



**Proposal for a draft Regulation on  
Animal Health  
COM (2013) 260 final**

**FVE Comments**

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**Introduction**

On 6 May 2013, the European Commission adopted a proposal for a single, comprehensive Regulation on animal health to replace the numerous animal health rules currently in place. The Regulation on animal health aims to allow a better early detection and control of animal diseases, including emerging diseases, putting great effort for policy to prevent diseases occurring rather than having to control them. The legislative proposals are now subject to discussion and adoption at the European Parliament and at the Council.

**General comments**

FVE welcomes the Commission's initiative to bring the large body of EU animal health legislation into one single and clearer regulatory framework. The potential benefits of enhanced animal health and welfare are great; for animals, their owners, society, public health and the wider economy. FVE expressly welcomes the aims of the EU Animal Health Strategy namely placing greater emphasis on preventative measures and on the "One Health" aspect.

Many important detailed rules will need to be determined by the Commission through delegated and implementing acts. Some of this secondary legislation form essential components to implement this Regulation. Therefore FVE suggests the Commission to prepare a roadmap for the drafting of the secondary legislation (timetable, priority, consultation foreseen).

It is important that the drafting of this secondary legislation is done transparently with proper consultation of all stakeholders (see whereas 160), including the veterinary profession and the Chief Veterinary Officers. FVE especially wants to be consulted on the drafting of the secondary legislation on Art 5-9, Art 11.3 and Art 24.

**President**

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## FVE WISHES TO DRAW SPECIFIC ATTENTION TO:

1. the fact that effective *Veterinary services have a major public good dimension* and the need to better *understand and recognise the different roles veterinarians play*

FVE recommendation: To clarify the different roles veterinarians play and to introduce definitions for “Veterinarian” and “Official Veterinarian”

2. the need to clarify ‘*Aquatic Animal Health Professionals*’, only veterinarians can diagnose, treat and prescribe

FVE recommendation: FVE strongly opposes that in this Regulation ‘Aquatic Animal Health Professionals’ are dealt with as Veterinarians in the field of aquaculture.

3. the importance of recognising the *intrinsic link between animal health, welfare, public health and environment*

FVE recommendation: To look at prevention in a holistic approach (not only biosecurity, but improved animal husbandry and role of vaccination), to include a reference to Art 13 of the Treaty, to foresee and prevent as much as possible welfare complications due to disease control

4. Recognise that a *regular health visit is a cornerstone of the ‘prevention is better than cure’ strategy*.

FVE recommendation: to recognise the importance of regular veterinary visits to farms to improve animal health, welfare and public health and to “guarantee the quality of the products”; to ensure that the FVE and other relevant stakeholders are consulted regarding the secondary legislation in Art. 24

5. the recognition of *antimicrobial resistance (AMR)* and use of vaccination

FVE recommendation: Commission must clarify how they foresee the practical implementation of the AMR policy in disease control measures (Art 6.1.a (iv), Art 46 and Art 47) and strengthen vaccination as a control strategy to avoid mass culling

6. the need for more *consistency between European and International legislation*

FVE recommendation: to further align the definitions on aquatic animals and aquaculture with the OIE, together with the listed diseases and disease-free status approach

7. the *risk based approach for categorisation of diseases*

FVE recommendation: Commission to clarify secondary legislation and ensure stakeholder consultation, to also take into account companion animals and wild animals and environment

8. the need to preparing a smooth *implementation, transposition and enforcement*

FVE recommendation: develop a proper, practical and funded communication, transposition plan ensuring commitment all stakeholders

1. **Effective Veterinary services have a major public good dimension. It is therefore important to understand and recognise the different roles veterinarians play.** (See inter alia: Whereas 46; article 11; article 16)

### *Effective Veterinary services*

National Veterinary Services are considered as being a ‘public good’. The concept refers to the animal health, food safety and animal welfare governance by Member States. National Veterinary Services are part of the so called “Competent Authority”. As the regulation states (whereas 45, article 12), Member States should not only support but ensure the access to adequate financial, infrastructural and personnel resources throughout their territories, including laboratory capacity. However, so far missions of the Food and Veterinary Office have revealed several weaknesses at these points. These weaknesses should be resolved in order for any legislation to be effective.

### *Role and responsibilities*

FVE believes that new law (Art 11) should better clarify the responsibilities and tasks of the veterinary profession – including both public and private partners. It is obvious that when it comes to disease outbreak, the role and responsibilities of official veterinarians are different from the role and responsibilities of veterinary practitioners. However, in some countries and for certain tasks private practitioner can be mandated to perform official tasks. The text does not take these realities into account. Most of the time, the draft refers to “veterinarians” in general without any definition on who is the veterinarian. (Furthermore, there are veterinarians who do not work as practitioners nor as officials).

FVE adopted in the 2011 General Assembly a definition of the veterinarian. FVE strongly recommends including definitions for the term “*Veterinarian*” and “*Official Veterinarian*”.

*‘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 health and welfare of animals, the interest of the client and of the society.”<sup>1</sup>  
*“Official veterinarian’* means a veterinarian appointed by the competent authority to act on its behalf.”

