (G. morhua), Pacific salmon (Oncorhynchus spp.) rainbow trout (O. mykiss), rockling (Onos mustelus), brown trout (Salmo trutta), turbot (Scophthalmus maximus), sprat (Sprattus sprattus), grayling (Thymallus thymallus) and olive flounder (Paralichthys olivaceus)
Infectious haematopoeitic necrosis (IHN)	0	0	X	X	X	Chum salmon (Oncorhynchus keta), coho salmon (O. kisutch), Masou salmon (O. masou), rainbow or steelhead trout (O. mykiss), sockeye salmon (O. nerka), pink salmon (O. rhodurus) chinook salmon (O. tshawytscha).
Koi herpes virus (KHV) disease	0	0	X	X	X	Common carp and koi carp (Cyprinus carpio)
Infectious salmon anaemia (ISA)	0	0	X	X	X	Rainbow trout (Oncorhynchus mykiss), Atlantic salmon (Salmo salar), and brown and sea
Infection with Marteilia refringens	0	0	X	X		Australian mud oyster (Ostrea angasi), Chilean flat oyster (O. chilensis), European flat oyster (O. edulis), Argentinian oyster (O. puelchana), blue mussel (Mytilus edulis) and Mediterranean mussel (M. galloprovincialis)

Infection with Bonamia ostreae	0	0	X	X	Australian mud oyster (Ostrea angasi), Chilean 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 disease	0	0	X	X	All decapod 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 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"

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Proposal for a regulation Annex III – point 1

Text proposed by the Commission

Directive 64/432/EEC	This Regulation
Article 1	-
Article 2	Articles 4 (partially), 150(3) and 220(3)
Article 3(1)	Articles 121 and 123
Article 3(2)	Articles 121 (2), 123(1) and 146(3) and (4)
Article 4(1)	Article 121(1)
Article 4(2) and (3)	Article 122(1) and (2)
Article 5(1)	Article 140(1), 142 and 143,
Article 5(2)	Article 146(3) and (4),
Article 5(2)(a)	Article 144(a)
Article 5(2)(b)	Article 141(1)(b),
Article 5(3)	Article 146(3) and (4),
Article 5(4)	Article 150,
Article 5(5)	Articles 130, 132 and 150
Article 6	Articles 127, 128, 129
Article 6 a	-
Article 7	Articles 129, 130, 131(a) and 132
Article 8	Articles 16, 17, 18 and Articles 16(3), 17(3), 18(3) and 19
Article 9	Articles 30(1), 31, 32 and Article 30 (3) and (4), 31(2)
Article 10	Articles 30(2), 31, 32, 36, 41, 42 and Articles 39, 40, 41(3) and 42(5) and (6)
Article 11(1)	Article 89(1)(a), 92, 93 and Article 92(2),
Article 11(2)	Articles 97, 100 and 101
Article 11(3)	Articles 93, 94
Article 11(4)	Article 95
Article 11(5) and (6)	Article 92(1)(d) and (2)(d)

Article 12(1)
Article 12(2)
Article 12(2)
Article 12(3)
Article 12(3)
Article 12(1)(a) and (b)
Article 12(4)
Article 140(3)

Article 12(5) and (6) -

Article 13(1) and (2) Articles 89, 92, 93, 94, 97, 100 and 101

Article 13(3) Article 95

Article 13(4) -

Article 13(5) and (6) Article 96

Article 14(1) and (2)

Article 14(3)A and B

Article 14(3) C Article 103

Article 14(4) to (6) -

Article 15(1) Article 256

 Article 15(2) to (4)

 Article 16

 Article 17

 Article 17 a

Article 18 Article 103

Article 19 Article 20 -

Amendment

deleted

Amendment 284

Proposal for a regulation Annex III – point 18

Text proposed by the Commission

Regulation (EC) No1760/2000 This Regulation

Article 1 Article 102

Autiala	Autiala A (nautiallu)
Article 2	Article 4 (partially)
Article 3	Article 102(2) and 105
Article 4	Articles 106(a), 108, 114, 115 and 117
Article 5	Article 103(1)(a)
Article 6	Article 104, 106(b), 108, 114, 115 and 117
Article 7	Article 97, 100, 101 and 106(b) (i) and (c)
Article 8	Article 105
Article 9	-
Article 10(a) to (c)	Articles 114, 115, 117
Article 10(d) to (e)	-
Article 10(f)	Article 258
Article 11	-
Article 12	-
Article 13	-
Article 14	-
Article 15	-
Article 16	-
Article 17	-
Article 18	-
Article 19	-
Article 20	-
Article 21	-
Article 22	-
Article 23	-
Article 24	-
Article 25	-