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<sup>1</sup> FVE Position paper : Definition of veterinarian

## **2. Need to better define ‘Aquatic Animal Health Professionals’, only veterinarians can diagnose, treat and prescribe**

FVE strongly opposes that in this Regulation ‘Aquatic Animal Health Professionals’ are dealt with as Veterinarians in the field of aquaculture. Veterinary medicine is a regulated profession. The veterinarian is licensed by the legal authority to carry out his tasks, something that shall be done in an independent, ethical and personally responsible capacity. The veterinarian is accountable to the licensing authority. In addition, in order to get a degree in veterinary medicines, a broad training is needed covering in addition to animal health, welfare and public health training also training in epidemiology, toxicology and pharmacology. ‘Aquatic Animal Health Professionals’ in most countries do not have this broad training, neither are they a regulated profession in other words subject to disciplinary actions. In the Regulation it is unclear what kind of education requirements are needed to obtain the title of aquatic health professional and which official body will be responsible to decide if the education requirements are met and how the accountability of these professionals will be ensured.

Therefore, FVE strongly opposes to the insertion of “Aquatic animal health professionals” as defined in the Regulation if all these conditions are not ensured. In addition, the term “aquatic medicine biologists” (as used in Norway) better defines these professionals than “aquatic animal health professionals”.

## **3. “Prevention is better than cure “: recognising the intrinsic link between animal health, welfare, public health and environment**

FVE is pleased to see that the Animal Health Law recognises the relations between Animal Health, Animal Welfare, Public Health and Environment. Only in combination can these be effectively promoted. A complete separation in policy making in these respective domains is neither possible, neither desirable. Especially if a holistic and pro-active ‘One Health’ view is to be followed in EU animal health legislation, these links need to be recognised and reflected in the legislation.

“Prevention is better than cure” should be looked at in a holistic manner, and be broader than just implementing biosecurity measures. Animals that are cared for appropriately and in accordance with existing health and welfare standards are more likely to be healthy, and less likely to contract or spread disease. It is therefore essential for all animal owners to have the necessary knowledge and skills to care for their animals, exercising good practice, understand biosecurity measures, understand the importance of a regular health visit and have knowledge about responsible use of medicines.

In the livestock industry minimising disease and welfare impacts through good husbandry, this will maximise profitability and help maintain rural sustainability. The control of listed disease often requires the compulsory slaughter of animals to eradicate or control the spread of disease. This is disruptive to industry and costly both to the rural economy and the taxpayer and should therefore be prevented as much as possible.

Disease control and eradication poses specific risks to animal welfare (Art. 55 and others). In case of outbreaks, it is important to recognise that animals are sentient and to foresee and prevent as much as possible welfare complications due to disease control measures and especially movement restrictions. See also lessons learned from [FMD outbreak in UK 2001](#)

Consistency between this Regulation and pre-existing animal welfare, medicinal products, as well as any legislation concerning animals needs to be ensured. For that matter, FVE recommends adding in the proposal cross references to the animal welfare related texts; especially to Council Directive 98/58/EC, Council Regulation (EC) No 1/2005 Council Regulation 1099/2009/EC and to the legislation on veterinary medicinal products; especially . These references would help clarifying the situation and would contribute to reinforcing the link between animal health, welfare, public health and environment.

#### **4. A regular animal health visit is a cornerstone of the ‘*prevention is better than cure*’ strategy**

FVE especially welcomes the additional article on animal health visits (article 23) requesting operators to ensure that “establishments under their responsibility receive animal health visits from a veterinarian when appropriate due to the risks posed by the establishment”. FVE considers a regular farm visit is a cornerstone of the ‘prevention is better than cure’ strategy.

Regular farm visits are especially important to:

- to develop a holistic strategy to prevent diseases,
- to ensure the early recognition of diseases,
- to ensure vigilance for emerging diseases,
- to advise operators on biosecurity,
- to advise operators on protecting the environment,
- to ensure the integrity of the food chain information,
- to prioritise measures to control any existing problems and manage risks, including the responsible use of medicines,
- to supplement the surveillance undertaken by operators,
- to assist operators on record keeping,
- to ensure close collaboration and exchange of knowledge between operators and veterinarians.

In order for article 23 to be meaningful it is necessary that the content and frequency is further worked out in secondary legislation (Art 24).

#### **5. Antimicrobial resistance and use of vaccination to prevent culling**

FVE welcomes that the animal health law (whereas 29, 54, article 6) takes into account antimicrobial resistance and microorganisms that have developed resistance to antimicrobials. Nevertheless, FVE would like more clarity on how

this is foreseen to be implemented in practice as prevention and control of these pathogens is different from other listed diseases.

FVE would also like to clarify the scope of Article 46, the way it is written gives the option to the Commission to ban products and to restrict use. Clarification of the scope of the disease list and the types of prohibitions and restrictions is necessary to avoid potentially negative therapeutic implications.

Every expansion of groups with the right to prescribe medicines will heighten the risk of increasing the use of medicines in general, and antibiotics in particular. Therefore FVE strongly objects to expanding the prescription write to aquatic animal health professionals.

Recital 74 sets forth that vaccination should be considered as an integral element of a comprehensive disease control strategy. Nevertheless, Articles 61 Par.1d, 65 and 69 contain only weak references to the possibility of emergency vaccinations in the event of the occurrence of diseases. Article 47 gives the impression, that the commission is the only decision-making body concerning the use of vaccination. Article 46, that describes the opportunity of the member states, seems meaningless in this connection.

Article 46/47 shall set out clearly that the mass culling of healthy animals in the event of an outbreak must be avoided by means of emergency vaccination if marker vaccines are available or the situation permits the use of a conventional vaccine and the testing of animals in the surveillance zone. FVE also propose to investigate the setting up a Vaccine Commission under the auspices of EFSA to make recommendations on preventative vaccinations.

## **6. Consistency between European and International legislation**

This revision of the EU animal health legislation gives the opportunity to bring greater consistency between the European and International animal health legislation. European legislation must remain a world reference point with often higher standards, while ensuring that it is closely aligned to international standards. To ensure this alignment, FVE suggest some additional changes such as to cross-reference to article 13 of the Treaty on the Functioning of the EU in the preamble and to cross-reference the definitions on aquatic animals and aquaculture with the OIE definition. Also listing of diseases and rules on free-status and compartmentalisation should be as closely aligned as possible.

## **7. Risk-based approach for categorisation of diseases**

Articles 5 to 8 form the backbone of this Regulation and as such disease control efforts by the European Union. These articles give a lot of power to the Commission; empowering the Commission to list diseases, if necessary amend the criteria in Art 6 and develop a list of species which will be affected by the disease specific rules. The adoption of this secondary legislation is a prerequisite for the Regulation on Animal Health to come into force.

As a consequence to the importance of the secondary legislation in Art 5-8, the Commission should clarify as soon as possible how they foresee the drafting and how they will ensure that this is done in a transparent way ensuring enough consultation with stakeholders.

Care should be taken not only to cover the obvious diseases of production animals. The listing of diseases and species should be done as holistic as possible to proactively improve animal and public health. Wildlife<sup>2</sup> often plays a role as a reservoir of diseases or in the emergence of new diseases and therefore should not be overlooked. All diseases for which wildlife acts as a reservoir and have an impact on animal populations (wild and domestic), economies and humans or a combination of all, need to be listed.

Companion animals are another group of animals in which should not be overlooked, see CALLISTO<sup>3</sup> project. General requirements concerning registration, record keeping and movements within the Union should also apply to pet breeders and traders (whereas 21, art 3.4)

## **8. Preparing a smooth implementation, transposition and enforcement (whereas 157)**

Any policy initiative, however, carefully constructed or scientifically sound, will not achieve the desired effect if it is not effectively translated into action. The reasons why and when the EU animal health Regulation intervenes in animal diseases and its chosen method of intervention need to be clearly communicated and understood, so that delivery priorities are clear.

The engagement of stakeholders in the decision-making and implementation process will increase their understanding and commitment to achieving the desired outcome. Delivering is dependent on a strong partnership approach between everyone interested in animal health and welfare. The changes this new legislation brings will need to be well-communicated and funds need to be set-aside to foresee the communication and also training of key actors.

### ***National measures***

Some Member States take national measures to limit the impact of transmissible animal diseases other than listed diseases within their territory. While we recognised that those national measures should – as much as possible - not interfere with the rules on the internal market laid down in Union legislation, for a “prevention is better than cure” these national measures should be allowed as long as they are proportional, justified and non-discriminatory. (Whereas 125)

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<sup>2</sup> OIE Factsheet on Wildlife diseases

[http://www.oie.int/fileadmin/Home/eng/Media\\_Center/docs/pdf/Fact\\_sheets/WD\\_EN\\_FS\\_01.pdf](http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Fact_sheets/WD_EN_FS_01.pdf)

<sup>3</sup> CALLISTO project: <http://www.callistoproject.eu/joomla/>

## Specific Comments

Whereas	FVE Suggestions & Comments
<p>(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.</p>	<p>(21) The keeping of pet animals, including ornamental aquatic animals in households and non-commercial ornamental aquaria, both indoors and outdoors, also represents <del>a lower</del> health risk <del>compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture</del></p> <p>While it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union apply to <del>pet keepers</del>, as this would represent an unjustified administrative burden and cost, <del>registration and record keeping should apply to pet breeders and traders. Registration and record keeping requirements should therefore not apply to pet keepers.</del> registration and record keeping should apply to pet breeders and traders.</p>
<p><u>Justification:</u> In most industrialized countries, companion animals are becoming an integral part of households, living in very close relation with their owners. Just to illustrate the estimated percentage of pet owners who allow dogs and cats on their beds is 14%–62%. Keeping companion animals, while having many positive aspects, can cause public health risks, including increased emergence of zoonoses. Just to give a few examples; toxoplasma infection in cats, Salmonella infections, etc. The water in which ornamental fish are transported can harbor potential zoonotic disease pathogens of clinical relevance (eg Mycobacteria). Therefore basic requirements should apply to all animals. Permanent identification and registration of dogs in a database compatible with an EU database should be explicitly required.</p>	
<p>(29) Action nr 5 []. Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. [...] 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.</p>	<p>Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. [...] As a result, microorganisms that have developed resistance to antimicrobials should be <del>treated as if they were transmissible diseases, and thus</del> covered by the scope of this Regulation.</p>
<p><u>Justification:</u> correction of terminology</p>	
<p>(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.</p>	<p>(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. <del>Operators and other animal professionals should therefore acquire such knowledge as appropriate. Member States shall ensure that operators and animal professionals acquire, maintain and develop the basic knowledge of animal health provided through relevant programmes in agricultural or aquaculture sectors.</del> Operators and other animal professionals should therefore acquire such knowledge as appropriate. Member States shall ensure that operators and animal professionals acquire, maintain and develop the basic knowledge of animal health provided through relevant programmes in agricultural or aquaculture sectors.</p>
<p><u>Justification:</u> Education is a Member State responsibility.</p>	
<p>(42) Veterinarians and aquatic animal health professionals play a crucial role in all aspects of animal health</p>	<p>(42) Veterinarians <del>and aquatic animal health professionals</del> play a crucial role in all aspects of animal health management, and general</p>