deleted

PROCEDURE

Title	Animal Health
References	COM(2013)0260 - C7-0124/2013 - 2013/0136(COD)
Committee responsible Date announced in plenary	AGRI 23.5.2013
Opinion by Date announced in plenary	ENVI 23.5.2013
Associated committee(s) - date announced in plenary	21.11.2013
Rapporteur Date appointed	Kartika Tamara Liotard 13.6.2013
Discussed in committee	5.11.2013
Date adopted	22.1.2014
Result of final vote	+: 58 -: 3 0: 1
Members present for the final vote	Elena Oana Antonescu, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Lajos Bokros, Franco Bonanini, Milan Cabrnoch, Martin Callanan, Yves Cochet, Spyros Danellis, Chris Davies, Anne Delvaux, Bas Eickhout, Edite Estrela, Jill Evans, Elisabetta Gardini, Gerben-Jan Gerbrandy, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Klaß, Claus Larsen-Jensen, Jo Leinen, Peter Liese, Kartika Tamara Liotard, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Miroslav Ouzký, Vladko Todorov Panayotov, Gilles Pargneaux, Antonyia Parvanova, Andrés Perelló Rodríguez, Pavel Poc, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Kārlis Šadurskis, Daciana Octavia Sârbu, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Salvatore Tatarella, Thomas Ulmer, Glenis Willmott, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Gaston Franco, Filip Kaczmarek, Marusya Lyubcheva, Miroslav Mikolášik, Justas Vincas Paleckis, Vittorio Prodi, Giancarlo Scottà, Alda Sousa, Rebecca Taylor, Vladimir Urutchev, Andrea Zanoni

OPINION OF THE COMMITTEE ON FISHERIES

for the Committee on Agriculture and Rural Development

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))

Rapporteur: Isabella Lövin

SHORT JUSTIFICATION

The Commission's proposal on a new EU regulation on animal health is intended to be the legal framework to support the Animal Health Strategy published in 2007. Bearing in mind that this proposal limits its scope to only deal with transmissible diseases, and that the Commission intends to propose a new regulation concerning animal welfare specifically, the rapporteur still considers that some parts of the present proposal needs to be strengthened to reflect the overall EU objective of improving animal welfare. As stated in the Treaty of the Functioning of the EU (TFEU), article 13: "In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals".

There is a well-established link between animal welfare and animal health. Animals that are forced to live in stressful conditions develop a lower immune defence system, and are therefore more likely to attract, and develop diseases, including transmissible diseases. Since the EU Animal Health Strategy has the motto "Prevention is better than cure", the rapporteur proposes to introduce a new subparagraph to article 9.1 adding to the responsibilities of animal professionals to take appropriate animal welfare measures, with the aim of achieving good animal health. This is also in line with the intention of article 10 that gives animal professionals the obligation to acquire knowledge about the interaction between animal health and animal welfare, as well as knowledge about diseases and biosecurity principles.

One of the biggest threats to both human and animal health is the rapid development and spread of antibiotic resistance. According to WHO (2011), in the EU alone over 25 000 people die from infections caused by antibiotic-resistant bacteria each year. Antibiotic use in food animals allows resistant bacteria and resistant genes to spread from animals to humans through the food-chain. In aquaculture, improved management, including lower densities of fish and introduction of vaccines, can significantly reduce the usage of antibiotics. This

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illustrates the importance of disease prevention which is relevant to all food-animal production.

Parasites and diseases of all sorts, including transmissible diseases, are a plague in most aquaculture activities. A new disease, *francisella sp.*, was discovered in Norwegian farmed cod in 2005 and a few years later it was identified in wild cod on the west coast of Sweden. The interaction between farmed and wild fish in generally very large when aquaculture activities take place in the open sea, or in lakes. Wild fish are often found feeding around the cages, and farmed fish all too often escape from the cages during storms or when cages wreck out of other reasons. Therefore great attention has to be made to the risks of new transmissible diseases developing in aquaculture spreading to wild populations, not only risking the health of fish, but actually threatening entire ecosystems. If for instance wild cod were to be greatly impacted by a disease, it would not only affect the fishing industry, but also the balance between species in the food-web. Therefore the rapporteur believes it is extremely important to add to the article 9.1 (b) that operators have the responsibility not only prevent the spread of diseases between different kept animals, but also between kept animals and wild animals.

The definition of kept animals proposed by the Commission is not appropriate when it comes to aquatic animals, since it defines it as being solely "aquaculture animals". Concerning aquatic animals, it is clear that transmissible aquatic diseases might also stem from animals kept in aquariums in restaurants or in private homes that are then released into the wild, in some cases by fishermen or anglers that tries to introduce new species. Therefore the last part of the definition of kept animals should be deleted.