<p>management, and general rules concerning their roles and responsibilities should be laid down in this Regulation.</p> <p>(43) Veterinarians have the education and the professional qualifications which ensure that they have acquired the knowledge, skills and competencies necessary, inter alia, to diagnose diseases and treat animals. In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called "aquatic animal health professionals". These professionals are traditionally not veterinarians but they practice aquatic animal medicine. This Regulation should therefore respect the decision of those Member States who recognise that profession. In those cases, aquatic animal health professionals should have the same responsibilities and obligations as veterinarians</p>	<p>rules concerning their roles and responsibilities should be laid down in this Regulation.</p> <p>(43) Veterinarians have the education and the professional qualifications, which ensure that they have acquired the knowledge, skills and competencies necessary, inter alia, to diagnose diseases and treat animals. In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called "aquatic medicine biologists". These professionals are traditionally not veterinarians but they practice <b>certain designated tasks in a territory in the field of aquatic animal medicine and under the supervision of a veterinarian. These professionals should have received appropriate qualifications and training to perform these tasks.</b> This Regulation should therefore respect the decision of those Member States who recognise that profession. <del>In those cases, aquatic animal health professionals should have the same responsibilities and obligations as veterinarians</del></p>
<p><b>Justification:</b> We suggest merging whereas 42 and 43 together as they are complementary. ‘Aquatic Animal Health Professionals’ are NOT Veterinarians in the field of aquaculture and they are NOT ‘health professionals’. Veterinary medicine is a regulated profession. Veterinary education has to meet EU harmonised standards which includes in addition to animal health, welfare and public health training also training in epidemiology, toxicology and pharmacology. In addition, the veterinarian needs to be licensed and can be disciplined. ‘Aquatic Animal Health Professionals’ in most countries do not have this broad training, neither are they a regulated profession in other words subject to disciplinary actions. FVE also questions that while aquatic animal health professionals may have been needed in the past, this is still that case as many veterinary faculties in the recent years have enormously increased their training in aquaculture.</p>	
<p>(47) To ensure a 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.</p>	<p>(47) To ensure a close collaboration and exchange of knowledge between operators and <del>veterinarians or aquatic animal health professionals</del>, <b>to prevent diseases, to advise operators on biosecurity, to ensure the integrity of the food chain information</b> 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</p>
<p><b>Justification:</b> A crucial element in the prevention of health and welfare issues is a reliable surveillance system. In our view the proposed Animal Health Visit (article 23) is one of the cornerstones to reach a “prevention is better than cure” approach. However the effectiveness of these visits will depend on how it will be filled in by the following delegated acts and the preparedness and political will to implement and maintain such legislation.</p>	
<p>(50) Veterinarians are key actors in the investigation of diseases and a key link between operators and the competent authority.</p> <p>Therefore they should be notified by the operator in cases of abnormal mortalities, other serious disease problems or significantly decreased production rates with an undetermined cause.</p>	<p>Veterinarians are key actors in the investigation of diseases, <b>epidemiological analysis</b> and a key link between operators and the competent authority.</p> <p>Therefore they <b>must</b> be notified by the operator in cases of abnormal mortalities, other serious disease problems or significantly decreased production rates with an undetermined cause.</p>
<p><b>Justification:</b> The veterinary profession is one of the only 7 professions in Europe which has EU set minimum training</p>	

<p>requirements. In order to get a degree in veterinary medicines, a broad training is needed covering in addition to animal health, welfare and public health training also training in epidemiology, toxicology and pharmacology.</p>	
<p>(61) In some cases, and depending on the epidemiological profile of a disease and relevant risk factors, a structured surveillance programme may need to be put in place. In that case it is appropriate that Member States develop epidemiologically based surveillance programmes. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission concerning the surveillance design, the criteria for official confirmation of outbreaks and the case definitions of those diseases and requirements for surveillance programmes in relation to their contents, information to be included and the period of application.</p>	<p>(61) In some cases, and depending on the epidemiological profile of a disease and relevant risk factors, a structured surveillance programme <b>must</b> need to be put in place. In that case it is appropriate that Member States develop epidemiologically based surveillance programmes. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission concerning the surveillance design, the criteria for official confirmation of outbreaks and the case definitions of those diseases and requirements for surveillance programmes in relation to their contents, information to be included and the period of application.</p>
<p>(72) To ensure the applicability of contingency plans in real emergency situations, it is essential to practise and test that the systems are working. For that purpose the competent authorities of the Member States should carry out simulation exercises, in cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.</p>	<p>(72) To ensure the applicability of contingency plans <del>in real emergency situations</del>, it is essential to practise and test that the systems are working. For that purpose the competent authorities of the Member States <b>must</b> carry out simulation exercises, in cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.</p>
<p>(117) In cases where an animal health certification issued by the competent authority is not required, an operator who moves animals to other Member States should issue a self-declaration document which confirms that the animals meet the movement requirements in this Regulation.</p>	<p>(117) In cases where an animal health certification issued by the competent authority is not required, and <b>provided that there are no animal welfare, animal health, public health and environmental implications</b>, an operator who moves animals to other Member States should issue a self-declaration document which confirms that the animals meet the movement requirements in this Regulation.</p>
<p><b>Justification:</b> Animal health certification has always been the backbone to the safe movement. In this Regulation, references to self-declaration are made in several Articles such as 124, 131, 141, 148, 193 and 218. Waiving animal health certifications bring in serious risks. Derogations to providing an animal health certificate should not be given lightly and only when strict conditions are met. As animals are sentient being, which can suffer but also spread zoonotic diseases, derogations should only be given if there are no animal welfare, animal health and public health implication.</p>	
<p>(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.</p>	<p>(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 <b>be proportionate, justified, non-discriminatory and – as much as possible -</b> 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.</p>
<p>(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.</p>	<p>(160) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at <b>stakeholder and at</b> 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.</p>

Articles	Articles
<p><b>Article 4</b> <b>Definitions</b></p> <p>(6) 'aquaculture' means the rearing of aquatic animals using techniques designed to increase the production of those animals beyond the natural capacity of the environment and where the animals remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting, excluding the harvesting or catching for the purposes of human consumption of wild aquatic animals which are subsequently temporarily kept awaiting slaughter without being fed;</p> <p>(30) 'official control' means an official control as defined by point (1) of Article 2 of the OC regulation</p> <p>(37) 'outbreak' means one or more cases in an establishment, household or other place where animals are kept or located;</p> <p>(38) 'case' means the official confirmation of the presence of a listed disease or an emerging disease in a live or dead animal</p> <p>....</p>	<p><b>Article 4</b> <b>Definitions</b></p> <p>(6) “aquaculture” means the farming of aquatic animals with some sort of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators, etc.’</p> <p>(30) ‘other official activities’ means any activity, other than an official control, which is performed by competent authorities in accordance with the provisions laid down in the proposal for a Regulation on official controls.</p> <p>(37) ‘outbreak’ means the occurrence of one or more cases in an epidemiological unit.</p> <p>(38) ‘case’ means an individual animal infected by a pathogenic agent, with or without clinical signs.</p> <p><u>Extra definitions:</u></p> <p>(extra) ‘Aquatic medicine biologist means a person who is authorised by the Competent Authority to carry out certain designated tasks in a territory and has the appropriate qualifications and training to perform the designated tasks under the veterinary supervision.</p> <p>(extra) ‘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;</p> <p>(extra) ‘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 the proposal for a Regulation on official controls.</p>
<p><u>Definitions:</u></p> <p>It is obvious that, such when it comes to disease outbreak, the role and responsibilities of official veterinarians are different from the role and responsibilities of veterinary practitioners. The text does not take these realities into account. Most of the time, the draft refers to “veterinarians” in general (furthermore, there are veterinarians who do not work as practitioners nor as officials). As such, it is important to define veterinarians and official veterinarian in the definitions.</p> <p>It is very confusing to have different definitions for the same term in different pieces of legislation, especially if they cover the same topic. Therefore, FVE suggests – as much as possible – that the Regulation on Animal Health, the Regulation on Official Control and the Terrestrial and Aquatic Code of OIE to use the same definitions.</p> <p>FVE suggest to use the OIE definitions for: “aquaculture”, “aquatic animals”, “outbreak”, “case”</p> <p>FVE suggest to cross reference in the Regulation on Animal Health to the definition of ‘Official veterinarian’ and ‘Other official activities’ is the Regulation on Official Controls</p>	

<p><b>Chapter 2: Listed diseases and emerging diseases and listed species</b></p> <p><b>Art 5 LISTING OF DISEASES</b></p> <p>2. The Commission shall, by means of implementing acts, establish a list of listed diseases, as referred to in paragraph 1(a).</p> <p>That list shall comprise diseases which meet with the conditions laid down in the following points (a) and (b) of this paragraph, taking into account the criteria for listing diseases laid down in Article 6:</p> <p>(a) diseases which are likely to have a significant impact on at least one of the following:</p> <ul style="list-style-type: none"> <li>(i) public health;</li> <li>(ii) agricultural or aquaculture production or related sectors of the economy;</li> <li>(iii) the society in Member States and where appropriate in third countries or territories;</li> <li>(iv) the environment;</li> </ul> <p><b>Article 6 CRITERIA</b>  <b>Article 7 LISTING OF SPECIES</b>  <b>Article 8 DISEASE LISTS</b></p>	<p><b>Art 5 LISTING OF DISEASES</b></p> <p>2. The Commission shall, by means of implementing acts, establish a list of listed diseases, as referred to in paragraph 1(a).</p> <p>That list shall comprise diseases which meet with the conditions laid down in the following points (a) and (b) of this paragraph, taking into account the criteria for listing diseases laid down in Article 6:</p> <p>(a) diseases which are likely to have a significant impact on at least one of the following:</p> <ul style="list-style-type: none"> <li>(i) public health;</li> <li>(extra) <a href="#">animal health and welfare</a></li> <li>(ii) agricultural or aquaculture production or related sectors of the economy;</li> <li>(iii) the society in Member States and where appropriate in third countries or territories;</li> <li>(iv) the environment;</li> </ul>
<p><u>Justification:</u> Article 5 to 8 form the backbone of this Regulation and as such disease control efforts by the European Union. These articles give a lot of power to the Commission; empowering the Commission to list diseases, if necessary amend the criteria in Art 6 and develop a list of species which will be affected by the disease specific rules. The adoption of this secondary legislation is a prerequisite for the Regulation on Animal to come into force.</p> <p>Seen the huge importance of the secondary legislation in Art 5-8, the Commission should clarify as soon as possible how they foresee the drafting and how they will ensure that this is done in a transparent way ensuring enough consultation with stakeholders.</p> <p>Care should be taken not only to cover the obvious diseases covering production animals. The listing of diseases and species should be done as holistic as possible to proactively improve animal and public health. Wildlife often plays a role as reservoir of diseases or in the emerging of new diseases and therefore should be overlooked. All diseases for which wildlife act as a reservoir and have an impact on animal populations (wild and domestic), economies and humans or a combination of all, need listing. Companion animals are another group of animals in which should not be overlooked. Due to the close contact between owners and companion animals, the categorization outcome of the CALLISTO project can be used.</p>	
<p><b>Article 10</b></p> <p>1. Operators and animal professionals shall acquire knowledge of:</p> <ul style="list-style-type: none"> <li>(a) animal diseases, including those that are transmissible to humans;</li> <li>(b) biosecurity principles;</li> <li>(c) the interaction between animal health, animal welfare and human health.</li> </ul> <p>2. []</p> <p>3. The knowledge provided for in paragraph 1 shall be acquired in one of the following ways:</p> <ul style="list-style-type: none"> <li>(a) professional experience or training;</li> <li>(b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;</li> <li>(c) formal education.</li> </ul>	<p>1. Operators and animal professionals shall acquire knowledge of:</p> <ul style="list-style-type: none"> <li>(extra) <a href="#">animal behaviour and husbandry</a></li> <li>(a) animal diseases, including those that are transmissible to humans;</li> <li>(b) biosecurity principles;</li> <li>(c) the interaction between animal health, animal welfare, human health <a href="#">and the environment</a>.</li> </ul> <p>2. []</p> <p><a href="#">3. The knowledge provided for in paragraph 1 shall be acquired in one of the following ways:</a></p> <ul style="list-style-type: none"> <li><a href="#">(a) professional experience or training;</a></li> <li><a href="#">(b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;</a></li> <li><a href="#">(c) formal education</a></li> </ul>