Finally, most slaughter of aquaculture animals, even for the purpose of disease control, is executed in ordinary processing establishments. For a better understanding of requirements and responsibilities according to this regulation the terminology "processing establishments" should be used in parallel with "disease control aquatic food establishments".

AMENDMENTS

The Committee on Fisheries calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Protecting animal welfare is listed in the Treaty of the Functioning of the European Union (Title II) as one of the key principles that the Union should respect, on an equal footing with other

key principles mentioned in the same title such as protecting human health, promoting sustainable development and ensuring consumer protection. Article 13 states that: "In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals".

Amendment 2

Proposal for a regulation Article 1– paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 3

Proposal for a regulation Article 1 – paragraph 2 – point a – point - i (new)

Text proposed by the Commission

Amendment

(- i) an improved animal health;

Amendment 4

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

Text proposed by the Commission

Amendment

- antibiotic resistance;

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

Text proposed by the Commission

Amendment

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

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

Justification

The definition of kept aquatic animals should also comprise ornamental animals, pet animals and wild animals kept by humans. Many diseases are spread into the nature by ornamental aquatic animals meant for aquaria or wild caught crustaceans meant for restaurants. These animals need to be included for a better prevention and traceability of diseases.

deleted

Amendment 6

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

Text proposed by the Commission

Amendment

- (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 7

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

Text proposed by the Commission

(50a)'processing establishment' means a

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Amendment

food business approved in accordance with Article 4 of regulation (EC) No 853/2004 for processing aquaculture animals for food purpose.

Justification

Most slaughter of aquaculture animal, even for the purpose of disease control, is executed in ordinary processing establishments. For a better understanding of requirements and responsibilities according to this regulation the terminology 'processing establishments' should be used in parallel with 'disease control aquatic food establishments'.

Amendment 8

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 of this Regulation for the slaughter of aquatic animals for disease control purposes in accordance with Title II of Part IV.

Amendment 9

Proposal for a regulation Article 5 – paragraph 2 – point a – point -i (new)

Text proposed by the Commission

Amendment

(-i) animal health;

Amendment 10

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

Text proposed by the Commission

Amendment

(b) take appropriate biosecurity measures, taking into account the risks involved, to

(b) take appropriate biosecurity measures, taking into account the risks involved, to

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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:

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, or from such kept animals and wild animals, of diseases, except where that is specifically authorised for scientific purposes, as appropriate for:

Amendment 11

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

Text proposed by the Commission

Amendment

(ba) take appropriate animal welfare measures with the aim of ensuring animal health.

Amendment 12

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

Text proposed by the Commission

Amendment

(bb) follow good practice in taking care of their animals, including good husbandry practice where relevant, including the reduction of the need to use antimicrobial drugs and so contributing to the prevention of the development and spread of antimicrobial resistance in kept animals and products.

Amendment 13

Proposal for a regulation Article 10 – paragraph 1 – point c a (new)

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Text proposed by the Commission

Amendment

(ca) general principles of development and spread of antimicrobial resistance.

Amendment 14

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

Text proposed by the Commission

Amendment

(iiia) contributing to the responsible use of antimicrobial drugs in order to prevent development and spread of antimicrobial resistance;

Amendment 15

Proposal for a regulation Article 12 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) an action plan of disease prevention measures for the monitoring, prevention and control of transmissible animal diseases, with the aim of reducing the use of antibiotics and thereby the risk of development of antimicrobial resistance. The action plan shall be updated on regular basis.

Amendment 16

Proposal for a regulation Article 46 – paragraph 1

Text proposed by the Commission

Amendment

1. The Member States *may* take measures concerning the use of veterinary medicinal

1. The Member States *shall* take measures concerning the *responsible* use of

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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

veterinary medicinal products for *transmissible* 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 17

Proposal for a regulation Article 46 – paragraph 2

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 18

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

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

Amendment 19

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

Text proposed by the Commission

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

Amendment

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

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products or products from such animals;

products from such animals;

Amendment 20

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 21

Proposal for a regulation Article 177 – title

Text proposed by the Commission

Approval of disease control aquatic food establishments

Amendment

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

Amendment 22

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 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).

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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 24

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 25

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 26

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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control aquatic food establishments

establishments and disease control aquatic food establishments

Amendment 27

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 28

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 29

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:

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Proposal for a regulation Article 187 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Transporters of aquaculture animals and wild aquatic animals intended for aquaculture *or release in natural waters* shall keep up-to date records on:

Amendment 31

Proposal for a regulation Article 193 – paragraph 1

Text proposed by the Commission

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:

Justification

The requirements should apply to all aquatic animals for a better prevention and traceability of diseases.