<p><u>Justification</u>: In order to recognise disease symptoms and prevent, knowledge is required on normal animal behaviour and needs and husbandry. Therefore it is vital that operators should also acquire this information and not only about disease symptoms. Paragraph 3 is deleted as education is a Member State responsibility.</p>	
<p><b>Article 11</b></p> <p><b><i>Responsibilities of veterinarians and aquatic animal health professionals</i></b></p> <p>1. Veterinarians shall in the course of their activities which fall within the scope of this Regulation:</p> <p>(a) take all appropriate measures to prevent the introduction, development and spread of diseases;</p> <p>(b) ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease before symptomatic treatment is commenced;</p> <p>(c) play an active role in:</p> <p>(i) raising animal health awareness;</p> <p>(ii) disease prevention;</p> <p>(iii) the early detection and rapid response to diseases.</p> <p>(d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.</p> <p>2. Aquatic animal health professionals may undertake activities attributed to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so under national legislation. In that event, paragraph 1 shall apply to those aquatic animal health professionals.</p> <p>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.</p>	<p><b>Article 11</b></p> <p><b><i>Responsibilities of veterinarians and aquatic medicine biologists</i></b></p> <p>1. Veterinarians shall in the course of their activities which fall within the scope of this Regulation:</p> <p>(a) <b>advise</b> on all appropriate measures to prevent the introduction, development and spread of diseases;</p> <p>(b extra) <b>advise operators about measures to minimise the risk of zoonotic diseases, food borne pathogens, residues, contaminants in order to ensure safe food</b></p> <p>(b) ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis <del>to rule out or confirm a disease before symptomatic treatment is commenced;</del></p> <p>(c) play an active role in:</p> <p>(i) raising animal health <b>and welfare</b> awareness;</p> <p>(ii) disease prevention;</p> <p>(iii) the early detection and rapid response to diseases.</p> <p>(iv) <b>raising awareness on antimicrobial resistance and implications that might follow</b></p> <p>(extra d) <b>ensure the integrity of veterinary certification</b></p> <p>(extra d) <b>ensure the integrity of the food chain information</b></p> <p>(d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.</p> <p>2. Aquatic <b>medicine biologists</b> may undertake <del>activities attributed to veterinarians under this Regulation</del> <b>certain designated tasks in a territory in the field of aquatic animals under the supervision of a veterinarian</b>, provided that they are authorised to do so under national legislation. In that event, <b>some aspects of paragraph 1 can</b> apply to those aquatic animal health professionals. <b>Aquatic medicine biologists should have the same responsibilities and obligations as veterinarians.</b> Member States need to notify other countries if they will authorise aquatic medicine biologists on their territory and should provide evidence that these will have the necessary training and skills and will meet the same responsibilities and obligations as veterinarians.</p> <p>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the <b>training</b> of veterinarians and <b>the training and qualifications of aquatic medicine biologists</b> undertaking activities which fall within the scope of this Regulation.</p>
<p><u>Justification</u>: Veterinary medicine is a regulated profession. The veterinarian is licensed by the legal authority to carry out his tasks, something that shall be done in an independent, ethical and personally responsible capacity. The veterinarian is accountable to the licensing authority. This position should be recognized in the legislation, especially where the competent authority delegates tasks to the veterinarian or to other professionals.</p> <p>References: <a href="#">FVE Veterinary Act and Code of Conduct</a></p>	

FVE Policy Paper: <a href="#">Herd Health Plan</a>	
<p><b>Art 12</b> <b>MS responsibilities</b></p> <p>1. In order to ensure the competent authority for animal health has the capability to take the necessary and appropriate measures, and carry out the activities, required by this Regulation, the Member States shall ensure that it has:</p> <p>(a) qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;</p> <p>(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;</p> <p>(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 11 which fall within the scope of this Regulation. [...]</p> <p>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.</p>	<p><b>Art 12</b> <b>MS responsibilities</b></p> <p>1. In order to ensure the competent authority for animal health has the capability to take the necessary and appropriate measures, and carry out the activities, required by this Regulation, the Member States shall ensure that it has:</p> <p>(a) qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;</p> <p>(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;</p> <p>(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 11 which fall within the scope of this Regulation. [...]</p> <p>2. Member States shall <b>ensure</b> operators and animal professionals in acquiring, maintaining and developing the basic knowledge of animal health provided for in Article 10 <del>through relevant programmes in agricultural or aquaculture sectors or formal education.</del></p>
<p><u>Justification:</u> FVE is happy to see that the Regulation clearly considers the maintenance of “Animal Health Services” (in terms of legislation, structure, organisation, resources, capacity, the role of the private sector and paraprofessionals) as a minimum goal. FVE is pleased to see Article 12 dealing with Member States responsibilities in this area. However we also wish to point out that so far missions of the Food and Veterinary Office have revealed several weaknesses at these points. Weaknesses that should be resolved for any legislation to be effective.</p>	
<p><b>Art 13</b> <b>Competent authority's delegation of other official activities</b></p> <p>1. The competent authority may delegate one or more of the following activities to veterinarians:</p> <p>(a) activities concerning notification and reporting as provided for in Chapter 1 of Part II and surveillance as provided for in Chapter 2 of that Part;</p> <p>(b) activities related to:</p> <p>(i) disease awareness, preparedness and control as provided for in Part III;</p> <p>(ii) registration, approval, traceability and movements as provided for in Part IV;</p> <p>(iii) emergency measures as provided for in Part VI.</p> <p>2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253, concerning:</p> <p>(a) the circumstances and conditions for delegating the activities provided for in paragraph 1;</p> <p>(b) which other activities may be delegated to veterinarians in addition to those provided for in paragraph 1 of this Article, and under which circumstances and under which conditions;</p> <p>(c) minimum requirements for the training of veterinarians provided for in Article 12(1)(c).</p>	<p><b>More clarification are needed on ‘other official activities’ in the AH domain.</b></p> <p><b>Cross reference should be made with the ‘other official activities’ in the Official Controls Regulation.</b></p>

<p>The Commission shall take account of the nature of those tasks and the international obligations of the Union and the Member States, when adopting those delegated acts.</p>	
<p><b>Article 15</b> <b>Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products</b></p> <p>[ ]</p>	<p><b>Article 15</b> <b>Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products</b></p> <p>[ ]</p> <p><b>Clarification is necessary of the specific purpose of this article as no cross-reference is made to existing regulation in the EU such as biosafety levels of lab and workers safety or transport of dangerous good (Dir 2008/68; 90/291 and 2000/54)</b></p>
<p><b>Article 23</b> <b>Animal health visits</b></p> <p>1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian when appropriate due to the risks posed by establishment, taking into account:</p> <p>(a) the type of establishment;</p> <p>(b) the categories and species of kept animals on the establishment;</p> <p>(c) any other relevant surveillance, quality assurance schemes or official controls that the kept animals and type of establishment are subject to.</p> <p>Those animal health visits shall be at frequencies that are proportionate to the risks posed by the establishment. They may be combined with visits for other purposes.</p> <p>2. The animal health visits referred to in paragraph 1 shall be for the purposes of:</p> <p>(a) detecting of any signs indicative for the occurrence of a listed or emerging diseases;</p> <p>(b) providing advice to the operator on biosecurity and other animal health matters, as relevant for the type of establishment and the categories and species of animals kept.</p>	<p><b>Article 23</b> <b>Animal health visits</b></p> <p>1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian <b>regularly visiting the farm due to the risks</b> posed by the establishment, taking into account:</p> <p>(a) the type <b>and size</b> of establishment;</p> <p>(b) the categories and species of kept animals on the establishment;</p> <p>(c) any other relevant surveillance, quality assurance schemes or official controls the animals and type of establishment are subject to.</p> <p>Those animal health visits shall be at frequencies that are proportionate to the risks to <b>animal health, welfare, environment and public health</b> posed by the establishment. They may be combined with visits for other purposes.</p> <p>2. The animal health visits referred to in paragraph 1 shall be for the purposes of:</p> <p>(a) detecting of any signs indicative for the occurrence of a listed or emerging diseases;</p> <p>(b) providing advice to the operator on biosecurity and other animal health, <b>animal welfare and public health</b> matters, as relevant for the type of establishment and the categories and species of animals kept.</p>
<p><b>Justification:</b> Regular farm visits are especially important to:</p> <ul style="list-style-type: none"> <li>• to develop a holistic strategy to prevent diseases,</li> <li>• to ensure the early recognition of diseases</li> <li>• to advise operators on biosecurity,</li> <li>• to advise operators on correct disposal of veterinary medicines and waste,</li> <li>• to ensure the integrity of the food chain information</li> <li>• to prioritise measures to control any existing problems and manage risks, including the responsible use of medicines</li> <li>• to supplement the surveillance undertaken by operators</li> <li>• to assist operators on record keeping</li> <li>• to ensure close collaboration and exchange of knowledge between operators and veterinarians</li> </ul>	