Amendment 32

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

Text proposed by the Commission

Amendment

(i) the *aquaculture* animals received;

(i) the *aquatic* animals received;

Amendment 33

Proposal for a regulation Article 196 – title

Text proposed by the Commission

Amendment

Movement of *aquaculture* animals

Movement of kept aquatic animals

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intended for Member States, zones or compartments which have been declared disease free or which are subject to an eradication programme and delegated acts 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 34

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 point (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 35

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 36

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;

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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 38

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

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.

Justification

It is always a risk to release aquatic animals into the wild in a disease free zone. Extra caution needs to be taken with wild animals since they are less controlled than aquaculture animals. Therefore wild animals also need to be included in this article.

Amendment 39

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

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 40

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 eradication programme and delegated acts

Amendment

Movement of *kept aquatic* animals intended for *human consumption in*Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme and delegated acts

Justification

It is important to also include caught wild animals, for instance crustaceans meant for restaurants.

Amendment 41

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

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

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listed species for those listed diseases and they are:

listed species for those listed diseases and they are:

Amendment 42

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

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.

Amendment 43

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:

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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 45

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 46

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;

Amendment 47

Proposal for a regulation Article 200 – paragraph 3 – 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;

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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 49

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;

Amendment 50

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

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

Amendment 51

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

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

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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.

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 52

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

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

Amendment 53

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

Text proposed by the Commission

(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 54

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.

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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 56

Proposal for a regulation Article 222 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Aquatic pet animal moved for the purpose of non-commercial ornamental aquaria or any other specific purpose, shall not be used for any purpose other than the intended one.

PROCEDURE

Title	Animal Health
References	COM(2013)0260 - C7-0124/2013 - 2013/0136(COD)
Committee responsible Date announced in plenary	AGRI 23.5.2013
Opinion by Date announced in plenary	PECH 23.5.2013
Rapporteur Date appointed	Isabella Lövin 12.6.2013
Discussed in committee	17.10.2013 27.11.2013
Date adopted	22.1.2014
Result of final vote	+: 13 -: 6 0: 1
Members present for the final vote	John Stuart Agnew, Antonello Antinoro, Alain Cadec, Chris Davies, João Ferreira, Carmen Fraga Estévez, Pat the Cope Gallagher, Dolores García-Hierro Caraballo, Isabella Lövin, Gabriel Mato Adrover, Guido Milana, Maria do Céu Patrão Neves, Ulrike Rodust, Raül Romeva i Rueda, Struan Stevenson, Isabelle Thomas, Jarosław Leszek Wałęsa
Substitute(s) present for the final vote	Izaskun Bilbao Barandica, Ole Christensen, Jens Nilsson

PROCEDURE

Title	Animal Health
References	COM(2013)0260 - C7-0124/2013 - 2013/0136(COD)
Date submitted to Parliament	6.5.2013
Committee responsible Date announced in plenary	AGRI 23.5.2013
Committee(s) asked for opinion(s) Date announced in plenary	ENVI PECH 23.5.2013 23.5.2013
Associated committee(s) Date announced in plenary	ENVI 21.11.2013
Rapporteur(s) Date appointed	Marit Paulsen 12.6.2013
Legal basis disputed Date of JURI opinion	JURI 21.1.2014
Date adopted	11.2.2014
Result of final vote	+: 31 -: 6 0: 3
Members present for the final vote	John Stuart Agnew, Eric Andrieu, Liam Aylward, José Bové, Luis Manuel Capoulas Santos, Vasilica Viorica Dăncilă, Michel Dantin, Paolo De Castro, Albert Deß, Herbert Dorfmann, Hynek Fajmon, Iratxe García Pérez, Julie Girling, Béla Glattfelder, Martin Häusling, Esther Herranz García, Peter Jahr, Elisabeth Jeggle, Jarosław Kalinowski, Elisabeth Köstinger, Agnès Le Brun, James Nicholson, Wojciech Michał Olejniczak, Marit Paulsen, Britta Reimers, Alfreds Rubiks, Giancarlo Scottà, Czesław Adam Siekierski, Sergio Paolo Francesco Silvestris, Alyn Smith, Ewald Stadler, Marc Tarabella, Janusz Wojciechowski
Substitute(s) present for the final vote	Pilar Ayuso, Francesca Barracciu, Spyros Danellis, Karin Kadenbach, Giovanni La Via, Astrid Lulling, Véronique Mathieu Houillon, Petri Sarvamaa
Date tabled	19.2.2014