<p><b>Article 46</b> <b>The use of VMPs for disease prevention and control</b></p> <p>Paragraph 1: ‘The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient disease prevention or control for those diseases, provided that such measures comply with the rules on the use of veterinary medicinal products laid down in delegated acts adopted pursuant to article 47. Those measures may cover the following: (a) prohibitions and restrictions on the use of veterinary medicinal products’</p> <p><b>Article 47</b> Delegation of powers for the use of veterinary medicinal products Paragraph 1: ‘The Commission shall be empowered to adopt delegated acts in accordance with article 253 concerning: (a) prohibitions and restrictions on the use of veterinary medicinal products’</p>	<p><b>Article 46</b> <b>The use of VMPs for disease prevention and control</b></p> <p>Paragraph 1: ‘The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient disease prevention or control for those diseases, provided that such measures comply with the rules on the use of veterinary medicinal products laid down in delegated acts adopted pursuant to article 47. Those measures may cover the following: (a) prohibitions and restrictions on the use of veterinary medicinal products which may mask disease or render differential diagnosis impossible a) guidance and education on the responsible use of veterinary medicinal products including involvement in continuous professional development (CPD) as per Articles 10, 11 and 12.</p> <p><b>Article 47</b> Article 47 gives option to the Commission to ban products and to restrict use. Clarification of the scope of the disease list and the types of prohibitions and restrictions is necessary to avoid severe therapeutic implications.</p>
<p><b>Chapter 3</b> <b>Movements within the Union of kept terrestrial animals other than terrestrial pet animals</b> <b>SECTION 2</b> <b>MOVEMENTS BETWEEN MEMBER STATES</b></p> <p><b>Article 123</b> <b>General requirements for movements of kept terrestrial animals between Member States</b></p> <p>2. Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in another Member State unless they need to stop at a place of resting for animal welfare reasons.</p>	<p><b>Chapter 3</b> <b>Movements within the Union of kept terrestrial animals other than terrestrial pet animals</b> <b>SECTION 2</b> <b>MOVEMENTS BETWEEN MEMBER STATES</b></p> <p><b>Article 123</b> <b>General requirements for movements of kept terrestrial animals between Member States</b></p> <p>2. Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in another Member State unless they need to stop at a place of resting for animal welfare reasons <a href="#">in accordance with the dispositions laid down by Regulation 1/2005 (EC)</a></p>
<p><u>Justification</u>: Council Regulation 1/2005 on the protection of animals during transport and related operation defines journey times for the different species. As such it is necessary to make a cross-reference to this Regulation.</p>	
<p><b>SECTION 6</b> <b>DEROGATING FROM AND SUPPLEMENTING RISK MITIGATION MEASURES</b></p> <p><b>Article 136</b> <b>Derogations concerning recreational use, sporting and cultural events, grazing and work near borders</b></p> <p>1. The competent authority of the place of destination may</p>	<p><b>SECTION 6</b> <b>DEROGATING FROM AND SUPPLEMENTING RISK MITIGATION MEASURES</b></p> <p><b>Article 136.1</b> <b>Derogations concerning recreational use, sporting and cultural events, grazing and work near borders</b></p>



<p>grant derogations from the requirements of Sections 2 to 5, with the exception of Article 123(a) and (b) and Articles 124 and 125, for intra-Union movements of kept terrestrial animals between Member States where such movements are for:</p> <p>(a) recreational use near borders;</p> <p>(b) exhibitions, and for sporting, cultural and similar events organised near borders;</p> <p>(c) grazing of kept terrestrial animals in grazing areas shared between Member States;</p> <p>(d) work of kept terrestrial animals near borders of Member States.</p> <p><b>Article 137</b>  <b>Delegation of power concerning derogations for circuses, exhibitions, sporting events and recreational use, zoos, pet shops, and wholesalers</b></p>	<p><a href="#">/!\ Derogations for circuses, zoos, etc...</a>  One has to be careful with derogations for recreational events and exhibitions, as these might represent high risk One should also avoid legal voids.</p> <p><b>Article 137</b>  <b>Same remarks as the ones made for article 136.</b></p>
<p><u>Justification:</u>  It is not known how many animals are involved in movement for recreational, exhibitions, sporting and cultural events, but numbers are believed to be in the tens of thousands. For various reasons, these animals can represent an animal and public health risk, for example, if they are moved into an establishment from an unknown source, taken across borders, or relocated from one environment into another environment without the necessary checks. Appropriate preventive measures should be taken to avoid the spread of transmissible animal disease through the movement of these animals.</p> <p><b>Reference:</b> <a href="#">Conclusions wild animals conference</a></p>	
<p>Article 168-169 National measures concerning movements of animals and germinal products – national measures for limiting the impact of diseases other than listed diseases</p>	<p><a href="#">Should the case of situations occurring near borders be taken into account here, as it is already laid down in other articles?</a></p>
<p>Art 230  Requirements for entry into the Union</p>	<p><a href="#">It might be worthwhile to add here and in all article deriving from it (231, 233, 234, 235, 236, 239) a reference that all decisions should be based on good scientific standards serving the purpose of this law and avoiding differently motivated trade barriers.</a></p>
<p>Article 233  Suspension and withdrawal from the list of third countries and territories</p>	<p><a href="#">In principle Paragraph 1 should also have a reference to public health as it is mentioned in paragraph 2b</a></p>